Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL08-06 December 21, 2007

NOTE: Some models addressed in this Alert also appear in Patient Safety Alert AL07-07 issued on April 18, 2007. This Alert provides new information addressing a new battery problem.

Item: FDA CLASS II recall of Boston Scientific Corporation's Cardiac Rhythm Management Division (previously called Guidant) Implantable Cardiac Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds).

Specific Incident: A subset of the following Guidant ICD and CRT-D device models have a buildup of internal battery impedance that may lengthen ICD and CRT-D charge times and display the Elective Replacement Indicator (ERI) or End of Life Indicator (EOL) even though battery voltage and capacity remain available. This issue can result in delayed delivery of shock therapy.

Device Model Name	Model Numbers
Vitality DS DR/VR	T125/T135
Vitality EL DR	T127
Vitality VR/DR	1870/1871
Vitality DR+	1872
Vitality AVT	A135
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 AVT	M155
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 of the issuance of this Alert, electrophysiology/cardiology staff or other appropriate caregivers must identify all affected patients by implementing both of the following steps a and b. 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) 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

Technical Services - U.S. tech.services@guidant.com 1.800.CARDIAC (227.3422)
Technical Services - Europe eurtechservice@guidant.com +32 2 416 9357

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.

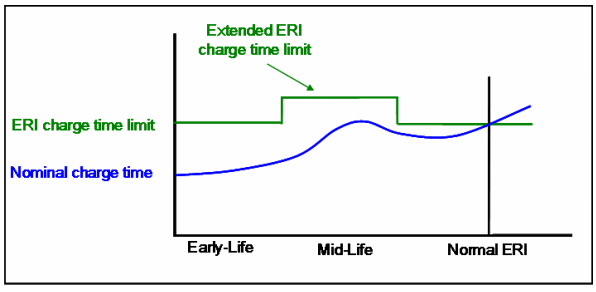


Figure 1. Charge time behavior and extended ERI charge time limit

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.

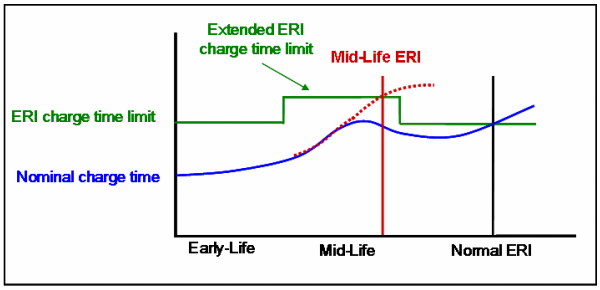


Figure 2. ERI is displayed during mid-life if charge time does not recede

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)

- Atrial Tachy Response (ATR) available
- Anti-tachy pacing (ATP) unavailable
- Atrial detection and atrial therapy options unavailable
- Automatic capacitor reforms disabled
- Audible tones (16 R-wave synchronous tones every 6 hours)
- Upon device interrogation, yellow programmer message indicating EOL has been reached

Patient Management Considerations

- Charge time information is being provided so that physicians can consider individual patients needs relative to the potential device behaviors associated with mid-life display of ERI or EOL.
- Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the pulse generator reaches ERI.
- Last measured charge time and date are stored in device memory and are available during device interrogation. Commanding a manual capacitor reform may be helpful in characterizing the current charge time.
- If ERI or EOL is triggered, device replacement should be scheduled.

