4807

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

Third Semi-Annual Clinical Evaluation Report To The UNITED STATES ATOMIC ENERGY COMMISSION

November 24, 1974

FOIA-86-805
A/3.

Medtronic

TABLE OF CONTENTS

LIST OF ILLUSTRATIONS

LIST OF TABLES

LIST OF APPENDICES

INTRODUCTION

This is the third in a series of semi-annual reports, to be submitted to the Materials Branch of the United States Atomic Energy 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.

It should be noted that there has been a five-month pause in the manufacture of the Model 9000. On April 4, 1974, Medtronic received notice from the Materials Branch, Directorate of Licensing of the United States Atomic Energy Commission, that a new guide had been issued entitled "Interim Safety Guide for the Design and Testing of Nuclear Powered Cardiac Pacemakers" dated March 26, 1974. This guide contained a new and longer time for the cremation test plus emphasis on nondispersibility of the fuel form. In light of the new requirement, Medtronic stopped the manufacture of the Model 9000 until a new fuel capsule capable of meeting the guide could be approved.

Having met these guidelines and received approval, Medtronic has recently resumed the manufacture of the Model 9000.

Throughout this third report, an attempt is made to point out changes since the previous report. In general, there have been no significant changes in the characteristics or results of the study.

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.

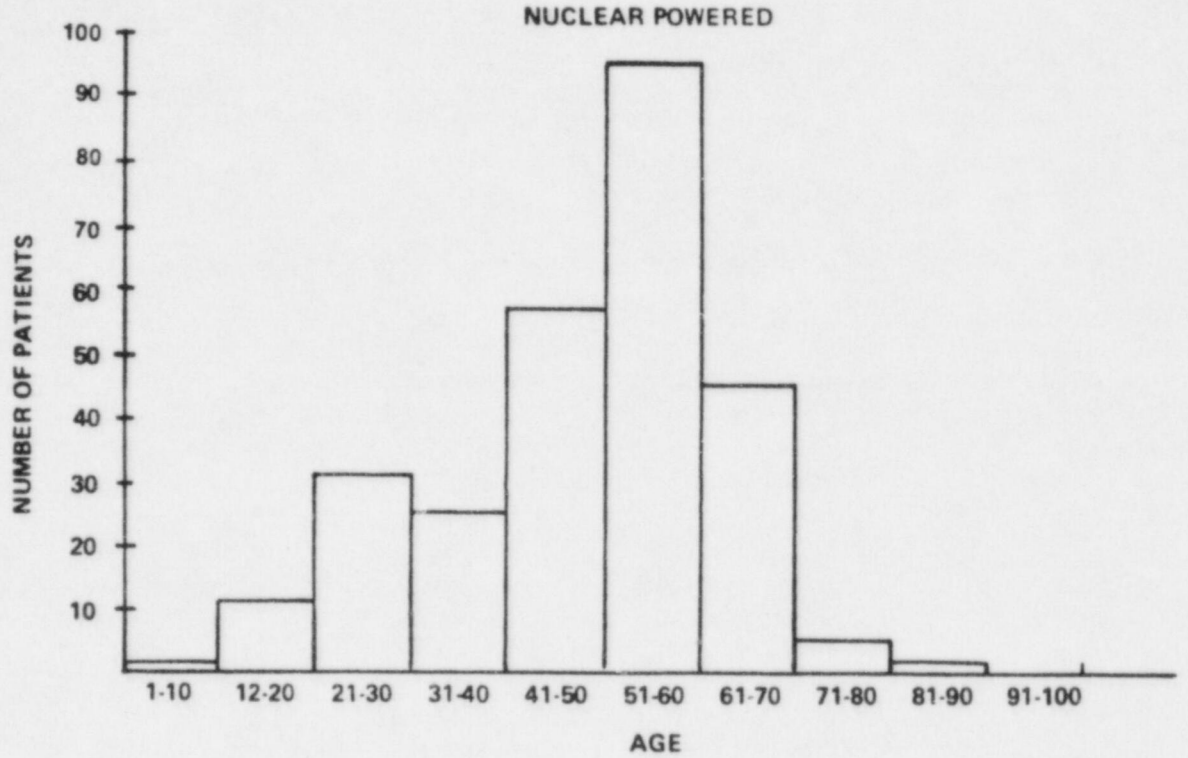
The age/sex distributions of both the nuclear and the chemically powered pulse generator bearers in the study are displayed in Table 1. Comparison of the ages of nuclear and chemically powered pacemaker bearers reveals the nuclear group to be significantly younger. Indeed, the difference is quite consistent both for males and females, being 18.0 and 20.6 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 again 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. This age difference has been consistent throughout the study period.

TABLE 1. COMPOSITION OF PATIENT POPULATIONS BY AGE[1] AND SEX (TO 10/1/74)

	NUCLEAR POWERED			CHEMICALLY POWERED		
Age	Male	Female	Total	Male	Female	Total
1-10	1	0	1	2	1	3
11-20	9	2	11	2	0	2
21-30	18	13	31	2	1	3
31-40	15	10	25	1	3	4
41-50	33	24	57	4	4	8
51-60	62	33	95	20	9	29
61-70	40	6	46	35	20	55
71-80	3	2	5	33	31	64
81-90	0	1	1	18	9	27
91-100	0	0	0	2	1	3
Total No.	181	91	272	119	79	198
Average Age	49.5	47.1	48.7	67.5	67.7	67.5

[1]Age at Implant



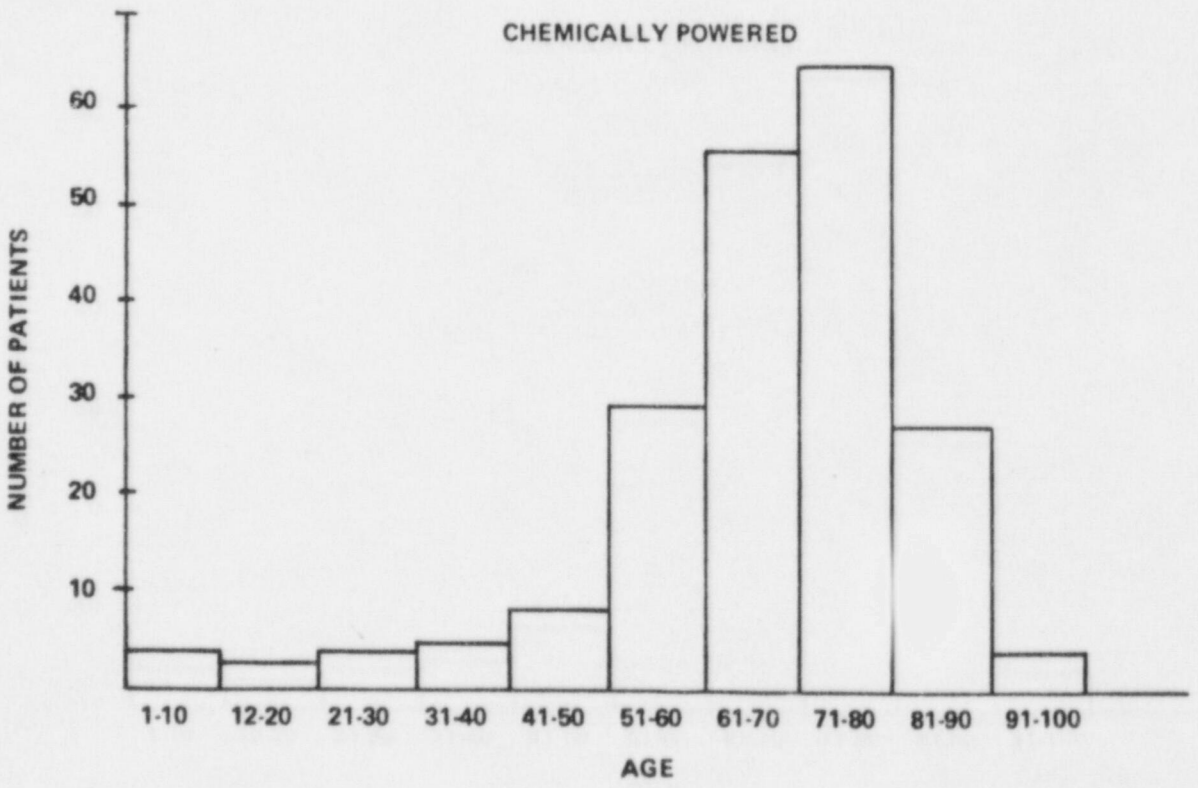


FIGURE 1. HISTOGRAMS OF PATIENT POPULATIONS BY AGE (TO 10-1-74)

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. It is again significant (reference is made to the Model 9000 clinical report dated June 28, 1974) that 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 use of a new Registration and Implantation Data Form (Appendix II of this report) at Medtronic for all products in clinical evaluation has generated the data exhibited in Tables 2B and 2C. Note that the new form asks for more information with greater detail than the previous form. Although the form is not extensively used as yet, it is expected to elicit valuable data in the future. 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.

GENERAL PATIENT INFORMATION[1] (TO 10-1-74)

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

Age	NUCLEAR POWERED					CHEMICALLY POWERED				
Etiology	Surgically Induced	Congenital	Unknown	Other (See Table 2B)	Total	Surgically Induced	Congenital	Unknown	Other (See Table 2B)	Total
1 - 20	2	8	2	0	12	1	4	0	0	5
21 - 40	8	19	12	17	56	0	2	2	3	7
41 - 60	6	7	55	84	152	1	0	8	28	37
61 - 80	0	0	12	39	51	0	1	32	86	119
81+	0	0	0	1	1	0	0	8	22	30
TOTAL	16	34	81	141	272	2	7	50	139	198

[1] Key to Abbreviations:

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-Sayers 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								
1 - 20	0	0	0	0	6	2	0	0	0	0	0	0	1	0
21 - 40	4	3	0	1	23	12	1	0	0	1	0	0	0	15
41 - 60	64	8	7	5	11	7	9	0	1	2	0	0	1	36
61 - 80	35	4	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	104	15	12	7	40	22	13	0	1	4	1	0	4	56
						CHEMICALLY POWERED								
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	20	4	6	2	0	1	6	0	0	3	1	0	1	9
61 - 80	63	8	11	2	1	0	13	0	0	10	1	0	4	27
81+	18	0	2	0	0	0	3	0	0	2	0	0	0	3
TOTAL	102	13	19	4	6	3	24	0	0	16	2	0	5	44

Table 2C. Type of Conduction Disturbance

Age / Disturbance	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 (Drug Induced)	Other Disturbances: Digitalis Toxicity	Other Disturbances: Other Drug Idiosyncrasy
NUCLEAR POWERED																						
1 - 20	9	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
21 - 40	37	9	2	0	3	3	1	1	1	0	0	0	1	0	2	2	0	0	0	0	0	0
41 - 60	85	17	8	1	12	9	7	2	5	0	1	8	3	1	3	7	0	1	2	0	3	0
61 - 80	30	5	1	0	4	6	4	0	1	0	0	2	0	0	2	0	0	0	3	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	162	31	11	1	20	19	13	4	7	0	1	10	4	1	7	9	0	1	5	0	3	0
CHEMICALLY POWERED																						
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	20	6	4	0	6	2	0	0	3	0	0	4	0	1	0	0	0	0	1	0	0	0
61 - 80	49	18	12	0	15	8	9	4	7	0	1	3	0	2	14	7	1	0	6	0	0	0
81+	17	3	3	0	3	2	3	1	3	0	0	3	0	0	0	7	0	0	0	0	1	0
TOTAL	93	27	20	0	25	13	13	5	13	0	1	10	0	3	14	15	1	0	7	0	1	0

