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ARCO-3057-16

RADIOISOTOPE POWERED CARDIAC PACEMAKER PROGRAM

Quarterly Progress Report, November 1, 1973—January 31, 1974

Arco Nuclear Company
Leechburg, Pennsylvania

MASTER

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Price: Paper Copy **\$5.45**
Microfiche **\$1.45**

Quarterly Progress Report
for
Radioisotope Powered
Cardiac Pacemaker Program

November 1, 1973 to January 31, 1974

Prepared for

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

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INTRODUCTION

This is the sixteenth 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 November 1, 1973 to January 31, 1974.

TASK 1.0 - PROGRAM MANAGEMENT, CONTROL AND PLANNING

A total of forty-five (45) AEC-ARCO NU-5 model radioisotope powered cardiac pacemakers have thus far been implanted in clinics across the United States. The program, now entering its eleventh month of progress, has resulted in an accumulation of 28.02 unit years of reliability data.

The animal implant program, now entering its twentieth month, is being conducted at the National Institute of Health and has resulted in an accumulation of 43.77 unit years of reliability data.

Contained in this report is a summary of the series of impact testing performed at Sandia Corporation in New Mexico on the new fuel capsule design.

Special testing of electronics modules was conducted, the results of which are presented in Task 4.0.

Electronic circuit life test data represents a total of 472.87 unit years with no failures. The proven reliability is 94.73 for an 11 year mission time at a 90 percent confidence level based on the Random Mode.

TASK 2.0 - HUMAN INVESTIGATIONAL STUDY

The Human Investigational Study, now entering its tenth month, represents an accumulation of 28.02 unit years of reliability data. Thus far, a total of 45 NU-5 model fixed rate pacemakers have been implanted with the rate of implant since April of 1973 being depicted in Figure 1.0. Table 1.0 provides data which includes the date of implant of each pacemaker, the pulse rate at implant and 24 hours after implant, and the total number of days accumulated by that unit. Each pacemaker which is implanted must be monitored at regular intervals and the most recent collection of data under this surveillance program is listed in Table 2.0.

A gradual, constant rate decline has been observed in several implanted pacemakers. Declining pulse rates have been associated with implantable pacemakers for many years. It is not uncommon for conventional pacemaker rates to decline, not because of battery depletion, but as a result of moisture infiltrating the electronic circuit through the epoxy encapsulation used on conventional units. Figure 12.0 illustrates the long term pacemaker drift seen in several makes of conventional pacemakers as reported in Pacemaker Diagnostic Newsletter dated September 1973.

Declining pulse rates for the nuclear pacemakers have not been detected in the 29 dog implants which have been in progress for approximately 19 months nor in life test units over the past 7 years. A study was conducted to determine the cause of this rate decline, the results of which are as follows:

- a. The pacers with declining rates are from a single lot produced at about the same time and the rate decline is apparently due to entrapped moisture in the electronics case. The nuclear battery is not affected.

- b. All other pulse parameters including pulse amplitude remain constant as well as the nuclear battery output.
- c. It is predicted, based on accelerated tests, that pulse rates will stabilize at an acceptable level (Figure 14.0). In the interim, since pulse amplitude is not affected, pacer outputs will remain well above pacing thresholds.
- d. Satisfactory modifications in manufacturing and quality control procedures have been made that will preclude electronics case moisture entrapment and hence rate declines in future units.

During this report period, an infection developed in the patient wearing unit 109. The pacemaker pocket was opened to treat the infection and at that time pacemaker 109 was replaced by pacemaker 158. Subsequently, unit 109 was returned to ARCO and is presently under test. Unit 109 is one of the units exhibiting the gradual rate decline previously discussed. Approximately one month after implantation of pacemaker 158, the patient was readmitted due to a reoccurrence of the abdominal pacemaker bursa infection. At that time, pacemaker 158 was replaced with unit 138 and in addition, a new endocardial lead was used. The switch from pacemaker 158 to 138 was the result of sound surgical practice that would preclude taking a foreign body from one infected area and transplanting it into a different area without sterilizing it in between which was impractical to achieve at the time. Pacemaker 158 has subsequently been resterilized and is awaiting implant at the institution involved.

RATE OF IMPLANT

Figure 1.0

Table 1.0
Initial Human Implant Data

Factor #	Rate at AECOD (98°F)	Implant Date	Institution	Rate at Implant	24 Hours After Implant	Duration (days) as of January 31, 1974
83	73.7	4/9/73	NIH	73	73.8	298
76	71.8	4/9/73	NBIMC	72	71.9	298
85	73.3	4/9/73	NBIMC	73	73.1	298
100	72.9	4/9/73	NBIMC	73	72.6	298
101	72.5	4/9/73	NBIMC	72	72.0	298
102	73.3	4/9/73	NBIMC	73	73.3	298
103	73.7	4/9/73	NBIMC	73	73.6	298
106	74.1	4/9/73	NBIMC	74	73.7	298
108	73.3	4/9/73	NBIMC	73	73.3	298
61	71.8	4/10/73	NBIMC	72	71.9	297
70	71.4	4/10/73	NBIMC	71	71.6	297
9	72	4/10/73	NBIMC	72	71.9	297
83	72.6	4/10/73	NBIMC	73	72.6	297
86	73.7	4/10/73	NBIMC	73	73.7	297
90	73.4	4/10/73	NBIMC	74	73.6	297
107	74.1	4/10/73	NBIMC	74	73.5	297
73	73.1	5/7/73	THI	73.2	73.3	270
74	74.4	5/12/73	THI	74.3	74.5	259
95	74.9	5/18/73	LAC-USC	74.8	74.9	253
94	73.8	6/5/73	JMH	76	75.1	240
97	73.6	6/5/73	JMH	73	72.9	240
113*	74.2	6/5/73	LAC-USC	72.8	73.3	190
126	74.2	6/12/73	PGGH	74	74.0	233
128	74.0	6/12/73	PGGH	75	75.0	233

*Removed 113 in favor of 78

Table 1.0 (continued)
Initial Human Implant Data

<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 January 31, 1974</u>
121	74.4	6/13/73	PGGH	75	75.0	232
125	74.0	6/13/73	PGGH	75	75.0	238
129	74.1	6/13/73	MH	73	74	232
131	74.9	6/13/73	MH	74	75	232
140	73.6	6/13/73	MH	73	74	232
142	74.1	6/15/73	MH	73	74	230
109**	73.8	6/25/73	NIH	73	72.7	108
114	73.9	7/6/73	LAC-USC	72.0	72.4	209
115	74.2	7/6/73	MH-NY	72.7	72.8	209
116	73.8	7/20/73	LAC-USC	70.9	71.6	195
120	73.4	7/24/73	PGGH	75	73	191
144	73.7	7/27/73	MH-NY	73.4	73.5	188
99	73.3	8/3/73	JMH	72	74	181
149	73.7	8/7/73	MH-NY	73.3	73.5	177
136	74.8	9/12/73	MH-NY	74.3	74.8	141
145	73.4	9/14/73	MH-NY	73.5	73.3	139
156	75.9	9/19/73	VAB	75	75	134
78	72.8	10/11/73	LAC-USC	72.0	72.5	112
157	74.7	11/23/73	VAB	76	76	72
162	74.2	11/29/73	VAB	74	72	66
155	75.4	12/3/73	JMH	75	75.6	59
75	72.9	12/4/73	VAB	72	72	58
138	75.2	12/10/73	NIH	74.9	75.4	52
158***	75.3	11/15/73	NIH	75		26