Appendix A. Normal Charge Time Performance and ERI Charge Time Limits by Device Family

	Product	Early-Life Performance		Mid-Life Performance	
		Nominal Charge Time at BOL [a]	ERI Charge Time Limit During Early-Life and Late-Life [b]	Nominal Charge Time During Mid-Life [a]	Extended ERI Charge Time Limit During Mid-Life [b, c]
Standard Energy	VITALITY VR / DR Models 1870 / 1871	**10 sec**	17.9 sec	**16 sec**	23.0 sec
	VITALITY DR+ Model 1872	**10 sec**	17.9 sec	**19 sec**	23.0 sec
	VITALITY AVT Model A135	**10 sec**	17.9 sec	**16 sec**	23.0 sec
	VITALITY AVT Model A155	**7.0 sec**	13.1 sec	**9 sec**	18.9 sec
	VITALITY DS DR / VR Models T125 / T135	**7.5 sec**	13.1 sec	**9 sec**	18.9 sec
	VITALITY EL Model T127	**7.5 sec**	13.1 sec	**11 sec**	18.9 sec
	VITALITY 2 DR / VR Models T165 / T175	**7.0 sec**	13.1 sec	**9 sec**	18.9 sec
	VITALITY 2 EL DR / VR Models T167 / T177	**7.0 sec**	13.1 sec	**11 sec**	18.9 sec
	CONTAK RENEWAL 3 & 4 Models H170 / H173 / H175 / H190 / H195	**6.1 sec**	12.5 sec	**10 sec**	20.0 sec
	CONTAK RENEWAL 3 & 4 RF Models H210 / H215 / H230 / H235	**6.1 sec**	12.5 sec	**10 sec**	20.0 sec
	CONTAK RENEWAL 3 AVT Models M150 / M155	**6.1 sec**	12.5 sec	**10 sec**	20.0 sec
	CONTAK RENEWAL 4 AVT Models M170 / M175	**6.1 sec**	12.0 sec	**10 sec**	20.0 sec
	ASSURE Model B301	**7.0 sec**	13.1 sec	**9 sec**	18.9 sec
High Energy (HE)	VITALITY DR HE Model T180	**7.8 sec**	14.6 sec	**13 sec**	26.1 sec
	CONTAK RENEWAL 3 & 4 HE Models H177 / H179 / H197 / H199	**7.8 sec**	13.1 sec	**13 sec**	26.1 sec
	CONTAK RENEWAL 3 & 4 RF HE Models H217 / H219 / H239	**7.8 sec**	13.1 sec	**13 sec**	26.1 sec
	CONTAK RENEWAL 3 & 4 AVT HE Models M157 / M159 / M177 / M179	**7.8 sec**	13.1 sec	**13 sec**	23.0 sec

[a] Charge times represent a maximum energy shock following a capacitor reformation.

[b] Two qualifying charge times in excess of the specified ERI charge time limit within a 24-hour window are required to trigger ERI. One qualifying charge time in excess of 30 seconds is required to trigger EOL.

[c] Mid-life occurs during a monitoring voltage of approximately 2.52 V to 3.00 V (varies by model).

ATTACHMENT 2

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

VA National ICD Surveillance Center

December 20, 2007

Dear colleagues:

This document is to provide you with some general guidelines to deal with a safety problem that affects a subset of Boston Scientific (Guidant) ICDs and CRT-Ds. This problem has been classified by FDA on November 27, 2007 as a Class II recall. The problem had been addressed by Boston Scientific in a Product Update published on March 10, 2007 on their website.

Device Model Affected:

Note: Not all devices are affected; only a subset of devices within the device models listed are affected:

Device Model Name	Model Numbers
Vitality DS DR/VR	T125/T135
Vitality EL DR	T127
Vitality VR/DR	1870/1871
Vitality DR+	1872
Vitality AVT	A135
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 AVT	M155
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

The Problem:

The root cause: Buildup of internal battery impedance in the “mid-life” phase in the silver vanadium oxide batteries used in the affected devices can lengthen charge times.

Reported incidence: Product family specific, ranging from 1-2% to 8-10% in devices implanted prior to July 2005.

Boston Scientific reported no deaths or serious injuries in association with this recall.

Potential adverse consequences of the problem:

- Excessive lengthening of ICD and CRT-D charge times
- ERI (Elective Replacement Indicator) or EOL (End-of-Life Indicator) is declared because of the long charge time even though the battery voltage is still above that for replacement indication.

