# Patient Safety Alert

Veterans Health Administration Warning System
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**Item:** Boston Scientific Corporation's Cardiac Rhythm Management Division (previously called Guidant) recall of Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds).

**Specific Incident:** The following Guidant ICD and CRT-D device models have low-voltage capacitors that may be subject to degradation and may cause accelerated battery depletion.

| Device Name | Model Numbers |
|---|---|
| Vitality DS DR/VR | T125/T135 |
| Vitality EL DR | T127 |
| Vitality AVT | A155 |
| Vitality 2 DR/VR | T165/T175 |
| Vitality 2 EL DR/VR | T167/T177 |
| Vitality DR HE | T180 |
| Contak Renewal 3 | H170/H175 |
| Contak Renewal 3 HE | H177/H179 |
| Contak Renewal 4 | H190/H195 |
| Contak Renewal 4 HE | H197/H199 |
| Contak Renewal 3 RF | H210/H215 |
| Contak Renewal 3 RF HE | H217/H219 |
| Contak Renewal 4 RF | H230/H235 |
| Contak Renewal 4 RF HE | H239 |
| Contak Renewal 4 AVT | M170/M175 |
| Contak Renewal 4 AVT HE | M177/M179 |

**Actions:** 1. Within 14 calendar days, electrophysiology/cardiology staff or other appropriate caregivers must identify all affected patients by implementing each of the following steps a through c. It is important that ALL INFORMATION sources be reviewed to insure that patients will not be missed, as they may be found on one list and not on another.

a) Review the manufacturers letters (see the links under Additional Information).

b) Retrieve and review a list of your patients with the affected devices (ICDs and CRT-Ds) on the VA National ICD Surveillance Center intranet website (https://icd.sanfrancisco.med.va.gov, VA Only, see Attachment 2 for instructions). This list consists of all the patients in Guidant's database that have implanted devices affected by this and previous recalls (some devices are affected by more than one recall).

c) Review your patient records for all patients with implanted Guidant devices affected by this recall.

2. Within the next 30 calendar days, follow the actions contained in Attachment 1. This guidance was prepared by Dr. Edmund Keung, Director of the VA National ICD Surveillance Center, as the best course of action for your patients.

**NOTE:** Because the incidence rate is very low and early battery depletion can be identified with close monitoring (see information contained within the links below), premature replacement of the devices is not recommended.

**Addl Information:** Boston Scientific sent letters to physicians and patients notifying them of this risk. (See links below for letters and FDA's Q&As.)

a. Boston Scientific dear doctor letter, dated April 5, 2007.
http://www.guidant.com/physician_communications/ap_shortened_replacement_phy_040507.pdf

b. Boston Scientific dear patient letter, dated April 5, 2007.
http://www.guidant.com/patient/communication/AP_Shortened_Replacement_Window.pdf

c. FDA's Questions and Answers on Boston Scientific/Guidant Recall, dated April 10, 2007.
http://www.fda.gov/cdrh/news/guidantrecall.html

d. Guidant Device Lookup/Search for affected devices.
http://www.guidant.com/webapp/emarketing/lookup.jsp?lang=en&cc=US

**Attachments:** 1) VA National ICD Surveillance Center Memo dated April 18, 2007
2) Instructions to access the VA National ICD Surveillance Center

**Source:** Boston Scientific Corporation

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Dr. Edmund Keung at VA National ICD Surveillance Center at (415) 221-4810 Ext. 3182

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

**ATTACHMENT 1**
**VA National ICD Surveillance Center Memo**

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

**VA National ICD Surveillance Center**

April 18, 2007

Dear colleagues:

This document is to provide you with some general guidelines to deal with the most recent Product Advisory issued by Boston Scientific on April 5, 2007, regarding a subset of Guidant ICDs and CRT-Ds. This issue has been classified by FDA on April 10, 2007, as a recall.

Devices affected:

| Device Name | Model Numbers |
|---|---|
| Vitality DS DR/VR | T125/T135 |
| Vitality EL DR | T127 |
| Vitality AVT | A155 |
| Vitality 2 DR/VR | T165/T175 |
| Vitality 2 EL DR/VR | T167/T177 |
| Vitality DR HE | T180 |
| Contak Renewal 3 | H170/H175 |
| Contak Renewal 3 HE | H177/H179 |
| Contak Renewal 4 | H190/H195 |
| Contak Renewal 4 HE | H197/H199 |
| Contak Renewal 3 RF | H210/H215 |
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The Problem:

