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RADIOISOTOPE POWERED CARDIAC PACEMAKER PROGRAM

Quarterly Progress Report, February 1, 1973—April 30, 1974

Arco Nuclear Company
Leechburg, Pennsylvania

MASTER

UNITED STATES ATOMIC ENERGY COMMISSION
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Quarterly Progress Report
for
Radioisotope Powered
Cardiac Pacemaker Program

February 1, 1974 to April 30, 1974

Prepared for

UNITED STATES ATOMIC ENERGY COMMISSION
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TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
TASK 1.0 - PROGRAM MANAGEMENT, CONTROL AND PLANNING	2
TASK 2.0 - HUMAN INVESTIGATIONAL STUDY	3
TASK 3.0 - SYSTEM FABRICATION AND QUALITY ASSURANCE	15
TASK 4.0 - SYSTEM TESTING	18
TASK 5.0 - ENVIRONMENTAL ASSESSMENT	35

LIST OF TABLES

<u>Table</u>		<u>Page</u>
1	Initial Human Implant Data	5
2	RPCP Human Rate Data	7
3	Life Test Data Through April 1974	16
4	Dog Rate Data	19

LIST OF FIGURES

<u>Figure</u>		<u>Page</u>
1	Rate of Implant	4
2	Dog Implant, NU-5 RPCP Serial No. 3	21
3	Dog Implant, NU-5 RPCP Serial No. 41	22
4	Step Change in Temperature (Room Temperature to 60° C)	24
5	Step Change in Temperature (Room Temperature to -40° C)	25
6	Axis Orientation of Shipping Package Test	29
7	Time-Temperature Profile, RPCP Cremation Test Unit B17-3	36
8	RPCP Cremation Test Unit B17-3, Before and After Cremation	38
9	RPCP Cremation Test Unit B17-3, Fuel Capsule Assembly	39
10	RPCP Cremation Test Unit B17-3, Transverse Section of Fuel Capsule	40

INTRODUCTION

This is the seventeenth 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, 1974 to April 30, 1974.

TASK 1.0 - PROGRAM MANAGEMENT, CONTROL AND PLANNING

A total of 39.4 unit years of reliability data has been accumulated under the Human Investigational Program. The program has successfully passed the one year milestone.

The electronic circuits on life test have accumulated a total of 504.4 unit years and no failures have been observed. This represents a proven reliability in excess of 95% for an 11 year mission at a 90% confidence level.

The dog implants continue showing proper pacemaker function with the implants approaching the two year milestone. A total of 51.77 unit years have been amassed over this period with one malfunction resulting.

Within this report is a summary of cremation and pressurized capsule tests performed in accordance with the new Interim Guide.

Preliminary packaging shipment results and package response to a step change in temperature is discussed.

TASK 2.0 - HUMAN INVESTIGATIONAL STUDY

There has been a total of 47 implants thus far using the NU-5 model nuclear pacemaker. The program has now passed the one year mark and has accumulated a total of 39.4 unit years of reliability data. Figure 1 is an update of the graph which plots the number of implants versus months. Table 1 provides initial implant data while Table 2 provides the latest post implant follow-up data. Each pacemaker, which is implanted, is checked via telephone monitoring systems weekly for the first 8 weeks, monthly for the next 22 months, and once every three months thereafter.

RATE OF IMPLANT

Figure 1

Table 1
Initial Human Implant Data - Nuclear Patients

<u>Pacer #</u>	<u>Rate at ARCO (98°F)</u>	<u>Implant Date</u>	<u>Institution</u>	<u>Rate at Implant</u>	<u>24 Hours After Implant</u>	<u>Duration (days) as of May 1, 1974</u>
88	73.7	4/9/73	NIH	73	73.8	386
76	71.8	4/9/73	NBIMC	72	71.9	386
85	73.3	4/9/73	NBIMC	73	73.1	386
100	72.9	4/9/73	NBIMC	73	72.6	386
101	72.5	4/9/73	NBIMC	72	72.0	386
102	73.3	4/9/73	NBIMC	73	73.3	386
103	73.7	4/9/73	NBIMC	73	73.6	386
106	74.1	4/9/73	NBIMC	74	73.7	386
108	73.3	4/9/73	NBIMC	73	73.3	386
61	71.8	4/10/73	NBIMC	72	71.9	385
70	71.4	4/10/73	NBIMC	71	71.6	385
5 72	71.8	4/10/73	NBIMC	72	71.9	385
83	72.6	4/10/73	NBIMC	73	72.6	385
86	73.7	4/10/73	NBIMC	73	73.7	385
90	73.4	4/10/73	NBIMC	74	73.6	385
107	74.1	4/10/73	NBIMC	74	73.5	385
73	73.1	5/7/73	THI	73.2	73.3	358
74	74.4	5/12/73	THI	74.3	74.5	347
95	74.9	5/18/73	LAC-USC	74.8	74.9	341
94	73.8	6/5/73	JMH	76	75.1	328
97	73.6	6/5/73	JMH	73	72.9	328
113*	74.2	6/5/73	LAC-USC	72.8	73.3	190
126	74.2	6/12/73	PGGH	74	74.0	321
128	74.0	6/12/73	PGGH	75	75.0	321

