Medtronic™ Implantable Demand ISOTOPIC PULSE GENERATOR Laurens-Alcatel Model 9000

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Medtronic

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INTRODUCTION

This is the fourth in a series of semi-annual reports, to be submitted to the Materials Branch of the United States Nuclear Regulatory Commission, detailing the progress of a clinical evaluation study of the MEDTRONIC™ LAURENS-ALCATEL MODEL 9000 ISOTOPIC PULSE GENERATOR.

As stated in the Medtronic Clinical Investigation Plan for the Model 9000, dated March 21, 1973, one objective of the study has been to compare the performance, in vivo, of the Model 9000 and its chemically powered counterparts. Another objective has been to assess the feasibility of a patient follow-up system which ensures complete pulse generator accountability and recovery upon patient death, or in the event of complications necessitating explantation of the nuclear device.

Throughout this fourth report, an attempt is made to point out changes since the previous report. In general, there have been no significant changes in the characteristics of the study. It is significant that there have been no cell failures, and that the random component failure rate continues to drop.

PATIENT POPULATION CHARACTERISTICS

To be able to fully understand the significance of the clinical results presented herein, it is essential first to define the characteristics of the patient population.

The age/sex distributions of both the nuclear and the chemically powered pulse generator bearers in the study are displayed in Table 1. Comparison of the ages of nuclear and chemically powered pacemaker bearers reveals the nuclear group to be significantly younger. The difference is quite consistent both for males and females, being 19.3 and 22.2 years, respectively.

The combined age distributions of males and females for each of the two pacemaker types are graphically compared in Figure 1. It is noteworthy that the most frequent age bracket characterizing chemically powered pacemaker bearers is 71 to 80 years, whereas a typical nuclear pacemaker bearer is only 51 to 60 years of age.

Medical information pertaining to the general patient population is illustrated in Table 2. The distributions in terms of age and etiology of arrhythmia are shown in Table 2A. A large percentage of the population falls under "other." This category incorporates all etiologies which are pathological. A breakdown of this category can be found in Table 2B, which portrays factors accompanying the etiology of the arrhythmia.

TABLE 1. COMPOSITION OF PATIENT POPULATIONS BY AGE[1] AND SEX (TO 5-12-75)

	NUCLEAR POWERED			CHEMICALLY POWERED		
Age	Male	Female	Total	Male	Female	Total
1-10	1	0	1	2	1	3
11-20	11	3	14	2	0	2
21-30	20	16	36	2	1	3
31-40	19	12	31	1	3	4
41-50	42	26	68	4	4	8
51-60	72	40	112	24	12	36
61-70	45	9	54	46	24	70
71-80	5	2	7	44	41	85
81-90	0	1	1	25	13	38
91-100	0	0	0	4	2	6
Total No.	215	109	324	154	101	255
Average Age	49.6	46.9	48.7	68.9	69.1	69.0

[1] Age at implant

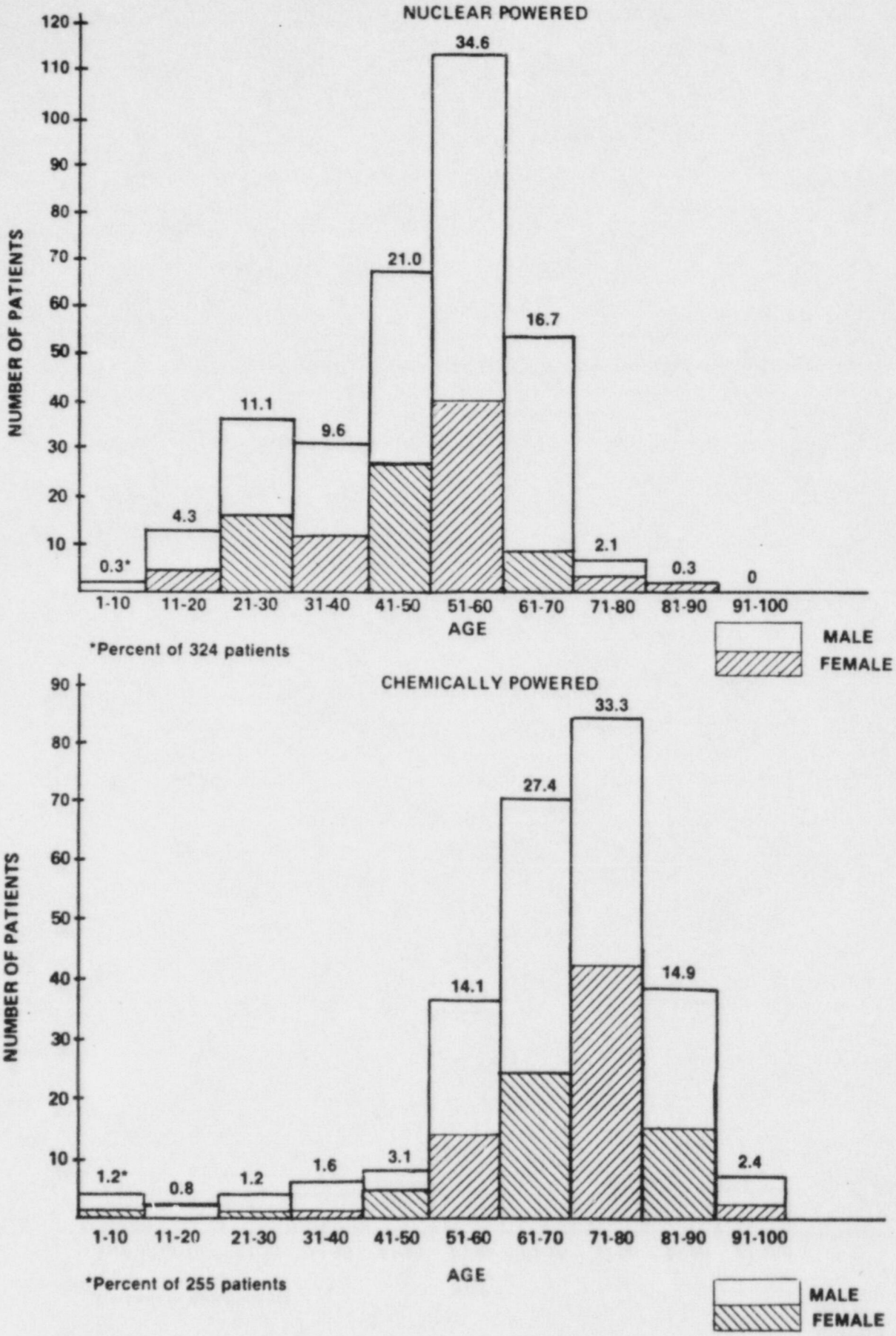


FIGURE 1. HISTOGRAMS OF PATIENT POPULATIONS BY AGE (TO 5-12-75)

As reported earlier, the typically younger nuclear group contains a much higher percentage of patients with congenital heart block than does the older, chemically powered pacemaker group. The only meaningful conclusion to be garnered from Tables 2B and 2C is that the chemically powered group of patients is very similar to the nuclear powered group with respect to conduction disturbance and factors accompanying the disturbance.

PULSE GENERATORS INVOLVED IN THE STUDY

Technical aspects of the two pulse generator groups were explained in a previous report. More extensive information can be found in the Medtronic™ Implantable Demand Isotopic Pulse Generator, Laurens-Alcatel Model 9000 Technical Manual. Figure 2 is a photograph of the Model 9000, and Table 3 lists electrical and physical specifications. The model numbers, dates of initial production, and numbers of implanted units of each of the chemically powered models are shown in Table 4 and Figure 3.

GENERAL PATIENT INFORMATION[1] (TO 5-12-75)

Table 2A. Numbers of Patients by Age and Etiology of Arrythmia

Age	NUCLEAR POWERED 324 Implants					CHEMICALLY POWERED 255 Implants				
Etiology	Surgically Induced	Congenital	Unknown	Other (See Table 2B)	Total	Surgically Induced	Congenital	Unknown	Other (See Table 2B)	Total
1 - 20	3	9	3	1	16	1	4	0	0	5
21 - 40	9	24	17	17	67	0	2	2	3	7
41 - 60	6	8	69	97	180	1	0	10	33	44
61 - 80	0	0	20	40	60	0	1	42	112	155
81+	0	0	0	1	1	0	0	11	33	44
TOTAL	18	41	109	156	324	2	7	65	181	255
% OF IMPLANTS	5.6	12.6	48.2	33.6	100	0.8	2.7	25.5	71.0	100

[1] Key to Abbreviations:

CHB - Congenital Heart Block
ASHD - Arteriosclerotic Heart Disease
ASCVD- Arteriosclerotic Cerebrovascular Disease
CHD - Coronary Heart Disease
RBBB - Right Bundle Branch Block
RAD - Right Axis Deviation
LAD - Left Axis Deviation
A-V Block - Atrio-Ventricular Block
S-A Block - Sino-Atrial Block

OTHER - (See Glossary for an explanation of these terms)
1. - Viral Cardiomyopathy
2. - Sclerosis of conduction system with no arteriosclerotic heart disease.
3. - Diphtheritic Myocarditis
4. - Myotonia Dystrophica
5. - Sarcoidosis
6. - Lenegre's Disease (Trifascicular Fibrosis)
7. - Kearns-Sayre's Syndrome
8. - Rheumatic Myocarditis
9. - Cardiomyopathy
10. - Ventricular Aneurysm
11. - Hypersensitive carotid sinus with sinus arrest.
12. - Rheumatic heart disease with mitral stenosis.

Table 2B. Accompanying Factors
(May also be the etiology)

Age / Factor[1]	ASHD/ASCVD/CHD	Hypertension	Diabetes Mellitus	Rheumatic Heart Disease	Congenital Heart Disease	Cardiac Surgery	Myocardial Infarction	Bacterial Endocarditis	Syphilis	Congestive Heart Failure	Cerebrovascular Accident	Chagas' Disease	Undetermined Heart Disease	Other
NUCLEAR POWERED (324 Implants)														
1 - 20	0	0	0	0	7	3	0	0	0	0	0	0	1	1
21 - 40	4	3	0	2	28	14	1	0	0	1	0	0	1	17
41 - 60	69	9	7	8	13	7	11	0	1	3	0	0	2	40
61 - 80	36	5	5	1	0	1	3	0	0	1	1	0	2	5
81+	1	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	110	17	12	11	48	25	15	0	1	5	1	0	6	63
% OF IMPLANTS	34.0	5.3	3.7	3.4	14.8	7.7	4.6		0.3	1.5	0.3		1.9	19.1
CHEMICALLY POWERED (255 Implants)														
1 - 20	0	0	0	0	3	2	1	0	0	0	0	0	0	2
21 - 40	1	1	0	0	2	0	1	0	0	1	0	0	0	3
41 - 60	23	4	6	2	0	1	7	0	0	4	1	0	1	9
61 - 80	86	13	12	2	1	2	14	0	0	12	1	0	4	29
81+	27	1	4	0	0	0	3	0	0	2	0	0	1	3
TOTAL	137	19	22	4	6	5	26	0	0	19	2	0	6	46
% OF IMPLANTS	53.7	7.5	8.6	1.6	2.4	2.0	10.2			7.5	0.8		2.4	18.0

Table 2C. Type of Conduction Disturbance

Age	A-V Block: Complete (3rd Degree)	A-V Block: Intermittent Complete	A-V Block: Incomplete (2nd/1st Degree)	A-V Block: Variable	S-A Block: Sinus Bradycardia	S-A Block: Sick Sinus Syndrome	S-A Block: Sinus Arrest	S-A Block: Other	Bundle Branch Block: Right BBB	Bundle Branch Block: Left Posterior-Inferior	Bundle Branch Block: Left Anterior-Superior	Bundle Branch Block: Left Complete	Bundle Branch Block: RBBB & Left Posterior Hemiblock (RAD)	Bundle Branch Block: RBBB & Left Anterior Hemiblock (LAD)	Other Disturbances: Atrial Arrythmia	Other Disturbances: Ventricular Arrythmia	Other Disturbances: Hypersensitive Carotid Sinus	Other Disturbances: Wolff-Parkinson-White Syndrome	Other Disturbances: Brady-Tachy Arrythmia	Other Disturbances: Long Q-T Interval	Other Disturbances: Digitalis Toxicity (Drug Induced)	Other Disturbances: Other Drug Idiosyncrasy
NUCLEAR POWERED (324 Implants)																						
1 - 20	13	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21 - 40	42	11	4	1	4	4	1	2	1	0	1	0	1	0	3	3	0	1	0	0	0	0
41 - 60	97	22	8	1	16	11	8	3	6	0	1	9	0	2	4	8	1	1	7	0	0	0
61 - 80	37	5	1	0	4	6	4	0	1	0	0	2	0	0	2	1	0	0	4	0	0	0
81+	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL	190	38	13	2	25	22	14	6	8	0	2	11	1	2	9	12	1	2	11	0	0	0
% OF IMPL.	58.6	11.7	4.0	0.6	7.7	6.8	4.3	1.9	2.5	0	0.6	3.4	0.3	0.6	2.8	3.7	0.3	0.6	3.4			
CHEMICALLY POWERED (255 Implants)																						
1 - 20	4	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21 - 40	3	0	0	0	1	1	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
41 - 60	27	6	4	0	6	2	0	0	3	0	0	4	1	1	0	0	0	0	2	0	0	0
61 - 80	73	19	14	0	15	10	9	6	7	0	1	7	0	3	16	7	1	0	8	0	0	0
81+	27	3	4	0	3	3	3	1	3	0	0	5	0	1	0	1	0	0	0	0	1	0
TOTAL	134	28	23	0	25	16	13	7	13	0	1	16	1	5	16	9	1	0	10	0	1	0
% OF IMPL.	52.6	11.0	9.0	0	9.8	6.3	5.1	2.8	5.1	0	0.4	6.3	0.4	2.0	6.3	3.4	0.4	0	3.9	0	0.4	0

