

Patient Safety Alert

Veterans Health Administration Warning System
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January 9, 2006

Item: Physician Advisory issued by Medtronic Inc. on the Sigma Series single and dual chamber pacemakers (SD203, SD303, SDR203, SDR303, SDR306, SVDD303, SS103, SS106, SS203, SS303, SSR203, SSR303, SSR306, SVVI103)

Specific Incident: Medtronic is reporting 19 failures out of 38,000 devices (0.05%) due to: loss of rate response; premature battery depletion; intermittent or total loss of telemetry; or loss of pacing output in the identified Sigma pacemaker units. The cause of the failure has been identified as separation of (i.e. loss of contact) redundant interconnection wires from the hybrid block in the pacemaker circuit.

Actions: 1. By the close of business (COB) Monday, January 30, 2006, electrophysiology/cardiology staff or other appropriate parties 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 (See "Links" below).
 - b) Review the patient list posted on the VA Western Pacemaker Surveillance Center intranet website (See Attachment 2).
<https://pacemaker.sanfrancisco.med.va.gov>
 - 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 Tuesday, February 14, 2006, interrogate all implanted affected Sigma Series devices and discuss the safety issue with the patient.
3. Follow the actions contained in the Attachment 1 prepared by the VA National ICD Surveillance Center.

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.

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

Contact: Your local Medtronic representative or Field Clinical Engineer or the Medtronic Brady Technical Services Department at 1-800-505-4636 or,
Edmund Keung, MD at the VA National ICD Surveillance Center at (415) 221-4810 Extension 3182 or,
Ron Jones at the VA National Registry, and the VA Eastern Pacemaker Surveillance Center at Washington VAMC at (202) 745-8504 or,
Bryanne Patail at the National Center for Patient Safety at (734) 930-5890

Attachment: VA National ICD Surveillance Center Memo dated December 5, 2005

Links: Medtronic "Important Patient Management Information" dated November 2005
<http://www.medtronic.com/crmLetter.html>

ATTACHMENT 1



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

VA National ICD Surveillance Center

December 5, 2005

Dear Colleagues:

This document is to provide you with some general guidelines to deal with the most recent Important Patient Management Information issued by Medtronic regarding a special subset of Sigma series pacemakers. As of this date, this issue has *not* been classified by FDA as a recall.

Device affected:

Device	Model Numbers (Dual Chamber)	Model Numbers (Single Chamber)	Serial Numbers
Sigma pacemakers	SD203, SD303, SDR203, SDR303, SDR306, SVDD303	SS103, SS106, SS203, SS303, SSR203, SSR303, SSR306, SVVI103	<i>certain</i>

Problem:

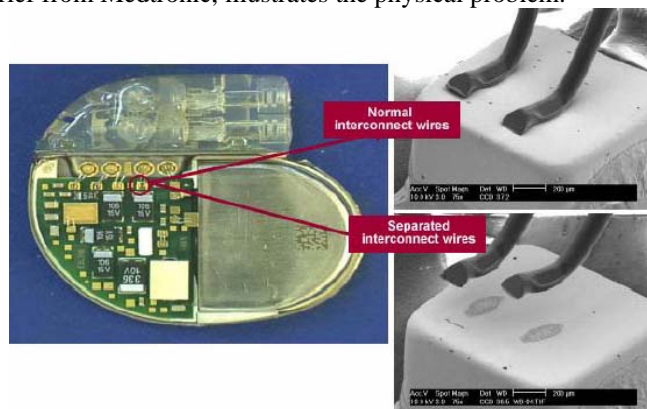
Reported incidence (as of 11/2005) = 19/38,000 (0.05%)
(No reported patient injuries or death)

According to Medtronic modeling: failure rate between 0.17 and 0.30% over the remaining lifetime of these pacemakers

The following clinical malfunctions have been observed in 14 units (the remaining 5 were discovered during analysis on explanted units that were removed for device upgrade and infection):

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

According to the manufacturer, the above problems occurred when the both of the 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. Hybrid circuits used in this subset of devices were cleaned during manufacturing with a particular cleaning solvent that could potentially reduce the strength of the interconnect wire bond over time. The photo below, reproduced from the Technical Brief from Medtronic, illustrates the physical problem.