*Removed 113 in favor of 78

Table 1 (continued)
Initial Human Implant Data - Nuclear Patients

<u>Pacer #</u>	<u>Rate at ARCO (98^oF)</u>	<u>Implant Date</u>	<u>Institution</u>	<u>Rate at Implant</u>	<u>24 Hours After Implant</u>	<u>Duration (days) as of May 1, 1974</u>
121	74.4	6/13/73	PGGH	75	75.0	320
125	74.0	6/13/73	PGGH	75	75.0	320
129	74.1	6/13/73	MH	73	74	320
131	74.9	6/13/73	MH	74	75	320
140	73.6	6/13/73	MH	73	74	320
142	74.1	6/15/73	MH	73	74	318
109**	73.8	6/25/73	NIH	73	72.7	108
114	73.9	7/6/73	LAC-USC	72.0	72.4	297
115	74.2	7/6/73	MH-NY	72.7	72.8	297
116	73.8	7/20/73	LAC-USC	70.9	71.6	283
120	73.4	7/24/73	PGGH	75	73	279
144	73.7	7/27/73	MH-NY	73.4	73.5	276
99	73.3	8/3/73	JMH	72	74	269
149	73.7	8/7/73	MH-NY	73.3	73.5	265
136	74.8	9/12/73	MH-NY	74.3	74.8	229
145	73.4	9/14/73	MH-NY	73.5	73.3	227
156	75.9	9/19/73	VAB	75	75	222
78	72.8	10/11/73	LAC-USC	72.0	72.5	200
157	74.7	11/23/73	VAB	76	76	160
162	74.2	11/29/73	VAB	74	72	154
155	75.4	12/3/73	JMH	75	75.6	147
75	72.9	12/4/73	VAB	72	72	146
138	75.2	12/10/73	NIH	74.9	75.4	140
158***	75.3	11/15/73	NIH	75		114
82	73.6	2/6/74	VAB	70	72	81
80	73.8	2/19/74	NBIMC	73.5	73.8	68

**Removed 109 in favor of 158

***Removed 158 in favor of 138

RPCP Human Rate Data

[illegible]

TABLE 2

RPCP Human Rate Data (continued)

[illegible]

TABLE 2
RPCP Human Rate Data (continued)

Pacer #	9/30 - 10/6	10/7 - 10/13	10/14 - 10/20	10/21 - 10/27	10/28 - 11/3	11/4 - 11/10	11/11 - 11/17	11/18 - 11/24	11/25 - 12/1	12/2 - 12/8	12/9 - 12/15	12/16 - 12/22	12/23 12/29
88	-	-	-	74.1	-	-	-	-	-	-	-	-	-
76	72.4	-	-	-	-	72.5	-	-	-	72.5	-	-	-
85	72.4	-	-	-	72.2	-	-	-	-	72.1	-	-	-
100	72.5	-	-	-	72.5	-	-	-	-	72.3	-	-	-
101	71.9	-	-	-	-	71.8	-	-	-	71.7	-	-	-
102	72.8	-	-	-	72.7	-	-	-	-	72.7	-	-	-
103	73.0	-	-	-	-	72.4	-	-	-	72.8	-	-	-
108	70.4	-	-	-	70.0	-	-	-	-	69.5	-	-	-
106	70.8	-	-	-	70.4	-	-	-	-	69.9	-	-	-
61	72.5	72.5	72.5	72.5	72.6	72.6	-	-	-	72.6	-	-	-
70	-	-	72.2	-	72.2	-	-	-	-	-	-	-	-
72	72.4	-	-	-	-	72.4	-	-	-	72.5	-	-	-
83	72.2	-	-	-	-	72.1	-	-	-	72.2	-	-	-
86	74.2	-	-	-	-	74.3	-	-	-	74.3	-	-	-
90	73.9	-	-	-	-	73.9	-	-	-	74.0	-	-	-
107	70.5	-	-	-	-	69.9	-	-	-	-	-	-	-
73	74.1	-	-	-	-	73.8	-	-	-	74.1	-	-	-
74	-	74.9	-	-	-	75.1	-	-	-	-	75.1	-	-
95	-	75.1	-	-	-	-	75.1	-	-	-	75.2	-	-
94	-	-	79.4	-	-	-	79.7	-	-	-	80.1	-	-
97	-	-	-	-	-	-	-	-	70.0	-	-	-	-
113*	70.2	-	-	-	-	-	-	-	-	-	-	-	-
126	74.4	74.4	-	-	74.3	74.5	74.3	74.5	74.5	74.5	74.5	74.5	74.5
128	74.2	74.2	-	-	74.2	74.2	74.2	74.2	74.3	74.3	74.3	74.3	74.3
121	75.2	75.2	-	-	75.2	75.3	75.3	75.3	75.3	75.3	-	75.3	75.3
125	74.2	74.3	-	-	74.3	74.4	74.3	74.3	74.3	74.4	74.4	74.4	74.4
129	-	-	74.4	-	-	-	-	-	-	74.5	-	-	-
131	-	-	-	-	-	-	-	75.3	-	-	-	-	-
140	-	-	74.1	-	-	-	-	74.2	-	-	-	74.2	-
142	-	74.6	-	-	-	74.6	-	-	-	74.7	-	-	-
109**	70.9	-	70.7	-	70.5	-	-	-	-	-	-	-	-
114	-	70.9	-	-	-	-	69.2	-	-	68.8	-	-	-
115	71.1	71.0	70.8	70.7	70.6	70.5	70.3	70.2	70.1	70.0	69.9	69.7	69.6
116	-	-	69.0	-	-	-	68.5	-	-	-	68.0	-	-
120	73.4	73.4	-	-	73.3	73.4	73.4	73.4	73.4	73.4	73.4	-	73.5
144	73.6	73.6	73.8	73.7	-	-	-	-	73.8	-	-	-	73.9
99	70.4	-	-	-	-	-	69.6	-	-	-	-	69.1	-
149	73.6	73.6	73.6	73.7	-	-	-	-	73.8	-	-	73.8	-
136	74.8	74.8	74.8	74.8	74.8	74.8	74.8	-	-	-	74.8	-	-
145	73.5	73.5	73.6	73.5	73.6	73.5	73.5	-	-	73.7	73.7	-	-

*113 Removed in favor of 78; **109 Removed in favor of 138

TABLE 2
RPCP Human Rate Data (continued)

<u>Pacer #</u>	<u>9/30 - 10/6</u>	<u>10/7 - 10/13</u>	<u>10/14 - 10/20</u>	<u>10/21 - 10/27</u>	<u>10/28 - 11/3</u>	<u>11/4 - 11/10</u>	<u>11/11 - 11/17</u>	<u>11/18 - 11/24</u>	<u>11/25 - 12/1</u>	<u>12/2 - 12/8</u>	<u>12/9 - 12/15</u>	<u>12/16 - 12/22</u>	<u>12/23 - 12/29</u>
156										75.6			
78		72.6	72.6	-	72.6	72.6	72.5	-	72.4	72.5	72.5	-	-
157													
162													
155										75.6	75.0	75.0	75.0
75													
138											75.4	-	-