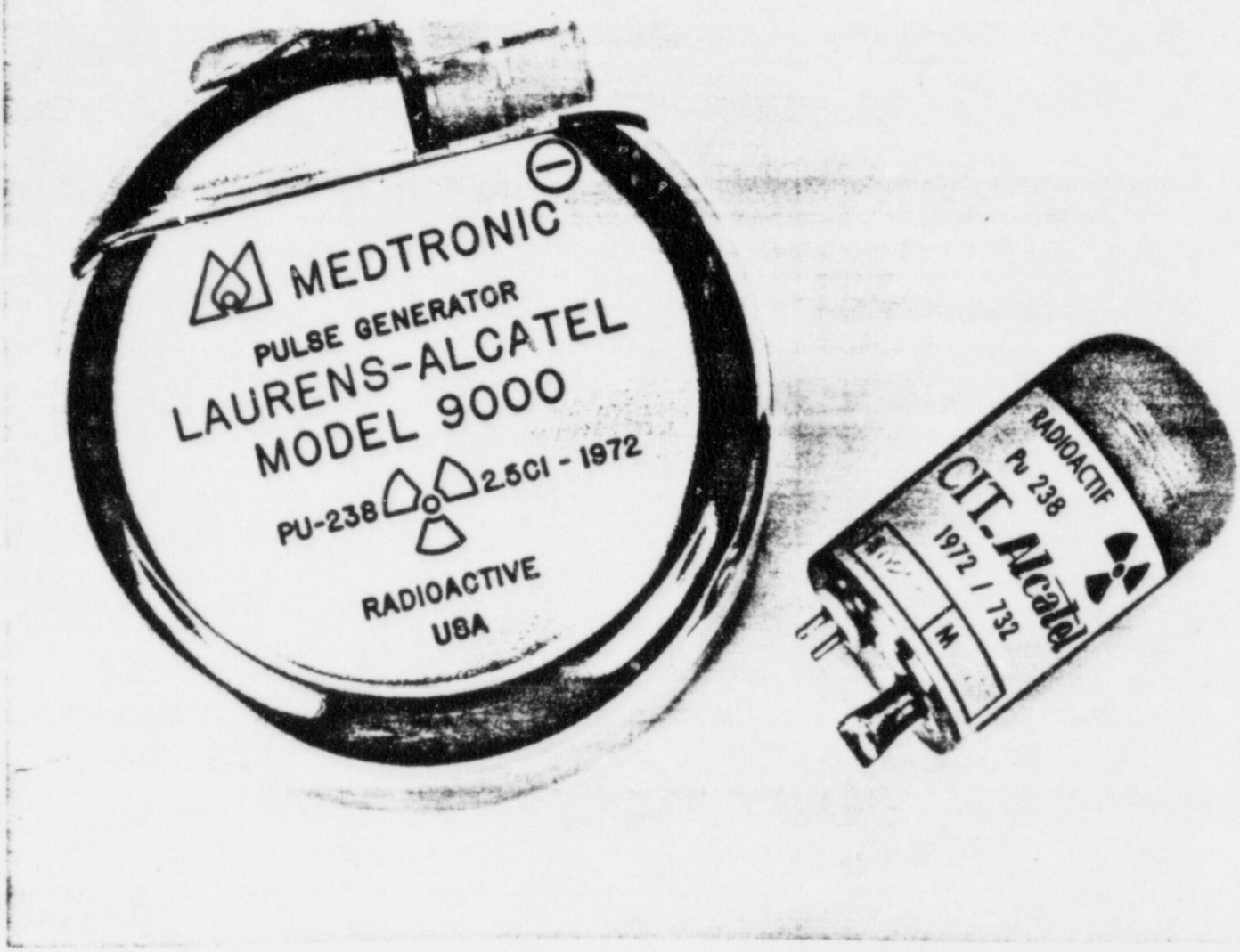


FIGURE 2. MEDTRONIC™ IMPLANTABLE DEMAND ISOTOPIC PULSE GENERATOR LAURENS-ALCATEL MODEL 9000 AND FUEL CELL

TABLE 3. ELECTRICAL AND PHYSICAL SPECIFICATIONS
FOR MODEL 9000

Electrical

Pacing Rate	72 ppm
Pulse Interval	Pacing - 833 milliseconds Sensing - 940 milliseconds
Reversion Rate (in presence of strong interference)	Approximately 50 ppm
Pulse Amplitude	5.4 volts, 10.8 ma. (minimum) into a standard 500 ohm load at 0.5 msec. into the pulse
Pulse Duration	1.1 millisecond
Output Energy (Pacing)	60 microjoules (minimum)
Sensitivity to R-wave Potential*	2.5 to 3.5 millivolts
Refractory Period	250 to 350 Milliseconds

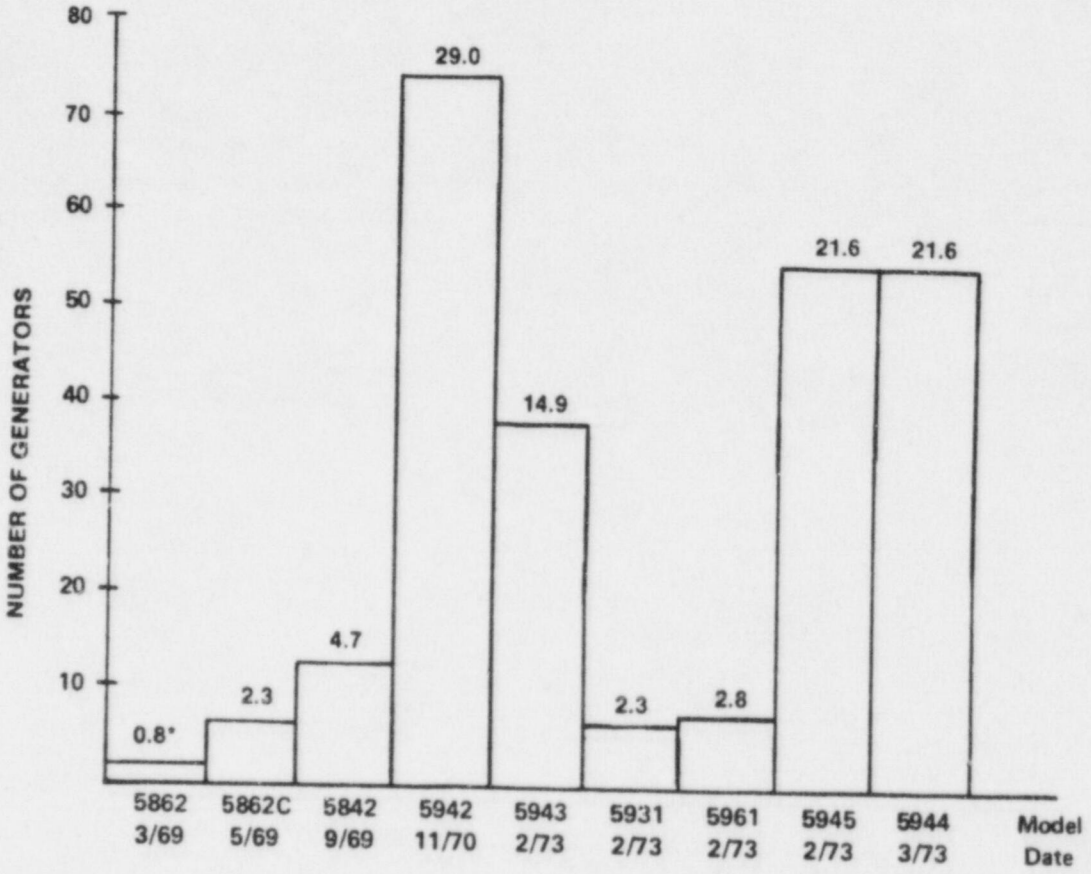
Physical

Diameter	7.0 cm
Thickness	2.6 cm
Weight	170 grams
Volume	90 cc
Encapsulating Material	Epoxy resin
External Housing Material	Titanium (Grade 1)
Lead System	All Medtronic myocardial or endocardial leads
Type Connector	Setscrew

*As measured with a 40 millisecond sine-squared pulse (the sensitivity is 1.0 - 1.7 millivolts using a 45 ms square wave test signal).

TABLE 4. DISTRIBUTION OF NUMBERS OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL NUMBER AND DATE OF INITIAL PRODUCTION (TO 5-12-75)

Model Number	Initial Production Date	Number Implanted
5862	3/69	2
5862C	5/69	6
5842	9/69	12
5942	11/70	74
5943	11/70	38
5931	2/73	6
5961	2/73	7
5945	2/73	55
5944	3/73	55
TOTAL		255



*Percent of 255 implants

FIGURE 3. HISTOGRAM OF MODELS OF CHEMICALLY POWERED PULSE GENERATORS IN ORDER OF DATE OF INITIAL PRODUCTION.

CURRENT STATUS OF THE INVESTIGATION

Analysis of Pulse Generator Data

From July 18, 1972 to May 12, 1975, three hundred and twenty-four (324)* Model 9000 isotopic pulse generators have been implanted in patients presently located within the United States (Table 5). Among the one hundred and nine (109) physicians participating in the investigation, the numbers of isotopic units implanted per physician have ranged from zero to twenty-nine (29).

During the same period, two hundred and fifty-five (255) investigational controls have been submitted, with the number per physician varying from zero to thirty-seven (37). Sixty-nine (69) isotopic investigators have not as yet submitted controls, although one physician has supplied thirty-seven (37) investigational controls for his fourteen (14) isotopic implants.

Numbers of complications per physician (Table 5B) range from zero to five (5) among the nuclear patients and from zero to seven (7) among the controls. The complication rates of the two groups may be directly compared by means of the hypothesis testing procedure described by Conover

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*The number of implants in the United States exceeds this number - 324 is the number for which implant data has been completely processed by the computer.

(1971), whereby the complication and implantation frequencies for each group are arranged in a contingency table, and subjected to a chi-squared test of significance. Calculation yields a $\chi^2 = 0.507$ with one degree of freedom, thereby substantiating the hypothesis of no difference. Explanted devices to date (Table 5A) consist of nineteen (19) isotopic pulse generators and thirty-two (32) chemically powered units.

There has been one pulse generator failure in each group. A nuclear unit was explanted in September, 1974 because it exhibited low output pulses. The unit was returned to Medtronic, Inc., for investigation. Analysis revealed that the low output was caused by a corroded negative output tab which connects the electrode connector to the hermetically sealed circuitry can. This tab is normally potted with Hysol by a backfill procedure after the can is totally assembled. This particular unit had a void in the backfill which allowed body fluids to enter the can in the area around the tab and corrode through it. The positive tab was totally covered with Hysol and did not exhibit any corrosion. This device failure was in no way related to the isotopic power source or pulse generator circuitry. The void in the backfill was subsequently identified and characterized on the final packaging x-ray. X-rays of all units presently implanted have been reviewed and, with this new information involved in interpreting x-rays, no other cases of voids were found.

TABLE 5A. NUMBERS OF IMPLANTATIONS, EXPLANTATIONS, AND ASSOCIATED COMPLICATIONS BY PARTICIPATING HOSPITAL (TO 5-12-75)

	NUCLEAR POWERED			CHEMICALLY POWERED		
Hospital Code	Implants	Explants[1]	Complications[2]	Implants	Explants[3]	Complications[2]
1002	4	0	1	3	0	0
1003	3	0	0	0	0	0
1004	1	0	0	2	1	0
1005	1	0	0	0	0	0
1006	2	0	0	0	0	0
1007	1	0	0	3	0	0
1008	0	0	0	1	1	0
1010	1	0	0	0	0	0
1012	1	0	0	0	0	0
1015	5	0	0	0	0	0
1016	2	0	0	2	0	0
1017	4	0	0	4	1	2
1018	14	0	4	23	0	0
1019	4	1	0	3	0	1
1020	0	0	0	1	0	0
1021	0	0	0	2	1	0
1022	2	0	0	0	0	0
1023	29	2	4	15	2	1
1024	4	0	4	0	0	0
1025	3	0	4	4	0	0
1026	6	1	5	7	2	1
1027	9	0	0	13	3	3
1028	4	1	1	7	1	1
1029	0	0	0	1	1	0
1031	0	0	0	1	1	1
1032	1	0	1	0	0	0
1035	3	0	0	0	0	0
1038	0	0	0	1	0	0
1046	3	0	0	3	0	0
1059	1	0	0	0	0	0
1060	5	0	1	0	0	0
1062	0	0	0	2	0	0
1063	0	0	0	1	0	0
1064	0	0	0	9	6	0
1065	0	0	0	3	0	0
1067	0	0	0	1	0	1
1071	2	0	0	0	0	0
1094	0	0	0	1	0	0
1095	0	0	0	5	0	1
1096	0	0	0	1	0	0
1097	0	0	0	1	0	0
1099	0	0	0	1	0	0
2001	1	0	0	0	0	0
2002	9	0	0	15	3	0
2003	22	1	5	3	0	0
2004	1	0	0	0	0	0
2005	6	0	0	0	0	0
2006	4	0	0	0	0	0
2007	1	0	0	0	0	0
2008	2	0	1	0	0	0
2010	2	0	0	0	0	0
2011	6	0	0	0	0	0
2012	1	0	0	0	0	0
2013	5	0	0	0	0	0
2014	5	1	1	0	0	0
2015	1	0	0	0	0	0
2016	10	3	3	10	1	4
2017	4	1	0	4	0	0
2020	3	0	0	0	0	0
2022	3	0	1	19	1	6

Continued

[1] See Appendix 3 for itemization of explantations (nuclear).
[2] See Appendix 4 for itemization of explantations (chemicals).
[3] See Table 7 for itemization of complications.

TABLE 5A. - Continued

Hospital Code	NUCLEAR POWERED			CHEMICALLY POWERED		
	Implants	Explants[1]	Complications[2]	Implants	Explants[3]	Complications[2]
2023	1	0	0	1	0	0
2024	1	0	0	0	0	0
2025	1	0	0	3	0	0
2026	3	0	0	3	0	0
2027	5	0	0	0	0	0
2029	2	0	0	4	0	0
2031	2	0	0	0	0	0
2032	3	1	0	2	0	2
2034	1	0	0	0	0	0
2069	1	0	0	0	0	0
2071	0	0	0	2	0	1
2072	0	0	0	1	0	0
2073	1	0	0	0	0	0
2075	1	0	0	0	0	0
2080	1	0	2	1	0	0
2101	1	0	0	0	0	0
2102	1	0	0	0	0	0
3001	9	0	3	3	1	3
3002	1	0	0	2	0	1
3003	1	0	0	3	0	0
3006	1	1	0	0	0	0
3007	2	1	0	0	0	0
3008	1	0	0	0	0	0
3011	1	1	0	6	0	3
3013	4	0	0	9	0	0
3015	3	0	0	0	0	0
3016	2	0	0	2	0	0
3018	1	0	0	0	0	0
3020	4	0	0	8	0	0
3021	1	0	0	0	0	0
3022	6	1	1	4	0	0
3024	1	0	0	0	0	0
3025	1	0	0	0	0	0
3026	1	0	0	0	0	0
3027	3	0	1	1	0	0
3029	2	0	0	0	0	0
3031	1	0	0	1	0	0
3034	1	0	0	0	0	0
3035	2	0	0	0	0	0
3036	1	0	0	0	0	0
3037	2	0	0	0	0	0
3038	2	0	0	1	0	0
3039	4	0	0	1	0	0
3040	7	0	0	1	1	1
3041	0	0	0	1	0	0
3042	0	0	0	1	0	0
3043	0	0	0	1	0	0
3044	0	0	0	1	0	0
3045	0	0	0	1	0	0
3046	1	0	0	0	0	0
3050	2	0	0	1	0	0
3051	5	0	1	8	3	1
3052	2	0	0	0	0	0
3053	1	0	0	0	0	0
3054	2	1	0	0	0	0
3055	4	1	4	7	1	0
3056	0	0	0	1	1	0
3057	2	0	0	0	0	0
3058	3	0	1	0	0	0
3059	1	0	0	0	0	0
3061	4	0	0	1	0	0
3081	1	0	0	0	0	0
3106	2	0	0	0	0	0
3113	1	0	0	0	0	0
3114	1	0	0	0	0	0
TOTAL	324	19	50	255	32	34

[1] See Appendix 3 for itemization of explantations (nuclear).
[2] See Appendix 4 for itemization of explantations (chemical).
[3] See Table 7 for itemization of complications.

