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ICD and Pacemaker Recall Information

Compiled by Westby G. Fisher, MD, FACC

(Last Updated 28 Jun 2006)

MEDTRONIC SIGMA Series Pacemakers - Advisory Dated 29 Nov 2005

A specific subset of Medtronic Sigma pacemakers has a problem with interconnect wires that exist between the header of the device and the main circuitry of the pacemaker, and occasionally can cause the device to fail. As of November 2005, it is estimated that there are 28000 of these devices reamining worldwide and approximately 6,650 remaining in the U.S., out of an initial population of 40,000 devices implanted worldwide. The specific model and serial numbers of the devices affected are available online at http://SigmaSNList.medtronic.com.

Mechanism of Failure

It was found that this was caused by the use of a solvent during the wire-cleaning process that degraded the connection contacts on occasion over time. It is estimated the probablility of the problem occuring over the life of the device is low, demonstrating a failure rate between 0.17% and 0.30% over the lifetime of the device.

Failures to Date

There have been 19 failures worldwide to date. No deaths have resulted in this defect. There is no provocative testing that can predict this failure. Device failure occurred in the affected devices between 17 and 38 months after implant.

Recommendations by Medtronic:

- Device replacement is not recommended prior to the normal device elective replacement indicator based on the low probablilty of an occurrence of a serious event in this population.

- Continue routine follow-up.
- Patients should seek attention immediately if they experience loss of conciousness or lightheadedness.
- Patients shuld discuss with their doctor if replacement is warranted given their particular medical history and balancing the relative risks of an invasive procedure. Medtronic will replace the device if it is deemed necessary with an unaffected Sigma pacemaker or Kappa 700 model pacemaker. Upgraded devices will be charged the difference between the price of the upgraded device and the device being replaced. $800 of unreimbursed medical expenses will also be funded by Medtronic.

MEDTRONIC MARQUIS Family of ICD and CRT-D Devices

Includes the following devices manufactured BEFORE December, 2003:

1. Medtronic Marquis DR, Model 7274
2. Medtronic Marquis VR, Model 7230
3. Medtronic Insync Marquis, Model 7277
4. Medtronic Insync II Marquis, Model 7289
5. Medtronic Insync III Marquis, Model 7279

Mechanism of Failure

Found to have a battery short, particularly in the second half of the device's overall battery life. NOTE: Only effects devices MANUFACTURED before December, 2003. See www.medtronicinfo.com for more specific information about your device and the recall in general.

Failures to Date

17 devices have failed as of June 15, 2005 of 87,000 produced (0.2%), 12 in the second half of the battery life of the device. Of these 9 occurred in the last quarter of device life, and six occurred in the last 10% of device file. No reported cases of serious injuries or deaths so far, according to a Medtronic "dear doctor" letter dated 1 July 2005. Of the 17 returns, 11 occurred by detection of a routine follow-up visit or hospitalization, five were detected by warmth of the pocket, and one patient experienced symptoms of a slow heart rate (dizziness, lightheadedness, or loss of conciousness briefly).

Medtronic's follow-up recommendations:

- Conduct quarterly (every 3 month) follow-up of the device
- Inform patients that if they experience warmth aroundthe device to seek follow-up care immediately
- Be sure the doctor has programmed "ON" the low battery voltage Elective Placement Indicator Alert to "ON HIGH." This results in an audible tone in the case where battery depletion occurs slowly over a number of days.
  NOTE THAT MOST BATTERY DEPLETIONS OCCURRED RAPIDLY AND WERE NOT DETECTED BY THIS FEATURE.
- Be sure you have a hand-held magnet to test your device daily by placing the magnet over the device daily to assure an audible tone lasting approximately 20 seconds occurs. If no tome is heard, follow-up care should be sought immediately.
- Patients who are pacemaker dependent or receive frequent anti-tachycardia pacing or shocks should probably have their device replaced.

Source: Medtronic "Dear Doctor" letter dated 1 July 2005

A full list of Medtronic's pacemaker and ICD performance "advisories" on Medtronic products can be found at: http://www.medtronic.com/crm/performance/advisories.