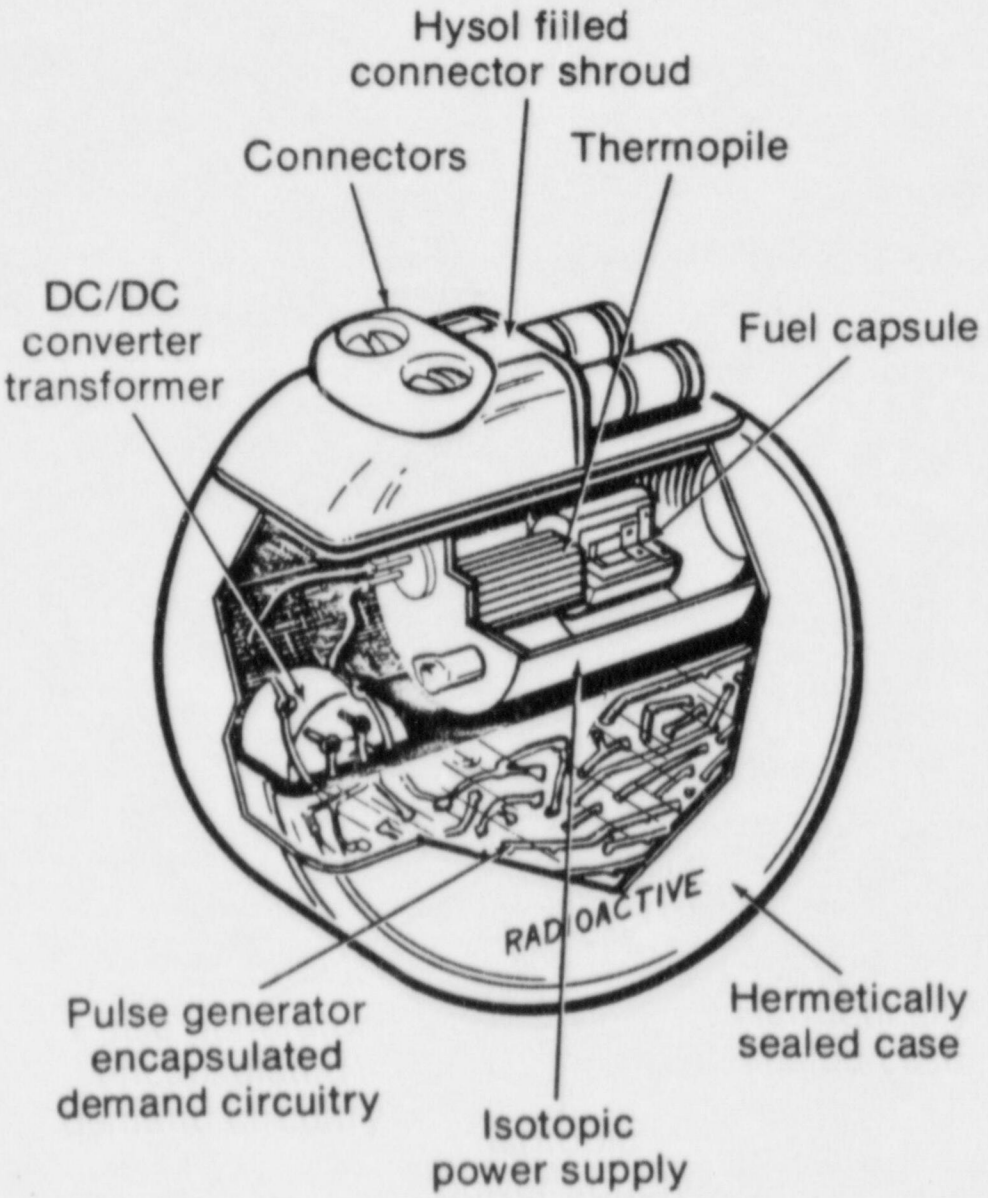


Figure 2. Cutaway View of Medtronic™ Implantable Demand Isotopic Pulse Generator Laurens-Alcatel Model 9000

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

TABLE 4. DISTRIBUTION OF NUMBERS OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL NUMBER AND DATE OF INITIAL PRODUCTION (TO 10/1/74)

Model Number	Initial Production Date	Number Implanted
5862	3/69	2
5862C	5/69	6
5842	9/69	12
5942	11/70	72
5943	11/70	29
5945	2/73	38
5931	2/73	5
5961	2/73	2
5944	3/73	32
TOTAL		198

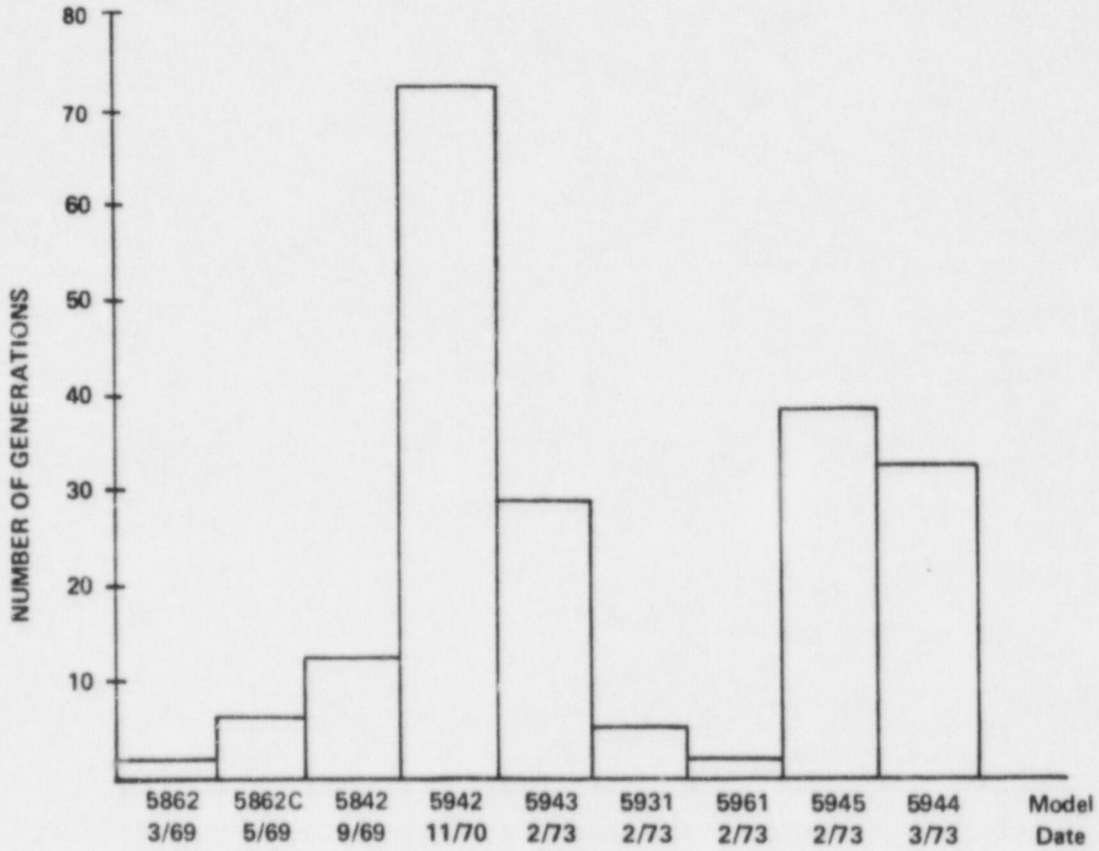


FIGURE 3. HISTOGRAM OF MODELS OF CHEMICALLY POWERED PULSE GENERATORS IN DATE OF INITIAL PRODUCTION ORDER (10-1-74)

PULSE GENERATORS INVOLVED IN THE STUDY

Technical aspects of the two pulse generator groups were explained in the 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 cut-away view 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.

CURRENT STATUS OF THE INVESTIGATION

Analysis of Pulse Generator Data

From July 18, 1972 to October 1, 1974, two hundred and seventy-two (272) Model 9000 isotopic pulse generators have been implanted in patients presently located within the United States (Table 5). Among the ninety-seven physicians participating in the investigation, the numbers of isotopic units implanted per physician have ranged from zero to twenty-six (26).

During the same period, one hundred and ninety-eight (198) investigational controls have been submitted, with the number per physician varying from zero to twenty-one (21). Fifty-five (55) isotopic investigators have not as yet

submitted controls, although one physician has supplied twenty-one (21) investigational controls for his three (3) isotopic implants.

Numbers of complications per physician (Table 5B) range from zero to four (4) 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 (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 $\chi^2 = 1.244$ with one degree of freedom, thereby substantiating the hypothesis of no difference. Explanted devices to date (Table 5A) consist of fourteen (14) isotopic pulse generators and twenty-seven (27) 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

TABLE 5A. NUMBERS OF IMPLANTATIONS, EXPLANTATIONS, AND ASSOCIATED COMPLICATIONS BY PARTICIPATING HOSPITAL (TO 10/1/74)

Hospital Code	NUCLEAR POWERED			CHEMICALLY POWERED		
	Implants	Explants[1]	Complications[2]	Implants	Explants[3]	Complications[2]
1001	2	0	0	0	0	0
1002	4	0	1	2	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	1	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	4	0	0	0	0	0
1016	2	0	0	2	0	0
1017	4	0	0	3	0	1
1018	12	0	1	1	0	0
1019	3	0	0	3	0	0
1020	0	0	2	1	0	1
1021	0	0	0	2	0	0
1022	1	0	0	0	0	0
1023	26	1	4	4	2	1
1024	4	0	1	0	0	0
1025	2	0	1	4	0	0
1026	6	1	2	7	2	0
1027	8	0	0	13	3	2
1028	4	1	1	7	1	1
1029	0	0	0	1	1	0
1032	1	0	1	0	0	0
1035	1	0	0	0	0	0
1038	0	0	0	1	0	0
1046	0	0	0	3	0	0
1059	1	0	0	0	0	0
1060	4	0	1	0	0	0
1062	0	0	0	2	0	0
1063	0	0	0	1	0	0
1064	0	0	0	9	5	0
1067	0	0	0	1	0	1
2001	1	0	0	0	0	0
2002	8	0	0	15	4	0
2003	21	1	3	0	0	0
2005	6	0	0	0	0	0
2006	3	0	0	0	0	0
2007	1	0	0	0	0	0
2010	2	0	0	0	0	0
2011	5	0	0	0	0	0
2012	1	0	0	0	0	0
2013	4	0	0	0	0	0
2014	4	1	1	0	0	0
2015	1	0	0	0	0	0
2016	8	2	1	10	0	3
2017	4	1	0	4	0	0
2020	3	0	0	0	0	0
2022	3	0	1	19	0	7
2023	1	0	0	1	0	0
2025	1	0	0	3	0	0

