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RADIOISOTOPE-POWERED CARDIAC PACEMAKER

REPORT TO:
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NOTICE

Quarterly Progress Report for Radioisotope Powered Cardiac Pacemaker Program

November 1, 1972 to January 31, 1973

Prepared for

UNITED STATES ATOMIC ENERGY COMMISSION
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MASTER

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INTRODUCTION

This is the eleventh 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, 1972 to January 31, 1973.

TASK 1.0 - PROGRAM MANAGEMENT, CONTROL AND PLANNING

During this report period, pilot production continued at a satisfactory rate with a total of approximately 36 units being completed for future human implantation. Presently, all 30 NU-5 units implanted in animals at the National Heart and Lung Institute continue to operate properly. However, during this report period, one unit, #13, displayed a reduced pulse rate and amplitude for a short period of time. This unit is presently operating properly. At the end of January, the animal testing has statistically demonstrated a reliability in excess of existing commercial pacemaker levels.

During this report period, plans were formulated and work initiated to sterilize the 52 RPCP units for human implantation. It is anticipated that the units for human implantation will be supplied to the participating clinics in a sterilized condition.

During this report period, the document entitled "Analysis of Accidental RPCP Earth Burial and Cremation" was prepared and submitted. This document discussed in detail the effects of accidental burial and accidental cremation of the RPCP system.

Also during this report period, all 250 electronic circuits continued to operate without failure and statistically have reached a proven reliability in excess of 98% for a 2 year mission time at a 90% confidence level. Also a total of approximately 20 internal quality control audits were performed.

TASK 2.0 - RELIABILITY AND QUALITY ASSURANCE

Reliability Data

At the end of January, the NU-4 type production nuclear batteries on life test have accumulated a total of 27.90 unit years of operation.

The Phase II electronic circuits consist of three groups: (1) a preproduction group of ten circuits to establish design criterion, (2) a pilot production group of 39 circuits, and (3) a production group of 200 circuits. At the end of January, the preproduction circuits have accumulated 14.24 unit years of operation with no failures, the pilot production circuits have accumulated 51.58 unit years of operation with no failures, and the production circuits have accumulated 218.50 unit years of operation with no failures for a total of 284.32 unit years with no failures. These circuits have reached a proven reliability in excess of 98% for a 2 year mission time at a 90% confidence level.

At the end of January, the NU-5 modified production nuclear batteries have accumulated a total of 32.60 units of operation. The 30 units implanted at NIH have accumulated 14.22 unit years of operation in dogs.

Tables 1, 2, 3, and 4 summarize the status of the Modified Production Systems, Production Systems, Experimental Models, and Prototype Models, respectively. Units 61 and 70 thru 135 in Table 1 are, at the present time, designated as life test batteries. However, upon completion, most of these will be used for human implantation.

Internal Quality Control Audits

During the months of November, December, and January, 20 operating process procedures were audited by the Quality Control Department for compliance to operating and record keeping. The 20 procedures audited were Fabrication (7 procedures), Assembly (11 procedures), and Quality Control (2 procedures). The audits indicated the procedures were being followed and records were kept in order and up-to-date.

Qualification Testing

In order to qualify the wrapping of the thermopiles as acceptable, every eighth thermopile is assembled into a nuclear battery and subjected to the following series of tests:

Table 1
Modified Production Model Life Test Data (NU5-)
(1-31-73)

Unit (NU5-)	Accumulated Hours	B.O.L. DATA Battery Output (μw)	With Electronics Output, ma.	BPM	Present Data Output*	BPM	UNITS PRODUCED Implant Units Implanted	Removed	Special Test	Life Test	Comments
1	5894	203.5	6.0	71.5	5.8 ma	74.0				X	
2	5894	215.0	6.5	72.5	6.3 ma	74.0				X	
3	5822	236.7	6.2	72.0			7-10-72				
5	5822	223.9	6.1	71.0			7-10-72				
6	5822	241.7	6.3	71.0			7-10-72				
7	302	225.2			(Disassembled)				X		Qualification test unit
9	5678	242.1	6.4	72.0			7-10-72				
10	1430	238.8	6.4	72.0	(Disassembled)				X		
11	5678	238.5	6.6	72.0			7-17-72				
13	5534	236.7	6.3	72.5			7-17-72				
14	182	259.1			(Disassembled)				X		Qualification test unit
15	5534	224.9	6.4	72.0			7-17-72				
17	5366	230.3			230.4 μw					X	
18	5366	214.3			214.0 μw					X	
20	5366	219.5	6.4	72.5			7-17-72				
21	5294	223.5	6.3	73.5			7-24-72				
22	446	247.6			(Disassembled)				X		Qualification test unit
23	5294	226.4	6.5	72.0			7-24-72				
24	5296	229.8	6.6	72.0			7-24-72				
25	398	212.4			(Disassembled)				X		Void areas
26	5030	245.5	7.0	72.0			7-24-72				
27	3542	235.2			(Disassembled)				X		
28	277	238.3			(Disassembled)				X		Qualification test unit
29	4909	233.9	6.4	71.0			7-31-72				
30	4815	250.4	6.8	71.0			7-31-72				
31	3901	243.5			(Disassembled)						
32	None	(Scrapped due to internal shorting during degassing)									
33	4815	223.3	6.0	70.0			7-31-72				
34	4815	238.6	6.4	71.0			7-31-72				
35	134	250.8			(Disassembled)				X		Qualification test unit
36	4670	242.3	6.5	71.0			8-7-72				
37	3662	257.5			(Disassembled)						

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

Table 1 (Cont'd)
Modified Production Model Life Test Data (NU5-)
(1-31-73)

Unit (NU5-)	Accumulated Hours	B.O.L. DATA Battery Output (μw)	With Electronics Output, ma.	With Electronics BPM	Present Data Output*	Present Data BPM	UNITS PRODUCED Implant Units Implanted	Implant Units Removed	Special Test	Life Test	Comments
38	4670	226.7	6.4	71.0			8-7-72				
39	4970	212.2			(Disassembled)				X		Cold side defect
40	4574	228.9	6.3	71.0			8-14-72				
41	4574	224.8	6.5	72.0			8-7-72				
42	4574	244.9	6.6	72.0			8-7-72				
43	158	218.3			(Disassembled)				X		Qualification test unit
45	4502	236.4	6.6	70.0			8-14-72				
46	4502	228.6	6.4	71.0			8-14-72				
47	4502	220.6	6.3	70.0			8-14-72				
48	3301	225.8	6.5	72.0	(Disassembled)						
49	4309	231.0	6.4	72.0			8-21-72				
50	3301	208.0	5.9	73.0	(Disassembled)						
51	4309	214.2			(Under test)				X		Qualification test unit
52	4125	242.3	6.6	72.0			8-28-72				
53	3117	245.3	6.7	73.0	(Disassembled)						
54	4125	229.3	6.2	73.0			8-28-72				
55	4125	231.1	6.6	73.0			8-28-72				
56	3997	232.9	6.4	73.0			8-28-72				
57	3997	238.6	6.6	73.0			8-28-72				
58	3181	227.7			(Disassembled)				X		Qualification test unit
60	1189	235.2			(Disassembled)				X		
61	3397	230.8	6.3	71.0	6.3 ma	71.5				X	
62	2893	214.9			(Disassembled)				X		Getter test
63	2893	229.5			(Disassembled)				X		Getter test
64	None	30.1			(Disassembled)				X		Getter test
65	None	152.1			(Disassembled)				X		Getter test
66	374	232.8			(Disassembled)				X		Qualification test unit
67	None	27.6			(Disassembled)				X		Getter test
68	1069	179.2			(Disassembled)				X		Qualification test unit
69	None	207.3			(Disassembled)				X		Getter test

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

Table 1 (Cont'd)
Modified Production Model Life Test Data (NU5-)
(1-31-73)

Unit (NU 5-)	Accumulated Hours	B.O.L. DATA: Battery Output (µw)	With Electronics: Output, ma.	With Electronics: BPM	Present Data: Output*	Present Data: BPM	UNITS PRODUCED: Implant Units: Implanted	Implant Units: Removed	Special Test	Life Test	Comments
70	2005	249.3	6.6	70.0	6.6 ma	71.0				X	
71	2005	256.6	6.6	71.0	6.7 ma	71.5				X	
72	2005	240.2	6.6	71.0	6.8 ma	71.5				X	
73	2005	249.6	6.6	72.0	7.0 ma	73.0				X	
74	1910	240.4	6.6	73.0	6.7 ma	74.0				X	
75	1910	234.4	6.3	72.0	6.3 ma	72.5				X	
76	1910	246.3	6.6	71.0	6.8 ma	72.0				X	
77	1094	226.2			(Disassembled)						
78	1861	225.7	6.3	72.5	6.4 ma	72.5				X	
79	1861	233.7	6.4	74.0	(Under Test)				X		Qualification test unit
80	1861	219.7	6.3	73.5	6.5 ma	73.5				X	
82	1861	236.3	6.3	73.0	6.6 ma	73.5				X	
83	1742	219.9	6.1	72.5	6.3 ma	72.5				X	
84	1742	251.0			(Under Test)				X		Qualification test unit
85	1742	222.4	6.2	73.0	6.3 ma	73.0				X	
86	1742	218.5	6.4	73.5	6.4 ma	73.0				X	
87	None	135.5			(Disassembled)						
88	1693	237.1	6.7	73.5	6.7 ma	73.5				X	
89	877	223.6			(Disassembled)						
90	1693	234.3	6.5	73.5	6.7 ma	73.0				X	
92	1214	246.1			(Tested to Failure)				X		Qualification test unit
93	1382	229.2	6.5	75.0	6.5 ma	75.0				X	
94	1382	232.0	6.5	73.5	6.5 ma	73.5				X	
95	1382	239.8	6.5	74.5	6.5 ma	74.5				X	
96	854	237.5			(Disassembled)					X	
97	1358	233.1	6.6	73.5	6.8 ma	73.5				X	
98	662	235.8			(Disassembled)				X		Qualification test unit
99	1358	222.9	6.3	73.5	6.4 ma	73.0				X	
100	1188	232.5	6.6	72.5	6.6 ma	72.5				X	
101	1188	234.8	6.4	72.5	6.4 ma	72.5				X	
102	1188	212.0	6.0	73.0	6.0 ma	73.0				X	
103	1188	228.8	6.5	73.0	6.5 ma	73.0				X	

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

Table 1 (Cont'd)
Modified Production Model Life **Test Data** (NU5-)
(1-31-73)

Unit (NU 5-)	Accumulated Hours	B.O.L. DATA: Battery Output (μw)	B.O.L. DATA: With Electronics Output, ma.	B.O.L. DATA: With Electronics BPM	Present Data Output*	Present Data BPM	UNITS PRODUCED Implant Units: Implanted	UNITS PRODUCED Implant Units: Removed	Special Test	Life Test	Comments
104	902	214.7			(Disassembled)				X		Qualification test unit
104-Q	924	237.1			(Under Test)				X		Qualification test unit
105	566	214.3			(Disassembled)					X	
105-Q	828	236.7			(Under Test)				X		Qualification test unit
106	1070	217.5	6.5	73.5	6.5 ma	73.5				X	
107	1070	210.4	6.0	73.5	6.0 ma	73.5				X	
108	1022	211.3	5.8	73.5	5.8 ma	73.5				X	
109	1022	221.8	6.3	73.5	6.3 ma	73.5				X	
110	1022	217.6	6.2	74.0	6.2 ma	74.0				X	
112	1022	222.4	6.4	74.0	6.4 ma	74.5				X	
113	974	227.4	6.4	73.0	6.6 ma	73.5				X	
114	974	221.7	6.3	73.0	6.4 ma	73.5				X	
115	974	206.9	6.0	73.0	5.9 ma	73.5				X	
116	828	228.2	6.6	72.5	6.7 ma	73.5				X	
117	780	227.7			(Diassembled)				X		Getter test
118	636	252.1			(Under Test)				X		Getter test
118-Q	180	207.5			207.5 μw				X		Qualification
119	828	222.4	0.5	73.5	6.6 ma	74.5				X	test unit
120	636	233.4			**					X	
120-Q	469	220.0			(Under Test)				X		Qualification
121	636	244.7			**					X	test unit
122	468	222.4			(Disassembled)					X	
123	469	202.4			**					X	
124	469	202.6			**					X	
125	469	213.0			**					X	
126	300	222.5			**					X	
127	300	232.6			**					X	

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

** Unit in production.

Table 1 (con't)
Modified Production Model Life Test Data (NU5-)
(1-31-73)

Unit (NU -)	Accumulated Hours	B.O.L. DATA Battery Output (μw)	With Electronics Output, ma.	With Electronics BPM	Present Data Output*	Present Data BPM	UNITS PRODUCED Implant Units Implanted	Implant Units Removed	Special Test	Life Test	Comments
128	300	225.5			**					X	
129	180	221.8			**					X	
130-Q	132	194.1			**				X		Qualification test unit
131	180	219.5			**					X	
132	84	229.1			(Disassembled)					X	
133	132	211.3			**					X	
135	132	216.6			**					X	
Total 285,556 hrs.					Totals		30	0			

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

Table 2
Production Model Life Test Data (NU4)
(1-31-73)

