

# Patient Safety Alert

Veterans Health Administration Warning System  
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AL08-07

January 25, 2008

**Item:** Implant orientation of Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Devices (CRT-Ds) manufactured by Boston Scientific Corporation's Cardiac Rhythm Management Division, previously under the name Guidant.

**Specific Incident:** A subset of the following Guidant ICDs and CRT-Ds models implanted in a specific location and in an uncommon orientation - beneath the pectoral muscle with the serial number facing the ribs - may be subject to component damage and device malfunction. This can impact the device's ability to deliver appropriate shock therapy.

## May 12, 2006 Population

Device Model Name	Model Numbers
Contact Renewal 3 & 3 HE	H170/H173/H175/H177/H179
Contact Renewal 3 AVT & 3 AVT HE	M150/M155/M157/M159
Contact Renewal 4 & 4 HE	H190/H195/H197/H199
Contact Renewal 4 AVT & 4 AVT HE	M170/M175/M177/M179
Vitality DR HE	T180

## January 4, 2008 Population

Device Model Name	Model Numbers
Vitality 2 EL DR/VR	T167/T177
Vitality EL	T127
Vitality DR+	1872

- Actions:**
1. By Close of Business (COB) April 30, 2008, electrophysiology and/or cardiology staff or other appropriate caregivers must identify all affected patients by implementing steps a, b, c and step d if indicated. 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) on the VA National ICD Surveillance Center intranet website (<https://icdpm.sanfrancisco.med.va.gov>, see Attachment 3 for instructions. This list includes 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.
    - c) Review implant surgical notes and post implant Chest X-rays (CXRs) of patients with affected devices identified in steps a and b above, to

determine if device's location and orientation are verifiable. If device location or orientation is not verifiable or a post-implant CXR is not available then proceed to step d.

If device orientation is verified as beneath the pectoral muscle with the serial number facing the ribs then proceed to Action 2 below.

d) Contact the patients identified at step c above (those with device orientation or location not verifiable) to have an Anterior/Posterior (AP) Chest x-ray to determine/verify specific device orientation or to have a physical examination of the implant area to best determine the location of the device.

2. Review and plan appropriate action as discussed in Attachment 2 prepared by Dr. Edmund Keung, Director of the VA National ICD Surveillance Center.

**Source:** Boston Scientific Corporation (BSCI)

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

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

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

**Attachments:**

- 1) Boston Scientific Urgent Medical Device Information (Update to May, 2006 Product Advisory) dated January 4, 2008
- 2) VA National ICD Surveillance Center Memo dated January 24, 2008
- 3) Instructions to access the VA National ICD Surveillance Center Web portal

**URGENT MEDICAL DEVICE INFORMATION**  
Update to May, 2006 *Product Advisory*  
January 4, 2008



**Cardiac Rhythm Management**  
4100 Hamline Avenue North  
St. Paul, MN 55112-5798  
www.bostonscientific.com

<b>Summary</b>	
<b>Issue:</b>	Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in certain ICD and CRT-D devices implanted subpectorally with the serial number facing the ribs (susceptible orientation shown in Figure 2). Devices implanted subcutaneously or in a subpectoral position with the serial number facing away from the ribs are not included in this advisory. <b>This update identifies additional VITALITY<sup>®</sup> ICD models (Table 1) that are also subject to this failure mechanism if implanted in a susceptible orientation.</b>
<b>Frequency:</b>	A total of 13 failures have been confirmed from an estimated 950 devices implanted in a susceptible orientation. The failure rate prediction is estimated to be 3% to 4% at 60 months.
<b>Consequence:</b>	Loss of shock therapy, loss of pacing therapy (intermittent or permanent), or loss of telemetry communications.
<b>Actions:</b>	Review patient records to determine if device was implanted subpectorally. Use an AP radiograph to determine specific device orientation. If a subpectoral implant is in a susceptible orientation, consider repositioning or replacement for physically active patients or for patients who regularly need device therapy. Follow patients with susceptible devices at 3-month intervals in accordance with device labeling.