TABLE 5B. NUMBERS OF IMPLANTATIONS, EXPLANTATIONS, AND ASSOCIATED COMPLICATIONS BY PARTICIPATING INVESTIGATOR (TO 5-12-75)

	NUCLEAR POWERED			CHEMICALLY POWERED		
Physician Code	Implants	Explants[1]	Complications[2]	Implants	Explants[3]	Complications[2]
1001	3	0	0	3	0	0
1002	1	0	1	0	0	0
1004	3	0	0	0	0	0
1005	1	0	0	2	1	0
1006	6	0	1	0	0	0
1007	2	0	0	0	0	0
1008	1	0	0	4	1	0
1012	1	0	0	0	0	0
1013	1	0	0	0	0	0
1016	5	0	0	0	0	0
1017	3	0	0	3	0	0
1018	2	0	0	2	0	0
1019	4	0	0	4	1	2
1020	14	0	4	37	1	2
1021	4	1	0	6	1	1
1022	1	0	0	0	0	0
1023	29	2	5	15	2	1
1024	4	0	4	0	0	0
1025	3	0	4	4	0	0
1026	6	1	5	21	8	2
1027	8	0	0	13	3	3
1028	4	1	1	8	2	1
1031	1	0	1	0	0	0
1034	3	0	0	0	0	0
1035	1	0	0	0	0	0
1063	1	0	0	0	0	0
1066	1	0	0	0	0	0
1083	2	0	0	0	0	0
2001	1	0	0	0	0	0
2002	10	0	0	15	3	0
2003	2	0	0	0	0	0
2004	20	1	5	3	0	0
2005	1	0	0	0	0	0
2006	7	0	0	0	0	0
2007	3	0	0	0	0	0
2008	1	0	0	0	0	0
2009	2	0	1	0	0	0
2011	2	0	0	0	0	0
2012	6	0	0	0	0	0
2013	1	0	0	0	0	0
2014	1	0	0	0	0	0
2015	4	0	0	0	0	0
2016	5	1	1	0	0	0
2017	1	0	2	0	0	0
2018	1	1	1	2	1	3
2019	9	3	2	8	0	1
2020	4	1	0	4	0	0
2023	1	0	0	0	0	0
2025	4	0	0	0	0	0
2027	3	0	1	22	1	7
2028	1	0	0	0	0	0
2029	0	0	0	1	0	0
2030	1	0	0	0	0	0
2031	1	0	0	3	0	0
2032	3	0	0	3	0	0

Continued

[1] See Appendix 3 for itemization of explantations (nuclear).
[2] See Appendix 4 for itemization of explantations (chemical).
[3] See Table 7 for itemization of complications.

TABLE 5B. - Continued

Physician Code	NUCLEAR POWERED			CHEMICALLY POWERED		
	Implants	Explants[1]	Complications[2]	Implants	Explants[3]	Complications[2]
2033	5	0	0	0	0	0
2037	2	0	0	4	0	0
2039	2	0	0	0	0	0
2040	3	1	0	2	0	2
2042	1	0	0	0	0	0
2117	1	0	0	0	0	0
2147	1	0	0	0	0	0
2148	1	0	0	0	0	0
3001	9	1	3	3	1	3
3002	1	0	0	2	0	1
3003	1	0	0	3	0	0
3008	1	1	0	0	0	0
3009	2	1	0	0	0	0
3013	1	0	0	6	0	3
3015	4	0	0	9	0	0
3017	7	0	0	1	0	0
3018	1	0	0	1	0	0
3019	1	0	0	0	0	0
3020	0	0	0	1	0	0
3021	2	0	0	0	0	0
3022	1	0	0	0	0	0
3024	0	0	0	1	0	0
3025	1	0	0	2	0	0
3026	3	0	0	5	0	0
3027	1	0	0	0	0	0
3029	5	1	1	4	0	0
3030	1	0	0	0	0	0
3032	1	0	0	0	0	0
3033	1	0	0	0	0	0
3036	1	0	0	0	0	0
3037	0	0	0	1	0	0
3038	2	0	1	0	0	0
3039	2	0	0	0	0	0
3041	3	0	0	3	0	0
3044	1	0	0	0	0	0
3045	2	0	0	0	0	0
3046	1	0	0	0	0	0
3047	2	0	0	0	0	0
3048	2	0	0	1	0	0
3049	2	0	0	0	0	0
3050	7	0	0	6	1	1
3051	1	0	0	0	0	0
3054	3	0	0	1	0	0
3055	5	0	1	8	4	1
3056	1	0	0	0	0	0
3057	3	1	0	0	0	0
3058	4	1	4	8	1	0
3059	3	0	0	0	0	0
3060	3	0	1	0	0	0
3061	1	0	0	0	0	0
3091	1	0	0	0	0	0
3103	1	0	0	0	0	0
3116	1	0	0	0	0	0
3117	1	0	0	0	0	0
TOTAL	324	19	50	255	32	34

[1] See Appendix 3 for itemization of explantations (nuclear).
[2] See Appendix 4 for itemization of explantations (chemical).
[3] See Table 7 for itemization of complications.

All future units, as well as all units in stock, will undergo this revised quality assurance procedure. The corroded unit had been implanted for twelve (12) months before it was explanted.

Among the group of chemically powered control units, there was also one failure. This failure occurred in July, 1974, eleven (11) months after implant. The device was returned to Medtronic for analysis, which revealed a rate drop to fifty-five (55) beats per minute due to a leaky capacitor in the timing circuit.

Table 6 displays the number of implants, explants, and complications in terms of pacemaker-months, or more precisely, months since implant either to May 12, 1975, or to the date of explantation. The number of device-months (Table 6) accumulated to date in the isotopic group is 5,292 after allowances for explants; whereas the comparable figure in the control group is 4,840. The upper 95% confidence limits on the underlying true random failure rates in each group are 0.09% per month and 0.10% per month, respectively. These figures have improved since the previous report, (0.12 and 0.15 % per month) and compare favorably to the 0.15% per month random failure rate adopted as the standard of comparison (Medtronic Clinical Evaluation Plan dated March 21, 1973). At the best estimate or 50% confidence level, the random component failure rates for these same samples are 0.032% per month for the isotopic group and 0.035% per month for the control group.

TABLE 6. NUMBERS OF IMPLANTATIONS, EXPLANTATIONS, AND ASSOCIATED COMPLICATIONS BY MONTHS SINCE IMPLANTATION (TO 5-12-75)

Months in Patient	NUCLEAR POWERED			CHEMICALLY POWERED		
	Implants[1]	Explants[2]	Complications[3]	Implants[1]	Explants[2]	Complications[3]
0	0	0	11	0	0	16
1	6	3	5	1	4	5
2	14	2	4	2	5	1
3	8	0	4	0	0	3
4	7	2	4	0	3	1
5	6	0	1	0	1	1
6	4	1	2	1	2	0
7	4	2	5	3	0	0
8	4	2	3	0	0	0
9	6	0	2	6	3	2
10	8	0	0	2	2	1
11	16	0	2	4	3	0
12	18	2	2	2	2	0
13	21	0	1	13	3	1
14	17	0	1	12	0	0
15	20	1	0	19	0	0
16	16	0	0	19	0	0
17	13	2	1	14	0	0
18	24	1	1	31	0	0
19	25	0	0	22	1	1
20	17	1	0	13	0	0
21	18	0	0	26	0	0
22	17	0	1	10	1	1
23	9	0	0	5	0	1
24	1	0	0	6	2	0
25	2	0	0	9	0	0
26	5	0	0	5	0	0
27	2	0	0	14	0	0
28	0	0	0	9	0	0
29	5	0	0	0	0	0
30	3	0	0	2	0	0
31	3	0	0	0	0	0
32	3	0	0	0	0	0
33	2	0	0	2	0	0
36	0	0	0	1	0	0
45	0	0	0	1	0	0
49	0	0	0	1	0	0
TOTAL	324	19	50	255	32	34
Device Months	5,292			4,840		

[1]Months in patient are computed from date of implant to May 12, 1975 or date of explant.

[2]Non-returned units associated with patients' deaths are classified as explants.

[3]Computed from date of implant to date of complication.

Medtronic, Inc., also has access to data concerning isotopic units implanted worldwide. Of the six-hundred and seventy-seven (677) implants of the Model 9000 outside of the United States, forty-five (45) have been explanted for various reasons. There has been only one explant due to pulse generator malfunction, resulting from a random failure of an electronic component. Using the 9,227 effective device-months accumulated, the upper 95% confidence limit on the underlying true random failure rate for this non-U.S. group is 0.05% per month, well below the standard of comparison. By combining all Model 9000 units implanted worldwide, we arrive at a random failure rate of 0.04% per month with a 95% confidence.

Another significant feature of Table 6 is the high incidence of early complications, most of which occurred during or immediately following surgery. Complications appear to be not a random phenomenon over time and may have no relationship to numbers of device-months of pulse generator experience. Rather, they should be evaluated in relation to the numbers of devices implanted.

Analysis of Complications

In Table 7 are the details of every complication reported thus far in the study. Infections are seen to have played a more extensive role in the isotopic group than among the controls

(10 versus 6). When subjected to a chi-squared test of significance (yielding $\chi^2 = 0.28$ with one degree of freedom), this difference is found to be not statistically significant.

Most sensing problems have been determined to be lead-related. There are two cases, however, which require special mention. The pulse generator with serial number 3R00142 was explanted because the intracardiac potentials were of insufficient amplitude to be sensed by the pulse generator. A similar situation was encountered with device number 4R00024. In both cases, analysis revealed that the pulse generators were performing within their specifications.

In the nuclear group, among thirty-nine (39) units there were fifty (50) complications, while in the chemical group, there were thirty-three (33) complications. Among the complications noted, no significance can be attributed to the differences between the nuclear models and the control group.

Analysis of Lead Data

Table 8 presents the currently available data on leads used in the clinical study by lead type and months since lead implantation. In the nuclear group, 88% of the leads used were manufactured by Medtronic. This figure is 92% for the control group. The miscellaneous category is a catch-all for those leads which could not be positively identified as to type.

TABLE 7A. ITEMIZATION OF COMPLICATIONS AND MODES OF TREATMENT[1] FOR MODEL 9000 (TO 5-12-75)

Serial Number	Hospital Code	Physician Code	Patient Code	Implant Date	Complication Date	Months In Patient[2]
2R00068	2016	2019	S01538	01/30/73	10/04/73	8
2R00106	2003	2004	B01588	12/05/72	06/03/74	18
2R00222	2016	2018	M01529	04/02/73	04/06/73	0
3R00011	3051	3055	G01379	06/07/73	04/17/75	22
3R00019	2003	2004	R01036	07/24/73	07/24/73	0
3R00020	2003	2004	G01034	10/05/73	10/17/73	0
3R00021	1060	1006	P01003	07/06/73	05/23/74	11
3R00028	2003	2004	S01037	06/26/73	08/02/74	13
3R00028	2003	2004	S01037	06/26/73	12/08/74	17
3R00052	1002	1002	S01317	11/28/73	04/17/74	5
3R00064	1018	1020	B01039	07/16/73	09/10/74	14
3R00073	1028	1028	G01101	07/16/73	10/16/73	3
3R00085	2014	2016	J01071	08/08/73	03/05/74	7
3R00090	1018	1020	F01040	11/05/73	11/05/73	0
3R00093	1023	1023	D01005	09/04/73	08/20/74	12
3R00104	3022	3029	H01048	08/21/73	04/29/74	8
3R00120	3001	3001	A01021	09/04/73	01/14/74	4
3R00120	3001	3001	A01021	09/04/73	06/12/74	9
3R00122	3055	3058	M01087	11/21/73	11/22/73	0
3R00122	3055	3058	M01087	11/21/73	02/21/74	3
3R00123	3027	3038	P01013	09/20/73	02/06/74	4
3R00136	3055	3058	S01059	09/17/73	12/17/73	3
3R00142	1023	1023	W01097	10/29/73	11/29/73	1
3R00145	3055	3058	S01114	12/13/73	06/19/74	7
3R00161	2022	2027	G01093	10/17/73	09/13/74	11
3R00175	1023	1023	M01166	11/07/73	12/07/73	1
3R00179	1023	1023	S01169	12/03/73	12/05/73	0
3R00220	3001	3001	S01260	03/04/74	03/19/74	0
3R00233	1026	1026	A01103	11/06/73	11/28/73	1
3R00233	1026	1026	A01103	11/06/73	01/08/75	2
3R00276	2016	2019	F01807	06/17/74	08/06/74	2
3R00281	1024	1024	I01288	03/20/74	05/15/74	2
3R00281	1024	1024	I01288	03/20/74	06/06/74	2
3R00281	1024	1024	I01288	03/20/74	06/21/74	3
3R00281	1024	1024	I01288	03/20/74	03/25/75	12
3R00288	2080	2117	L01581	09/04/74	09/05/74	0
3R00288	2080	2117	L01581	09/04/74	03/25/75	7
3R00289	1018	1020	G01162	01/04/74	01/09/74	0
3R00332	3058	3060	L01271	02/22/74	09/03/74	6
3R00334	1025	1025	N01258	03/05/74	03/25/74	1
3R00334	1025	1025	N01258	03/05/74	07/15/74	4
3R00334	1025	1025	N01258	03/05/74	10/20/74	7
3R00334	1025	1025	N01258	03/05/74	12/20/74	9
3R00334	1032	1031	C01351	05/13/74	05/13/74	0
4R00024	1023	1023	A01679	07/01/74	03/14/75	8
4R00035	1018	1020	C01819	10/02/74	04/21/75	7
4R00037	1026	1026	G01396	07/02/74	07/02/74	0
4R00057	1026	1026	H01373	06/05/74	07/03/74	1
4R00057	1026	1026	H01373	06/05/74	11/27/74	6
4R00069	2008	2009	M02066	12/09/74	04/04/75	4