Unit (NU4-)	Accumulated Hours	B.O.L. DATA Battery Output (μw)	With Electronics Output, ma.	With Electronics BPM	Present Data Output*	Present Data BPM	UNITS PRODUCED Implant Units Implanted	UNITS PRODUCED Implant Units Removed	Special Test	Life Test	Comments
2	10,596	271.9	6.8	76.0	7.4 ma	77.0				X	
3	10,596	271.2			272.1 μw					X	
4	10,596	284.2	7.2	75.5	7.9 ma	76.0				X	
5	10,596	279.5	6.8	75.0	7.1 ma	76.0				X	
6	9348	295.7	7.9	76.5	8.1 ma	77.0				X	
7	1766	283.0			(Disassembled)				X		Drop tested to destruction
8	1838	251.2	6.8	74.0	(Disassembled)		1-31-72	3-15-72			2 tapes open
9	1262	212.3	6.0	73.5	(Disassembled)		1-31-72	3-6-72			5 tapes open
10	1692	264.8	7.3	74.5	(Disassembled)		2-7-72	3-20-72			2 tapes open
11	1428	275.1	7.0	75.5	(Disassembled)		2-7-72	3-20-72			5 tapes open
12	1644	258.5	7.2	74.5	(Disassembled)				X		Drop tested to destruction
13	1692	282.9	7.4	74.0	(Disassembled)		2-7-72	3-20-72			No open tapes
14	8152	267.1	7.0	74.0	(Disassembled)		2-14-72	3-20-72			No open tapes
15	1624	269.1	7.6	73.5	(Disassembled)					X	Internal shock
17	8152	293.6	7.6	73.5	(Disassembled)		2-14-72	3-15-72			No open tapes
18	1560	267.8	7.8	74.5	(Disassembled)		2-22-72	4-10-72			
19	1218	262.8	7.4	74.5	(Disassembled)		2-22-72	3-30-72			5 tapes open
20	1818	291.8	7.8	74.5	(Disassembled)		2-22-72	4-24-72			
21	7770	295.4	7.7	75.0	(Disassembled)		2-28-72	7-17-72			1 tape open
22	7716	279.1	7.8	74.5	(Disassembled)		2-28-72	7-24-72			1 tape open
23	7716	270.7	7.6	74.5	(Disassembled)		2-28-72	7-17-72			2 tapes open
24	7716	279.9	7.8	74.5	(Disassembled)		2-22-72	7-10-72			Analyzing physical condition
25	7548	289.5	7.8	75.0	(Disassembled)		2-28-72	7-17-72			No open tapes
26	7548	277.5	7.8	74.5	(Disassembled)		3-6-72	7-10-72			2 tapes open
27	8364	280.1	7.8	75.0	75.2 μw		3-6-72	7-10-72			4 tapes open
28	8364	299.7	7.8	75.0	41.8 μw		3-6-72	7-17-72			Analyzing physical condition
29	7428	287.0	7.7	74.5	(Disassembled)		3-13-72	7-24-72			2 tapes open
30	8244	264.5	7.4	74.0	63.8 μw		3-13-72	7-17-72			3 tapes open
31	7428	271.7	7.5	74.5	(Disassembled)		3-13-72	7-31-72			No open tapes
32	1044	238.0			(Disassembled)				X		Environmental testing
33	7911	247.9	7.0	74.0	78.6 μw		3-13-72	7-17-72			2 tapes open

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

Table 2 (Cont'd)
Production Model Life Test Data (NU4)
(1-31-73)

Unit (NU4-)	Accumulated Hours	B.O.L. DATA Battery Output (µW)	With Electronics Output, ma.	With Electronics BPM	Present Data Output*	Present Data BPM	UNITS PRODUCED Implant Units Implanted	UNITS PRODUCED Implant Units Removed	Special Test	Life Test	Comments
34	4959	243.8	7.2	74.0	(Disassembled)		3-20-72	7-31-72			
35	848	258.6	7.0	74.5	(Disassembled)				X		Shock test
37	893	256.6	7.2	73.5	(Disassembled)				X		Paint shaker
38	4767	266.7	7.5	73.5	(Disassembled)		3-20-72	7-24-72			
39	4767	248.0	7.0	74.0	(Disassembled)		3-27-72	7-10-72			
40	4791	239.8	6.9	73.5	(Disassembled)		3-27-72	7-10-72			
41	4695	250.4	6.5	74.0	(Disassembled)		3-27-72	7-24-72			
42	6879	265.5	7.0	74.0	(Disassembled)				X		Environmental testing
43	5703	304.0	7.7	74.5	(Tested to Failure)				X		Paint shaker
44	2367	265.3	6.8	74.0	(Disassembled)				X		Environmental testing
45	3589	285.8	7.5	74.0	(Disassembled)				X		Paint shaker
46	7813	267.2	7.4	74.0	(Tested to Failure)				X		
47	891	280.6	7.4	74.0	(Disassembled)				X		Paint shaker
48	800	279.4	7.4	74.0	(Disassembled)				X		Paint shaker
49	843	278.3	7.6	74.0	(Disassembled)				X		Paint shaker
50	597	283.0	7.4	73.5	(Disassembled)				X		Paint shaker
51	1428	296.3	7.9	74.0	(Disassembled)				X		Paint shaker
52	1452	272.4	7.5	74.0	(Disassembled)				X		Paint shaker
53	2527	297.6			(Disassembled)				X		Thump test
54	328	279.9			(Disassembled)				X		8g-20HZ vibra
55	2527	274.8			(Disassembled)				X		Wrist shaker
56	343	289.1			(Disassembled)				X		Vibration & paint shaker
TOTAL	244,446 HRS.					TOTALS	27	27			

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

Table 3

Experimental Model Life Test Data

(1-31-73)

Unit	Hours	Present Data Output*	Present Data Pulses/Minute	B.O.L. Data Pulses/Minute	B.O.L. Data Output*
E-3 (1) (2)	43,809	72.4 μw			84.8 μw
E-4	43,357	2.3 ma	76.0	78.6	2.9 ma
E-5 (8)	41,630	70.0 μw			79.6 μw
E-9 (2)	35,049	83.9 μw			82.3 μw
E-10 (5)	33,709	71.3 μw			77.5 μw
E-12 (4) (3)	34,478	243.7 μw			230.0 μw
E-13BB	28,742	7.2 ma	128.0	123.0	8.0 ma
E-14 (4) (6)	11,701				
E-16 (10) (12)	31,209	110.3 μw			202.4 μw
E-17 (4)	30,115	222.8 μw			196.1 μw
E-18 (9)	31,401	247.6 μw			247.8 ma
E-20 (7) (11)	21,276				260.5 μw
TOTAL	386,446				

(1) Battery Unit.

(2) Stopped pulsing 4-9-70 and could not be restarted. Electronics removed and load line obtained.

(3) Had stopped in dog test. Electronics failed - removed 6-30-70.

(4) Implanted in dog.

(5) Not pulsing 7-14-70. Disconnected and removed electronics 7-16-70.

(6) Returned 7-23-70. Not pulsing. Hours shown to 7-23-70. Module and electronics failed.

(7) Disconnected and removed electronics 7-10-70.

(8) Disconnected and removed electronics 7-29-71.

(9) Disconnected and removed electronics 7-27-71.

(10) Electronics failed 8-31-71.

(11) Unit used for testing. Hours shown to 5-8-72.

(12) Unit is presently under observation.

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

Table 4

Prototype Model Life Test Data

(1-31-73)

Unit	Hours	Present Data Output	Present Data Pulses/Minute	B.O.L. Data Pulses/Minute	B.O.L. Data Output
P-1 (2) (1)	28,092	5.9 ma	125.0	125.3	5.5 ma
P-2 (12)	19,885			126.9	5.7 ma
P-3 (2) (5)	27,045	5.6 ma	125.0	126.5	5.7 ma
P-4 (2) (6)	6,742				
P-5 (2) (10)	11,437				
P-6 (2) (3)	2,938				
TOTAL	97,139				
XP-10 (4) (7)	1.344				
XP-14 (8)	560				
XP-15 (9)	540				
PD-1 (11)	207.5				261.96 μw

(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.

(1) 5 hours on the paint shaker

(2) 4 atm pressure

(3) thermal cycling

(4) 5' fall to concrete (4500 g shock)

(5) 3000-50g shocks

(6) 96-545g shocks

If the battery maintained an open circuit voltage greater than 1.9 volts throughout the tests, then the battery was acceptable. The preceeding 7 thermopiles were then declared acceptable provided no other deviations were noted throughout their production. Many of the test batteries were then placed back on the paint shaker and taken to destruction. Some of them, however, were still operating within the voltage limits after accumulating 30 hours on the shaker.

By the end of January 1973, a total of 26 nuclear batteries have been tested in that manner. The results of these tests are presented in Table 5. The qualification test results of production batteries are shown in Figure 1.

Q. C. Inspection Summary

Table 6 summarizes the component inspection conducted during the months of November 1972, December 1972, and January 1973. It should be noted that Quality Control first inspects the components and marks them as either acceptable or nonconforming. If nonconforming, they are submitted to the Material Review Board for further investigation. Final disposition is based on the action of the MRB. In many cases, a component may not be accpetable for use in a standard production pacer but could be useable in a special test. These items are labled for use as special test only.

TABLE 5

TESTING RESULTS ON PRE-PRODUCTION AND PRODUCTION NU5 UNITS

UNIT	AFTER FIVE HOURS ON PAINT SHAKER	AFTER STANDARD QUALIFICATION TEST	TIME TO FAILURE 1ST TAPE	2ND TAPE	3RD TAPE	4TH TAPE	COMPLETE	COMMENTS
NU5-Q1	Acceptable	Acceptable	800 min.	1260 min.		1670 min.	1841 min.	Unit began shorting at 1730 minutes. Test stopped when V_{OC} dropped to 1.24 volts
NU5-Q2	Acceptable	1st tape failed after 24th-545 g shock in x axis					610 min.	Unit began shorting at 570 minutes. Test stopped when V_{OC} dropped to 1.84 volts
NU5-7	Acceptable	Acceptable	600 min.		1431 min.		1594 min.	Unit began shorting at 1420 minutes. Test stopped when V_{OC} dropped to 1.64 volts
NU5-14	Acceptable	Acceptable	731 min.				1402 min.	Unit began shorting at 410 minutes. Test stopped when V_{OC} dropped to 1.67 volts
NU5-22	Acceptable	Acceptable	1300 min.		1420 min.		1926 min.	
NU5-28	Acceptable	Acceptable		610 min.			741 min.	At 650 minutes the resistance began to vary from 14,200 to 8000 ohms
NU5-35	Acceptable	1st tape failed after 5' fall to concrete			316 min.		560 min.	

TABLE 5 (continued)

TESTING RESULTS ON PRE-PRODUCTION AND PRODUCTION NU5 UNITS

UNIT	AFTER FIVE HOURS ON PAINT SHAKER	AFTER STANDARD QUALIFICATION TEST	TIME TO FAILURE 1ST TAPE	2ND TAPE	3RD TAPE	4TH TAPE	COMPLETE	COMMENTS
NU5-10	Acceptable	Acceptable						Contained electronics unit still pulsing at 1200 minutes
NU5-25	Acceptable	Acceptable	580 min.		710 min.		903 min.	
NU5-28	Acceptable	Acceptable		620 min.		650 min.	740 min.	Shorted
NU5-35	Acceptable	1st Tape Out		316 min.			550 min.	Complete failure due to possible shorting. This unit had <u>one</u> tape open prior to testing.
NU5-39	Acceptable	Acceptable						No tapes open after 30 hours on the shaker.
NU5-43	Acceptable	Acceptable	420 min.				841 min.	Complete failure due to shorting
NU5-51	Acceptable	Acceptable	520 min.	590 min.				Operating after 15 hrs. on the paint shaker.
NU5-58	One Tape Open	Res. Returned to 5200	500 min.	590 min.	870 min.			28 hrs. on the paint shaker and unit still operating. This unit was assembled with questionable tapes.

TABLE 5 (continued)

TESTING RESULTS ON PRE-PRODUCTION AND PRODUCTION NU5 UNITS

UNIT	AFTER FIVE HOURS ON PAINT SHAKR	AFTER STANDARD QUALIFICATION TEST	TIME TO FAILURE 1ST TAPE	2ND TAPE	3RD TAPE	4TH TAPE	COMPLETE	COMMENTS
NU5-66	Acceptable	Acceptable	820 min.				860 min.	Complete failure due to shorting Voc- .03 volts
NU5-68	Acceptable	Acceptable	710 min.	720 min.	870 min.		1260 min.	Test concluded due to shorting.
NU5-84	Acceptable	*1st tape (See Comments)	* (See Comments)	550 min.	840 min.		no failure	Achieved 15 hrs. and removed from shaker.
NU5-79	Acceptable	Acceptable					no failure	Removed from shaker afer 16 hrs. tested with electronics installed.
NU5-92	* (See Comments)	Acceptable					no failure	Rebrazed tapes-* 2 tapes out after 5 hrs. on shaker unit survived 25 hrs. on shaker with acceptable Voc.
NU5-98	Acceptable	Acceptable	390 min.		810 min.		1020 min.	Unit began shorting, test stopped when VOC was 1.82 volts.
NU5-104	Acceptable	Acceptable					no failure	After 15 hrs. pacer was removed from shaker.
NU5-104Q	Acceptable	*1st tape (See Comments)					12 hrs.	Failure due to shorting.
NU5-105Q	Acceptable	Acceptable					no failure	17 hrs. on paint shaker with no open tapes.
NU4-46							30 min.	Complete pacer (with electronics). Unit used as a standard and failed rapidly.