TABLE 2

RPCP Human Rate Data (continued)

Pacer #	12/30- 1/5	1/6- 1/12	1/13- 1/19	1/20- 1/26	1/27- 2/2	2/3- 2/9	2/10- 2/16	2/17- 2/23	2/24- 3/2	3/3- 3/9	3/10- 3/16	3/17- 3/23	3/24- 3/30	3/31- 4/6
88	-	74.1	-	-	-	-	-	-	74.1	-	-	-	-	-
76	-	72.5	-	-	-	72.6	-	-	-	72.7	-	-	-	72.6
85	-	72.0	-	-	-	71.9	-	-	-	-	-	-	-	71.7
100	72.2	-	-	-	-	72.1	-	-	-	72.1	-	-	-	72.0
101	-	71.6	-	-	-	71.5	-	-	-	71.5	-	-	-	71.4
102	-	-	-	-	-	72.5	-	-	-	72.5	-	-	-	72.5
103	-	72.7	-	-	-	72.9	-	-	-	72.5	-	-	-	72.5
108	69.1	-	-	-	-	68.8	-	-	-	68.5	-	-	-	-
106	69.6	-	-	-	-	69.2	-	-	-	69.0	-	-	-	-
61	-	-	72.7	-	-	72.7	-	-	-	72.9	-	-	-	72.8
70	72.4	-	-	-	-	-	-	-	-	-	72.4	-	-	-
72	-	72.5	-	-	-	72.5	-	-	-	72.7	-	-	-	72.7
83	-	72.0	-	-	-	71.9	-	-	-	71.9	-	-	-	71.8
86	-	-	-	-	-	74.3	-	-	-	74.4	-	-	-	74.4
90	-	74.0	-	-	-	74.0	-	-	-	74.0	-	-	-	74.0
107	-	69.2	-	-	-	68.9	-	-	-	68.7	-	-	-	-
73	-	74.1	-	-	-	74.2	-	-	-	74.2	-	-	-	-
74	75.1	-	-	-	-	-	75.2	-	-	-	75.2	-	-	-
95	-	75.2	-	-	-	75.2	-	-	-	-	75.2	-	-	-
94	-	80.3	-	-	-	-	-	-	80.7	-	-	-	80.8	-
97	-	-	-	-	-	-	-	-	-	-	-	-	-	-
113*														
126	74.5	74.5	74.5	74.5	74.5	74.5	-	-	-	74.5	-	-	-	74.5
128	-	74.3	74.3	74.3	74.3	74.3	74.3	-	-	-	-	-	74.9	74.3
121	75.3	75.3	75.3	75.4	75.4	75.4	75.3	-	-	-	-	-	75.0	75.0
125	74.5	74.4	74.4	74.5	74.4	74.5	74.5	-	-	-	-	-	74.3	74.4
129	74.4	-	-	-	74.4	-	-	-	-	-	-	-	74.5	-
131	-	-	-	-	-	-	-	-	-	75.2	-	-	-	-
140	-	-	-	74.3	-	-	-	74.4	-	-	-	-	74.5	-
142	-	74.7	-	-	-	74.8	-	-	-	-	-	-	74.9	-
109**														
114	-	68.2	-	-	-	-	67.7	-	-	-	67.4	-	-	-
115	69.5	69.4	69.3	-	-	-	-	-	-	-	-	-	68.5	68.4
116	-	68.2	67.4	-	-	-	67.1	-	-	-	66.8	-	-	-
120	73.5	73.4	73.4	73.4	73.5	73.5	73.5	-	-	-	-	-	73.5	73.4
144	-	-	-	-	73.9	-	-	-	74.0	-	-	-	74.0	-
99	-	-	-	-	68.6	-	-	-	-	-	-	-	-	-
149	-	-	-	-	-	-	-	-	-	-	-	-	-	73.7
136	-	-	-	-	-	-	-	-	-	-	-	74.9	-	-
145	-	-	-	-	-	-	-	-	-	-	-	-	73.9	-

*113 Removed in favor of 78; **109 Removed in favor of 138

TABLE 2
RPCP Human Rate Data (continued)

<u>Pacer #</u>	<u>12/30- 1/5</u>	<u>1/6- 1/12</u>	<u>1/13- 1/19</u>	<u>1/20- 1/26</u>	<u>1/27- 2/2</u>	<u>2/3- 2/9</u>	<u>2/10- 2/16</u>	<u>2/17- 2/23</u>	<u>2/24- 3/2</u>	<u>3/3- 3/9</u>	<u>3/10- 3/16</u>	<u>3/17- 3/23</u>	<u>3/24- 3/30</u>	<u>3/31- 4/6</u>
156														
78	-	72.4	-	-	-	72.3	-	-	-	72.3	-	-	-	72.1
157														
162														
155	75.0	75.0	75.0	75.0	75.0	75.0	-	-	-	75.0	-	-	-	75.0
75	-	-	-	-	-	-	-	-	-	-	-	-	-	78.0
138	-	-	75.4	-	75.4	75.4	75.4	75.5	75.5	-	-	-	75.5	
82						72.0								
80														73.9

TABLE 2
RPCP Human Rate Data (continued)

Pacer #	4/7- 4/13	4/14- 4/20	4/21- 4/27	4/28- 5/4
88	74.1	-	-	
76	-	72.6		
85	-	71.7		
100	-	72.0		
101	-	71.4		
102	-	72.5		
103	-	72.5		
108	-	68.2		
106				
61	-	72.9		
70	-	72.55		
72	-	72.7		
83	-	71.9		
86	-	74.4		
90	-	74.0		
107	-	68.41		
73	74.4			
74	75.3			
95				
94	-	-	81.0	
97	69.0	68.9		
113*				
126				
128				
121				
125				
129				
131				
140	-	-	-	74.5
142				
109**				
114				
115				
116				
120				
144				
99	-	-	67.8	
149				
136				
145				

*113 Removed in favor of 78; **109 Removed in favor of 138

TABLE 2

RPCP Human Rate Data

(continued)

<u>Pacer #</u>	<u>4/7- 4/13</u>	<u>4/14- 4/20</u>	<u>4/21- 4/27</u>	<u>4/28- 5/4</u>
156				
78				
157				
162				
155				
75				
138				
82				
80	73.9			

TASK 3.0 - SYSTEM FABRICATION AND QUALITY ASSURANCE

The attached data (Table 3) summarizes the AEC units on life test.