In the Boston Scientific ICDs and CRT-Ds, ERI is determined by a combination of charge time and battery voltage. The values for these combination criteria vary among product families. To avoid declaration of ERI or EOL when the charge time is excessively prolonged because of the above-mentioned battery impedance behavior (even when the battery voltage is still above the voltage indicator, usually 2.48-2.50 V), Boston Scientific raised the upper limit of the charge time values that would lead to declaration of ERI and EOL for a given range of battery voltage (extended ERI charge time limit during Mid-life). For example, for the T125 and T135 Vitality DS DR/VR ICD the charge time cutoff was increased to 18.9 sec at battery voltage of 3.0-2.53 V before the device will declare ERI. For some high energy ICDs and CRT-Ds, Boston Scientific extended the cutoff charge time for ERI to as high as 26.1 sec.

The most important problem for the clinicians is that excessive charge time will delay delivery of shock therapy, which may result in adverse outcomes such as loss of consciousness before restoration of normal rhythm or, rarely, failed therapy in some patients, no matter what the battery voltage. The frequency and mode of monitoring for the affected devices are highly dependent on the acceptable upper limit of charge time for the clinicians, which may be different for some patients.

Some important facts regarding automatic charge time measurement and notification:

- After Beginning of Life (during and after mid-life), the charge time is automatically measured every 30 days. If the extended ERI charge time limit is reached, we will be notified in the following ways:

    1. For all devices, the alert tone, if left in its nominal setting of ON, will sound within 48 hours (after a second confirmation within the next 24 hours).
    2. For wireless devices monitored by Latitude, it will be posted as a Yellow Alert within 48 hours
    3. For non-wireless devices monitored by Latitude, it will be posted as a Yellow Alert within 8 days, depending on how many days after the last weekly surveillance transmission the automatic capacitor reform is performed (if the clinic has not turned off the weekly surveillance transmission function).

- The alert (tone or Yellow Alert) trigger level for charge time and the frequency of automatic charge time measurement <u>cannot</u> be programmed or modified.

<u>Recommendations</u>:

- Because the extended ERI charge time limit can be identified with close monitoring, replacement of the devices is not recommended.
- Review Attachment 1 (Boston Scientific Product Update dated March 10, 2007).
- Within 90 days, as suggested by the VA Alert Memo, review the charge time on your last interrogation report on the affected ICDs and CRT-Ds (either performed in your clinic or with Latitude Remote Monitoring). If the last recorded charge time is more than 3 months old, perform a clinic interrogation or instruct the patient to perform a Latitude transmission as soon as possible.
- At the next regularly scheduled clinic visit, interrogate the device with the programmer. Review the Setup page to make sure that the programmable feature “Beep When ERI is Reached” is ON (nominally setting is ON). From the same page, temporarily program “Beep on Sensed and Paced Events” to ON to demonstrate the audible alert tone to patients (make sure to reprogram it back to OFF after the tone demonstration). Instruct patients to contact their clinicians and perform a Latitude remote monitoring transmission (if applicable) when their devices emit the alert
- Replace the device if ERI/EOL is declared.

- Continue regular monitoring (clinic and remote) of the affected devices. To enroll patients in the LATITUDE Patient Management System via the VA National ICD Surveillance Center (NISC), go to its Web site (VA ONLY - https: //icdpm.sanfrancisco.med.va.gov). Most of the patients are already in the NISC database.

- However, if you feel that the extended ERI charge time limits during Mid-life (with ERI/EOL declaration) are too excessive for some of your patients or you want to monitor your device more frequently than the standard every 3 month interval, charge time can be followed monthly by Latitude remote monitoring. For more frequent monitoring, manual capacitor reform will have to be performed in clinic to measure the charge time.

- Discuss this safety issue with your patients within 90 days, or as soon as you can. Document your actions in CPRS and update your patient information on the NISC website. A new Safety Alert Management Utility module has been added to the VA National ICD Surveillance website site to assist you to identify and track your actions steps in response to the recall. See Attachment 3 for instruction.
- 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.