QUALIFICATION TEST RESULTS
OF
PRODUCTION BATTERIES

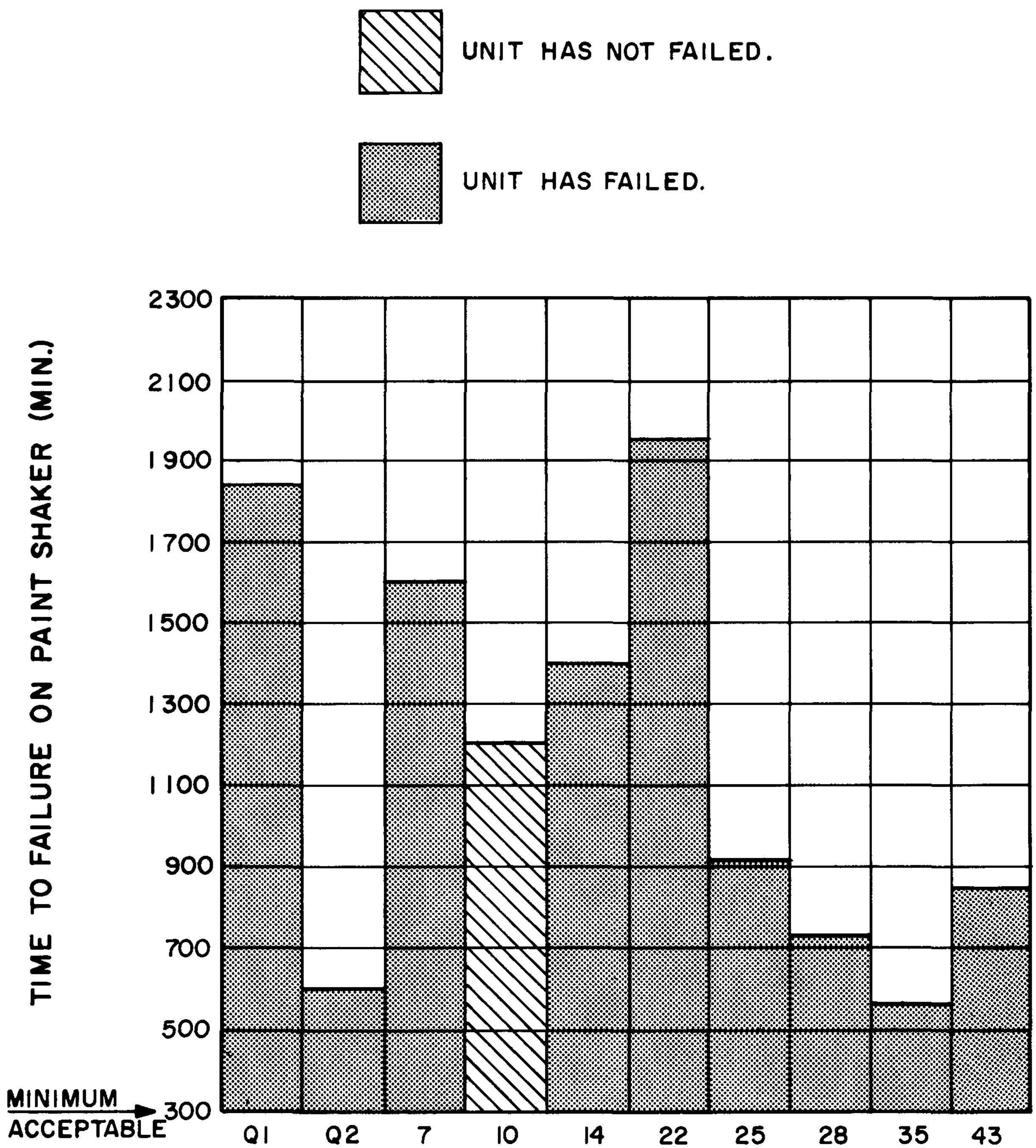


Figure 1

QUALIFICATION TEST RESULTS
OF
PRODUCTION BATTERIES

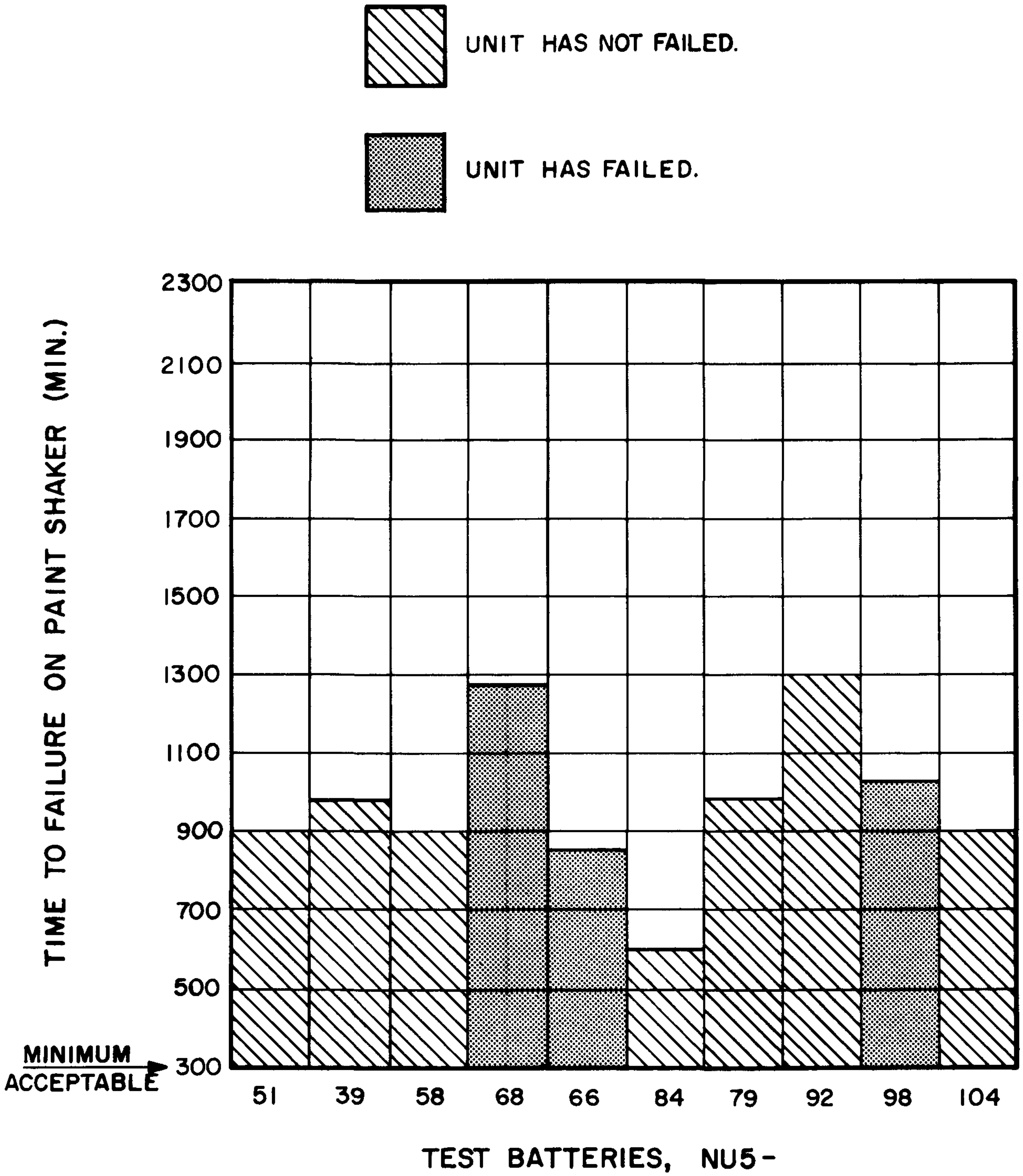


Figure 1
(continued)

QUALIFICATION TEST RESULTS
OF
PRODUCTION BATTERIES

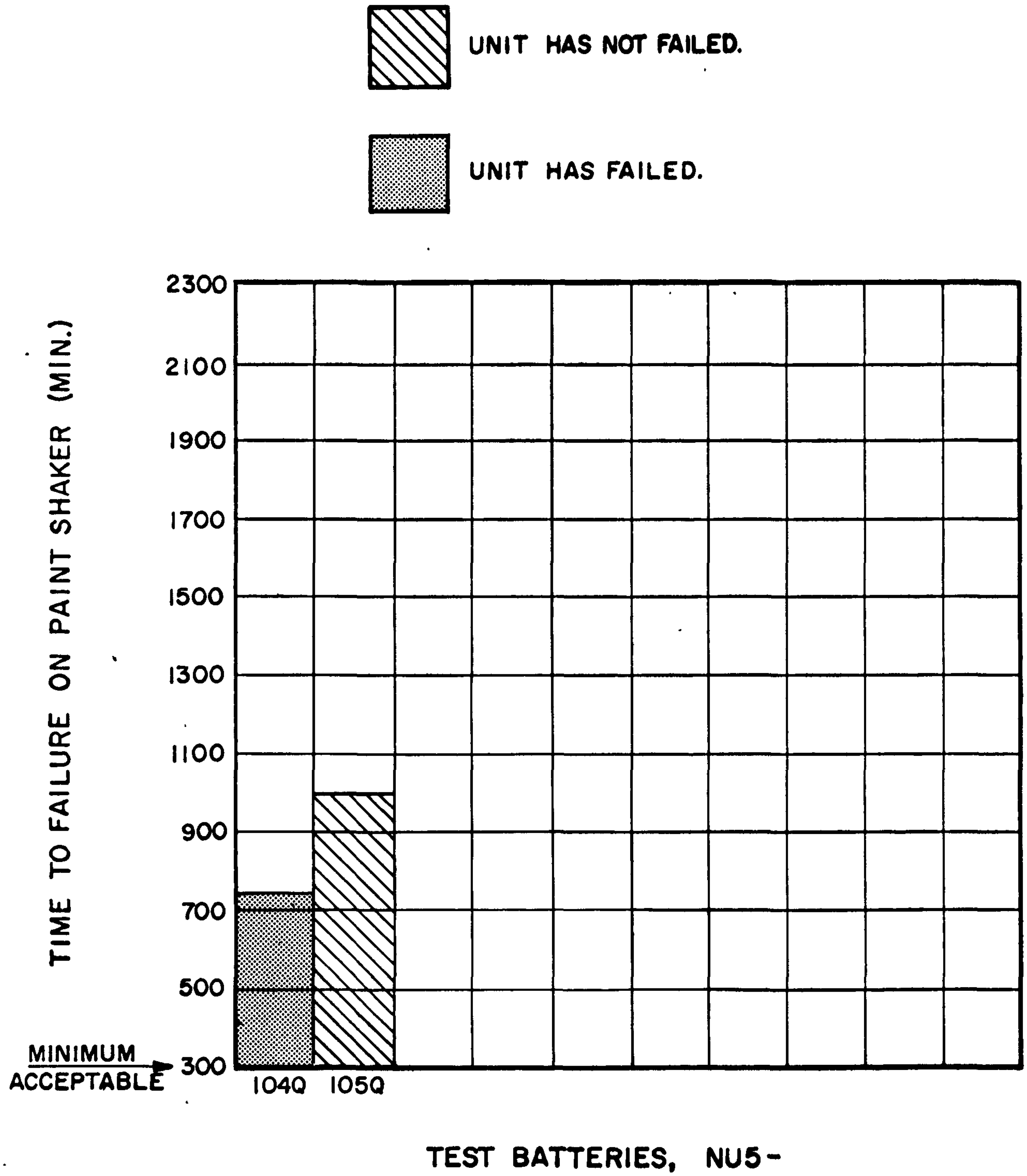


Figure 1
(continued)