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GUIDANT INSIGNIA AND NEXUS PACEMAKERS, CONTAK RENEWAL TR/TR2 CARDIAC RESYNCHRONIZATION PACEMAKERS, AND VENTAK, PRISM 2, VITALITY AND VITALITY 2 IMPLANTABLE CARDIAC DEFIBRILLATORS (23 JUN 2006)

Devices Effected:

DEVICE FAMILY	MODEL NUMBERS
INSIGNIA PACEMAKERS	0482, 0484, 0485, 0882, 0982, 0985, 0986 1190, 1192, 1194, 1195, 1198, 1290, 1291, 1292, 1294, 1295, 1296, 1297, 1298
NEXUS PACEMAKERS	1325, 1326, 1328, 1390, 1392, 1394, 1395, 1398, 1426, 1428, 1432, 1466, 1467, 1468, 1490, 1491, 1492, 1494, 1495
CONTAK RENEWAL TR	H120, H125
CONTAK RENEWAL TR 2	H140, H145
VENTAK PRISM 2	1860,1861
VITALITY	1870, 1871, T125, T127, T135
VITALITY 2	T165, T167, T175, T177

PROBLEM IDENTIFIED:

Five reports of malfunction of the above devices caused by a defective low-voltage capacitor from a single component supplier that can cause these devices to malfunction. 27,200 devices have been implanted worldwide.

Clinical Implications:

This failure mechanism can result in one or more of the following device behaviors:

- Intermittent or permanent loss of output, telemetry, or premature battery depletion
- Loss of pacing therapy

To date, no deaths have been reported. Two patients experienced syncope due to loss of pacing output and reuired device replacement. One failure was discovered before device implantation.

Recommendations by Guidant:

In-clinic follow-up evaluation as soon as possible looking for abnormal device behaviours. Guidant has offered to refund up to $2500 of the non-reimbursed medical expenses and the cost of a new device. Although NOT part of Guidant's recommendations, consieration of device replacement in pacemaker-dependent patients should be considered.

GUIDANT VITALITY HE and CONTAK RENEWAL 3 and 4 CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATORS (12 May 2006)

Devices Effected:

DEVICE FAMILY	MODEL NUMBERS
CONTAK RENEWAL 3	H170/H173/H175
CONTAK RENEWAL 3 HE	H177/H179
CONTAK RENEWAL 3 AVT	M150/M155
CONTAK RENEWAL 3 AVT HE	M157/M159
VITALITY HE	T180
CONTAK RENEWAL 4	H190/H195
CONTAK RENEWAL 4 HE	H197/H199
CONTAK RENEWAL 4 AVT	M170/M175
CONTAK RENEWAL 4 AVT HE	M177/M179

PROBLEM IDENTIFIED:

Two reports of malfunction of the above devices occurred when the device was implanted subpectorally (BELOW
THE BREAST MUSCLE) with the serial number facing the ribs. It seems the stress applied to the circuitry when the device is implanted in the position can cause the device to malfunction.

Clinical Implications:

This failure mechanism can result in one or more of the following device behaviors:

- Loss if shock therapy

- Loss of pacing therapy
- Loss of telemetry communications
- Beeping (16 tones every six hours) with a programmer warning screen displayed when interrogated

To date, no deaths have been reported. One patient required immediate external pacing and immediate device replacement due to lack of pacing therapy.

Recommendations by Guidant:

Obtain CXR to determine orientation of device in patients *with subpectorally-implanted devices*. If the leads exit the device in a counterclockwise orientation NO device change is needed. If the device is in a susceptible orientation, then the patient should be advised of the potential for device failure, and follow-up instituted at least once per quarter. Consider device replacement for very active patients or for patients who regularly require device therapy. Guidant has offered to refund up to $2500 of the non-reimbursed medical expenses and the cost of a new device.

GUIDANT CONTACT RENEWAL AND CONTACT RENEWAL II, AND VENTAK PRIZM 2 DR DEVICES

Devices Effected:

DEVICE FAMILY	MODEL NUMBERS
CONTACT RENEWAL	H135
CONTACT RENEWAL 2	H155
VENTAK PRISM 2 DR	1861

PROBLEM IDENTIFIED:

Deterioration of a wire insulator surrounding a high voltage wire within the header of the device (lead connector block) can short to the can of the device, preventing effective shock therapy to the patient. This can cause loss of ability to communicate with the device with the programmer, loss of tachycardia detection and therapy delivery, loss of pacing output, or programmer can display a red or yellow warning screen to the physician. ***A September 12, 2005 subsequent communication demonstrated that the failure rate is higher than expected for Models H135 (Contact Renewal®) and H155 (Contact Renewel 2®) to 0.72-1.83% of devices implanted with 21 clinical failures and three (3) deaths attributed to this failure defect through 31 Aug 2005, but no change to management recommendations were made in that communication because failure rates remain near the estimated 0.13%).*** *These results were reported in a FDA Communication dated 13 October 2005*. As a result, it was advised that doctors take these failures into account as they continue to follow the patients who retain either of these devices.

