Medtronic, Inc
8200 Coral Sea Street NE
MS MVS33
Mounds View, MN 55112

February 19, 2010

Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville, Road STE 210
Lisle, IL 60532-4352

License No. SNM-1156
Docket No. 070-01209
Medtronic, Inc.
7000 Central Ave NE
Minneapolis, MN

To whom it may concern.

I am writing to request that the Medtronic's U.S. Nuclear Regulatory Commission (NRC) Materials License governing recovery, analysis and storage of explanted nuclear pacemaker be terminated, for the following reasons.

- Since 2006 the Medtronic Model 9000 program has been under the control of the Minnesota Department of Health (MDH) which is classified as an agreement state by the NRC.

- Under this transfer agreement we are complying with the Radioactive Materials rules which ensure compliance with the code of Federal Regulations, Title 10, part 20 as well as the ORDER FOR INCREASED CONTROLS FOR CERTAIN RADIOACTIVE MATERIALS LICENSEES EA 05-090

- Our current NRC license includes a requirement in section 10.B. which authorizes Medtronic to "store (1) Medtronic Model 9000 isotopic pulse generator at each of the licensee's seven district office Storage at district offices shall not exceed 30 days.

- When our radiation safety program was transferred to the MDH it was our understanding that maintaining our NRC license was necessary since we were storing Model 9000 isotopic pulse generators outside the state of Minnesota at district offices until delivery to our main location in Minnesota.

- Since 2006 we have modified our process for recovery of our Model 9000 isotopic pulse generators. Currently our process requires an IATA certified Medtronic employee to travel to the recovery site package the device and ship the device directly to our returned product department located at the designated facility in Minneapolis, MN. Currently no Model 9000 isotopic pulse generators are stored at Medtronic district offices.

- Section 10.B is no longer applicable to our radiation protection program. To reflect this, ***our*** current MDH license no longer includes this requirement as part of our license requirements for device recovery.

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- Since we no longer store our Model 9000 isotopic pulse generators at district offices and instead ship the devices directly to Minneapolis, maintaining a license with the NRC is redundant as compliance is overseen by the MDH which is an agreement state.

For your reference I have attached a copy of our current licensees with the NRC the Minnesota Department of health as well as a copy of our current process for recovery of our Model 9000 isotopic pulse generators.

I am eager to discuss this issue with you, please contact me at 1-800-328-2518 (x 61545)

Sincerely,

Medtronic, Inc.

Keith Holloman

Keith Holloman
Sr. Clinical Research Specialist/Radiation Safety Officer- Model 9000 Radiation Protection Program
Cardiac Rhythm Disease Management
Clinical Research and Reimbursement

NRC FORM 314 (4-2008)
10 CFR 30.36(j)(1); 40.42(j)(1); 70.38(j)(1); and 72.54(k)(5)(i)(1)

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0028 EXPIRES: 08/31/2010

Estimated burden per response to comply with this mandatory collection request: 30 minutes. This submittal is used by NRC as part of the basis for its determination that the facility is released for unrestricted use. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0028), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

CERTIFICATE OF DISPOSITION OF MATERIALS

LICENSEE NAME AND ADDRESS	LICENSE NUMBER	DOCKET NUMBER
Medtronic, Inc **7000 Central Ave N.E.** **Minneapolis, MN 55432**	**SNM-1156**	**070-01209**
	LICENSE EXPIRATION DATE **06/30/2012**	

A. LICENSE STATUS *(Check the appropriate box)*

☐ This license has expired. ☑ This license has not yet expired; please terminate it.

B. DISPOSAL OF RADIOACTIVE MATERIAL

(Check the appropriate boxes and complete as necessary. If additional space is needed, provide attachments)

The licensee, or any individual executing this certificate on behalf of the licensee, certifies that:

☐ 1. No radioactive materials have ever been procured or possessed by the licensee under this license.

☐ 2. All activities authorized by this license have ceased, and all radioactive materials procured and/or possessed by the licensee under this license number cited above have been disposed of in the following manner.

☐ a. Transfer of radioactive materials to the licensee listed below:

☐ b. Disposal of radioactive materials:

☐ 1. Directly by the licensee:

☐ 2. By licensed disposal site:

☐ 3. By waste contractor:

See Attached Cover Letter For Rationale Related to Request for Terminating License.

☐ c. All radioactive materials have been removed such that any remaining residual radioactivity is within the limits of 10 CFR Part 20, Subpart E, and is ALARA.

C. SURVEYS PERFORMED AND REPORTED

☐ 1. A radiation survey was conducted by the licensee. The survey confirms:

☐ a. the absence of licensed radioactive materials

☐ b. that any remaining residual radioactivity is within the limits of 10 CFR 20, Subpart E, and is ALARA.

☐ 2. A copy of the radiation survey results:

☐ a. is attached; or ☐ b. is not attached (Provide explanation); or ☐ c. was forwarded to NRC on: _____ (Date)

☑ 3. A radiation survey is not required as only sealed sources were ever possessed under this license, and

☐ a. The results of the latest leak test are attached; and/or ☑ b. No leaking sources have ever been identified.

The person to be contacted regarding the information provided on this form:

NAME	TITLE	TELEPHONE *(Include Area Code)*	E-MAIL ADDRESS
Keith Holloman	**RSO**	**(763) 526-1545**	

Mail all future correspondence regarding this license to:
Keith Holloman Keith.holloman@medtronic.com

C. CERTIFYING OFFICIAL

I CERTIFY UNDER PENALTY OF PERJURY THAT THE FOREGOING IS TRUE AND CORRECT

PRINTED NAME AND TITLE	SIGNATURE	DATE
Keith Holloman, RSO	Keith Holla	2/19/2010

WARNING: FALSE STATEMENTS IN THIS CERTIFICATE MAY BE SUBJECT TO CIVIL AND/OR CRIMINAL PENALTIES. NRC REGULATIONS REQUIRE THAT SUBMISSIONS TO THE NRC BE COMPLETE AND ACCURATE IN ALL MATERIAL RESPECT. 18 U.S.C. SECTION 1001 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

MODEL 9000
RADIATION PROTECTION PROGRAM

MEDTRONIC, INC.

RADIATION PROTECTION PROGRAM

MEDTRONIC, INC.

APPENDICES

MEDTRONIC RADIATION PROTECTION PROGRAM

Medtronic is committed to minimize worker radiation exposure to a level that is "as low as is reasonably achievable" (ALARA). This Radiation Protection is designed to implement and document procedures for handling and storage of the Model 9000 pacemaker until all available Model 9000s are returned to Medtronic. These pacemakers will ultimately be packaged and shipped for disposal at an approved facility.

Medtronic is required to comply with Nuclear Regulatory Commission (NRC) regulations governing nuclear material. Medtronic manufactured nuclear powered pacemakers in the 1970s and is obligated to accept them when explanted and returned. These pacemakers contain plutonium-238. In order to legally and safely handle and store the pacemakers, Medtronic follows specific procedures and requirements set forth in a unique NRC "Special Materials" license.