11-27-72 J.D. EC-870

TABLE 6

QUARTERLY INSPECTION SUMMARY NOV. 72, DEC. 72, JAN. 73

Description	Accountability Inventory	Accountability Incoming	Accountability Total	Q.C. Inspection Total Insp.	Q.C. Inspection Total Acc	Q.C. Inspection Total N.C.	Total Reviewed	MRB Action Total Acc	MRB Action For Test	REWORK	Total Rej	Accept Total Q.C. Acc	Accept Total MRB Acc	Accept Total Total Acc	% Acc	% Test
Brazed Tapes				379	326	53	53	1	8	0	44	326	1	327	86.3	2.1
Coated Ceramic Tabs				1155	1014	141	141	0	0	0	141	1014	0	1014	87.8	0.0
Tophel Plated Tapes Sect.				630	581	49	49	7	0	0	42	581	7	588	93.3	0.0
Cupron Plated Tapes Sect.				624	582	42	42	4	0	0	38	582	4	586	93.9	0.0
Insulation Tape I.C. Yds.				1765	0	1765	1765	being held for evaluation								
Al_2O_3 inches				14430	14430	0	0	N/A	N/A	N/A	0	14430	N/A	14430	100.0	0.0
Degass inches				13680	11310	2370	2370	550	100	0	1720	11310	550	11860	86.7	0.7
Cut Strips				1151	1151	0	0	N/A	N/A	N/A	0	1151	N/A	1151	100.0	0.0
NiTi Feedthroughs P/R				73/29	37/19	36/1	16/11*	0/1	4/8	12/0	0/2	37/19	0/1	37/20	55.9	11.8
CuAg Feedthroughs				65	62	3	3	0	1	0	2	62	0	62	95.4	1.5
Hot Straps				106	106	0	0	N/A	N/A	N/A	0	106	0	106	100.0	0.0
Cold Straps				48	46	2	2	0	1	0	1	46	0	46	95.8	2.1
Hot Shoes				261	256	5	5	0	0	0	5	256	0	256	98.1	0.0
Cold Shoes				241	229	12	12	0	0	0	12	229	0	229	95.0	95.0
Closure plugs				320	320	0	0	N/A	N/A	N/A	0	320	N/A	320	100.0	0.0
Thermopile support bracket				57	57	0	0	N/A	N/A	N/A	0	57	N/A	57	100.0	0.0
Getter supports				292	292	0	0	N/A	N/A	N/A	0	292	N/A	292	100.0	0.0
Insulation Circles				3574	3574	0	0	N/A	N/A	N/A	0	3574	N/A	3574	100.0	0.0
Electronics Case feedthrough flange				121	120	1	1	0	0	0	1	120	0	120	99.2	0.0
Exterior Case				44	19	25	25	0	23	0	2	19	0	19	43.2	52.3
Heat shields				6208	6077	131	131	0	0	0	131	6077	0	6077	97.9	0.0
Kapton pieces (88)				170	170	0	0	N/A	N/A	N/A	0	170	N/A	170	100.0	0.0
Kapton pieces (89)				180	180	0	0	N/A	N/A	N/A	0	180	N/A	180	100.0	0.0
Getter retainer				152	152	0	0	N/A	N/A	N/A	0	152	N/A	152	100.0	0.0
Support bracket brace				315	214	101	101	0	101	0	0	214	0	214	67.9	32.1
Ext. case feedthrough flange				202	191	11	11	0	0	0	11	191	0	191	94.6	0.0

TABLE 6 (continued)

QUARTERLY INSPECTION SUMMARY NOV. 72, DEC. 72, JAN. 73

Description	Accountability			Q.C. Inspection			MRB Action					Accept Total				
	Inventory	Incoming	Total	Total Insp.	Total Acc	Total N.C.	Total Reviewed	Total Acc	For Test	Rework	Total Rej	Q.C. Acc	MRB Acc	Total Acc	% Acc	% Test
Nuc. battery L.C.				36	35	1	1	0	0	1	0	35	0	35	97.2	0.0
Ext. case, lettering				29	23	6	6	3	3	0	0	23	3	26	89.7	10.3
Ceramic tube (44)				74	74	0	0	N/A	N/A	N/A	0	74	N/A	74	100.0	0.0
Ext. case lid				111	7	104	104	70	16	18	0	7	70	77	69.4	14.4
Middle capsule plug				92	92	0	0	N/A	N/A	N/A	0	92	N/A	92	100.0	0.0
Middle capsule				20	20	0	0	N/A	N/A	N/A	0	20	N/A	20	100.0	0.0
Thermopile wrap				8	7	1	1	0	1	0	0	7	0	7	87.5	12.5
Getter baskets				141	141	0	0	N/A	N/A	N/A	0	141	N/A	141	100.0	0.0
Closure plug flange				82	82	0	0	N/A	N/A	N/A	0	82	N/A	82	100.0	0.0
Ext. case polish				21	16	5	5	0	5	0	0	16	0	16	76.2	23.8

TASK 3.0 - SYSTEM FABRICATION AND PRODUCTION DEVELOPMENT

Tape Brazing

During this report period, the acceptance rate for tape brazing has increased to 90 percent (usual rates previously were ≈ 75 percent). An evaluation was performed to ascertain the quality of tapes where braze is added to grooves in which there is a deficiency of braze material. Special test units made with this type of braze modification were built and subjected to qualification tests. The results showed that the addition of braze is unaccpetable. Two brazing problems existed during this period: (1) Some tabs would not braze to the cold shoes due to an oxidation of the titanium on the shoes. This batch was rejected and no further problem was found. Apparently, backfilling occurred at a slightly high temperature and was noted in a production meeting. No further problems are expected. (2) The resistance of some (≈ 10) tapes had slightly decreased during storage. This problem will be followed closely during the next report period although the number of low tapes seemed to decrease in January.

Thermopiles Wrapped

During this period, 57 thermopiles were wrapped as shown in Figure 2. This data on production is recorded weekly and includes five weeks in November, four in December, and five in January for a total of 14 weeks. Some problems existed during assembly including five units with low resistance and two with broken wires. It is possible the low thermopile values were related to the lowering tape resistance but no certain evidence was obtained. Also, the units require a very tight wrap which would cause both the lower resistance and broken wires. However, the tightness is required for the long fatigue life on the paint shaker and is not considered a problem.

Batteries Sealed

During this report period, a total of 55 batteries were sealed at the weekly rates as shown in Figure 2. Since the getter problem has been solved and sealing has been resumed, output performance has been good with the results showing a relatively small variance. New performance limits have been set based on the output data shown in Tables 7, 8, and 9. This data gave 2σ limits of 204 μ watts to 254 μ watts and 2.09 volts to 2.32 volts (open circuit). Only three units were lost for human implant by imposing

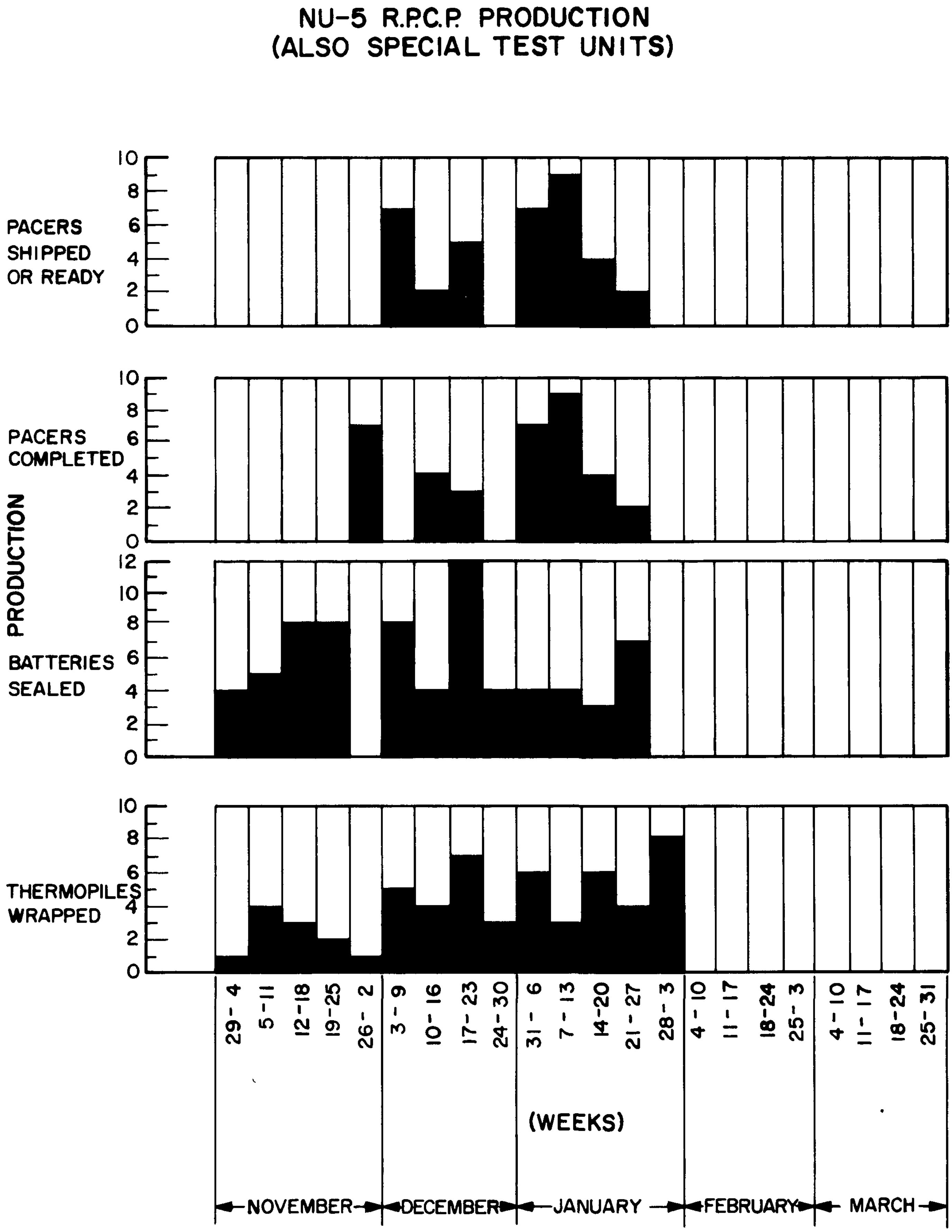


Figure 2

EC-851 G.M. 12-11-72

TABLE 7

Performance Data for Units Assembled in November

Unit	Date Sealed	Leak Checked	Disposition	O.C.V. Volts	Output μ Watts	Res. Ω	Fuel Watts	Efficiency %	Fuel #	Type
GT-6	11-1-72		Getter Test	1.562	113.8*	16,070	.2303	.0494 (gas)	A-45	Oxide
GT-7	11-2-72		Getter Test	2.17	228.8*	15,429	.2314	.0988	A-64	Oxide
GT-5	11-2-72	No	Getter Test	2.24	212.9*	15,775	.2237	.0951	A-34	Oxide
NU-5-66	11-7-72	Yes	Qualification	2.21	232.8	5,196	.2311	.1007	A-43	Oxide
NU-5-70	11-9-72	Yes	Ready for Shipping	2.28	249.3	5,213	.2260	.1103	A-27	Oxide
NU-5-71	11-9-72	Yes	Life Test**	2.33	256.5	5,244	.2286	.1122	A-31	Oxide
NU-5-72	11-9-72	Yes	Ready for Shipping	2.26	240.2	5,315	.2292	.1047	A-33	Oxide
NU-5-73	11-9-72	Yes	Ready for Shipping	2.30	249.6	5,297	.2313	.1079	A-36	Oxide
NU-5-74	11-13-72	Yes	Ready for Shipping	2.26	240.4	5,310	.2263	.1062	A-42	Oxide
NU-5-75	11-13-72	Yes	Ready for Shipping	2.23	234.4	5,256	.2296	.1020	A-44	Oxide
NU-5-76	11-13-72	Yes	Ready for Shipping	2.28	246.3	5,275	.2295	.1073	A-55	Oxide
NU-5-77	11-13-72	Yes	Opened for Fuel	2.20	226.2	5,348	.2205	.1025	A-81	Oxide
NU-5-78	11-15-72	Yes	Ready for Shipping	2.19	225.7	5,263	.2238	.1008	A-82	Oxide
NU-5-79	11-15-72	Yes	Qualification	2.23	233.6	5,273	.2243	.1041	A-83	Oxide
NU-5-80	11-15-72	Yes	Ready for Shipping	2.16	219.6	5,310	.2253	.0974	A-84	Oxide
NU-5-82	11-15-72	Yes	Ready for Shipping	2.24	236.3	5,308	.2234	.1057	A-85	Oxide
NU-5-83	11-20-72	Yes	Ready for Shipping	2.16	219.9	5,302	.2226	.0987	A-86	Oxide
NU-5-84	11-20-72	Yes	Qualification	2.30	251.0	5,268	.24486	.1025	PF-1-2	Metal
NU-5-85	11-20-72	Yes	Ready for Shipping	2.18	222.4	5,314	.2258	.0984	A-87	Oxide
NU-5-86	11-20-72	Yes	Ready for Shipping	2.16	218.5	5,336	.2248	.0971	A-88	Oxide
NU-5-87	11-22-72	Yes	Opened for Fuel	1.691	135.5	5,268	.2230	.0607 (gas)	A-89	Oxide
NU-5-88	11-22-72	Yes	Ready for Shipping	2.24	237.1	5,291	.2209	.1073	A-90	Oxide
NU-5-89	11-22-72	Yes	Opened for Fuel	2.18	223.6	5,312	.2221	.1006	A-91	Oxide
NU-5-90	11-22-72	Yes	Ready for Shipping	2.24	234.3	5,354	.2243	.1044	A-92	Oxide

*Corrected to 6 tape performance.
**Changed from ready for shipping to life test because of new output limits.