As of October 13, 2005, no additional clinical failures have been reported for the Model 1861 (Ventak Prizm® 2DR) since the FDA's July 14, 2005 Preliminary Public Health Notification. Guidant informed FDA and the clinical community that there were a total of 28 clinical failures of the Model 1861 out of 26,000 devices (0.11%), including 1 patient death, worldwide as of June 17, 2005, with no new reports since that date. Therefore, the FDA's previous recommendations remain unchanged for patients implanted with the Prizm® 2 DR

Recommendations by Guidant:

Because the incidence of failure was very low, they are NOT recommending replacement of the device. There HAS been at least one death attributed to this component failure. Patient's are encouraged to discuss appropriate follow-up with their physician. Follow-up recommendations include:

- Every three month evaluations of the device
- See your doctor for evaluation of your device after any shock delivered
- During your routine device checks, be sure your doctor checks the Last Delivered Shock Impedance (displayed on the Battery Status screen) for evidence of out-of-range values and
- If a yellow warning screen is displayed, contact your doctor immediately
- If a beeping tone is heard from the device, contact your doctor immediately.

GUIDANT CONTACT RENEWAL III, CONTACT RENEWAL IV AVT AND RENEWAL RF DEVICES

Devices Effected:

DEVICE FAMILY	MODEL NUMBERS
CONTACT RENEWAL 3	H170, H173, H175
CONTACT RENEWAL 3 HE	H177, H179
CONTACT RENEWAL 4	H190, H195
CONTACT RENEWAL 4 HE	H197, H199
CONTACT RENEWAL 3 AVT	M150, M155
CONTACT RENEWAL 3 AVT HE	M157, M159
CONTACT RENEWAL 4 AVT	M170, M175
CONTACT RENEWAL 4 AVT HE	M177, M179
RENEWAL RF*	H230, H235
RENEWAL RF HE*	H239

* Not available in the United States

PROBLEM IDENTIFIED:

The magnetic switch (reed switch) may stick in a closed position, and may limit appropriate therapy delivery. In normal use, a magnet placed over the device closes the magnetic switch and prevents delivery of treatment of atrial or ventricular arrhythmias. Normally, when the magnet is removed, this switch is supposed to "open" again, reestablishing therapy. The problem here is the switch stays closed, even if the magnet is removed, and therapy might not be delivered appropriately.

Reduced battery longevity (Additional info from a August 1, 2005 physician communication from Guidant):

If an unintended switch closure occurs WHILE the magnet use is enabled on the device (be sure your doctor has turned this OFF), then device *battery depletion can be SIGNIFICANTLY effected* and can even deplete earlier than the recommended 3-month follow-up interval

that most patients use. But even WITH the magnet use DISABLED, *battery longevity can be shortened by as much as 44%*. So even with this programming change, it now appears the battery life will be severely shortened.

RATE OF OCCURRENCE (Source: Update communication from Guidant dated Aug 1, 2005)

Five occurrences of clinically-significant reed switch locking have occurred out of approximately 46,000 devices sold worldwide (0.0109%) with no occurrences documented since their earlier 23 Jun 2005 communication.

RECOMMENDATIONS BY GUIDANT:

Program Enable Magnet Use to "OFF" ensure appropriate therapy for atrial and ventricular arrhythmias will be delivered. However, with this setting:

- A magnet will no longer limit therapy.
- The programmer can suspend therapy delivery if necessary.
- You should seek attention immediately if a tone is heard from the device.