Dear Doctor,

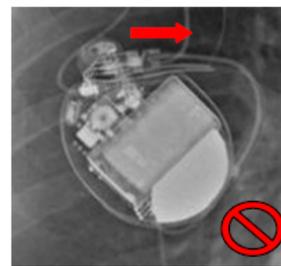
On May 12, 2006, Boston Scientific CRM issued a **Product Advisory** describing the potential for device malfunction in certain ICDs and CRT-Ds when implanted subpectorally with the serial number facing the ribs. Further clinical experience and testing indicate that additional VITALITY device models are also subject to this failure mechanism (Table 1).

**Description of Issue**

Accelerated life testing has shown that repetitive mechanical stress applied to the serial number side of the titanium case can induce component damage and device malfunction. This has occurred *only* when the device was implanted subpectorally with the serial number facing the ribs (Figure 2).



**Figure 1.** Optimal orientation for subpectoral implants. Leads exit in a counter clockwise direction. Serial number is facing away from the ribs.



**Figure 2. Photo and X-ray.** Avoid this orientation for subpectoral implants. Leads exit in a clockwise direction. Serial number is facing the ribs.

**Devices Affected**

**Table 1.** Model numbers potentially affected if implanted subpectorally with serial number facing the ribs.

<b>May 12, 2006 Population*</b>	
CONTAK RENEWAL <sup>®</sup> 3 & 3 HE	H170/H173/H175/H177/H179
CONTAK RENEWAL 3 AVT & 3 AVT HE	M150/M155/M157/M159
CONTAK RENEWAL 4 & 4 HE	H190/H195/H197/H199
CONTAK RENEWAL 4 AVT & 4 AVT HE	M170/M175/M177/M179
VITALITY DR HE	T180
<b>January 4, 2008 Population*</b>	
VITALITY 2 EL DR/VR	T167/T177
VITALITY EL	T127
VITALITY DR+	1872

Notes:

\*Not all devices are approved in all geographies.

Standard life VITALITY devices are not included in this advisory (one observation of this type in over 125,000 devices implanted to date).

A device model and serial number search tool is available at [www.bostonscientific.com](http://www.bostonscientific.com).

#### Clinical Implications

While there is no way to predict if or when a device in the susceptible orientation will fail, one or more of the following device behaviors indicate that a failure has occurred: loss of shock therapy, loss of pacing therapy (intermittent or permanent), loss of telemetry communications, beeping (16 tones every six hours), and display of a warning screen upon programmer interrogation.

#### Rate of Occurrence

Six additional failures (total of eight) have been confirmed from the May 12, 2006 population of 70,200 devices. Five failures have been confirmed from 24,700 devices in the January 4, 2008 population. There have been no reported patient deaths associated with this issue.

Because the implant orientation of devices is not reported to Boston Scientific, rate of occurrence or failure rate projections specific to a subpectoral implant with the serial number facing the ribs can only be estimated. ***If it is assumed that 1% of the total population is implanted in a susceptible orientation:***

- A total of 13 failures to date represents 1.4% of approximately 950 devices implanted in a susceptible orientation.
- The projected failure rate for devices implanted in the susceptible orientation is estimated to be 3% to 4% (28 to 38 devices) at 60 months for both the May 12, 2006 population and the January 4, 2008 population.

#### Recommendations

Patient management recommendations for both populations remain unchanged from May 12, 2006:

1. For patients implanted with a model listed in Table 1, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory.
2. For subpectoral implants, use an AP radiograph to determine specific device orientation.
  - If the leads exit the pulse generator in a counter clockwise direction (Figure 1), this advisory does not apply and no change to your current patient management is necessary.
  - If the device is in a susceptible orientation (Figure 2),
    - Advise patient of the potential for device failure.
    - Follow patient at 3 month intervals in accordance with device labeling.
    - Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.

Where available, the LATITUDE<sup>®</sup> Patient Management System can enable remote follow-ups and facilitate patient monitoring between follow-ups.