TABLE 8

Performance Data for Units Assembled in December

Unit	Date Sealed	Leak Checked	Disposition	O.C.V. Volts	Output μ Watts	Res. Ω	Fuel Watts	Efficiency %	Fuel #	Type
NU5-92	12-5-72	Yes	Qualification	2.30	246.1	5374	.2244	.1096	PF-1-19	Metal
NU5-93	12-5-72	Yes	Ready for Shipping	2.21	229.2	5278	.2239	.1023	A-32	Oxide
NU5-94	12-5-72	Yes	Ready for Shipping	2.22	231.9	5311	.2311	.1003	A-43	Oxide
NU5-95	12-5-72	Yes	Ready for Shipping	2.27	239.7	5325	.2303	.1040	A-45	Oxide
NU5-96	12-6-72	Yes	Opened for Fuel[1]	2.26	237.5	5376	.2285	.1039	A-62	Oxide
NU5-97	12-6-72	Yes	Ready for Shipping	2.23	233.1	5286	.2314	.1007	A-64	Oxide
NU5-98	12-6-72	Yes	Qualification	2.24	235.8	5318	.2257	.1044	A-93	Oxide
NU5-99	12-6-72	Yes	Ready for Shipping	2.17	222.9	5233	.2262	.0985	A-94	Oxide
NU5-100	12-12-72	Yes	Ready for Shipping	2.23	232.5	5298	.2265	.1026	A-95	Oxide
NU5-101	12-12-72	Yes	Ready for Shipping	2.23	234.8	5246	.2185	.1074	A-96	Oxide
NU5-102	12-12-72	Yes	Ready for Shipping	2.13	212.0	5399	.2254	.0940	A-97	Oxide
NU5-103	12-12-72	Yes	Ready for Shipping	2.22	228.8	5383	.2229	.1026	A-98	Oxide
NU5-104	12-18-72	Yes	Qualification	2.14	214.7	5331	.2272	.0944	A-99	Oxide
NU5-105	12-18-72	Yes	Opened for Fuel[2]	2.14	214.3	5342	.2249	.0952	A-100	Oxide
NU5-106	12-18-72	Yes	Ready for Shipping	2.15	217.5	5263	.2261	.0961	A-101	Oxide
NU5-107	12-18-72	Yes	Ready for Shipping	2.11	210.4	5240	.2223	.0946	A-102	Oxide
NU5-108	12-20-72	Yes	Ready for Shipping	2.12	211.3	5316	.2240	.0943	A-103	Oxide
NU5-109	12-20-72	Yes	Ready for Shipping	2.18	221.8	5356	.2253	.0984	A-104	Oxide
NU5-110	12-20-72	Yes	Ready for Shipping	2.15	217.6	5261	.2237	.0972	A-105	Oxide
NU5-112	12-20-72	Yes	Ready for Shipping	2.18	222.4	5341	.2251	.0988	A-106	Oxide
NU5-104Q	12-22-72	Yes	Qualification	2.24	237.1	5291	.23999	.0987	PF-1-4	Metal
NU5-113	12-22-72	Yes	Ready for Shipping	2.19	227.4	5223	.2258	.1007	A-107	Oxide
NU5-114	12-22-72	Yes	Ready for Shipping	2.18	221.7	5359	.2261	.0980	A-108	Oxide
NU5-115	12-22-72	Yes	Ready for Shipping	2.10	206.9	5327	.2234	.0926	A-109	Oxide
NU5-116	12-28-72	Yes	Ready for Shipping	2.22	228.2	5399	.2285	.0998	A-35	Oxide
NU5-117	12-28-72	Yes	Opened for Fuel[3]	2.20	227.7	5314	.2275	.1000	A-66	Oxide
NU5-105Q	12-28-72	Yes	Qualification	2.25	236.6	5301	.23845	.0992	PF-1-6	Metal
NU5-118	12-28-72	Yes	Life Test	2.19	222.3	5343	.2278	.0975	A-67	Oxide

[1]Shorted during degas run to one-half normal resistance. [2]Electronics weld problem. [3]Loose thermopile wrap.

TABLE 9

Performance Data for Units Assembled in January

Unit	Date Sealed	Leak Checked	Disposition	O.C.V. Volts	Output μ Watts	Res. Ω	Fuel Watts	Efficiency %	Fuel #	Type
NU-5-118	1-5-73	Yes	Life Test	2.32	252.1	5336	.2398	.1051	PF-1-7	Metal
NU-5-120	1-5-73	Yes	Note 1	2.22	233.4	5278	.2256	.1035	A-74	Oxide
NU-5-121	1-5-73	Yes	Note 1	2.29	244.7	5310	.2272	.1077	A-76	Oxide
NU-5-122	1-5-73	Yes	Opened for Fuel	2.18	222.4	5341	.2252	.0988	A-78	Oxide
NU-5-123	1-12-73	Yes	Life Test*	2.06	202.4	5239	.2237	.0905	A-34	Oxide
NU-5-120Q	1-12-73	Yes	Qualification	2.14	220.0	5202	.2318	.0949	PF-1-13	Metal
NU-5-124	1-12-73	Yes	Life Test*	2.08	202.6	5336	.2205	.0919	A-81	Oxide
NU-5-125	1-12-73	Yes	Note 1	2.14	213.0	5374	.2230	.0955	A-89	Oxide
NU-5-126	1-19-73	Yes	Note 1	2.19	222.5	5338	.2183	.1019	A-28	Oxide
NU-5-127	1-19-73	Yes	Note 1	2.22	232.6	5296	.2286	.1017	A-39	Oxide
NU-5-128	1-19-73	Yes	Note 1	2.19	225.5	5268	.2304	.0979	A-60	Oxide
NU-5-129	1-24-73	Yes	Note 1	2.19	221.8	5356	.2285	.0971	A-62	Oxide
NU-5-118Q	1-24-73	Yes	Qualification	2.07	207.5	5112	.2260	.0918	A-5	Metal
NU-5-131	1-24-73	Yes	Note 1	2.17	219.5	5312	.2249	.0976	A-100	Oxide
NU-5-132	1-26-73	Yes	Opened for Fuel	2.21	229.1	5281	.2252	.1017	A-78	Oxide
NU-5-133	1-26-73	Yes	Opened for Fuel**	2.11	211.3	5216	.2221	.0951	A-91	Oxide
NU-5-130Q	1-26-73	Yes	Qualification	2.00	194.1	5152	.2241	.0866	PF-1-28	Metal
NU-5-135	1-26-73	Yes	Opened for Fuel	2.12	216.6	5186	.2257	.0960	A-93	Oxide

Note 1 - Electronics installed - ready for lid.

* Will be used for life test because of new output limits.

** Performance not improved after sealing.

these new limits. The gettering problem seems to have been well solved since all units but two (NU-5-87 and 133) had better beginning of life performance (after degassing and sealing) than in the unsealed units before degassing. Not only are all units checked to assure that the performance has improved after degassing and sealing (a typical cycle of output open circuit voltages is given in Figure 3), but all are held one week and monitored (no degradation allowed) before adding electronics. Several did short during degassing but as previously stated on thermopiles, the tight wrap needed for mechanical fatigue probably leads to a natural yield loss causing shorting. The performance results for each month are plotted in Figures 4, 5, and 6.

New end shield material was received and successfully tested in a qualification unit, NU-5-104. Although the initial tests were very successful, there exists a possibility that either cases or end shields are increasing the end shield tightness and may have lowered performance in some units. This will be checked out thoroughly during the next period. Also, several batteries had a TIG welding problem discussed in the section on TIG welding.

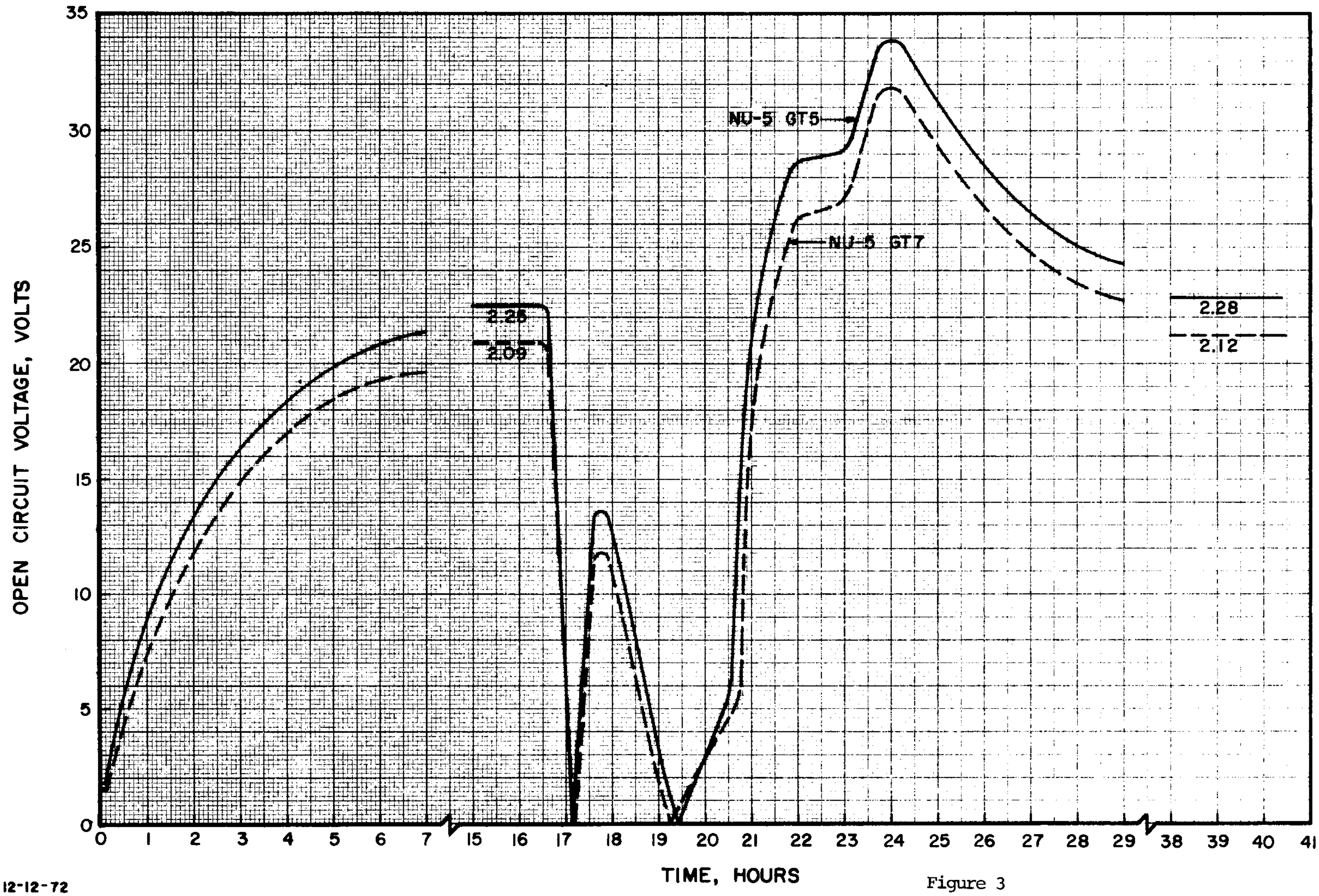
Final Assembly

The final assembly of adding electronics, welding the electronics case lid, and potting have proceeded fairly well. The total ready for shipment for human implants (Figure 2) is 36. One unit that had been ready for shipment was lost by the setting of new 2σ limits. As discussed in the section on TIG welding, several had a problem in electronics case lid welds, probably due to RTV potting. It is expected that the total of 52 for implant should be ready at the end of February. The acceptance factor from tapes to final units for implants including the qualification units (as losses) has been somewhat lower than expected at 48.7 percent (57 percent in November, 48 percent in December, and 40 percent in January) but production has not had major problem areas. Some of the problems of lower yields are due to new tighter quality control standards, which are deemed necessary for units to be used for the first human implants.

Production Control

Improved production control methods have been developed to better define assembly costs and improve reporting of costs, yields, and inventories at the weekly production meetings. Tables 10 and 11 show the old and new weekly production reports.