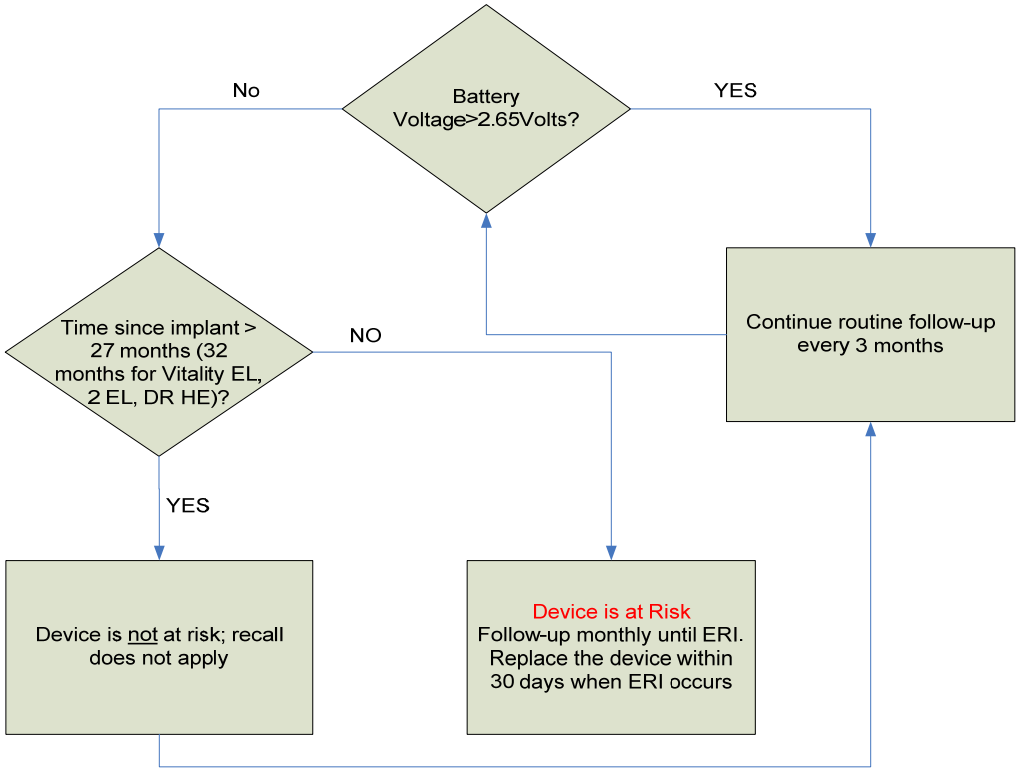
- The root cause: Degradation of low-voltage capacitors.
- Performance failure: Acceleration of battery depletion which may result in reduced time between elective replacement indicator (ERI) and end of life (EOL) to less than 3 months.
- Reported incidence of accelerated battery depletion ~ 19/73,000 devices (~0.026%).
  Guidant estimated <2% of this device population may exhibit a shortened ERI to EOL time.
- Guidant reported no deaths or series injuries in association with this recall.

Recommendations:

- Because the incidence rate is very low and early battery depletion can be identified with close monitoring (see below), replacement of the devices is not recommended.

- Perform an interrogation on your patients with the affected ICD and CRT-D and discuss this safety issue with your patients as soon as you can (within 30 days as suggested by the VHA Patient Safety Alert).

- Use the following flowchart to determine if the device is at risk and monitoring intervals:




- It is strongly recommended that patients with the affected devices be remotely monitored by enrolling them in the LATITUDE Patient Management System via the VA National ICD Surveillance Center (NISC). Contact your local Boston Scientific representative to schedule a training session for your staff on the LATITUDE program. After the training is completed, you can enroll patients with the affected devices on the NISC website (https://icd.sanfrancisco.med.va.gov).

- Document your actions in CPRS and update your patient information on the NISC website.

- 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 the appropriate action for your patients.

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**ATTACHMENT 2:**
**Instructions on how to access the VA National ICD Surveillance Center database**

Perform the following steps to access your patient list supplied by Guidant on the VA National ICD Surveillance Center:

1. VA intranet URL: https://icd.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 <Queries & Reports> and <Patient Device Search and Export>.
4. Select `ICD Generator` from the Filter by Device Type dropdown list.
5. Select `Guidant` from the Filter by Manufacturer drop-down list.
6. Leave the Search Model textbox blank if you want all Guidant models. Otherwise, enter a model number (e.g., T165).
7. Use `Select`, `FDA Recall/Alert` and `No recall/alert` from the Alert dropdown list to filter your patient list to obtain all your patients with the device(s) identified in #6, with Guidant alerts, and your patients not affected by the alert, respectively. **Some devices are affected by more than one recall.**
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.

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 Boston Scientific.

You will notice that some patients have SSN (social security number) of 888-88-7777 and phone numbers of (888)888-8888, (999)999-9999 or (415)221-4810. In these patients, Boston Scientific did not include their SSN and phone numbers in their list. Please update the information.