# Medtronic® Implantable Demand ISOTOPIC PULSE GENERATOR Laurens-Alcatel Model 9000

# Fifth Semi-Annual Clinical Evaluation Report To The UNITED STATES NUCLEAR REGULATORY COMMISSION

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Medtronic

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# INTRODUCTION

This is the fifth 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 fifth report, an attempt is made to point out changes since the previous report. There have been no significant changes in the general characteristics of the study. It is significant that there have been no nuclear cell failures, and that the random component failure rate continues to drop. It is also important to note that the accountability effort has become increasingly difficult. Twenty percent (20%) of the follow-up information reported was obtained via telephone, since routine data forms were not returned to Medtronic per the protocol agreement. In addition, implant information has not been submitted for twenty-three (23) of the nuclear pulse generators which are known to be implanted through patient registration sources.

## PATIENT POPULATION CHARACTERISTICS

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 consistent both for males and females, being 20 and 22 years, respectively.

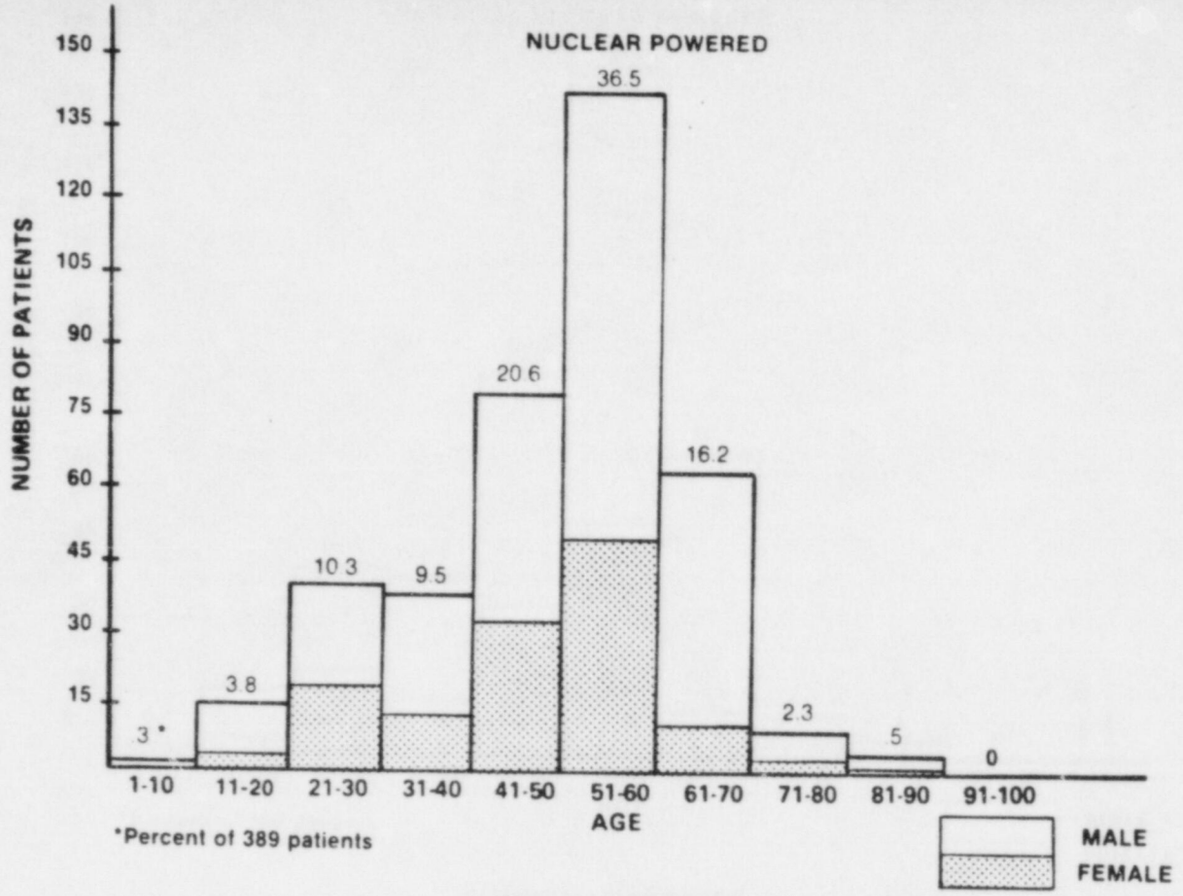
The combined age distributions of males and females for each of the two pacemaker types are graphically compared in Figure 1. It is noteworthy that the most frequent age bracket characterizing chemically powered pacemaker bearers is 71 to 80 years, whereas a typical nuclear pacemaker bearer is only 51 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 11-5-75)

| | NUCLEAR POWERED | | | CHEMICALLY POWERED (CONTROL GROUP) | | |
|---|---|---|---|---|---|---|
| Age | Male | Female | Total | Male | Female | Total |
| 1-10 | 1 | 0 | 1 | 2 | 1 | 3 |
| 11-20 | 12 | 3 | 15 | 2 | 0 | 2 |
| 21-30 | 21 | 19 | 40 | 2 | 1 | 3 |
| 31-40 | 24 | 13 | 37 | 1 | 3 | 4 |
| 41-50 | 47 | 33 | 80 | 4 | 4 | 8 |
| 51-60 | 92 | 50 | 142 | 28 | 12 | 40 |
| 61-70 | 53 | 10 | 63 | 53 | 25 | 78 |
| 71-80 | 6 | 3 | 9 | 61 | 42 | 103 |
| 81-90 | 1 | 1 | 2 | 37 | 13 | 50 |
| 91-100 | 0 | 0 | 0 | 4 | 2 | 6 |
| Total No. | 257 | 132 | 389 | 194 | 103 | 297 |
| Average Age | 50.2 | 47.2 | 49.2 | 70.2 | 69.2 | 69.8 |

[1]Age at Implant



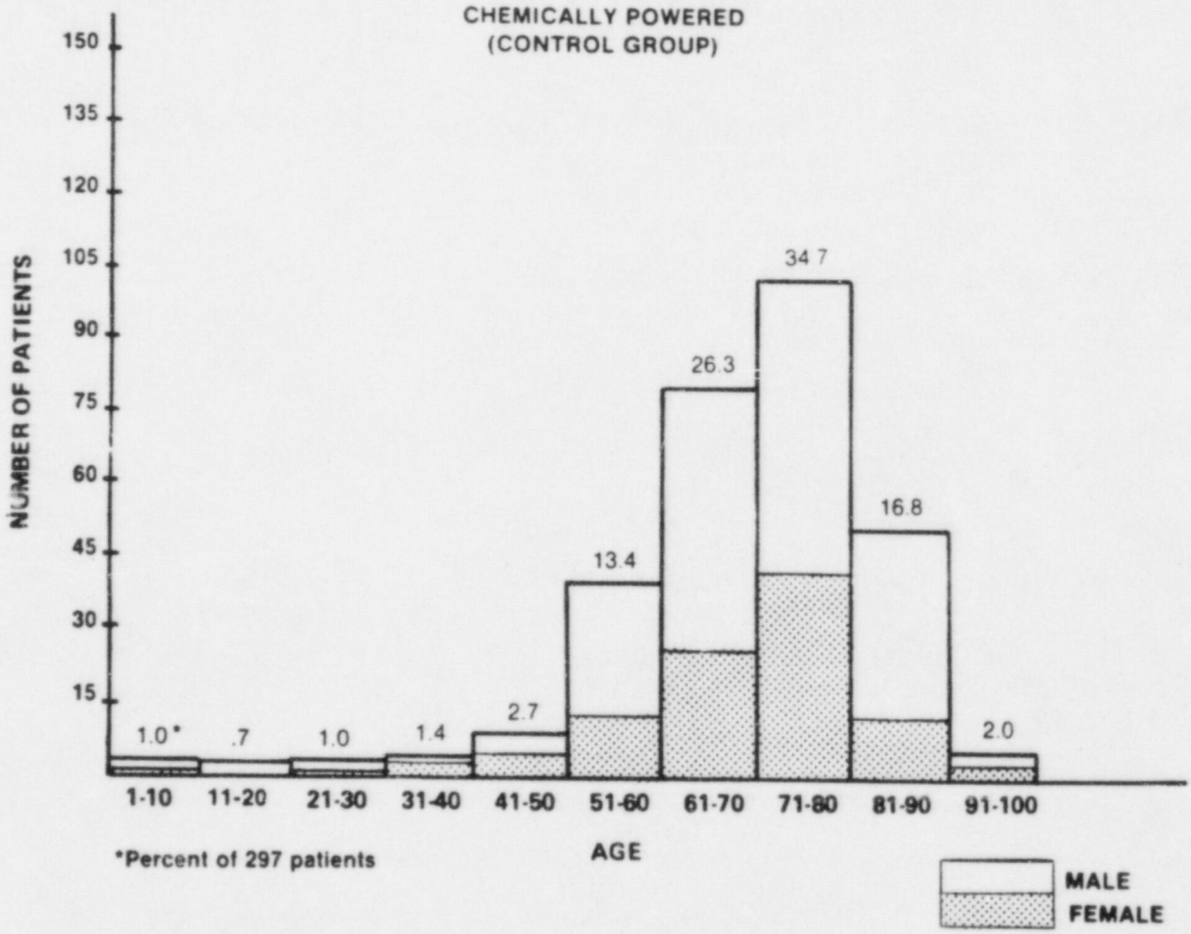




FIGURE 1. HISTORGRAMS OF PATIENT POPULATIONS BY AGE (TO 11-5-75)

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 data in Tables 2B and 2C indicates 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.[8] 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 11-5-75)

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

| Age | NUCLEAR POWERED 389 Implants | | | | | CHEMICALLY POWERED 297 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 | 11 | 26 | 20 | 20 | 77 | 0 | 2 | 2 | 3 | 7 |
| 41 - 60 | 6 | 10 | 87 | 119 | 222 | 1 | 0 | 10 | 37 | 48 |
| 61 - 80 | 0 | 0 | 29 | 43 | 72 | 0 | 1 | 56 | 124 | 181 |
| 81+ | 0 | 0 | 1 | 1 | 2 | 0 | 0 | 14 | 42 | 56 |
| TOTAL | 20 | 45 | 140 | 184 | 389 | 2 | 7 | 82 | 206 | 297 |
| % OF IMPLANTS | 5.1 | 11.6 | 47.3 | 36.0 | 100 | 0.7 | 2.4 | 69.3 | 27.6 | 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 (389 Implants) | | | | | | | | |
| 1 - 20 | 0 | 0 | 0 | 0 | 7 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| 21 - 40 | 4 | 3 | 0 | 2 | 30 | 16 | 1 | 0 | 0 | 2 | 1 | 0 | 3 | 20 |
| 41 - 60 | 85 | 14 | 11 | 11 | 15 | 8 | 17 | 0 | 1 | 3 | 0 | 0 | 3 | 47 |
| 61 - 80 | 43 | 7 | 5 | 1 | 0 | 3 | 5 | 0 | 0 | 1 | 1 | 0 | 2 | 6 |
| 81+ | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 133 | 25 | 16 | 14 | 52 | 30 | 23 | 0 | 1 | 6 | 2 | 0 | 9 | 74 |
| % OF IMPLANTS | 34.2 | 6.4 | 4.1 | 3.6 | 13.3 | 7.7 | 5.9 | | 0.2 | 1.5 | 0.5 | | 2.3 | 19.0 |
| | | | | | | CHEMICALLY POWERED (297 Implants) | | | | | | | | |
| 1 - 20 | 0 | 0 | 0 | 0 | 3 | 2 | 1 | 0 | 0 | [illegible] | 0 | 0 | 0 | 2 |
| 21 - 40 | 1 | 1 | 0 | 0 | 2 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 3 |
| 41 - 60 | 26 | 5 | 7 | 2 | 0 | 1 | 7 | 0 | 0 | 5 | 1 | 0 | 1 | 10 |
| 61 - 80 | 102 | 17 | 13 | 2 | 1 | 2 | 20 | 0 | 0 | 12 | 2 | 0 | 4 | 29 |
| 81+ | 36 | 2 | 4 | 0 | 0 | 0 | 5 | 0 | 0 | 2 | 0 | 0 | 1 | 4 |
| TOTAL | 165 | 25 | 24 | 4 | 6 | 5 | 34 | 0 | 0 | 20 | 3 | 0 | 6 | 48 |
| % OF IMPLANTS | 55.5 | 8.4 | 8.1 | 1.3 | 2.0 | 1.7 | 11.4 | | | 6.7 | 1.0 | | 2.0 | 16.2 |