VOLTAGE DURING DEGASSING CYCLE



EC.-852 G.M. 12-12-72

Figure 3

PERFORMANCE RESULTS FOR UNITS SEALED IN NOVEMBER

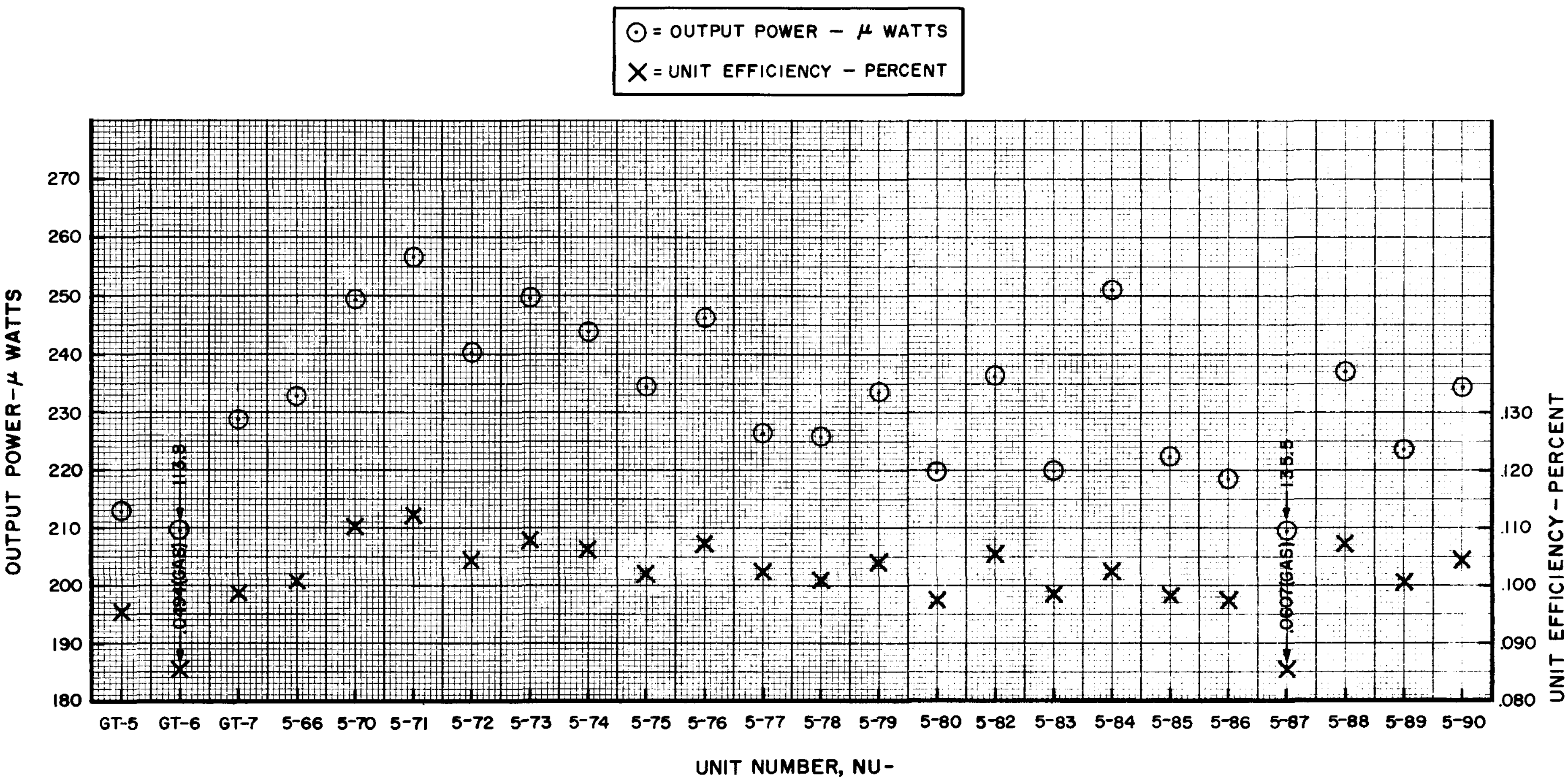


Figure 4

EC-850 G.M. 12-8-72

PERFORMANCE RESULTS FOR UNITS SEALED IN DECEMBER

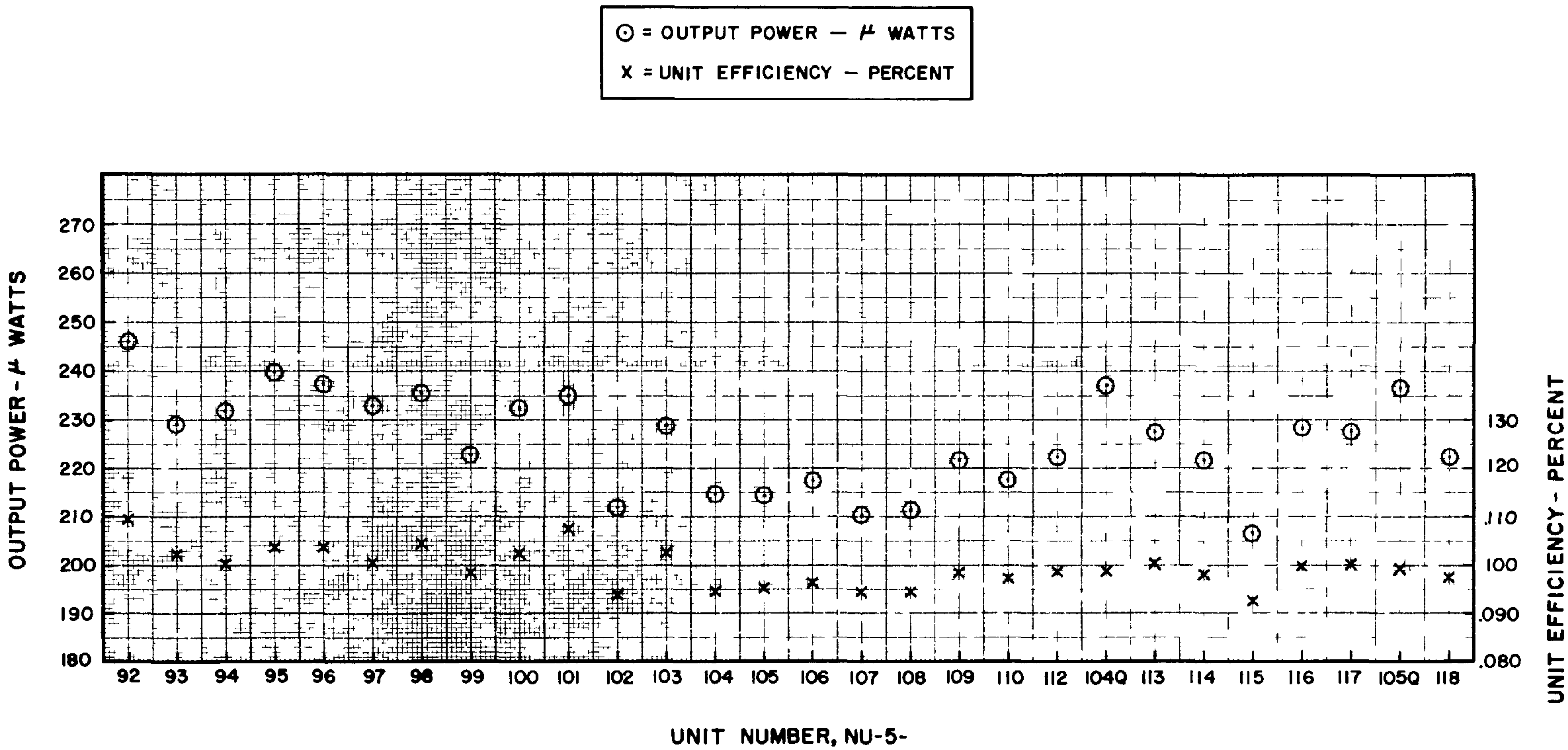


Figure 5

EC-857 G.M 1-19-73

PERFORMANCE RESULTS FOR UNITS SEALED IN JANUARY

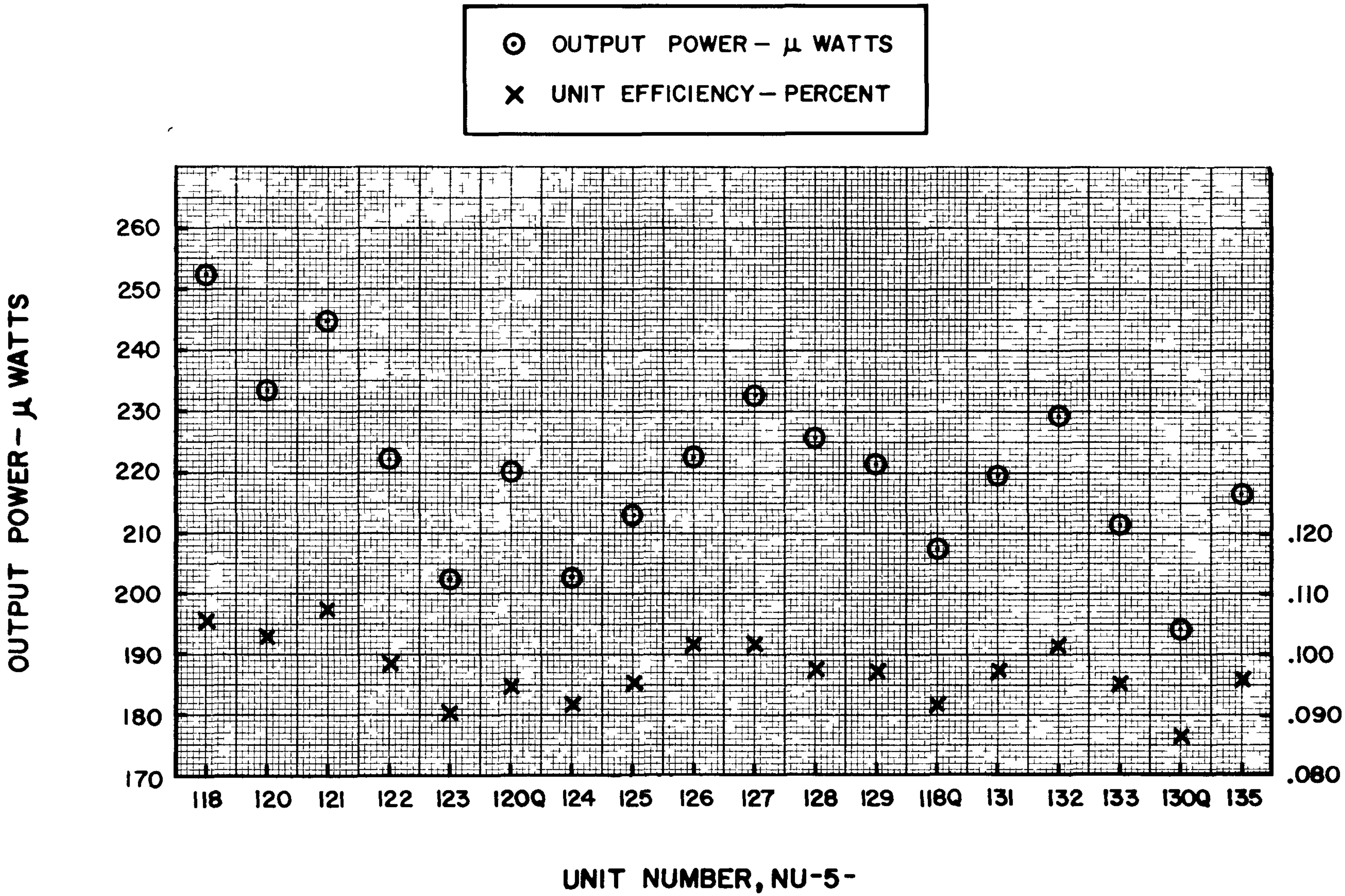


Figure 6

2-13-73 GM. EC-864

TABLE 10

PRODUCTION RECORD

DATE ______________ (Old Report)

			Produced	Accept	Reject	Inventory
Chem Lab						
	Ceramic Tabs					
		Ti Coating				
		First Grind				
		Electroplate & Alloy				
		Second Grind				
		Completed				
	Outer Case Etch					
	Cupron					
	Cupron (plated)					
	Tophel					
	Tophel (plated)					
	Cold Strap					
	Hot Shoes					
	Cold Shoes					
	Feedthroughs Braze	Ni-Ti P/R				
		Cu-Ag				
	Insulation Tape					
Mechanical Fabrication						
	Tape Brazing					
	Outer Case Polish					
	Thermopile Wrap Thru Q.C.					
	Battery Assembly Thru Leak Ck.					
	Battery Closure Thru Leak Ck.					
	Battery El. Thru El. Perf.					
	TIG Weld El. Thru E.B. Weld					
	Epoxy Molding Finished					
	Completed Ready for Shipping					

TABLE 11
PRODUCTION REPORT ON NUCLEAR PACER

Week Ending ________

(New Report)

Assembly	Completed	Inspection		In-Process Inventory	Inventories	
		ACC	NC		Raw	Finished
1. Battery Feedthrough ___ hrs					X	
2. Electronic Feedthrough ___ hrs 1 2					X X	
3. Tapes thru Braze ___ hrs	X	X	X	X	X	X
Tapes Brazed					X	
Tabs Processed						
Cupron Processed						
Tophel Processed						
4. Thermopile Wrap & Wire ___ hrs					X	
Insulation Processed						Raw Sets
Cold Straps Processed					X	
5. Battery thru Seal ___ hrs					X	
Outer Cases Polished						
Outer Cases Etched					X	
6. Electronics to Finishing for Shipment ___ hrs					X	
Electronics	X			X	X	
7. Fuel				X	X	
8. Heart Lead	X			X	X	

Ti Gr 35A Evaluation

A new lot of .010 and .025 inch thick Ti Gr 35A was ordered and tested for forming capability. The formability of the material proved to be excellent. An order was placed for lids and cases. As a parallel effort, a study was made to determine the optimum annealing temperature which would allow correct forming of the cases and yet provide a high quality case after polishing. Twenty cases were annealed at 1000°F and twenty cases were annealed at 1200°F. These cases will be used for special test only because of the deviation from the process specification. Additional cases which were annealed to specification (1300°F) are being fabricated and will be used to complete the schedule for human implants. Evaluation of the polishing and forming of the exterior case will continue. Ninety-three battery lids were completed and submitted to Q. C. for dimensional inspection. The remainder of the order for cases and lids will be completed by the end of February.

TIG Welder

The chills used for TIG welding of the electronics case to the exterior case have been modified to provide a better fit at the corners and have resulted in a more uniform weld bead. A sample weld, using the modified chills, was sectioned and a micro study of the weld bead was completed. The results indicated a good quality weld bead. Several battery case to battery lid welds were found nonacceptable during this report period due to an excessive melt in the weld area. This problem did not reoccur. It is felt that there was a residue on the electronics case from the plating operation of the feedthrough. This residue may have caused an alloying effect which lowered the melting temperature of the titanium case. Several electronic case lid weld closures were also unacceptable during this report period. It is believed that a small amount of RTV was left near the weld area during potting of the electronics. The potting procedure is being reviewed and corrective action will be taken to eliminate this problem.

TASK 4.0 - SYSTEM TESTING

Progress of the In-Vivo Study of the RPCP in Dogs

With the intent of accessing the in-vivo reliability of the Radioisotope Powered Cardiac Pacemaker, pacing units which were implanted between June 10, 1972 and September 12, 1972 have now accumulated as of January 31, 1973 a total of 14.22 unit years. Rates have been measured on a weekly basis since implantation and the aggregate of data is given in Table 12. The general tendency has been for the rate to gradually increase and then stabilize. Electrocardiograms were obtained at monthly intervals on each dog and used to validify that each pacer was capturing the canine's heart. Femoral artery checks, as part of the usual procedure, were performed on a weekly basis to ascertain at shorter intervals that the pacer is capturing the heart.