The NRC 1979 Final Generic Environmental Statement on Plutonium Powered Batteries (NUREG 0600, Subpart 1) states that the "risk to environment is low" from nuclear powered pacemakers. The containment around the radioactive source is constructed in a secure manner that precludes any exposures under any probable scenarios. Extensive testing done by the manufacturer showed that the battery is extremely resistant to crushing, temperature extremes and impact.

This program is designed to comply with the Code of Federal Regulations, Title 10, Part 20, effective January 1, 1994 as well of the order for increased controls for certain radioactive materials licensees EA 05-090 (effective November 14, 2005)

In March of 2006 the NRC completed a transfer agreement with the State of Minnesota to assume part of the NRC regulatory authority over certain radioactive materials. Consequently the Model 9000 program must also comply with the Minnesota Department of Health (MPH) Radioactive Materials rules, Chapter 4731.

Each of the Model 9000s is tested upon return. The precautions taken during the receiving and testing of incoming explanted Model 9000s detailed in this Program are sufficient to protect Medtronic employees from the remote possibility of exposure.

Radiation Safety Officer

Medtronic has an assigned a Radiation Safety Officer (RSO) to implement and interpret this Program and serve as a liaison between the NRC and Medtronic. The RSO is responsible for ensuring that an annual test of the storage and receiving is conducted, adequate training is given to workers who handle the Model 9000s, and an annual review of this program is made.

The radiation test of the storage and receiving areas should be conducted according to the provisions in the Materials license, and documented in the Event Analysis Reporting System (EARS). Since multiple copies of the Program can be found at the Rice Creek facility, the RSO's Program manual will be considered the Master Copy, and will be electronically stored in documentum (a secure, electronic archiving system). All test data will be electronically stored in (EARS).

The RSO is also responsible for ensuring that all employees assigned to work with the Model 9000s have been properly trained in the proper handling procedures, and are made aware of the potential hazards of radioactive materials. This is accomplished through a dedicated section in the annual Employee Right-to-Know training exercise.

The RSO will also ensure that the processing of all returned Model 9000s will be done in a timely manner, and that any revisions of procedures involving handling of the Model 9000s are incorporated into this plan.

History and Background

Medtronic and other manufacturers used plutonium batteries to power some pacemakers manufactured in the 1970s. The radioactive material in the batteries was encased in a series of enclosures that isolates the plutonium-238 from the environment. The Model 9000 is considered a "sealed source" by the NRC. Extensive testing done by the manufacturer showed that the battery is extremely resistant to crushing, temperature extremes and impact.

As detailed below, actual employee contact with returned Model 9000s is limited to receiving, processing, leak testing, and performance testing. The pacemakers are then stored in the sterilizer room of the Returned Products Analysis Lab (RPA).

The Model 9000 unit is designed and manufactured for use in the human body and should not pose any significant radioactive health hazard as long as the unit remains sealed and intact. The total amount of time that each Model 9000 is actually handled by an employee during the procedures listed above is approximately 10 minutes from receipt to storage. The frequency of returned Model 9000s going through receiving and testing procedures is usually two or less pacemakers during an average year. The calculated maximum amount of time an employee handles Model 9000 is less than 0.01% of an average work year (2080 hours), or less than 30 minutes/year. The potential for approaching any yearly regulatory exposure limit is remote.

Copies of the NRC and MDH material licenses are found in Appendix A and B respectively. The three procedures in Appendix C D, and E are the current procedures involving shipping, storage, handling, and testing of the Model 9000s. Appendix F contains an example of the return information and paperwork sent to the explant location.

Summary of Receiving and Testing Procedures, Model 9000
(As of July 1, 2008, Subject to procedure revisions)

1. Medtronic RPA Department is notified of a Model 9000 explant. Personnel from RPA travel to location of Model 9000 explant, prepares shipping documents and packages the Model 9000 for shipment to the RPA Department at Medtronic (See Appendix C, Nuclear Device return Kit Instructions (Model 9000), CSS.2103.0001-0034.1, Version1.0, 01-OCT-2007)
2. RPA records serial number of Model 9000 upon receipt and performs radioactive leak testing using calibrated alpha scintillater and rate counter. (See Appendix D, Model 9000 Radioactivity Leak Test and Storage Requirements, CSS.2103.00001-0005, Version 2.0, 07-JUL-2007). Approximately five to ten minutes are required for this test.
3. If the swipe test shows no leakage, the exterior of the Model 9000 is cleaned and prepared for sterilization (See Appendix E, Functional Test Procedure, CSS.2103.0001-0009. Version 2.0-31-MAR-2008)
4. Sterilization is performed in an ethylene oxide sterilizer.
5. After the Model 9000 pacemaker has been received, cleaned and sterilized, it is placed in the Model 9000 pacemaker storage box. This box is located in a secure safe in the RPA Sterilization room.
6. Only four (4) Model 9000 pacemakers can be stored in the safe at any time. When the total count of Model 9000 pacemakers is four (4), the devices will need to be transferred to an approved offsite disposal facility.

STORAGE AND SECURITY

The security provided for storage of these materials is of great importance for successful compliance with NRC licensing provisions. When not in the testing or cleaning processes, the units are stored in a secure location. The entire Rice Creek building is restricted access, with entrances controlled by a security system and security staff. Permanent device storage in the RPA is a locked safe. The combination of the safe is known only to the Returned Goods Coordinator, Project Coordinator, and responsible RPA technician. Procedures dictate that the safe can contain up to 4 Model 9000s. When the fourth returned Model 9000 is received and processed, the devices are transferred to an approved off-site storage site facility.

APPENDIX A

SPECIAL MATERIAL LICENSE FOR MEDTRONIC RICE CREEK FACILITY

NRC FORM 374

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 25

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	**In accordance with letter dated October 25, 2002, and April 4, 2003,**
1. Medtronic, Inc.	3. License number SNM-1156 is **amended** in its entirety to read as follows:
2. 7000 Central Avenue N.E. Minneapolis, MN 55432	4. Expiration date June 30, 2012
	5. Docket No. 070-01209 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Plutonium (Principal) radionuclide Pu-238)	A. Sealed Source(s) (Alcatel-Gipsie)	A. 150 grams total, no single source to exceed 1 gram Pu-238

9. Authorized Use:

A. Recovery, analysis and storage of explanted nuclear pacemakers.

CONDITIONS

10. A. License material may be used at the licensee's Rice Creek Facility, 7000 Central Avenue N.E., Minneapolis, Minnesota.

B. The licensee is authorized to store one (1) Medtronic Model 9000 isotopic pulse generator at each of the licensee's seven district offices in accordance with letters dated September 8, 1977, September 27, 1977, June 26, 1985, and August 8, 1991. Storage at district offices shall not exceed 30 days.

11. License material shall be used by, or under the supervision of, individuals designated by the licensee's Radiation Safety Committee, Charles Swanson, Chairman.

