

**Veterans  
Administration**

In Reply Refer To: 539/115

United States Nuclear Regulatory Commission  
Region III  
799 Roosevelt Road  
Glen Ellyn, IL 60137

Gentlemen:

The following response is pursuant to renewal of the Nuclear Powered Pacemaker License. Our NRC license number is SNM-1735 and our program code number is 22160.

- (a) License Number: SNM-1735  
Expiration Date: May 31, 1987  
Program Code: 22160
- (b) Veterans Administration Medical Center  
3200 Vine Street  
Cincinnati, Ohio 45220
- (c) Two pacemakers have been authorized, NRC number SNM-1735 reference number 070-02580 (not to exceed 210 milligrams each). Both are Medtronic Model 9000 Nuclear Powered Pacemakers. One remains implanted; the other was removed and returned to Medtronics on 9-18-86. (See enclosed sheet)
- (d) We are requesting authorization to follow the patients with implanted pacemakers, not for implantation or reimplantation.
- (e) Please add the following physicians who are involved in the pacemaker program:
  - 1. Jon Rogers, M.D., Staff Cardiologist
  - 2. Yitzchak Hermoni, M.D., Staff Cardiologist(See enclosed information)

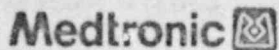
Sincerely,

DONALD L. ZIEGENHORN  
Medical Center Director

Enclosures: 2

8803080453 880217  
REG3 LIC70  
SNM-1735 PDR

  
JAMES W. FLETCHER, M.D.  
Director, Nuclear Medicine Service (115)  
Veterans Administration  
Washington, DC 20420



## PRODUCT EVALUATION REPORT

Instructions: Use this form to report your experience with a Medtronic product or when returning a device for analysis. This information is necessary and will expedite processing for warranty consideration.

Please indicate model and serial numbers of the device(s) involved:

Pulse Generator

Lead(s)

Model No.:

Serial No.:

Model No.:

Serial No.:

Model No.:

Serial No.:

9000

5R00217

### GENERAL INFORMATION

Physician

M. BRANCO

Patient Name

Hospital

V-A

Street Address

Date of Implant

Date of Explant

9/15/86

City

Lexington

State

Zip

KY

### CLINICAL INFORMATION

NOTE: Please include all pertinent medical records including EKG's.

Reported Experience:

- |  |   |   |  |
|--|---|---|--|
| <input type="checkbox"/> Elective Replacement    | <input type="checkbox"/> Battery Depletion          | <input checked="" type="checkbox"/> Noncapture  | <input type="checkbox"/> Positioning Difficulty  |
| <input type="checkbox"/> Patient Expired         | <input type="checkbox"/> Rate Change                | <input type="checkbox"/> Oversensing            | <input type="checkbox"/> High Threshold Readings |
| <input type="checkbox"/> Infection               | _____ bpm to _____ bpm                              | <input type="checkbox"/> Undersensing           | <input type="checkbox"/> Fractured Lead          |
| <input type="checkbox"/> Erosion                 | <input type="checkbox"/> No Output                  | <input type="checkbox"/> Programming Difficulty | <input type="checkbox"/> Stylet Difficulty       |
| <input type="checkbox"/> Other (please explain): | <input type="checkbox"/> Visual Irregularity: _____ |   |  |

Reported experience was observed:

☒

Continuously

☒

Intermittently

Pacing Mode while implanted:

☐

DDD

☒

VVI

☐

DVI

☐

Programmed Parameters While Implanted:

Pulse magnitude: \_\_\_\_\_ (volts) Pulse Width: \_\_\_\_\_ Pulse Interval (Rate): \_\_\_\_\_

Sensitivity: \_\_\_\_\_ Refractory: \_\_\_\_\_ A-V Interval: \_\_\_\_\_

Lead Status:

☐

Reused

☐

Repaired

☐

Unipolarized

☐

Repositioned

☒

Replaced

☐

Capped

### REPLACEMENT INFORMATION

If replaced, indicate replacement device(s)

Pulse Generator

HJ202723H

Lead(s)

Model No.:

Model No.:

Serial No.:

Serial No.:

Model No.:

Serial No.:

8422

6962-58

UB0076310V

### FOLLOW-UP INFORMATION

Please indicate the name, address and phone number of the person to receive follow-up information:

Name

M. BRANCO

Area Code

Phone

Address

City

Lexington

State

Zip

KY

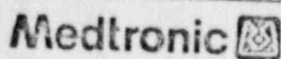
If you have a complaint, please specify:

Evaluation Report completed by

V. CEPLER

Date

9/15/86



## PRODUCT EVALUATION REPORT

Instructions: Use this form to report your experience with a Medtronic product or when returning a device for analysis. This information is necessary and will expedite processing for warranty consideration.