TABLE 7A. - Continued

Complication	Treatment	Lead Related[3]	Pulse Generator Related[3]	Surgery Related[3]
Infection/pocket site	Pocket drained	No	Yes	Yes
Dizziness/pain in apex of heart	Pt. hospitalized/observed	Yes	Yes	Yes
Perforation of ventricle	Lead replaced	Yes	No	Yes
Syncope	Observation	Yes	Yes	No
Temporary sensing impairment	None/self-corrected	Yes	No	Yes
Wound separation/infection/lead displacement	Antibiotics/attempted lead replacement/explant	Yes	Yes	Yes
Lead fracture	New leads implanted	Yes	No	No
Skin erosion at pocket site	Transportation of unit closer to sternum	No	Yes	No
Skin erosion at pocket site	Pulse generator reimplanted in left pectoral area. New lead inserted.	No	Yes	Yes
Myocardial lead fractures	New leads inserted, 4/17/74	Yes	No	No
Wound infection/erosion	Pulse generator repositioned to new site/antibiotics	No	Yes	No
Intermittent hiccoughs	None/self-corrected	Yes	No	Yes
Lead displacement	Explant	Yes	No	Yes
Wound infection	Antibiotics/pocket irrigation	No	Yes	Yes
Infection, wound separation exposing lead	Replaced lead/antibiotics	Yes	No	No
Diaphragmatic stimulation	Lead repositioned and converted to unipolar	Yes	No	No
Lead fracture	Lead replaced	Yes	No	No
Wound infection	Antibiotics	No	Yes	Yes
Diaphragmatic stimulation	None	Yes	No	Yes
Ventricular fibrillation	Defibrillation	No	No	No
Episode of syncope	None	No	No	No
Lead disconnected	Reconnected	Yes	No	No
Fail to sense	Lead replaced	Yes	Yes	No
Necrosis of pocket	Explanted	No	Yes	No
Bipolar lead fracture	Leads unipolarized	Yes	No	No
Twitching in pulse generator pocket	Pulse generator repositioned in same pocket	No	Yes	No
Blood in pocket site	None	No	Yes	Yes
Diaphragmatic stimulation	Lead replaced and pulse generator repositioned	Yes	No	Yes
Muscle inhibition	None	Yes	Yes	No
Muscle inhibition	None	Yes	Yes	No
Muscle stimulation	None	Yes	Yes	Yes
Diaphragmatic stimulation/lead displacement	Repositioned lead	Yes	No	No
Lead displacement	Repositioned lead	Yes	No	No
Muscle twitch in chest wall/lead displaced	New lead inserted, pulse generator repositioned to new site	Yes	No	No
Complete loss of capture/fractured lead	Converted to unipolar	Yes	No	No
Failure to sense	New lead inserted 9/8/74	Yes	Yes	No
Inappropriate sensing	None	Yes	Yes	No
Wound infection	Antibiotics	No	Yes	Yes
Loss of capture/failure to sense fractured lead	New leads implanted	Yes	No	No
Pocket wound infection	Wound aspiration, antibiotics, new pocket	No	Yes	Yes
Pocket wound infection	Wound revised	No	Yes	Yes
Pocket wound infection	Removed pacemaker temporarily/ reimplanted pulse generator 12/11/74 with new lead	Yes	Yes	Yes
Lead displacement	Repositioned lead	Yes	No	No
Tachycardia during procedure	0_2/temporarily stopped procedure	No	No	Yes
Sensing problem	Attempted lead repositioning/ explant of unit	Yes	Yes	No
Failure to sense	To be admitted for insertion of new leads	Yes	Yes	No
Muscle stimulation	None	Yes	Yes	Yes
Muscle inhibition	None	Yes	Yes	Yes
Muscle inhibition	None	Yes	Yes	Yes
Muscle stimulation	None	Yes	Yes	Yes

TABLE II. ITEMIZATION OF COMPLICATIONS AND MODES OF TREATMENT[1] FOR THE CONTROL GROUP (TO 5/12/75)

Serial Number	Hospital Code	Physician Code	Patient Code	Implant Date	Complication Date	Months In Patient[2]
2K24492	3051	3055	T01199	07/09/73	04/09/74	9
3A01599	3001	3001	T01226	09/13/73	01/10/74	4
3E00982	2022	2027	N01125	11/07/73	11/28/73	1
3E01047	3011	3013	N01295	12/14/73	12/17/73	0
3E01334	3011	3013	M01294	02/22/74	02/22/74	0
3G02050	3011	3013	L01291	01/21/74	01/21/74	0
3G02978	1095	1020	P02358	01/11/74	01/11/74	0
3G10521	2022	2027	V01286	03/01/74	03/26/74	1
3G11740	1027	1027	B01147	11/07/73	01/31/74	3
3G11740	1027	1027	B01147	11/07/73	12/12/74	13
3G23535	2071	2027	J01583	04/02/74	04/02/74	0
3K04486	2022	2027	R01284	03/15/73	03/15/74	0
3K04682	1028	1028	N01186	04/10/73	04/19/73	0
3K13661	3040	3050	G01203	08/10/73	05/31/74	10
3K14525	3002	3002	W01298	09/10/73	09/12/73	0
3K15609	2022	2027	G01154	09/12/73	12/24/73	3
3K20689	2022	2027	R01124	11/01/73	11/03/73	0
3K23006	2022	2027	M01281	01/16/74	03/15/74	2
3K32733	2032	2040	M01494	08/08/74	08/15/74	0
3K34544	2032	2040	B01495	07/22/74	07/29/74	0
3L01139	2016	2019	G01141	07/05/73	07/05/73	0
3L01731	3001	3001	H01227	06/04/73	06/04/73	0
3L01865	1031	1020	T02364	06/14/73	04/16/75	22
3L03892	2016	2019	S01143	07/12/73	02/05/75	19
3L04224	2016	2019	B01138	07/19/73	08/13/73	1
3L05972	2016	2019	P01142	10/01/73	03/07/74	5
3L06027	1019	1021	B01262	11/21/73	11/21/73	0
3M02390	1027	1027	W01190	10/05/73	01/05/74	3
3S00446	1017	1019	T01285	08/03/73	04/18/74	9
3S00719	1017	1019	H01280	08/09/73	08/14/73	0
3S01782	3001	3001	D01228	08/03/73	09/18/73	1
3T17710	1023	1023	T01443	04/10/74	04/10/74	0
XX4681	1067	1026	G01407	01/04/73	01/22/73	1
XX4695	1026	1026	Y01403	01/10/73	12/10/74	23

[1] All complications listed in this table were successfully managed and corrected with the treatment indicated.

[2] Months in patient are computed from implant date to the date on which the complication occurred.

[3] A "yes" designation implies that the factor in question cannot be positively excluded as a possible cause of the complication.

Table 7B (Continued)

Complication	Treatment	Lead Related[3]	Pulse Generator Related[3]	Surgery Related[3]
Infected pocket site	Explant/inserted new pulse generator and lead	Yes	Yes	Yes
Loss of capture	Lead replaced	Yes	No	No
Ventricular perforation	Lead re-inserted	Yes	No	Yes
Lead fracture	None	Yes	No	No
Cardiac arrest during implant	External massage/Isuprel	No	No	No
Failure to capture	Lead replaced	Yes	No	Yes
Lead displaced	Repositioned lead	Yes	No	Yes
Ventricular perforation	New leads placed	Yes	No	Yes
Lead displacement	Repositioned	Yes	No	Yes
Complete loss of capture/lead displacement	New lead placed	Yes	No	Yes
Cardiac arrest during implant	Resuscitation measures	No	No	Yes
Loss of capture	Self corrected	Yes	No	Yes
Wound infection	Unknown/explant	No	Yes	Yes
Occasional dizziness	Pulse width increased	No	Yes	No
Hematoma	Fluid withdrawn	No	Yes	Yes
Loss of capture	Self-corrected	Yes	No	Yes
Ventricular perforation/pulmonary emboli	Unknown	Yes	No	Yes
Ventricular perforation	New leads placed	Yes	No	Yes
Pain in pocket area	Drugs	No	Yes	No
Pocket edema	Wound aspiration	No	Yes	Yes
Infection electrode site	Patient scheduled for lead replacement	Yes	No	Yes
Lead displaced	Repositioned	Yes	No	Yes
Elective pulse generator change	Explant-replaced with new generator	No	Yes	No
Infected electrode site	Scheduled for explant	Yes	No	No
Muscle twitch/electrode perforation	Lead repositioned	Yes	No	Yes
High threshold/electrode perforation	Lead repositioned	Yes	No	Yes
Lead displacement	Repositioned	Yes	No	Yes
Wound infection	Unknown/explant	No	Yes	Yes
Infection/skin erosion at site of old abandoned lead	Antibiotics	Yes	No	No
Lead displacement	Repositioned	Yes	No	Yes
Loss of capture	Lead replaced	Yes	No	No
Lead displacement	Inserted new myocardial leads	Yes	No	No
Exit block, loss capture and failure to sense (dislocated lead)	Lead repositioned	Yes	No	Yes
Muscle inhibition	None	Yes	Yes	Yes

Within the isotopic group of patients, there are sixteen (16) leads on which no information can be obtained, and ten (10) in the control group. For this reason there is a smaller total number of leads than of pulse generators in each group.

One of the significant items of interest in Table 8 is the range of lead lives represented. One lead in the isotopic group, for example, is more than twelve (12) years old and is still functioning. There have been only seven (7) confirmed lead fractures, so the information to date does not indicate that leads will limit longevity.

The ratio of endocardial to myocardial leads has been running approximately 1:1 among the isotopic implants, and among conventional implants it has been predictably higher at nearly 3:1.

In a few cases, the Model 9000, which is a bipolar generator, was used with a unipolar lead to pace in the unipolar mode. This may have caused a sensing problem in at least one instance.

TABLE 8. NUMBERS OF LEADS ON CURRENTLY FUNCTIONING PULSE GENERATORS BY LEAD TYPE AND MONTHS SINCE LEAD IMPLANTATION (TO 5-12-75)

Months in Present	NUCLEAR POWERED						CHEMICALLY POWERED					
	Myocardial		Endocardial		Misc	Total	Myocardial		Endocardial		Misc	Total
	Unipolar	Bipolar	Unipolar	Bipolar			Unipolar	Bipolar	Unipolar	Bipolar		
1			1	2		3			1			1
2		3	1	3		7			1			1
3		2		1		3						0
4		2		2		4				2		2
5		1				1						0
6		1		1		2			1	1		2
7						0				1		1
8		2		2		4						0
9		3		1		4				2	1	3
10		2	1	2		5				1		1
11	2	3	1	2	1	9		1			2	3
12	1	3		3		7		1		1		2
13	3	2	2	1	1	9	1	4	1	3	1	10
14		2		2		4		2	1	5	2	10
15	2	2	3	4		12			1	5		6
16	1	4	1	3		9		1	3	3	1	9
17	2	3	1	1	1	7	2	1	1	5	1	10
18	1	6	2	3		12	2	5	6	8	1	22
19		5		4	1	10	1	2	6	7	3	19
20		3		5	1	9	1	2	2	5	1	11
21	1	5		4		10		2	5	10	1	18
22	1	2		5	1	9			3	2	1	6
23	1	1		1	1	4				3		3
24	1	1				2	1	2		3		6
25		1		1		2	1	1	2			4
26		1		2	1	4			3	1		4
27		1			2	3		2	1	1	2	6
28					1	1		1	3	1		5
29		2		1	2	5		1				1
30	1			2	2	5				1		1
31			1	3		4					1	1
32	1	1		2	3	7						0
33		1		1	2	4				1		1
34				2	2	4				2		2
35				2	2	4				1	1	2
36		1		1	1	3				1	1	2
37				2	1	3				2	1	3
38		1		3		4						0
39		1		1	1	3					1	1
40					1	1		1	1	1	1	4
41		4		3	3	10		1				1
42		1		2	3	6			1	1	2	4
43				4	2	6			2	3	1	6
44		1			1	2				1	4	5
45			1	1	2	4		1		2	2	5
46		1		2	2	5				1		1
47		1			1	2					1	1
48					4	4				2	4	6
49		1		1	1	3		1	1	1	3	6
50				1	2	3				2		2
51				2	3	5				1	1	2
52		1		1		2						0
53				1		1		1		2		3
54				2		2				1		1
55						0					1	1

(Continued)

TABLE 8, continued

Months in Patient	NUCLEAR POWERED						CHEMICALLY POWERED					
	Myocardial		Endocardial		Misc	Total	Myocardial		Endocardial		Misc	Total
	Unipolar	Bipolar	Unipolar	Bipolar			Unipolar	Bipolar	Unipolar	Bipolar		
56				1	1	2				1	1	2
57					1	1						0
58				1	1	2				*		0
59				1	3	4					1	1
60		1				1						0
61					1	1						0
62						0					2	2
63				1		1					1	1
64				2		2				1	1	2
65				2	1	3				1		1
66				1	1	2						0
67		1				1						0
68				1	1	2					1	1
69		2				2						0
70				1	1	2						0
71						0					1	1
72						0						0
73					1	1						0
74	1				2	3						0
75						0				1	1	2
76				2		2						0
77						0						0
78						0				2		2
79				1		1						0
80		1			1	2						0
81				2		2				1		1
82					1	1						0
83						0						0
84						0						0
85				1		1						0
86						0						0
87						0						0
88						0						0
89						0						0
90						0						0
91					1	1						0
92						0						0
93						0						0
94						0						0
95						0						0
96						0						0
97						0						0
98						0						0
99					1	1						0
100						0						0
101						0					1	1
102						0					1	1
*103		1				1						0
107		1				1						0
109				1		1						0
118					1	1						0
122						0						0
123					1	1						0
131					1	1						0
138					1	1						0
145		1				1						0
146					1	1						0
Total	19	86	15	113	75	308	9	34	46	103	53	245
Lead Months	395	2279	240	3713	3812	10,439	171	774	1005	2851	2183	6984

* Months in patient are not continuous from this point on.

SUMMARY AND CONCLUSIONS

To date, there has been 100% accountability of the Model 9000. Medtronic has verified that all patients with Model 9000 Isotopic Pulse Generators have been seen by their physicians, and all units are functioning normally. Additionally, Medtronic knows the location of all units which have been explanted and all units which have not yet been implanted. The physicians and hospitals involved in the study are to be commended for the cooperation and assistance they have given the Medtronic Clinical Evaluation team.