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 (Drug Induced) | Other Disturbances: Digitalis Toxicity | Other Disturbances: Other Drug Idiosyncrasy |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **NUCLEAR POWERED (389 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 | 45 | 14 | 4 | 1 | 7 | 5 | 4 | 2 | 1 | 0 | 1 | 0 | 1 | 1 | 4 | 3 | 0 | 1 | 1 | 0 | 0 | 0 |
| 41 - 60 | 114 | 27 | 15 | 2 | 22 | 18 | 8 | 3 | 9 | 0 | 1 | 11 | 0 | 4 | 8 | 12 | 1 | 1 | 10 | 0 | 0 | 0 |
| 61 - 80 | 42 | 7 | 2 | 0 | 5 | 7 | 5 | 0 | 2 | 0 | 0 | 2 | 1 | 2 | 3 | 2 | 0 | 0 | 4 | 0 | 0 | 0 |
| 81+ | 2 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 216 | 48 | 21 | 3 | 36 | 31 | 18 | 6 | 12 | 0 | 2 | 13 | 2 | 7 | 15 | 17 | 1 | 2 | 15 | 0 | 0 | 0 |
| % OF IMPL. | 55.5 | 12.3 | 5.4 | 0.8 | 9.3 | 8.0 | 4.6 | 1.5 | 3.0 | 0 | 0.5 | 3.3 | 0.5 | 1.8 | 3.8 | 4.4 | 0.2 | 0.5 | 3.8 | | | |
| **CHEMICALLY POWERED (297 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 | 29 | 5 | 5 | 0 | 7 | 3 | 0 | 0 | 3 | 0 | 0 | 5 | 1 | 1 | 0 | 0 | 0 | 0 | 2 | 0 | 1 | 0 |
| 61 - 80 | 84 | 21 | 16 | 0 | 18 | 16 | 9 | 6 | 7 | 0 | 2 | 9 | 0 | 5 | 18 | 9 | 1 | 0 | 8 | 0 | 1 | 0 |
| 81+ | 34 | 3 | 5 | 0 | 4 | 6 | 4 | 1 | 4 | 0 | 0 | 5 | 0 | 1 | 3 | 3 | 1 | 0 | 1 | 0 | 1 | 0 |
| TOTAL | 154 | 29 | 27 | 0 | 30 | 26 | 14 | 7 | 14 | 0 | 2 | 19 | 1 | 7 | 21 | 13 | 2 | 0 | 11 | 0 | 3 | 0 |
| % OF IMPL. | 51.9 | 9.7 | 9.1 | | 10.1 | 8.8 | 4.7 | 2.3 | 4.7 | | 0.7 | 6.4 | 0.3 | 2.3 | 7.1 | 4.4 | 0.7 | | 3.7 | | 0.1 | |


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<br>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 |

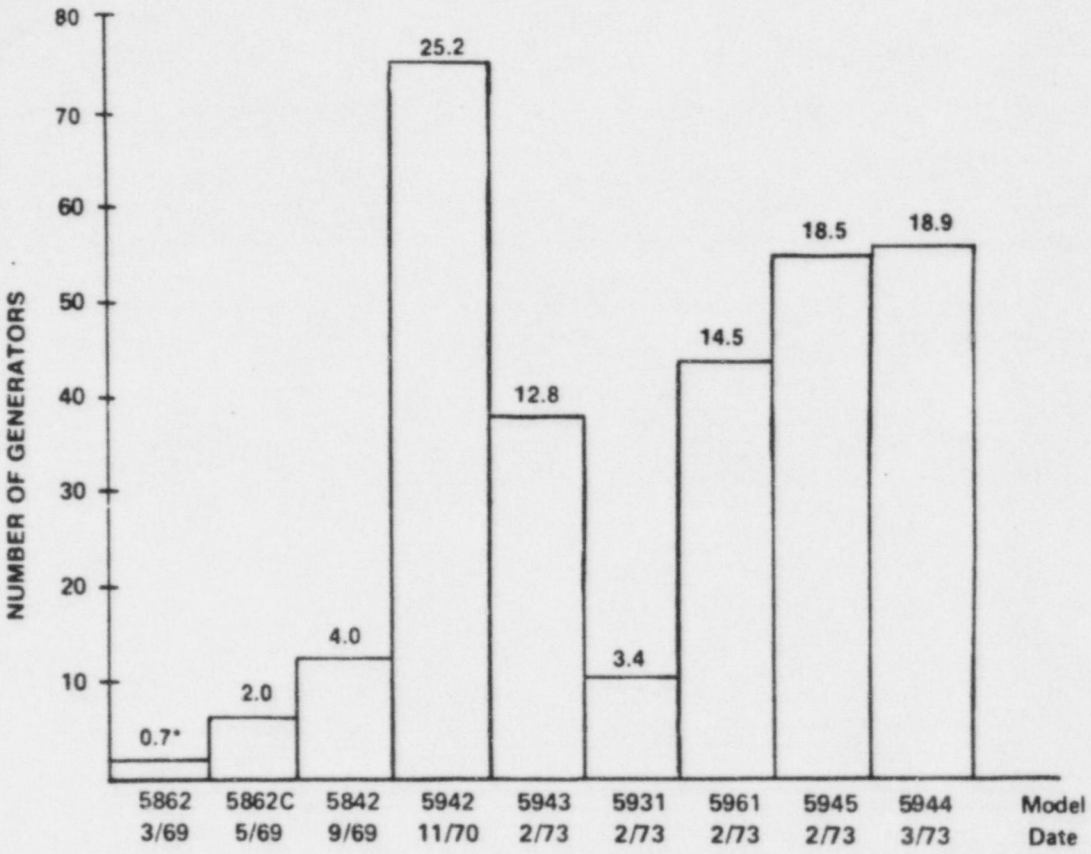
Physical

| | |
|---|---|
| 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 11-5-75)

| Model Number | Initial Production Date | Number Implanted |
|---|---|---|
| 5862 | 3/69 | 2 |
| 5862C | 5/69 | 6 |
| 5842 | 9/69 | 12 |
| 5942 | 11/70 | 75 |
| 5943 | 11/70 | 38 |
| 5931 | 2/73 | 10 |
| 5961 | 2/73 | 43 |
| 5945 | 2/73 | 55 |
| 5944 | 3/73 | 56 |
| TOTAL | | 297 |




*Percent of 297 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 November 5, 1975, three hundred and eighty-nine (389) Model 9000 isotopic pulse generators have been implanted in patients presently located within the United States (Table 5). Among the one hundred and twenty-two (122) physicians participating in the investigation, the numbers of isotopic units implanted per physician have ranged from zero to thirty-one (31).

During the same period, two hundred and ninety-seven (297) investigational controls have been submitted, with the number per physician varying from zero to forty-one (41). Seventy-seven (77) isotopic investigators have not as yet submitted controls, although one physician has supplied forty-one (41) investigational controls for his twenty-four (24) isotopic implants.

Numbers of complications per physician (Table 5B) range from zero to ten (10) 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 $\chi^2 = 3.92$ with one degree of freedom, indicat-

ing significance at the 5% level. The explanation for this is not clear, but is believed to be related to the fact that seventy-seven physicians have submitted no controls. In general, the follow-up reporting of the control group has been less frequent and not as comprehensive as that for the nuclear group. Explanted devices to date (Table 5A) consist of twenty-seven (27) isotopic pulse generators and sixty (60) chemically powered units.

There has been one pulse generator failure in the nuclear 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 11-5-75)

| | NUCLEAR POWERED | | | CHEMICALLY POWERED | | |
|---|---|---|---|---|---|---|
| Hospital Code | Implants | Explants[1] | Complications[2] | Implants | Explants[3] | Complications[2] |
| 1002 | 4 | 0 | 1 | 3 | 0 | 0 |
| 1003 | 6 | 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 | 2 | 1 | 0 | 0 | 0 | 0 |
| 1012 | 2 | 0 | 0 | 0 | 0 | 0 |
| 1013 | 1 | 0 | 0 | 0 | 0 | 0 |
| 1015 | 5 | 0 | 0 | 0 | 0 | 0 |
| 1016 | 2 | 0 | 0 | 2 | 0 | 0 |
| 1017 | 7 | 0 | 1 | 4 | 1 | 2 |
| 1018 | 17 | 0 | 5 | 24 | 4 | 4 |
| 1019 | 5 | 1 | 0 | 3 | 1 | 1 |
| 1020 | 0 | 0 | 0 | 1 | 1 | 0 |
| 1021 | 0 | 0 | 0 | 2 | 1 | 0 |
| 1022 | 2 | 0 | 0 | 0 | 0 | 0 |
| 1023 | 31 | 6 | 8 | 16 | 3 | 3 |
| 1024 | 4 | 0 | 4 | 0 | 0 | 0 |
| 1025 | 4 | 0 | 4 | 4 | 1 | 0 |
| 1026 | 6 | 1 | 10 | 7 | 2 | 2 |
| 1027 | 10 | 0 | 0 | 13 | 4 | 3 |
| 1028 | 4 | 1 | 2 | 7 | 1 | 1 |
| 1029 | 0 | 0 | 0 | 1 | 1 | 0 |
| 1030 | 2 | 0 | 0 | 1 | 0 | 0 |
| 1031 | 0 | 0 | 0 | 1 | 1 | 0 |
| 1032 | 1 | 0 | 1 | 0 | 0 | 0 |
| 1033 | 1 | 0 | 0 | 0 | 0 | 0 |
| 1035 | 4 | 0 | 1 | 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 | 2 | 0 | 0 | 0 |
| 1062 | 0 | 0 | 0 | 2 | 0 | 0 |
| 1063 | 0 | 0 | 0 | 1 | 0 | 1 |
| 1064 | 0 | 0 | 0 | 9 | 7 | 0 |
| 1065 | 0 | 0 | 0 | 3 | 0 | 0 |
| 1067 | 0 | 0 | 0 | 1 | 0 | 1 |
| 1071 | 3 | 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 | 10 | 0 | 0 | 15 | 3 | 0 |
| 2003 | 26 | 1 | 5 | 42 | 6 | 2 |
| 2004 | 2 | 0 | 0 | 0 | 1 | 0 |
| 2005 | 7 | 0 | 5 | 0 | 0 | 0 |
| 2006 | 5 | 0 | 0 | 0 | 0 | 0 |
| 2007 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2008 | 5 | 0 | 1 | 0 | 0 | 0 |
| 2010 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2011 | 9 | 0 | 0 | 0 | 0 | 0 |
| 2012 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2013 | 5 | 0 | 1 | 0 | 0 | 0 |
| 2014 | 6 | 1 | 1 | 0 | 0 | 0 |
| 2015 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2016 | 12 | 3 | 4 | 10 | 2 | 5 |
| 2017 | 4 | 1 | 0 | 4 | 0 | 0 |
| 2020 | 3 | 0 | 0 | 0 | 0 | 0 |
| 2022 | 3 | 0 | 1 | 19 | 1 | 6 |
| 2023 | 1 | 0 | 0 | 1 | 1 | 0 |
| 2024 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2025 | 1 | 0 | 0 | 3 | 1 | 0 |
| 2026 | 3 | 0 | 0 | 3 | 0 | 0 |
| 2027 | 5 | 0 | 2 | 0 | 0 | 0 |
| 2029 | 2 | 0 | 0 | 4 | 0 | 0 |
| 2031 | 3 | 0 | 0 | 0 | 0 | 0 |

[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 5A. - Continued

| Hospital Code | NUCLEAR POWERED | | | CHEMICALLY POWERED | | |
|---|---|---|---|---|---|---|
| | Implants | Explants[1] | Complications[2] | Implants | Explants[3] | Complications[2] |
| 2032 | 3 | 1 | 0 | 2 | 0 | 2 |
| 2034 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2069 | 2 | 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 | 1 | 5 | 1 | 1 | 0 |
| 2101 | 3 | 0 | 1 | 0 | 0 | 0 |
| 2102 | 1 | 0 | 1 | 0 | 0 | 0 |
| 2103 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2106 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3001 | 9 | 0 | 4 | 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 | 3 | 1 | 0 | 0 | 0 | 0 |
| 3008 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3011 | 1 | 1 | 0 | 6 | 0 | 3 |
| 3013 | 7 | 1 | 0 | 9 | 0 | 0 |
| 3015 | 3 | 0 | 0 | 0 | 0 | 0 |
| 3016 | 2 | 0 | 0 | 2 | 0 | 0 |
| 3018 | 2 | 0 | 0 | 0 | 0 | 0 |
| 3019 | 2 | 0 | 0 | 0 | 0 | 0 |
| 3020 | 5 | 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 | 4 | 0 | 1 | 1 | 0 | 0 |
| 3029 | 2 | 0 | 1 | 0 | 0 | 0 |
| 3031 | 1 | 0 | 0 | 1 | 0 | 0 |
| 3032 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3034 | 2 | 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 | 3 | 0 | 0 | 1 | 1 | 0 |
| 3039 | 4 | 0 | 0 | 1 | 0 | 0 |
| 3040 | 7 | 0 | 0 | 1 | 1 | 1 |
| 3041 | 0 | 0 | 0 | 1 | 1 | 0 |
| 3042 | 0 | 0 | 0 | 1 | 1 | 0 |
| 3043 | 0 | 0 | 0 | 1 | 0 | 0 |
| 3044 | 0 | 0 | 0 | 1 | 1 | 0 |
| 3045 | 0 | 0 | 0 | 1 | 1 | 0 |
| 3046 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3048 | 0 | 0 | 0 | 1 | 0 | 0 |
| 3050 | 2 | 0 | 0 | 1 | 0 | 0 |
| 3051 | 7 | 0 | 1 | 8 | 4 | 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 | 2 | 0 |
| 3056 | 0 | 0 | 0 | 1 | 1 | 0 |
| 3057 | 2 | 0 | 0 | 0 | 0 | 0 |
| 3058 | 4 | 0 | 1 | 0 | 0 | 0 |
| 3059 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3061 | 4 | 0 | 0 | 1 | 0 | 0 |
| 3074 | 1 | 1 | 0 | 0 | 0 | 0 |
| 3081 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3105 | 2 | 0 | 0 | 0 | 0 | 0 |
| 3106 | 3 | 0 | 0 | 0 | 0 | 0 |
| 3113 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3114 | 2 | 0 | 1 | 0 | 0 | 0 |
| 3115 | 1 | 0 | 1 | 0 | 0 | 0 |
| TOTAL | 389 | 27 | 81 | 297 | 60 | 44 |