Continued

[1] See Appendix 1C for itemization of explantations (nuclear).
[2] See Appendix 1D for itemization of explantations (chemical).
[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]
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	2	0	0	2	0	2
2034	1	0	0	0	0	0
2069	1	0	0	0	0	0
2071	0	0	0	1	0	0
2072	0	0	0	1	0	0
2073	1	0	0	0	0	0
2080	1	0	0	0	0	0
3001	8	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
3011	1	0	0	6	0	0
3013	2	0	0	7	0	3
3015	2	0	0	0	0	0
3016	2	0	0	2	0	0
3018	1	0	0	0	0	0
3020	2	0	0	5	0	0
3021	1	0	0	0	0	0
3022	6	1	1	4	0	0
3024	1	0	0	0	0	0
3027	2	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	1	0	0	1	0	0
3039	4	0	0	1	0	0
3040	5	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	0	8	4	0
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	0	0
3057	2	0	0	0	0	0
3058	3	0	1	0	0	0
3059	1	0	0	0	0	0
3061	2	0	0	1	0	0
3081	0	0	0	1	0	0
TOTAL	272	14	31	193	27	27

[1] See Appendix 1C for itemization of explantations (nuclear).
[2] See Appendix 1D 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 10/1/74)

Physician Code	NUCLEAR POWERED			CHEMICALLY POWERED		
	Implants	Explants[1]	Complications[2]	Implants	Explants[3]	Complications[2]
1001	2	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	5	0	1	0	0	0
1007	2	0	0	0	0	0
1008	1	1	0	4	1	0
1012	1	0	0	0	0	0
1013	1	0	0	0	0	0
1016	4	0	0	0	0	0
1017	3	0	0	2	0	0
1018	2	0	0	2	0	0
1019	4	0	0	4	0	1
1020	12	0	3	1	0	1
1021	3	0	0	6	0	0
1022	1	0	0	0	0	0
1023	26	1	4	4	2	1
1024	4	0	1	0	0	0
1025	2	0	1	4	0	0
1026	6	1	2	21	7	1
1027	8	0	0	13	3	2
1028	4	1	1	8	2	1
1031	1	0	1	0	0	0
1034	1	0	0	0	0	0
1066	1	0	0	0	0	0
2001	1	0	0	0	0	0
2002	9	0	0	15	4	0
2003	2	0	0	0	0	0
2004	19	1	3	0	0	0
2006	7	0	0	0	0	0
2007	2	0	0	0	0	0
2008	1	0	0	0	0	0
2011	2	0	0	0	0	0
2012	5	0	0	0	0	0
2013	1	0	0	0	0	0
2014	3	0	0	0	0	0
2015	1	0	0	0	0	0
2016	4	1	1	0	0	0
2017	1	0	0	0	0	0
2018	1	1	0	2	0	3
2019	7	1	1	8	0	0
2020	4	1	0	4	0	0
2023	1	0	0	0	0	0
2025	3	0	0	0	0	0
2027	3	0	1	21	0	7
2028	1	0	0	0	0	0
2029	0	0	0	1	0	0
2031	1	0	0	3	0	0

Continued

[1] See Appendix 1C for itemization of explantations (nuclear).
[2] See Appendix 1D 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]
2032	3	0	0	3	0	0
2033	4	0	0	0	0	0
2034	1	0	0	0	0	0
2037	2	0	0	4	0	0
2039	2	0	0	0	0	0
2040	2	0	0	2	0	2
2042	1	0	0	0	0	0
2132	1	0	0	0	0	0
3001	8	0	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	0
3015	2	0	0	7	0	3
3017	4	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
3022	1	0	0	0	0	0
3024	0	0	0	1	0	0
3025	1	0	0	1	0	0
3026	1	0	0	3	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
3035	1	0	0	0	0	0
3037	0	0	0	1	0	0
3038	1	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	1	0	0	1	0	0
3049	2	0	0	0	0	0
3050	5	0	0	6	1	1
3051	1	0	0	0	0	0
3054	2	0	0	1	0	0
3055	5	0	0	8	5	0
3056	1	0	0	0	0	0
3057	3	1	0	0	0	0
3058	4	1	4	8	0	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
TOTAL	272	14	31	198	27	27

1 See Appendix 1C for itemization of explantations (nuclear).
2 See Appendix 1D for itemization of explantations (chemical).
3 See Table 7 for itemization of complications.

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. 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 not returned to Medtronic for analysis, but reportedly exhibited a rate drop to fifty-five (55) beats per minute.

Table 6 displays the number of implants, explants, and complications in terms of pacemaker-months, or more precisely, months since implant either to October 1, 1974, or to the date of explantation. The effective number of device-months (Table 6) acculated to date in the isotopic group is 2,776 after allowances for explants; whereas the comparable figure in the control group is 2,519. When

TABLE 6. NUMBERS OF IMPLANTATIONS, EXPLANTATIONS, AND ASSOCIATED COMPLICATIONS BY MONTHS SINCE IMPLANTATION (TO 10/1/74)

Months in Patient[1]	NUCLEAR POWERED			CHEMICALLY POWERED		
	Implants	Explants[2]	Complications	Implants	Explants[2]	Complications
0	2	0	12	0	0	16
1	3	3	3	1	4	2
2	5	2	0	1	5	2
3	11	0	4	1	0	2
4	17	2	3	1	2	1
5	15	0	1	3	1	1
6	25	0	1	7	2	0
7	16	2	1	14	0	1
8	18	1	1	11	0	1
9	13	0	2	16	3	0
10	20	0	0	21	2	0
11	24	0	2	23	3	0
12	20	1	0	14	1	1
13	21	0	0	15	2	0
14	16	0	1	15	0	0
15	16	1	0	4	0	0
16	4	0	0	5	0	0
17	2	1	0	5	0	0
18	3	0	0	8	0	0
19	4	0	0	8	1	0
20	1	1	0	16	0	0
21	2	0	0	2	0	0
22	4	0	0	1	0	0
23	2	0	0	1	0	0
24	3	0	0	0	1	0
25	3	0	0	2	0	0
26	2	0	0	0	0	0
27	0	0	0	0	0	0
28	0	0	0	1	0	0
29	0	0	0	0	0	0
30	0	0	0	0	0	0
31	0	0	0	0	0	0
32	0	0	0	0	0	0
33	0	0	0	0	0	0
34	0	0	0	0	0	0
35	0	0	0	0	0	0
36	0	0	0	0	0	0
37	0	0	0	0	0	0
38	0	0	0	1	0	0
39	0	0	0	0	0	0
40	0	0	0	0	0	0
41	0	0	0	0	0	0
42	0	0	0	1	0	0
Total	272	14	31	198	27	27
Device Months	2776	99		2519	187	

[1] Months in patient are computed from date of implant to date of complication.

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

calculated to the time of the first device failure, these numbers become 2,504 and 1,924 respectively. The upper 95% confidence limits on the underlying true random failure rates in each group are 0.12% per month and 0.15% per month, respectively. These figures have improved from the previous report, (0.206 and 0.204 % per month) despite the fact that the upper confidence limit was raised from 90% to 95%.

If a 0.15% per month random failure rate is adopted as the standard of comparison (Medtronic Clinical Evaluation Plan dated March 21, 1973), the minimum number of device-months required to confirm a true rate less than this figure is 1,518, a figure exceeded by our current totals.

Medtronic, Inc., also has access to data concerning isotopic units implanted in Europe. Of the six-hundred and forty-two (642) implants of the Model 9000 in Europe, twenty-six (26) 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 4,488 effective device-months accumulated, the upper 95% confidence limit on the underlying true random failure rate for this group is 0.07% per month, well below the standard of comparison. By combining all Model 9000 units implanted world wide, 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 having occurred thus far in the study. Wound infections are seen to have played a more extensive role in the isotopic group than among the controls (5 versus 1). When subjected to a chi-squared test of significance (yielding $\chi^2 = 1.61$ with one degree of freedom), this difference is found to be not statistically significant.

In the nuclear group, among twenty-eight (28) units there were thirty-three (33) complications, of which twenty-one (21) were lead related. In the chemical group, twenty-seven (27) units exhibited complications, twenty (20) of which were related to the lead system. Among the other complications noted, no significance can be attributed to the differences between the nuclear models and the control group.

TABLE 7. ITEMIZATION OF COMPLICATIONS AND MODES OF TREATMENT[1] (TO 10/1/74)

Hospital Code	Physician Code	Patient Code	Serial Number	Implant Date	Complication Date	Months In Patient[2]
			NUCLEAR POWERED			
H3001	D3001	A01021	3R00120	09/04/73	01/14/74	13
H3058	D3058	M01087	3R00122	11/21/73	11/22/73	11
H2003	D2004	G01034	3R00020	10/05/73	10/17/73	12
H2003	D2004	R01036	3R00019	07/24/73	07/27/73	15
H1020	D1020	F01040	3R00090	11/05/73	11/05/73	11
H1020	D1020	G01162	3R00289	01/04/74	01/09/74	9
H1023	D1023	S01169	3R00179	12/03/73	12/05/73	10
H2014	D2016	J01071	3R00085	08/08/73	03/05/74	14
H1028	D1028	G01001	3R00073	07/16/73	10/16/73	15
H1023	D1023	M01166	3R00175	11/07/73	12/07/73	11
H1023	D1023	W01097	3R00142	10/29/73	11/29/73	12
H3022	D3029	H01048	3R00104	08/21/73	04/29/74	14
H3001	D3001	A01021	3R00120	09/04/73	06/12/74	13
H3001	D3001	S01260	3R00220	03/04/74	03/19/74	7
H3055	D3058	M01087	3R00122	11/21/73	11/22/73	11
H3055	D3058	M01087	3R00122	11/21/73	02/21/74	11
H3055	D3058	S01059	3R00136	09/17/73	12/17/73	13
H3055	D3058	S01114	3R00145	12/13/73	06/19/74	10
H3027	D3038	P01013	3R00123	09/20/73	02/06/74	13
H2022	D2027	G01093	3R00161	10/17/73	09/13/74	12
H2016	D2018	M01529	2R00222	04/02/73	04/06/73	18
H1026	D1026	A01103	3R00233	11/06/73	11/28/73	11
H1002	D1002	S01317	3R00052	11/28/73	04/17/74	10
H1026	D1026	H01373	4R00057	06/05/74	07/03/74	4
H1025	D1025	N01258	3R00334	03/05/74	03/25/74	7
H1058	D1060	P01003	3R00021	07/06/73	05/23/74	15
H1018	D1020	B01304	3R00064	03/27/74	09/10/74	7
H1032	D1031	C01351	3R00344	05/13/74	05/13/74	5
H1024	D1024	I01288	3R00281	03/20/74	05/15/74	7
H1024	D1024	I01288	3R00281	03/20/74	06/06/74	7
H1024	D1024	I01288	3R00281	03/20/74	06/21/74	7
H1023	D1023	D01005	3R00093	09/04/73	08/20/74	13
H2003	D2004	S01037	3R00028	06/26/73	08/02/74	16