At the end of April, a total of 47 AEC-ARCO NU-5 model Radioisotope Powered Cardiac Pacemakers have been implanted. Over the past 11 months, the human implants have accumulated 39.4 unit years with no failures.

There are also 13 high voltage units on life test which have accumulated 13.24 unit years.

Presently, 126 Phase II electronic circuits are on life test operating at 2.2 volts at room temperature with a simulated battery resistance of 5300 ohms. The accumulated life test time represents 504.37 unit years with no failures. The proven reliability is 95.04 for an 11 year mission time at a 90% confidence level.

TABLE 3
LIFE TEST DATA THROUGH APRIL 1974

Modified Production Model

B.O.L. Data

<u>Unit No.</u>	<u>Battery Output</u>	<u>Electronics Output</u>		<u>Present Output</u>		
	μ w	ma	BPM	μ w	BPM	ma
2	215.0	6.5	72.5		73.82	6.0
17	230.3			220.3		
18	214.3			204.0		
160	218.6	6.6	73.5		73.88	6.3
163	237.7			236.4		
164	261.9			263.2		
165	266.3				73.98	6.4
166	249.7			249.5		
167	230.0			228.3		
169	226.1			228.3		
170	247.9				74.35	6.3
171	235.2			232.2		
172	230.2			232.4		

Accumulated Hours = 1.492×10^5 unit hours

<u>High Voltage Units</u>						
NU5D-1	225.7	8.5	67.1	67.12	9.2	
2	235.2	8.6	66.5	66.43	9.3	
3	229.7			81.54		
4	250.2			84.70		
5	240.0			79.25		
6	242.5			79.11		
7	221.6			80.12		
8	245.9			244.4		
9	230.7			228.7		
10	231.7			232.4		
11	204.2			232.4		
12	229.1			228.7		
13	215.0			214.2		

Accumulated Hours = 1.160×10^5 unit hours

TABLE 3 (continued)

LIFE TEST DATA THROUGH APRIL 1974

Experimental ModelB.O.L. Data

<u>Unit No.</u>	<u>Battery Output</u>	<u>Electronics Output</u>		<u>Present Output</u>		
	μW	ma	BPM	μW	BPM	ma
E-3	84.8			70.7		
E-5	79.6			69.1		
E-9	82.3			82.7		
E-10	77.5			66.5		
E-12	230.0			240.4		
E-13BB		8.0	123.0		128.7	5.5
E-16	202.4			196.1		
E-17	196.1			217.3		
E-18	249.0			244.1		
P-1		5.7	125.3		125.4	5.6
P-3		5.4	126.5		124.8	5.4

Accumulated Hours = 6.059×10^5 unit hours

TASK 4.0 - SYSTEM TESTING

In-Vivo Study of the NU-5 RPCP in Dogs

A total of 30 NU-5 model nuclear pacemakers were implanted beginning in June of 1972 and a total of 29 units are still implanted and have accumulated a total of 51.77 unit years of reliability data. The most recent rate data is provided in Table 4. Graphs of the rate data recorded thus far for two dog implants are shown in Figures 2 and 3. Radioisotope Powered Cardiac Pacer serial number 3 was the first of the NU-5 model pacers to be implanted. These curves are representative of the 29 units implanted in dogs.

Pacemaker Shipping Container Changes

To simplify the pacer shipping package without sacrificing shock transmissibility, the outer polystyrene box was eliminated. Now the package consists of an outer corrugated cardboard box with a two inch layer of soft polyurethane (805 white presto) foam to reduce shock transmissibility to the inner plastic box holding the pacer within inserts. Previous preliminary tests (page 30, Quarterly Progress Report, November 1, 1973 to January 31, 1974) indicated that with one inch foam thickness of 805 presto foam, the drop height (for a given g level) was considerably less than two inches of other foam combinations, especially at lower g levels.

1. Thermal Test of Pacemaker Shipping Container

An NU-5 nuclear pacemaker with the nuclear battery but no electronics was instrumented with two copper-constantan thermocouples that were welded

TABLE 4

DOG RATE DATA

<u>Dog #</u>	<u>P.M. #</u>	<u>Date Implanted</u>	<u>Initial Rate</u>	<u>9-17-73</u>	<u>10-17-73</u>	<u>11-30-73</u>	<u>1-24-74</u>	<u>3-22-74</u>	<u>4-26-74</u>
1P029	3	7-10-72	73.4	73.8	73.8	73.9	73.9	73.8	73.9
1R481	5	7-10-72	72.6	72.5	72.2	72.2	72.3	72.3	72.3
1P086	6	7-10-72	72.8	71.5	71.7	71.6	71.4	71.4	71.6
1560	9	7-13-72	73.4	73.4	73.3	73.3	73.3	73.3	73.4
95	11	7-17-72	73.6	75.1	75.8	75.8	75.9	76.1	76.2
1P127	15	7-17-72	73.5	75.1	75.3	75.2	75.3	75.3	75.5
1R483	20	7-17-72	73.4	74.4	74.4	74.4	74.9	74.8	74.8
1814	13*	7-17-72	73.1	-----	-----	-----	-----	-----	-----
1P108	23	7-24-72	74.5	75.5	75.6	75.6	75.7	75.7	75.7
1R494	21	7-24-72	73.9	75.4	75.5	75.4	75.6	75.6	75.6
6 1P101	24	7-24-72	74.0	75.8	75.4	75.7	75.6	75.9	75.5
1P103	26	7-24-72	72.7	74.2	74.2	74.3	74.4	74.5	74.5
1Q980	33	7-31-72	72.2	73.6	73.6	73.8	73.8	73.9	73.9
1504	30	7-31-72	72.6	73.9	73.7	73.9	73.8	74.0	74.0
135	29	7-31-72	72.9	74.1	74.1	74.0	74.0	74.1	-----
2188	34	7-31-72	73.1	74.2	74.2	74.2	74.3	74.5	74.4
1612	38	8-7-72	73.0	74.0	74.0	74.2	74.1	74.3	74.4
2296	42	8-7-72	72.4	73.2	73.2	73.2	73.1	73.1	73.3
1P656	36	8-11-72	72.6	73.4	73.5	73.5	73.5	73.5	73.6
1P666	40	8-14-72	73.2	74.6	74.7	74.8	74.9	74.9	75.1
1P668	45	8-14-72	72.2	73.5	73.5	73.6	73.7	73.7	73.8
1P611	46	8-14-72	72.4	73.8	73.9	73.9	73.9	74.0	74.0
1P618	47	8-14-72	72.2	73.4	73.5	73.4	73.3	73.3	73.3

*Pacer received 5-5-73 and returned to ARCO for analysis purposes.