GUIDANT PULSAR MAX, PULSAR, DISCOVERY, MERIDIAN, PULSAR MAX II, DISCOVERY II VIRTUS PLUS II, INTELIS II, AND CONTAK TR PACEMAKER SAFETY AND CORRECTIVE ACTION DATED 18 JUL 2005

Devices Effected:

DEVICE DESCRIPTION	MODEL NUMBER
PULSAR	0470, 0870, 0970, 0972, 1172, 1272
PULSAR MAX	1170, 1171, 1270
DISCOVERY	1174, 1175, 1273, 1274, 1275
MERIDIAN	0476, 0976,1176, 1276
PULSAR MAX II	1180, 1181, 1280
DISCOVERY II	0481, 0981, 1184, 1186, 1187, 1283, 1284, 1285, 1286
CONTAK TR	1241
VIRTUS PLUS II	1380, 1480
INTELIS II	1483, 1484, 1485, 1384, 1385, 1349, 1499

PROBLEM IDENTIFIED:

Pacemaker devices manufactured between 25 November 1997 and 26 October 2000 above can have a problem with the hermetic sealing of the device, resulting in unexpected gradual degradation, resulting in a higher-than-normal moisture content in the device causing potentially:

- Premature battery depletion resulting in loss of pacing output or ability to communicate with the device
- Inappropriate accelerometer function of the device resulting in sustained pacing at the maximum sensor rate or lack of appropriate

sensor response to activity (this occurred in 60% of failures reported to date, but cannot be relied upon as an early detector of problems with these devices)
- Appearance of a reset warning message when the device is communicated with
- Inappropriate early display of replacement indicators

No test exists which can predict if these behaviors will occur in the future.

Findings: Approxiately 27,000 such devices exist still implanted in patients of more than 78,000 manufactured. As of 11 July 2005, 52 such device failures have occurred worldwide and returned to Guidant, 13 were found to have the same failure but NOT returned to Guidant, and four are still under evaluation, representing a failure rate between 0.17 and 0.51% of the remaining device lifetimes. Twenty (20) patients experienced loss of pacing output associated with this failure mode.

Recommendations by Guidant:

- Replace devices for pacemaker-dependent patients
- Patients that have prolonged rapid heart rates, loss of conciousness, or lightheadedness should seek immediate medical attention
- Consider increasing the frequency of follow-up

GUIDANT INSIGNIA and NEXUS PACEMAKERS AND CORRECTIVE ACTION DATED 22 SEP 2005

Devices Effected:

GUIDANT PACEMAKERS	MODEL NUMBERS
INSIGNIA Entra SSI	0464, 0485
INSIGNIA Entra DDD	0985, 0986
INSIGNIA Entra SR	1195, 1196
INSIGNIA Entra DR	1294, 1295, 1296
INSIGNIA Ultra SR	1190
INSIGNIA Ultra DR	1290, 1291
INSIGNIA Plus SR	1194
INSIGNIA Plus DR	1297, 1298
INSIGNIA AVT SSI	482
INSIGNIA AVT VDD	882
INSIGNIA AVT DDD	982
INSIGNIA AVT SR	1192
INSIGNIA AVT DR	1292

GUIDANT INTERMEDICS PACEMAKERS	MODEL NUMBERS
NEXUS Entra SSI	1325, 1326

NEXUS Entra DDD	1425, 1426
NEXUS Entra SR	1395, 1398
NEXUS Entra DR	1466, 1494, 1495
NEXUS Ultra SR	1390
NEXUS Ultra DR	1490, 1491
NEXUS Plus SR	1394
NEXUS Plus DR	1467, 1468
NEXUS AVT SSI	1328
NEXUS AVT VDD	1428
NEXUS AVT DDD	1432
NEXUS AVT SR	1392
NEXUS AVT DR	1492

PROBLEM IDENTIFIED:

These pacemaker devices can have a two issues: (1) contaminant of a timing crystal in one case and (2) an a second type of timing crystal contamination which can lead to potentially:

- Intermittent or permanent loss of pacing output without warning
- Intermittent or permanent loss of telemetry with the device
- Reversion to VVI mode or appearance of a reset warning message upon interrogation

No test exists which can predict if these behaviors will occur in the future.

Findings: As of 30 November 2005, thirty-seven (37) failures out of 49,500 devices manufactured have been confirmed worldwide (0.075%) with the first crystal contaminant type of failure. The majority of failures occurred early in the device life with a mean implant time of 7 months and appears to decrease in incidence over time: no failures have occured to date after 22 months. It is estimated that 22,000 of these devices remain in the United States. *Importantly, NO device failures from this failure mode were noted in devices shipped after 12 March 2004 (the defective foreign material in the crystal chamber was removed)*. As of 12 December 2005, a second cause for failure has now been determined to be a contaminated timing crystal failure from one of two suppliers of these crystals to Guidant and has been identified in 17 of 257,000 devices worldwide (0.0066%). In these cases a no output condition was exibited at the implant procedure or pre-implant testing. One patient had syncope after implant and resusitated cardiac arrent during an elective pacemaker replacement. It is estimated that 145,000 of these devices are active in the United States.