Recommendations:

- The incidence rate is low (For your reference, the incidence rate for Guidant 1861 Ventak Prizm 2 DR was 0.11% for the Medtronic Marquis family ICD was 0.01%, and for Guidant Insignia family pacemaker was 0.073%). At this time we do not recommend replacement of the 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 (within 31 days as suggested by the VA Alert Memo).

For those patients in whom replacement is not being considered, we recommend the following steps, which are based on the manufacturer's recommendations:

- 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.

There are a total of 166 affected pacemakers in our database (data source: manufacturer, Eastern Pacemaker and Western Pacemaker Surveillance Programs and Registry), of which 42 patients had expired. If you locate more affected pacemakers in your practice, please register them at <https://pacemaker.sanfrancisco.med.va.gov>.



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

ATTACHMENT 2

Instructions on how to access the Western Pacemaker Surveillance Website

Perform the following steps to access your patient list compiled with data from Medtronic, the Pacemaker Surveillance Programs and National Registry:

1. VA intranet URL: <https://pacemaker.sanfrancisco.med.va.gov>
2. You have to register as a user first. Len Roberts, our administrator (Leonard.Roberts@med.va.gov) will review the information you provided and grant you access within 24 hours or less
3. After you log in, click on <Queries & Reports> and <Patient DeviceSearch>.
4. Select `Pacemaker` from the Filter by Device Type dropdown list.
5. Select `Medtronic` from the Filter by Manufacturer drop-down list.
6. Enter `Sigma` in the Search Model textbox.
7. Use `Select`, `FDA recall`, and `No alert or recall` from the Alert dropdown list to filter your patient list to obtain all your Insignia patients, your patients with Guidant Insignia alert, and your patients not affected by the alert, respectively.
8. 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 or just print it.

You will see patients from your VA hospitals only. However, if you do implant for other VA facilities, you may see their patients as well. Please update and correct our database with any information you have.

The medical centers listed under the column VAMC are the hospitals where they had their device implanted or the follow-up clinics, according to Medtronic's records.

The screenshot shows a web application titled "PatientDevices" with a navigation menu on the left and a main content area. Red callout boxes are placed over the interface as follows:

- Box 3:** Points to the "Admin" link in the left navigation menu.
- Box 4:** Points to the "Filter by Device Type" dropdown menu, which is currently set to "Pacemaker".
- Box 5:** Points to the "Filter by Manufacturer" dropdown menu, which is currently set to "Medtronic".
- Box 6:** Points to the "Search Model" input field, which contains the text "Sigma".
- Box 7:** Points to the "Search Patient Name" input field.
- Box 8:** Points to the "Go" button next to the search patient name field.

The main content area includes a table of patient records with the following columns: Patient, SSN, Status, Phone number, VAMC, Implant Date, Manufacturer, Model, Serial, and Alert. The table contains 10 rows of data, all for Medtronic SDR303 Sigma DR pacemakers.

Patient	SSN	Status	Phone number	VAMC	Implant Date	Manufacturer	Model	Serial	Alert
Abbott, Aaron A.	519-16-719	Active	(208) 22	VA-Spokane	Apr 20 2004	Medtronic	SDR303 Sigma DR	PJD4	N
Abraham, Kenneth C.	477-20-	Expired	(5) 9514	VA-Tucson	Jun 12 2001	Medtronic	SSR303 Sigma SR	PJC	N
Abreu, John	508-72-	Active	(54) 67	VA-San Francisco	Jun 16 2000	Medtronic	SDR303 Sigma DR	PJD1	N
Abshier jr, Thomas	308-26-	Registration	(8) 3983	VA-Indianapolis	Oct 9 2001	Medtronic	SSR303 Sigma SR	PJG15	N
Abshire, Earl	264-09-	Registration	(35) 20	VA-Gainesville	Jan 12 2001	Medtronic	SDR303 Sigma DR	PJD1	N
Abraham, Charles	088-09-	Registration	(6) 61	VA-Northport	Apr 6 2001	Medtronic	SDR303 Sigma DR	PJC	N
Abraham, Marvin W.	503-20-	Active	(60) 38	VA-Sioux Falls	Jan 12 2004	Medtronic	SDR303B Sigma DR	PJD4	N
Adair, William	15	Active	(25) 12	VA-Temple	Sep 27 2002	Medtronic	SDR303B Sigma DR	PJD1	N
Adam, William	610-14-	Active	(60) 42	VA-Sioux Falls	Jan 5 2001	Medtronic	SDR303 Sigma DR	PJD	N