a) 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 (VA ONLY - https: //icdpm.sanfrancisco.med.va.gov, see Attachment 3 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).

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

2. Within the next 90 calendar days of the issuance of this Alert, follow the actions contained in Attachment 2. 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 prolongation of charge time and ERI/EOL can be identified by close monitoring (see information contained within the Attachments below), prophylactic replacement of the devices is not recommended.

Attachments: 1) Boston Scientific Product Update dated March 10, 2007
2) VA National ICD Surveillance Center Memo dated December 20, 2007
3) Instructions to access the VA National ICD Surveillance Center

Source: Boston Scientific Corporation (BSCI) and FDA

Contacts: BSCI/Guidant (800) 227- 3422.

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

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

Product Update

Boston Scientific

ERI Charge Time Limit Extended During Mid-Life and Mid-Life Display of Replacement Indicators

Product Update articles provide clinical and/or technical information focused on the performance behaviors of Boston Scientific Cardiac Rhythm Management (CRM) products. This version provides additional information beyond the first edition of this article, which was published in March of 2006.

Executive Summary

The first part of this article provides educational information regarding a normal extension of the Elective Replacement Indicator (ERI) charge time limit in Boston Scientific ICDs and CRT-Ds, and is described in the section "Normal Charge Time Behavior."

- A mid-life increase in charge time that remains below a normal, mid-life extension of ERI charge time limit should ***not*** be mistaken for device malfunction. See Appendix A for nominal charge times and ERI charge time limits for each product family.

The second part of this article provides performance information related to an observed pattern of device behavior in which ERI or End of Life (EOL) is displayed during mid-life (typically 24-48 months), even though battery capacity remains available. This pattern is further described in the section "Atypical Charge Time Behavior."

- If ERI or EOL is triggered, device replacement should be scheduled.
- Remaining battery capacity allows devices that have displayed ERI or EOL due to this pattern of mid-life behavior to continue to provide brady and left ventricular (LV) pacing and maximum energy shocks for several months, and in most cases more than one year.
- In some cases, the time between ERI and EOL can be shorter than expected.
- If ERI is triggered, charge times can be up to 30 seconds. If EOL is triggered, charge times will be greater than 30 seconds.
- There have been no reports of patient injury related to this behavior, beyond device replacement.
- Device groups with a greater probability of triggering ERI or EOL during mid-life are described.

Products Referenced* See Appendix A

**Products referenced herein may not be approved in all geographies.*

Contact Information

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NORMAL CHARGE TIME BEHAVIOR

SVO Batteries

Silver Vanadium Oxide (SVO) batteries have been used extensively in the medical device industry for both ICDs and CRT-Ds. An inherent characteristic of SVO technology is a buildup of internal battery impedance that occurs in mid-life (approximately 2.52 to 3.00 volts). This mid-life rise in impedance can lengthen ICD and CRT-D charge times.

Extension of ERI Charge Time Limit During Mid-life

In addition to several design strategies to minimize mid-life elevations in battery impedance, certain Boston Scientific ICDs and CRT-Ds include an extension of ERI charge time limit to accommodate a mid-life rise in battery impedance. For example, the expected charge time of a VITALITY® DR device is 10 seconds in early-life. As the device moves into mid-life, charge times typically increase to a range between 13 and 20 seconds. To minimize the possibility of triggering ERI in mid-life, the ERI charge time limit is automatically and temporarily extended from 17.9 to 23.0 seconds during mid-life. After the mid-life period of elevated battery impedance has passed, the charge time typically recedes and the ERI charge time limit is returned to 17.9 seconds. Eventually, as battery voltage decreases, charge times increase once again and ERI is triggered, as illustrated in Figure 1. The extended ERI charge time limit allows mid-life charge times to exceed those seen earlier and later in device life. ***Charge times during mid-life that remain below a normal extension of the ERI charge time limit should not be mistaken for device malfunction.*** Refer to Appendix A for nominal charge times (early-life and mid-life) and ERI charge time limits by device family.