12. The Radiation **Safety** Officer for the activities authorized by this license is **Keith Holloman.**

13. A. (1) The source(s) specified in Item(s) 7.A. shall be tested for leakage and/or contamination at intervals not to exceed 6 months. Any source received from another person which is not accompanied by a certificate indicating that a test was performed within 6 months before the transfer shall not be put into use until tested.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
SNM-1156

Docket or Reference Number
070-01209

Amendment No. 25

(2) Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting material or 10 microcuries or less of alpha emitting material.

B. Any source in storage and not being used need not be tested. When the source is removed from storage for use or transfer to another person, it shall be tested before use or transfer.

C. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the source shall be removed from service and decontaminated, repaired, or disposed of in accordance with Commission regulations. A report shall be filed within 5 days of the date the leak test result is known with the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, IL 60532-4351, ATTN: Director, Division of Nuclear Materials Safety. The report shall specify the source involved, the test results, and corrective action taken. Records of leak test results shall be kept in units of microcuries and shall be maintained for inspection by the Commission. Records may be disposed of following Commission inspection.

D. Tests for leakage and/or contamination shall be performed by the licensee or by other persons specifically licensed by the Commission or an Agreement State to perform such services.

14. Sealed sources containing licensed material shall not be opened.

15. Medtronic, Inc., shall collect, tally and submit a report annually to the U.S. Nuclear Regulatory Commission, Region III, 801 Warrenville Road, Lisle, IL 60532-4351, ATTN: Director, Division of Nuclear Materials Safety. The report shall include data received from all investigators in accordance with the procedures described in pages 2 and 3 of "Medtronic Laurens-Alcatel Model 9000 Isotopic Pulse Generator CLINICAL INVESTIGATION PLAN" dated March 21, 1973.

16. The licensee may transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number
SNM-1156

Docket or Reference Number
070-01209

Amendment No. 25

17. Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be delivered to a carrier for shipment by air transport or transported in an aircraft by the licensee except in packages the design of which the NRC has specifically approved for transport of plutonium by air.

18. The licensee shall maintain records of information important to safe and effective decommissioning at the address specified in License Item 2. per the provisions of 10 CFR 70.25(g) until this license is terminated by the Commission.

19. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

20. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Application dated August 7, 1969 and supplements dated May 26, 1970, October 23, 1970, May 14, 1971, August 18, 1971, September 14, 1971, February 28, 1972, August 29, 1972, March 5, 1973, March 23, 1973, May 10, 1973, September 5, 1974, March 24, 1975, April 8, 1976, October 7, 1976, February 10, 1977, September 8, 1977, September 27, 1977, and October 25, 2002; and

    B. Letters dated June 26, 1985 (Renewal), May 21, 1986, August 8, 1991, December 5, 1991, December 6, 2001 (excluding request to add Keith Holloman as RSO) and October 25, 2002.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date JUL 13 2003

By Colleen C. Casey
Colleen C. Casey
Materials Licensing Branch
Region III

APPENDIX B

MDH SPECIAL MATERIAL LICENSE FOR MEDTRONIC RICE CREEK FACILITY

RADIOACTIVE MATERIALS LICENSE

Pursuant to Minnesota Statute 144.12 and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive materials designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the rules. This license is subject to all applicable rules and orders of the Minnesota Department of Health including the Minnesota Radioactive Materials Rules, Chapter 4731, now or hereafter in effect, and to any conditions specified below.

LICENSEE

1. MEDTRONIC, INC.

2. 7000 CENTRAL AVENUE NORTHEAST
MINNEAPOLIS, MINNESOTA 55432

In accordance with the documents listed in Item 18, the Minnesota Department of Health Radioactive Materials License is issued to read as follows:

3. License Number: 1171-102-27

4. Expiration Date: June 30, 2012

Program Codes		
Primary: 22162	Secondary:	Other:

5. By Product, Source, Special Nuclear and/or Natural Occurring; or Accelerator Produced Radioactive Material	6. Chemical and/or Physical Form	7. Maximum Amount That Licensee May Possess At Any One Time Under This License
A. Plutonium (Principal radionuclide Pu-238)	A. Sealed source(s) (Alcatel-Gipsie)	A. No single source to exceed 0.21 grams (3.6 curies [133 GBq]) of Pu-238. Total not to exceed 0.88 grams (15 curies [555 GBq])

8. **AUTHORIZED USE**

A. Recovery, analysis and storage of explanted nuclear pacemakers.

CONDITIONS

9. License material may be analyzed and stored at the licensee's Rice Creek Facility, 7000 Central Avenue NE, Minneapolis, Minnesota.

10. The Radiation Safety Officer for this license is Keith Holloman.

11. License material shall be used by, or under the supervision of, individuals designated by the licensee's Environmental Health and Safety Committee.

12. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as specified by the certificate of registration.

B. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source received from another person shall not be put into use until tested and the test results received.

C. Sealed sources need not be tested if they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

D. Sealed sources may be stored for a period of no more than 3 years without being tested for leakage and/or contamination. When sealed sources are removed from storage for use or for transfer to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer.

RADIOACTIVE MATERIALS LICENSE

E. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerel) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerel) or more of removable contamination, a report shall be filed with the Minnesota Department of Health in accordance with 4731.3110, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Minnesota Department of Health regulations.

F. Tests for leakage and/or contamination shall be performed by the license or other persons specifically licensed by the NRC or an Agreement State to perform such services.

13. Sealed sources containing licensed material shall not be opened by the licensee.

14. Medtronic, Inc. shall collect, tally and submit a report annually to the Minnesota Department of Health. The report shall include data received from all investigators in accordance with the procedures described in pages 2 and 3 of "Medtronic Laurens-Alcatel Model 9000 Isotopic Pulse Generator Clinical Investigation Plan" dated March 21, 1973.

15. Except for plutonium contained in a medical device designed for individual human application, no plutonium, regardless of form, shall be delivered to a carrier for shipment by air transport or transported in an aircraft by the licensee except in packages the design of which the US Nuclear Regulatory Commission has specifically approved for transport of plutonium by air.

16. The licensee shall maintain records of information important to safe and effective decommissioning at the address specified in License Item 2 in accordance with the provisions of 4731.0580 until this license is terminated by the Minnesota Department of Health.

17. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

18. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Minnesota Department of Health's rules shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the rules.

A. NRC applications dated August 7, 1969 and supplements dated:

May 26, 1970, October 23, 1970, May 14, 1971, August 18, 1971, September 14, 1971, February 28, 1972, August 29, 1972, March 5, 1973, March 23, 1973, May 10, 1973, September 5, 1974, March 24, 1975, April 8, 1976, October 7, 1976, February 10, 1977, September 8, 1977 and September 27, 1977.