**Removed 109 in favor of 158

***Removed 158 in favor of 138

RPCP Human Rate Data

[illegible]

Table 2.0 (continued)

RPCP Human Rate Data

Pacer #	7/1 - 7/7	7/8 - 7/14	7/15 - 7/21	7/22 - 7/28	7/29 - 8/4	8/5 - 8/11	8/12 - 8/18	8/19 - 8/25	8/26 - 9/1	9/2 - 9/8	9/9 - 9/15	9/16 - 9/22	9/23 - 9/29
88	-	74.0	-	-	-	-	-	74.1	-	-	-	74.1	-
76	72.5	72.4	-	-	72.3	-	-	-	-	72.3	-	-	-
85	72.8	-	-	-	72.6	-	-	-	-	72.5	-	-	-
100	72.8	-	-	-	-	72.7	-	-	-	72.6	-	-	-
101	72.3	-	-	-	72.2	-	-	-	-	72.1	-	-	-
102	73.1	-	-	-	-	73.0	-	-	-	72.9	-	-	-
103	73.4	73.6	-	-	73.2	-	-	-	-	73.2	-	-	-
108	72.0	-	-	-	-	71.5	-	-	-	70.8	-	-	-
106	-	-	-	72.0	-	71.7	-	-	-	71.3	-	-	-
61	72.2	-	-	-	72.3	-	-	-	-	72.4	-	-	-
70	71.9	-	-	-	-	72.0	-	-	-	-	72.1	-	-
72	72.1	-	-	-	72.2	-	-	-	-	72.3	-	-	-
83	72.5	-	-	-	72.4	-	-	-	-	72.4	-	-	-
86	-	73.9	-	-	-	-	-	-	-	74.1	-	-	-
90	-	73.8	-	-	73.8	-	-	-	-	73.9	-	-	-
107	72.1	72.0	-	-	71.5	71.4	-	-	-	71.0	-	-	-
73	73.6	-	-	-	-	-	-	73.7	-	73.8	-	-	-
74	74.7	74.7	-	-	74.8	-	-	-	-	75.0	-	-	-
95	75.0	75.0	75.0	-	-	-	75.0	-	-	-	75.0	-	-
94	-	-	-	-	-	77.9	78.0	-	-	-	76.8	-	-
97	72.5	-	-	-	-	-	-	-	-	-	71.1	-	-
113	72.6	72.4	72.2	72.0	71.8	71.7	-	-	-	70.9	-	-	-
126	74	74	74.3	74.3	74.0	74.0	-	-	-	74.4	74.4	-	-
128	74	74	74.3	74.3	74.3	74.3	-	-	-	74.2	74.1	-	-
121	74	74	75.1	75.1	75.1	75.0	-	-	-	75.1	75.1	-	-
125	74	74	73.3	73.3	73.3	73.3	-	-	-	74.1	74.2	-	-
129	74.2	74.3	74.3	74.4	-	74.3	-	-	-	-	-	-	-
131	75.1	75.1	75.2	75.2	75.2	75.1	-	-	-	-	-	-	-
140	74.1	74.1	74.1	74.1	74.1	74.1	-	-	-	74.1	-	-	-
142	74.1	74.3	74.3	74.3	74.4	74.4	-	-	-	74.5	-	-	-
109	72.6	72.5	72.4	72.2	-	72.0	71.9	71.7	71.6	-	71.4	71.3	-
114	-	72.4	72.1	71.9	71.7	71.5	71.3	71.1	-	70.7	-	-	-
115	-	73.0	-	72.7	72.5	72.3	72.2	72.0	71.8	71.7	71.5	71.3	-
116	-	-	-	71.4	71.1	70.9	70.8	70.5	70.3	70.2	69.9	-	-
120	-	-	-	73.3	73.3	73.3	73.4	-	-	73.4	73.4	-	-
144	-	-	-	73.5	73.6	73.6	73.6	73.6	73.6	73.7	-	73.7	73.7
99	-	-	-	-	-	71.7	71.5	71.4	71.2	71.1	70.9	70.7	-
149	-	-	-	-	-	73.5	73.6	73.6	73.5	73.6	-	73.6	73.6
136	-	-	-	-	-	-	-	-	-	-	-	74.8	74.7
145	-	-	-	-	-	-	-	-	-	-	-	73.5	73.5

Table 2.0 (continued)
RPCP Human Rate Data

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	-	-
128	74.2	74.2	-	-	74.2	74.2	74.2	74.2	74.3	74.3	74.3	-	-
121	75.2	75.2	-	-	75.2	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	-	-
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	-	-
144	73.6	73.6	73.8	73.7	-	-	-	-	-	-	-	-	-
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	-	-	-	-	-	-
145	73.5	73.5	73.6	73.5	73.6	73.5	73.5	-	-	73.7	-	-	-

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

TABLE 2.0 (continued)
RCP Human Rate Data

Pacer #	12/30- 1/5	1/6- 1/2	1/13- 1/19	1/20- 1/26	1/27- 2/2	2/3- 2/9	2/10- 2/6	2/17- 2/23	2/24- 3/2
88	-	74.1							
76	-	72.5							
85	-	72.0							
100	72.2								
101	-	71.6							
102									
103	-	72.7							
108	69.1								
106	69.6								
61									
70									
72									
83	-	72.0							
86									
90	-	74.0							
107	-	69.2							
73	-	74.1							
74	75.1								
95	-	75.2							
94	-	80.3							
97									
113*									
126									
128									
121									
125									
129	74.4								
131									
140	-	-	-	74.3					
142	-	74.7							
109**									
114	-	68.2							
115	69.5	69.4	69.3						
116									
120									
144									
99	-	-	-	-	68.6				
149									
136									
145									

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

Table 2.0 (continued)

RPCP Human Rate Data

<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											75.0	75.0	75.0
75													
138													

Table 2.0 (continued)
RPCP Human Rate Data

<u>Pacer #</u>	<u>12/30 - 1/5</u>	<u>1/6 - 1/12</u>	<u>1/13 - 1/19</u>	<u>1/25 - 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>
156									
78	-	72.4							
157									
162									
155									
75		75.0	75						
138			75.4	-	75.4	75.4			

TASK 3.0 - SYSTEM FABRICATION AND QUALITY ASSURANCE

Reliability Data

The attached data (Table 3.0) summarizes the AEC units on life test.