Complication	Treatment	Lead Related[3]	Pulse Generator Related[3]	Surgery Related[3]
	NUCLEAR POWERED			
Lead fracture	Lead replaced	Yes	No	No
Intermittent hiccoughs	None	Yes	No	Yes
Wound separation/infection/lead displacement	Antibiotics/attempted lead replacement/explant	Yes	Yes	Yes
Temporary sensing impairment	None/self-corrected	Yes	No	Yes
Wound infection	Antibiotics/pocket irrigation	No	Yes	Yes
Wound infection	Antibiotics	No	Yes	Yes
Blood in pocket site	None	No	Yes	Yes
Lead displacement	Explant	Yes	No	Yes
Intermittent hiccoughs	None/self-corrected	Yes	No	Yes
Twitching in pulse generator pocket	Pulse generator repositioned in same pocket	No	Yes	No
Fail to sense	Lead replaced	Yes	Yes	No
Diaphragmatic stimulation	Lead repositioned and converted to unipolar	Yes	No	No
Wound infection	Antibiotics	No	Yes	Yes
Diaphragmatic stimulation	Lead replaced and pulse generator repositioned	Yes	No	Yes
Diaphragmatic stimulation	None	Yes	No	Yes
Ventricular fibrillation	Defibrillation	No	No	No
Lead disconnected	Reconnected	Yes	No	No
Necrosis of pocket	Pulse generator repositioned	No	Yes	No
Episode of syncope	None	No	No	No
Bipolar lead fracture	Lead unipolarized	Yes	No	No
Perforation of ventricle	Lead replaced	Yes	No	Yes
Positive muscle potential tests	Observation	Yes	Yes	No
Myocardial lead fractures	New leads inserted, 4/17/74	Yes	No	No
Positive muscle inhibition tests	Observation	Yes	Yes	No
Pocket wound infection	Wound aspiration, antiobiotics, new pocket	No	Yes	Yes
Lead fracture	New leads implanted	Yes	No	No
Wound infection/erosion	Pulse generator repositioned to new site/antibiotics	No	Yes	No
Tachycardia during procedure	O_2/temporarily stopped procedure	No	No	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
Infection, wound separation exposing lead	Replaced lead/antibiotics	Yes	No	No
Skin erosion at pocket site	Transposition of unit closer to sternum	No	Yes	No

TABLE 7 continued

Hospital Code	Physician Code	Patient Code	Serial Number	Implant Date	Complication Date	Months In Patient [2]
			CHEMICALLY POWERED			
H3001	D3011	H01227	3L01731	06/04/73	06/04/73	16
H3002	D3002	W01298	3K14525	09/10/73	09/12/73	13
H3013	D3013	L01291	3G02050	01/21/74	01/21/74	9
H3013	D3013	M01294	3E01334	02/22/74	02/22/74	8
H3013	D3013	N01295	3E01047	12/14/73	12/17/73	10
H2016	D2019	G01141	3L00139	07/05/73	07/05/73	15
H2016	D2019	B01138	3L04224	07/19/73	08/13/73	15
H2016	D2019	P01142	3L05972	10/01/73	03/07/74	12
H2022	D2027	R01124	Unknown	11/01/73	11/03/73	11
H2022	D2027	G01154	3K15609	09/12/73	12/24/73	13
H2022	D2027	R01284	3K04486	03/15/73	03/15/74	19
H2022	D2027	N01125	3E00982	11/07/73	11/28/73	11
H1027	D1027	W01190	3M02390	10/05/73	01/05/74	12
H1028	D1028	N01186	3K04682	04/10/73	04/19/73	18
H1021	D1021	B01262	3L06027	11/21/73	11/21/73	11
H1027	D1027	B01147	3G11740	11/07/73	01/31/74	11
H1017	D1019	H01280	3S00719	08/09/73	08/14/73	14
H3001	D3001	D01228	3S01782	08/02/73	09/18/73	14
H3001	D3001	T01226	3A01599	09/13/73	01/10/74	13
H3040	D3050	G01203	3K13661	08/10/73	05/31/74	14
H2032	D2040	M01494	3K32733	08/08/74	08/15/74	2
H2032	D2040	B01495	3K34544	07/22/74	07/29/74	2
H1067	D1026	G01407	XX4681	01/04/73	01/22/73	21
H2022	D2027	M01281	3K23006	01/16/74	03/15/74	8
H2022	D2027	V01286	3G10521	03/01/74	03/26/74	7
H1023	D1023	T01443	3T17710	04/10/74	04/10/74	6
H1017	D1019	T01285	3S00446	09/17/73	04/18/74	13

[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 10/1/74, data cut-off for this report.

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

Complication	Treatment	Lead Related[3]	Pulse Generator Related[3]	Surgery Related[3]
	CHEMICALLY POWERED			
Lead displaced	Repositioned	Yes	No	Yes
Blood in pocket site	Fluid withdrawn	No	Yes	Yes
Failure to capture	Lead replaced	Yes	No	Yes
Cardiac arrests during implant	External massage/Isuprel	No	No	No
Lead fracture	None	Yes	No	No
Muscle twitch	None	Yes	No	Yes
Muscle twitch/electrode perforation	Lead repositioned	Yes	No	Yes
High threshold/electrode perforation	Lead repositioned	Yes	No	Yes
Ventricular perforation/ pulmonary emboli	Unknown	Yes	No	Yes
Loss of capture	Self-corrected	Yes	No	Yes
Ventricular perforation	Lead re-inserted	Yes	No	Yes
Ventricular perforation	Self-corrected	Yes	No	Yes
Wound infection	Unknown/explant	No	Yes	Yes
Lead displacement	New lead inserted	Yes	No	Yes
Lead displacement	Repositioned	Yes	No	Yes
Failure to capture	New lead inserted	Yes	No	Yes
Lead displacement	Repositioned	Yes	No	Yes
Loss of capture	Lead replaced	Yes	No	No
Occasional dizziness	Pulse width increased	No	Yes	No
Pain in pocket area	Drugs	No	Yes	No
Pocket; hematoma	Antibiotics wound aspiration	No	Yes	Yes
Pocket edema	Wound aspiration	No	Yes	Yes
Exit block, loss capture and failure to sense (dislocated lead)	Lead repositioned	Yes	No	Yes
Ventricular perforation	New leads placed	Yes	No	Yes
Recurrent lead dislocation (endocardial)	Epicardial leads inserted	Yes	No	Yes
Lead displacement	Inserted new myocardial leads	Yes	No	No
Infection/skin erosion at site of old abandoned lead	Antibiotics	Yes	No	No

TABLE 8. NUMBERS OF LEADS ON CURRENTLY FUNCTIONING PULSE GENERATORS BY LEAD TYPE AND MONTHS SINCE LEAD IMPLANTATION (TO 10/1/74)

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

Continued

TABLE 8, continued

Months in Patient	NUCLEAR POWERED						CHEMICALLY POWERED					
	Myocardial		Endocardial				Myocardial		Endocardial			
	Unipolar	Bipolar	Unipolar	Bipolar	Misc	Total	Unipolar	Bipolar	Unipolar	Bipolar	Misc	Total
49	0	0	0	1	1	2	0	0	0	1	1	2
51	0	0	0	1	2	3	0	0	0	0	1	1
52	0	0	0	0	2	2	0	0	0	0	0	0
53	0	1	0	0	0	1	0	0	0	0	0	0
54	0	0	0	0	1	1	0	0	0	0	1	1
55	0	0	0	1	0	1	0	0	0	0	0	0
56	0	0	0	2	0	2	0	0	0	0	0	0
57	0	0	0	1	1	2	0	0	0	1	1	2
58	0	0	0	1	1	2	0	0	0	1	0	1
59	0	0	0	1	0	1	0	0	0	0	0	0
60	0	1	0	0	1	2	0	0	0	0	1	1
61	0	0	0	1	0	1	0	0	0	0	1	1
62	0	2	0	0	0	2	0	0	0	0	0	0
63	0	0	0	1	0	1	0	0	0	0	0	0
64	0	0	0	0	0	0	0	0	0	0	0	0
65	0	0	0	0	0	0	0	0	0	0	0	0
66	0	0	0	0	2	2	0	0	0	0	0	0
67	0	0	0	0	1	1	0	0	0	1	0	1
68	0	0	0	2	0	2	0	0	0	0	0	0
69	0	0	0	0	0	0	0	0	0	0	0	0
71	0	0	0	0	0	0	0	0	0	2	0	2
72	0	1	0	1	0	2	0	0	0	0	0	0
73	0	0	0	0	1	1	0	0	0	0	0	0
74	0	0	0	2	0	2	0	0	0	0	0	0
75	0	0	0	0	1	1	0	0	0	0	0	0
77	0	0	0	1	0	1	0	0	0	0	0	0
84	0	0	0	0	1	1	0	0	0	0	0	0
86	0	0	0	0	0	0	0	0	0	0	0	0
90	0	0	0	0	0	0	0	0	0	0	0	0
91	0	0	0	0	0	0	0	0	0	0	0	0
92	0	0	0	0	1	1	0	0	0	0	0	0
94	0	1	0	0	0	1	0	0	0	0	1	1
95	0	0	0	0	0	0	0	0	0	0	1	1
96	0	1	0	0	0	1	0	0	0	0	0	0
98	0	0	0	0	0	0	0	0	0	0	0	0
100	0	1	0	0	0	1	0	0	0	0	0	0
102	0	0	0	1	0	1	0	0	0	0	0	0
111	0	0	0	0	1	1	0	0	0	0	0	0
119	0	0	0	0	0	0	0	0	0	0	0	0
123	0	0	0	0	1	1	0	0	0	0	0	0
131	0	0	0	0	1	1	0	0	0	0	0	0
138	0	1	0	0	0	1	0	0	0	0	0	0
139	0	0	0	0	1	1	0	0	0	0	0	0
Total	16	78	12	94	59	259	8	31	37	84	27	192
Device Months	168	1782	140	2728	2711	7529	92	502	614	1866	1178	4252

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. The miscellaneous category is a catch-all for non-Medtronic leads which could not be positively identified as to type.

Within the isotopic group of patients, there are thirteen (13) leads on which no information can be obtained, and six (6) on 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 eleven years old and is still functioning. There have been only two confirmed lead fractures (both at 86 months from implant), so the information to date does not indicate that leads will limit longevity.

For the endocardial unipolar implants, no further details were available. 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.

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. Their help has been particularly appreciated considering the fact that the procedures for documentation of registration, follow-up, and recovery, required of licensees by the A.E.C., are time-consuming and require a great deal of effort on the part of both the physicians and Medtronic. The computerized system of patient follow-up generates the data contained in this report and assists greatly in the accountability effort.

No significant new facts have been revealed during the past six months of the study. However, the addition to the study of thirty (30) implanting physicians, one-hundred and eight (108) nuclear units, and fifty-eight (58) control units clarifies the characteristics that emerged during the previous report period. These characteristics include the age of the patient population, etiology of arrhythmia, validity of the

patient control group, random failure rates of electronic components, and possible adverse side effects of the pacemaking system.

Conventional pacemaker bearers are, on the average, nineteen 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.

The validity of the patient control group is in question. Of the implanting physicians, fifty-five (55) submitted no controls. Among the thirty-eight (38) physicians who fully participated, there is a non-significant correlation ($r = 0.216$) between the numbers of nuclear and chemical pacemaker implants per participating physician. This means that any real differences which exist between the two patient/pacemaker populations are confounded with physician/hospital related differences.

One of the performance criteria sought is a low incidence of random failures. The rate for both Model 9000 and control groups compares 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 third 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.

REFERENCES

1. Beyer, W. H., Handbook of Tables for Probability and Statistics, The Chemical Rubber Company, Cleveland, 1968.

2. Bliss, C. I., Statistics in Biology, Volume I., McGraw-Hill Book Company, New York, 1967, p. 42.

3. Conover, W. J., Practical Nonparametric Statistics, John Wiley & Sons Inc., New York, 1971, p. 142.

4. Kearns, T. P., M. D., External ophthalmoplegia, pigmentary degeneration of the retina, and cardiomyopathy: a newly recognized syndrome. Transactions of the American Ophthalmological Society, 1965, Volume 63, pp. 559-625.

