

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL09-22

June 8, 2009

NOTE: This Patient Safety Alert is similar to Patient Safety Alert AL06-08 issued on January 9, 2006; however, AL06-08 dealt with a 2005 subset of Medtronic Sigma cardiac pacemakers.

Items: Physician Advisory issued by Medtronic Inc. on subsets of: Kappa 600/700/900 series dual chamber and single chamber pacemakers and Sigma 100/200/300 series dual chamber and single chamber cardiac pacemakers

Specific Incident: Medtronic is reporting loss of rate response; premature battery depletion; intermittent or total loss of telemetry; or loss of pacing output in a subset of Kappa and Sigma cardiac pacemaker units. The cause of the failure has been identified as separation of redundant interconnection wires from the hybrid block in the pacemaker circuit (i.e., loss of contact). Predicted failure rates are 1.1% and 4.8% respectively, for Kappa 600/700/900 series and Sigma 100/200/300 series pacemakers. (Updated modeling for the 2005 subset predicts a failure rate of 3.9% over the remaining device life.)

Actions: 1. By close of business (COB) June 22, 2009, **electrophysiology/ cardiology staff or other appropriate clinical staff** must identify all affected patients by completing steps a through d.

It is important that ALL INFORMATION SOURCES be reviewed to insure that patients are identified; it is possible for affected patients to be on one list and not on another.

- a) Review the manufacturer's letter
<http://www.medtronic.com/kappasigma/physician.html>.
- b) Review the patient list posted on the VA National ICD Surveillance Center intranet website
<https://ICDPM.sanfrancisco.med.va.gov> (see Attachment 1).
- c) Review your patient records for all patients with implanted Medtronic devices affected by this recall. Affected serial numbers are available online at
<http://SigmaSNList.medtronic.com>.

d) Consult with your local Medtronic representative as they may have an additional list of VA patients and their follow-up physician.

2. By COB August 15, 2009, **electrophysiology/cardiology staff or other appropriate clinical staff** must follow the actions contained in Attachment 2, prepared by the VA National ICD Surveillance Center.

3. By COB August 15, 2009, the **Patient Safety Manager** shall document the status of this Patient Safety Alert on the VHA Hazardous Recalls/Alerts website. <http://vaww.nbc.med.va.gov/visn/recalls/index.cfm>.

Reimbursement: If you elect to replace an affected pacemaker, Medtronic will provide a replacement unit at no cost. Please contact your local Medtronic Representative or contact the Medtronic's Patient Service Group at 1-800-551-5544 for more information. See Attachment 3 for the Medtronic Warranty Replacement Form.

Source: Medtronic: <http://www.medtronic.com>

Attachments:

- 1) Instructions on how to access the VA National ICD Surveillance Center database.
- 2) VA National ICD Surveillance Center Memo dated May 29, 2009.
- 3) Medtronic Warranty Replacement Form.

Contact: Your local Medtronic representative or Field Clinical Engineer or the Medtronic Brady Technical Services Department at 1-800-505-4636,

Edmund Keung, MD at the VA National ICD Surveillance Center at (415) 221-4810 Extension 3182, or

Bryanne Patail at the National Center for Patient Safety at (734) 930-5890.

ATTACHMENT 1 - Instructions on how to access the VA National ICD Surveillance Center database

Perform the following steps to access your patient list of active Kappa and Sigma pacemakers on the VA National ICD Surveillance Center:

1. Go to VA intranet URL: <https://ICDPM.sanfrancisco.med.va.gov>
2. You have to register as a user first. Len Roberts, our administrator (Leonard.Roberts@va.gov) will review the information you provided and grant you access within 24 hours or less.
3. After you log in, click on <Safety Alerts and Recalls> and <Alert Management Utility> (see the figure on the following page).
4. Select **Medtronic** from the Filter by Manufacturer dropdown list.
5. Select **Pacemaker/CRT-P** from the Filter by Device Type dropdown list.
6. Select **MDT-Wire separation: Loss of function (Kappa/Sigma) (05/19/09)** from the Filter by Alert dropdown list.
7. Click "Go" to obtain your list.

The device alert status is listed in the far right corner under the column heading Alert (Y=Yes). Do not forget that there may be more than one page for the list, depending on how many patients you have. You can export the table to an Excel spreadsheet by clicking on the [CSV Data Export] button or just print it.

The medical centers listed under the column VAMC are the hospitals where they had their device implanted or the follow-up clinics, according the records of the National ICD Surveillance Center and Medtronic.