TABLE 4

<u>DOG RATE DATA</u>				(continued)					
<u>Dog #</u>	<u>P.M. #</u>	<u>Date Implanted</u>	<u>Initial Rate</u>	<u>9-17-73</u>	<u>10-17-73</u>	<u>11-30-73</u>	<u>1-24-74</u>	<u>3-22-74</u>	<u>4-26-74</u>
1Q132	49	8-22-72	72.9	74.5	74.6	74.7	74.8	74.8	74.9
1R482	52	8-28-72	72.8	74.4	74.3	74.4	74.6	74.5	74.8
1P802	54	8-28-72	72.6	74.2	74.1	74.2	74.2	74.3	74.5
1P764	55	8-30-72	72.8	74.5	74.4	74.5	74.8	74.8	74.9
1P785	41	9-8-72	73.1	73.6	73.7	73.7	73.7	73.7	73.7
1P654	56	9-8-72	72.9	74.7	74.6	74.8	74.8	74.8	75.0
1P776	57	9-12-72	73.4	75.2	75.5	75.6	75.7	75.8	76.0

DOG IMPLANT
NU-5 RPCP SERIAL NO. 3

Figure 2

DOG IMPLANT
NU-5 RPCP SERIAL NO.41

Figure 3

on the case lid weld bead. This pacemaker battery was then placed inside the shipping container consisting of an outer corrugated cardboard box with two inches of shock absorbing polyurethane foam surrounding a plastic box holding inserts to suspend the pacer.

This package was temperature stabilized at ambient room temperature and then placed in the environmental chamber at 60° C or -40° C. Figure 4 shows the temperature rise of the nuclear battery case in the shipping package subjected to 60° C environment. Assuming a first order linear system, the thermal time constant is 1.9 hours.

Figure 5 shows the temperature drop of the nuclear battery case in the shipping container subjected to -40° C environment. Again, assuming a first order linear system, the thermal time constant is 1.85 hours. These two time constants are very close considering possible error in experimental data and the fact that the nuclear battery itself has a time constant around 2 hours (from case to fuel capsule).

The steady state pacer temperature tended to stabilize 6 - 7 degrees centigrade higher than the environment at room temperature and at 60° C. However, the steady state pacer temperature was 13 degrees centigrade higher than the -40 ° C environment.

2. Shipping Package Environmental Factors Recorded in Air Carriers

Four shipping package containers were instrumented with simulated pacers (weighted impact-o-graph accelerometers). Also, thermometers capable of retaining low and high temperatures were positioned between the inner and outer one inch thick 805 presto polyurethane foam. These thermometers are equipped with indicators that register and hold either the high or low temperature.

STEP CHANGE IN TEMPERATURE (ROOM TEMPERATURE TO 60°C)

24

Figure 4

STEP CHANGE IN TEMPERATURE (ROOM TEMPERATURE TO -40°C)

Figure 5

In the first shipment, the four packages were sent round trip to Houston, Texas; Miami, Florida; Los Angeles, California; and Zurich, Switzerland from Pittsburgh. The impact-o-graphs (ball-spring trip mechanism) were set at 50 g's (5" drop height on pad) and could be triggered by an 18" drop to concrete. All shipping package impact-o-graphs were tripped. The high and low temperatures for the various shipments are as follows:

	<u>High</u>	<u>Low</u>
Miami, Florida	90° F	22° F
	Mercury Separated	
Houston, Texas	78° F	20° F
	Mercury Separated	
Los Angeles, California	75° F	20° F
	Mercury Separated	
Zurich, Switzerland	86° F	24° F

Note on three thermometers the mercury separated where an estimated reading was taken.

For the second shipment, the impact-o-graph accelerometers were set at 100 g's (14" drop height on pad) (could be triggered by a 60" drop to concrete) and shipped to Boston via Philadelphia from Pittsburgh. No impact-o-graphs were tripped. The high and low temperatures were as follows:

	<u>High</u>	<u>Low</u>
Box #1	76° F	54° F
Box #2	88° F	46° F
Box #3	78° F	56° F
Box #4	67° F	48° F

Now a second shipment to Miami, Florida; Houston, Texas; Los Angeles, California; and Zurich Switzerland with 100 g impact-o-graphs should confirm the Boston shipment that 100 g's is the maximum shock level encountered in shipping.

3. Shock Transmissibility and Drop Testing of the Pacemaker Shipping Container at Associated Testing Laboratories

Transporting a nuclear pacer by air carriers and ground vehicles requires a shipping container that protects the pacer from extremes of shock, vibration, and temperature, and this report covers the final controlled shock testing of the pacer shipping container at Associated Testing Laboratories. Preliminary shock testing was performed by dropping a shipping container with a mock-up pacer (weighted impact-o-graph) to concrete and noting dislodgment of the ball indicators. This testing with various foams and foam thicknesses indicated that a two inch thickness of 805 Presto urethane foam would provide adequate shock protection (AEC Quarterly Progress Report for RPCP, Pages 27-31, November 1, 1973 to January 31, 1974). The complete pacer shipping package consisted of an outer corrugated cardboard box, a two inch thickness of Presto 805 urethane foam entirely surrounding the plastic box (styrene) with the 'lexan' and impact styrene inserts suspending the pacer from the sides of the plastic box. Preliminary drop testing of this complete shipping package was performed at ARCO Polymers, Inc., Monaca, Pennsylvania, from 30 and 60 inch drop heights to concrete on three axes measuring shock levels with an instrumented mock-up pacer equipped with a triaxial accelerometer which confirmed earlier shock testing with the impact-o-graph accelerometers.