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

ATTACHMENT 3

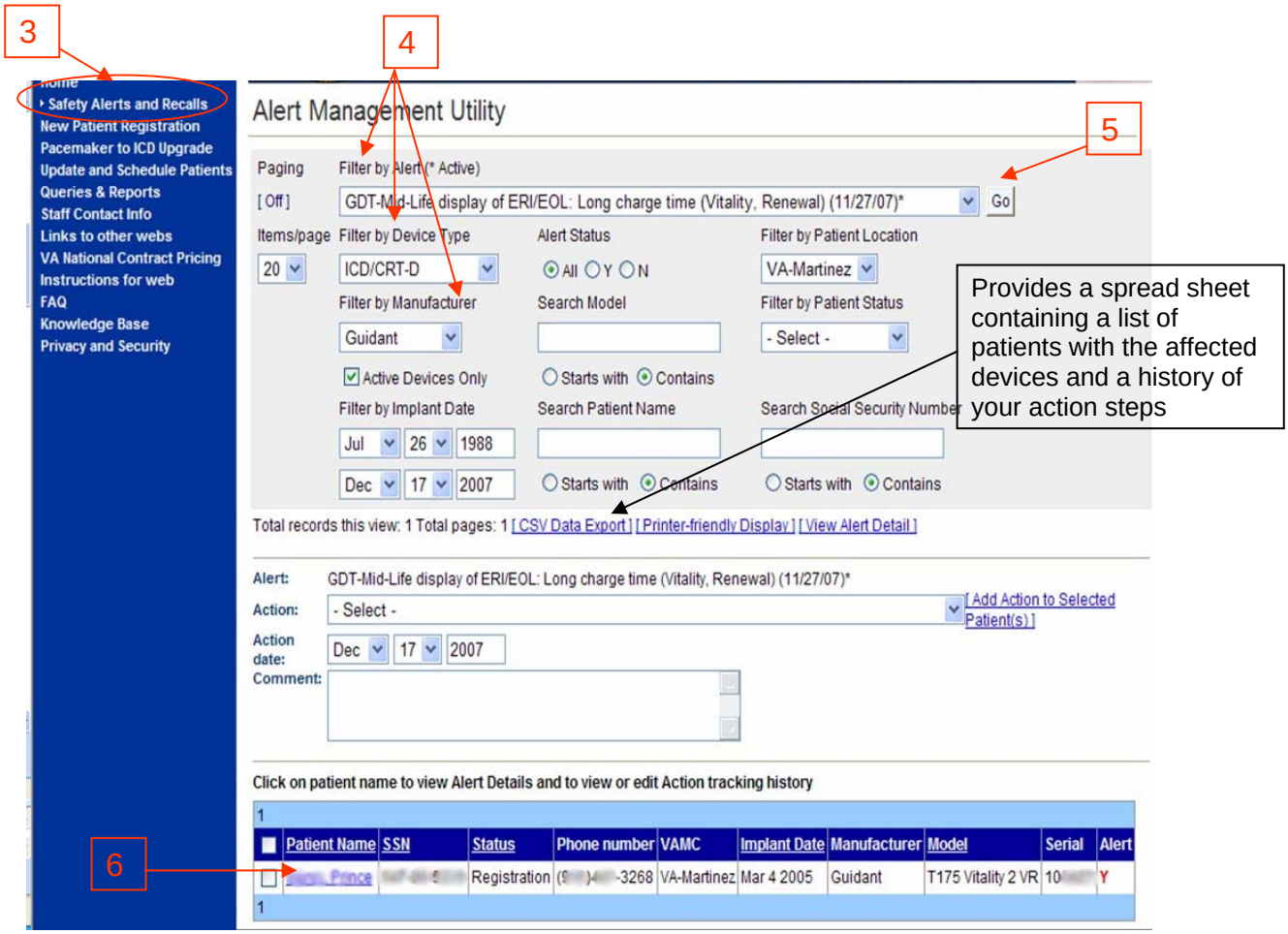
Instructions on how to access the VA National ICD Surveillance center database and on using the Safety Alerts and Recalls Module to manage the recall.