[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 11-5-75)

| | 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 | 6 | 0 | 0 | 0 | 0 | 0 |
| 1005 | 1 | 0 | 0 | 2 | 1 | 0 |
| 1006 | 6 | 0 | 2 | 0 | 0 | 0 |
| 1007 | 2 | 0 | 0 | 0 | 0 | 0 |
| 1008 | 1 | 0 | 0 | 4 | 1 | 0 |
| 1012 | 1 | 1 | 1 | 0 | 0 | 0 |
| 1013 | 2 | 0 | 0 | 0 | 0 | 0 |
| 1014 | 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 | 7 | 0 | 1 | 4 | 1 | 3 |
| 1020 | 17 | 0 | 5 | 38 | 6 | 5 |
| 1021 | 5 | 1 | 0 | 6 | 3 | 1 |
| 1022 | 1 | 0 | 0 | 0 | 0 | 0 |
| 1023 | 31 | 6 | 8 | 16 | 3 | 3 |
| 1024 | 4 | 0 | 4 | 0 | 0 | 0 |
| 1025 | 4 | 0 | 4 | 4 | 1 | 0 |
| 1026 | 6 | 1 | 10 | 21 | 9 | 4 |
| 1027 | 8 | 0 | 0 | 13 | 4 | 3 |
| 1028 | 4 | 1 | 2 | 8 | 2 | 1 |
| 1029 | 2 | 0 | 0 | 1 | 0 | 0 |
| 1031 | 1 | 0 | 1 | 0 | 1 | 0 |
| 1034 | 4 | 0 | 1 | 0 | 0 | 0 |
| 1035 | 1 | 0 | 1 | 0 | 0 | 0 |
| 1063 | 1 | 0 | 0 | 0 | 0 | 0 |
| 1066 | 1 | 0 | 0 | 0 | 0 | 0 |
| 1083 | 3 | 0 | 0 | 0 | 0 | 0 |
| 1093 | 1 | 0 | 0 | 0 | 0 | 0 |
| 1096 | 0 | 0 | 0 | 1 | 0 | 0 |
| 2001 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2002 | 11 | 0 | 0 | 15 | 3 | 0 |
| 2003 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2004 | 24 | 1 | 5 | 41 | 6 | 2 |
| 2005 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2006 | 7 | 0 | 5 | 0 | 0 | 0 |
| 2007 | 5 | 0 | 0 | 0 | 0 | 0 |
| 2008 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2009 | 5 | 0 | 1 | 0 | 0 | 0 |
| 2011 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2012 | 9 | 0 | 0 | 0 | 0 | 0 |
| 2013 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2014 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2015 | 5 | 0 | 1 | 0 | 0 | 0 |
| 2016 | 6 | 1 | 1 | 0 | 0 | 0 |
| 2017 | 1 | 0 | 2 | 0 | 0 | 0 |
| 2018 | 1 | 1 | 1 | 2 | 1 | 3 |
| 2019 | 10 | 3 | 3 | 8 | 1 | 1 |
| 2020 | 4 | 1 | 0 | 4 | 0 | 0 |
| 2022 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2023 | 2 | 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 | 1 | 0 |
| 2030 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2031 | 1 | 0 | 0 | 3 | 1 | 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 | 2 | 0 | 0 | 0 |
| 2037 | 2 | 0 | 0 | 4 | 0 | 0 |
| 2039 | 3 | 0 | 0 | 0 | 0 | 0 |
| 2040 | 3 | 1 | 0 | 2 | 0 | 2 |
| 2042 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2116 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2117 | 1 | 1 | 3 | 0 | 0 | 0 |
| 2147 | 2 | 0 | 0 | 0 | 0 | 0 |
| 2148 | 3 | 0 | 1 | 0 | 0 | 0 |
| 2150 | 1 | 0 | 0 | 0 | 0 | 0 |
| 2152 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3001 | 9 | 1 | 4 | 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 | 3 | 1 | 0 | 0 | 0 | 0 |
| 3010 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3013 | 1 | 0 | 0 | 6 | 0 | 3 |
| 3015 | 6 | 1 | 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 | 3 | 0 | 0 | 0 | 0 | 0 |
| 3022 | 2 | 0 | 0 | 0 | 0 | 0 |
| 3023 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3024 | 0 | 0 | 0 | 1 | 0 | 0 |
| 3025 | 2 | 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 | 1 | 0 | 0 | 0 |
| 3041 | 3 | 0 | 0 | 3 | 0 | 0 |
| 3042 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3044 | 2 | 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 | 3 | 0 | 0 | 1 | 0 | 0 |
| 3049 | 2 | 0 | 0 | 0 | 1 | 0 |
| 3050 | 7 | 0 | 0 | 6 | 5 | 1 |
| 3051 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3054 | 3 | 0 | 0 | 1 | 0 | 0 |
| 3055 | 8 | 1 | 1 | 8 | 5 | 1 |
| 3056 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3057 | 3 | 1 | 0 | 0 | 0 | 0 |
| 3058 | 4 | 1 | 4 | 8 | 2 | 0 |
| 3059 | 3 | 0 | 0 | 0 | 0 | 0 |
| 3060 | 4 | 0 | 1 | 0 | 0 | 0 |
| 3061 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3091 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3103 | 2 | 0 | 0 | 0 | 0 | 0 |
| 3116 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3117 | 1 | 0 | 1 | 0 | 0 | 0 |
| 3119 | 1 | 0 | 1 | 0 | 0 | 0 |
| 3120 | 1 | 0 | 0 | 0 | 0 | 0 |
| 3124 | 1 | 0 | 0 | 0 | 0 | 0 |
| TOTAL | 389 | 27 | 82 | 297 | 60 | 44 |

[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.

This revised quality assurance procedure has been incorporated into the normal manufacturing procedure. The corroded unit had been implanted for twelve (12) months before it was explanted.

Among the group of chemically powered control units, there were two failures. One 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) pulses per minute due to a leaky capacitor in the timing circuit. The other was a premature battery failure at fifteen (15) months due to an internal short in one of the cells.

Table 6 displays the number of implants, explants, and complications in terms of pacemaker-months, or more precisely, months since implant either to November 5, 1975, or to the date of explantation. The number of device-months (Table 6) accumulated to date in the isotopic group is 7,188 after allowances for explants; whereas the comparable figure in the control group is 6,771. The upper 95% confidence limits on the random failure rates in each group are 0.07% per month and 0.09% per month, respectively. These figures have improved since the previous report, (0.09 and 0.10% per month) and compare favorably to the 0.15% per month random failure rate adopted as the standard of comparison (Medtronic Clinical Investigation Plan dated March 21, 1973)[6]. At the best estimate or 50% confidence level, the random component failure rates for these same samples are 0.03% per month for the isotopic group and 0.04% per month for the control group.

NUMBER OF IMPLANTATIONS, EXPLANTATIONS, AND ASSOCIATED COMPLICATIONS BY MONTHS SINCE IMPLANTATION (TO 11-5-75)

| Months in Patient | NUCLEAR POWERED | | | CHEMICALLY POWERED (CONTROL GROUP) | | |
|---|---|---|---|---|---|---|
| | Implants[1] | Explants[2] | Complications[3] | Implants[1] | Explants[2] | Complications[3] |
| 0 | 0 | 1 | 16 | 0 | 4 | 17 |
| 1 | 2 | 3 | 7 | 2 | 4 | 5 |
| 2 | 5 | 2 | 4 | 5 | 5 | 1 |
| 3 | 5 | 3 | 6 | 0 | 0 | 3 |
| 4 | 12 | 2 | 4 | 2 | 3 | 1 |
| 5 | 8 | 0 | 3 | 5 | 1 | 1 |
| 6 | 19 | 1 | 3 | 4 | 2 | 0 |
| 7 | 19 | 2 | 10 | 4 | 1 | 1 |
| 8 | 16 | 2 | 3 | 2 | 1 | 0 |
| 9 | 5 | 0 | 2 | 1 | 3 | 2 |
| 10 | 11 | 0 | 0 | 1 | 4 | 3 |
| 11 | 4 | 1 | 3 | 2 | 4 | 0 |
| 12 | 4 | 2 | 2 | 2 | 2 | 1 |
| 13 | 3 | 0 | 2 | 5 | 3 | 1 |
| 14 | 6 | 0 | 1 | 1 | 0 | 0 |
| 15 | 5 | 2 | 0 | 7 | 0 | 0 |
| 16 | 8 | 0 | 1 | 1 | 0 | 0 |
| 17 | 18 | 3 | 1 | 6 | 0 | 1 |
| 18 | 19 | 1 | 4 | 5 | 1 | 1 |
| 19 | 22 | 1 | 0 | 14 | 5 | 2 |
| 20 | 18 | 1 | 0 | 19 | 2 | 0 |
| 21 | 16 | 0 | 1 | 16 | 0 | 0 |
| 22 | 16 | 0 | 6 | 21 | 1 | 1 |
| 23 | 19 | 1 | 0 | 23 | 3 | 1 |
| 24 | 22 | 1 | 2 | 21 | 6 | 0 |
| 25 | 23 | 0 | 0 | 28 | 1 | 1 |
| 26 | 21 | 0 | 0 | 10 | 1 | 0 |
| 27 | 16 | 0 | 0 | 25 | 1 | 0 |
| 28 | 16 | 0 | 0 | 7 | 0 | 1 |
| 29 | 5 | 0 | 0 | 8 | 0 | 0 |
| 30 | 1 | 0 | 0 | 6 | 1 | 0 |
| 31 | 3 | 0 | 0 | 8 | 1 | 0 |
| 32 | 5 | 0 | 1 | 8 | 0 | 0 |
| 33 | 1 | 0 | 0 | 15 | 0 | 0 |
| 34 | 1 | 0 | 0 | 5 | 0 | 0 |
| 35 | 5 | 0 | 0 | 1 | 0 | 0 |
| 36 | 2 | 0 | 0 | 1 | 0 | 0 |
| 37 | 3 | 0 | 0 | 0 | 0 | 0 |
| 38 | 3 | 0 | 0 | 0 | 0 | 0 |
| 39 | 2 | 0 | 0 | 2 | 0 | 0 |
| 42 | 0 | 0 | 0 | 1 | 0 | 0 |
| 51 | 0 | 0 | 0 | 1 | 0 | 0 |
| TOTAL | 389 | 27 | 82 | 297 | 60 | 44 |
| Device Months | 7,188 | | | 6,771 | | |

[1]Months in patient are computed from date of implant to November 5, 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 more than seven hundred implants of the Model 9000 outside of the United States, there has been only one explant due to pulse generator malfunction, resulting from a random failure of an electronic component. Using the more than 13,000 device-months accumulated, the upper 95% confidence limit on the underlying random failure rate for this non-U.S. group is 0.04% per month, well below the standard of comparison. By combining all Model 9000 units implanted worldwide, we arrive at a random failure rate of 0.03% 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

(12 versus 6). When subjected to a chi-squared test of significance (yielding $\chi^2 = 0.74$ with one degree of freedom), this difference is found to be not statistically significant.

Among the ten (10) generators reported to have sensing problems in the nuclear group, five (5) may be attributed to the generator and five (5) to the lead system. In all cases, analysis revealed that the pulse generators were performing within their specifications.