ATTACHMENT 1 – continued

June 05, 2009
 Help | Logoff
 Edmund Keung
 PW exp 25 days

Home
 > Safety Alerts and Recalls
 New Patient Registration
 Pacemaker to ICD Upgrade
 Update and Schedule Patients
 Review and Update
 Queries & Reports
 Staff Contact Info
 User Admin
 Portal Administration
 Links to other webs
 VA National Contract Pricing
 Instructions for web
 FAQ
 Paceart Pt Link to Portal
 Knowledge Base
 Privacy and Security
 Admin

UNITED STATES
 DEPARTMENT OF VETERANS AFFAIRS INTRANET

Text/HTML Edit

National ICD and Western Pacemaker Surveillance Center
 4150 Clement Street, San Francisco, CA 94121
 Tel: 1-800-733-0508; 415-750-2077 Fax: 415-750-6967
 Email: leonard.roberts@va.gov
 (For Administrative Information and Questions)
 Email: edmund.keung@va.gov

Alert Management Utility

Paging: [Off] Filter by Alert (* Active): MDT-Wire separation: Loss of function 2009 (Kappa/Sigma) (05/19/09)* Go

Items/page: 20 Filter by Device Type: Pacemaker/CRT-P Alert Status: All Y N Filter by Patient Location: VA-San Francisco

Filter by Manufacturer: Medtronic Search Model: - Select - Filter by Patient Status: - Select -

Active Devices Only Starts with Contains

Filter by Implant Date: Feb 6 1990 Search Patient Name: Search Social Security Number: Jun 5 2009 Starts with Contains Starts with Contains

Total records this view: 1 Total pages: 1 [\[CSV Data Export \]](#) [\[Printer-friendly Display \]](#) [\[View Alert Detail \]](#)

- Select - [\[Add Alert to Selected Patient\(s\) \]](#)

Alert: MDT-Wire separation: Loss of function 2009 (Kappa/Sigma) (05/19/09)* [\[Add Action to Selected Patient\(s\) \]](#)

Action: - Select -

Action date: Jun 5 2009

Comment:

Click on patient name to view Alert Details and to view or edit Action tracking history

	Patient Name	SSN	Status	Phone number	VAMC	Implant Date	Manufacturer	Model	Serial	Alert
1	Veteran, John L	123-45-6789	Active	(415)750-2077	VA-San Francisco	Mar 1 2001	Medtronic	KDR701 Kappa DR	PGU123456H	Y


Provide a list of all your patients with the affected device models and your action steps

If you choose to use the Alert Management Utility Module to assist you in tracking and managing the recall, please follow the instructions below.

8. Click on a patient’s name in the above list table and you will be taken to page 1 of the patient’s detail alert page.
9. Click on the appropriate Alert Identifier (if there is more than one alert affecting the device) to go to page 2 to view the alert details and to enter your actions in response to this alert. See the figure on the following page.

ATTACHMENT 1 – continued

Alerts:

Identifier	FDA Status	Issue date	Active
Wire separation: Loss of function 2009	Manufacturer Safety Alert	May 19, 2009	Yes 

Click on Alert Identifier to view Alert details and to edit Action Tracking history

- Select -  [\[Add Alert\]](#)

Other devices:

Device type	Description	Implant date	Removal date	Alert flag
Lead	Medtronic 5076 CapsureFix Novus	Jul 10, 2001		N
Lead	Medtronic 5076 CapsureFix Novus	Jul 10, 2001		N

Click on Device Type for device and alert details

10. Click on the Action dropdown manual to select the alert action accomplished and enter its appropriate Action date and Comment. See the figure on the following page.
11. Click the [Add Action] button to link this action to the patient. Repeat steps #8 and #9 for each applicable action step.
12. Click the [Plain text summary] button to obtain a text-file of the information displayed on this page. The content can be copied and pasted onto a CPRS progress note for record keeping.

ATTACHMENT 1 – continued

Alerts:

Identifier	FDA Status	Issue date	Active
Wire separation: Loss of function 2009	Manufacturer Safety Alert	May 19, 2009	Yes <input type="checkbox"/>

Click on Alert Identifier to view Alert details and to edit Action Tracking history

- Select -

Alert details:

Identifier: Wire separation: Loss of function 2009
FDA Status: Manufacturer Safety Alert
Issue Date: May 19, 2009
Description: A Patient Safety Alert was issued in 2005 for a subset of Sigma pacemakers susceptible to separation of redundant interconnect on hybrid terminal blocks. Device failure occurs only where both interconnect wires separate from a hybrid terminal block. Malfunctioning may present as loss of rate response, premature battery depletion, intermittent or total loss of telemetry, or no output. Same problem has now been found in a subset of Kappa and a new subset of Sigma pacemakers. The predicted failure rates were 1.1% (Kappa) and 4.8% (Sigma) over the remaining lifetime. The root cause for the separation of the interconnect wire for the 2009 new subsets has yet to be determined. To verify if a specific device is affected, go to <http://KappaSigmaSNList.medtronic.com>