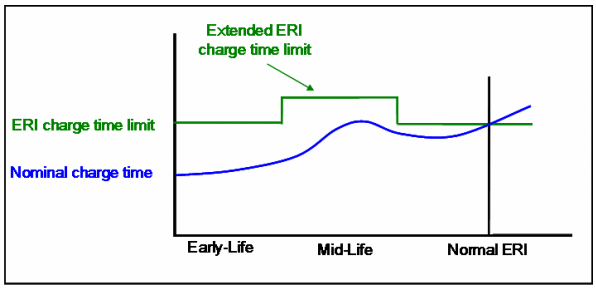


Figure 1. Charge time behavior and extended ERI charge time limit

ATYPICAL CHARGE TIME BEHAVIOR

Mid-life Display of Replacement Indicators

Boston Scientific has observed a pattern of device behavior in which ERI or EOL is displayed during mid-life (typically 24-48 months), even though battery voltage (typically ≥ 2.65 volts) and capacity remain available (see Figure 2). This behavior is caused by high battery impedance rather than low battery voltage, and should not be mistaken for premature battery depletion. There have been no reports of patient injury beyond device replacement. Confirmed malfunctions within the pattern "Mid-life Display of Replacement Indictors" can be found in Boston Scientific's CRM Product Performance Report found at http://www.guidant.com/ppr/.

Important note: Devices that have triggered charge time-based ERI or EOL during mid-life have several months, and in most cases more than one year of remaining battery voltage and capacity, which allows the devices in this pattern to continue to provide brady and LV pacing and maximum energy shocks. However, if ERI or EOL is triggered, device replacement should be scheduled.

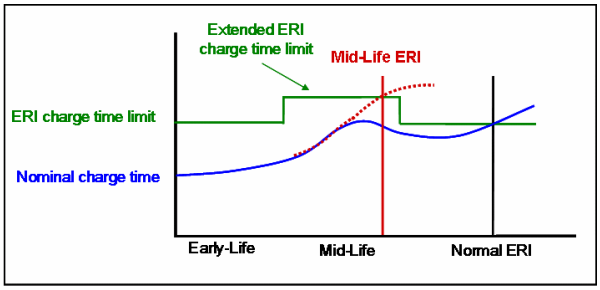


Figure 2. ERI is displayed during mid-life if charge time does not recede

Boston Scientific has created groups by approximate implant timeframes, which are based on battery manufacturing improvements. Devices in Table 1, implanted prior to July 2005, have a greater probability of triggering ERI or EOL during mid-life.

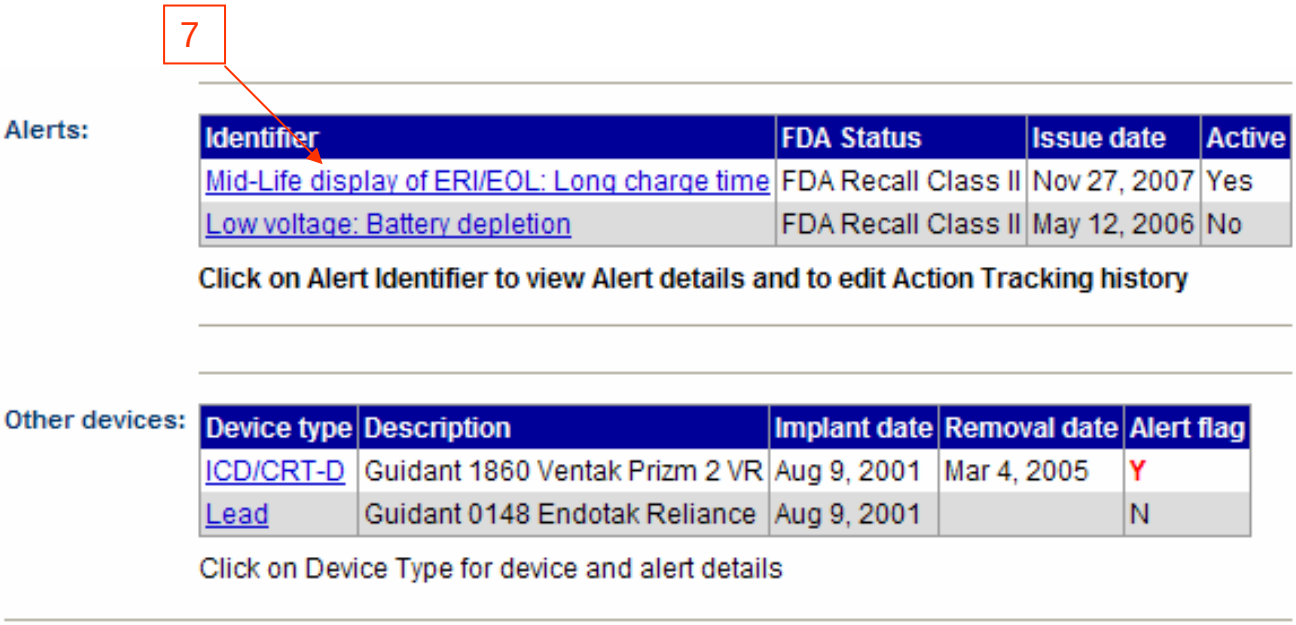
Table 1. Projected Rate of Mid-Life Display of Replacement Indicators