In the nuclear group, among fifty-four (54) units there were eighty-two (82) complications, while in the chemical group, there were forty-four (44) complications. This finding is of uncertain significance, but may be related to the fact that information received for the control group has not been as regular nor as comprehensive as that for the nuclear 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 11-5-75)

| 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 |
| 2R00223 | 3001 | 3001 | O01102 | 11/29/73 | 05/08/75 | 18 |
| 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 |
| 3R00021 | 1060 | 1006 | P01003 | 07/06/73 | 05/01/75 | 21 |
| 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 | G01001 | 07/16/73 | 10/16/73 | 3 |
| 3R00073 | 1028 | 1028 | G01001 | 07/16/73 | 01/15/75 | 18 |
| 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 |
| 3R00126 | 2005 | 2006 | C01050 | 09/12/73 | 07/17/75 | 22 |
| 3R00126 | 2005 | 2006 | C01050 | 09/12/73 | 07/30/75 | 22 |
| 3R00126 | 2005 | 2006 | C01050 | 09/12/73 | 07/30/75 | 22 |
| 3R00126 | 2005 | 2006 | C01050 | 09/12/73 | 07/31/75 | 22 |
| 3R00126 | 2005 | 2006 | C01050 | 09/12/73 | 08/05/75 | 22 |
| 3R00133 | 1023 | 1023 | C01241 | 09/21/73 | 08/23/75 | 24 |
| 3R00133 | 1023 | 1023 | C01241 | 09/21/73 | 08/29/75 | 24 |
| 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 |

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 |
| Probable thrombosis subclavian vein | No treatment | Yes | Yes | 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 |
| Lead fracture | System converted to unipolar | Yes | No | Yes |
| 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 |
| Muscle stimulation | No treatment | Yes | Yes | 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 |
| Loss of capture/intermittent failure to sense/lead fracture | System converted to unipolar | Yes | No | Yes |
| Loss of capture | Indifferent lead repositioned | Yes | No | Yes |
| Hematoma in pocket | Pocket evacuated | Yes | Yes | Yes |
| Diaphragmatic stimulation | Observation | Yes | Yes | Yes |
| Loss of capture | Reimplanted pulse generator in new pocket/implanted new lead | Yes | Yes | Yes |
| Complete loss of capture/fractured lead | System converted to unipolar | Yes | No | Yes |
| Lead dislodged by suction apparatus during heart bypass surgery. Problem not noticed since patient not pacemaker dependent. | New lead implanted | Yes | No | Yes |
| Lead disconnected | Reconnected | Yes | No | No |
| Fail to sense | Lead replaced | Yes | Yes | No |
| Necrosis of pocket | Explanted | No | Yes | No |
| Bipolar lead fracture | System converted to unipolar | 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 |

TABLE 7A.

| Serial Number | Hospital Code | Physician Code | Patient Code | Implant Date | Complication Date | Months In Patient[2] |
|---|---|---|---|---|---|---|
| 3R00233 | 1026 | 1026 | A01103 | 11/06/73 | 04/09/75 | 16 |
| 3R00233 | 1026 | 1026 | A01103 | 11/06/73 | 08/06/75 | 32 |
| 3R00272 | 2027 | 2033 | M01176 | 01/16/74 | 08/01/75 | 7 |
| 3R00272 | 2027 | 2033 | M01176 | 01/16/74 | 08/08/75 | 7 |
| 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 |
| 3R00283 | 1026 | 1026 | K01230 | 01/22/74 | 06/25/75 | 18 |
| 3R00288 | 2080 | 2117 | L01581 | 09/04/74 | 09/05/74 | 0 |
| 3R00288 | 2080 | 2117 | L01581 | 09/04/74 | 09/05/74 | 0 |
| 3R00288 | 2080 | 2117 | L01581 | 09/04/74 | 03/25/75 | 7 |
| 3R00288 | 2080 | 2117 | L01581 | 09/04/74 | 03/25/75 | 7 |
| 3R00288 | 2080 | 2117 | L01581 | 09/04/74 | 09/29/75 | 13 |
| 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 | 1032 | 1031 | C01351 | 05/13/74 | 05/13/74 | 0 |
| 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 |
| 3R00338 | 1023 | 1023 | C01307 | 05/24/74 | 10/30/75 | 6 |
| 4R00024 | 1023 | 1023 | A01679 | 07/01/74 | 03/14/75 | 8 |
| 4R00035 | 1018 | 1020 | C01819 | 10/02/74 | 04/21/75 | 7 |
| 4R00035 | 1018 | 1020 | C01819 | 10/02/74 | 05/05/75 | 7 |
| 4R00037 | 1026 | 1026 | G01396 | 07/02/74 | 07/02/74 | 0 |
| 4R00037 | 1026 | 1026 | G01396 | 07/02/74 | 06/12/75 | 11 |
| 4R00037 | 1026 | 1026 | G01396 | 07/02/74 | 10/01/75 | 3 |
| 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 |
| 4R00091 | 2013 | 2015 | W02528 | 02/26/75 | 05/01/75 | 3 |
| 4R00097 | 2102 | 1035 | W02444 | 02/13/75 | 08/06/75 | 7 |
| 4R00146 | 3029 | 3039 | -- | 03/27/75 | 05/01/75 | 1 |
| 4R00188 | 1023 | 1023 | G02514 | 03/11/75 | 03/14/75 | 0 |
| 4R00208 | 1035 | 1034 | H02515 | 03/13/75 | 07/25/75 | 5 |
| 4R00235 | 3114 | 3117 | A02622 | 04/10/75 | 04/11/75 | 0 |
| 4R00291 | 1017 | 1019 | B02725 | 05/01/75 | 05/02/75 | 0 |
| 4R00297 | 3115 | 3119 | S02758 | 06/10/75 | 06/22/75 | 0 |
| 4R00337 | 2016 | 2019 | M02636 | 04/21/75 | 10/07/75 | 5 |
| 4R00353 | 2101 | 2148 | T02735 | 05/26/75 | 06/24/75 | 1 |

TABLE 7A. - Continued

| Complication | Treatment | Lead Related[3] | Pulse Generator Related[3] | Surgery Related[3] |
|---|---|---|---|---|
| Muscle inhibition | No treatment | Yes | Yes | Yes |
| Muscle stimulation/muscle inhibition | No treatment | Yes | Yes | Yes |
| Intermittent loss of capture/failure to sense/fractured lead | New lead implanted | Yes | No | Yes |
| Seroma/infection | Pulse generator removed, re-sterilized and reimplanted on 08-13-75 | Yes | Yes | Yes |
| 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 |
| Muscle stimulation | No treatment | Yes | Yes | Yes |
| Failure to sense | New lead inserted 9/8/74 | Yes | Yes | No |
| Intermittent sensing | System converted to unipolar | Yes | Yes | Yes |
| Inappropriate sensing | None | Yes | Yes | No |
| Improper sensing | No treatment | Yes | Yes | Yes |
| Continuous problem with sensing | Explanted | No | 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 |
| Tachycardia during procedure | $O_2$/temporarily stopped procedure | No | No | 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 |
| Muscle stimulation (unipolar system) | Unit explanted | Yes | Yes | 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 |
| Failure to sense/repeated lead dislodgement | Implanted new leads/moved pulse generator to new pocket | Yes | No | Yes |
| Muscle stimulation | None | Yes | Yes | Yes |
| Muscle stimulation | No treatment | Yes | Yes | Yes |
| Muscle stimulation | No treatment | Yes | Yes | Yes |
| Muscle inhibition | None | Yes | Yes | Yes |
| Muscle inhibition | None | Yes | Yes | Yes |
| Muscle stimulation | None | Yes | Yes | Yes |
| Pulmonary embolus | Anticoagulants | Yes | Yes | Yes |
| Soreness in vicinity of pocket | No treatment | Yes | Yes | Yes |
| Infection | Explanted | Yes | Yes | Yes |
| Inadequate sensing/increased threshold | Explanted | Yes | Yes | Yes |
| Migration of pulse generator | No treatment | No | Yes | Yes |
| Unsatisfactory sensing and pacing | Lead explanted/former lead system utilized | Yes | No | Yes |
| Hematoma | Observation | Yes | Yes | Yes |
| Post-pericardiotomy syndrome | Rest, steroids, surgical pericardial aspiration | No | No | Yes |
| Muscle stimulation | No treatment | Yes | Yes | Yes |
| Seroma | Observation | Yes | Yes | Yes |

[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. ITEMIZATION OF COMPLICATIONS AND MODES OF TREATMENT[1] FOR THE CONTROL GROUP (TO 11/5/75)

| 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 |
| 3A00298 | 2003 | 2004 | H02874 | 06/04/73 | 10/23/74 | 17 |
| 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 |
| 3G02272 | 1018 | 1020 | T02343 | 02/22/74 | 08/04/75 | 18 |
| 3G02978 | 1095 | 1020 | P02358 | 01/11/74 | 01/11/74 | 0 |
| 3G10521 | 2022 | 2027 | V01286 | 03/01/74 | 03/26/74 | 1 |
| 3G10553 | 1018 | 1020 | K02354 | 12/23/73 | 07/10/75 | 19 |
| 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 |
| 3G25480 | 1018 | 1020 | D02362 | 07/16/74 | 05/14/75 | 10 |
| 3G25480 | 1018 | 1020 | D02362 | 07/16/74 | 07/08/75 | 12 |
| 3G33190 | 2003 | 2004 | F02532 | 03/12/75 | 03/12/75 | 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 |
| 3L03892 | 2016 | 2019 | S01143 | 07/12/73 | 02/05/75 | 19 |
| 3L03892 | 2016 | 2019 | S01143 | 02/27/73 | 02/13/75 | 24 |

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 |
| Failure to capture/lead defect | New lead implanted | Yes | No | No |
| 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 |
| Erosion of generator | Surgical and medical treatment in pocket area | No | Yes | No |
| Lead displaced | Repositioned lead | Yes | No | Yes |
| Ventricular perforation | New leads placed | Yes | No | Yes |
| Pocket infection | Explanted | No | Yes | 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 |
| Lead eroded through skin (clavicular region) | Antibiotics applied | Yes | No | Yes |
| Erosion of generator | Surgical closure | No | Yes | No |
| Lead displacement | Reposition lead | Yes | 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 |
| Infected electrode site | Scheduled for explant | Yes | No | No |
| Erosion of electrode | Explanted generator and lead | Yes | No | No |

TABLE 7B

| Serial Number | Hospital Code | Physician Code | Patient Code | Implant Date | Complication Date | Months In Patient[2] |
|---|---|---|---|---|---|---|
| 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 |
| 3S01702 | 3001 | 3001 | D01228 | 08/03/73 | 09/18/73 | 1 |
| 3T17710 | 1023 | 1023 | T01443 | 04/10/74 | 04/10/74 | 0 |
| 3T17710 | 1023 | 1023 | T01443 | 04/10/74 | 11/18/74 | 7 |
| 3T17110 | 1023 | 1023 | T01443 | 04/10/74 | 02/13/75 | 10 |
| XX4681 | 1067 | 1026 | G01407 | 01/04/73 | 01/22/73 | 1 |
| XX4683 | 1063 | 1026 | M01377 | 01/18/73 | 03/26/75 | 26 |
| XX4695 | 1026 | 1026 | Y01403 | 01/10/73 | 12/10/74 | 23 |
| XX4695 | 1026 | 1026 | Y01403 | 01/10/73 | 05/07/75 | 28 |

[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] |
|---|---|---|---|---|
| Muscle twitch/electrode perforation | Lead respositioned | 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 |
| Loss of capture/exit block | Explanted | Yes | No | No |
| Erosion of electrode | Generator and lead explanted | Yes | No | Yes |
| Exit block, loss capture and failure to sense (dislocated lead) | Lead repositioned | Yes | No | Yes |
| Muscle inhibition | None | Yes | Yes | Yes |
| Muscle inhibition | None | Yes | Yes | Yes |
| Muscle inhibition | None | Yes | Yes | Yes |

Within the isotopic group of patients, there are twenty-two (22) leads on which no information can be obtained, and thirteen (13) 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 nearly fourteen (14) years old and is still functioning. There have been only ten (10) 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 4:1.

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 been a contributing factor in at least one instance of sensing difficulty.