5. Kearns, T.P., M.D., and Sayre, G.P., M.D., Retinitis pigmentosa, external ophthalmoplegia, and complete heart block: unusual syndrome with histologic study in one of two cases, A. M. A. Archives of Ophthamology, 1958, Volume 60, pp. 280-289.

6. Medtronic, Inc., Medtronic™ Laurens-Alcatel Model 9000 Isotopic Pulse Generator CLINICAL INVESTIGATION PLAN. Minneapolis, Unpublished Manuscript, March 21, 1973.

7. Medtronic, Inc., Status Report No. 1 on the Clinical Investigation of the Medtronic™ Laurens-Alcatel Model 9000 Isotopic Pulse Generator. Minneapolis, Unpublished Manuscript, November 20, 1973.

8. Medtronic, Inc., Status Report No. 2 on the Clinical Investigation of the Medtronic™ Laurens-Alcatel Model 9000 Isotopic Pulse Gererator. Minneapolis, Unpublished Manuscript, June 28, 1974.

9. W. B. Saunders Company, Dorland's Illustrated Medical Dictionary, Philadelphia, 1965.

10. Uppal, S. C., M. D., Kearns' Syndrome, A New Form of Cardiomyopathy, British Heart Journal, 1973, Volume 35, pp. 766-769.

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.

CHAGA'S 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 1A. ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 10-1-74)

LEGEND:
* Removed Pulse Generator
** Reimplanted Pulse Generator

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
MJ1531	2003	2004	9000	2R00009	08/17/72	04/11/72
TJ1533	2003	2004	9000	2R00035	07/18/72	05/03/72
PJ1534	2003	2004	9000	2R00037	07/19/72	04/11/72
RJ1537	2016	2019	9000	2R00040	08/14/72	05/10/72
WJ1586	2003	2004	9000	2R00043	10/24/72	08/22/72
EJ1534	2016	2019	9000	2R00053	08/28/72	06/27/72
DJ1104	2016	2019	9000	2R00055	09/25/72	06/27/72
NJ1535	2016	2019	9000	2R00064	09/25/72	06/27/72
QJ1532	2003	2004	9000	2R00065	09/13/72	06/23/72
SJ1536	2016	2019	9000	*2R00068	01/30/73	06/20/72
SJ1535	2003	2004	9000	*2R00096	10/24/72	08/22/72
GJ1536	2016	2019	9000	*2R00105	11/20/72	08/23/72
BJ1588	2003	2004	9000	2R00106	12/05/72	09/21/72
HJ1589	2003	2004	9000	2R00108	12/04/72	09/21/72
TJ1411	1015	1016	9000	2R00124	11/17/72	09/08/72
WJ1587	2003	2003	9000	2R00131	02/22/73	09/11/72
FJ1412	1015	1016	9000	2R00135	11/09/72	09/11/72
GJ1014	3022	3029	9000	2R00172	06/28/73	11/16/72
CJ1526	3022	3029	9000	*2R00174	02/05/73	11/20/72
GJ1527	1007	1008	9000	*2R00175	02/14/73	11/16/72
AJ1531	2023	2028	9000	2R00178	02/20/73	11/20/72
DJ1580	3054	3057	9000	*2R00191	03/02/73	12/05/72
HJ1590	2003	2004	9000	2R00193	03/15/73	12/05/72
CJ1532	2028	2032	9000	2R00195	03/09/73	01/17/73
HJ1382	3045	3051	9000	2R00206	03/07/74	01/31/73
HJ1331	3061	3017	9000	2R00208	04/12/74	01/31/73
MJ1086	1024	1024	9000	2R00209	06/08/73	01/30/73
RJ1047	1024	1024	9000	2R00214	05/24/73	01/23/73
HJ1308	3029	3039	9000	2R00216	03/12/74	01/23/74
BJ1045	3040	3050	9000	2R00219	05/31/73	01/30/73
AJ1002	1001	1001	9000	2R00220	10/10/73	01/30/73
BJ1539	1015	1016	9000	2R00221	04/26/73	02/07/73
MJ1529	2016	2018	9000	2R00222	04/02/73	02/07/73
KJ1528	1001	1001	9000	2R00223	05/15/73	02/07/73
FJ1093	3022	3029	9000	2R00224	07/24/73	01/23/73
JJ1008	1060	1006	9000	2R00226	06/07/73	01/31/73
JJ1326	1010	1012	9000	2R00227	07/09/73	01/31/73
LJ1032	2003	2004	9000	3R00005	06/11/73	01/30/73
BJ1533	3040	3050	9000	3R00006	05/15/73	02/07/73
BJ1029	2003	2004	9000	3R00008	06/12/73	02/05/73
HJ1031	2003	2003	9000	3R00009	06/07/73	02/05/73
WJ1024	3003	3003	9000	3R00010	06/05/73	02/05/73
GJ1379	3051	3055	9000	3R00011	06/07/73	02/05/73
GJ1030	2003	2004	9000	3R00012	06/13/73	02/05/73
RJ1302	3037	3047	9000	3R00013	03/22/74	02/05/73
GJ1091	3051	3055	9000	3R00014	06/04/73	02/05/73
SJ1005	1027	1027	9000	3R00015	06/11/73	02/05/73
MJ1035	2003	2004	9000	3R00016	06/14/73	02/06/73
LJ1033	2003	2004	9000	3R00018	06/26/73	04/03/73
RJ1036	2003	2004	9000	3R00019	07/24/73	04/03/73
TJ1100	2003	2004	9000	3R00020	12/12/73	04/03/73
GJ1034	2003	2004	9000	**3R00020	10/05/73	04/03/73
PJ1003	1060	1006	9000	3R00021	07/06/73	04/02/73
KJ1043	1017	1019	9000	3R00022	07/27/73	04/02/73
HJ1084	2016	2019	9000	3R00023	07/02/73	04/02/73
HJ1009	1027	1027	9000	3R00024	07/11/73	04/02/73
KJ1007	1060	1006	9000	3R00025	08/08/73	04/02/73
HJ1008	1027	1027	9000	3R00026	06/26/73	04/02/73
WJ1042	1017	1019	9000	3R00027	08/02/73	04/21/73
SJ1037	2003	2004	9000	3R00028	06/26/73	04/03/73
SJ1028	3036	3046	9000	3R00029	07/02/73	04/03/73
MJ1082	3053	3057	9000	3R00030	06/28/73	04/03/73
TJ1054	3002	3002	9000	3R00031	07/11/73	04/03/73
CJ1088	3051	3055	9000	3R00034	07/09/73	05/01/73
RJ1079	2029	2037	9000	3R00036	09/05/73	05/01/73
KJ1016	1016	1018	9000	3R00039	07/13/73	05/01/73
HJ1007	1027	1027	9000	3R00046	09/06/73	05/11/73
CJ1089	3051	3055	9000	3R00049	07/27/73	05/16/73
RJ1081	3054	3057	9000	3R00050	08/16/73	05/16/73

APPENDIX 1A. ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 10-1-74)

LEGEND:
* Removed Pulse Generator
** Reimplanted Pulse Generator

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
SJ1057	1018	1020	9000	3R00051	08/21/73	05/16/73
SJ1317	1002	1002	9000	3R00052	11/28/73	05/16/73
WJ1318	1060	1006	9000	3R00055	04/08/74	05/16/73
YJ1004	1027	1027	9000	3R00061	09/07/73	05/14/73
MJ1104	2020	2025	9000	3R00062	07/30/73	05/14/74
BJ1039	1018	1020	9000	3R00064	07/16/73	05/29/73
PJ1156	2025	2031	9000	3R00069	11/05/73	05/29/73
QJ1577	3035	3045	9000	3R00070	10/16/73	05/17/73
GJ1041	1028	1028	9000	3R00073	07/16/73	05/29/73
FJ1041	1018	1020	9000	3R00074	07/25/73	05/29/73
LJ1085	1024	1024	9000	3R00075	10/11/73	05/29/73
MJ1015	2017	2020	9000	3R00076	09/13/73	05/29/73
MJ1169	1023	1023	9000	3R00077	08/03/73	05/29/73
HJ1074	2011	2012	9000	3R00078	08/07/73	05/29/73
CJ1096	1016	1018	9000	3R00079	12/28/73	05/29/73
MJ1320	1002	1017	9000	3R00081	11/28/73	05/30/73
JJ1071	2014	2016	9000	*3R00085	08/08/73	06/14/73
GJ1076	1006	1007	9000	3R00088	08/20/73	05/30/73
BJ1250	2002	2002	9000	3R0008N	01/31/74	UNKNOWN
FJ1046	1018	1020	9000	3R00090	11/05/73	06/14/73
JJ1004	1023	1023	9000	3R00091	09/12/73	06/14/73
AJ1173	1023	1023	9000	3R00092	10/15/73	06/14/73
CJ1005	1023	1023	9000	3R00093	09/04/73	05/31/73
SJ1172	1023	1023	9000	3R00094	09/28/73	06/14/73
RJ1044	2031	2039	9000	3R00096	08/09/73	06/14/73
PJ1000	2002	2002	9000	3R00097	08/16/73	06/14/73
MJ1048	1028	1028	9000	3R00103	08/20/73	06/14/73
GJ1019	3022	3029	9000	3R00104	08/21/73	06/14/73
BJ1022	2002	2002	9000	3R00105	08/09/73	06/14/73
EJ1010	1019	1021	9000	3R00108	08/09/73	06/14/73
LJ1011	1019	1021	9000	3R00109	09/09/73	06/14/73
GJ1088	2031	2039	9000	3R00111	08/09/73	06/14/73
DJ1096	3038	3048	9000	3R00112	08/21/73	06/14/73
MJ1002	1028	1028	9000	3R00114	10/08/73	06/14/73
CJ1003	1028	1028	9000	*3R00115	09/21/73	02/05/73
PJ1259	1019	1021	9000	3R00116	08/22/73	02/06/73
AJ1021	3001	3011	9000	3R00117	02/15/74	06/14/73
SJ1027	2002	2002	9000	3R00120	09/04/73	06/19/73
MJ1087	3055	3058	9000	3R00121	09/11/73	06/19/73
PJ1013	3027	3038	9000	3R00122	11/21/73	06/19/73
MJ1006	1027	1027	9000	3R00123	09/20/73	06/19/73
VJ1073	3059	3061	9000	3R00124	10/02/73	07/02/73
CJ1090	2006	2006	9000	3R00125	08/27/73	06/19/73
FJ1049	3022	3030	9000	3R00126	09/12/73	06/19/73
NJ1082	3050	3054	9000	3R00127	09/18/73	06/19/73
DJ1052	3031	3041	9000	3R00128	10/23/73	06/19/73
FJ1083	2026	2032	9000	3R00129	08/25/73	06/19/73
RJ1174	1023	1023	9000	3R00130	08/28/73	06/19/73
CJ1241	1023	1023	9000	3R00132	10/22/73	06/19/73
MJ1107	1023	1023	9000	3R00133	09/21/73	06/19/73
SJ1023	1003	1004	9000	3R00134	10/08/73	06/19/73
SJ1059	3055	3058	9000	3R00135	09/11/73	06/19/73
				3R00136	09/17/73	06/19/73
WJ1051	2015	2017	9000	3R00138	08/14/73	06/18/73
BJ1075	2011	2012	9000	3R00139	10/05/73	06/18/73
MJ1395	2027	2033	9000	3R00140	06/24/74	06/22/73
GJ1115	1023	1023	9000	*3R00141	10/04/73	07/02/73
WJ1097	1023	1023	9000	*3R00142	10/29/73	07/02/73
SJ1309	2005	2006	9000	*3R00143	11/16/73	07/02/73
NJ1001	1003	1004	9000	*3R00144	11/13/73	06/22/73
SJ1114	3056	3058	9000	*3R00145	12/13/73	07/02/73
WJ1201	2005	2006	9000	3R00146	11/21/73	07/02/73
FJ1209	2005	2006	9000	3R00147	03/06/74	07/02/73
TJ1094	2007	2008	9000	3R00148	10/08/73	07/02/73
LJ1095	2020	2025	9000	3R00149	09/17/73	07/02/73
AJ1098	1005	1006	9000	3R00150	12/14/73	07/02/73
RJ1046	3001	3011	9000	3R00151	09/19/73	07/02/73
BJ1018	3001	3011	9000	3R00152	10/15/73	07/02/73
BJ1038	1018	1020	9000	3R00154	11/05/73	07/02/73