Product Family	Models	Projected Rates		
		Implanted Prior to July 2005	Implanted Between July 2005 – July 2006	Implanted After July 2006
VITALITY VR / DR VITALITY AVT® VITALITY DR+	1870 / 1871 A135 1872	8-10%	1%	< 1%
VITALITY AVT ASSURE™ VITALITY DS DR / VR VITALITY 2 DR / VR	A155 B301 T125 / T135 T165 / T175	4-7%	1%	< 1%
VITALITY EL VITALITY 2 EL DR / VR VITALITY DR HE CONTAK RENEWAL® 3 & 4 CONTAK RENEWAL 3 & 4 RF CONTAK RENEWAL 3 & 4 AVT CONTAK RENEWAL 3 & 4 HE CONTAK RENEWAL 3 & 4 RF HE CONTAK RENEWAL 3 & 4 AVT HE	T127 T167 / T177 T180 H170 / H173 / H175 / H190 / H195 H210 / H215 / H230 / H235 M150 / M155 / M170 / M175 H177 / H179 / H197 / H199 H217 / H219 / H239 M157 / M159 / M177 / M179	1-2%	1%	< 1%

Continuous manufacturing improvements intended to reduce variability in battery performance have been implemented by our battery supplier, which mitigate the occurrence of mid-life display of replacement indicators. Based on the above projections, Boston Scientific is confident that today's devices will not exhibit mid-life ERI or EOL at historical levels.

Device Behaviors Associated with Charge Time-Based Mid-Life Display of ERI or EOL