TABLE 8. NUMBERS OF LEADS ON CURRENTLY FUNCTIONING PULSE GENERATORS BY LEAD TYPE AND MONTHS SINCE LEAD IMPLANTATION (TO 11-5-75)

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

(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 | 4 | 5 | | | | | 1 | 1 |
| 57 | | | | 4 | 1 | 5 | | | | 1 | | 1 |
| 58 | | 1 | | 1 | | 2 | | | | | | 0 |
| 59 | | | | | 1 | 1 | | 1 | | 2 | | 3 |
| 60 | | | | 2 | | 2 | | | | 1 | | 1 |
| 61 | | | | | | 0 | | | | | 1 | 1 |
| 62 | | | | 1 | 1 | 2 | | | | 1 | 1 | 2 |
| 63 | | | | 1 | 1 | 2 | | | | | | 0 |
| 64 | | | | 1 | 2 | 3 | | | | | 1 | 1 |
| 65 | | | | 1 | 2 | 3 | | | | | | 0 |
| 66 | | 1 | | | | 1 | | | | | | 0 |
| 67 | | 1 | | | 1 | 2 | | | | | 1 | 1 |
| 68 | | | | | | 0 | | | | | 1 | 1 |
| 69 | | | | 2 | | 2 | | | | | 1 | 1 |
| 70 | | | | 2 | 1 | 3 | | | | 1 | 1 | 2 |
| 71 | | | | 1 | | 1 | | | | 1 | | 1 |
| 72 | | | | 1 | 1 | 2 | | | | | | 0 |
| 73 | | 1 | | | 1 | 2 | | | | | | 0 |
| 74 | | | | 1 | | 1 | | | | | 1 | 1 |
| 75 | | | | | 3 | 3 | | | | | | 0 |
| 76 | | | | 1 | | 1 | | | | | | 0 |
| 77 | | | | | | 0 | | | | | 1 | 1 |
| 78 | | | | | | 0 | | | | | 1 | 1 |
| 79 | | | | | 2 | 2 | | | | | | 0 |
| 80 | 1 | | | | 1 | 2 | | | | 1 | 1 | 2 |
| 81 | | | | 1 | | 1 | | | | | 1 | 1 |
| 82 | | | | 1 | | 1 | | | | | | 0 |
| 83 | | | | | | 0 | | | | | | 0 |
| 84 | | | | | | 0 | | | | 2 | | 2 |
| 85 | | 1 | | 1 | | 2 | | | | | | 0 |
| 86 | | | | | 1 | 1 | | | | | | 0 |
| 87 | | | | 2 | | 2 | | | | 1 | | 1 |
| 88 | | | | | 1 | 1 | | | | | | 0 |
| 89 | | | | | | 0 | | | | | | 0 |
| 90 | | | | 1 | | 1 | | | | | | 0 |
| 91 | | | | | | 0 | | | | | | 0 |
| 92 | | | | | | 0 | | | | | | 0 |
| 93 | | | | | | 0 | | | | | | 0 |
| 94 | | | | | | 0 | | | | | | 0 |
| 95 | | | | | | 0 | | | | | | 0 |
| 96 | | | | | | 0 | | | | | | 0 |
| 97 | | | | | 1 | 1 | | | | | | 0 |
| 98 | | | | | | 0 | | | | | | 0 |
| 99 | | | | | | 0 | | | | | | 0 |
| 100 | | | | | 1 | 1 | | | | | | 0 |
| 105 | | | | | 1 | 1 | | | | | | 0 |
| 107 | | | | | | 0 | | | | | 1 | 1 |
| 108 | | | | | | 0 | | | | | 1 | 1 |
| 109 | | 1 | | | | 1 | | | | | | 0 |
| 113 | | 1 | | | | 1 | | | | | | 0 |
| 115 | | | | 1 | | 1 | | | | | | 0 |
| 119 | | 1 | | | | 1 | | | | | | 0 |
| 124 | | | | | 1 | 1 | | | | | | 0 |
| 128 | | | | | 1 | 1 | | | | | | 0 |
| 137 | | | | | 1 | 1 | | | | | | 0 |
| 144 | | | | | 1 | 1 | | | | | | 0 |
| 151 | | 1 | | | | 1 | | | | | | 0 |
| 152 | | | | | 1 | 1 | | | | | | 0 |
| 167 | | | | | 1 | 1 | | | | | | 0 |
| Total | 19 | 103 | 16 | 140 | 89 | 367 | 10 | 34 | 75 | 104 | 61 | 284 |
| Lead Months | 510 | 2,934 | 333 | 5,081 | 4,961 | 13,819 | 228 | 969 | 1,597 | 3,483 | 2,840 | 9,117 |

## 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. It is, however, becoming increasingly difficult to retrieve, on a regular basis, information as to the whereabouts and performance of the generators.

The addition to the study of sixty-five (65) nuclear units, and forty-two (42) 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 0.03% 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 some difference noted 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 fifth 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.

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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.

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.

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.

POST-PERICARDIOTOMY SYNDROME: delayed pericardial or pleural reaction following opening of the pericardium, characterized by fever, chest pain, and signs of pleural and/or pericardial inflammation.

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 9000 NUCLEAR POWERED PULSE GENERATORS (TO 11-5-75)

| 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 | F01594 | 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 | F01534 | 2016 | 2019 | 08/28/72 | 06/27/72 |
| 2R00055 | 9000 | D01164 | 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 | R01598 | 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 | D01580 | 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 | R01308 | 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 | B01539 | 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 | T01150 | 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 | F01084 | 2016 | 2019 | 07/01/73 | 04/02/73 |
| 3R00024 | 9000 | H01069 | 1027 | 1027 | 07/11/73 | 04/02/73 |
| 3R00025 | 9000 | K01007 | 1060 | 1006 | 08/08/73 | 04/02/73 |
| 3R00026 | 9000 | H01068 | 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 |
| 3R00034 | 9000 | C01088 | 3051 | 3055 | 07/09/73 | 05/01/73 |
| 3R00036 | 9000 | F01079 | 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 |

## APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 11-5-75)

| | SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|---|
| | 3R00052 | 9000 | S01317 | 1002 | 1002 | 11/28/73 | 05/16/73 |
| | 3R00055 | 9000 | W01318 | 1060 | 1006 | 04/08/74 | 05/16/73 |
| | 3P00061 | 9000 | Y01064 | 1027 | 1027 | 09/07/73 | 05/14/73 |
| | 3R00062 | 9000 | N01104 | 2020 | 2025 | 07/30/73 | 05/14/74 |
| | 3R00064 | 9000 | G01039 | 1018 | 1020 | 07/16/73 | 05/29/73 |
| | 3R00069 | 9000 | F01158 | 2025 | 2031 | 11/05/73 | 05/29/73 |
| | 3R00070 | 9000 | L01577 | 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 | N01165 | 1023 | 1023 | 08/03/73 | 05/29/73 |
| | 3R00078 | 9000 | F01074 | 2011 | 2012 | 08/07/73 | 05/29/73 |
| | 3R00079 | 9000 | C01096 | 1016 | 1018 | 12/28/73 | 05/29/73 |
| | 3R00081 | 9000 | N01320 | 1002 | 1017 | 11/28/73 | 05/30/73 |
| ** | 3R00085 | 9000 | D01321 | 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 |
| | 3R00088 | 9000 | B01256 | 2002 | 2002 | 01/31/74 | / 01/ |
| | 3R00090 | 9000 | F01040 | 1018 | 1020 | 11/05/73 | 06/14/73 |
| | 3R00091 | 9000 | J01004 | 1023 | 1023 | 09/12/73 | 06/14/73 |
| * | 3R00092 | 9000 | B01173 | 1023 | 1023 | 10/15/73 | 06/14/73 |
| | 3R00093 | 9000 | D01005 | 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 | B01044 | 2002 | 2002 | 08/16/73 | 06/14/73 |
| | 3R00103 | 9000 | F01060 | 1028 | 1028 | 08/20/73 | 06/14/73 |
| | 3R00104 | 9000 | T01048 | 3022 | 3029 | 08/21/73 | 06/14/73 |
| | 3R00105 | 9000 | G01019 | 2002 | 2002 | 08/09/73 | 06/14/73 |
| | 3R00108 | 9000 | E01022 | 2002 | 2002 | 08/09/73 | 06/14/73 |
| | 3R00109 | 9000 | E01010 | 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 | C01056 | 3038 | 3048 | 10/08/73 | 06/14/73 |
| * | 3R00115 | 9000 | F01062 | 1028 | 1028 | 09/21/73 | 02/05/73 |
| | 3R00116 | 9000 | C01063 | 1028 | 1028 | 08/22/73 | 02/06/73 |
| ** | 3R00117 | 9000 | F01259 | 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 |
| | 3P00124 | 9000 | M01066 | 1027 | 1027 | 10/02/73 | 07/02/73 |
| | 3R00125 | 9000 | V01073 | 3059 | 3061 | 08/27/73 | 06/19/73 |
| | 3R00126 | 9000 | C01050 | 2005 | 2006 | 09/12/73 | 06/19/73 |
| | 3R00127 | 9000 | F01049 | 3022 | 3030 | 09/18/73 | 06/19/73 |
| | 3R00128 | 9000 | M01092 | 3059 | 3054 | 10/23/73 | 06/19/73 |
| | 3R00129 | 9000 | D01052 | 3031 | 3041 | 08/25/73 | 06/19/73 |
| | 3R00130 | 9000 | F01083 | 2025 | 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 | F01051 | 2015 | 2017 | 08/14/73 | 06/18/73 |
| | 3R00139 | 9000 | B01075 | 2011 | 2012 | 10/05/73 | 06/18/73 |
| | 3R00140 | 9000 | F01395 | 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 | F01393 | 2017 | 2020 | 11/12/73 | 07/02/73 |

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| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 3R00158 | 9000 | E01020 | 3001 | 3001 | 10/22/73 | 07/13/73 |
| 3R00159 | 9000 | O01118 | 3039 | 3041 | 01/02/74 | 07/13/73 |
| 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 | 2015 | 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 | H01168 | 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 |
| 3P00212 | 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 |
| 3R00226 | 9000 | B01120 | 3013 | 3015 | 12/19/73 | 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 | / 01/ |
| 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 | M01175 | 1003 | 1004 | 01/18/74 | 11/05/73 |
| 3R00257 | 9000 | F01361 | 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 |
| * 3P00271 | 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 | F01243 | 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 | E01239 | 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 |

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| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 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 | F01244 | 1026 | 1026 | 02/06/74 | 11/06/73 |
| 3R00297 | 9000 | J01301 | 3035 | 3045 | 03/26/74 | 11/06/73 |
| 3R00298 | 9000 | J01270 | 2006 | 2007 | 03/13/74 | 11/06/73 |
| 3R00303 | 9000 | L01159 | 1018 | 1020 | 01/07/74 | 11/06/73 |
| 3R00314 | 9000 | F01330 | 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 | F01338 | 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 | F01345 | 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 | M01258 | 1025 | 1025 | 03/05/74 | 12/01/73 |
| 3R00335 | 9000 | F01810 | 3038 | 3048 | 11/05/74 | 12/01/73 |
| 3R00336 | 9000 | K02156 | 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 | 2005 | 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 | F01381 | 3037 | 3047 | 06/14/74 | 02/27/74 |
| 4R00011 | 9000 | F01353 | 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 | F01380 | 3001 | 3001 | 06/27/74 | 03/14/74 |
| 4R00021 | 9000 | F01440 | 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 | 1025 | 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 | F02231 | 1025 | 1025 | 12/18/74 | 03/19/74 |
| 4R00044 | 9000 | F01906 | 3105 | 3021 | 08/08/74 | 03/19/74 |
| 4R00046 | 9000 | P01818 | 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 | L01425 | 2027 | 2033 | 05/02/74 | 03/19/74 |

## APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000 NUCLEAR POWERED PULSE GENERATORS (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 4R00051 | 9000 | M01355 | 1022 | 1022 | 05/03/74 | 03/19/74 |
| 4R00052 | 9000 | G02452 | 1022 | 1053 | 02/07/75 | 05/19/74 |
| 4R00054 | 9000 | K01452 | 3040 | 3050 | 08/19/74 | 03/19/74 |
| 4R00055 | 9000 | H01322 | 2010 | 2011 | 05/15/74 | 03/19/74 |
| 4R00056 | 9000 | V01391 | 1017 | 1019 | 06/06/74 | 03/19/74 |
| 4R00057 | 9000 | H01373 | 1026 | 1026 | 06/05/74 | 03/19/74 |
| 4R00058 | 9000 | M01632 | 3081 | 3059 | 06/03/74 | 03/19/74 |
| 4R00061 | 9000 | S02311 | 3015 | 3017 | 12/10/74 | 10/23/74 |
| 4R00062 | 9000 | S02055 | 3013 | 3015 | 12/11/74 | 10/23/74 |
| 4R00063 | 9000 | G02779 | 3007 | 3009 | 06/24/75 | / 0/ |
| 4R00064 | 9000 | Z02627 | 1030 | 1029 | 12/17/74 | / 0/ |
| 4R00065 | 9000 | H02456 | 3113 | 3054 | 02/10/75 | / 0/ |
| 4R00066 | 9000 | A02989 | 3020 | 3025 | 12/12/74 | / 0/ |
| 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 |
| 4R00073 | 9000 | G02721 | 3038 | 3048 | 05/14/75 | / 0/ |
| 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 | / 0/ |
| 4R00084 | 9000 | F02498 | 3061 | 3017 | 02/18/75 | / 0/ |
| 4R00085 | 9000 | A02454 | 2002 | 2002 | 01/17/75 | 11/19/74 |
| 4R00087 | 9000 | L02453 | 3008 | 3010 | 01/23/75 | 11/21/74 |
| 4R00091 | 9000 | W02528 | 2013 | 2015 | 02/26/75 | / 0/ |
| 4R00092 | 9000 | S02466 | 2006 | 2007 | 02/26/75 | 11/21/74 |
| 4R00093 | 9000 | S02832 | 2014 | 2016 | 07/10/75 | / 0/ |
| 4R00094 | 9000 | H02457 | 3061 | 3017 | 02/06/75 | 11/21/74 |
| 4R00096 | 9000 | E02618 | 3040 | 3050 | 01/20/75 | / 0/ |
| 4P00097 | 9000 | W02444 | 2102 | 1035 | 02/13/75 | / 0/ |
| 4R00098 | 9000 | S02761 | 1018 | 1020 | 06/12/75 | / 0/ |
| 4R00099 | 9000 | F02445 | 2008 | 2009 | 02/24/75 | 11/21/74 |
| 4R00101 | 9000 | S02562 | 1019 | 1021 | 03/26/75 | / 0/ |
| 4R00102 | 9000 | W02747 | 3106 | 3021 | 03/06/75 | / 0/ |
| 4R00105 | 9000 | N02467 | 3026 | 3116 | 02/28/75 | / 0/ |
| 4R00110 | 9000 | N02600 | 1018 | 1020 | 03/20/75 | / 0/ |
| 4R00131 | 9000 | S02387 | 3001 | 3001 | 02/06/75 | 11/26/74 |
| 4R00133 | 9000 | G02489 | 1027 | 2147 | 03/07/75 | / 0/ |
| 4R00134 | 9000 | H02775 | 2002 | 2002 | 05/13/75 | / 0/ |
| 4R00136 | 9000 | P02529 | 3027 | 3038 | 03/10/75 | / 0/ |
| 4R00140 | 9000 | R02965 | 3058 | 3060 | 08/11/75 | / 0/ |
| 4R00149 | 9000 | R03005 | 3013 | 3124 | 09/18/75 | / 0/ |
| 4R00154 | 9000 | H02620 | 3013 | 3015 | 04/11/75 | / 0/ |
| 4R00165 | 9000 | S02619 | 1018 | 1020 | 03/21/75 | / 0/ |
| 4R00167 | 9000 | E02869 | 1018 | 1020 | 07/25/75 | / 0/ |
| *4R00188 | 9000 | G02514 | 1023 | 1023 | 03/11/75 | / 0/ |
| 4R00192 | 9000 | D02614 | 1023 | 1023 | 04/01/75 | / 0/ |
| 4R00203 | 9000 | G02628 | 1010 | 2150 | 04/01/75 | / 0/ |
| 4R00207 | 9000 | F02772 | 3032 | 3042 | 06/11/75 | / 0/ |
| 4R00208 | 9000 | H02515 | 1035 | 1034 | 03/13/75 | / 0/ |
| 4R00211 | 9000 | E02625 | 1013 | 1014 | 03/27/75 | / 0/ |
| 4R00215 | 9000 | P02615 | 3114 | 3117 | 04/08/75 | / 0/ |
| 4R00216 | 9000 | B02522 | 2101 | 2148 | 03/12/75 | / 0/ |
| 4R00220 | 9000 | H02455 | 2069 | 2023 | 02/12/75 | / 0/ |
| 4R00224 | 9000 | G02572 | 1012 | 1013 | 03/27/75 | / 0/ |
| 4R00225 | 9000 | B02714 | 3051 | 3055 | 03/31/75 | / 0/ |
| 4R00233 | 9000 | F02566 | 3025 | 3033 | 03/06/75 | / 0/ |
| 4R00234 | 9000 | M02601 | 1003 | 1004 | 03/12/75 | / 0/ |
| 4R00235 | 9000 | A02622 | 3114 | 3117 | 04/10/75 | / 0/ |
| 4R00237 | 9000 | K02777 | 2004 | 2005 | 04/25/75 | / 0/ |
| 4R00241 | 9000 | W02530 | 2103 | 2116 | 03/20/75 | / 0/ |
| 4R00243 | 9000 | N02535 | 1071 | 1083 | 03/13/75 | / 0/ |
| 4R00244 | 9000 | E02534 | 1019 | 1021 | 03/11/75 | / 0/ |
| 4R00246 | 9000 | A02726 | 1017 | 1019 | 05/01/75 | / 0/ |
| 4R00247 | 9000 | W02716 | 1025 | 1025 | 05/01/75 | / 0/ |
| 4R00251 | 9000 | F02490 | 2011 | 2012 | 02/05/75 | 12/14/74 |
| 4R00255 | 9000 | G02637 | 2006 | 2007 | 04/21/75 | / 0/ |
| 4R00257 | 9000 | L02602 | 1003 | 1004 | 03/12/75 | / 0/ |
| 4R00258 | 9000 | B02774 | 2005 | 2007 | 06/12/75 | / 0/ |
| 4R00262 | 9000 | E02611 | 2003 | 2004 | 04/01/75 | / 0/ |
| 4R00263 | 9000 | W02623 | 2031 | 2039 | 04/11/75 | / 0/ |
| 4R00267 | 9000 | C02638 | 2003 | 2004 | 04/21/75 | / 0/ |

APPENDIX 1: ITEMIZATION OF IMPLANTED MODEL 9000
NUCLEAR POWERED PULSE GENERATORS (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 4R00268 | 9000 | AC2733 | 2011 | 2012 | 05/01/75 | / 0/ |
| 4R00269 | 9000 | BC2962 | 3034 | 3044 | 08/14/75 | / 0/ |
| 4R00275 | 9000 | CC2749 | 2008 | 2009 | 05/29/75 | / 0/ |
| 4R00282 | 9000 | SC2961 | 3105 | 3103 | 08/19/75 | / 0/ |
| 4R00291 | 9000 | BC2725 | 1017 | 1019 | 05/01/75 | / 0/ |
| 4R00297 | 9000 | SC2758 | 3115 | 3119 | 06/10/75 | / 0/ |
| 4R00301 | 9000 | SC2734 | 2101 | 2148 | 04/28/75 | / 0/ |
| 4R00306 | 9000 | SC2776 | 1030 | 1029 | 06/05/75 | / 0/ |
| 4P00310 | 9000 | GC2631 | 1033 | 1093 | 04/15/75 | / 0/ |
| * 4R00311 | 9000 | FC2715 | 3074 | 3055 | 04/10/75 | / 0/ |
| 4R00315 | 9000 | MC2653 | 2003 | 2004 | 04/28/75 | / 0/ |
| 4R00319 | 9000 | RC2799 | 1027 | 2147 | 07/01/75 | / 0/ |
| 4R00327 | 9000 | CC2727 | 2106 | 2022 | 05/21/75 | / 0/ |
| 4R00331 | 9000 | DC2630 | 1035 | 1034 | 04/16/75 | / 0/ |
| 4R00336 | 9000 | NC2370 | 1023 | 1023 | 09/22/75 | / 0/ |
| 4R00337 | 9000 | MC2636 | 2016 | 2019 | 04/21/75 | / 0/ |
| 4R00338 | 9000 | AC2801 | 3027 | 3120 | 07/01/75 | / 0/ |
| 4R00342 | 9000 | UC2629 | 2103 | 2116 | 04/11/75 | / 0/ |
| 4R00346 | 9000 | EC2830 | 2011 | 2012 | 06/16/75 | / 0/ |
| 4R00349 | 9000 | CC2962 | 1017 | 1019 | 07/17/75 | / 0/ |
| 4R00353 | 9000 | TC2735 | 2101 | 2148 | 05/26/75 | / 0/ |
| 4R00358 | 9000 | FC2981 | 2008 | 2009 | 08/27/75 | / 0/ |
| 4R00359 | 9000 | CC2651 | 2016 | 2152 | 05/05/75 | / 0/ |
| 4R00360 | 9000 | CC2773 | 1071 | 1083 | 05/27/75 | / 0/ |
| 4R00361 | 9000 | DC2748 | 1003 | 1004 | 05/15/75 | / 0/ |
| 4R00369 | 9000 | SC2863 | 3051 | 3055 | 06/14/75 | / 0/ |
| 4R00370 | 9000 | HC2802 | 2003 | 2004 | 06/23/75 | / 0/ |
| 4R00372 | 9000 | RC2809 | 3019 | 3023 | 07/01/75 | / 0/ |
| 5R00001 | 9000 | FC2990 | 2011 | 2012 | 09/03/75 | / 0/ |
| 5R00004 | 9000 | FC2800 | 2008 | 2009 | 06/25/75 | / 0/ |
| 5R00008 | 9000 | BC2851 | 2003 | 2004 | 07/17/75 | / 0/ |
| 5R00015 | 9000 | LC2850 | 3018 | 3022 | 07/08/75 | / 0/ |

LEGNED:

* Removed Pulse Generator
** Reimplanted Pulse Generator

# APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 2M04433 | 5842 | E01132 | 1027 | 1027 | 03/01/73 | 11/28/72 |
| 3M01641 | 5842 | M01292 | 1017 | 1019 | 08/01/73 | 05/02/73 |
| 3M01734 | 5842 | C01133 | 1027 | 1027 | 08/06/73 | 05/14/73 |
| 3M01739 | 5842 | E01189 | 1027 | 1027 | 07/09/73 | 05/02/73 |
| 3M01784 | 5842 | E01193 | 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 | C01148 | 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 |
| 3D00334 | 5862 | M01153 | 2022 | 2027 | 07/19/73 | 05/24/73 |
| 3D00507 | 5862 | M01299 | 3011 | 3013 | 01/24/74 | 06/14/73 |
| 2E01603 | 5862C | C01201 | 3051 | 3055 | 07/24/73 | 10/31/72 |
| 3E00379 | 5862C | M01429 | 1046 | 1041 | 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 |
| 2S00167 | 5931 | C02875 | 2003 | 2004 | 11/13/72 | 09/07/72 |
| 2S00491 | 5931 | K02871 | 2003 | 2004 | 11/22/72 | 10/04/72 |
| 3S00445 | 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 |
| 4S00571 | 5931 | T02978 | 2003 | 2004 | 08/25/75 | 02/04/75 |
| UNKNOWN | 5931 | P02640 | 2003 | 2004 | 04/21/75 | / 01/ |
| 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 | E01210 | 1016 | 1018 | 01/24/73 | 05/22/72 |
| 2K24181 | 5942 | C01185 | 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 | L01151 | 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 | C02346 | 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 | P01601 | 2026 | 2032 | 07/17/73 | / 01/ |
| 3K07126 | 5942 | F01150 | 2022 | 2027 | 04/09/73 | / 01/ |
| 3K09055 | 5942 | G01209 | 3038 | 3048 | 07/10/73 | 04/13/73 |
| 3K11159 | 5942 | W01208 | 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 | C01203 | 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 |

## APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 3K16939 | 5942 | FC1129 | 3013 | 3015 | 11/29/73 | 09/12/73 |
| 3K17336 | 5942 | MC1206 | 3043 | 3050 | 09/24/73 | 08/02/73 |
| 3K17486 | 5942 | CC1254 | 3020 | 3025 | 01/18/74 | 06/25/73 |
| 3K17603 | 5942 | MC1205 | 3044 | 3050 | 09/11/73 | 06/28/73 |
| 3K17744 | 5942 | LC1204 | 3045 | 3050 | 09/26/73 | 08/11/73 |
| 3K17765 | 5942 | CC1214 | 2002 | 2002 | 10/24/73 | 08/11/73 |
| 3K18053 | 5942 | RC1247 | 3020 | 3024 | 01/31/74 | 07/24/73 |
| 3K19070 | 5942 | JC1221 | 2002 | 2002 | 10/02/73 | 08/07/73 |
| 3K19855 | 5942 | RC1131 | 3013 | 3015 | 12/10/73 | 08/21/73 |
| 3K20547 | 5942 | CC1277 | 2022 | 2027 | 10/24/73 | 07/17/73 |
| 3K20689 | 5942 | RC1124 | 2022 | 2027 | 11/01/73 | 08/27/73 |
| 3K21215 | 5942 | AC1603 | 2026 | 2032 | 11/19/73 | 09/05/73 |
| 3K21505 | 5942 | LC1215 | 2002 | 2002 | 10/16/73 | 08/14/73 |
| 3K21563 | 5942 | MC1293 | 3011 | 3013 | 11/28/73 | 08/29/73 |
| 3K21606 | 5942 | RC1296 | 3011 | 3013 | 02/07/74 | 12/28/73 |
| 3K21787 | 5942 | CC1278 | 3016 | 3018 | 10/30/73 | 09/07/73 |
| 3K21793 | 5942 | OC1266 | 3055 | 3058 | 12/14/73 | 09/21/73 |
| 3K22057 | 5942 | KC1130 | 3013 | 3015 | 11/14/73 | 09/20/73 |
| 3K22396 | 5942 | FC1152 | 2022 | 2027 | 10/10/73 | 08/11/73 |
| 3K22919 | 5942 | CC1155 | 2022 | 2027 | 10/10/73 | 08/13/73 |
| 3K22983 | 5942 | LC1310 | 1002 | 1017 | 12/12/73 | 08/28/73 |
| 3K23006 | 5942 | MC1281 | 2022 | 2027 | 01/16/74 | 10/11/73 |
| 3K23049 | 5942 | CC1582 | 2022 | 2027 | 01/18/74 | 10/11/73 |
| 3K23434 | 5942 | SC1126 | 2022 | 2027 | 12/20/73 | 09/21/73 |
| 3K23992 | 5942 | LC1253 | 1021 | 1021 | 12/14/73 | 10/02/73 |
| 3K25082 | 5942 | FC1127 | 3013 | 3015 | 12/04/73 | 10/11/73 |
| 3K25598 | 5942 | FC1334 | 3061 | 3017 | 01/17/74 | 10/11/73 |
| 3K25785 | 5942 | HC1251 | 1021 | 1021 | 01/31/74 | 10/16/73 |
| 3K27863 | 5942 | WC1300 | 3013 | 3015 | 03/11/74 | 12/13/73 |
| 3K28573 | 5942 | CC2626 | 1030 | 1029 | 04/23/74 | / /01 |
| 3K30308 | 5942 | KC1339 | 2002 | 2002 | 04/30/74 | 02/14/74 |
| 3K32733 | 5942 | MC1494 | 2032 | 2040 | 08/08/74 | 05/03/74 |
| 3K34544 | 5942 | PC1495 | 2032 | 2040 | 07/22/74 | 03/12/74 |
| 3K35708 | 5942 | AC1428 | 1046 | 1001 | 11/09/72 | / /01 |
| 3K40484 | 5942 | BC1212 | 2002 | 2002 | 01/29/73 | 11/08/72 |
| 3XX0380 | 5942 | CC1354 | 1025 | 1025 | 01/02/74 | 03/28/73 |
| UNKNOWN | 5942 | SC1188 | 1028 | 1028 | 12/18/72 | / /01 |
| UNKNOWN | 5942 | TC1232 | 1028 | 1028 | 05/05/73 | / /01 |
| 2L10789 | 5943 | PC2339 | 1096 | 1020 | 06/08/73 | 07/07/72 |
| 2L30063 | 5943 | DC1135 | 3003 | 3003 | 04/23/73 | 09/21/72 |
| 2L30208 | 5943 | CC1272 | 3022 | 3029 | 02/01/73 | 09/19/72 |
| 2L31000 | 5943 | CC1111 | 2023 | 2029 | 02/12/73 | 09/22/72 |
| 2L33389 | 5943 | FC2350 | 1095 | 1020 | 09/10/73 | 02/08/73 |
| 2L33486 | 5943 | CC1197 | 1028 | 1028 | 12/28/72 | 10/25/72 |
| 3L00015 | 5943 | CC1196 | 3055 | 3058 | 06/22/73 | 03/29/73 |
| 3L00186 | 5943 | CC1236 | 2017 | 2020 | 11/17/73 | 09/26/73 |
| 3L00280 | 5943 | SC1195 | 3055 | 3058 | 06/05/73 | 03/26/73 |
| 3L00443 | 5943 | DC2229 | 1018 | 1020 | 07/17/73 | 03/26/73 |
| 3L00929 | 5943 | WC1107 | 1007 | 1008 | 05/23/73 | 03/14/73 |
| 3L01139 | 5943 | GC1141 | 2016 | 2019 | 07/05/73 | 02/06/73 |
| 3L01731 | 5943 | FC1227 | 3001 | 3001 | 06/04/73 | 01/13/73 |
| 3L01865 | 5943 | TC2364 | 1031 | 1020 | 06/14/73 | 04/27/73 |
| 3L01942 | 5943 | GC1137 | 2016 | 2018 | 07/24/73 | 03/13/73 |
| 3L03115 | 5943 | MC1182 | 2025 | 2031 | 09/10/73 | 04/10/73 |
| 3L03128 | 5943 | CC2357 | 1018 | 1020 | 07/26/73 | / /01 |
| 3L03229 | 5943 | GC1820 | 1065 | 1020 | 07/13/73 | / /01 |
| 3L03453 | 5943 | MC1235 | 2017 | 2020 | 11/09/73 | 09/13/73 |
| 3L03822 | 5943 | SC2344 | 1097 | 1020 | 09/07/73 | 05/02/73 |
| 3L03892 | 5943 | SC1143 | 2016 | 2019 | 07/12/73 | 02/27/73 |
| 3L04019 | 5943 | PC1263 | 3055 | 3058 | 12/27/73 | 03/26/73 |
| 3L04224 | 5943 | EC1138 | 2016 | 2019 | 07/19/73 | 04/02/73 |
| 3L04250 | 5943 | SC1181 | 2025 | 2031 | 07/20/73 | 04/04/73 |
| 3L04256 | 5943 | OC1146 | 2016 | 2019 | 09/17/73 | 04/04/73 |
| 3L04379 | 5943 | HC2337 | 1018 | 1020 | 08/09/73 | 04/10/73 |
| 3L04428 | 5943 | SC1358 | 1018 | 1020 | 07/18/73 | 03/27/73 |
| 3L04774 | 5943 | FC1198 | 2029 | 2037 | 10/31/73 | 04/23/73 |
| 3L05244 | 5943 | FC1139 | 2016 | 2019 | 11/08/73 | 09/06/73 |
| 3L05916 | 5943 | MC1346 | 3055 | 3058 | 10/18/73 | 08/09/73 |
| 3L05972 | 5943 | FC1142 | 2016 | 2019 | 10/01/73 | 08/09/73 |

# APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 3L06027 | 5943 | R01262 | 1019 | 1021 | 11/21/73 | 07/27/73 |
| 3L06095 | 5943 | C01265 | 3055 | 3058 | 12/30/73 | 09/11/73 |
| 3L06233 | 5943 | F02356 | 1099 | 1020 | 09/14/73 | 07/06/73 |
| 3L06406 | 5943 | K01144 | 2016 | 2019 | 11/05/73 | 08/28/73 |
| 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 |
| 3G00022 | 5944 | R01219 | 2002 | 2002 | 10/11/73 | 07/08/73 |
| 3G00133 | 5944 | R01218 | 2002 | 2002 | 08/01/73 | 05/14/73 |
| 3G00580 | 5944 | K02348 | 1018 | 1020 | 07/10/73 | 04/17/73 |
| 3G00599 | 5944 | S01194 | 1027 | 1027 | 10/12/73 | 06/07/73 |
| 3G01342 | 5944 | F01045 | 1008 | 1008 | 08/02/73 | 05/21/73 |
| 3G01352 | 5944 | K02334 | 1018 | 1020 | 09/25/73 | 05/17/73 |
| 3G01481 | 5944 | C01213 | 2002 | 2002 | 11/01/73 | 09/18/73 |
| 3G01863 | 5944 | M01283 | 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 | S02333 | 1094 | 1020 | 02/14/74 | 09/26/73 |
| 3G02272 | 5944 | T02343 | 1018 | 1020 | 02/22/74 | 11/07/73 |
| 3G02632 | 5944 | F01596 | 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 |
| 3G10618 | 5944 | R01367 | 1004 | 1005 | 12/11/73 | 10/25/73 |
| 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 |
| 3G11270 | 5944 | L01323 | 1025 | 1025 | 02/27/74 | 10/10/73 |
| 3G11328 | 5944 | L01112 | 3051 | 3055 | 11/09/73 | 09/07/73 |
| 3G11740 | 5944 | F01147 | 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 | K02230 | 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 | S01356 | 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 |
| 3G13979 | 5944 | S01325 | 2022 | 2027 | 03/20/74 | 12/17/73 |
| 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 | 1021 | 05/17/74 | 02/06/74 |
| 3G23535 | 5944 | J01583 | 2071 | 2027 | 04/02/74 | 01/03/74 |
| 3G23576 | 5944 | K02338 | 1018 | 1020 | 05/15/74 | 01/08/74 |
| 3G25480 | 5944 | D02362 | 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 | P02345 | 1065 | 1020 | 07/31/74 | 06/10/74 |
| 3G29634 | 5944 | K01805 | 3013 | 3015 | 07/30/74 | 06/11/74 |
| 3G33190 | 5944 | R02342 | 1018 | 1020 | 07/10/74 | 04/03/74 |
| UNKNOWN | 5944 | N02349 | 1018 | 1020 | 11/06/73 | / 01/ |
| 3T00092 | 5945 | P02044 | 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 |

# APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 3T11212 | 5945 | LC1426 | 1023 | 1023 | 10/24/73 | 07/26/73 |
| 3T11560 | 5945 | WC2449 | 1023 | 1023 | 10/24/73 | 07/25/73 |
| 3T12186 | 5945 | LC2183 | 1023 | 1023 | 09/18/73 | / 0/ |
| 3T12780 | 5945 | SC2365 | 1065 | 1020 | 10/25/73 | 08/29/73 |
| 3T13041 | 5945 | MC2034 | 1023 | 1023 | 02/19/74 | 11/08/73 |
| 3T13224 | 5945 | CC2336 | 1018 | 1020 | 05/06/74 | 10/23/73 |
| 3T13332 | 5945 | CC1356 | 1023 | 1023 | 12/10/73 | 08/24/73 |
| 3T13838 | 5945 | KC1252 | 3020 | 3026 | 01/07/74 | 09/20/73 |
| 3T13896 | 5945 | KC1108 | 2002 | 2002 | 11/08/73 | 08/29/73 |
| 3T13983 | 5945 | RC2031 | 1023 | 1023 | 12/19/73 | 09/11/73 |
| 3T14018 | 5945 | FC1109 | 2002 | 2002 | 11/23/73 | 09/11/73 |
| 3T14520 | 5945 | FC2335 | 1095 | 1020 | 05/17/74 | 10/04/73 |
| 3T14580 | 5945 | TC1180 | 2025 | 2031 | 12/20/73 | 10/31/73 |
| 3T15475 | 5945 | BC1524 | 3031 | 3041 | 06/05/74 | 12/26/73 |
| 3T16134 | 5945 | SC1343 | 3020 | 3026 | 01/31/74 | 11/07/73 |
| 3T16222 | 5945 | JC1344 | 3020 | 3026 | 02/09/74 | 12/07/73 |
| 3T16301 | 5945 | DC1249 | 1020 | 1021 | 01/06/74 | 11/20/73 |
| 3T16494 | 5945 | NC1333 | 3016 | 3020 | 02/04/74 | 12/05/73 |
| 3T17686 | 5945 | CC2042 | 1023 | 1023 | 04/05/74 | 12/28/73 |
| 3T17710 | 5945 | TC1443 | 1023 | 1023 | 04/10/74 | 12/28/73 |
| 3T18564 | 5945 | WC2030 | 1023 | 1023 | 03/27/74 | 12/28/73 |
| 3T18605 | 5945 | GC1824 | 3020 | 3026 | 04/01/74 | 01/22/74 |
| 3Y13449 | 5945 | GC2450 | 1023 | 1023 | 10/26/73 | / 0/ |
| 4T00861 | 5945 | JC1890 | 3020 | 3026 | 09/17/74 | 06/17/74 |
| 4T01528 | 5945 | FC2359 | 1018 | 1020 | 10/03/74 | 07/15/74 |
| 4T02618 | 5945 | SC2351 | 1095 | 1020 | 10/20/74 | 07/03/74 |
| XX4519 | 5945 | GC2064 | 1018 | 1020 | 08/11/73 | 12/05/72 |
| XX4559 | 5945 | WC1387 | 1064 | 1026 | 03/27/73 | 01/04/73 |
| XX4563 | 5945 | FC1398 | 1026 | 1026 | 02/12/73 | 12/27/72 |
| XX4568 | 5945 | FC1397 | 1026 | 1026 | 02/05/73 | 01/04/73 |
| XX4576 | 5945 | HC1408 | 1064 | 1026 | 02/08/73 | 01/04/73 |
| XX4580 | 5945 | GC1105 | 1007 | 1008 | 02/12/73 | 01/05/73 |
| XX4586 | 5945 | WC1399 | 1064 | 1026 | 03/21/73 | 01/03/73 |
| XX4587 | 5945 | CC1388 | 1064 | 1026 | 03/28/73 | 01/03/73 |
| XX4663 | 5945 | SC1386 | 1064 | 1026 | 03/20/73 | 01/05/73 |
| XX4678 | 5945 | WC1390 | 1064 | 1026 | 01/08/73 | 12/14/72 |
| XX4681 | 5945 | GC1407 | 1067 | 1026 | 01/04/73 | 12/12/72 |
| XX4682 | 5945 | TC1404 | 1064 | 1026 | 01/04/73 | 12/14/72 |
| XX4683 | 5945 | MC1377 | 1063 | 1026 | 01/18/73 | 12/14/72 |
| XX4684 | 5945 | HC1378 | 1038 | 1026 | 01/29/73 | 12/18/72 |
| XX4685 | 5945 | HC1385 | 1062 | 1026 | 01/15/73 | 12/14/72 |
| XX4686 | 5945 | GC1374 | 1026 | 1026 | 01/08/73 | 12/14/72 |
| XX4688 | 5945 | GC1400 | 1064 | 1026 | 03/27/73 | 12/14/72 |
| XX4689 | 5945 | HC1401 | 1062 | 1026 | 01/03/73 | 12/14/72 |
| XX4690 | 5945 | SC1375 | 1026 | 1026 | 01/24/73 | 12/14/72 |
| XX4694 | 5945 | MC1376 | 1026 | 1026 | 01/08/73 | 12/14/72 |
| XX4695 | 5945 | YC1403 | 1026 | 1026 | 01/10/73 | 12/14/72 |
| XX4696 | 5945 | GC1405 | 1064 | 1026 | 01/17/73 | 12/14/72 |
| XX4698 | 5945 | BC1402 | 1026 | 1026 | 02/05/73 | 12/12/72 |
| XX4826 | 5945 | TC2347 | 1018 | 1020 | 09/07/73 | 09/12/72 |
| XX4872 | 5945 | TC1106 | 1007 | 1008 | 03/15/73 | 01/09/73 |
| 3A000002 | 5961 | RC2184 | 1023 | 1023 | 01/29/74 | 05/08/73 |
| 3A000045 | 5961 | HC1279 | 1017 | 1019 | 07/05/73 | 05/04/73 |
| 3A000298 | 5961 | HC2374 | 2003 | 2004 | 06/04/73 | / 0/ |
| 3A000401 | 5961 | BC2890 | 2003 | 2004 | 05/17/73 | / 0/ |
| 3A000663 | 5961 | RC2186 | 1023 | 1023 | 06/18/73 | 02/06/73 |
| 3A000751 | 5961 | BC2451 | 1023 | 1023 | 02/05/74 | / 0/ |
| 3A000976 | 5961 | BC2877 | 2003 | 2004 | 09/16/74 | / 0/ |
| 3A001203 | 5961 | FC2888 | 2003 | 2004 | 02/06/74 | / 0/ |
| 3A001364 | 5961 | CC2872 | 2003 | 2004 | 12/27/73 | 08/29/73 |
| 3A001599 | 5961 | TC1226 | 3001 | 3011 | 09/13/73 | 06/28/73 |
| 3A002246 | 5961 | FC2867 | 2003 | 2004 | 01/31/75 | / 0/ |
| 3A002523 | 5961 | AC2804 | 2003 | 2004 | 03/06/74 | / 0/ |
| 3A003494 | 5961 | DC2870 | 2003 | 2004 | 10/03/74 | 01/08/74 |
| 3A003705 | 5961 | BC2889 | 2003 | 2004 | 05/03/74 | 12/19/73 |
| 3A003759 | 5961 | BC2886 | 2003 | 2004 | 05/31/74 | / 0/ |
| 3A003982 | 5961 | LC2876 | 2003 | 2004 | 07/11/74 | / 0/ |
| 3A004265 | 5961 | LC2878 | 2003 | 2004 | 02/04/74 | 11/27/73 |
| 3A005321 | 5961 | BC2780 | 2003 | 2004 | 10/25/74 | / 0/ |
| 3A006795 | 5961 | CC2897 | 2003 | 2004 | 11/08/74 | / 0/ |
| 3A007443 | 5961 | BC2805 | 2003 | 1096 | 11/21/74 | / 0/ |