APPENDIX 1A. ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 10-1-74)

LEGEND:
* Removed Pulse Generator
** Reimplanted Pulse Generator

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
TJ1046	1004	1005	9000	3R00155	10/04/73	07/02/73
SJ1017	2017	2020	9000	**3R00157	10/23/73	07/02/73
RJ1393	2017	2020	9000	3R00157	11/12/73	07/02/73
CJ1026	3001	3001	9000	3R00158	10/22/73	07/13/73
OJ1118	3039	3041	9000	3R00159	01/02/74	07/13/73
SJ1025	2002	2002	9000	3R00160	10/05/73	07/13/73
GJ1093	2022	2027	9000	3R00161	10/17/73	07/13/73
FJ1491	3040	3050	9000	3R00163	04/17/74	07/13/73
WJ1116	3015	3017	9000	3R00164	12/19/73	07/13/73
AJ1100	3055	3058	9000	3R00165	12/06/73	07/13/73
TJ1072	2013	2014	9000	3R00166	10/09/73	07/13/73
MJ1076	1027	1027	9000	3R00167	10/24/73	07/13/73
VJ1012	3050	3054	9000	3R00174	10/17/73	08/07/73
MJ1106	1023	1023	9000	3R00175	11/07/73	08/07/73
HJ1108	1023	1023	9000	3R00178	10/29/73	08/07/73
SJ1109	1023	1023	9000	3R00179	12/03/73	08/07/73
MJ1170	1023	1023	9000	3R00180	11/20/73	08/07/73
WJ1171	1023	1023	9000	3R00197	11/27/73	08/08/73
YJ1445	1023	1023	9000	3R00204	02/26/74	09/25/73
SJ1922	1023	1023	9000	3R00207	01/24/74	09/20/73
SJ1009	3015	3017	9000	3R00210	11/02/73	09/25/73
VJ1341	1023	1023	9000	3R00212	02/09/74	09/25/73
KJ1342	1023	1023	9000	3R00213	02/04/74	09/25/73
RJ1393	1023	1023	9000	3R00214	03/19/74	09/25/73
KJ1426	3040	3050	9000	3R00217	12/15/73	09/20/73
WJ1413	1023	1023	9000	3R00219	03/11/74	09/25/73
SJ1260	3001	3001	9000	3R00220	03/04/74	09/25/73
WJ1399	1018	1020	9000	3R00222	12/19/73	09/24/73
CJ1102	3001	3001	9000	3R00223	11/29/73	09/25/73
EJ1126	3013	3015	9000	3R00226	12/19/73	09/25/73
WJ1312	2013	2015	9000	3R00232	01/30/74	09/25/73
AJ1103	1029	1026	9000	3R00233	11/06/73	09/25/73
SJ1026	2002	2002	9000	3R00235	11/06/73	09/25/73
BJ1101	1018	1020	9000	3R00239	12/12/73	09/20/73
DJ1103	2014	2016	9000	3R00241	12/11/73	09/25/73
SJ1080	1023	1023	9000	3R00244	06/03/74	09/25/73
MJ1119	2027	2033	9000	3R00245	01/02/74	11/05/73
WJ1337	2014	2016	9000	3R00248	04/30/74	09/25/73
MJ1117	3057	3059	9000	3R00251	12/28/73	11/05/73
LJ1098	2011	2012	9000	3R00252	11/13/73	09/25/73
LJ1257	2013	2014	9000	3R00253	02/26/74	09/25/73
TJ1359	3022	3029	9000	3R00254	04/03/74	11/05/73
WJ1382	1012	1013	9000	3R00255	02/09/74	11/05/73
MJ1175	1003	1004	9000	3R00256	01/18/74	11/05/73
HJ1361	3039	3049	9000	3R00257	04/10/74	11/05/73
CJ1242	2002	2002	9000	3R00258	02/01/74	11/05/73
CJ1238	2029	2037	9000	3R00261	01/28/74	11/05/73
BJ1177	2022	2027	9000	3R00263	01/09/74	11/05/73
WJ1090	3051	3055	9000	3R00264	11/01/73	09/25/73
MJ1394	2017	2020	9000	3R00265	01/18/74	11/05/73
WJ1406	1015	1016	9000	3R00266	08/07/74	09/25/73
SJ1231	2011	2012	9000	3R00268	01/29/74	11/05/73
HJ1329	3052	3056	9000	3R00269	01/15/74	11/05/73
RJ1077	2032	2040	9000	3R00271	11/06/73	09/25/73
MJ1176	2027	2034	9000	3R00272	01/16/74	11/05/73
RJ1290	1025	1025	9000	3R00273	03/11/74	11/06/73
TJ1311	1017	1019	9000	3R00275	05/20/74	11/06/73
TJ1357	1018	1020	9000	3R00277	05/14/74	11/06/73
CJ1409	2020	2025	9000	3R00278	05/10/74	11/06/73
HJ1243	1027	1027	9000	3R00279	02/19/74	11/06/73
HJ1287	3013	3015	9000	3R00280	03/19/74	11/06/73
IJ1208	1024	1024	9000	3R00281	03/20/74	11/06/73
JJ1302	3057	3059	9000	3R00282	03/12/74	11/06/73
KJ1230	1026	1026	9000	3R00283	01/22/74	11/06/73
BJ1239	3058	3060	9000	3R00284	02/08/74	11/06/73
SJ1379	3011	3013	9000	3R00286	01/17/74	11/05/73
CJ1365	2013	2014	9000	3R00287	04/30/74	11/06/73
LJ1561	2080	2132	9000	3R00288	09/04/74	11/05/73
GJ1102	1018	1020	9000	3R00289	01/04/74	11/06/73

APPENDIX 1A. ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 10-1-74)

LEGEND:
* Removed Pulse Generator
** Reimplanted Pulse Generator

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
KJ1237	3021	3027	9000	3R00290	01/29/74	11/06/73
GJ1176	3018	3022	9000	3R00291	01/15/74	09/25/73
FJ1161	2034	2042	9000	3R00292	01/03/74	11/06/73
MJ1275	2022	2027	9000	3R00295	03/06/74	11/06/73
PJ1244	1026	1026	9000	3R00296	02/06/74	11/06/73
JJ1301	3035	3045	9000	3R00297	03/26/74	11/06/73
JJ1270	2006	2007	9000	3R00298	03/13/74	11/06/73
LJ1159	1018	1020	9000	3R00303	01/07/74	11/06/73
PJ1330	3016	3019	9000	3R00314	05/03/74	12/10/73
JJ1324	1026	1026	9000	*3R00316	03/13/74	12/01/73
AJ1319	1002	1017	9000	3R00318	04/16/74	12/10/73
SJ1245	2012	2013	9000	3R00319	02/16/74	12/01/73
MJ1314	2011	2012	9000	3R00320	04/23/74	12/01/73
MJ1273	3016	3018	9000	3R00321	02/19/74	12/01/73
PJ1336	2069	2023	9000	3R00322	04/25/74	12/01/73
TJ1246	3020	3025	9000	3R00323	02/10/74	12/01/73
LJ1308	2003	2004	9000	3R00324	04/10/74	12/01/73
FJ1208	1006	1007	9000	3R00325	03/08/74	12/01/73
GJ1433	3009	3008	9000	*3R00326	03/14/74	12/01/73
MJ1303	2005	2006	9000	3R00328	03/20/74	12/10/73
PJ1345	3020	3026	9000	3R00330	03/26/74	12/10/73
LJ1371	1002	1017	9000	3R00331	02/09/74	12/01/73
LJ1271	3058	3060	9000	3R00332	02/22/74	12/01/73
NJ1256	1025	1025	9000	3R00334	03/05/74	12/01/73
BJ1304	1018	1020	9000	3R00337	03/27/74	12/01/73
CJ1367	1023	1023	9000	3R00338	05/24/74	12/01/73
LJ1272	2001	2001	9000	3R00340	03/08/74	12/01/73
RJ1274	2010	2011	9000	3R00341	03/12/74	12/01/73
KJ1269	3024	3032	9000	3R00343	03/13/74	12/01/73
CJ1351	1032	1031	9000	3R00344	05/13/74	12/10/73
BJ1240	1059	1056	9000	3R0089N	10/04/73	07/09/73
MJ1681	1023	1023	9000	4R00003	06/02/74	12/28/73
KJ1347	2006	2007	9000	4R00004	04/09/74	12/28/73
TJ1305	2027	2033	9000	4R00007	04/01/74	12/28/73
BJ1336	2073	2002	9000	4R00008	05/06/74	12/28/73
MJ1361	3037	3047	9000	4R00009	06/14/74	02/27/74
PJ1363	3007	3009	9000	4R00011	04/22/74	02/27/74
CJ1332	3001	3001	9000	4R00017	04/29/74	02/27/74
RJ1681	3027	3035	9000	4R00018	08/19/74	02/27/74
KJ1380	3001	3001	9000	4R00020	06/27/74	03/14/74
PJ1446	3052	3091	9000	4R00021	07/16/74	03/14/74
CJ1328	3034	3044	9000	4R00023	05/31/74	03/14/74
AJ1679	1023	1023	9000	4R00024	07/01/74	03/14/74
KJ1383	1018	1020	9000	4R00025	07/09/74	03/14/74
HJ1369	1035	1034	9000	4R00028	07/01/74	03/14/74
LJ1578	3058	3060	9000	4R00029	05/03/74	03/14/74
GJ1505	2014	2016	9000	4R00030	05/13/74	04/14/74
AJ1522	3039	3049	9000	4R00033	09/17/74	03/14/74
JJ1372	1023	1023	9000	4R00034	06/04/74	03/04/74
AJ1327	3029	3039	9000	4R00036	05/14/74	03/19/74
GJ1396	1026	1026	9000	4R00037	07/02/74	03/19/74
CJ1441	3061	3017	9000	4R00038	07/23/74	03/19/74
PJ1313	2032	2040	9000	4R00040	05/28/74	03/19/74
AJ1370	2005	2006	9000	4R00041	05/01/74	03/19/74
MJ1364	3007	3009	9000	4R00042	05/07/74	03/19/74
DJ1348	2005	2006	9000	4R00047	05/15/74	03/19/74
GJ1424	3039	3041	9000	4R00049	07/12/74	03/19/74
UJ1425	2027	2033	9000	4R00050	05/02/74	03/19/74
MJ1355	1022	1022	9000	4R00051	05/03/74	03/19/74
KJ1422	3040	3050	9000	4R00054	08/19/74	03/19/74
HJ1322	2010	2011	9000	4R00055	05/15/74	03/19/74
VJ1391	1017	1019	9000	4R00056	06/06/74	03/19/74
MJ1373	1026	1026	9000	4R00057	06/05/74	03/19/74
MJ1632	3081	3059	9000	4R00058	06/03/74	03/19/74