B. Letter to NRC dated June 26, 1985 (Renewal).

C. Letter to NRC dated May 21, 1986.

D. Letter to NRC dated August 8, 1991 and December 5, 1991.

E. Letter to NRC dated December 6, 2001 (excluding request to add Keith Holloman as Radiation Safety Officer).

F. Letter to NRC dated October 25, 2002.

G. NRC application dated October 25, 2002.

H. Letter to NRC dated March 2, 2006.

I. Letter to MDH dated June 2, 2006.

J. Letter to MDH dated July 24, 2008.

RADIOACTIVE MATERIALS LICENSE

FOR THE MINNESOTA DEPARTMENT OF HEALTH

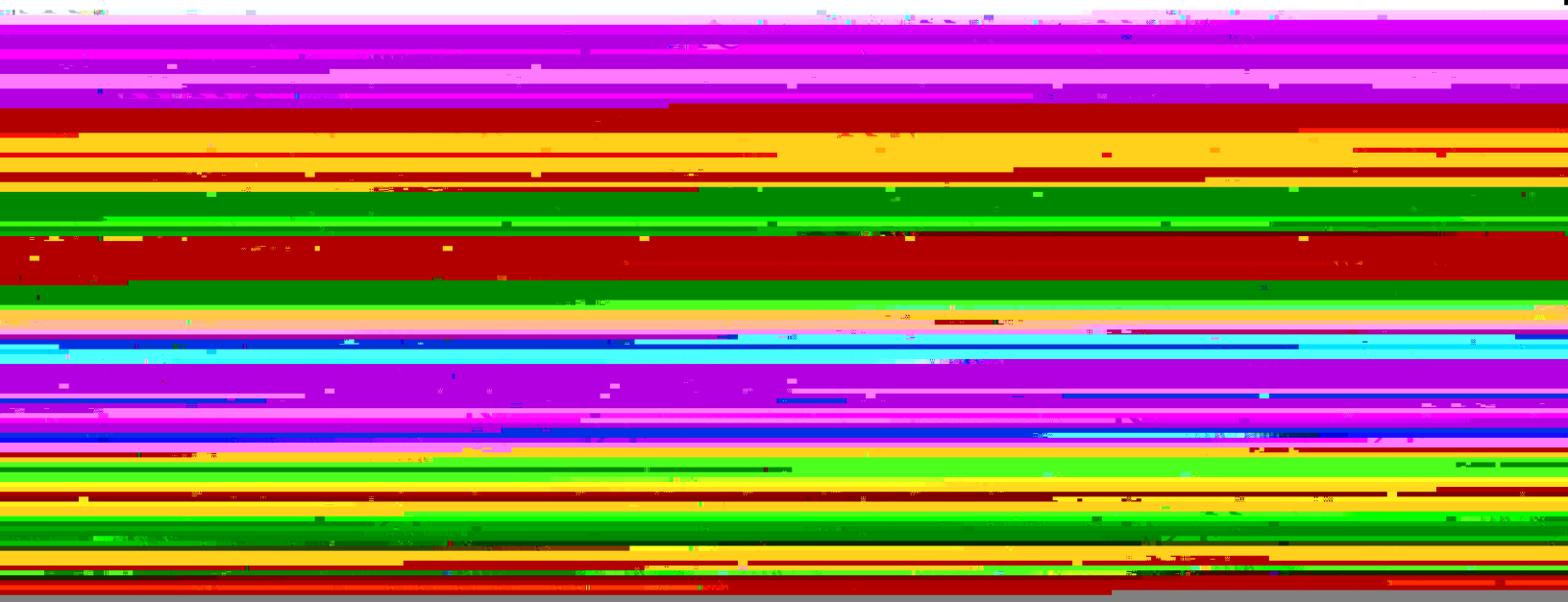
Prepared by: _____ Date: 9/2/08
Radioactive Materials Unit Staff

Reviewed by: _____ Date: 9/2/08
Radioactive Materials Unit Staff

Approved by: _____ Date: 09/02/08
Radioactive Materials Unit Supervisor

APPENDIX C

NUCLEAR DEVICE RETURN KIT INSTRUCTIONS



Medtronic

Nuclear Device Return Kit Instructions (Model 9000)

Cardiac Rhythm Disease Management
Business and Quality Management System

CSS.2103.0001-0034.1, Version 1.0
Effective Date: 01-OCT-2007

1.0 Purpose

The instructions here will outline the steps and information necessary for IATA/ICAO trained Returned Products Analysis (RPA) staff to prepare and pack the shipping container to be used only for the transport of the Medtronic Model 9000 nuclear-powered Implantable Pulse Generators (IPG).

2.0 Scope

This document provides the instructions for proper assembly and shipping a container to the customer for the purpose of the return of explanted Medtronic Model 9000 nuclear-powered IPGs.

3.0 References

IATA Dangerous Goods Regulations

HMR Hazardous Materials Regulations

CSS.2103.0001-0034, Nuclear Device Preparation and Shipping (Model 9000)

4.0 Abbreviations, Acronyms, and Definitions

Name	Description
CRDM	Cardiac Rhythm Disease Management
HMR	Hazardous Materials Regulations
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IPG	Implantable Pulse Generators
RPA	Released Product Analysis

5.0 Instruction Responsibility

CRDM RPA Lab is responsible for the tasks described in this document.

6.0 Instruction

This instruction is only used to prepare the Model 9000 IPGs to be returned and will be used after the return materials have been sent to the appropriate location for device retrieval.

6.1 Materials

A. The material needed will be available from the return kit forwarded to the appropriate location.

B. The only additional material is the Model 9000 device to be returned and shipping tape to close the box.

6.2 Open box and review instructions.

Note: ***Only one Model 9000 may be sent back in the package.***

Note: ***Have the Model 9000 available before beginning the following steps.***

A. Open the shipping box and make sure to save the inner package and all the packing material within. This inner box is the return shipping box.

B. Open the envelope containing the return documentation and separate the two plastic bags.

C. Open the inner box and removing the canister carefully to aid repacking.

D. Place the Model 9000 inside the bag labeled Contaminated Products and seal securely.

E. Place this bag between the two layers of absorbent material in the larger plastic bag and seal securely. See example in Figure 1.

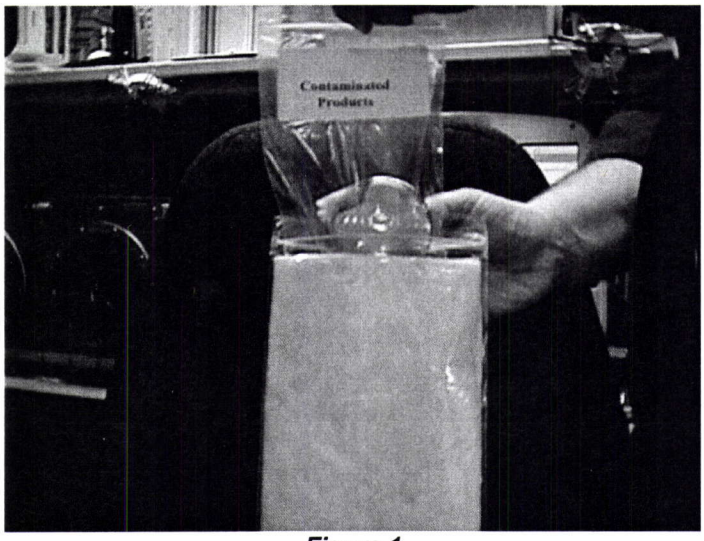


Figure 1

6.3 Open Metal canister.

A. Open the metal canister by sliding the button on the latch toward the lid and lift and disengage the latch. See Figure 2.