At the end of January, a total of 45 AEC-ARCO NU-5 Model Radioisotope Powered Cardiac Pacemakers have been implanted. Over the past nine months the human implants have accumulated 28.02 unit years with no failures.

There are also 13 high voltage units on life test which have accumulated 10.00 unit years.

At the present time, 126 Phase II electronic circuits are on life test. These circuits are operating at 2.2 volts at room temperature with a simulated battery resistance of 5300 ohms. The accumulated life test time represents 472.87 unit years with no failures. The proven reliability is 94.73 for an 11 year mission time at a 90 percent confidence level.

Q.C. Inspection

The Quarterly Inspection Summary (Table 4.0) lists the component inspection and indicates the percentages of components for production and percentages of components used for special tests.

Q. C. Test Summary

Table 5.0 and Table 6.0 summarizes the qualification tests conducted through the months of November, December 1973 and January 1974. The test results include the NU-5 high voltage test units and the NU-5 four tape test units.

Thermopiles, Battery, and Pacemaker Assembly

During this report period, 13 thermopiles were wrapped. Three of the high voltage thermopiles were not used, one due to an open tape and two were lost during degassing due to a vacuum system malfunction.

Table 3.0
Life Test Data Through January 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		73.68	5.9
17	230.3				220.1	
18	214.3				204.1	
160	218.6	6.6	73.5		73.63	5.8
163	237.7				232.2	
164	261.9				258.2	
165	266.3				73.90	6.7
166	249.7				244.9	
167	230.0				232.4	
169	226.1				232.4	
170	247.9				74.20	6.6
171	235.2				236.4	
172	230.2				228.1	

Accumulated Hours = 1.210×10^5 unit hours

<u>High Voltage Units</u>						
NU5-1	225.7	8.5	67.1		66.93	9.3
2	235.2	8.6	66.5		66.31	9.3
3	229.7			229.6		
4	250.2			250.2		
5	240.0			240.8		
6	242.5			240.8		
7	221.6			226.8		
8	245.9			246.5		
9	230.7			226.8		
10	231.7			232.4		
11	204.2			232.4		
12	229.1			229.6		
13	215.0			216.0		

Accumulated Hours = 8.766×10^4 unit hours

Table 3.0 (continued)
Life Test Data Through January 1974
Experimental Model

<u>Unit No.</u>	<u>Battery Output</u>	<u>B.O.L. Data</u>		<u>Present Output</u>		
	μ	ma	BPM	μ W	BPM	ma
E-3	84.8			70.7	70.7	
E-5	79.6			69.2	69.2	
E-9	82.3			80.8	80.8	
E-10	77.5			69.8	69.8	
E-12	230.0			238.9	238.9	
E-13BB		8.0	123.0	5.4	128.7	5.4
E-16	202.4				197.8	
E-17	196.1				217.3	
E-18	249				242.6	
P-1		5.5	125.3	5.6	125.2	5.6
P-3		5.7	126.5	5.4	121.3	5.4

Accumulated Hours = 5.819×10^5 unit hours

Table 4.0

QUARTERLY INSPECTION SUMMARY FOR NOVEMBER, DECEMBER, 1973 AND JANUARY, 1974

Task	Description	Q. C. Inspection			MRB Action					Accept Total			% Acc.	% Test
		Total Insp.	Total Acc.	Total N.C.	Total Reviewed	Total Acc.	For Test	Rework	Total Rej.	Q. C. Acc.	MRB Acc.	Total Acc.		
397	Brazed Tapes	95	83	12	12	1			11	83	1	84	88.4	0
320	Plated Ceramic Tabs	163	161	2	2				2	161	0	161	98.7	0
320	Insulation Tape	41	397	14	14				14	397	0	397	96.6	0
320	Insulation Heat Shields	86	486	0	NA					486	0	486	100.0	0
320	Cupron Plated Tape	178	156	22	22				22	156	0	156	87.6	0
320	Tophel Plated Tape	15	145	0	5				5	145	0	145	96.6	0
395	Battery Leak Check	6	6	0	NA					6	0	6	100.0	0
395	Battery X-Ray	19	19	0	NA					19	0	19	100.0	0
001	Inner Capsules	13	13	0	NA					13	0	13	100.0	0
001	Inner Plugs	10	10	0	NA					10	0	10	100.0	0
001	Middle Capsules	17	17	0	NA					17	0	17	100.0	0
001	Middle Plugs	35	35	0	NA					35	0	35	100.0	0
001	Outer Capsules	25	12	13	13		13		0	12	0	12	48.0	0
001	Outer Plugs	12	12	0	NA					12	0	12	100.0	0
320	Exterior Cases	12	12	0	NA					12	0	12	100.0	0
320	Cold Shoes	43	129	14	14				14	129	0	129	90.2	0
320	Cold Straps	23	23	0	NA					23	0	23	100.0	0
320	Battery Lids	7	7	0	NA					7	0	7	100.0	0
394	N1 T1 Feedthroughs (L.C.)	1	1	0	NA					1	0	1	100.0	0

Table 5.0

Testing Results on NU-5 High Voltage
Test Units With New Fuel Capsule

Unit	After Five Hours on Paint Shaker	After Standard Qualification Test	First Tape	Second Tape	Third Tape	Fourth Tape	Complete	Comments
NU5-D 13P	Acceptable	Acceptable						Life Test Unit
NU5-D 14P	Acceptable	Acceptable						Life Test Unit
NU5-D 15P	Acceptable	Acceptable						Life Test Unit
NU5-D 16P	Acceptable	Acceptable						Life Test Unit
NU5-D 17P	Acceptable	Acceptable						Life Test Unit

Table 5.0 (continued)
 Testing Results on NU-5 High Voltage
 Test Units With New Fuel Capsule

Unit	After Five Hours on Paint Shaker	After Standard Qualification Testing	First Tape	Second Tape	Third Tape	Fourth Tape	Complete	Comments
NU-5 18P	Acceptable	Acceptable						Life Test Unit
NU-5 19P	Acceptable	Acceptable						Life Test Unit
6 NU-5 20P	Acceptable	Acceptable		360 min.			420 min.	Destruction Unit Unit began shorting @ 360 min. Shorted completely @ 420 min. Voc = 1.32
NU-5 21P	Acceptable	Acceptable						Life Test Unit
NU-5 22P	Acceptable	Acceptable						Life Test Unit
NU-5 23P	Acceptable	Acceptable						Life Test Unit
NU-5 24P	Acceptable	Acceptable						Life Test Unit
NU-5 25P	Unacceptable							Failed During The First 2 1/2 Hours On Paint Shaker.