To date, the results of the in-vivo tests show that twenty-nine (29) out of thirty (30) units have performed very reliably without the slightest malfunction. One unit, pacemaker 13, displayed a reduced pulse rate and amplitude for a short period of time; however, it is functioning properly at the present time. It had exhibited a degraded output presumably due to an intermittent short within the nuclear battery resulting from the high amplitude shocks generated by the dogs. Except for minor medical complications which have appeared in eight dogs, no other disorder has compounded the overall excellent results of the animal implants.

Discussion of Medical Complications

Since the first implant, a total of eight dogs have developed ailments requiring medical attention; however, in all of these dogs no degradation of the NU-5 pacing system (except # 13 as noted above) is apparent since all rates, ECGs, and femoral checks have resulted in favorable data. Because two inflammations of the pacemaker sight became hazardous to the animal, pacemaker 33 and 49 were removed and reimplanted within two days in two new dogs, 1470 and Q132 respectively. Of the six remaining dogs, five had superficial inflammations and are treated frequently and injected with antibiotics on a regular schedule. The general medical opinion is that the abnormalities seen are not due to any type of rejection process since such phenomena manifest different symptoms. It is also believed that the swelling is not due to unsterile conditions at the time of implantation, because if that were the case, infections would have appeared within two weeks after surgery. In all cases, the development time has been at least two months and it is highly

TABLE 12

NU-5 RPCP Animal Implant Data

Dog #	P.M. #	Date Implanted	7-28-72	8-4-72	8-11-72	8-18-72	8-25-72	9-1-72	9-8-72	9-15-72	9-22-72	9-29-72	10-6-72
1P029	3	7-10-72	73.4	73.4	73.5	73.6	73.4	73.6	73.6	73.7	73.7	73.8	73.8
1P076	5	7-10-72	72.6	72.6	72.6	72.6	72.6	72.6	72.6	72.5	72.7	72.6	72.6
1P086	6	7-10-72	72.8	72.8	72.7	72.8	73.0	72.6	72.7	72.7	72.6	72.7	72.8
1560	9	7-13-72	73.4	73.4	73.5	73.6	73.7	73.6	73.7	73.7	73.6	73.6	73.7
1P026	11	7-17-72	73.6	73.7	73.7	73.8	73.8	73.9	74.0	73.9	73.9	74.0	74.1
1P127	15	7-17-72	73.5	73.5	73.5	73.6	73.6	73.7	73.7	73.8	73.8	73.9	73.9
F501	20	7-17-72	73.4	73.4	73.3	73.4	73.5	73.4	73.5	73.3	73.9	73.5	73.7
1814	13	7-17-72	73.1	73.2	73.2	73.4	73.4	73.6	73.7	73.9	73.8	73.8	73.9
1P108	23	7-24-72	74.5	74.5	74.5	74.5	74.6	74.6	74.6	74.7	74.7	74.8	74.8
1494	21	7-24-72	73.9	73.9	73.9	74.0	74.1	74.1	74.2	74.5	74.4	74.5	74.5
1P101	24	7-24-72	74.0	74.0	74.3	74.4	74.4	74.3	74.3	74.5	74.5	74.5	74.5
1P103	26	7-24-72	72.7	72.7	72.7	72.7	72.8	72.8	72.8	72.9	72.9	73.0	73.0
1470	33	7-31-72		72.2	72.2	72.3	72.5	72.6	72.6	72.7	72.7	72.8	72.8
1504	30	7-31-72		72.6	72.6	72.6	72.7	72.8	72.8	72.9	73.0	73.0	73.0
1P585	29	7-31-72		--	72.9	72.8	72.9	72.9	73.0	73.0	73.0	73.1	73.1
1P614	34	7-31-72		73.2	73.1	73.1	73.1	73.1	73.2	73.2	73.3	73.4	73.4
1612	38	8-7-72			73.0	73.0	73.0	73.1	73.2	73.3	73.3	73.4	73.4
W432	42	8-7-72			72.4	72.3	72.3	72.3	72.4	72.5	72.5	72.6	72.6
1P656	36	8-11-72				72.6	72.6	72.6	72.7	72.8	72.8	72.9	72.9
1P666	40	8-14-72				73.2	73.2	73.2	73.2	73.2	73.3	73.3	73.4
1P668	45	8-14-72				72.4	72.2	72.2	72.2	72.2	72.2	72.3	72.5
1P611	46	8-14-72				72.4	72.4	72.4	72.5	72.4	72.5	72.5	72.6
1P618	47	8-14-72				72.3	72.2	72.1	72.2	72.3	72.3	72.5	72.5
Q132	49	8-22-72					72.9	72.8	72.8	72.9	73.0	73.1	73.2
1N969	52	8-28-72						72.8	72.8	72.8	72.9	73.0	73.0
1P802	54	8-28-72						72.7	72.6	72.7	72.8	72.7	72.7
1P764	55	8-30-72						72.7	72.8	72.8	72.8	72.9	73.0
1P785	41	9-8-72								73.1	73.1	73.1	73.1
1P654	56	9-8-72								73.0	72.9	73.1	73.1
1P776	57	9-12-72								73.4	73.4	73.4	73.5

TABLE 12 (continued)

NU-5 RPCP Animal Implant Data

Dog #	P.M. #	Date Implanted	10-20-72	10-27-72	11-3-72	11-10-72	11-16-72	12-1-72	12-8-72	12-15-72	12-21-72	1-4-73	1-12-73
1P029	3	7-10-72	73.7	73.7	73.8	73.8	73.7	73.6	73.7	73.8	73.8	73.9	73.7
1P076	5	7-10-72	72.4	72.5	72.5	72.5	72.5	72.5	72.4	72.4	72.4	72.4	72.7
1P086	6	7-10-72	72.7	72.6	72.8	72.7	72.6	72.6	72.5	72.5	72.6	72.5	72.3
1560	9	7-13-72	73.5	73.6	73.7	73.6	73.7	73.4	73.5	73.4	73.6	73.5	73.4
1P026	11	7-17-72	74.1	74.3	74.3	74.4	74.4	74.6	74.6	74.6	74.6	74.7	74.7
1P127	15	7-17-72	74.0	74.0	74.2	74.0	74.1	74.3	74.2	74.3	74.2	74.2	74.1
F501	20	7-17-72	73.4	73.7	73.8	73.6	73.8	73.8	73.9	73.9	74.1	74.0	74.1
1814	13	7-17-72	73.9	73.9	74.0	74.0	60.0	74.4	74.4	74.3	74.3	74.2	74.3
1P108	23	7-24-72	74.8	74.8	74.8	74.8	74.8	74.9	74.9	74.9	75.0	75.0	75.1
1494	21	7-24-72	74.5	74.5	74.6	74.8	74.5	74.7	74.8	74.8	74.8	75.0	74.9
1P101	24	7-24-72	74.7	74.5	74.7	74.7	74.6	74.8	74.9	74.9	75.1	75.0	74.9
1P103	26	7-24-72	73.1	73.1	73.3	73.4	73.3	73.4	73.4	73.4	73.5	73.5	73.6
1470	33	7-31-72	72.8	72.9	72.9	73.0	73.0	73.2	73.2	73.2	73.2	73.2	73.2
1504	30	7-31-72	73.0	73.1	73.1	73.2	73.2	73.2	73.2	73.2	73.3	73.4	73.3
1P585	29	7-31-72	73.2	73.2	73.3	73.3	73.3	73.4	73.4	73.4	73.4	73.4	73.5
1P614	34	7-31-72	73.4	73.5	73.5	73.6	73.6	73.6	73.7	73.7	73.7	73.7	73.8
1612	38	8-7-72	73.4	73.5	73.6	73.5	73.6	73.6	73.6	73.3	73.6	73.7	73.6
W432	42	8-7-72	72.8	72.8	72.8	72.8	72.8	72.9	72.9	72.8	72.8	72.8	72.8
1P656	36	8-11-72	72.9	72.9	73.0	73.0	73.0	73.0	73.1	73.1	73.1	73.1	73.2
1P666	40	8-14-72	73.4	73.5	73.6	73.6	73.6	73.7	73.7	73.8	73.8	73.8	73.9
1P668	45	8-14-72	72.6	72.6	72.7	72.7	72.7	72.8	72.8	72.8	72.8	72.9	72.9
1P611	46	8-14-72	72.7	72.7	72.8	72.8	72.8	73.0	73.0	73.0	73.1	73.0	73.1
1P618	47	8-14-72	72.4	72.5	72.7	72.6	72.5	72.6	72.7	72.9	72.9	72.8	72.8
Q132	49	8-22-72	73.2	73.4	73.5	73.6	73.6	73.6	73.7	73.7	73.7	73.8	73.9
1N969	52	8-28-72	73.2	73.2	73.2	73.3	73.3	73.5	73.5	73.5	73.5	73.6	73.7
1P802	54	8-28-72	72.8	72.8	72.8	72.8	72.9	73.0	73.0	73.1	73.1	73.2	73.2
1P764	55	8-30-72	73.0	73.1	73.3	73.2	73.3	73.4	73.4	73.4	73.5	73.6	73.5
1P785	41	9-8-72	73.1	73.1	73.2	73.1	73.2	73.2	73.2	73.2	73.2	73.3	73.3
1P654	56	9-8-72	73.2	73.2	73.3	73.2	73.4	73.4	73.4	73.5	73.5	73.6	73.6
1P776	57	9-12-72	73.7	73.8	73.9	73.9	73.9	74.1	74.1	74.2	74.2	74.3	74.3

unlikely that an infection could be harbored subcutaneously that long. A possible explanation for the arisen inflammations could be that since the pacer does extrude from the dog's back, it is easily smashed against surroundings causing excessive irritation and internal bruising of the surrounding tissue resulting in fluid buildup.

The sixth dog, 1P585, has a case of ascites and continues to receive careful attention including periodic draining of accumulated abdominal fluid. It is felt, at this time, that despite his appearance, the dog is not suffering and that no reason exists to predicate removal of his pacemaker.

History of Pacemaker 13

On November 17, 1972, a rate determination of pacer 13 was unattainable and an electrocardiogram indicated that capture did not exist and that a decreased rate and amplitude were present. These findings, validified many times, dictated the excision the next day of unit 13 for examination. Observations made at the time were (1) the epoxy was clear and not degraded, (2) the set screw was tight and no existance of a bad connection was evident, (3) all fluid and tissue appeared free from infection, and (4) the pacing threshold was determined to be, roughly, two milliamperes. After the unit was extracted, it was checked with an external load of 470 ohms and oscilloscope pictures were taken which showed the impulse signal having a reduced amplitude, a normal pulse width of 1.5 msec, and a reduced rate of 60 BPM. In an attempt to restore the pacemaker's performance, it was tapped and, upon examination, its rate, amplitude, pulse width, and wave shape were reestablished as the original parameters of the unit.

Radiographs were then taken and the pacer was weighed. Radiographs showed a slight movement of the end shields, which is similar to shaker tests at ARCO Nuclear. The weight was identical to the weight at the time of implant, 123 grams, which implies that the epoxy had not absorbed body fluids. The pacer was then placed in a sterilizer and reimplanted on November 21, 1972 in dog 1814.

The heart lead in dog 1470 has since been removed and returned to ARCO Nuclear Company for inspection. Initial investigations have shown (1) electrical continuity, (2) an impedance of 90 ohms which is a normal value, and (3) upon investigation under a microscope, there were no indications of fractures or corroded areas.

On January 4, 1973 during routine monthly ECGs, anomalous behavior of unit 13 again was sighted and was recorded on an electrocardiographic recorder for the duration of irregularity which was approximately thirty seconds. The abnormal performance very much resembled that which was previously observed on November 17, 1972 as seen by comparison of ECGs (Figure 7). The unit did function properly after the interval of irregular performance and was left remaining in the animal. Successive rate checks made the following weeks during routine examination show the rate to within +.2 BPM of its proper value.

Sterilization of the RPCP for Human Implantation

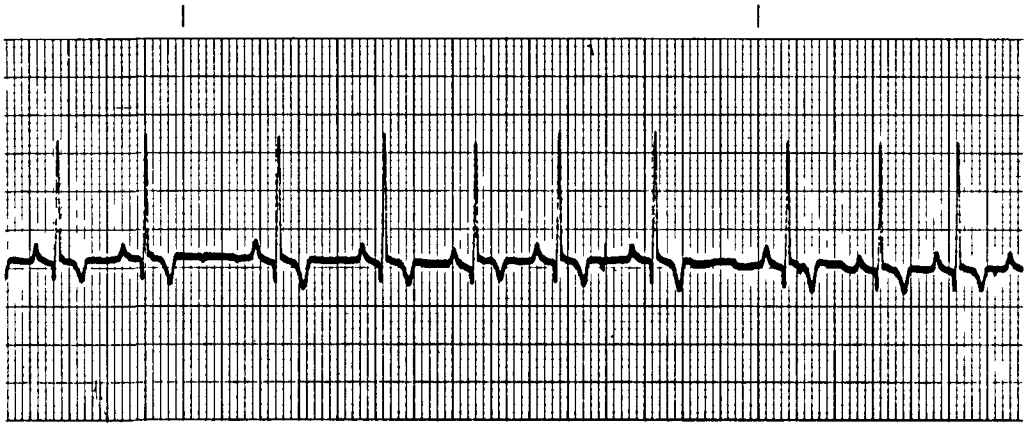
Physicians, in general, expect to receive implantable pacemakers in implant ready condition, meaning the manufacturer must accept the responsibility of providing the device in a sterile state. Manufacturers accept this responsibility not only to satisfy the physician but to reduce the frequency of sterility failures.