The addition to the study of fifty-two (52) nuclear units, and fifty-seven (57) control units clarifies the characteristics that emerged during the previous report period. These characteristics include the age of the patient population, etiology of arrhythmia, random failure rates of electronic components, and possible adverse side effects of the pacemaking system.

Conventional pacemaker bearers are, on the average, twenty (20) years older than the typical isotopic pacemaker candidate. Another significant and related difference is a much higher incidence of congenital heart block in the younger, nuclear group.

One of the performance criteria sought is a low incidence of random failures. The rates for both Model 9000 and control groups compare favorably to the accepted norm of 0.15% per month and incidentally, the whole international Model 9000 program offers the very favorable rate of 0.04% per month.

Analysis of the occurrence of adverse side effects to the patient from his pacemaking system reveals that most of the complications are lead related, with no significant difference between the two groups.

At this time in the study, it is not possible from the data to compare longevities or to observe the number of reimplants required over the life of the patient population. The European data affords a longer and larger view, and strengthens the favorable indications for the use of isotopic pulse generators. The information contained in this report offers no contraindications to the use of the Model 9000.

In summary, the clinical evaluation study at the time of this fourth semi-annual report, comprises a significant cross-section of cardiologists and thoracic surgeons throughout the United States. The results of the study to date suggest that the Medtronic Model 9000 pulse generator is at least as reliable as chemically powered pulse generators and is as free from pulse generator related complications.

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GLOSSARY OF TERMS

ARRHYTHMIA: any abnormal rhythm of the heart with respect to its rate or regularity. Arrhythmias generally fall into two classes: a) disorders in the origin of the impulse and b) disturbances in the propagation (conduction) of the impulse.

ARTERIOSCLEROTIC HEART DISEASE: also known as Arteriosclerotic Cardiovascular Disease and Coronary Heart Disease, terms applied to a number of pathologic conditions in which there is thickening, hardening, and loss of elasticity of the walls of blood vessels, especially arteries; this results in altered function of tissues and organs, in this case especially the heart or affecting the heart.

ASPIRATION: withdrawing of fluid from a cavity by means of suction.

BACTERIAL ENDOCARDITIS: inflammation of the inner lining of the heart muscle, caused by bacterial invasion and may be rapidly progressive when part of an acute septicemia.

CARDIOMYOPATHY: a subacute or chronic disease of heart muscle, often with endocardial and sometimes pericardial involvement.

CEREBROVASCULAR ACCIDENT: injury to the blood vessels in the brain, commonly known as a "stroke", and often resulting in neurological embarrassment, especially paralysis.

CHAGAS DISEASE: a form of tropical heart diesase found in Central and South America, resulting from an infection by a microscopic parasite. Often results in complete heart block.

CONGENITAL HEART BLOCK: a condition present at birth due to improper development of the impulse-conducting system of the heart, resulting in altered rhythm and rate of heart beat.

DEFIBRILLATION: conversion of fibrillation to a normal rhythm; can be effectively done only with an electrical defibrillator.

DIPTHERITIC MYOCARIDITIS: inflammation of the myocardium caused by the infectious disease diptheria, which is characterized by formation of false membranes.

EDEMA: condition in which the body tissues contain an excessive amount of tissue fluid.

EMBOLUS (pl. emboli): mass of undissolved matter present in a blood or lymphatic vessel brought there by the blood or lymph current.

ENDOCARDIAL: pertaining to the inner lining or surface of the heart.

EPICARDIAL: pertaining to the outermost layer of the wall of the heart.

ESCAPE INTERVAL: the time between the sensing of a spontaneous ventricular depolarization and, without an intervening ventricular depolarization, the delivery of a succeeding pulse.

ETIOLOGY: the cause of a disease or injury; the science or study of the causes of disease or injury.

FIBRILLATION: quivering of muscular fibers, i.e., tremor or rapid action of the heart.

HEMATOMA: tumor-like mass produced by coagulation of blood in a tissue or cavity.

HEMIBLOCK: a block in one of the subdivisions of the left bundle branch of the heart.

HYPERSENSITIVE CAROTID SINUS WITH SINUS ARREST: a dilatation of the carotid artery, which when stimulated, causes slowing or cessation of heart rate.

HYSTERESIS: the characteristic of a demand pulse generator in which the escape interval is different than the pulse interval.

KEARNS-SAYRE SYNDROME: a rare disease of unknown etiology and ominous prognosis, characterized by the unusual association of retinal pigmentary degeneration, external ophthalmoplegia, cardiomyopathy, and complete heart block.

LENEGRE'S DISEASE (TRIFASCICULAR FIBROSIS): a thickening of the trifascicular valve in the ventricular conduction system.

MYOCARDIAL INFARCTION: condition in which an area of tissue in the heart undergoes necrosis following cessation of blood supply.

MYOTONIA DYSTROPHICA: a rare disease characterized by stiffness and progressive atrophy of the muscles.

PULSE DURATION: the time interval of the wave shape measured in milliseconds at specified reference points, e.g., 50% amplitude, maximum slope, etc.

PULSE INTERVAL: the time between the leading edges of two consecutive pulse generator pulses when the pulse generator is not inhibited and is operating at its repetition rate.

QT INTERVAL: in electrocardiography, the time extending from the beginning of the QRS complex to the end of the T-wave varies with heart rate; at normal rates, ranges from 0.3 to 0.4 seconds.

REFRACTORY PERIOD: the time interval (specified in milliseconds) required by the pulse generator sensing circuitry to return to original specifications following the delivery of a pacing impulse.

REPETITION RATE: the number of pulses per minute (ppm) at which the pulse generator operates when not inhibited by patient's intrinsic rate.

RHEUMATIC HEART DISEASE WITH MITRAL STENOSIS: a disease process which causes a narrowing of the left atrioventricular orifice (mitral valve) due to rheumatism.

RHEUMATIC MYOCARDITIS: inflammation of the myocardium caused by a disease known as rheumatism which characteristically affects the valves of the heart, and the presence of Aschoff bodies in the myocardium and skin.

SARCOIDOSIS: a disorder involving many organs, with formation of epithelioid cell tubercles in affected tissues.

SCLEROSIS OF CONDUCTION SYSTEM WITH NO ARTERIOSCLEROTIC HEART DISEASE: hardening or thickening of the conduction system only, not relating to blood vessels or arteries.

SURGICALLY INDUCED: term applied to a number of conditions in which surgical disruption of the heart's impulse-conducting system results in a permanently altered rhythm and rate of heart beat.

TACHYCARDIA: abnormally rapid heart rate.

VENTRICULAR ANEURYSM: circumscribed dilatation of a cardiac ventricle due to weakening of the musculature.

VIRAL CARDIOMYOPATHY: a subacute or chronic disorder of heart muscle, etiology being a virus, often with endocardial and sometimes pericardial involvement.

WOLFF PARKINSON WHITE SYNDROME: an arrhythmia in which impulses passing down accessory conduction pathways (Kent or James fibers) result in premature activation of part of the ventricular muscle. This produces a "slurring" or premature upswing of the initial part of the QRS complex.

APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 900
NUCLEAR POWERED PULSE GENERATORS (TC 5-12-75

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
2R00009	9000	M01591	2003	2004	08/17/72	04 / 11 / 72
2R00035	9000	T01593	2003	2004	07/18/72	05 / 03 / 72
2R00037	9000	P01594	2003	2004	07/19/72	04 / 11 / 72
2R00040	9000	R01537	2016	2019	08/14/72	05/10/72
2R00043	9000	W01586	2003	2004	10/24/72	08/22/72
2R00053	9000	E01534	2016	2019	08/28/72	06/27/72
2R00055	9000	C01164	2016	2019	09/25/72	06/27/72
2R00064	9000	N01535	2016	2019	09/25/72	06/27/72
2R00065	9000	C01592	2003	2004	09/13/72	06/23/72
*2R00068	9000	S01538	2016	2019	01/30/73	06/20/72
2R00096	9000	S01595	2003	2004	10/24/72	08/22/72
*2R00105	9000	G01536	2016	2019	11/20/72	08/23/72
2R00106	9000	B01588	2003	2004	12/05/72	09/21/72
2R00108	9000	H01589	2003	2004	12/04/72	09/21/72
2R00118	9000	C01530	2026	2032	11/15/72	09/20/72
2R00124	9000	T01411	1015	1016	11/17/72	09/08/72
2R00131	9000	W01587	2003	2003	02/22/73	09/11/72
2R00135	9000	F01412	1015	1016	11/09/72	09/11/72
2R00172	9000	G01014	3022	3029	06/28/73	11/16/72
*2R00174	9000	C01526	3022	3029	02/05/73	11/20/72
2R00175	9000	G01527	1007	1008	02/14/73	11/16/72
2R00178	9000	A01531	2023	2028	02/20/73	11/20/72
*2R00191	9000	C01580	3054	3057	03/02/73	12/05/72
2R00193	9000	H01590	2003	2004	03/15/73	12/05/72
2R00195	9000	C01532	2026	2032	03/09/73	01/17/73
2R00206	9000	H01382	3046	3051	03/07/74	01/31/73
2R00208	9000	H01331	3061	3017	04/12/74	01 / 31 / 73
2R00209	9000	M01086	1024	1024	06/08/73	01/30/73
2R00214	9000	R01047	1024	1024	05/24/73	01/23/73
2R00216	9000	H01308	3029	3039	03/12/74	01/23/74
2R00219	9000	B01095	3040	3050	05/31/73	01/30/73
2R00220	9000	A01002	1046	1001	10/10/73	01/30/73
2R00221	9000	P01539	1015	1016	04/26/73	02/07/73
2R00222	9000	M01529	2016	2018	04/02/73	02/07/73
2R00223	9000	K01528	1046	1001	10/15/73	02/07/73
2R00224	9000	F01053	3022	3029	07/24/73	01/23/73
2R00226	9000	J01008	1060	1006	06/07/73	01/31/73
2R00227	9000	J01326	1010	1012	07/09/73	01 / 31 / 73
3R00005	9000	L01032	2003	2004	06/11/73	01/30/73
3R00006	9000	B01533	3040	3050	05/15/73	02/07/73
3R00008	9000	B01029	2003	2004	06/12/73	02/05/73
3R00009	9000	H01031	2003	2003	06/07/73	02/05/73
3R00010	9000	W01024	3003	3003	06/05/73	02/05/73
3R00011	9000	G01379	3051	3055	06/07/73	02/05/73
3R00012	9000	G01030	2003	2004	06/13/73	02/05/73
3R00013	9000	R01362	3037	3047	03/22/74	02 / 05 / 73
3R00014	9000	G01091	3051	3055	06/04/73	02/05/73
3R00015	9000	S01065	1027	1027	06/11/73	02/05/73
3R00016	9000	M01035	2003	2004	06/14/73	02/06/73
3R00018	9000	L01033	2003	2004	10/26/73	04/03/73
3R00019	9000	R01036	2003	2004	07/24/73	04/03/73
3R00020	9000	T01160	2003	2004	12/12/73	04/03/73
**3R00020	9000	G01034	2003	2004	10/05/73	04/03/73
3R00021	9000	P01003	1060	1006	07/06/73	04/02/73
3R00022	9000	K01043	1017	1019	07/27/73	04/02/73
3R00023	9000	H01084	2016	2019	07/02/73	04/02/73
3R00024	9000	P01069	1027	1027	07/11/73	04/02/73
3R00025	9000	K01007	1060	1006	08/08/73	04/02/73
3R00026	9000	P01068	1027	1027	06/26/73	04/02/73
3R00027	9000	W01042	1017	1019	08/02/73	04/21/73
3R00028	9000	S01037	2003	2004	06/26/73	04/03/73
3R00029	9000	S01028	3036	3046	07/02/73	04/03/73
3R00030	9000	M01082	3053	3057	06/28/73	04/03/73
3R00031	9000	T01054	3002	3002	07/11/73	04/03/73
*R00034	9000	C01088	3051	3055	07/09/73	05/01/73
3R00036	9000	R01079	2029	2037	07/05/73	05/01/73
3R00039	9000	R01016	1016	1018	07/13/73	05/01/73
3R00046	9000	H01067	1027	1027	09/06/73	05/11/73
3R00049	9000	C01089	3051	3055	07/27/73	05/16/73
3R00050	9000	R01081	3054	3057	08/16/73	05/16/73
3R00051	9000	S01057	1018	1020	08/21/73	05/16/73
3R00052	9000	S01317	1002	1002	11/28/73	05 / 16 / 73

APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000
NUCLEAR POWERED PULSE GENERATORS (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
3R00055	9000	W01318	1060	1006	04/08/74	05/16/73
3R00061	9000	Y01064	1027	1027	09/07/73	05/14/73
3R00062	9000	M01104	2020	2025	07/30/73	05/14/74
3R00064	9000	B01039	1018	1020	07/16/73	05/29/73
3R00069	9000	P01158	2025	2031	11/05/73	05/29/73
3R00070	9000	U01577	3035	3045	10/16/73	05/17/73
3R00073	9000	G01001	1028	1028	07/16/73	05/29/73
3R00074	9000	F01041	1018	1020	07/25/73	05/29/73
3R00075	9000	L01085	1024	1024	10/11/73	05/29/73
3R00076	9000	M01015	2017	2020	09/13/73	05/29/73
3R00077	9000	M01165	1023	1023	08/03/73	05/29/73
3R00078	9000	H01074	2011	2012	08/07/73	05/29/73
3R00079	9000	C01096	1016	1018	12/28/73	05/29/73
3R00081	9000	M01320	1002	1017	11/28/73	05/30/73
*3R00085	9000	D01821	2014	2016	10/21/74	06/14/73
3R00085	9000	J01071	2014	2016	08/08/73	06/14/73
3R00088	9000	G01076	1006	1007	08/20/73	05/30/73
3R0008N	9000	R01256	2002	2002	01/31/74	UNKNOWN
3R00090	9000	F01040	1018	1020	11/05/73	06/14/73
3R00091	9000	J01004	1023	1023	09/12/73	06/14/73
3R00092	9000	A01173	1023	1023	10/15/73	06/14/73
3R00093	9000	C01005	1023	1023	09/04/73	05/31/73
3R00094	9000	S01172	1023	1023	09/28/73	06/14/73
3R00096	9000	S01078	2031	2039	08/09/73	06/14/73
3R00097	9000	R01044	2002	2002	08/16/73	06/14/73
3R00103	9000	P01060	1028	1028	08/20/73	06/14/73
3R00104	9000	H01048	3022	3029	08/21/73	06/14/73
3R00105	9000	G01019	2002	2002	08/09/73	06/14/73
3R00108	9000	F01022	2002	2002	08/09/73	06/14/73
3R00109	9000	F01010	1019	1021	09/09/73	06/14/73
3R00111	9000	L01011	1019	1021	08/09/73	06/14/73
3R00112	9000	G01080	2031	2039	08/21/73	06/14/73
3R00114	9000	D01056	3038	3048	10/08/73	06/14/73
*3R00115	9000	H01062	1028	1028	09/21/73	02/05/73
3R00116	9000	C01063	1028	1028	08/22/73	02/06/73
*3R00117	9000	P01259	1019	1021	02/15/74	06/14/73
*3R00120	9000	A01021	3001	3001	09/04/73	06/19/73
3R00121	9000	S01027	2002	2002	09/11/73	06/19/73
3R00122	9000	M01087	3055	3058	11/21/73	06/19/73
3R00123	9000	F01013	3027	3038	09/20/73	06/19/73
3R00124	9000	M01066	1027	1027	10/02/73	07/02/73
3R00125	9000	V01073	3059	3061	08/27/73	06/19/73
3R00126	9000	C01050	2006	2006	09/12/73	06/19/73
3R00127	9000	F01049	3022	3030	09/18/73	06/19/73
3R00128	9000	N01092	3050	3054	10/23/73	06/19/73
3R00129	9000	D01052	3031	3041	08/25/73	06/19/73
3R00130	9000	F01083	2026	2032	08/28/73	06/19/73
3R00132	9000	R01174	1023	1023	10/22/73	06/19/73
3R00133	9000	C01241	1023	1023	09/21/73	06/19/73
3R00134	9000	M01167	1023	1023	10/08/73	06/19/73
3R00135	9000	S01023	1003	1004	09/11/73	06/19/73
3R00136	9000	S01059	3055	3058	09/17/73	06/19/73
3R00138	9000	W01051	2015	2017	08/14/73	06/18/73
3R00139	9000	B01075	2011	2012	10/05/73	06/18/73
3R00140	9000	H01395	2027	2033	06/24/74	06/22/73
3R00141	9000	G01115	1023	1023	10/04/73	07/02/73
*3R00142	9000	W01097	1023	1023	10/29/73	07/02/73
3R00143	9000	S01369	2005	2006	11/16/73	07/02/73
3R00144	9000	N01061	1003	1004	11/13/73	06/22/73
*3R00145	9000	S01114	3055	3058	12/13/73	07/02/73
3R00146	9000	W01261	2005	2006	11/21/73	07/02/73
3R00147	9000	F01269	2005	2006	03/06/74	07/02/73
3R00148	9000	T01094	2007	2008	10/08/73	07/02/73
3R00149	9000	L01055	2020	2025	09/17/73	07/02/73
3R00150	9000	A01098	1005	1006	12/14/73	07/02/73
3R00151	9000	R01006	3001	3001	09/19/73	07/02/73
3R00152	9000	B01018	3001	3001	10/15/73	07/02/73
3R00154	9000	B01038	1018	1020	11/05/73	07/02/73
3R00155	9000	T01046	1004	1005	10/04/73	07/02/73
**3R00157	9000	S01017	2017	2020	10/23/73	07/02/73
3R00157	9000	R01393	2017	2020	11/12/73	07/02/73
3R00158	9000	E01020	3001	3001	10/22/73	07/13/73
3R00159	9000	C01118	3039	3041	01/02/74	07/13/73

APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000
NUCLEAR POWERED PULSE GENERATORS (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
3R00160	9000	S01025	2002	2002	10/05/73	07/13/73
3R00161	9000	G01093	2022	2027	10/17/73	07/13/73
3R00163	9000	F01451	3040	3050	04/17/74	07/13/73
3R00164	9000	W01116	3015	3017	12/19/73	07/13/73
3R00165	9000	A01100	3055	3058	12/06/73	07/13/73
3R00166	9000	T01072	2013	2014	10/09/73	07/13/73
3R00167	9000	M01070	1027	1027	10/24/73	07/13/73
3R00174	9000	V01012	3050	3054	10/17/73	08/07/73
3R00175	9000	M01166	1023	1023	11/07/73	08/07/73
3R00178	9000	F01168	1023	1023	10/29/73	08/07/73
3R00179	9000	S01169	1023	1023	12/03/73	08/07/73
3R00180	9000	M01170	1023	1023	11/20/73	08/07/73
3R00197	9000	W01171	1023	1023	11/27/73	08/08/73
3R00204	9000	Y01445	1023	1023	02/26/74	09/25/73
3R00207	9000	S01525	1023	1023	01/24/74	09/20/73
3R00210	9000	S01009	3015	3017	11/02/73	09/25/73
3R00212	9000	V01341	1023	1023	02/09/74	09/25/73
3R00213	9000	K01342	1023	1023	02/04/74	09 / 25 / 73
3R00214	9000	R01353	1023	1023	03/19/74	09/25/73
3R00217	9000	K01450	3040	3050	12/15/73	09/20/73
3R00219	9000	W01413	1023	1023	03/11/74	09/25/73
3R00220	9000	S01260	3001	3001	03/04/74	09/25/73
3R00221	9000	G01982	1035	1034	12/05/74	09/20/74
3R00222	9000	W01099	1018	1020	12/19/73	09/24/73
3R00223	9000	C01102	3001	3001	11/29/73	09/25/73
3R00232	9000	W01312	2013	2015	01/30/74	09 / 25 / 73
3R00233	9000	A01103	1026	1026	11/06/73	09/25/73
3R00235	9000	S01026	2002	2002	11/06/73	09/25/73
3R00236	9000	J02312	2032	2040	01/24/75	09/25/73
3R00239	9000	B01101	1018	1020	12/12/73	09/20/73
3R00241	9000	D01163	2014	2016	12/11/73	09 / 25 / 73
3R00244	9000	S01680	1023	1023	06/03/74	09/25/73
3R00245	9000	M01119	2027	2033	01/02/74	11/05/73
3R00248	9000	W01337	2014	2016	04/30/74	09 / 25 / 73
3R00249	9000	K02617	3040	3050	12/02/74	09 / 25 / 73
3R00251	9000	M01117	3057	3059	12/28/73	11/05/73
3R00252	9000	L01058	2011	2012	11/13/73	09/25/73
3R00253	9000	L01257	2013	2015	02/26/74	09/25/73
3R00254	9000	T01359	3022	3029	04/03/74	11/05/73
3R00255	9000	W01392	1012	1013	02/09/74	11/05/73
3R00256	9000	F01175	1003	1004	01/18/74	11/05/73
3R00257	9000	H01361	3039	3049	04/10/74	11 / 05 / 73
3R00258	9000	C01242	2002	2002	02/01/74	11/05/73
3R00261	9000	C01238	2029	2037	01/28/74	11/05/73
3R00263	9000	B01177	2022	2027	01/09/74	11/05/73
3R00264	9000	W01090	3051	3055	11/01/73	09/25/73
3R00265	9000	M01394	2017	2020	01/18/74	11/05/73
3R00266	9000	W01406	1015	1016	08/07/74	09/25/73
3R00268	9000	S01231	2011	2012	01/29/74	11/05/73
3R00269	9000	F01329	3052	3056	01/15/74	11 / 05 / 73
*3R00271	9000	R01077	2032	2040	11/06/73	09/25/73
3R00272	9000	M01176	2027	2033	01/16/74	11/05/73
3R00273	9000	R01290	1025	1025	03/11/74	11/06/73
3R00275	9000	T01311	1017	1019	05/20/74	11 / 06 / 73
3R00276	9000	F01807	2016	2019	06/17/74	11/06/73
3R00277	9000	T01357	1018	1020	05/14/74	11/06/73
3R00278	9000	C01409	2020	2025	05/10/74	11/06/73
3R00279	9000	H01243	1027	1027	02/19/74	11/06/73
3R00280	9000	F01287	3013	3015	03/19/74	11/06/73
3R00281	9000	I01288	1024	1024	03/20/74	11/06/73
3R00282	9000	J01302	3057	3059	03/12/74	11/06/73
3R00283	9000	K01230	1026	1026	01/22/74	11/06/73
3R00284	9000	B01239	3058	3060	02/08/74	11/06/73
3R00286	9000	S01579	3011	3013	01/17/74	11/05/73
3R00287	9000	U01335	2013	2015	04/30/74	11/06/73
3R00288	9000	L01581	2080	2117	09/04/74	11/05/73
3R00289	9000	G01162	1018	1020	01/04/74	11/06/73
3R00290	9000	K01237	3021	3027	01/29/74	11/06/73
3R00291	9000	C01178	3018	3022	01/15/74	09/25/73
3R00292	9000	F01161	2034	2042	01/03/74	11/06/73
3R00295	9000	M01275	2022	2027	03/06/74	11/06/73
3R00296	9000	P01244	1026	1026	02/06/74	11/06/73
3R00297	9000	J01301	3035	3045	03/26/74	11/06/73

APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
3R00298	9000	J01270	2006	2007	03/13/74	11/06/73
3R00303	9000	L01159	1018	1020	01/07/74	11/06/73
3R00314	9000	P01330	3016	3019	05/03/74	12/10/73
*3R00316	9000	J01324	1026	1026	03/13/74	12/01/73
3R00318	9000	A01319	1002	1017	04/16/74	12/10/73
3R00319	9000	S01245	2012	2013	02/16/74	12/01/73
3R00320	9000	M01314	2011	2012	04/23/74	12/01/73
3R00321	9000	M01273	3016	3018	02/19/74	12/01/73
3R00322	9000	P01338	2069	2023	04/25/74	12/01/73
3R00323	9000	T01246	3020	3025	02/15/74	12/01/73
3R00324	9000	L01368	2003	2004	04/10/74	12/01/73
3R00325	9000	F01268	1006	1007	03/08/74	12/01/73
*3R00326	9000	G01453	3006	3008	03/14/74	12/01/73
3R00327	9000	K02063	3013	3015	12/04/74	12/01/73
3R00328	9000	M01303	2005	2006	03/20/74	12/10/73
3R00330	9000	P01345	3020	3026	03/26/74	12/10/73
3R00331	9000	L01371	1002	1017	02/09/74	12/01/73
3R00332	9000	L01271	3058	3060	02/22/74	12/01/73
3R00333	9000	F01809	2075	2025	11/04/74	12/01/73
3R00334	9000	N01258	1025	1025	03/05/74	12/01/73
3R00335	9000	P01810	3038	3048	11/05/74	12/01/73
3R00336	9000	W02156	1060	1006	12/19/74	12/01/73
3R00337	9000	B01304	1018	1020	03/27/74	12/01/73
3R00338	9000	C01307	1023	1023	05/24/74	12/01/73
3R00339	9000	B01826	3020	3026	05/08/74	09/24/73
3R00340	9000	L01272	2001	2001	03/08/74	12/01/73
3R00341	9000	R01274	2010	2011	03/12/74	12/01/73
3R00343	9000	K01289	3024	3032	03/13/74	12/01/73
3R00344	9000	C01351	1032	1031	05/13/74	12/10/73
3R00345	9000	C02136	1071	1083	12/19/74	12/01/73
3R0089N	9000	B01240	1059	1066	10/04/73	07/09/73
4R00003	9000	M01681	1023	1023	06/02/74	12/28/73
4R00004	9000	K01347	2006	2007	04/09/74	12/28/73
4R00006	9000	L01825	3020	3026	09/24/74	12/28/73
4R00007	9000	T01305	2027	2033	04/01/74	12/28/73
4R00008	9000	B01336	2073	2002	05/06/74	12/28/73
4R00009	9000	H01381	3037	3047	06/14/74	02/27/74
4R00011	9000	F01363	3007	3009	04/22/74	02/27/74
4R00017	9000	C01332	3001	3001	04/29/74	02/27/74
4R00018	9000	R01631	3027	3036	08/19/74	02/27/74
4R00020	9000	R01380	3001	3001	06/27/74	03/14/74
4R00021	9000	P01440	3052	3091	07/16/74	03/14/74
4R00023	9000	C01328	3034	3044	05/31/74	03/14/74
*4R00024	9000	A01679	1023	1023	07/01/74	03/14/74
4R00025	9000	K01383	1018	1020	07/09/74	03/14/74
4R00026	9000	B01823	3013	3015	08/14/74	03/14/74
4R00028	9000	H01389	1035	1034	07/01/74	03/14/74
4R00029	9000	L01578	3058	3060	05/03/74	03/14/74
4R00030	9000	S01585	2014	2016	05/13/74	04/14/74
4R00033	9000	A01522	3039	3049	09/17/74	03/14/74
4R00034	9000	J01372	1023	1023	06/04/74	03/04/74
4R00035	9000	C01819	1018	1020	10/02/74	03/19/74
4R00036	9000	A01327	3029	3039	05/14/74	03/19/74
4R00037	9000	G01396	1026	1026	07/02/74	03/19/74
4R00038	9000	C01441	3061	3017	07/23/74	03/19/74
*4R00039	9000	S01808	2016	2019	07/25/74	03/19/74
4R00040	9000	P01313	2032	2040	05/28/74	03/19/74
4R00041	9000	A01370	2005	2006	05/01/74	03/19/74
*4R00042	9000	M01364	3007	3009	05/07/74	03/19/74
4R00043	9000	H02231	1025	1025	12/18/74	03/19/74
4R00044	9000	P01806	3106	3021	08/08/74	03/19/74
4R00046	9000	B01818	3105	3103	10/31/74	03/19/74
4R00047	9000	D01348	2005	2006	05/15/74	03/19/74
4R00048	9000	A01817	2024	2030	10/10/74	03/19/74
4R00049	9000	G01454	3039	3041	07/12/74	03/19/74
4R00050	9000	U01425	2027	2033	05/02/74	03/19/74
4R00051	9000	M01355	1022	1022	05/03/74	03/19/74
4R00052	9000	G02452	1022	1063	02/07/75	05/19/74
4R00054	9000	K01452	3040	3050	08/19/74	03/19/74
4R00055	9000	P01322	2010	2011	05/15/74	03/19/74
4R00056	9000	W01391	1017	1019	06/06/74	03/19/74
4R00057	9000	M01373	1026	1026	06/05/74	03/19/74
4R00058	9000	M01632	3081	3059	06/03/74	03/19/74

APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
4R00061	9000	S02311	3015	3017	12/10/74	10/23/74
4R00062	9000	S02065	3013	3015	12/11/74	10/23/74
4R00065	9000	H02456	3113	3054	02/10/75	10 / 23 / 74
4R00068	9000	K02095	1023	1023	12/10/74	10/23/74
4R00069	9000	M02066	2008	2009	12/09/74	05/29/73
4R00070	9000	F02269	3106	3021	12/27/74	10/23/74
4R00074	9000	A02383	1046	1001	01/07/75	11/21/74
4R00075	9000	M02419	1015	1016	02/17/75	11/21/74
4R00082	9000	K02157	2004	2005	01/03/75	11/21/74
4R00083	9000	M02513	1023	1023	03/06/75	11 / 20 / 74
4R00084	9000	P02498	3061	3017	02/18/75	11 / 21 / 74
4R00085	9000	A02454	2002	2002	01/17/75	11/19/74
4R00087	9000	L02453	3008	3010	01/23/75	11/21/74
4R00091	9000	K02528	2013	2015	02/26/75	11 / 21 / 74
4R00092	9000	S02466	2006	2007	02/26/75	11/21/74
4R00094	9000	H02457	3061	3017	02/06/75	11/21/74
4R00096	9000	B02618	3040	3050	01/20/75	11 / 21 / 74
4R00097	9000	K02444	2102	1035	02/13/75	11 / 21 / 74
4R00099	9000	P02445	2008	2009	02/24/75	11 / 21 / 74
4R00105	9000	N02467	3026	3116	02/28/75	11 / 25 / 74
4R00110	9000	N02600	1018	1020	03/20/75	11 / 27 / 74
4R00131	9000	S02387	3001	3001	02/06/75	11 / 26 / 74
4R00133	9000	G02489	1027	2147	03/07/75	11 / 27 / 74
4R00136	9000	B02529	3027	3038	03/10/75	11 / 27 / 74
4R00192	9000	D02614	1023	1023	04/01/75	12 / 06 / 74
4R00208	9000	H02515	1035	1034	03/13/75	12 / 09 / 74
4R00215	9000	B02615	3114	3117	04/08/75	12 / 06 / 74
4R00216	9000	B02522	2101	2148	03/12/75	12 / 06 / 74
4R00233	9000	F02566	3025	3033	03/06/75	12 / 13 / 74
4R00243	9000	N02535	1071	1083	03/13/75	12 / 14 / 74
4R00244	9000	B02534	1019	1021	03/11/75	12 / 13 / 74
4R00251	9000	F02490	2011	2012	02/05/75	12 / 14 / 74
4R00262	9000	P02611	2003	2004	04/01/75	12 / 06 / 74

APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 5-12-7

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE IMPLANTED	DATE OF MANUFACTURE
2M04433	5842	B01132	1027	1027	03/01/73	11/28/72
3M01641	5842	M01282	1017	1019	08/31/73	05/02/73
3M01734	5842	C01133	1027	1027	08/06/73	05/14/73
3M01739	5842	B01189	1027	1027	07/09/73	05/02/73
3M01784	5842	B01193	1027	1027	09/14/73	05/14/73
3M02022	5842	S01122	1027	1027	09/24/73	05/22/73
3M02246	5842	S01121	1027	1027	10/03/73	06/20/73
3M02332	5842	G01148	1027	1027	11/06/73	06/28/73
3M02341	5842	K01191	1027	1027	10/02/73	06/22/73
3M02390	5842	M01190	1027	1027	10/05/73	06/28/73
3M02490	5842	L01136	1027	1027	11/05/73	07/09/73
XX4012	5842	C01349	1025	1025	10/01/73	02 / 27 / 73
3000507	5862	M01299	3011	3013	01/24/74	06 / 14 / 73
3D00334	5862	M01153	2022	2027	07/19/73	05/24/73
2E01603	5862C	C01201	3051	3055	07/24/73	10/31/72
3E00379	5862C	M01429	1046	1001	08/29/73	03/05/73
3E00982	5862C	N01125	2022	2027	11/07/73	08/01/73
3E01047	5862C	N01295	3011	3013	12/14/73	08/23/73
3E01334	5862C	M01294	3011	3013	02/22/74	10/25/73
3E01786	5862C	A01156	2022	2027	06/28/73	01/09/74
2S00087	5931	S02043	1023	1023	01/22/73	07/11/72
3S00446	5931	T01285	1017	1019	08/03/73	12/04/73
3S00719	5931	H01280	1017	1019	08/09/73	01/23/73
3S00824	5931	V01123	3003	3003	01/19/73	11/15/72
3S01186	5931	S01134	3003	3003	11/08/73	04/13/73
3S01782	5931	D01228	3001	3001	08/03/73	12/20/72
1K05974	5942	C01523	3039	3041	07/14/71	02/09/71
2K04385	5942	A01183	1029	1028	05/02/72	06/08/72
2K22159	5942	L01315	1028	1028	08/04/72	05/23/72
2K23782	5942	B01210	1016	1018	01/24/73	05/22/72
2K24181	5942	D01185	1028	1028	10/28/72	06/08/72
2K24492	5942	T01199	3051	3055	07/09/73	09/26/73
2K40540	5942	B01223	3022	3029	01/05/73	10/23/72
2K41511	5942	U01151	2022	2027	04/13/73	12/21/72
2K44344	5942	C01225	3022	3029	03/02/73	11/22/72
3G14430	5942	M01827	3020	3025	03/24/74	11/15/73
3G21913	5942	H01316	1028	1028	08/02/72	01/14/74
3K00531	5942	O02346	2080	1020	07/17/73	02/22/73
3K00719	5942	C01200	3051	3055	08/25/73	03/13/73
3K02350	5942	C01207	3042	3050	05/23/73	02/28/73
3K03117	5942	M01224	3022	3029	03/28/73	12/21/72
3K03257	5942	C01202	3050	3054	10/13/73	01/29/73
3K03441	5942	C01197	2029	2037	05/11/73	02/21/73
3K03865	5942	H01229	3027	3037	05/07/73	02/20/73
3K04486	5942	R01284	2022	2027	03/15/73	01/04/73
3K04682	5942	N01186	1028	1028	04/10/73	01/02/73
3K05661	5942	F01217	2002	2002	04/27/73	01/22/73
3K06167	5942	L01234	2017	2020	08/05/73	04/02/73
3K06376	5942	M01601	2026	2032	07/17/73	03 / 01 / 73
3K07126	5942	B01150	2022	2027	04/09/73	UNKNOWN
3K09055	5942	G01209	3038	3048	07/10/73	04/13/73
3K11159	5942	M01208	3041	3050	08/07/73	05/21/73
3K11900	5942	F01113	3051	3055	09/08/73	07/03/73
3K11984	5942	M01292	3002	3002	08/02/73	06/15/73
3K12315	5942	S01211	1016	1018	07/17/73	05/11/73
3K12635	5942	L01216	2002	2002	07/16/73	05/31/73
3K13661	5942	G01203	3040	3050	08/10/73	05/16/73
3K13800	5942	F01157	2022	2027	08/13/73	05/16/73
3K14318	5942	T01184	3051	3055	08/21/73	05/15/73
3K14525	5942	M01298	3002	3002	09/10/73	06/27/73
3K14844	5942	F01602	2026	2032	10/12/73	06 / 08 / 73
3K15270	5942	V01233	2017	2020	09/10/73	06/28/73
3K15609	5942	G01154	2022	2027	09/12/73	07/06/73
3K16938	5942	H01129	3013	3015	11/29/73	09/12/73

APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
3K17336	5942	M01206	3043	3050	09/24/73	08/02/73
3K17486	5942	C01254	3020	3025	01/18/74	06/25/73
3K17603	5942	M01205	3044	3050	09/11/73	06/28/73
3K17744	5942	L01204	3045	3050	09/26/73	08/11/73
3K17765	5942	C01214	2002	2002	10/24/73	08/11/73
3K18053	5942	B01247	3020	3024	01/31/74	07/24/73
3K19070	5942	Z01221	2002	2002	10/02/73	08/07/73
3K19855	5942	R01131	3013	3015	12/10/73	08/21/73
3K20547	5942	C01277	2022	2027	10/24/73	07/17/73
3K20689	5942	R01124	2022	2027	11/01/73	08/27/73
3K21215	5942	A01603	2026	2032	11/19/73	09/05/73
3K21505	5942	L01215	2002	2002	10/16/73	08/14/73
3K21563	5942	M01293	3011	3013	11/28/73	08/29/73
3K21606	5942	R01296	3011	3013	02/07/74	12/28/73
3K21787	5942	C01278	3016	3018	10/30/73	09/07/73
3K21793	5942	C01266	3055	3058	12/14/73	09/21/73
3K22057	5942	K01130	3013	3015	11/14/73	09/20/73
3K22396	5942	F01152	2022	2027	10/10/73	08/11/73
3K22919	5942	C01155	2022	2027	10/10/73	08/13/73
3K22983	5942	L01310	1002	1017	12/12/73	08/28/73
3K23006	5942	M01281	2022	2027	01/16/74	10/11/73
3K23049	5942	C01582	2022	2027	01/18/74	10/11/73
3K23434	5942	S01126	2022	2027	12/20/73	09/21/73
3K23992	5942	L01253	1021	1021	12/14/73	10/02/73
3K25082	5942	H01127	3013	3015	12/04/73	10/11/73
3K25598	5942	H01334	3061	3017	01/17/74	10 / 11 / 73
3K25785	5942	H01251	1021	1021	01/31/74	10/16/73
3K27863	5942	K01300	3013	3015	03/11/74	12/13/73
3K30308	5942	K01339	2002	2002	04/30/74	02/14/74
3K32733	5942	M01494	2032	2040	08/08/74	05/03/74
3K34544	5942	B01495	2032	2040	07/22/74	03/12/74
3K35708	5942	A01428	1046	1001	11/09/72	UNKNOWN
3K40484	5942	B01212	2002	2002	01/29/73	11 / 08 / 72
3XX0380	5942	C01354	1025	1025	01/02/74	03 / 28 / 73
UNKNOWN	5942	T01232	1028	1028	05/05/73	UNKNOWN
UNKNOWN	5942	S01188	1028	1028	12/18/72	UNKNOWN
2L10789	5943	B02339	1096	1020	06/08/73	07/07/72
2L30063	5943	D01135	3003	3003	04/23/73	09/21/72
2L30208	5943	C01222	3022	3029	02/01/73	09/19/72
2L31000	5943	C01111	2023	2029	02/12/73	09/22/72
2L33389	5943	F02350	1095	1020	09/10/73	02/08/73
2L33486	5943	C01187	1028	1028	12/28/72	10/25/72
3L00015	5943	C01196	3055	3058	06/22/73	03/29/73
3L00186	5943	C01236	2017	2020	11/17/73	09/26/73
3L00280	5943	S01195	3055	3058	06/05/73	03/26/73
3L00443	5943	D02229	1018	1020	07/17/73	03/26/73
3L00929	5943	W01107	1007	1008	05/23/73	03/14/73
3L01139	5943	G01141	2016	2019	07/05/73	02/06/73
3L01731	5943	H01227	3001	3001	06/04/73	01/13/73
3L01865	5943	T02364	1031	1020	06/14/73	04/27/73
3L01942	5943	G01137	2016	2018	07/24/73	03/13/73
3L03115	5943	M01182	2025	2031	09/10/73	04/10/73
3L03229	5943	G01820	1065	1020	07/13/73	03/08/73
3L03453	5943	M01235	2017	2020	11/09/73	09/13/73
3L03822	5943	S02344	1097	1020	09/07/73	05/02/73
3L03892	5943	S01143	2016	2019	07/12/73	02/27/73
3L04019	5943	B01263	3055	3058	12/27/73	03/26/73
3L04224	5943	B01138	2016	2019	07/19/73	04/02/73
3L04250	5943	S01181	2025	2031	07/20/73	04/04/73
3L04256	5943	C01146	2016	2019	09/17/73	04/04/73
3L04379	5943	H02337	1018	1020	08/09/73	04/10/73
3L04428	5943	S01358	1018	1020	07/18/73	03 / 27 / 73
3L04774	5943	R01198	2029	2037	10/31/73	04/23/73
3L05244	5943	F01139	2016	2019	11/08/73	09/06/73
3L05916	5943	M01346	3055	3058	10/18/73	08 / 09 / 73
3L05972	5943	P01142	2016	2019	10/01/73	08/09/73
3L06027	5943	B01262	1019	1021	11/21/73	07/27/73
3L06095	5943	O01265	3055	3058	12/30/73	09/11/73
3L06233	5943	P02356	1099	1020	09/14/73	07 / 06 / 73
3L06406	5943	W01144	2016	2019	11/05/73	08/28/73

APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
3L07190	5943	M01140	2016	2019	11/05/73	08/30/73
3L07655	5943	S01267	3055	3058	12/14/73	09/11/73
3L08509	5943	C01264	3056	3058	10/04/73	08/23/73
3L33128	5943	C02357	1018	1020	07/26/73	UNKNOWN
3G00022	5944	R01219	2002	2002	10/11/73	07/08/73
3G00133	5944	R01218	2002	2002	08/01/73	05/14/73
3G00580	5944	W02348	1018	1020	07/10/73	04/17/73
3G00599	5944	B01194	1027	1027	10/12/73	06/07/73
3G01342	5944	F01045	1008	1008	08/02/73	05/21/73
3G01352	5944	W02334	1018	1020	09/25/73	05/17/73
3G01481	5944	C01213	2002	2002	11/01/73	09/18/73
3G01863	5944	N01283	2029	2037	03/07/74	11/01/73
3G02009	5944	F02340	1018	1020	11/26/73	08/14/73
3G02050	5944	L01291	3011	3013	01/21/74	10/29/73
3G02149	5944	B02333	1094	1020	02/14/74	09/26/73
3G02272	5944	T02343	1018	1020	02/22/74	11/07/73
3G02632	5944	F01598	2022	2027	02/06/74	11/05/73
3G02970	5944	S01220	2002	2002	10/22/73	09/11/73
3G02978	5944	F02358	1095	1020	01/11/74	11/05/73
3G10018	5944	G01192	1027	1027	10/24/73	09/07/73
3G10521	5944	V01286	2022	2027	03/01/74	11/26/73
3G10553	5944	K02354	1018	1020	12/23/73	09/24/73
10/25/73	5944	R01367	1004	1005	12/11/73	UNKNOWN
3G10718	5944	M02355	1018	1020	12/11/73	04/30/73
3G10865	5944	F01350	1025	1025	11/08/73	09/05/73
3G10874	5944	B02351	1018	1020	12/19/73	09/05/73
3G11141	5944	M01149	3051	3055	10/31/73	09/05/73
10/10/73	5944	L01323	1025	1025	02/27/74	UNKNOWN
3G11328	5944	L01112	3051	3055	11/09/73	09/07/73
3G11740	5944	B01147	1027	1027	11/07/73	09/05/73
3G11790	5944	G02341	1095	1020	03/29/74	10/25/73
3G11792	5944	G01250	3051	3055	12/01/73	09/18/73
3G12069	5944	C02366	1018	1020	12/31/73	08/23/73
3G12152	5944	W02330	1018	1020	01/17/74	10/26/73
3G12671	5944	F01128	3013	3015	12/10/73	10/02/73
3G12804	5944	C01110	2002	2002	12/05/73	10/01/73
3G13434	5944	S01366	1004	1005	02/12/74	10/29/73
3G13454	5944	C01248	1019	1021	01/18/74	10/22/73
3G13595	5944	A01276	2022	2027	02/08/74	11/02/73
12/17/73	5944	S01325	2022	2027	03/20/74	UNKNOWN
3G14222	5944	L02353	1018	1020	03/11/74	11/13/73
3G14414	5944	G02363	1018	1020	03/13/74	11/14/73
3G14805	5944	C01584	2072	2027	03/19/74	11/21/73
3G14882	5944	S01255	1019	1021	02/06/74	11/05/73
3G15060	5944	A01309	1002	1017	01/08/74	10/29/73
3G15496	5944	S01297	3013	3015	03/15/74	11/01/73
3G15592	5944	R01384	2029	2037	04/10/74	11/02/73
3G16313	5944	R01414	2071	2027	03/13/74	11/26/73
3G18532	5944	S01360	2002	2002	03/04/74	12/20/73
3G22348	5944	H01427	1046	1001	05/17/74	02/06/74
3G23535	5944	J01583	2071	2027	04/02/74	01/03/74
3G23576	5944	W02338	1018	1020	05/15/74	01/08/74
3G25480	5944	C02362	1018	1020	07/16/74	04/29/74
3G25615	5944	F01804	1002	1017	06/20/74	05/03/74
3G25894	5944	C02360	1018	1020	09/20/74	05/23/74
3G27551	5944	U01822	3013	3015	07/26/74	06/05/74
3G27874	5944	H02345	1065	1020	07/31/74	06/10/74
3G29634	5944	K01805	3013	3015	07/30/74	06/11/74
3G33190	5944	F02342	1018	1020	07/10/74	04/03/74
3T00092	5945	F02044	1023	1023	09/05/73	02/21/73
3T00256	5945	K01365	1023	1023	09/13/73	09/20/73
3T10506	5945	C01496	3092	3041	02/22/74	11/12/73
3T10990	5945	S01145	2016	2018	09/18/73	07/20/73
3T11212	5945	D01426	1023	1023	10/24/73	07/26/73
3T11560	5945	W02449	1023	1023	10/24/73	07/25/73
3T12780	5945	S02365	1065	1020	10/25/73	08/29/73
3T13041	5945	N02034	1023	1023	02/19/74	11/08/73
3T13224	5945	C02336	1018	1020	05/08/74	10/23/73

APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 5-12-75)

SERIAL NUMBER	MODEL NUMBER	PATIENT CODE	HOSPITAL CODE	PHYSICIAN CODE	DATE OF IMPLANT	DATE OF MANUFACTURE
3T13332	5945	C01356	1023	1023	12/10/73	08/24/73
3T13838	5945	K01252	3020	3026	01/07/74	09/20/73
3T13896	5945	K01108	2002	2002	11/08/73	08/29/73
3T13983	5945	F02031	1023	1023	12/19/73	09/11/73
3T14018	5945	H01109	2002	2002	11/23/73	09/11/73
3T14520	5945	F02335	1095	1020	05/17/74	10/04/73
3T14580	5945	T01180	2025	2031	12/20/73	10/31/73
3T15475	5945	B01524	3031	3041	06/05/74	12/26/73
3T16134	5945	S01343	3020	3026	01/31/74	11/07/73
3T16222	5945	J01344	3020	3026	02/09/74	12/07/73
3T16301	5945	D01249	1020	1021	01/06/74	11/20/73
3T16494	5945	N01333	3016	3020	02/04/74	12/05/73
3T17686	5945	C02042	1023	1023	04/05/74	12/28/73
3T17710	5945	T01443	1023	1023	04/10/74	12/28/73
3T18564	5945	W02030	1023	1023	03/27/74	12/28/73
3T18605	5945	C01824	3020	3026	04/01/74	01/22/74
3T2186	5945	L02183	1023	1023	09/18/73	UNKNOWN
3Y13449	5945	G02450	1023	1023	10/26/73	08/10/73
4T00866	5945	J01890	3020	3026	09/17/74	06/17/74
4T01528	5945	H02359	1018	1020	10/03/74	07/15/74
4T02618	5945	S02361	1095	1020	10/20/74	07/03/74
XX4519	5945	G02064	1018	1020	08/11/73	12/05/72
XX4559	5945	K01387	1064	1026	03/27/73	01/04/73
XX4563	5945	F01398	1026	1026	02/12/73	12/27/72
XX4568	5945	M01397	1026	1026	02/05/73	01/04/73
XX4576	5945	H01408	1064	1026	02/08/73	01/04/73
XX4580	5945	G01105	1007	1008	02/12/73	01/05/73
XX4586	5945	K01399	1064	1026	03/21/73	01/03/73
XX4587	5945	C01388	1064	1026	03/28/71	01/03/73
XX4663	5945	S01386	1064	1026	03/20/73	01/05/73
XX4678	5945	W01390	1064	1026	01/08/73	12/14/72
XX4681	5945	G01407	1067	1026	01/04/73	12/12/72
XX4682	5945	T01404	1064	1026	01/04/73	12/14/72
XX4683	5945	M01377	1063	1026	01/18/73	12/14/72
XX4684	5945	H01378	1038	1026	01/29/73	12/18/72
XX4685	5945	H01385	1062	1026	01/15/73	12/14/72
XX4686	5945	G01374	1026	1026	01/08/73	12/14/72
XX4688	5945	G01400	1064	1026	03/27/73	12/14/72
XX4689	5945	H01401	1062	1026	01/03/73	12/14/72
XX4690	5945	S01375	1026	1026	01/24/73	12/14/72
XX4694	5945	M01376	1026	1026	01/08/73	12/14/72
XX4695	5945	Y01403	1026	1026	01/10/73	12/14/72
XX4696	5945	G01405	1064	1026	01/17/73	12/14/72
XX4698	5945	B01402	1026	1026	02/05/73	12/12/72
XX4826	5945	T02347	1018	1020	09/07/73	09/12/72
XX4872	5945	T01106	1007	1008	03/15/73	01/09/73
3A00002	5961	R02184	1023	1023	01/29/74	05/08/73
3A00045	5961	H01279	1017	1019	07/05/73	05/04/73
3A00663	5961	R02186	1023	1023	06/18/73	02/06/73
3A01599	5961	T01226	3001	3001	09/13/73	06/28/73
4A00382	5961	B02465	2003	2004	02/21/75	12/02/74
5A00005	5961	C02533	2003	2004	03/19/75	/ 01/
5A00382	5961	L02531	2003	2004	03/12/75	/ 01/

APPENDIX 3. ITEMIZATION OF EXPLANTATIONS
(NUCLEAR POWERED)

S/N	Hospital Code	Physician Code	Patient Code	Reason For Explant	Date of Explant/Death	Status of Pulse Generator
				NUCLEAR POWERED		
2R00068	H2016	D2019	S01538	Patient expired; cause unknown.	7/09/74	Returned to Medtronic.
2R00105	H2016	D2019	G01536	Patient expired; cause unknown.	12/24/72	Returned to Medtronic 2/4/74 and sent back to hospital 5/23/74.
2R00174	H3022	D3029	C01526	Patient expired. Death caused by peritonitis due to cancer of the lymph node system.	10/09/74	Unit not returned to Medtronic; retained by hospital.
2R00175	H1007	D1008	G01527	Patient expired; suicide.	5/27/74	Returned to Medtronic.
2R00191	H3054	D3057	D01580	Patient expired of cardio-vascular attack from clot in left ventricle.	4/17/73	Returned to Medtronic; 4/23/74.
3R00020	H2003	D2004	G01034	Wound separation/infection/lead displacement.	10/29/73	Not returned to Medtronic; re-implanted in same hospital.
3R00085	H2014	D2016	J01071	Excessive medical adhesive in the boot interfered with connection, resulting in failure to capture.	3/05/74	Returned to Medtronic; 3/5/74.
3R00115	H1028	D1028	H01062	Low output from pulse generator caused by an electrical open. A void in the Hysol backfill located behind the lead connectors allowed the negative solder tab to be exposed to body fluids causing the tab to be destroyed by corrosion.	9/18/74	Returned to Medtronic; 9/26/74.
3R00117	H1019	D1021	P01259	Patient expired of ameloid cardiomyopathy.	2/10/75	Returned to Medtronic; 2/26/75.
3R00120	H3001	D3001	A01021	Infection and abdominal skin erosion.	2/14/75	Not returned.
3R00142	H1023	D1023	W01097	Insufficient sensing in the presence of low voltage R-waves.	5/07/74	Unit not returned to Medtronic; retained by hospital.
3R00145	H3055	D3058	S01114	Erosion wound with necrosis at pocket.	7/08/74	Unit not returned to Medtronic; retained by hospital.
3R00157	H2017	D2020	S01017	Patient expired of causes unrelated to pacemaker.	11/02/73	Not returned to Medtronic; re-implanted in same hospital.
3R00271	H2032	D2040	R01077	Patient expired; myotonia dystrophica.	5/11/75	Unit returned to Medtronic on 11/11/74.
3R00316	H1026	D1026	J01324	Patient expired; coronary occlusion due to arteriosclerosis.	7/15/74	Returned to Medtronic.
3R00326	H3006	D3008	G01453	Patient expired; massive coronary; unrelated to pacemaker.	7/09/74	Unit not returned to Medtronic; retained by hospital.
4R00024	H1023	D1023	A01679	Inadequate sensing.	3/14/75	Unit not returned, retained by hospital.
4R00039	H2016	D2019	S01808	Patient expired; ASHD; severe CHF.	1/24/75	Unit not returned, retained by hospital.
4R00042	H3007	D3009	M01364	Patient expired; occlusion in right coronary artery due to arteriosclerotic heart disease.	7/13/74	Returned to Medtronic.

APPENDIX 4. ITEMIZATION OF EXPLANTATIONS
(CHEMICALLY POWERED)

S/N	Hospital Code	Physician Code	Patient Code	Reason For Explant	Date of Explant/Death	Status of Pulse Generator
2K04385	H1029	D1028	A01183	Elective replacement.	5/08/74	Unit not returned to Medtronic.
2K22159	H1028	D1028	L01315	Patient expired of causes unrelated to pacemaker.	3/05/74	Unit not returned to Medtronic.
2K24492	H3051	D3055	T01199	Pocket infection.	4/09/74	Unit not returned to Medtronic.
3K00719	H3051	D3055	C01200	Patient expired of ASHD, CHF.	6/09/74	Unit not returned to Medtronic.
3K13661	H3040	D3050	G01203	Pulse generator removed due to continual pain in pocket site.	8/01/74	Unit not returned to Medtronic.
3K14318	H3051	D3055	T01184	Pulse generator malfunction. Rate drop due to leaky capacitor.	7/25/74	Analysis in "Current Status" section.
3K23992	H1021	D1021	L01253	Patient expired; cardiac arrest.	Unknown	Not explanted; not pulse generator related.
3G01342	H1008	D1008	F01045	Patient expired; information NA*	6/ /74	Unit not returned to Medtronic.
3G02970	H2002	D2002	S01220	Patient expired; ventricular fibrillation.	11/16/74	Unit not returned to Medtronic.
3G10521	H2022	D2027	V01286	Patient expired; cerebral embolus; clot in left ventricle; not pacemaker related.	8/15/74	Unit not returned to Medtronic.
3G10618	H1004	D1005	R01367	Patient expired of causes unrelated to pacemaker.	2/20/74	Unit not returned to Medtronic.
3G11328	H3055	D3055	L01112	Patient expired; cause unknown.	1/21/74	Not explanted.
3L01865	H1031	D1020	T02364	Elective replacement.	4/16/75	Unit not returned to Medtronic.
3L01942	H2016	D2018	G01137	Patient expired; information NA*	12/29/73	Unit not returned to Medtronic.
3L08509	H3056	D3058	C01264	Patient expired; cause of death CVA; non-pacemaker related.	9/30/74	Returned, functionally OK.
3M01641	H1017	D1019	M01282	Patient expired; CA of the colon.	2/17/75	Unit not returned to Medtronic.
3M01739	H1027	D1027	B01189	Patient expired; cardiorespiratory arrest probably due to acute pulmonary edema; patient had known diabetes mellitus.	9/26/73	Not explanted at time of patient's demise.
3M02390	H1027	D1027	W01190	Unrelated to wound infection; pacemaker system removed because patient no longer needed it.	1/05/74	Generator functioning normally at time of explant; unit not returned to Medtronic.
3M02490	H1027	D1027	L01136	Patient expired; cause of death unknown. No autopsy, patient history of renal insufficiency & chronic brain syndrome.	12/17/73	Not explanted at time of patient's demise.
3S01782	H3001	D3001	D01228	Patient expired; death resulted from CVA.	5/31/74	Unit not returned to Medtronic.
3T00256	H1023	D1023	K01365	Patient expired of CVA.	11/01/73	Unit not returned to Medtronic.
3T13332	H1023	D1023	Ø01356	Patient expired of CHF.	12/10/73	Unit not returned to Medtronic.
3T13896	H2002	D2002	K01108	Patient expired; MI.	1/15/74	Not explanted.
3T14018	H2002	D2002	H01109	Patient expired; pulmonary embolus; cerebral infarction.	1/03/74	Not explanted at time of patient's demise.
XX4568	H1026	D1026	M01397	Patient expired; information NA	6/04/73	Unit not returned to Medtronic.
XX4576	H1064	D1026	H01408	Patient expired; information NA	1/29/74	Unit not returned to Medtronic.
XX4586	H1064	D1026	W01399	Patient expired; information NA	5/30/73	Unit not returned to Medtronic.
XX4587	H1064	D1026	C01388	Patient expired; information NA	7/23/73	Unit not returned to Medtronic.
XX4663	H1064	D1026	S01386	Patient expired; information NA	4/ /74	Unit not returned to Medtronic.
XX4678	H1064	D1026	W01390	Patient expired; information NA	10/17/73	Unit not returned to Medtronic.
XX4688	H1064	D1026	G01400	Patient expired; CVA.	3/04/75	Pacemaker functioning normally; returned to Medtronic.
XX4694	H1026	D1026	M01376	Patient expired; information NA	12/14/73	Unit not returned to Medtronic.

*NA = not available