Table 6.0
Testing Results on NU-5
Four Tape - Test Units

Unit	After Five Hours On Paint Shaker	After Standard Qualification Testing	First Tape	Second Tape	Third Tape	Fourth Tape	Complete	Comments
NU-5 4PD-1	Unacceptable	NA						Shorted Completely After 90 Min.
NU-5 4PD-2	Unacceptable	NA						Shorted Completely After 210 Min.
NU-5 4PD-4	Acceptable							Taken Off Test After 5 Hours on Paint Shaker.
NU-5 4PD-6	Acceptable	Acceptable	360 min.					Ran 13 Hours Shorted
NU-5 4PD-7	Acceptable	Unacceptable	One Tape Out After 3000, 50g Shocks Completed Rest of Qualification Test					Taken Off Test After Qualification Test

Three pacemakers were completed during the report period, (NU5-175, NU5-176, and NU5-177) all are human implant models.

Sixteen batteries were assembled and sealed, one was a human implant model (NU5-177), eleven were high voltage models with platinum middle fuel capsules and four of the four tape models.

The performance records for the units sealed during the report period are given in Table 7.0. Also included in the table are the units that were sealed during October, which were left off the performance table for the last quarterly.

Seven thermopiles have been used to complete the four tape battery tests. The first units tested, 4PD-1 and 4PD-2, had excellent outputs ~ 2.40 volts (fuel ~ 0.225 watts) but were not wrapped tight enough to withstand the paint shaker tests. The 4PD-1 unit used three insulation tapes per thermocouple tape and the 4PD-2 unit used two insulation tapes and inserted in cases with outside dimensions of approximately 0.985 inches. Examination of the failures showed extreme abrasion of the insulation and thermocouple tapes near the hot strap as in the NU4 units.

Several modifications were made to improve the units. A tighter wrap (new four tape cold strap) with three insulation tapes per T/C tape was used including extra insulation in the void areas between the hot shoes. A case was slit and rewelded (to obtain a narrow case without development work) to have a normal cylindrical contour on the bottom. Using these modifications a unit was sealed (4PD-4) and although the thermal performance was poor ~ 1.90 volts there was no visible damage to the thermopile after five hours on the shaker. It was found that the interior

Table 7.0

A.E.C. Units B.O.L. Performance

Data for Units Sealed October through January 1974

Battery No.	Date Sealed	Comments	O.C.V. (volts)	Output Power (μ watts)	Resistance (ohms)	Fuel No.	Fuel Loading* (watts)
NU5D-15P	10/12	High Voltage Unit	3.36	235.8	11,966	A111	0.2194
NU5D-16P	10/12	High Voltage Unit	3.22	218.4	11,864	A113	0.2217
NU5D-17P	10/12	High Voltage Unit	3.34	233.4	11,946	A114	0.2248
NU5D-18P	10/26	High Voltage Unit	3.47	251.1	11,915	A112	0.2278
NU5D-19P	10/26	High Voltage Unit	3.37	235.7	11,974	A117	0.2285
NU5D-20P	10/26	High Voltage Unit	2.85	168.6	11,953	A120	0.1783
NU5D-21P	11/6	Shorted, Cut Open	2.56	136.5	11,996	A122	0.1566
NU5D-22P	11/9	High Voltage Unit	2.41	119.6	12,036	A121	0.1484
NU5D-23P	11/16	High Voltage Unit	3.12	201.7	12,065	A119	0.1987
NU5D-24P	11/16	High Voltage Unit	2.48	126.8	12,121	A122	0.1566
NU5-175	11/16	For Human Implant	2.24	234.1	5356	A67	0.2278
NU5-176	11/16	For Human Implant	2.22	228.9	5381	A106	0.2251
4PD-1	11/30	Four Tape Test**	2.38	179.8	7876	PF-1-21	0.2252
4PD-2	11/30	Four Tape Test**	2.42	185.4	7893	A8	0.2287
NU5-177	12/20	Human Implant	2.30	246.9	5356	A109	0.2258
4PD-6	1/4	Design Evaluation	2.12	138.9	8085	PF-1-21	0.2252
4PD-7	1/4	Design Evaluation	2.18	147.0	8080	A-8	0.2287
4PD-7	1/4	Design Evaluation	1.66	Unit Leaked			
NU5D-25P	1/8	High Voltage Unit	2.80	162.5	12,059	A-120	0.1783

*No correction for decay. All high voltage unit fuels have been fabricated in 1973 and do not need correction.

**Only one rolled end shield on each end.

NU-5 R.P.C.P PRODUCTION AND SPECIAL TEST UNITS

Figure 2.0

NU-5 R.P.C.P. PRODUCTION AND SPECIAL TEST UNITS

Figure 2.0
(continued)
24

case length was under specification due to the EB weld seam and subsequent tests indicated that at the correct nominal spacing the unit should meet the voltage output specification. Therefore, two more thermopiles were assembled and batteries sealed and tested. These two batteries 4PD-6 and 4PD-7, both had quite satisfactory outputs before final sealing 2.3 volts and 2.18 volts. However, after sealing there was a leak in 4PD-7 which dropped the output, after sealing voltages were 2.33 volts and 1.66 volts.

Both batteries were subjected to the qualification test and passed readily. 4PD-6 had one tape open and an open circuit voltage of 2.25 volts after completing the qualification test, it was then reinstalled on the paint shaker and ran to failure. Failure came after 12 hours with an internal short as the failure mode. 4PD-7 was taken off of test after passing the standard test with an open circuit voltage of 1.74 volts and put on life test.

These tests concluded the study of the 4 tape units with an outside case dimension reduction from a nominal 1.220 inches to .975 inches.

Electronics Installation

The 3140 single component RTV which was used for potting the electronics into the electronics case is a humidity curing material which if not fully cured prior to sealing can give off moisture. If properly controlled (as shown by the dog implants) this RTV should pose no problems. However, to eliminate any possibility of moisture evolving and effecting the circuit pulse rate a procedure was developed to use the same two component 615 RTV which is used for pre-potting the entire circuit.

One problem with the 615 RTV was that the low viscosity ($\approx 1/3$ that of 3140) allows it to migrate between the electronics case and the pacer lid and up the sides of the case near the weld area. This can cause welding problems. Also, it is difficult to control the amount of RTV to properly hold the three leads attached to the circuit. These problems were solved by using a two step procedure. In the first step a controlled limited amount of 615 RTV is used to seal migration areas and to hold the circuit in place. After a one day cure a controlled larger amount of 615 RTV is added to hold the leads in place. The 615 RTV is cured in a dry (< 30 percent humidity) incubator at 37° C. for one week before attaching the electronics case lid. This one week dry cure will assure low moisture levels in the electronics circuit after the lid is welded in place and the circuit hermetically sealed.

Measurements have also been made to assure low moisture levels in the glove boxes used for attaching the electronics case lid. In addition to potting tests with electronics cases, a complete qualification pacemaker was fabricated with this procedure and successfully passed all qualification tests, including an additional ten hours on the paint shaker. Thus, this electronics potting method was qualified and will be part of the final manufacturing procedures.