## APPENDIX 2: ITEMIZATION OF CHEMICALLY POWERED PULSE GENERATORS BY MODEL (TO 11-5-75)

| SERIAL NUMBER | MODEL NUMBER | PATIENT CODE | HOSPITAL CODE | PHYSICIAN CODE | DATE OF IMPLANT | DATE OF MANUFACTURE |
|---|---|---|---|---|---|---|
| 4A00157 | 5961 | M02719 | 2003 | 2004 | 05/05/75 | 12/10/74 |
| 4A00328 | 5961 | D02973 | 2003 | 2004 | 08/13/75 | 02/19/75 |
| 4A00382 | 5961 | R02465 | 2003 | 2004 | 02/21/75 | 12/02/74 |
| 4A00416 | 5961 | L02409 | 2003 | 2004 | 08/06/75 | 02/18/75 |
| 4A00489 | 5961 | M02718 | 2003 | 2004 | 05/08/75 | 12/10/74 |
| 4A00614 | 5961 | M02736 | 2003 | 2004 | 05/22/75 | 01/16/75 |
| 4A00632 | 5961 | G02873 | 2003 | 2004 | 12/26/74 | 10/15/74 |
| 4A00667 | 5961 | J02422 | 2003 | 2004 | 09/26/75 | 01/02/75 |
| 4A00759 | 5961 | G02418 | 2003 | 2004 | 09/29/75 | 01/03/75 |
| 5A00005 | 5961 | C02533 | 2003 | 2004 | 03/19/75 | 12/13/74 |
| 5A00153 | 5961 | K02760 | 2003 | 2004 | 06/11/75 | 01/27/75 |
| 5A00189 | 5961 | A02757 | 2003 | 2004 | 05/31/75 | 01/27/75 |
| 5A00193 | 5961 | G02975 | 2003 | 2004 | 08/22/75 | 03/04/75 |
| 5A00206 | 5961 | C02732 | 2003 | 2004 | 05/21/75 | 02/24/75 |
| 5A00228 | 5961 | M02759 | 2003 | 2004 | 06/11/75 | 01/15/75 |
| 5A00251 | 5961 | H02675 | 2003 | 2004 | 05/01/75 | 01/02/75 |
| 5A00354 | 5961 | S02612 | 2003 | 2004 | 03/21/75 | 12/05/74 |
| 5A00376 | 5961 | A02674 | 2003 | 2004 | 05/05/75 | 12/18/74 |
| 5A00382 | 5961 | L02531 | 2003 | 2004 | 03/12/75 | 01/03/75 |
| 5A00750 | 5961 | N02717 | 2003 | 2004 | 05/12/75 | 12/10/74 |
| 5A00837 | 5961 | S02977 | 2003 | 2004 | 08/17/75 | 03/12/75 |
| UNKNOWN | 5961 | M02464 | 2003 | 2004 | 02/19/75 | / 01/ |
| UNKNOWN | 5961 | F02532 | 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 pelritonitis 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. |
| 2R00227 | H1010 | D1012 | J01326 | Patient expired; cause unknown | 7/14/75 | Returned to Medtronic; 7/28/75. |
| 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. |
| 3R00092 | H1023 | D1023 | A01173 | Patient expired; CHF | 6/07/75 | Unit not returned. |
| 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 | H3011 | D3011 | 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 | Wound separation; seroma. | 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. | 10/31/74 | Unit returned to Medtronic on 11/11/74. |
| 3R00288 | H2080 | D2117 | L01581 | Intermittent sensing. | 9/29/75 | Returned to Medtronic; 10/7/75. |
| 3R00316 | H1026 | D1026 | J01324 | Patient expired; coronary occlusion due to arteriosclerosis. | 7/15/74 | Returned to Medtronic. |
| 3R00338 | H1023 | D1023 | C01307 | Muscle stimulation. | 10/30/75 | Unit not returned, retained by hospital. |
| 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 | Sensing and refractory test idiosyncrasy. | 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. |
| 4R00083 | H1023 | D1023 | M02513 | Patient expired; MI. | 6/09/75 | Returned to Medtronic; 11/11/75 |
| 4R00188 | H1023 | D1023 | G02514 | Inadequate sensing. | 3/15/75 | Returned to Medtronic; 11/11/75 |
| 4R00254 | H3013 | D3015 | --- | Patient expired; MI. | 6/13/75 | Unit returned. |
| 4R00311 | H3074 | D3055 | F02715 | Patient expired; MI. | 6/18/75 | Unit not removed from patient. |

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. |
| 2L04428 | H1018 | D1020 | S01358 | Elective replacement | 9/21/75 | Unit not returned to Medtronic. |
| 2L31000 | H2023 | D2029 | C01111 | Elective replacement. | 9/19/75 | Unit not returned to Medtronic. |
| 2M04433 | H1027 | D1027 | B01132 | Patient expired; MI. | 11/30/74 | Unit not returned to Medtronic. |
| 3A01203 | H2003 | D2004 | F02888 | Patient expired; bronchopneumonia. | 2/23/74 | Unit not returned to Medtronic. |
| 3A02523 | H2003 | D2004 | A02804 | Patient expired; ASHD | 12/27/74 | Unit not returned to Medtronic. |
| 3A03494 | H2003 | D2004 | D02870 | Patient expired; MI. | 10/04/74 | Unit not returned to Medtronic. |
| 3G01342 | H1008 | D1008 | F01045 | Patient expired; information NA* | 6/07/74 | Unit not returned to Medtronic. |
| 3G01352 | H1018 | D1020 | W02334 | Patient expired; MI. | 4/24/75 | 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. |
| 3G10553 | H1018 | D1020 | K02354 | Pocket infection | 7/10/75 | 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. |
| 3G33190 | H1018 | D1020 | R02342 | Patient expired; Hypertensive crisis, cardiac arrhythmia. | 6/14/75 | Unit not returned to Medtronic. |
| 3K00531 | H2080 | D1020 | H02337 | Elective replacement. | 10/29/75 | Unit not returned to Medtronic. |
| 3K00719 | H3051 | D3055 | C01200 | Patient expired of ASHD, CHF. | 6/09/74 | Unit not returned to Medtronic. |
| 3K02350 | H3042 | D3050 | O01207 | Elective replacement. | 5/29/75 | Unit not returned to Medtronic. |
| 3K09055 | H3038 | D3048 | G01209 | Elective replacement. | 6/10/75 | Unit not returned to Medtronic. |
| 3K11159 | H3041 | D3050 | W01208 | Elective replacement. | 9/10/75 | Unit not returned to Medtronic. |
| 3K11900 | H3051 | D3055 | F01113 | Elective replacement | 8/27/75 | 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. |
| 3K17603 | H3044 | D3050 | M01205 | Elective replacement. | 9/08/75 | Unit not returned to Medtronic. |
| 3K17744 | H3045 | D3050 | L01204 | Elective replacement. | 9/30/75 | Unit not returned to Medtronic. |
| 3K239[illegible]2 | H1021 | D1021 | L01253 | Patient expired; cardiac arrest. | Unknown | Not explanted; not pulse generator related. |
| 3L01865 | H1031 | D1020 | T02364 | Elective replacement. | 4/16/75 | Unit not returned to Medtronic. |

APPENDIX 4, continued

| S/N | Hospital Code | Physician Code | Patient Code | Reason For Explant | Date of Explant/Death | Status of Pulse Generator |
|---|---|---|---|---|---|---|
| 3L01942 | H2016 | D2018 | G01137 | Patient expired; information NA* | 12/29/73 | Unit not returned to Medtronic. |
| 3L03115 | H2025 | D2037 | M01182 | Patient died; CHF. | 7/14/74 | Unit not returned to Medtronic. |
| 3L03229 | H1065 | D1020 | G01820 | Elective replacement. | 6/15/75 | Unit not returned to Medtronic. |
| 3L03892 | H2016 | D2019 | S01143 | Erosion of electrode. | 2/13/75 | Unit not returned to Medtronic. |
| 3L04379 | H1018 | D1020 | H02337 | Elective replacement | 10/16/75 | Unit not returned to Medtronic. |
| 3L06027 | H1019 | D1021 | B01262 | Elective replacement. | 11/1/75 | Unit not returned to Medtronic. |
| 3L06095 | H3055 | D3058 | O01265 | Premature cell depletion | 3/14/75 | 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. |
| 3S25001 | H2003 | D2031 | M01182 | Patient died; CHF. | 7/14/74 | 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. |
| 3T16301 | H1020 | D1021 | D01249 | Elective replacement | 9/17/75 | Unit not returned to Medtronic. |
| 3T17710 | H1023 | D1023 | T01443 | Loss of capture/exit block. | 11/18/74 | Returned to Medtronic 11-27-74. |
| 4A00209 | H2003 | D2004 | R02976 | Patient expired; ASHD; MI. | 9/8/75 | Returned by hospital. |
| 4A00632 | H2003 | D2004 | G02873 | Patient expired; cardiac arrest; ASCVD. | 12/28/74 | Unit not returned to Medtronic. |
| XX4012 | H1025 | D1025 | D01349 | Patient expired; Parkinson's disease. | 11-30-74 | Unit not returned to Medtronic. |
| 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