NCPS Issue Date:
NCPS/Mfr Recommended Actions:
US Physician [\[View PDF\]](#)
Letter:

Action tracking:

Description	Req	Action date	Entry date	By	Comment
Date alert status confirmed by NISC		May 28, 2009	May 28, 2009	Roberts, Len	<input type="checkbox"/>
Date patient first notified of alert	*				
Date of CPRS documentation of alert	*				
Date of next device clinic visit	*				
Date of last device clinic visit	*				
Date of last remote monitoring (if applicable)					
Unable to locate patient (enter last attempted contact date)					
Safeguard action: Increase frequency of/start remote monitoring (enter request/start date)					
Safeguard action: Increase clinic visit frequency (enter start date)					
Recall/alert does not apply to this device (enter today's date)					
Corrective action: Device replacement/abandonment (enter procedure date)					
Patient not followed by this VA facility (enter today's date)					
Patient expired (enter expired date, if known)					
Device not affected by the alert, confirmed by NISC					

10 →

Action: - Select -
Action date: Jun 5 2009
Comment:

↑ **11**

Other devices:

Device type	Description	Implant date	Removal date	Alert flag
Lead	Medtronic 5076 CapsureFix Novus	Jul 10, 2001		N
Lead	Medtronic 5076 CapsureFix Novus	Jul 10, 2001		N

Click on Device Type for device and alert details

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[\[Plain text summary\]](#) [\[Exit\]](#)

ATTACHMENT 2 - VA National ICD Surveillance Center Memo dated May 29, 2009



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
4150 Clement Street
San Francisco CA 94121

VA National ICD Surveillance Center

May 29, 2009

Dear colleagues:

This document is to provide you with some general guidelines to deal with the recent Important Patient Management Information issued by Medtronic regarding a special subset of Kappa and Sigma series pacemakers. The mechanism of failure is the same as that reported in 2005 for a subset of Sigma pacemakers. As of this date, this issue has *not* been classified by FDA as a recall.

Device affected:

Subsets of

Kappa 600/700/900 series dual chamber and single chamber pacemakers (15,200 units affected)

Sigma 100/200/300 series dual chamber and single chamber pacemakers (6,100 units affected)

Affected device serial number can be verified individually at <http://KappaSigmaSNList.medtronic.com>.

Problem:

Reported incidence (as of 5/2009):

Pacemaker	Estimated # active devices affected	Observed failure rate	Predicted life time failure rate
Kappa	15,200	0.49%	1.1%
Sigma	6,100	0.88%	4.8%

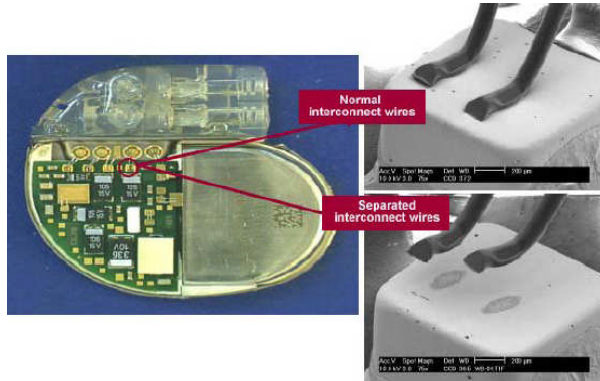
Two deaths may be related to device malfunctioning caused by this safety issue.

The following clinical malfunctions can occur:

- Loss of rate response
- Premature battery depletion
- Intermittent or total loss of telemetry
- Loss of pacing output

According to Medtronic, the above problems occurred when the both interconnect wires separate from a hybrid block in the integrated circuit board of the pacemakers. Depending on which hybrid block was affected, one of the above malfunctions will occur. The failure mechanism is similar to the one reported by in a subset of Sigma pacemakers in 2005. The cause of wire separation for the present subset has yet to be determined (For the 2005 subset, the wires were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time). The photo (see the following page), reproduced from the Technical Brief from Medtronic for the 2005 Sigma subset, illustrates the physical problem.