3. For future implants, when considering subpectoral implantation of a device from any product family listed in Table 1, orient the device with the serial number facing away from the ribs (Figure 1).

#### Warranty Supplement Program

Boston Scientific's warranty supplement program, subject to certain conditions, provides full credit for the purchase of a Boston Scientific replacement device and an offer of up to \$2500 patient assistance for unreimbursed medical expenses.

#### Further Information

Boston Scientific recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative, United States Technical Services at 1.800.CARDIAC (227.3422) or European Technical Services at +32 2 416 7222.

Sincerely,



William E. Young  
Vice President, Reliability and Quality Assurance  
Boston Scientific Cardiac Rhythm Management

**PHYSICIAN DEVICE ADVISORY NOTICE**

**Advisory Date: May 12, 2006 and January 4, 2008**

Manufacturer	Boston Scientific Corporation		
Product(s)	<i>Trade Name</i>		<i>Model Number</i>
	<u>May 12, 2006 Advisory</u> CONTAK RENEWAL® 3/ 3 HE CONTAK RENEWAL 3 AVT/ 3 AVT HE CONTAK RENEWAL 4/ 4 HE CONTAK RENEWAL 4 AVT/ 4 AVT HE VITALITY® DR HE		H170/H173/H175/H177/H179 M150/M155/M157/M159 H190/H195/H197/H199 M170/M175/M177/M179 T180
	<u>January 4, 2008 Advisory Update</u> VITALITY DR+ VITALITY EL VITALITY 2 EL DR/VR		1872 T127 T167/T177
Manufactured on or before (Date)			
Performance Failure	Loss of shock therapy, loss of pacing therapy (intermittent or permanent), or loss of telemetry communications		
Root Cause	Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in devices implanted subpectorally with the serial number facing the ribs.		
Date Manufacturer Corrected Product Available	For future implants, when considering subpectoral implantation of a device from a product family listed above, orient the device with the serial number facing away from the ribs		
Has all affected product been retrieved?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	See patient management recommendations

**FDA CLASSIFICATION STATUS**

Advisory classification	- Class II for May 12, 2006 population - Decision pending for January 4, 2008 population	
<b>CLINICAL ACUITY</b>	<i>(USA)</i>	<i>(Worldwide)</i>
a) Total number of units currently implanted	64,600	87,700
b) Estimated number of potentially affected devices of this mode	~700 in susceptible orientation (~1% of implanted population)	~950 in susceptible orientation (~1% of implanted population)
c) Estimated incidences of this performance failure over the projected life of the device	21 to 28 (3% to 4% of devices implanted in a susceptible orientation)	28 to 38 (3% to 4% of devices implanted in a susceptible orientation)
d) Total number with observed performance failure	6	13
% of performance failures d/b x 100 =	0.85%	1.4%
e) Mean age of product in implanted population	~32 months for May 12, 2006 population ~20 months for January 4, 2008 population	
f) Patient deaths reported	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Number of deaths =	0 related to this issue	
g) Patient deaths with probable relationship to device failure	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Number of deaths =	0	

\* The data analysis provided in this report was generated by the manufacturer and may be subject to change

**DEVICE COMPONENTS AT RISK OF PERFORMANCE FAILURE**

- |   |   |
|---|---|
| <input type="checkbox"/> Battery Failure                                | <input checked="" type="checkbox"/> CRT (left ventricular pacing) |
| <input type="checkbox"/> Diagnostic Data Failure                        | <input type="checkbox"/> Lead Failure                             |
| <input checked="" type="checkbox"/> Brady Therapies (lower rate pacing) | <input checked="" type="checkbox"/> Internal component            |
| <input type="checkbox"/> Brady Therapies (runaway pacing)               | <input type="checkbox"/> EMI Susceptibility                       |
| <input checked="" type="checkbox"/> Tachy Therapies (ATP)               | <input checked="" type="checkbox"/> Telemetry Failure             |
| <input checked="" type="checkbox"/> Tachy Therapies (shock)             | <input type="checkbox"/> Other                                    |