Figure 2

B. Rotate the lid counterclockwise until the slot in the lid lines up with the alignment label on the side and remove the lid. See Figure 3.

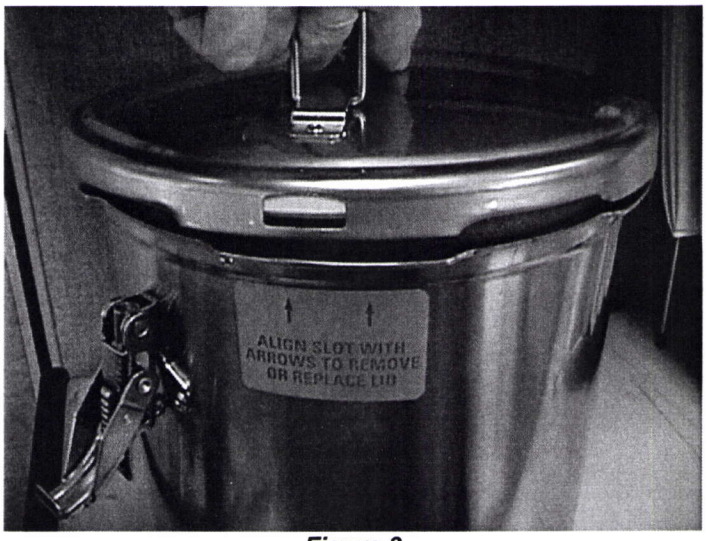


Figure 3

6.4 Placing Model 9000 in inner container

A. Lift out the blue liner top to expose the inner container.
B. Unhook the four latches on the inner container and remove the lid.
C. Place the Model 9000 device now in the two bags inside the inner container and reattach the lid. See Figure 4.

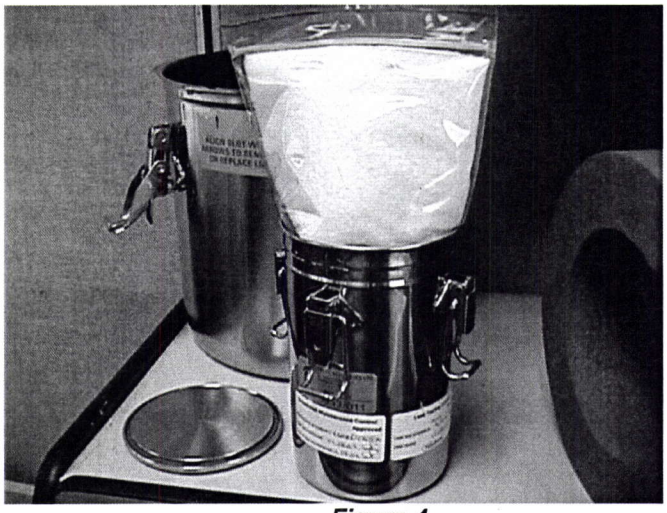


Figure 4

6.5 Returning container to packaging

A. Place the inner container back in the blue liner and replace the blue liner top.
B. Line the slot in the handled lid with the label and rotate clockwise until the slot lines up with the latch.
C. Attach the latch to make the container secure.
D. Return container to the labeled box. See Figure 5 for packing material configuration.
E. Cover container with the two sheets of bubble wrap from the original packaging.

Figure 5

6.6 Closing return package

A. Fold the flaps down so that when tape is applied, it does not go on the side of the box with the labels. See Figure 6.

B. Securely tape the box closed.

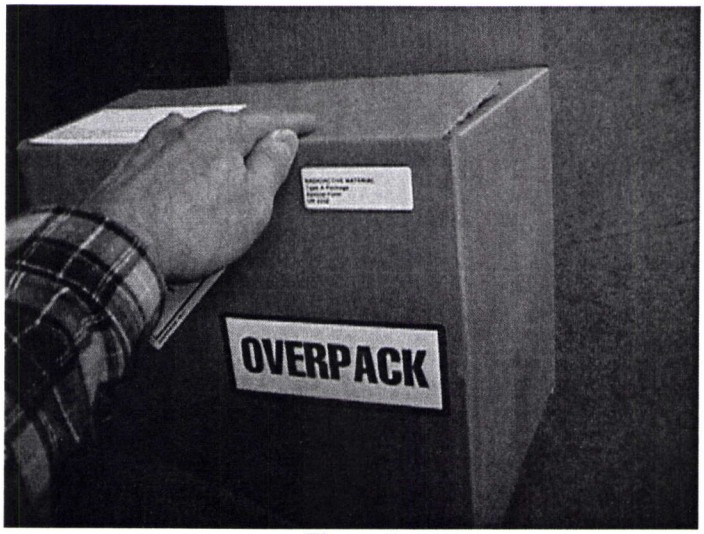


Figure 6

6.7 Federal Express Airbill

A. Fill out the following sections of the "FedEx USA Airbill."

1. Date
2. Sender's Name and Phone Number
3. Company
4. Address
5. City, State,

B. The pre-paid airbill (ship 2day air) should be placed in the pouch and attached to the box. It may be helpful to record the tracking number listed on the waybill in the event the package needs to be tracked.

Note: Be careful not to cover any label on the box and do not seal the pouch.

6.8 Filling out Dangerous Goods Form

WARNING: Training is required to complete this form. The Medtronic hazmat employee must be trained according to the requirements of IATA/ICAO for the transport of goods via air in order to sign the dangerous goods shipping papers (e.g. Dangerous Goods Declaration)

A. Parts to be completed are:
   1. Shipper – Name and Address
   2. Airport of Departure
   3. Name/Title of Signatory
   4. Place and Date
   5. Signature

B. Fold the declaration and place in the pouch on the top of the box. Do not seal the pouch.

6.9 Package preparation is complete

The instructions for assembling the package for returning the Medtronic Model 9000 nuclear-powered pacemaker are now complete.

7.0 Recertification Requirements

A. In order to maintain certification in this work instruction, the following steps need to be completed successfully:
   1. Read and acknowledge the steps in this work instruction.
   2. Maintain certification in hazardous material shipping through DOT and IATA.

B. At the successful completion of these steps an individual with prior certification in this work instruction will be considered recertified.

8.0 Records Retention

There are no records retained as part of this work instruction.

APPENDIX D

LEAK TEST AND STORAGE REQUIREMENTS

Medtronic

Model 9000 Radioactivity Leak Test and Storage Requirements

Cardiac Rhythm Disease Management
Business and Quality Management System

CSS.2103.0001-0005, Version 2.0
Effective Date: 07-JUL-2008

1.0 Purpose

This work instruction describes the method for radioactivity leak testing and storage requirements of Model 9000 nuclear-powered pulse generators.

2.0 Scope

This work instruction applies only to Model 9000 nuclear-powered pulse generators received and stored in the RPA safe.