TASK 4.0 - SYSTEM TESTING

In Vivo Study of the RPCP in Dogs

The reliability data resulting from the 29 RPCP's implanted in dogs has accumulated as of January, 1974 a total of 43.47 unit years. One unit, #13, was removed for analysis on 5-5-73 when its rate was observed to be approximately 60 BPM. The most recent accumulation of post implant data is provided in Table 8. ECG's were recorded at this time and all pacemakers were capturing.

Pacemaker Shipping Container

Preliminary drop testing of the pacemaker shipping container has been completed. The outer polystyrene box was built up from a one inch polystyrene sheet. The mock up pacer was held in place in a plastic styrene box with a 'lexan' and a white styrene pvc insert. An assortment of shock absorbing foams were tested for shock transmissibility at pacer g levels of 50, 100, 150, and in some cases 250 g's (depending on drop height). Impact-O-Graph accelerometers (with dislodgable ball-spring indicators) were weighted with modeling clay and lead shot. All drop tests were conducted with the shipping package in the normally horizontal position. Also, all drop tests were hand held and released to concrete.

Figure 3.0 gives the drop height versus g level for seven shipping package drop test configurations of foam, area, and/or thickness. The shock foam combination for minimum g level and maximum drop height consists of one inch of 805 Presto foam and one inch of 745N Presto foam. The drop height for this foam combination increased as the shock foam area on the pacer plastic box decreased even to one-fourth the normal area. However, shock foam at one-half the normal area was almost the same drop height and is easier to fabricate. The areas of the other two sides of the plastic pacer box are

Table 8.0

Dog Rate Data

<u>Dog #</u>	<u>P.M. #</u>	<u>Date Implanted</u>	<u>Initial Rate</u>	<u>6-29-73</u>	<u>7-20-73</u>	<u>9-17-73</u>	<u>10-17-73</u>	<u>11-30-73</u>	<u>1-24-74</u>
1P029	3	7-10-72	73.4	73.9	73.9	73.8	73.8	73.9	73.9
1R481	5	7-10-72	72.6	72.3	72.3	72.5	72.2	72.2	72.3
1P086	6	7-10-72	72.8	71.9	71.8	71.5	71.7	71.6	71.4
1560	9	7-13-72	73.4	73.5	73.5	73.4	73.3	73.3	73.3
95	11	7-17-72	73.6	75.3	75.5	75.1	75.8	75.8	75.9
1P127	15	7-17-72	73.5	75.0	75.0	75.1	75.3	75.2	75.3
1R483	20	7-17-72	73.4	74.4	74.3	74.4	74.4	74.4	74.9
1814	13*	7-17-72	73.1	---	---	---	---	---	---
1P108	23	7-24-72	74.5	75.4	75.5	75.5	75.6	75.6	75.7
1R494	21	7-24-72	73.9	75.3	75.4	75.4	75.5	75.4	75.6
1P101	24	7-24-72	74.0	75.3	72.5	75.8	75.4	75.7	75.6
1P103	26	7-24-72	72.7	74.1	74.1	74.2	74.2	74.3	74.4
1Q980	33	7-31-72	72.2	73.5	73.6	73.6	73.6	73.8	73.8
1504	30	7-31-72	72.6	73.8	73.8	73.9	73.7	73.9	73.8
135	29	7-31-72	72.9	74.0	74.0	74.1	74.1	74.0	74.0
2188	34	7-31-72	73.1	74.1	74.3	74.2	74.2	74.2	74.3
1612	38	8-7-72	73.0	74.1	74.1	74.0	74.0	74.2	74.1
2296	42	8-7-72	72.4	73.3	73.2	73.2	73.2	73.2	73.1
1P656	36	8-11-72	72.6	73.5	73.5	73.4	73.5	73.5	73.5
1P666	40	8-14-72	73.2	74.5	74.6	74.6	74.7	74.8	74.9
1P668	45	8-14-72	72.2	73.3	73.4	73.5	73.5	73.6	73.7
1P611	46	8-14-72	72.4	73.7	73.7	73.8	73.9	73.9	73.9
1P618	47	8-14-72	72.2	73.3	73.5	73.4	73.5	73.4	73.3

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

Table 8.0 (con't)

Dog Rate Data

<u>Dog #</u>	<u>P.M. #</u>	<u>Date Implanted</u>	<u>Initial Rate</u>	<u>6-29-73</u>	<u>7-20-73</u>	<u>9-17-73</u>	<u>10-17-73</u>	<u>11-30-73</u>	<u>1/24/74</u>
1Q132	49	8-22-72	72.9	74.5	74.5	74.5	74.6	74.7	74.8
1R482	52	8-28-72	72.8	74.2	74.3	74.4	74.3	74.4	74.6
1P802	54	8-28-72	72.6	74.0	74.0	74.2	74.1	74.2	74.2
1P764	55	8-30-72	72.8	74.4	74.5	74.5	74.4	74.5	74.8
1P785	51	9-8-72	73.1	73.7	73.7	73.6	73.7	73.7	73.7
1P654	56	9-8-72	72.9	74.4	74.6	74.7	74.6	74.8	74.8
1P776	57	9-12-72	73.4	75.1	75.2	75.2	75.5	75.6	75.7

DROP HEIGHT Vs G LEVEL

Figure 3.0

- ◇ 1" THICK 805 PRESTO FOAM.
- △ SAME AS ABOVE ◇ WITH 1/2 FOAM AREA.
- 1" THICK 3570 SE AND 1" THICK 745N PRESTO FOAM.
- SAME AS ABOVE ○ WITH 1/2 FOAM AREA.
- ⊙ 1" THICK 805 AND 1" THICK 745N PRESTO FOAM.
- △ SAME AS ABOVE ⊙ WITH 1/2 FOAM AREA.
- △ SAME AS ABOVE ⊙ WITH 1/4 FOAM AREA.

in the range of one-half to one-fourth the horizontal area of the plastic pacer box.

Even greater reduction in shock levels for a given drop height could be realized with thicker foam; however, this foam combination seems adequate to protect the pacer in normal anticipated shipping drops. Also, the 745N Presto foam has excellent vibration attenuation characteristics.

For clarity, the combination of 805 (soft) and 745N (stiff) Presto foam is sketched in Figure 4.0. This is the recommended design for the final pacer shipping package evaluation tests.

Pacer Capsule Rattle Reduction

The light rattling noises caused by inner, middle and outer capsule movement with respect to each other upon shaking can be eliminated with shims. These shims were mechanically rippled to function as a spring, holding adjacent capsules together tightly.

The outer shim (holding the outer and middle capsule together) is fabricated from 2 mil titanium stock. The inner shim (holding the middle and inner capsule together) is fabricated from 2 mil tantalum stock. These shim materials should not change the results of the cremation tests. Note this applies to both the Hastelloy C and the platinum 20% rhodium middle capsule. Also, these shims should tolerate the variation in component dimensions as laid out in the specs. The increase in weight due to these shims should be less than 2% of the combined capsules' weight. For clarity, the shims and capsules are illustrated in Figure 5.0.