<b>PATIENT MANAGEMENT RECOMMENDATIONS</b>		
Verify normal device function (at normal follow-up interval)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
Verify normal device function (as soon as possible)	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Patient management recommendations for both populations remain unchanged from May 12, 2006: 1. For patients implanted with advisory product, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory. 2. For subpectoral implants, use an AP radiograph to determine specific device orientation. <ul style="list-style-type: none"> <li>➤ If the leads exit the pulse generator in a counter clockwise direction (serial number facing <b>away</b> from the ribs), this advisory does not apply and no change to current patient management is necessary.</li> <li>➤ If the device is in a susceptible orientation (serial number facing the ribs),               <ul style="list-style-type: none"> <li>• Advise patient of the potential for device failure.</li> <li>• Follow patient at 3 month intervals in accordance with device labeling.</li> <li>• Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.</li> </ul> </li> </ul> <p style="margin-left: 40px;">Where available, the LATITUDE® Patient Management System can enable remote follow-ups and facilitate patient monitoring between follow-ups.</p> 3. For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.		
Programming changes	<input type="checkbox"/> Required	<input type="checkbox"/> Recommended
If programming changes are required, specify changes: none required		
Accelerated device follow-up	<input type="checkbox"/>	<input checked="" type="checkbox"/> No
Timeline - months:	3-month intervals per device labeling	

**CONTACT**

Boston Scientific Cardiac Rhythm Management

**Technical Services – U.S.**  
 1.800.CARDIAC (227.3422)  
[Tech.Services@guidant.com](mailto:Tech.Services@guidant.com)

**Technical Services – Europe**  
 +32 2 416 7222  
[eurtechservice@guidant.com](mailto:eurtechservice@guidant.com)

**LATITUDE Clinician Support**  
 1.800.CARDIAC (227-3422)  
[latitude@guidant.com](mailto:latitude@guidant.com)

**Patient Services**  
 1.866.484.3268 – U.S. and Canada  
 001.651.582.4000 – International



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

**VA National ICD Surveillance Center**

January 24, 2008

Dear colleagues:

On January 4, 2008, Boston's Scientific (Guidant) issued an Urgent Medical Device Information Notice that affects a subset of Boston Scientific (Guidant) ICDs and CRT-Ds. This document is to provide you with some general guidelines to deal with this safety problem. The present advisory is the same as the one issued by Boston Scientific on May 12, 2006; however, it has been updated to include additional Vitality ICD models that are also subject to this safety problem.

Device Model Affected:

Note: Not all devices are affected; susceptibility is determined by the implant configuration of the generators.

January 4, 2008 Population	
Device Model Name	Model Numbers
Vitality EL DR	T127
Vitality DR+	1872
Vitality 2 EL DR/VR	T167/T177
May 12, 2006 Population	
Device Model Name	Model Numbers
Contak Renewal 3 & 3 HE	H170/H173/H175/H177/H179
Contak Renewal 3 AVT & 3 AVT HE	M150/M155/M157/M159
Contak Renewal 4 & 4 HE	H190/H195/H197/H199
Contak Renewal 4 AVT & 4 AVT HE	M170/M175/M177/M179
Vitality DR HE	T180

The Problem:

The cause: Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in devices implanted subpectorally with the serial number facing the ribs.

Reported incidence: No data from Boston Scientific because the implant orientation of devices is not reported to the manufacturer. A total of 13 device failures worldwide (5 out of 24,700 total devices in the present population) have been reported to date. Boston Scientific projected a failure rate for devices implanted in the susceptible orientation to be 3-4% (assuming 1% implantations in the susceptible orientation).