APPENDIX 1B. ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
BJ1132	1027	1027	5842	2M04433	03/01/73	11/28/72
MJ1282	1017	1019	5842	3M01641	08/01/73	05/02/73
CJ1133	1027	1027	5842	3M01734	08/06/73	05/14/73
BJ1189	1027	1027	5842	3M01739	07/09/73	05/02/73
BJ1193	1027	1027	5842	3M01784	09/14/73	05/14/73
SJ1122	1027	1027	5842	3M02022	09/24/73	05/22/73
SJ1121	1027	1027	5842	3M02246	10/03/73	06/20/73
GJ1148	1027	1027	5842	3M02332	11/06/73	06/28/73
KJ1191	1027	1027	5842	3M02341	10/02/73	06/22/73
WJ1190	1027	1027	5842	3M02390	10/05/73	06/28/73
LJ1136	1027	1027	5842	3M02490	11/05/73	07/09/73
DJ1349	1025	1025	5842	XX4012	10/01/73	02/27/73
WJ1299	3011	3013	5852	3D00507	01/24/74	06/14/73
MJ1153	2022	2027	5852	3D00334	07/19/73	05/24/73
CJ1201	3051	3055	5852C	2E01603	07/24/73	10/31/72
MJ1429	1046	1001	5852C	3E00379	08/29/73	03/05/73
NJ1125	2022	2027	5852C	3E00982	11/07/73	08/01/73
NJ1295	3011	3013	5852C	3E01047	12/14/73	08/23/73
MJ1294	3011	3013	5862C	3E01334	02/22/74	10/25/73
AJ1156	2022	2027	5862C	3E01786	06/28/73	01/09/74
TJ1285	1017	1019	5931	3S00446	08/03/73	01/24/73
HJ1280	1017	1019	5931	3S00719	08/09/73	01/23/73
VJ1123	3003	3003	5931	3S00824	01/19/73	11/15/72
SJ1134	3003	3003	5931	3S01186	11/08/73	04/13/73
DJ1226	3001	3001	5931	3S01782	08/03/73	12/20/72
CJ1523	3039	3041	5942	1K05974	07/14/71	02/09/71
AJ1163	1029	1028	5942	2K04385	05/02/72	06/08/72
LJ1315	1028	1028	5942	2K22159	08/04/72	05/23/72
BJ1210	1016	1018	5942	2K23782	01/24/73	05/22/72
DJ1185	1028	1028	5942	2K24181	10/28/72	06/08/72
TJ1199	3051	3055	5942	2K24492	07/09/73	10/02/72
BJ1223	3022	3029	5942	2K40540	01/05/73	10/23/72
UJ1151	2022	2027	5942	2K41511	04/13/73	12/21/72
CJ1225	3022	3029	5942	2K44344	03/02/73	11/22/72
HJ1316	1028	1028	5942	3G21913	08/02/72	01/14/74
CJ1200	3051	3055	5942	3K00719	08/25/73	03/13/73
CJ1207	3042	3050	5942	3K02350	05/23/73	02/28/73
MJ1224	3022	3029	5942	3K03117	03/28/73	12/21/72
CJ1202	3050	3054	5942	3K03257	10/13/73	01/29/73
CJ1197	2029	2037	5942	3K03441	05/11/73	02/21/73
HJ1229	3027	3037	5942	3K03865	05/07/73	02/20/73
RJ1284	2022	2027	5942	3K04486	03/15/73	01/04/73
NJ1186	1028	1028	5942	3K04682	04/10/73	01/02/73
FJ1217	2002	2002	5942	3K05661	04/27/73	01/22/73
LJ1234	2017	2020	5942	3K06167	08/05/73	04/02/73
MJ1601	2026	2032	5942	3K06376	07/17/73	UNKNOWN
BJ1150	2022	2027	5942	3K07126	04/09/73	UNKNOWN
GJ1209	3038	3048	5942	3K09055	07/10/73	04/13/73
WJ1208	3041	3050	5942	3K11159	08/07/73	05/21/73
FJ1113	3051	3055	5942	3K11900	09/08/73	07/03/73
MJ1292	3002	3002	5942	3K11984	08/02/73	06/15/73
SJ1211	1016	1018	5942	3K12315	07/17/73	05/11/73
LJ1216	2002	2002	5942	3K12635	07/16/73	05/31/73
GJ1203	3040	3050	5942	3K13661	08/10/73	05/16/73
PJ1157	2022	2027	5942	3K13800	08/13/73	05/16/73
TJ1184	3051	3055	5942	3K14318	08/21/73	05/15/73
WJ1298	3002	3002	5942	3K14525	09/10/73	06/27/73
FJ1602	2026	2032	5942	3K14844	10/12/73	06/08/73
VJ1233	2017	2020	5942	3K15270	09/10/73	06/28/73
GJ1154	2022	2027	5942	3K15609	09/12/73	07/06/73
HJ1129	3013	3015	5942	3K16938	11/29/73	09/12/73
MJ1206	3043	3050	5942	3K17336	09/24/73	08/02/73

APPENDIX 1B. ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
CJ1254	3020	3025	5942	3K17486	01/18/74	06/25/73
MJ1205	3044	3050	5942	3K17603	09/11/73	06/28/73
LJ1204	3045	3050	5942	3K17744	09/26/73	08/11/73
CJ1214	2002	2002	5942	3K17765	10/24/73	08/11/73
BJ1247	3020	3024	5942	3K18053	01/31/74	07/24/73
ZJ1221	2002	2002	5942	3K19070	10/02/73	08/07/73
RJ1131	3013	3015	5942	3K19855	12/10/73	08/21/73
CJ1277	2022	2027	5942	3K20547	10/24/73	07/17/73
AJ1003	2026	2032	5942	3K21215	11/19/73	09/05/73
LJ1215	2002	2002	5942	3K21505	10/16/73	08/14/73
MJ1243	3011	3013	5942	3K21563	11/28/73	08/29/73
RJ1246	3011	3013	5942	3K21606	02/07/74	12/28/73
DJ1278	3016	3018	5942	3K21787	10/30/73	09/07/73
CJ1206	3055	3058	5942	3K21793	12/14/73	09/21/73
KJ1150	3013	3015	5942	3K22057	11/14/73	09/20/73
FJ1152	2022	2027	5942	3K22396	10/10/73	08/11/73
CJ1155	2022	2027	5942	3K22919	10/10/73	08/13/73
LJ1310	1002	1017	5942	3K22983	12/12/73	08/28/73
MJ1281	2022	2027	5942	3K23006	01/16/74	10/11/73
CJ1502	2022	2027	5942	3K23049	01/18/74	10/11/73
SJ1126	2022	2027	5942	3K23434	12/20/73	09/21/73
LJ1253	1021	1021	5942	3K23992	12/14/73	10/02/73
HJ1127	3013	3015	5942	3K25082	12/04/73	10/11/73
MJ1334	3061	3017	5942	3K25598	01/17/74	10/11/73
MJ1251	1021	1021	5942	3K25785	01/31/74	10/16/73
WJ1306	3013	3015	5942	3K27863	03/11/74	12/13/73
KJ1339	2002	2002	5942	3K30308	04/30/74	02/14/74
MJ1494	2032	2040	5942	3K32733	08/08/74	05/03/74
GJ1495	2032	2040	5942	3K34544	07/22/74	03/12/74
AJ1428	1046	1001	5942	3K35708	11/09/72	UNKNOWN
BJ1212	2002	2002	5942	3K40484	01/29/73	11/08/72
CJ1354	1025	1025	5942	3XX0380	01/02/74	03/28/73
SJ1188	1028	1028	5942	UNKNOWN	12/18/72	UNKNOWN
TJ1232	1028	1028	5942	UNKNOWN	05/05/73	UNKNOWN
RJ1124	2022	2027	5942	UNKNOWN	11/01/73	UNKNOWN
DJ1135	3003	3003	5943	2L30063	04/23/73	09/21/72
CJ1222	3022	3029	5943	2L30208	02/01/73	09/19/72
CJ1111	2023	2029	5943	2L31000	02/12/73	09/22/72
DJ1187	1028	1028	5943	2L33485	12/28/72	10/25/72
DJ1196	3055	3058	5943	3L00015	06/22/73	03/29/73
CJ1236	2017	2020	5943	3L00186	11/17/73	09/26/73
SJ1195	3055	3058	5943	3L00280	06/05/73	03/26/73
WJ1107	1007	1008	5943	3L00929	05/23/73	03/14/73
GJ1141	2016	2019	5943	3L01139	07/05/73	02/06/73
HJ1227	3001	3001	5943	3L01731	06/04/73	01/13/73
GJ1137	2016	2018	5943	3L01942	07/24/73	03/13/73
MJ1182	2025	2031	5943	3L03115	09/10/73	04/10/73
MJ1235	2017	2020	5943	3L03453	11/09/73	09/13/73
SJ1143	2016	2019	5943	3L03892	07/12/73	02/27/73
BJ1203	3055	3058	5943	3L04019	12/27/73	03/26/73
BJ1138	2016	2019	5943	3L04224	07/19/73	04/02/73
SJ1181	2025	2031	5943	3L04250	07/20/73	04/04/73
DJ1146	2016	2019	5943	3L04256	09/17/73	04/04/73
SJ1378	1018	1020	5943	3L04428	07/18/73	03/27/73
RJ1198	2029	2037	5943	3L04774	10/31/73	04/23/73
FJ1139	2016	2019	5943	3L05244	11/08/73	09/06/73
MJ1346	3055	3058	5943	3L05916	10/18/73	08/09/73
PJ1142	2016	2019	5943	3L05972	10/01/73	08/09/73
BJ1202	1019	1021	5943	3L06027	11/21/73	07/27/73
DJ1205	3055	3058	5943	3L06095	12/30/73	09/11/73
WJ1144	2016	2019	5943	3L06406	11/05/73	08/28/73
MJ1140	2016	2019	5943	3L07190	11/05/73	08/30/73
SJ1207	3055	3058	5943	3L07655	12/14/73	09/11/73
CJ1204	3056	3058	5943	3L08509	10/04/73	08/23/73
CJ1248	1019	1021	5944	36134S4	01/18/74	10/22/73
CJ1110	2002	2002	5944	3C12804	12/05/73	10/01/73