ARCO Humidity Indicators and Calibration Check

This summarizes a calibration check of ARCO humidity indicators. Up to

CROSS-SECTION OF PACER SHIPPING CONTAINER

Figure 4.0

CROSS-SECTION OF FUEL CAPSULES WITH NOISE REDUCING SHIMS

Figure 5.0

six humidity indicators were read simultaneously in a similar environment depending on the location. These six are:

1. Bacharach Instrument (Black Box)
2. Honeywell - portable
- 3.&4. Two Durotherms (gold)
5. Taylor humidiguide (wet bulb)
6. Honeywell system in clean room (fixed location)

Readings were taken in the life test room, clean room, glove box in clean room (flushed with dry argon), tig welding box, and life test circuit incubators.

After conducting extensive readings at various environmental conditions, the most consistently accurate portable humidity indicator seems to be the one from the Bacharach Instrument Company. Its maximum deviation was 6% difference of relative humidity at 40% relative humidity and 70°F. At the lower relative humidities around 16%, this humidity indicator read 13% relative humidity. Around 0% relative humidity, this instrument read below 0.

The two portable Durotherm hydrometers read 32% relative humidity when actually they should have read 16%. These two are then unacceptable in their present calibration. The portable Honeywell was within calibration at $\pm 9\%$ relative humidity ($\pm 3\%$ relative humidity for Honeywell and $\pm 6\%$ relative humidity from charts, considering wet bulb and dry thermometers were government certified accurate as $\pm 1^\circ\text{F}$). In the incubator in three readings, this Honeywell was once off by 16% relative humidity. This could be due to inadvertently reading the wrong meter.

CALIBRATION CHECK OF ARCO HYGROMETERS

Figure 6.0

Figure 6.0 illustrates the various humidity readings in the different environments with the different relative humidity indicators. An accurate humidity indicator (0-100 $\pm$ 2% relative humidity), the Abbeon AB-167 and a sling psychrometer for humidity indicator calibration will also be evaluated.

Electronic Testing

Due to the period increase observed in several human implant units, one which has not been observed in the dog implants, a study was conducted to determine the reason. Figure 7.0 is a graph of unit 106 and typically represents this lot of pacemakers, while Figure 8.0 displays an otherwise normal implant. After much evaluation, it was concluded that moisture entrapped in the electronics case was responsible for the decline in pacing rate. This was confirmed by the fact that life test units, which exhibited the period increase, showed no decrease in stimulation amplitude and it would be necessary for the stimulation amplitude to also be dropping in order for the battery to be degraded. As substantiating data, the electronics module was removed from unit 112 which had a declining rate and the nuclear battery performance was found to be essentially at beginning of life (B.O.L.). For this unit the test data is summarized as follows:

	Date	Open Circuit Voltage	Internal Resistance
B.O.L.	10/21/72	2.18 V	5390 Ω
Module Test	10/30/73	2.18 V	5330 Ω

Assuming all parameters are constant (supply open circuit voltage, temperature, etc.), the rate at which an electronics module paces does vary as a function of the relative humidity. It is known that moisture

PACEMAKER 106
POST IMPLANT DATA

Figure 7.0

TYPICAL RATE VARIATION OF HUMAN IMPLANT

Figure 8.0

can cause the circuit timing resistors to increase but only by a maximum amount of about 10% even under 100% relative humidity. Therefore, theoretically if moisture is present in the electronics compartment, it can assuredly diffuse through the RTV encapsulation and affect the timing resistors causing rate to decrease slightly. Laboratory experiments conducted, conclusively (Figure 9.0 and Figure 10.0) indicate that the electronics module is indeed affected by the amount of moisture present. The graphs in Figures 9.0 and 10.0 specify two conditions: (1) there exists a predictable relationship between rate and relative humidity, that is, the relative humidity is inversely proportional to rate, and (2) there exists an apparent maximum rate change in each direction as evidenced by the leveling in rate once an equilibrium has been reached.

It has been established that all circuits will be maintained for life test at the following conditions: 37°C @ a maximum R.H. of 30%. Figure 11.0 graphs one unit maintained at these conditions. It should be noted that all circuits must be kept at these environmental conditions prior to battery hookup a minimum of 28 days, which allows sufficient time for dehumidifying the circuit.

The apparent reason the circuits, although hermetically sealed, have seen an increase in concentration of moisture can be attributed to the potting procedure and potting RTV used (DOW 3140). The RTV that had been employed for construction of these units can release moisture if not cured for a sufficient time period, and therefore can act as a moisture source. To control this situation, GE 615 RTV has been employed with a more stringent

CIRCUIT IMMERSSED IN WATER

37 °C @ 100 % R.H.

CIRCUIT NO. 26

CIRCUIT SEALED IN A DESICCATOR
PURGED WITH ARGON
37°C @ $\approx 5-10\%$ RH.
CIRCUIT NO. 29

Figure 10.0
41

A.E.C. ELECTRONICS

BURN-IN DATA

CIRCUIT 154

Figure 11.0

installation procedure (see Electronic Installation Task 3.0) which requires a minimum of seven day cure time at an R.H. <30% at 37°C. GE 615 RTV was selected over DOW 3140 basically because even if the material is sealed in an uncured form, it will not emit moisture. This material, although more difficult to use from a manufacturing view is easier to cure in thick layers and yields material continuity since the electronics module is also potted in GE 615.

Several of the life test pacemakers (2 with a declining rate, 1 normal unit) were punctured through the electronics case and the gas evolved was chemically analyzed. The results recorded listed H₂O as the major constituent in each unit where the rate was declining while for the normal unit relatively minute quantities of various gases were found. This data substantiates the performance testing observed where moisture reduces the rate.

Each preventative measure instituted should allow deterrent of any rate decrease in future pacemakers so that the performance will closely follow the dog implants and remaining human implants which are showing negligible variations in period. Although the decrease is present, it should be mentioned that it is not uncommon for conventional pacemakers to drop, not because of battery depletion, but as a result of moisture infiltrating the electronic assembly. Figure 12.0* illustrates the long term pacemaker drift seen in several makes of pacemakers while Figure 13.0 shows the statistical spread for one of the models studied. Accumulated life test data and special test results indicate that the few human implant units with declining rates will eventually level in rate similar to that

*Pacemaker Diagnostic, Newsletter dated September 1973

MEAN BEHAVIOR OF SEVERAL DIFFERENT MODELS OF CONVENTIONAL PACEMAKERS

Figure 12.0

ONE MODEL STUDY
THE RATE DRIFT UNRELATED TO BATTERY EXHAUSTION
ATTRIBUTED TO MOISTURE OR COMPONENT AGE.

NOTE: EXTRACTED FROM PACEMAKER DIAGNOSTIC
NEWSLETTER DATED SEPTEMBER 1973

Figure 13.0

of conventional pacers. It is estimated that the rates will probably plateau in the vicinity of 65-67 beats per minute with a stimulation amplitude unchanged from B.O.L. Figure 14.0 shows actual data for one implanted unit (107) plotted against a curve which predicts circuit drift performance.