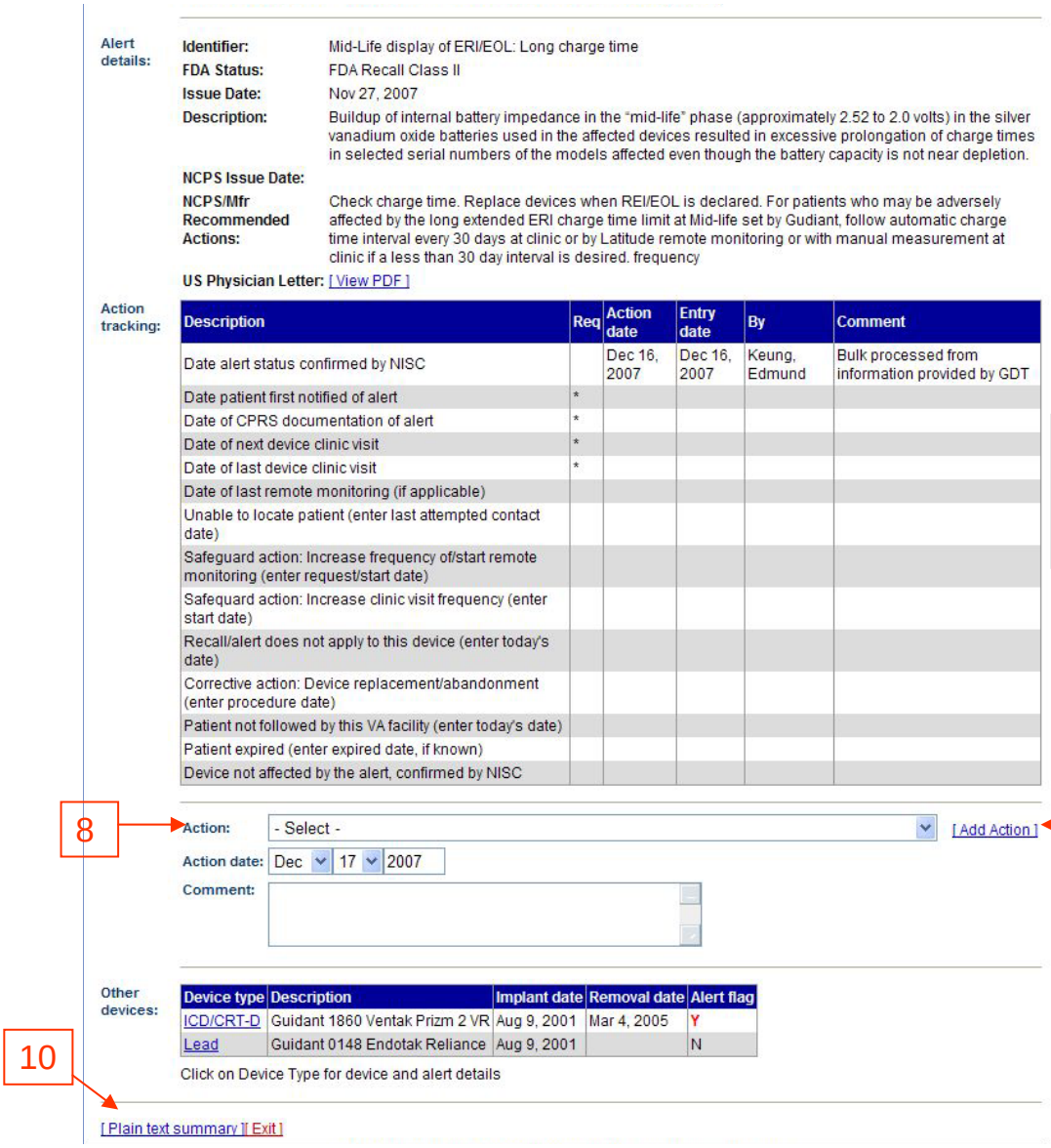
- ERI function that includes:
  - All therapies available
  - Charge times in excess of the ERI charge time limit (up to 30 seconds)
  - Audible tones (16 R-wave synchronous tones every 6 hours) if "Beep When ERI is Reached" is programmed ON
  - Upon device interrogation, yellow programmer message indicating ERI has been reached
- ERI to EOL time may be shorter than three months and/or EOL may be displayed with no prior ERI notification. However, devices that have triggered charge time-based ERI or EOL due to this pattern of mid-life behavior have several months, and in most cases more than one year of remaining battery capacity in which labeled ERI/EOL therapies are available as well as maximum energy shocks and brady and LV pacing.
- EOL function that includes:
  - Maximum energy shocks available (low-energy shocks disabled)
  - Brady and LV pacing available
  - Charge times in excess of EOL limit (>30 seconds)



8. Click on the Action dropdown manual to select the alert action accomplished and enter its appropriate Action date and Comment.

9. Click the [Add Action] button to a link this action to the patient. Repeat #8 and #9 for each applicable action step.

10. 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.



A description of the alert, recommendat-ions and physician letter from NCPS and mfr can be found here

A full display of recommended action steps and responses taken