Recommendations by Guidant as of their latest communications to physicians dated 12 Dec 2005:

- Normal monitoring, per device labeling since the events decrease in frequency over time and are very rare
- Patients that lose conciousness or lightheadedness should seek immediate medical attention
- For the second type of failure, the device should be checked in the operating room before implantation

Regarding ICD and Pacemaker Recommendation from Guidant, the reader is referred to:

http://www.guidant.com/physician_communications/

or in the patient communications at:

http://www.guidant.com/patient/communication/

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ST. JUDE EPIC DR, EPIC PLUS DR, ATLAS DR, ATLAS PLUS DR DEVICE ADVISORY

Models Effected:

DEVICE DESCRIPTION	MODEL NUMBER
EPIC DR/HF	V-233, V-337, V-338
EPIC PLUS DR/VR/HF	V-236, V-239, V196, V-239T, V196T, V-350
ATLAS DR	V-242
ATLAS PLUS DR/VR/HF	V-243, V193, V193C, V-340, V-341, V-343

PROBLEMS IDENTIFIED:

1. Problem can occur when one of the devices tries to deliver multiple shocks in rapid succession. Due to a software problem, it is possible that the device might miss a charging cycle if the battery is nearing its elective replacement indicator.
2. Noise generated during battery charging can be detected by the device's accelerometer causing a temporary increase in the pacing rate that may persist after the charge is completed. This problem was traced to a faulty component supplied to St. Jude and occurs ONLY in devices with serial numbers less than or equal to 141000. **Serial numbers GREATER THAN 141000 ARE NOT EFFECTED.**

Recommendations:

Patients with these devices should have their devices checked. At the end of device evaluation, a software fix for both of these problems is "injected" into your device and will take approximately 45 seconds to correct. Devices do NOT need to be replaced.

ST. JUDE PHOTON DR, PHOTON MICRO VR/DR, ATLAS VR/DR DEFIBRILLATORS (ICD's)

- Issued 6 Oct 2005

Models Effected:

DEVICE DESCRIPTION	MODEL NUMBER
PHOTON DR	V-230HV (certain serial numbers)
PHOTON MICRO VR	V-194
PHOTON MICRO DR	V-232
ATLAS VR	V-199
ATLAS DR	V-240

PROBLEM IDENTIFIED:

1. Atmospheric cosmic ionizing radiation can effect a "static random access memory " (SRAM) chip on older devices, causing rare episodes of high current drain that can deplete the battery voltage rapidly. This can result in the device possibly having no output for up to 48 hours with no pacing or defibrillation (shocking) therapy. After this, the device's battery will reach a voltage level at which the device will reach its "Hardware Reset Mode" and provide rudimentary ventricular (VVI) pacing support at a rate of 60 beats per minute and will not provide tachycardia (fast heart rhythm) detection or therapy. There are no tests to predict if a particular device's memory chip will exhibit this problem. It seems devices maufactured before 2002 are effected (a different vendor's chip was used after 2002 and is not susceptible to this problem.)
2. No serious patient injuries or deaths have occurred as of 6 Oct 2005. Sixty (60) of 36,000 devices have been found to be affected (incidence: 0.00167 of the devices at issue): 53 of these observed following device implant and 7 discovered before device implant. Approximatly 26,000 of these devices remain in service. The nature of the failure is random and constant over time.

Recommendations:

- Routine device monitoring every three months.
- If device is found in "Hardware Reset Mode," arrange for device replacement as soon as possible.
- Patients who are pacemaker dependent or who receive frequent anti-tachycardia therapies should discuss with their doctor if the device should be replaced or closely monitored, given the rare nature of the defect. If is is elected to replace the device, St. Jude will provide a replacement device at no cost to you. (*MedTees editor's note: Other surgical costs might be incurred, however*).
- Notify your doctor is there is any change in your symptoms and be dilligent about keeping follow-up appointments.

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DISCLAIMER

Data contained in this webpage are deemed correct, and supplied without warranty, and can change at any time. Actual recommendations for patient management can only be given by your health care provider. We have taken the liberty of trying to simplify the terms used by the manufacturers to make them easier to understand for patients. Readers are encouraged to seek additional information from their health care provider or appropriate device manufacturer.

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