This report covers the final controlled shock testing of the pacer shipping package done at Associated Testing Laboratories, Burlington, Massachusetts, including shock transmissibility of the complete shipping

package and plastic box with inserts (no cardboard box or foam) and dropping to concrete a bare pacer, plastic box (no cardboard box or foam) and a complete shipping container.

a. Test Setup

The complete shipping package as tested at Associated Testing Laboratories and ARCO Polymers includes the outer corrugated cardboard box, two inch thickness of shock absorbing Presto 805 urethane foam entirely surround the plastic box with the 'lexan' and impact styrene inserts suspending the pacer inside the plastic box.

The mock-up pacer was instrumented with a uniaxial Endevco accelerometer Model 2226C (3/8 inch diameter by 2 1/64 inch high) with the accelerometer mounted externally on the epoxy molding of the dummy pacer. The accelerometer signal was conditioned by a charge amplifier and displayed on an oscilloscope. Polaroid photos of the oscilloscope trace were taken of all drop tests. Figure 6 gives the axes orientation along which testing occurred for these drop and shock tests.

For shock transmissibility, a pneumatic powered drop table was accelerated over a 6-24 inch stroke and then impacted on a pad. The shock waveform shape was sinusoidal with duration determined mainly by the selection of the pad. The maximum shock impact was determined mostly by the stroke length and accelerating pneumatic pressure. For this shock transmissibility testing, shock impact levels of 50, 200, and/or 500 g's were selected.

For the free drops to concrete of the pacer shipping package, the plastic box (without the corrugated cardboard or two inches of shock absorbing foam), and the bare pacer, the items to be dropped were held at the specified height of 30 or 60 inches and released by hand. A different shipping container was used for shock and drop testing of each axis.

AXIS ORIENTATION OF SHIPPING PACKAGE TEST

Figure 6

The accuracy and calibrations of the equipment used for the shock testing at Associated Testing Laboratories is given in Attachment A.

b. Test Results

For shock transmissibility of the complete shipping package, a shock pulse width of 13 milliseconds was selected for preliminary shock transmissibility testing. However, at 50 and 200 g's, the shock transmissibility ratio (pacer shock level/input shock level) was essentially one indicating the shock pulse duration was too long for this particular shipping package in that the shock foam was compressed to the point that it was effectively solid since the pacer had the same shock level as that on the outside of the shipping container. A pulse duration of four milliseconds was evaluated because a half-sine waveform shock of four milliseconds pulse duration at 500 g's corresponds (from conservation of momentum) to an impact velocity of 41 ft/sec. which is approximately the terminal velocity of the shipping package in the horizontal position. For the complete pacer shipping package at shock inputs of 50, 200, and 500 g's at four milliseconds pulse duration the pacer shock levels were measured and the test results are given below:

FOUR MILLISECOND SINUSOIDAL SHOCK INPUT
TO SURFACE OF COMPLETE SHIPPING PACKAGE

<u>Shock Input (g's)</u>	<u>X-(Horizontal)</u>	<u>Pacer Peak g Levels</u>	
		<u>Axes</u>	
		<u>Y-(Side)</u>	<u>Z-(End)</u>
50	36	45	20
200	70,90	20*	60,70
500	250	380	200

* Brake catching on drop table

The shock transmissibility of the plastic box with inserts (no corrugated cardboard box or foam) was tested at shock inputs of 50 and 200 g's with a four millisecond pulse duration and the test results are given below:

FOUR MILLISECOND SINUSOIDAL SHOCK INPUT
TO SURFACE OF PLASTIC BOX

<u>Shock Input (g's)</u>	<u>Pacer Peak g Levels</u>		
	<u>Axes</u>		
	<u>X- (Horizontal)</u>	<u>Y- (Side)</u>	<u>Z- (End)</u>
50	38	86	20
200	300	*	*

* Broke plastic box and accelerometer popped off

For dropping the complete shipping package to concrete from 30 and 60 inch heights with an instrumented mock-up pacer, the average g level of five drops on each of the three axes is given below:

FREE DROP TO CONCRETE WITH INSTRUMENTED MOCK-UP PACER
IN COMPLETE SHIPPING CONTAINER

<u>Drop Height (Inches)</u>	<u>Pacer Peak g Levels</u>		
	<u>Axes (Surface Impacting)</u>		
	<u>X- (Horizontal)</u>	<u>Y- (Side)</u>	<u>Z- (End)</u>
30	80 (81.6)**	34 (73.7)	57.6 (81.5)
60	95 (105.6)	73 (106.4)	96 (88.3)

A triaxial accelerometer (three axes) was used at ARCO Polymers; whereas, a uniaxial accelerometer which measured g level only along axis normal to the impact surface was used at Associated Testing Laboratories. The shipping packages impacted flat on the concrete at ARCO Polymers and Associated Testing Laboratories so the g values should not differ because of this difference in accelerometers.

** Indicates shock values from similar drop testing at ARCO Polymers, Monaca, Pennsylvania.

The plastic box with inserts and mock-up pacer (no cardboard box or foam) was dropped 30 inches to concrete on the Z axis (end surface impacting) indicating a pacer g level of 260 g's. The plastic box was cracked around the hinges and latch and around the impacting surface.