3.0 References

CSS.2103.0001.0005.1 – Radioactive Leak Test Log sheet

CSS.2103.0001-0004 – Safe Handling of Contaminated Material and Returned Product Check In

CSS.2103.0001-0029 – Scanner System Operation

CSS.2103.0001-0040 – Secure Handling, Tracking, Retention, and Reporting of Legal Devices

CSS.1801.0010 – Product Vigilance and Reliability Training

4.0 Abbreviations, Acronyms, and Definitions

Name	Description
CRDM	Cardiac Rhythm Disease Management
EARS	Event Analysis Reporting System
RPA	Returned Product Analysis
RSO	Radiation Safety Officer

5.0 Instruction Responsibility

CRDM RPA Lab is responsible for the tasks described in this document.

6.0 Instruction

6.1 Equipment

ID Number	Description
ES009867	Model 43-2 Small Area Alpha Scintillator.
N/A	Model 2200 Scaler-Ratemeter.
071622 T-02	Delrin® Test Fixture with slide carrier

6.2 Materials

ID Number	Description
N/A	Swipe filter paper – cut into quarters. Whatman 4.25 cm Diameter
N/A	Am alpha Radiation Standard. Plated on a stainless steel wafer, activity: 3.10×10^{1} microcuries + 2%
CSS.2103.0001-0005.1	Radioactive Leak Test Log sheet

6.3 Leak Test Instructions

Note: ***These instructions are to be performed on all Model 9000 nuclear-powered pacemakers upon receipt and at a minimum of every six months thereafter, and just prior to shipment to an approved offsite disposal site. Each time a Model 9000 is received, all Model 9000 devices in inventory will be leak tested at the same time as the new device receipt. This will enable a common six month leak test schedule for every Model 9000 in inventory. The scheduling of the leak tests to meet the required intervals is the responsibility of the individuals performing the test.***

All counts listed in the subsequent instructions are counts per minute.

6.3.1 Perform Standard Count

A. This step is performed to obtain a standard radiation count of the safe.

B. Record each Model 9000 serial number to be tested onto a separate Radioactive Leak Test log sheet.

C. Take a zip lock plastic bag out of the cabinet in the RPA Sterilization room.

D. Plug in the power cord and set the Model 2200 Scaler-Ratemeter as follows:

1. Power Setting Knob – **Line**

Note: ***Model 2200 Scaler-Ratemeter requires at least five (5) minutes to warm up after turning the power-setting knob to line before any counting is done.***

2. Range Knob - **x100**
3. F/S toggle switch - **F**
4. Window On-Off toggle switch - **Off**
5. Threshold Setting - 1.0 (First dial is set to 0.0, Second dial is sent to 1.0)
6. High Voltage Setting (HV dial) – **240 (approx. 550 kV on the voltage meter)**

E. Open the safe

F. Remove the Am alpha Radiation Standard wafer from its blue storage container and place it specimen side up (Specimen side is the side with a ring on the outer surface of the disk) in the deep circle well of the Delrin® Test Slide.

CAUTION: Do not touch the top of the source wafer, handle the edges only.

G. Place the Delrin® Test Slide into the Delrin® Test Fixture with the Am wafer side in first.

H. Remove the red cap from the Alpha Scintillator and place over in the top opening of the Delrin® Test Fixture.

I. Depress "Count" button on the Model 2200 Scaler-Ratemeter.

Note: ***The red count indicator will illuminate while counting. At the conclusion of the test (1 minute) the red count indicator light will go off.***

J. Record standard Count reading in Radioactive Leak Test log sheet.

K. Remove the Alpha Scintillator from the Delrin® Slide and reinstall the red cap.

L. Remove Am wafer from slide and return the wafer to storage.

CAUTION: Do not touch the top of the source wafer, handle the edges only.

6.3.2 Perform Background Count

A. This step is performed at the test area to obtain a baseline radiation count of the test area.

B. Set Range knob to x1 on the Model 2200 Scaler-Ratemeter.

C. Place an unused quarter sheet of filter paper into the shallow circle well of the slide underneath the wire. Place the end of the slide containing the filter paper into the Delrin® test fixture.

D. Remove the red cap from the Alpha Scintillator and place over in the top opening of the Delrin® Test Fixture.

E. Depress the "Count" button.

Note: The red count indicator will illuminate while counting. At the conclusion of the test (1 minute) the red count indicator light will go off.

F. Remove the Alpha Scintillator from the Delrin® Slide and reinstall the red cap.

G. Record Background Count reading in Radioactive Leak Test log sheet.

6.3.3 Calculate Counting Efficiency

A. Subtract the background count (reading 6.3.2 part D) from the Am (standard) count (reading from 6.3.1 step G).

B. Divide this value by 67,080.

Note: The result of this division should be between 0.12 and 0.16. If the value is above or below this range, recheck the equipment set up or have equipment serviced.

C. Record counting efficiency in Radioactive Leak Test log sheet.

Note: Counting efficiency need only be calculated once if more than one pulse generator is to be tested while the Model 2200 Scaler-Ratemeter remains on.

6.3.4 Perform the Swipe Count

A. This step is performed and then repeated for each additional device.

B. Wearing surgical rubber gloves, remove filter paper used for the background count from the Delrin® Slide and wipe the entire weld seam of the Model 9000 pulse generator as well as the area where the leads were inserted into the connector.

Note: ***If multiple generators are being tested, the filter paper should not be reused. Take a new quarter piece of filter paper for each additional generator being tested.***

C. Place the exposed filter (wipe side up) on the Delrin® Slide and secure with the metal wire. Place the end of the slide with the filter paper into the Delrin® Test Fixture.

D. Remove the red cap from the Alpha Scintillator and place over in the top opening of the Delrin® Test Fixture.

E. Depress the **"Count"** button.

Note: ***The red count indicator will illuminate while counting. At the conclusion of the test (1 minute) the red count indicator light will go off.***

F. Remove the Alpha Scintillator from the Delrin® Slide and reinstall the red cap.

G. Record swipe count reading in Radioactive Leak Test log sheet.

H. Subtract Background Count (6.3.2) from Swipe Count (6.3.4) and record result in Radioactive Leak Test log sheet as Net Count.

I. If the Net Count is equal to or greater than 140, proceed to step 6.3.5. If the net count is less than 140, enter <0.005 under Microcuries on the Radioactive Leak Test log sheet and place the wipe sample into the zip lock plastic bag. If no further generators are being tested, proceed to step J.

Note: ***If more than one pulse generator is to be tested return to 6.3.4 step A and repeat swipe count process until all generators are tested. The standard count and background will remain the same as long as the Model 2200 Scaler-Ratemeter remains powered on.***

J. Remove the Alpha Scintillator from the Delrin® Slide and reinstall the red cap.

K. Set the Range Knob of the Model 2200 Scaler-Ratemeter to **x100**.

L. Turn Power Setting Knob to **OFF**.

M. Confirm each Model 9000 device leak test result is recorded on the correct Radioactive Leak Test log sheet.

N. Place surgical rubber gloves in the zip lock plastic bag along with the wipe sample and dispose as biohazard waste per CSS.2103.0001-0004.

O. Apply a barcode as described in CSS.2103.0001-0004 – Safe Handling of Contaminated Material and Returned Product Check In, to the Swipe test form and scan the document into its event record per CSS.2103.0001-0029.