ATTACHMENT 2 – continued



Recommendations:

The incidence rate is low. We concur with Medtronic and do not recommend replacement of all affected units. As in our previous communications regarding recalls and safety alerts on implantable devices, we urge you to weigh the incidence and consequence of failure against potential complications with generator replacement.

- Perform an interrogation on your patients with the affected pacemaker and discuss this safety issue with your patients as soon as you can (by August 15, 2009, as suggested by the VA Patient Safety Alert AL09-22).
- Consider device replacement in patients who are totally pacemaker dependent.

For those patients in whom replacement is not being considered, we recommend the following steps:

- Routine device interrogation in your clinic every 3 months for pacing-dependent patients and every 6 months for the non-dependent patients. Both groups should have trans-telephonic monitoring every 1 month by the Eastern and Western Pacemaker Surveillance Centers.
- Reinforce the importance of follow-up to the patients. Advise patients to seek attention immediately if they experience symptoms attributable to pacemaker failure (e.g., syncope, near-syncope, fatigue or dizziness).

These recommendations are only suggestions and are not binding. We have to evaluate individual patient's clinical conditions, advise the patients of the risks and benefits of specific treatment option compared to the level of device performance as reported and arrive at the best course of action. As always, you should make the final determination on a case-by-case basis regarding whether device replacement is warranted.

Ed Keung, MD
Director, Western Pacemaker Surveillance Center
Ph: 415-221-4810, extension 3182
Edmund.Keung@va.gov

ATTACHMENT 3 – Medtronic Warranty Replacement Form

Use for Kappa®/Sigma® Supplemental Limited Warranty replacements



Kappa®/Sigma® Supplemental Limited Warranty Form
May 18, 2009 through May 18, 2010
(U.S. Only)

As part of Medtronic’s May 2009 advisory regarding an identified subset of Kappa® and Sigma® pacemaker devices and a performance update on a subset of Sigma devices identified in a November, 2005 advisory (“Device(s)”), Medtronic communicated to physicians and patients that it may be appropriate to replace the Devices in pacemaker dependent patients. In light of this, Medtronic is offering this Supplemental Limited Warranty. This Supplemental Limited Warranty is designed to apply where the physician has made the medical judgment that prophylactic replacement is in the individual patient’s best interests.

Eligibility requirements for the Replacement Program are as follows:

- ◆ The replacement procedure must be carried out between May 18, 2009 and May 18, 2010;
- ◆ The physician and institution must sign and submit to Medtronic the Kappa/Sigma Supplemental Limited Warranty Form confirming that:
 - The patient is pacemaker dependent and the Device is not at ERI;
 - No charge will be made to the patient for the replacement Medtronic device; and
 - Claims for reimbursement will be submitted in accordance with all applicable requirements, including any such requirements relating to warranty products.
- ◆ The explanted Device must be returned to Medtronic within 30 days (except where the medical institution requires otherwise) and shall be the property of Medtronic.

Where the prophylactic replacement meets these eligibility requirements, Medtronic will (1) issue a credit against the purchase price of the Medtronic replacement device to the purchaser of the replacement device for the lesser of the net invoice price for the original pacemaker or the purchaser’s net contract price for a current, functionally comparable Medtronic pacemaker and (2) pay, for the benefit of the patient, up to Two Thousand Five Hundred Dollars (\$2500) of reasonable uninsured medical expenses associated with the prophylactic replacement of the Device.

This Supplemental Limited Warranty is limited to its express terms and does not constitute a representation, judgment, or admission or assumption of liability by Medtronic with respect to the replaced device or the replacement procedure. Please contact the following Medtronic numbers with questions about this warranty:

Information for patients: 1-800-551-5544 7 a.m. – 6 p.m., Monday – Friday, central time
Information for providers: 1-763-526-3333 8 a.m. – 5 p.m., Monday – Friday, central time

By signing below, you confirm that the explant of the Device meets the eligibility requirements set forth above.

Patient name: _____

Serial # of replaced Kappa/Sigma device: _____

Serial # of new Medtronic device: _____

Date of replacement procedure: _____

Physician name: _____

Signature of physician: _____

Medical institution where replacement will take or has taken place: _____

Name/Title of authorized representative of medical institution: _____

Signature of authorized representative of medical institution: _____

Medical institution Medtronic account number: _____

Medtronic sales representative name: _____

Please return this form with the explanted device within 30 days of explant to:

Medtronic, Inc
Returned Product Analysis RCE 172
7000 Central Ave NE
Minneapolis MN 55432
FAX: 800.341.8847
eMail: rs.customerprodcomm@medtronic.com

Use for Kappa®/Sigma® Supplemental Limited Warranty replacements