A bare pacer instrumented along the Z axis (end surface impacting) was dropped 60 inches to concrete. The impact orientation was difficult to control because the attached coaxial cable wire had a tendency to rotate the pacer as it fell. This was not a problem with dropping the complete shipping package and the plastic box with inserts because their moment of inertia and overall weight were much higher than the bare pacer. The accelerometer had a tendency to pop off the pacer upon impact (it was subsequently reattached). Also, the oscilloscope had to be triggered externally from the signal generated by the impacted accelerometer to display this same signal. The g level recorded for this drop, the most representative drop, was 5000 g's using an 80,000 Hz frequency response band pass filter. The accuracy for dropping the bare pacer to concrete was ± 1000 g's or more due to the variability of impact angle. Previous drop testing of a bare pacer to concrete gave an impact shock level of 4450 g's (AEC Quarterly Progress Report for RPCP Program, November 1, 1970 to January 31, 1971, Page 27).

c. Conclusions

The only visible damage to the complete shipping container for the shock transmissibility testing was slight compression of the outer cardboard box for each of the three axes. The shipping package showed a shock transmissibility ratio (pacer shock level/input shock level) around 0.4 to 0.7 at 50 g's and between 0.3 to 0.5 for shock levels of 200 and 500 g's at four millisecond shock pulse duration. For the

shock transmissibility of the plastic box with inserts (no cardboard box or foam), the plastic box cracked at 200 g's on the Y and Z axes but not the X-axis at four millisecond pulse duration. The shock transmissibility ratio at four millisecond pulse duration exceeded one for 50 g's impact level on the Y-axis (side surface impacting) and 200 g impact level on the X-axis (horizontal surface impacting) because the pneumatic accelerating stroke (prior to impact) in effect spring loaded the mock-up pacer via the inserts bending and then springing back on impact, contributing an additional accelerating force on the mock-up pacer.

For the numerous drops to concrete at 30 and 60 inches of the complete shipping package, there was no visible damage. The g levels obtained at Associated Testing and ARCO correspond within accuracies of the equipment (+ 10 percent at ARCO Polymers or approximately 10 g's at the 60 inch drop and + 9 percent or 9 g's at 60 inch drop at Associated Testing Laboratories using the root-mean-square of the accuracies quoted for the equipment as shown in Attachment A) except for 30 and 60 inch drops on the Y-axis (side impacting) and the 30 inch drops on the Z-axis (end impacting). The reason for this discrepancy is that the mock-up weighted pacer used at ARCO Polymers (an aluminum plate with attached accelerometer) did not fit the insert snugly as that used at Associated Testing Laboratories and could tilt on impact, whereas the mock-up pacer used at Associated Testing Laboratories was a dummy pacer model that fitted tightly into the inserts.

The 30 inch drop to concrete of the plastic box with inserts (no cardboard box or foam) with the end impacting (along Z-axis) indicated only 260 g's to the mock-up pacer but cracked the plastic box around the hinges and impacting surface.

For the 60 inch drop to concrete of the dummy instrumented pacer, the only visible damage was very slight indentations on the curved surfaces of the titanium case due to impact. The shock level was 5000 g's for the bare pacer impacting on the concrete from a 60 inch free fall drop.

In conclusion, the complete shipping package attenuated by a factor of 50 the g level experienced by a bare pacer dropped 60 inches to concrete. The shipping container will adequately protect the pacer from anticipated shipping shocks and drops.

TASK 5.0 - ENVIRONMENTAL ASSESSMENT

Crematory Testing

Two tempil holders were tested and returned from a crematory in London, England. This crematory uses a cyclonic retort which is advertised as the most advanced type of retort in that country. It operates on gas and has a relatively short cycle time -- 1 hr. 20 min. The two tempil holders were examined and the highest pellet that melted was 2000° F in one and 1900° F in the second holder. There are only two holders which have not been returned. There has been a total of 76 tempil holders tested at 54 crematories.

Cremation Test

Subsequent to the completion of previous cremation testing, the Interim Guide requirements were recently modified to require that the fuel capsule must remain leak tight down to 10^{-8} cc/sec when the pacemaker is exposed to a cremation cycle of two hours at a minimum temperature of 800° C in which there shall be a sustained temperature of 1300° C for at least 90 minutes, at anytime during the useful life of the pacemaker. Based on the previous tests and above discussions, it was concluded that the NU-5 pacemaker would pass the new cremation test. In order to verify this, an additional test was performed. A complete NU-5 pacemaker system was fabricated using an unloaded fuel capsule that had an internal pressure in excess of the maximum value which could be achieved over a 50 year life. This completed pacemaker was subjected to the time-temperature profile shown in Figure 7. After the pacemaker had cooled to room temperature, the inner fuel capsule was leak checked. It was found that the inner fuel capsule was still hermetically sealed with a leak rate less than 5×10^{-11} atm cc/second which was the limit of the leak rate detector sensitivity. It should be noted that the time-

TIME - TEMPERATURE PROFILE
RPCP CREMATION TEST UNIT B17-3
3-13-74

Figure 7

temperature profile is more severe than required as is the 50 year internal pressure of the fuel capsule. Over the first two hours of the test the minimum temperature was in excess of 1120° C and temperatures in excess of 1300° C (peak of 1326° C) were sustained in excess of 90 minutes as seen in Figure 7. The test was conducted in a muffle furnace and an excess supply of air was continuously supplied to the furnace in order to obtain an oxidizing atmosphere during the entire test. The temperature of the pacemaker was monitored and recorded continuously throughout the test using thermocouples. It should be noted that the pacemaker tested was fabricated identically to production units and it was not necessary to vent the pacemaker in any way. The pacemaker was positioned in the furnace by laying on its side (fully exposed) as would probably be the case in a normal cremation. The orientation of the pacemaker has no effect on the test results since the nuclear battery is symmetrical.

Figure 8 shows a photograph of the pacemaker following this test and it should be noted that the system remains intact and would be easily detected in the debris following a cremation. Figure 9 shows that the fuel capsule ends up surrounded in a protective "cocoon" made of the melted E-glass from the thermopile which would help contain the plutonium fuel if the fuel capsule had been breached (which it was not). Figure 10 shows a photomicrograph of a section taken of the inner fuel capsule after it was leak checked. The only effect is a slight oxidizing layer on the surface. Figure 10 indicates that a longer cremation time or higher temperature or both could be sustained. It should again be noted that this inner fuel capsule had an internal pressure equivalent to in excess of 50 years of operation. It should further be noted that the oxidizing environment of the test represents a worse case condition since oxygen can attack the

1X

TEST UNIT BEFORE CREMATION

1X

TEST UNIT AFTER CREMATION

Figure 8

2X

FUEL CAPSULE ASSEMBLY
AS REMOVED FROM BATTERY

2X

FUEL CAPSULE ASSEMBLY
WITH Ta-10W CAPSULE EXPOSED

Figure 9

TRANSVERSE SECTION OF Ta-10W FUEL CAPSULE
DARK FIELD ILLUMINATION
ETCHANT: HF, HNO₃, H₂O₂

10X

TRANSVERSE SECTION OF Ta-10W FUEL CAPSULE
TYPICAL OXIDIZED CASE DEPTH OF .004"

50X

ETCHANT: HF, HNO₃, H₂O₂

Figure 10

fuel capsule components. A reducing atmosphere would be much less severe since it does not represent a means of fuel capsule attack for the NU-5 pacemaker.