APPENDIX 1B. ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL

PATIENT CODE	HOSPITAL CODE	PHYSICAN CODE	MODEL NUMBER	SERIAL NUMBER	DATE OF IMPLANT	DATE OF MANUFACTURE
KJ1219	2002	2002	5944	3G00022	10/11/73	07/08/73
RJ1218	2002	2002	5944	3G00133	08/01/73	05/14/73
BJ1194	1027	1027	5944	3G00599	10/12/73	06/07/73
FJ1045	1008	1008	5944	3G01342	08/02/73	05/21/73
CJ1213	2002	2002	5944	3G01481	11/10/73	09/18/73
NJ1263	2029	2037	5944	3G01863	03/07/74	11/01/73
LJ1291	3011	3013	5944	3G02050	01/21/74	10/29/73
FJ1596	2022	2027	5944	3G02632	02/06/74	11/05/73
SJ1220	2002	2002	5944	3G02970	10/22/73	09/11/73
GJ1192	1027	1027	5944	3G10018	10/24/73	09/07/73
WJ1206	2022	2027	5944	3G10521	03/01/74	11/26/73
RJ1307	1004	1005	5944	3G10518	12/11/73	UNKNOWN
FJ1350	6410	2510	5944	3G10865	11/08/73	09/05/73
MJ1149	3051	3055	5944	3G11141	10/31/73	09/05/73
LJ1323	1025	1025	5944	3G11270	02/27/74	UNKNOWN
LJ1112	3051	3055	5944	3G11328	11/09/73	09/07/73
BJ1147	1027	1027	5944	3G11740	11/07/73	09/05/73
GJ1250	3051	3055	5944	3G11792	12/01/73	09/18/73
FJ1128	3013	3015	5944	3G12671	12/10/73	10/02/73
SJ1306	1004	1005	5944	3G13434	02/12/74	10/29/73
AJ1278	2022	2027	5944	3G13595	02/08/74	11/02/73
SJ1325	2022	2027	5944	3G13979	03/20/74	12/17/73
CJ1304	2072	2027	5944	3G14805	03/19/74	11/21/73
SJ1295	1019	1021	5944	3G14882	02/06/74	11/05/73
AJ1309	1002	1017	5944	3G15060	01/08/74	10/29/73
SJ1297	3013	3015	5944	3G15496	03/15/74	11/01/73
RJ1384	2029	2037	5944	3G15592	04/10/74	11/02/73
RJ1414	2071	2027	5944	3G16313	03/13/74	11/26/73
SJ1360	2002	2002	5944	3G18532	03/04/74	12/20/73
HJ1427	1046	1001	5944	3G22348	05/17/74	02/06/74
KJ1305	1023	1023	5945	3T00256	09/13/73	09/20/73
CJ1436	3092	3041	5945	3T10506	02/22/74	11/12/73
SJ1145	2016	2018	5945	3T10990	09/18/73	07/20/73
DJ1426	1023	1023	5945	3T11212	10/24/73	07/26/73
CJ1396	1023	1023	5945	3T13332	12/10/73	08/24/73
KJ1252	3020	3026	5945	3T13838	01/07/74	09/20/73
KJ1108	2002	2002	5945	3T13896	11/08/73	08/29/73
HJ1109	2002	2002	5945	3T14018	11/23/73	09/11/73
TJ1186	2025	2031	5945	3T14580	12/20/73	10/31/73
BJ1524	3031	3041	5945	3T15475	06/05/74	12/26/73
SJ1343	3020	3026	5945	3T16134	01/31/74	11/07/73
JJ1344	3020	3026	5945	3T16222	02/09/74	12/07/73
DJ1249	1020	1021	5945	3T16301	01/06/74	11/20/73
NJ1333	3016	3020	5945	3T16494	02/04/74	12/05/73
TJ1443	1023	1023	5945	3T17710	04/10/74	12/28/73
MJ1387	1064	1026	5945	XX4559	03/27/73	01/04/73
PJ1398	1026	1026	5945	XX4563	02/12/73	12/27/72
MJ1397	1026	1026	5945	XX4568	02/05/73	01/04/73
HJ1408	1064	1026	5945	XX4576	02/08/73	01/04/73
GJ1105	1007	1008	5945	XX4580	02/12/73	01/05/73
WJ1399	1064	1026	5945	XX4586	03/21/73	01/03/73
CJ1388	1064	1026	5945	XX4587	03/28/71	01/03/73
SJ1386	1064	1026	5945	XX4663	03/20/73	01/05/73
WJ1390	1064	1026	5945	XX4678	01/08/73	12/14/72
GJ1407	1067	1026	5945	XX4681	01/04/73	12/12/72
TJ1404	1064	1026	5945	XX4682	01/04/73	12/14/72
MJ1377	1063	1026	5945	XX4683	01/18/73	12/14/72
HJ1378	1038	1026	5945	XX4684	01/29/73	12/18/72
HJ1389	1062	1026	5945	XX4685	01/15/73	12/14/72
GJ1374	1026	1026	5945	XX4686	01/08/73	12/14/72
GJ1400	1064	1026	5945	XX4688	03/27/73	12/14/72
HJ1401	1062	1026	5945	XX4689	01/03/73	12/14/72
SJ1375	1026	1026	5945	XX4690	01/24/73	12/14/72
MJ1376	1026	1026	5945	XX4694	01/08/73	12/14/72
YJ1403	1026	1026	5945	XX4695	01/10/73	12/14/72
GJ1405	1064	1026	5945	XX4696	01/17/73	12/14/72
BJ1402	1026	1026	5945	XX4698	02/05/73	12/12/72
TJ1106	1007	1008	5945	XX4872	03/15/73	01/09/73
HJ1279	1017	1019	5961	3A0045	07/05/73	05/04/73
TJ1226	3001	3001	5961	3A01599	09/13/73	06/28/73

APPENDIX IC. ITEMIZATION OF EXPLANTATIONS
(NUCLEAR POWERED)

Hospital Code	Physician Code	Patient Code	Serial Number	Reason For Explant	Status of Pulse Generator
				NUCLEAR POWERED	
H2003	D2004	G01034	3R00020	Wound separation/infection/lead displacement. Explant originally done to treat wound separation and infection; intent was to reimplant the generator using a new lead system. Generator eventually not reimplanted because of inability to achieve satisfactory position with a new lead system, and because it was felt that further observation of the patient's cardiac disease was indicated before other procedures to place an electrode were done.	Not returned to Medtronic; reimplanted in same hospital, by same physician in patient number T01160 (unit retained same serial number).
H2014	D2016	J01071	3R00085	Lead displacement. Six months post-implant because of initial endocardial lead displacement; upon myocardial lead insertion, excessive medical adhesive in the boot interfered with the connection and resulted in failure to capture. Generator, itself, was functioning normally.	Returned to Medtronic; 3/5/74.
H2017	D2020	S01017	3R00157	Patient expired 11/2/73 of causes unrelated to pacemaker.	Not returned to Medtronic; reimplanted in same hospital, by same physician; unit retained same serial number.
H2016	D2019	G01536	2R00105	Patient expired 12/24/72; cause unknown.	Returned to Medtronic 2/4/74 and sent back to hospital 5/23/74.
H3054	D3057	D01580	2R00191	Patient expired 4/17/73 of cardiovascular attack from clot in left ventricle.	Returned to Medtronic; 4/23/74.
H1007	D1008	G01527	2R00175	Patient expired; suicide.	Returned to Medtronic.
H2016	D2019	S01538	2R00068	Patient expired, cause unknown.	Returned to Medtronic.
H1023	D1023	W01097	3R00142	Poor R-wave sensing.	Unit not returned to Medtronic; retained by hospital.
H1028	D1028	H01062	3R00115	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.	Returned to Medtronic; 9/26/74.
H3006	D3008	G01453	3R00126	Patient expired; massive coronary; unrelated to pacemaker.	Unit not returned to Medtronic; retained by hospital.
H3007	D3009	M01364	4R00042	Patient expired; occlusion in right coronary artery due to arterio-sclerotic heart disease.	Returned to Medtronic.
H1026	D1026	J01324	3R00316	Patient expired 7/15/74, coronary occlusion due to arteriosclerosis.	Returned to Medtronic.
H3055	D3058	S01114	3R00145	Erosion wound with necrosis at pocket.	Unit not returned to Medtronic; retained by hospital.
H3022	D3029	C01526	2R00174	Patient expired 10/9/74. Death caused by peritonitis due to cancer of the lymph node system.	Unit not returned to Medtronic; retained by hospital.

APPENDIX ID. ITEMIZATION OF EXPLANTATIONS
(CHEMICALLY POWERED)

Hospital Code	Physician Code	Patient Code	Serial Number	Reason For Explant	Status of Pulse Generator
			CHEMICALLY POWERED		
H1027	D1027	W01190	3M02390	Unrelated to wound infection; pacemaker system removed because patient no longer needed it.	Generator and lead system were functioning normally at time of explant; unit not returned to Medtronic.
H1027	D1027	B01189	3M01739	Patient expired 9/26/73. Cardiorespiratory arrest probably due to acute pulmonary edema; patient had known diabetes mellitus.	Not explanted at time of patient's demise.
H1027	D1027	L01136	3M02490	Patient expired 12/17/73. Cause of death unknown. No autopsy done, though had known renal insufficiency and chronic brain syndrome.	Not explanted at time of patient's demise.
H2002	D2002	H01109	3T14018	Expired 1/3/74. Pulmonary embolus; cerebral infarction.	Not explanted at time of patient's demise.
H2002	D2002	K01108	3T13896	Expired 1/13/74. Myocardial infarction.	Not explanted.
H3055	D3055	L01112	3G11328	Expired 1/21/74 at home.	Not explanted.
H1028	D1028	L01315	2K22159	Patient expired 3/5/74 of causes unrelated to pacemaker.	Unit not returned to Medtronic.
H1004	D1005	R01367	3G10618	Patient expired 2/20/74 of causes unrelated to pacemaker.	Unit not returned to Medtronic.
H1026	D1026	M01376	XX4694	Expired. No information available.	Unit not returned to Medtronic.
H1008	D1008	F01045	3G01342	Expired. No information available.	Unit not returned to Medtronic.
H3051	D3055	T01199	2K24492	Pocket infection.	Unit returned to Medtronic.
H1064	D1026	C01388	XX4587	Expired. No information available.	Unit not returned to Medtronic.
H1064	D1026	S01386	XX4663	Expired. No information available. available.	Unit not returned to Medtronic.
H1029	D1028	A01163	2K04385	Elective replacement; 5/8/74.	Unit not returned to Medtronic.
H3001	D3001	D01228	3S01782	Expired 5/31/74; death resulted from cerebrovascular accident.	Unit not returned to Medtronic.
H1064	D1026	W01390	XX4678	Expired. No information available.	Unit not returned to Medtronic.
H1064	D1026	H01408	XX4576	Expired. No information available.	Unit not returned to Medtronic.
H1026	D1026	M01397	XX4568	Expired. No information available.	Unit not returned to Medtronic.
H1064	D1026	W01399	XX4586	Expired. No information available.	Unit not returned to Medtronic.
H3051	D3055	T01184	3K14318	Pulse generator malfunction.	Unit not returned to Medtronic.
H3040	D3050	G01203	3K13661	Pulse generator removed due to continual pain in pocket site.	Unit not returned to Medtronic.
H1023	D1023	B01356	3T13332	Patient expired 12/10/73 of congestive heart failure.	Unit not returned to Medtronic.
H1023	D1023	K01365	3T00256	Patient expired 11/1/73 of cerebrovascular attack.	Unit not returned to Medtronic.
H3051	D3055	L01112	3G11328	Expired 1/21/74. Cause unknown.	Unit not returned to Medtronic.
H3051	D3055	C01200	3K00719	Expired 6/9/74 of arteriosclerotic heart disease; congestive heart failure.	Unit not returned to Medtronic.
H2002	D2002	H01109	3T14018	Expired 1/15/74. Myocardial infarction.	Unit not returned to Medtronic.
H2002	D2002	K01108	3T13896	Expired 1/3/74 of stroke.	Unit not returned to Medtronic.