Although it is well established that gaseous sterilization with ethylene oxide is the most advantageous means of sterilizing pacemakers, nevertheless, many important variables are involved. Experience has shown that ethylene oxide sterilization is not a simple process and that many factors limit the possibility of developing a standard sterilization for all materials or products. It is quite common that highly specialized cycles are developed for specific products.

Some of the variables which make ethylene oxide sterilization an extremely complicated process are temperature, exposure time, concentrations, humidity, packing materials, and aeration time. It is necessary that serious consideration is given to these parameters when developing a specific cycle for a particular product; and especially, considering that a pacemaker is an implantable device, it warrants even closer attention.

To institute proper packaging and sterilization of the 52 units necessary for the AEC investigational study in humans, two companies (American Sterilizer Company and Castle Company) with very reputable names in the sterilization field were contacted and visited. Basically, both companies were in general agreement since the standards and techniques as required for sterilization and sterility testing are clearly outlined in the U. S. Pharmacopeia.

November 17, 1972



January 11, 1973

Pacer 13 - Segments of Abnormal ECGs

Figure 7

The U. S. Pharmacopeia, a government compendia, provides the guidelines as to the types of sterilization, the number of items to be tested per lot, technical data concerning media, incubation times and temperature which must be employed before the processed items are adequately assessed as sterile. Since determination of whether or not a processed lot is sterile is based strictly on statistics, absolute assurance that any particular item is sterile cannot be made (by anyone); yet compliance with the U. S. Pharmacopeia underwrites the procedure.

Through discussion, it was concluded that even if a large capital investment were made to start a lab, our inexperience in this difficult field at the present time would be a major handicap. Therefore, ARCO Nuclear Company has proceeded to arrange the utilization of an outside vendor's research facility for the 52 RPCPs with the scope of work being:

1. Development of the kill kinetics associated with a sterilization cycle for the RPCP.
2. Pyrogen testing - This refers to examination of the product after sterilization to determine the quantity of dead micro-organisms remaining. These dead bacteria can cause a fever reaction in a patient if the concentration is high enough.
3. Development of an elution curve - The elution curve graphs ETO concentration versus time after sterilization. This is important since ETO characteristically kills organisms and may, if high residual concentrations remain cause adverse effects once implanted.
4. Sterilize 52 pacemakers and provide sterility documentation which certifies compliance with the U. S. Pharmacopeia. In addition, maximum traceability and accountability of all units will be maintained.

Non-Competitive Circuits

During this report period, an RFP for the delivery of non-competitive cardiac pacemaker circuits for use in the RPCP Program was submitted to 12 companies including all of the major domestic pacemaker companies. These circuits are to be powered by the nuclear battery and subjected to various tests including electromagnetic interference testing, reliability testing, compatibility testing, environmental testing and/or such other tests that are deemed desirable. The RFP specified three possible sets of battery characteristics and a maximum physical size for the electronic circuit as shown in Table 13. It was further stated that the maximum physical size could be exceeded in which case the circuit would not be hermetically sealed but should fit the epoxy dimension shown on system drawing 15-D-4189-32. Potting or sealing of the circuits prior to delivery was possibly.

It was also stated that the electrode system to be used is monopolar and in the event of circuit failure the failed circuit is to be returned intact to the vendor for replacement. Failed circuits shall be replaced at no cost to the Commission and shall be delivered within 30 days of receipt of the failed circuits. All circuit failure analysis was to be performed at no cost to the Commission.

Of the 12 companies receiving the RFP, only one submitted a responsive bid. Therefore, this vendor was awarded a fixed price purchase order for 15 non-competitive circuits. These circuits will be used to demonstrate the flexibility and maximum usefulness of the nuclear battery developed since it will be demonstrated that it has enough power and high enough output voltage to power the more commonly used pacer circuits.

Epoxy Evaluation

Testing of epoxy blocks in Ringer solution has been suspended. No deterioration of the epoxy was noted after three months. Six blocks were molded, two with a normal amount of hardener (for control units), two with 25 percent excess hardener, and two with 50 percent excess hardener.

In order to determine the effect of various mixtures of epoxy under in-vivo conditions and to, possibly, simulate the NU-4 pacemakers which had degraded epoxy, six mock-up pacers with different percentages of hardener were fabricated. Two mock-up units were made with normal compositions to serve as control units, while two have 50 percent excess hardener and two have 100 percent excess hardener. Previously, Hysol Corporation reported that samples of the degraded epoxy indicated that 100 percent excess hardener was added. These pacers were delivered to NH&LI where they will be implanted in six separate dogs under normal conditions. At the present time, the implants have been delayed until an order for mesh bags is received.

TABLE 13

Parameter	System A	System B	System C
Battery Nominal Open Circuit Voltage (volts)	1.1	2.2	3.3
Battery Nominal Resistance (ohms)	1.3 K	5.3 K	11.8 K
Battery Nominal Peak Power (microwatts)	230	230	230
Stimulating Electrode	Monopolar	Monopolar	Monopolar
Anode Material	Titanium	Titanium	Titanium
Anode Surface Area (cm^2)	71	71	71
Electronic Circuit* Physical Size (inches)	1.65 x .63 x .48 Maximum	1.65 x .63 x .48 Maximum	1.65 x .63 x .48 Maximum

*Maximum size compatible with existing hermetically sealed electronics case.

Paint Shaker Characterization

Several modifications have been completed on the new paint shaker. Clearance between the connecting rod and pins was increased to .010 inch. The drive end of the connecting rod was modified to provide a .005 inch clearance between the drive shaft and connecting rod. The output of the shaker was recorded after each rework. Test results indicate no significant change in output wave form. Reworks to the new shaker will continue in an effort to duplicate the output of the old shaker which is being used as the test vehicle for qualification units.

TASK 5.0 - SAFETY

During this report period, the document entitled "Analysis of Accidental RPCP Earth Burial and Cremation" was prepared and submitted. This document discussed the effects of accidental burial and accidental cremation on the RPCP. For both of these accidents, the analysis consisted of three parts:

1. a discussion of the actual conditions experienced by the RPCP as a consequence of the hypothetical occurrence of the accident,
2. a determination of the likelihood of occurrence of the accident, and
3. an analysis of the radiological effects of the accident on the general population.

General results of the analysis are that there is a great deal of safety conservatism in the design of the RPCP system.

Cremation

Forty-three crematories in the United States and Canada have tested 54 temperature indicators during actual cremations. A total of 67 temperature indicators have been sent out to crematories in this country and Europe. Eleven indicators still have not been tested. Testing at the 43 crematories represents test data from 11 different furnace manufacturers.

The highest temperature pellet melted is still 2200°F. One tempil holder was returned from a crematory in Seattle. Examination of the tempil holder indicated the holder was in direct contact with the flame. As a result, the tempil holder was partially melted. Due to the condition of the tempil holder, examination of the remaining pellets was impossible. Inconel 600 has a melting range of 2470°F to 2575°F. This crematory has oil fired burners and is a homemade unit. A second tempil holder was sent to this crematory and was tested in the same manner as the first. Examination of the second tempil holder showed the highest pellet that melted was the 2100°F pellet. The melted holder was analyzed and the report indicated the holder material was Inconel 600. Further testing is planned at this crematory. Crematories are still being contacted for additional cremation testing. Table 14 summarizes the cremation testing to date. All temperature indicators being sent out are now loaded with 50°F increment pellets.

TABLE 14

TEMPIL DATA DURING ACTUAL CREMATIONS

Crematory	Highest Temperature Pellet That Melted*	Furnace Manufacturer	Casket Type	Cycle Time	Pellet Holder #
A	2100°F	Jones (gas)	Pine	2 hrs.	8
	1800°F	Jones (gas)	Steel	2-1/2 hrs.	9
	2100°F	Jones (gas)	Pine	2-1/2 hrs.	32
B	Under 1500°F	All (gas)	Litter	2-1/4 hrs.	3A
	1900°F	All (gas)	Pine	2-1/4 hrs.	27
	1700°F	All (gas)	Metal	2 hrs.	14
C	1500°F	Jarvis (gas)	Pine	1-3/4 hrs.	17
	2100°F	Jarvis (gas)	Hardwood	2 hrs.	6A
	1700°F	Jarvis (gas)	Hardwood	1-1/4 hrs.	12
D	2100°F	I.E. (gas)	Pine	2-1/2 hrs.	18
	2200°F	I.E. (gas)	Metal	2 hrs.	20
	2200°F	I.E. (gas)	Hardwood	2 hrs.	25
	2200°F	I.E. (gas)	Hardwood	2 hrs.	1A
	2100°F	I.E. (gas)	Softwood	2 hrs.	21
	2100°F	I.E. (gas)	Metal	2 hrs.	24
	1750°F	Morse-Bolger	Wood	3 hrs. 40 min.	1A
E	1700°F	Cossar & Smith Eng. (oil)	Pine	2-1/4 hrs.	19
F	2100°F	Custom Built (gas)	Pine	2 hrs.	29
G	2100°F	Jones (oil)	Pine	2-1/2 hrs.	28
H		Calcinator (LP gas)/ Crematory			
	1700°F	Calcinator (LP gas)	Cardboard	4 hrs.	2A
	1900°F	Cremated	Hardwood	3 hrs.	26
	1800°F	Calcinator	Wood	3 hrs.	13

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

TABLE 14 (continued)

TEMPIL DATA DURING ACTUAL CREMATIONS

Crematory	Highest Temperature Pellet That Melted*	Furnace Manufacturer	Casket Type	Cycle Time	Pellet Holder #
I	1700°F	Pacific Delong (gas)	Oak	3 hrs. 20 min.	30
J	1800°F	Jones (oil)	Softwood	1 hr. 40 min.	16
K	1900°F	Jones (gas)	Softwood	1 hr. 40 min.	23
L	1700°F	Olsen (nat. gas)	Softwood	3 hrs.	15
M	2200°F	I. E. (gas)	Softwood	1 hr. 35 min.	7
N	2100°F	Morse Bolger (oil)	Hardwood	1 hr. 50 min.	31
O	2100°F	Gibson	Softwood	2-1/2 hrs.	3A
P	1900°F	I. E. (gas)	Softwood	3-1/2 hrs.	18
	1900°F	I. E. (gas)	Metal	3 hrs. 10 min.	17
Q	1600°F	Jarvis (gas)	Softwood	1 hr. 45 min.	23
R	2100°F	Jones (oil)	Softwood	1 hr. 30 min.	15
T	1700°F	Ray Burner Co. (gas)	Softwood	2 hrs. 10 min.	11
U	1800°F	Jarvis (gas)	Softwood	1 hr. 35 min.	24
V	1800°F	Incinomite Unipower (gas)	Softwood	2-1/2 hrs.	21
W	1500°F	Jarvis (gas)	Hardwood	2 hrs.	22

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

TABLE 14 (continued)

TEMPIL DATA DURING ACTUAL CREMATIONS

Crematory	Highest Temperature Pellet That Melted*	Furnace Manufacturer	Casket Type	Cycle Time	Pellet Holder #
X	2100°F	Bayco	Cardboard	5 hrs.	3A
Y**	1800°F	Jarvis	Softwood	3 hrs. 5 min.	11
Z**	1750°F	All	Softwood	2 hrs. 20 min.	15
AA**	(2200°F+)	Homemade	Softwood	1 hr. 35 min.	14
	2100°F	Homemade	Softwood	1 hr. 35 min.	7
BB**	1750°F	I.E.	Softwood	2-3/4 hrs.	31
CC**	1800°F	I.E.	Softwood	2-3/4 hrs.	2A 30
DD**					6A
	2050°F	I.E.	Metal	2 hrs.	1A
EE**	2150°F	I.E.	Oak	2 hrs. 15 min.	17
FF**	1950°F	I.E.	Softwood	1 hr.	18
GG**	2100°F	I.E.	Hardwood	1 hr. 45 min.	21
HH**	2050°F	Jones	Softwood	2 hrs. 45 min.	22
II**	2100°F	Jones	Softwood	3 hrs. 3 min.	24

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

**50°F Pellets.

NOTE: Pellet Holder 14 from Crematory AA was in direct contact with flame. Temperature could not be determined.

TABLE 14 (continued)

TEMPIL DATA DURING ACTUAL CREMATIONS

Crematory	Highest Temperature Pellet That Melted*	Furnace Manufacturer	Casket Type	Cycle Time	Pellet Holder #
JJ**		Jones (oil)			
KK**		Jones (oil)			
LL**	2000°F	Jones (oil)	Softwood	1 hr. 13 min.	18
MM**	1750°F	Jones (oil)	Wood	1 hr. 15 min.	31
NN**	1950°F	Jones (oil)	Cardboard	4 hrs. 35 min.	17
	2200°F	Jones (natural gas)	Wood Cedar	4 hrs.	21

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

**50°F Pellets.

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