Test Report No. NT-710-11No. of Pages 6

Report of Test on

HEART PACER SHIPPING CONTAINERSSHOCK TESTING

for

ARCO NUCLEAR COMPANY

Associated Testing Laboratories, Inc.

Date April 5, 1974

	Prepared	Checked	Approved
By	C. Muise Jr.	E. Mencow	E. Kulcsar
Signed	<i>C. Muise Jr.</i>	<i>E. Mencow</i>	<i>E. Kulcsar</i>
Date	<i>4/9/74</i>	<i>4/9/74</i>	<i>4-9-74</i>

Administrative Data

1.0 Purpose of Test:

To subject the submitted test specimens to shock and drop testing in accordance with the procedures of this report, evaluating the effects on the units.

2.0 Manufacturer: Arco Nuclear Company
River Road, Route No. 66
Leechburg, Pennsylvania

3.0 Manufacturer's Type or Model No.: None

4.0 Drawing, Specification or Exhibit: Verbal instructions
from Arco Nuclear
Company.

5.0 Quantity of Items Tested: Three Plastic Packages,
Three Cardboard Con-
tainers, and One dummy
6.0 Security Classification of Items: Heart Pacer.
Unclassified

7.0 Date Test Completed: March 27, 1974

8.0 Test Conducted By: Associated Testing Laboratories, Inc.

9.0 Disposition of Specimens: Returned to Arco
Nuclear Company.

10.0 Abstract:

The submitted test specimens were subjected to a series of shock and drop tests. The units were subjected to half-sine shock pulses in three axes. The Pacer was inside the Plastic Packages for all testing. The Plastic Packages were subjected to shocks up to 200g

10.0 Abstract (continued)

separately, and 500g when inside the Cardboard Boxes. The Plastic Packages were dropped from a height of 30" to a concrete floor. The Plastic Packages were then put into the Cardboard Containers and dropped from 30" and 60" onto a concrete floor. The Pacer by itself was also dropped from a height of 60" onto a concrete floor. During all drops a monitor accelerometer was attached to the Pacer to record the g level the Pacer received. Different units were used in each of the three axes.

The Cardboard Container at the conclusion of each axis showed signs on the sides and top of compression. The Plastic Packages and Pacer were not damaged when tested inside the Cardboard Containers. The Plastic Packages after the 200g test in both the Y and Z axis had tears and cracks in the material.

44

Report No. NT-720-11

45

Page 3

LIST OF APPARATUS

ITEM	MANUFACTURER	MODEL NO.	ACCURACY	CALIBRATION DATE	CALIBRATION DUE DATE
Shock Machine	Avco Corporation	Type 110 Model 3	N/A	N/A	Before Use
Accelerometer	Endevco Corporation	2226C	<u>+5%</u>	2/8/74	5/8/74
Oscilloscope	Tektronix	564	<u>+3%</u>	1/25/74	4/25/74
Shock Test Console	Associated Testing Laboratories, Inc.	---	<u>+5%</u>	1/14/74	4/14/74
Accelerometer	Endevco Corporation	2217A	<u>+5%</u>	2/8/74	5/8/74
Accelerometer	Endevco Corporation	2225	<u>+5%</u>	2/8/74/	5/8/74

SHOCK TEST

TEST PROCEDURE

The submitted Containers were subjected to shock testing in accordance with verbal instructions from Arco Nuclear Company as follows.

The units were securely attached to the carriage of the shock machine. Cardboard Container S/N 1 was dropped in the X axis only (vertical axis). Cardboard Container S/N 2 was dropped in the Y axis only (lateral axis). Cardboard Container S/N 3 was dropped in the Z axis only (parallel to longitudinal axis).

A dummy Pacemaker, with monitor accelerometer attached was placed in its Plastic Package, which was placed in the Cardboard Container. The shock machine was calibrated to produce a half-sine wave shock pulse having the following amplitudes and time durations:

<u>g Level</u>	<u>Time Duration in Milliseconds</u>
50	4
200	4
500	4

The Plastic Package with dummy Pacemaker was subjected to shock g levels of 50 and 200g. The Containers were subjected to one impact in each of three mutually perpendicular axes.

TEST RESULTS

All data pertaining to the output of the monitor accelerometer was retained by a representative of Arco Nuclear Company. The Cardboard Containers at the conclusion of each axis showed evidence of physical damage. The sides had compressed inward. The Plastic Packages and Pacer showed no evidence of physical damage.

SHOCK TEST

TEST RESULTS (continued)

The Plastic Packages after 200g level test in both the Y and Z axis had cracks in it. The impact styrene inside the Plastic Package did crack and tear as a result of the testing. The lexane insert had no damage.

DROP TEST

TEST PROCEDURE

The Plastic Package was subjected to a drop test in accordance with verbal instructions from Arco Nuclear Company as follows.

The Plastic Package with dummy Pacer inside was placed inside the Cardboard Container and dropped from heights of 30" and 60" onto a concrete floor. This was done a total of 5 times. A separate unit was used for each of the three axes. The Plastic Package was dropped from a height of 30" to the concrete floor in the Z axis only. The Pacer by itself was dropped from a height of 60" to a concrete floor in the Z axis only. A monitor accelerometer was attached to the Pacemaker for each drop.

TEST RESULTS

All data pertaining to the output of the monitor accelerometer was retained by a representative of Arco Nuclear Company. The Plastic Package did crack as a result of the drop from 30". There was no damage incurred to the Cardboard Container and Pacemaker as a result of the drop test.