6.3.5 Net Count Greater than 140

A. If the net count is equal to or great than 140, place the pulse generator, your gloves and test paper in the zip lock plastic bag.

B. Contact the RSO as listed in the Minnesota Department of Health notice posted in the clean room. Describe the leak and the measures taken to clean up the radioactive material.

C. RSO will provide additional directions as needed to mitigate exposure.

6.4 Storage and Inventory of Model 9000 Pacemakers

Note: ***All nuclear powered pacemakers must be stored in a properly labeled secure locked safe at all times. Units cannot be left unattended.***

A. After the Model 9000 pacemaker has been received, cleaned, sterilized, and the leak test completed and documented, place it in the Model 9000 pacemaker storage box. This box is located in the safe (this is located in the RPA lab Sterilization room). Change the device location in EARS per CSS.2103.0001-0040.

B. Only four (4) Model 9000 pacemakers can be stored in the safe at any time. When the total count of Model 9000 pacemakers is four (4), the devices will need to be transferred to an approved offsite disposal facility. Any inventory of Model 9000 less than the storage limit of four (4) may also be transferred to an approved offsite disposal facility. Contact the RSO as listed on the Minnesota Department of Health notice posted in the clean room or the RPA Manager or responsible RPA engineer for shipping directions.

C. A Model 9000 pacemaker may not be removed permanently from the safe unless it is being shipped to an approved offsite storage facility. It cannot be returned to the patient or physician.

D. There will be an inventory taken of all Model 9000 pacemakers stored in the safe. The inventory record will need to include the serial numbers of each Model 9000 in storage. This will also include an audit of the EARS event records for each Model 9000 in inventory to assure all devices and leak test results are included and were completed in the appropriate timeframe as stated in the note listed at the beginning of section 6.3. These two steps will be done at a minimum of every six months. An inventory of all Model 9000 will be performed every time a Model 9000 is received or any quantity of Model 9000 devices are sent to an approved offsite facility for disposal. The six month inventory time interval will start new with each Model 9000 receipt or disposal shipment. It is the responsibility of the individual performing the inventory to assure the task is completed in the appropriate timeframe. The results of the inventory and audit check will be provided to the RPA Manager, responsible RPA engineer, RSO and the current copy will be kept in the Model 9000 storage box in the safe.

7.0 Recertification Requirements

A. In order to maintain certification in this work instruction, the following steps need to be completed successfully:

1. Execute the leak test process on a single Model 9000 device (section 6.3).

B. At the successful completion of these steps an individual with prior certification in this work instruction will be considered recertified. The recertification will be recorded in accordance with CSS.1800.0010.

8.0 Records Retention

All records generated in this work instruction are electronically entered and stored in EARS.

APPENDIX E
FUNCTIONAL TEST PROCEDURE

Medtronic

Functional Test

Cardiac Rhythm Disease Management
Business and Quality Management System

CSS.2103.0001-0009, Version 2.0
Effective Date: 31-MAR-2008

1.0 Purpose

The purpose of this Work Instruction is to identify the mode of performing functional test on Medtronic IPGs and ICDs as well as instruct on methods of manual functional test.

2.0 Scope

This work instruction is applicable to all IPGs and ICDs that are distributed by Medtronic and have been received in the Returned Product Analysis Lab.

3.0 References

CRM.2104.0001 – Product Performance Code Designation

CSS.2103.0001-0024 – NGT System Operation

CSS.2103.0001-0025 – ATS System Operation

CSS.2103.0001-0009.1 – CRDM Returned Product Analysis Manual Functional Test Results

4.0 Abbreviations, Acronyms, and Definitions

Name	Description
AF	Atrial Fibrillation
AT	Atrial Tachycardia
ATS	Automatic Test System
BPM	Beats per Minute
CCW	Counterclockwise
CW	Clockwise
EARS	Event Analysis Reporting System
ERI	Elective Replacement Indicator
HVA/X	High Voltage A/X
HVB	High Voltage B
ICD	Implantable Cardioverter Defibrillator
IPG	Implantable Pulse Generator
NGT	Next Generation Test System
PPM	Pulses per Minute
PSA	5311 Pacing System Analyzer
RPA	Returned Product Analysis
RV	Right Ventricle
SVC	Superior Vena Cava
TNT	Threshold Margin Test
VF	High Voltage B
VPS	Elective Replacement Indicator
VT	Ventricular Tachycardia

5.0 Instruction Responsibility

CRDM RPA Lab is responsible for the tasks described in this document.

6.0 Instruction

6.1 Equipment

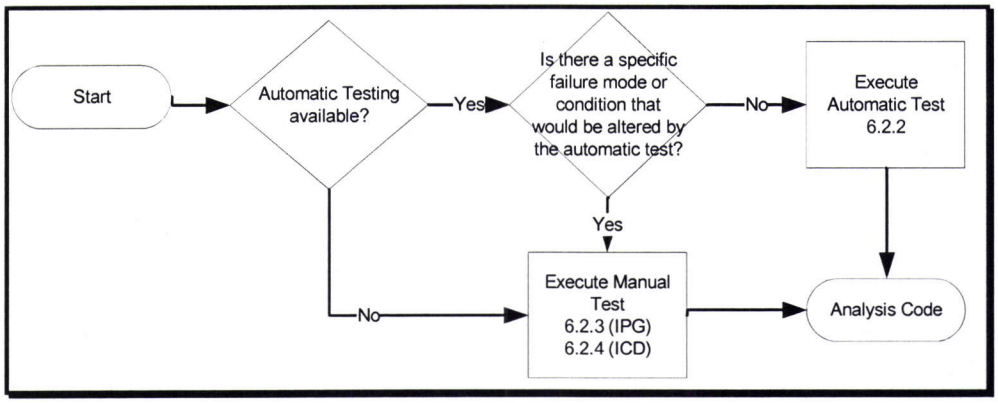
Description
500 ohm (+/- 10%) resistor
75 ohm (+/-10%) (25 watt) defibrillation resistor and a 500 ohm (+/- 10%) pacing resistor
ATS
Body Temperature Oven or equivalent
Connector Blocks specific to each model
Counter
External Magnet – equivalent to the magnet in the programming head of the Medtronic programmer
Medtronic Model 5311 Pacing Systems Analyzer
Medtronic Programmer
NGT
Oscilloscope

6.2 ANALYSIS PROCEDURE

6.2.1 IPG / ICD Functional Test Method Decision Flow Diagram

Note: Functional testing using automatic testers (ATS or NGT where applicable) is the method of choice for efficiency purpose.

A. The following flowchart depicts the process of determining whether a device will be tested manually or automatically.



Note: If there is a question regarding the use of the automatic test, consult with the appropriate RPA lab engineer or manager.