Perform the following steps to access your list of patient with the affected devices at the VA National ICD Surveillance Center Website. We created a new module to assist you to manage safety alerts and recalls:

1. 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 Recall> and <Alert Management Utility>
4. Select, in order:
    a. ICD/CRT-D from the Filter by Device Type dropdown list
    b. Guidant from the Filter by Manufacturer dropdown list
    c. GDT-Prolonged charge time (Vitality,Renewal,Assure) (11/27/07) from the Filter by Alert dropdown list.
5. 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.

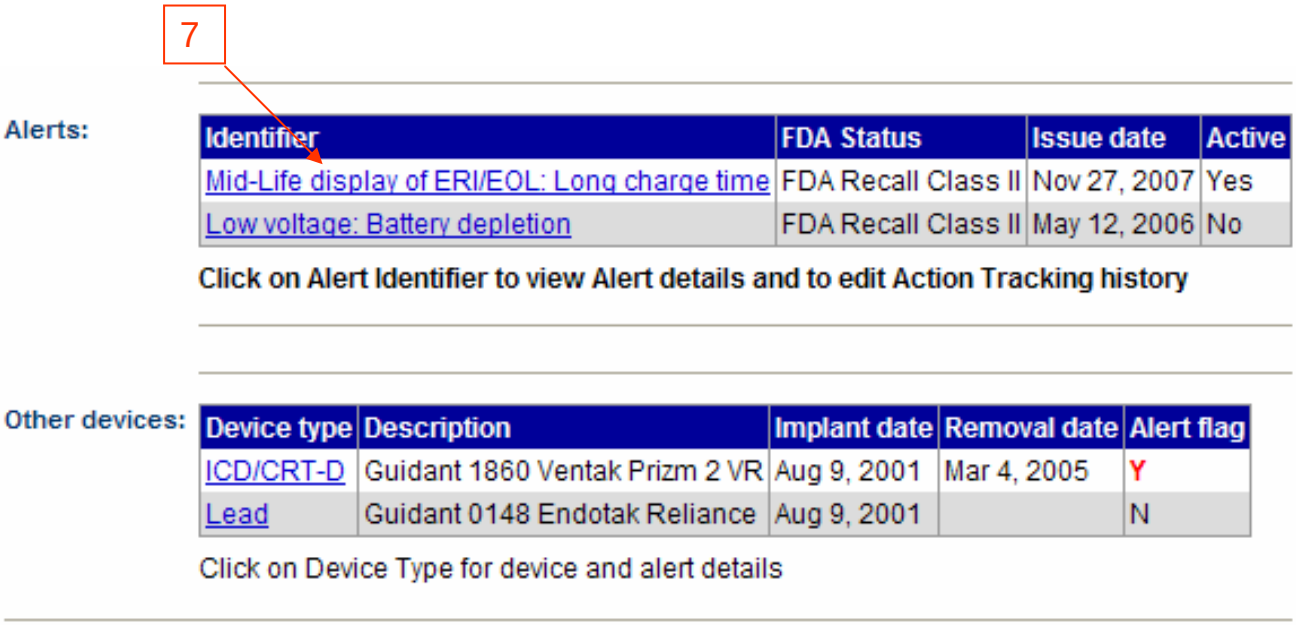
The medical centers listed under the column VAMC are the hospitals where they had their device implanted or the follow-up clinics, according the records of the National ICD Surveillance Center and Medtronic.



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

6. 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.