PREDICTED PULSE RATE DECAY WITH TIME
DUE TO HIGH MOISTURE CONDITION

Figure 14.0

TASK 5.0 - ENVIRONMENTAL ASSESSMENT

PuO₂ Cremation Stack Emission

This discussion attempts to explain the particle collecting capability of a crematory or incinerator. It should be noted that the fuel form used in the NU-5 pacemaker is a single large pressed and sintered pellet.

In general, emission standards for incinerators for particulate does not require particle size measurement. Rather particulate emission is based on weight of emission per unit volume of emission gas (Allegheny County Health Departments and Incinerator Institute of America).

Considering PuO₂ particle density as $11 \frac{\text{gm}}{\text{cm}^3}$ or specific gravity 11 and a 1 micron diameter, the settling velocity is 1.2×10^{-3} ft/sec (0.0366 cm/sec).¹ Note Stokes - Cunningham law applies in this range. Also, if one assumes that "normal" particulate is $2 \frac{\text{gm}}{\text{cm}^3}$ or specific gravity = 2 range, then for constant terminal velocity PuO₂ has a 0.4 micron diameter of $2 \frac{\text{gm}}{\text{cm}^3}$ particulate.² Thus, "normal" 2.5 micron diameter particulate and 1 micron diameter PuO₂ have the same terminal velocity. In the rest of this discussion, "normal" particulate size will be given with the equivalent PuO₂ particle size listed in parenthesis.

From WFI sciences (an air pollution testing laboratory in Pittsburgh, Pa.) (personal communications) estimated that air-borne particles under 5 microns (2 microns PuO₂) would probably all go up the stack thru a baffle filter used by crematories or incinerators and a large portion of those particles below 15-20 microns (6-8 microns PuO₂) would also go up the stack.

Buffalo Forge Company (a major impingement filter manufacturer with outlet in Pittsburgh, Pa.) (personal communication) estimated that an impingement type filter could collect 90% of 10 micron (4 micron PuO₂) particulate.

¹Chemical Handbook, Perry, p. 1019

²Ibid.

Century Spray Corporation (air filter manufacturer in Lauvona, Mich.) (personal communication) estimated that scrubber systems are more efficient than impingement filters. For a Leckenby Model SE-B6 scrubber collector, the efficiency of collection is 90% on 6 micron (2.4 micron PuO_2) and 80% on 3 micron (1.2 micron PuO_2) particles.³

Commonwealth Laboratory Incorporated (Richmond, Va.) which pollution tested an Industrial Equipment and Engineer Crematory (Orlando, Florida), the particulate was captured by an afterfilter on the stack. No particle size analysis was performed on the particulate; however, Commonwealth estimated (with a visual inspection of the filter) that the largest particles were 10-20 microns (4-8 microns for PuO_2).

In conclusion, the average crematory baffle filter would probably capture air-borne particles of 20 microns (8 microns PuO_2) or larger with high efficiency but not air-borne particulate of 1 micron (0.4 microns PuO_2) with high efficiency.

The PuO_2 fuel is now sintered in a ceramic pellet (1600°C (2912°F) for 3 hours in oxygen atmosphere) which is a higher temperature than any crematory would produce. Thus, in the incredible case that the capsules melted or ruptured, the PuO_2 would still be contained in one pellet.

Thus, emission of measurable PuO_2 up thru the crematory stack seem quite remote even if the average crematory is equipped to only capture 8 micron PuO_2 particles or larger.

³"Technique for Measuring Dust Collector Efficiency as a Function of Particle Size", Journal of Air Pollution Control, by H. Horvath and A. T. Rossano, Jr. April 1970, pp. 244-246.

Platinum Rhodium Middle Capsule Evaluation

Test Objectives:

Impact tests were conducted on six RPCP safety test capsules constructed with platinum rhodium middle capsules. The purpose of this test was to determine the feasibility and merits of using platinum rhodium metal in place of Hastelloy "C", the metal which is presently used. The impact testing was conducted as per specifications outlined in the RPCP investigational Interim Guide.

This test was conducted at the Sandia Corporation, Albuquerque, New Mexico between December 10 and December 13, 1973. The facility used was located in Area III of the Sandia base.

Test Capsule Materials:

The six test capsules, TC-32, -33, -35, -37, -38, and TC-40, were assembled and welded at Mound Laboratory, Miamisburg, Ohio. The safety test capsules contained the Tantalum 10% Tungsten inner capsule, Platinum Rhodium middle capsule, and the Titanium outer capsule. After the capsules were welded, the capsules were helium leak checked at Mound Laboratories and reported a leak rate of $<2 \times 10^{-9}$ std cc He/sec.

Impact Tests:

On Tuesday, December 11, 1973, test capsules TC-32 and TC-33 were impact tested at 70 meters/second. (Test No. 1).

Prior to impact testing, the capsules were fixed at a 45° angle, weld end down, and mounted on glass rods, held in position by dental cement (Figure 15.0) The glass rods were inserted into an aluminum honey comb fixture at a predetermined distance from the actuator that would allow the exact velocity upon impact (Figure 16.0).

Figure 15.0

Figure 16.0

An image motion camera was set up for velocity determination. High speed Fastax motion pictures at a speed of about 3700 frames/second were taken during the test. This photography not only allowed the observation of the impact and deformation of the capsules, but it also served as back up coverage for velocity calculations (Figure 17.0).

A programmer was used to trigger the initiation of the Fastax camera at - 600 milliseconds, start the image motion camera at - 150 milliseconds, and activate the actuator.

The actuator is a hollow steel tube with a 5 inch diameter x 1 inch thick steel cap and is driven by air pressure.

On Wednesday, December 12, 1973, test capsules TC-38 and TC-40 were impacted at 50 meters/second (Test #2). The same set up was utilized with exception to air pressure on the actuator.

On Thursday, December 13, 1973, test capsules TC-38 and TC-40 were impacted at 100 meter/second (Test #3). The same set up was utilized with exception to air pressure on the actuator.

Calibration trial runs were performed prior to all the above testing to confirm the calculated impact velocity parameters.

Test Results:

The first test at Sandia impact the test capsules to an impact velocity of 70 meters/second or 229.7 ft/sec. These two capsules, numbers TC-32 and TC-33, were impacted at angles of 45° . Figure 18.0 shows photographs of outer capsules TC-32 and TC-33 after the 45° angle impact at 229.7 ft/sec. Note that although the outer capsules have experienced some plastic deformation, the integrity of the capsules were good. From a visual examination of

Figure 17.0

PHOTOGRAPHY SET UP AT SANDIA CORPORATION

Figure 18.0

TITANIUM OUTER CAPSULES AFTER 45° IMPACT @ 70 M/SEC.

TC-32
70m/sec

TC-33

TC-32
70m/sec

TC-33

these capsules at Sandia, the outer capsules were expected to pass the standard helium leak check (Table 9.0 and 10.0).