6.2.2 IPG / ICD Automatic Functional Test

A. For NGT refer to CSS.2103.0001-0024
B. For ATS refer to CSS.2103.0001-0025

6.2.3 IPG Manual Functional Test

A. Prior to start of the test, the IPG shall be held at 98.6± 3.6F for one hour minimum.

B. The parameters and test conditions are set as such:
   1. Reset the battery status flag (ERI). If ERI is cannot be reset, record pacing parameters as is.
   2. Program the device to Nominal parameters.
   3. Program the device to a lower rate of 70 PPM.
   4. Program to DDD mode for dual chamber devices.
   5. Program to VVI mode for single chamber devices.
   6. Apply a 500 ohm resistor to the output terminal(s) of the device.

C. Measurement and Test Limits:
   1. All measured data are required to be entered into EARS. All the tests defined in this work instruction are subject to the test limits as defined in the Final Functional Test Specification. Refer to the PDM system for the specification appropriate for the device family:

D. Pulse Amplitude Measurement:
   1. Using the oscilloscope, measure the pulse amplitude per Product Specification.

E. Pulse Width Measurement:
   1. Using the counter, measure the pulse width per Product Specification.

F. Pulse Period Measurement:
   1. Using the counter, measure the pulse period per Product Specification.

G. Sensitivity and Ventricular Refractory Measurement:
   1. Using the PSA, press the All IPG measure button. For refractory measurement, select Refractory, and press measure.

   Note: Measurement will not be made if pulse amplitude is too low.

H. Reed Switch and Magnet Rate:
   1. Place an external magnet over the IPG. Ensure TMT pulses (at 600 ms) are observed. Report the magnet rate.

I. Fill in the form as shown in Table 1 to be scanned into EARS. Assign analysis code in EARS according to procedure CRM.2104.0001– Product Performance Code Designation.

6.2.4 ICD Manual Functional Test

A. Prior to start of the test, the IPG shall be held at 98.6± 3.6F for one hour minimum.
B. The parameters and test conditions are set as such:
   1. Program the device to Nominal parameters.
   2. Program the device to a lower rate of 70 bpm.
   3. Program to DDD mode for dual chamber devices.
   4. Program to VVI mode for single chamber devices.
   5. Apply a 500 ohm resistor to the output terminal(s) of the device.
C. Battery voltage:
   1. Using a Medtronic programmer interrogate the device and record the battery voltage.
D. Pulse Amplitude Measurement:
   1. Using the oscilloscope, measure the pulse amplitude per Product Specification.
E. Pulse Width Measurement:
   1. Using the counter, measure the pulse width per Product Specification.
F. Pulse Period Measurement:
   1. Using the counter, measure the pulse period per Product Specification.
G. Sensitivity and Ventricular Refractory Measurement:
   1. Using the PSA, press the "All IPG" button and then press the "MEAS" button. For refractory measurement, select Refractory, and press measure. (Note: Measurement will not be made if pulse amplitude is too low).
H. VT therapy: Verify correct VT therapy is delivered.
   1. Note the VT and VF detection intervals from the interrogation printout.
   2. Connect a 510 ohm resistor between VPS+ and VPS- on the connector.
   3. Connect an oscilloscope across the resistor so that the probe is connected to VPS- and the probe ground is connected to VPS+.
   4. Apply a 10-mv 40 ms sine-squared wave with a period within the VT detection zone but below the VF detection zone.
   5. Use a Medtronic programmer to set up the VT therapies and detection by selecting Parameters and then Detection with the programmer. Turn the VT detect ON and the VF detection OFF. Under the Parameters, select Therapies. On the Therapies screen, select VT and program Rx1 to Ramp.
   6. Monitor the oscilloscope to verify the delivery of the Ramp VT therapy.
   7. Interrogate the device. Select Episodes and Counters under the data icon. Select the therapy that was just delivered and record the therapy data on the CRM Manual Functional Testing Results sheet.

I. VF therapy: Verify correct VF therapy.
   1. Note the VF detection interval from the interrogation printout.
   2. Connect a 75 ohm 25 Watt resistor between HVA/X and HVB outputs.
   3. Connect and oscilloscope with a 100X probe across the resistor so that the probe is connected to HVA and the probe ground is connected to HVB. The trigger option of the oscilloscope should be set to single in order to capture and retain the output.
   4. Apply a 10-mv 40ms sine-squared wave with a period within the VF detection zone.
   5. Go to the Therapies screen on the programmer and set up Rx1 to AX>B and the maximum joule setting. Program VF detection ON.

   Note: If the battery is low it may be necessary to use a lower therapy energy setting.

   6. Monitor the oscilloscope and verify that the device delivered the VF therapy as programmed. Document the data from the oscilloscope on the CRM Manual Functional Testing Results sheet.

   Note: Where applicable, AT and AF should be tested following the same procedure as VT and VF.

J. Charge time:
   1. Charge the high voltage capacitors to full energy using the programmer CHARGE / DUMP function.
   2. Wait a minimum of 10 minutes to allow the capacitor to form in case the ICD has not delivered a shock for a prolonged period of time.
   3. Program a DUMP of any charge remaining after 10 minutes. Program a second full energy charge.
   4. Record this charge time in the functional testing checklist.

K. Program VT and VF detection OFF: Program VT and VF detection OFF to prevent accidental shock.

L. Fill in the form shown in Table 1 to be scanned into EARS. Assign analysis code in EARS according to procedure CRM.2104.0001– Product Performance Code Designation.

M. The form is CSS.2103.0001-0009.1 and is an extension of this work instruction.

CRDM Returned Product Analysis Manual Functional Test Results	
The following parameters were tested to verify the functionality of an IPG/ICD:	
Event number	
Serial number	
Model	
Battery voltage	
Pulse Amplitude (Ventricular)	
Pulse Width (Ventricular)	
Pulse Period	
Pulse Amplitude (Atrial)	
Pulse Width (Atrial)	
Ventricular Refractory Period	
Ventricular Sensitivity	
Atrial Sensitivity	
VT detect:	OK/Did not detect
VT therapy (Programmer Episode Data):	
VF detect:	OK/Did not detect
VF therapy (Oscilloscope Data):	
Atrial results for applicable models:	
AT detect	OK /Did not detect
AT therapy (Programmer Episode Data):	
AF detect	OK/Did not detect
AF therapy (Oscilloscope Data)	
Full Energy Charge time	
Program detection OFF	OK

Table 1: Sample Manual Functional Test Form

7.0 Recertification Requirements

A. In order to maintain certification in this work instruction, the following steps need to be completed successfully:
   1. Demonstrate functional understanding of the decision flow in 6.2.1
   2. Execute IPG Manual Functional Test (section 6.2.3).
   3. Execute ICD Manual Functional Test (section 6.2.4).
   4. Complete a Manual Functional Test form.

B. At the successful completion of these steps an individual with prior certification in this work instruction will be considered recertified.

8.0 Records Retention

Any records created with this Work Instruction are stored in EARS.

Medtronic

Keith Holloman
Medtronic
8200 Coral Sea Street NE
MVS33
Mounds View, MN 55112

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT OF THE RETURN ADDRESS. FOLD AT DOTTED LINE

CERTIFIED MAIL™

7007 0710 0000 9843 5274

Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road STE 210
Lisle, IL 60532-4352