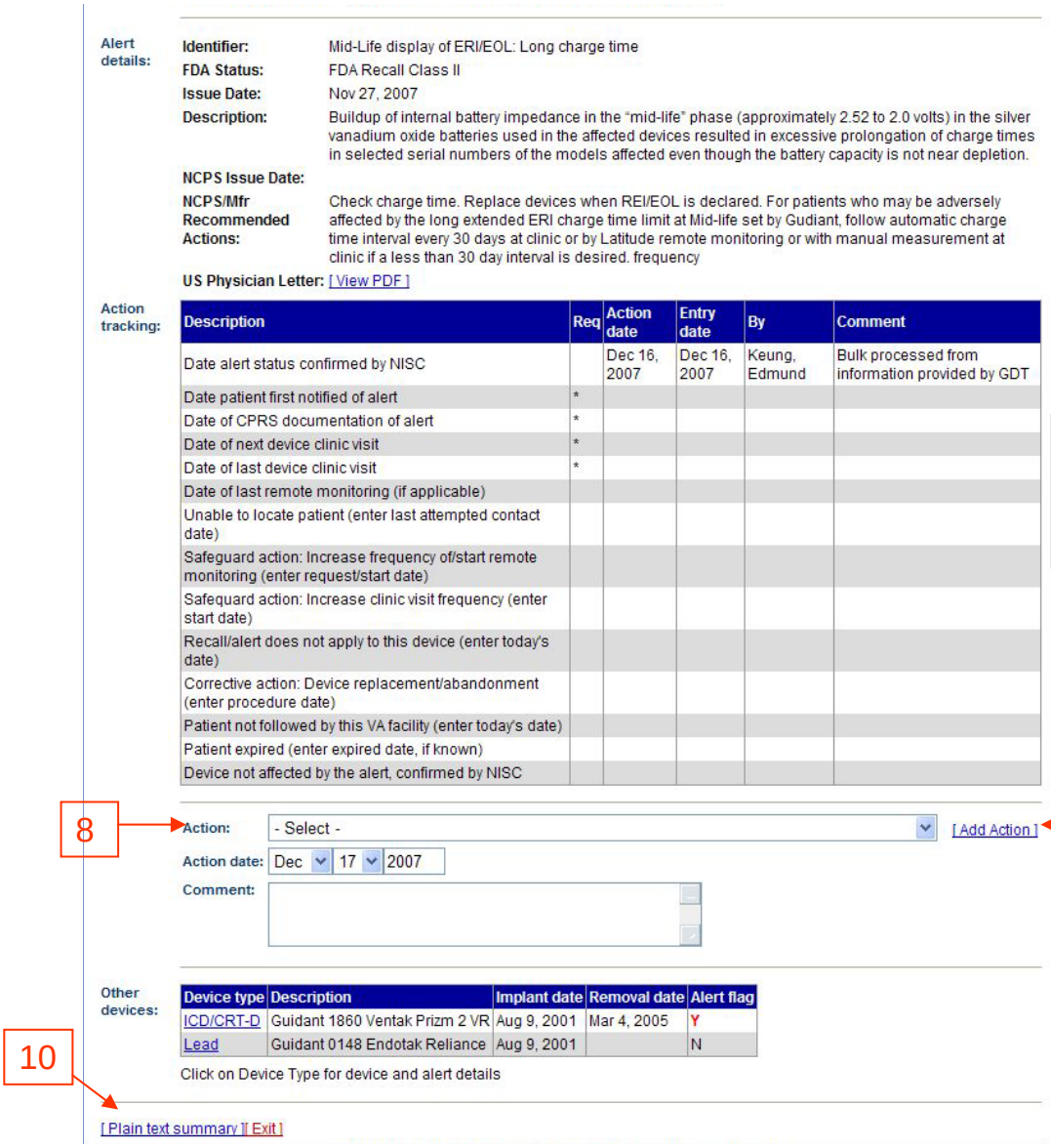
7. Click on the appropriate Alert Identifier (if there is more than one alert affecting the device) to go to page 2 to view the alert details and to enter your actions in response to this alert.



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