Please indicate model and serial numbers of the device(s) involved:

Pulse Generator

Lead(s)

Model No.:

Serial No.:

Model No.:

Serial No.:

Model No.:

Serial No.:

### GENERAL INFORMATION

Physician

Patient Name

Date of Implant

Date of Explant

Hospital

Street Address

City

State

Zip

### CLINICAL INFORMATION

NOTE: Please include all pertinent medical records including EKG's.

Reported Experience:

- |  |   |   |  |
|--|---|---|--|
| <input type="checkbox"/> Elective Replacement    | <input type="checkbox"/> Battery Depletion          | <input checked="" type="checkbox"/> Noncapture  | <input type="checkbox"/> Positioning Difficulty  |
| <input type="checkbox"/> Patient Expired         | <input type="checkbox"/> Rate Change                | <input type="checkbox"/> Oversensing            | <input type="checkbox"/> High Threshold Readings |
| <input type="checkbox"/> Infection               | _____ bpm to _____ bpm                              | <input type="checkbox"/> Undersensing           | <input type="checkbox"/> Fractured Lead          |
| <input type="checkbox"/> Erosion                 | <input type="checkbox"/> No Output                  | <input type="checkbox"/> Programming Difficulty | <input type="checkbox"/> Stylet Difficulty       |
| <input type="checkbox"/> Other (please explain): | <input type="checkbox"/> Visual Irregularity: _____ |   |  |

Reported experience was observed:

☐ Continuously ☒ Intermittently

Pacing Mode while implanted:

☐ DDD ☒ VVI ☐ DVI ☐ \_\_\_\_\_

Programmed Parameters While Implanted:

Pulse magnitude: \_\_\_\_\_ (volts) Pulse Width: \_\_\_\_\_ Pulse Interval (Rate): \_\_\_\_\_  
Sensitivity: \_\_\_\_\_ Refractory: \_\_\_\_\_ A-V Interval: \_\_\_\_\_

Lead Status:

☐ Reused ☐ Repaired ☐ Unipolarized ☐ Repositioned ☒ Replaced ☐ Capped

### REPLACEMENT INFORMATION

If replaced, indicate replacement device(s):

Pulse Generator

Model No.:

Serial No.:

Lead(s)

Model No.:

Serial No.:

Model No.:

Serial No.:

### FOLLOW-UP INFORMATION

Please indicate the name, address and phone number of the person to receive follow-up information:

Name

Area Code Phone

Address

City

State Zip

If you have a complaint, please specify:

This portion of report completed by:

Date:

Medical Center

3200 Vine Street  
Cincinnati OH 45220

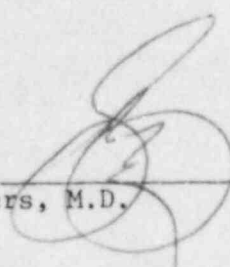


**Veterans  
Administration**

April 29, 1987

In Reply Refer To:

I have read the Nuclear Pacemaker Protocol approved by the  
Nuclear Regulatory Committee, and agree to follow this protocol  
concerning this patient.

  
\_\_\_\_\_  
Jon Rogers, M.D.

4/27/87.  
\_\_\_\_\_  
Date

*"America is #1—Thanks to our Veterans"*

1. Name	Jon M. Rogers, M.D.
2. Address	Cincinnati V.A. Medical Center Division of Cardiology 3200 Vine Street Cincinnati, Ohio 45220
3. Telephone number	861-3100 Extension 5072 (pager number 287)
4. License	Ohio 043831
5. Board	1) American Board of Internal Medicine (Specialty-Internal Medicine) 2) American Board of Internal Medicine (Subspecialty-Cardiovascular Disease)
6. Position at V.A.	Staff Cardiologist
7. Previous Experience with pacemakers	Pacemaker Clinic at the Cincinnati VAMC July, 1984 to present



**Veterans  
Administration**

April 21, 1987

In Reply Refer To:

I have read the Nuclear Pacemaker Protocol approved by the Nuclear Regulatory Committee, and agree to follow this protocol concerning this patient.

*Yitzchak Hermoni M.D.*

*4/27/87*

Yitzchak Hermoni, M.D.

Date

1. Name	Yitzchak Hermoni
2. Office Address	Cincinnati V.A. Medical Center Division of Cardiology 3200 Vine Street Cincinnati, Ohio 45220
3. Telephone Number	861-3100 Extension 5072 (pager number 273)
4. License	OHIO 49869 Maryland D28448
5. Board	1) American Board of Internal Medicine (Specialty- Internal Medicine) 2) American Board of Internal Medicine (Subspecialty- cardiovascular disease)
6. Position at V.A.	Staff Cardiologist
7. Previous Experience with pacemakers	Pacemaker Clinic at the Cincinnati VAMC July, 1980 to present