The second test impact the test capsules at an impact velocity of 50 meters/second or 164 ft/sec. These two capsules, numbers TC-35 and TC-37 were also impact tested at a 45° angle. Figure 19.0 shows a photograph of outer capsules TC-35 and TC-37 after the impact test. Upon visual examination, capsule TC-37 revealed a micro crack in the outside diameter weld region (Table 9.0 and 10.0).

The third test impact the test capsules at an impact velocity of 100 meters/second or 328 ft/sec. These two capsules TC-38 and TC-40 were also tested at a 45° angle. Figure 20.0 shows a photograph of these other capsules after impact testing. Upon visual examination, capsule TC-40 revealed a micro crack in the trepan region of the weld (Table 9.0 and 10.0).

All leak tests on these safety capsules tested at Sandia were performed subsequent to returning to ARCO Nuclear Company. In addition to the helium leak check, the safety capsules were helium pressurized to 300 psig. for 30 minutes and immediately submerged into a beaker of methanol alcohol and examined for bubble releases (Table 10.0). Each capsule, after leak check, was cut away to allow access to the next capsule containment. Each of the six middle capsules were photographed (Figure 21, 22, 23) and subjected to both the bubble test and helium leak check (Table 10.0). The middle capsules were cut away to allow access to the inner capsules. The inner capsules were photographed (Figure 24, 25, 26) and subjected to the bubble test and helium leak check (Table 10.0).

From this series of impact tests conducted at Sandia, one of two outer capsule welds breached at 50 m/sec. and one of two outer capsule welds at 100 m/sec. Although both outer capsules welds impacted at 70 m/sec. revealed approximately the same amount of plastic deformation, no leaks were detected. The six platinum rhodium middle capsules and the six tantalum 10% tungsten inner capsules revealed no evidence of breaching. These capsules were subjected to the bubble test and helium leak check to verify the hermetic seal.

The impact test data indicates the feasibility of substituting Platinum Rhodium metal for Hastelloy "C" metal in the middle capsule container. As mentioned in the opening paragraph, the impact testing was performed in compliance with the prototype testing as stated in the RPCP Interim Guide.

Figure 19.0

TITANIUM OUTER CAPSULES AFTER 45° IMPACT @ 50 M/SEC.

TC-35

50m/sec

TC-37

TC-35

50m/sec

TC-37

Table 9.0

Summary of Impact Test at Sandia

Test No.	Capsule No.	Impact Velocity, (ft/sec)		Angle of Impact ⁽¹⁾		Test Results ⁽²⁾
		Desired	Actual	Desired	Actual	
1	TC-32	229	232.9	45°	45°	No cracks or leaks in outer capsules on Test No. 1
1	TC-33	229	232.9	45°	45°	
2	TC-35	164	167.3	45°	45°	No cracks or leaks in outer capsule
2	TC-37	164	167.3	45°	45°	Crack and leak in outer capsule. No cracks or leaks in middle and inner capsules
3	TC-38	328	305.1	45°	45°	No cracks or leaks in outer capsule
3	TC-40	328	305.1	45°	45°	Crack and leak in outer capsule. No cracks or leaks in middle and inner capsules

(1) For all 45° angle tests, the impact was on the welded end of the capsule.

(2) In addition to those results listed, each of the test capsules showed a significant amount of plastic deformation of the outer capsule at the impacted region and at the unwelded end of the capsule due to the secondary impact.

Table 10.0

Summary of Leak Checks at ARCO Nuclear

Capsule No.	Capsule Assembly	Leak Rate Sensitivity, (ATM-cc/sec)		Helium Bubble Test		Results
		Desired	Actual (1)	Accept	Reject	
TC-32	Complete	2×10^{-9}	3×10^{-11}	X		Safety capsule passed bubble test and passed the desired leak rate
	Middle	2×10^{-9}	3×10^{-11}	X		
	Inner	2×10^{-9}	1.5×10^{-11}	X		
TC-33	Complete	2×10^{-9}	3×10^{-11}	X		Safety capsule passed bubble test and passed the desired leak rate
	Middle	2×10^{-9}	3×10^{-11}	X		
	Inner	2×10^{-9}	1.5×10^{-11}	X		
TC-35	Complete	2×10^{-9}	3×10^{-11}	X		Safety capsules passed bubble test and passed the desired leak rate
	Middle	2×10^{-9}	3×10^{-11}	X		
	Inner	2×10^{-9}	1.5×10^{-11}	X		
TC-37	Complete	2×10^{-9}	$>3 \times 10^{-6}$		X	Outer capsule was breached during impact tests. Middle and inner capsules passed all leak checks
	Middle	2×10^{-9}	3×10^{-11}			
	Inner	2×10^{-9}	1.5×10^{-11}			
TC-38	Complete	2×10^{-9}	3×10^{-11}	X		Safety capsules passed bubble test and passed the desired leak rate
	Middle	2×10^{-9}	3×10^{-11}	X		
	Inner	2×10^{-9}	1.5×10^{-11}	X		
TC-40	Complete	2×10^{-9}	$>3 \times 10^{-6}$		X	Outer capsule was breached during impact testing. Middle and inner capsules passed all leak rates
	Middle	2×10^{-9}	3×10^{-11}	X		
	Inner	2×10^{-9}	1.5×10^{-11}	X		

(1) This does not imply that the capsule does leak with this leak rate. Rather it signified that a leak check has been performed to only this sensitivity level.

Figure 20.0

TITANIUM OUTER CAPSULES AFTER 45° IMPACT @ 100 M/SEC.

TC-38
100m/sec
TC-40

TC-38
100m/sec
TC-40

Figure 21.0

PLATINUM RHODIUM MIDDLE CAPSULES AFTER 45° IMPACT @ 70 M/SEC.

PC-32
70 M/SEC
PC-33

Figure 22.0

PLATINUM RHODIUM MIDDLE CAPSULES AFTER 45° IMPACT @ 50 M/SEC.

PC-35
50 M/SEC
PC-37

PC-35
50 M/SEC
PC-37

Figure 23.0

PLATINUM RHODIUM MIDDLE CAPSULES AFTER 45° IMPACT @ 100 M/SEC.

PC-38
100 M/SEC
PC-40

PC-38
100 M/SEC
PC-40

Figure 24.0

TANTALUM-10% TUNGSTEN INNER CAPSULES AFTER 45° IMPACT @ 70 M/SEC.

TaC - 32

70m/sec

TaC - 33

TaC - 32

70m/sec

TaC - 33

Figure 25.0

TANTALUM-10% TUNGSTEN INNER CAPSULE AFTER 45° IMPACT @ 50 M/SEC.

TaC - 35

50m/sec

TaC - 37

TaC - 35

50m/sec

TaC - 37

Figure 26.0

TANTALUM-10% TUNGSTEN INNER CAPSULE AFTER 45° IMPACT @ 100 M/SEC.

TaC - 38

100m/sec

TaC - 40

TaC - 38

100m/sec

TaC - 40