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

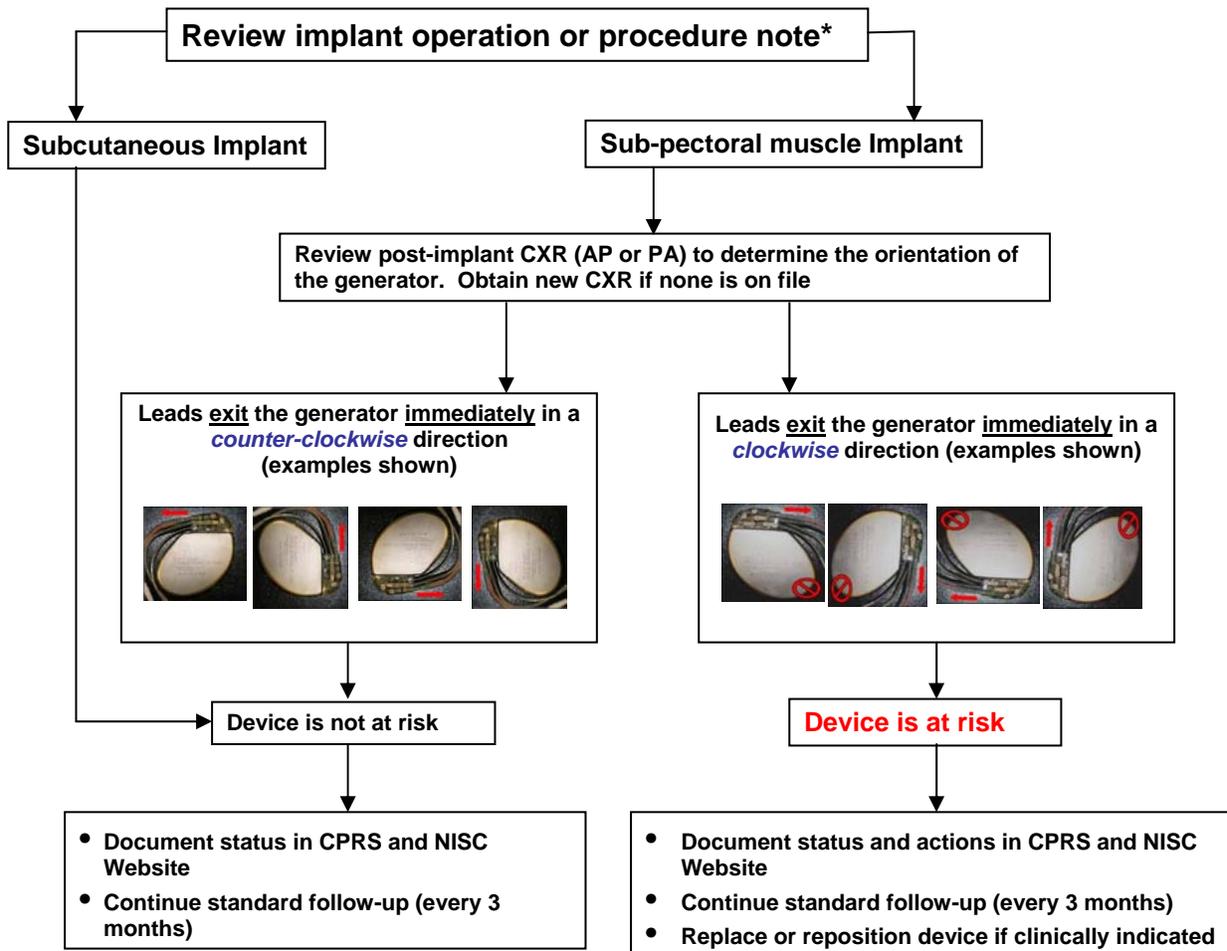
Potential adverse consequences of the problem:

- Unpredictable loss of shock therapy, loss of pacing therapy (intermittent or permanent), loss of telemetry communications, beeping (16 tones every six hours), and display of a warning screen upon programmer interrogation.

## ATTACHMENT 2 (Continued)

### Recommendations:

- The most important thing to do is to identify if patients implanted with a model listed above are susceptible to this advisory. Only devices implanted under the sub-pectoral muscles with the serial number facing the ribs are susceptible to this advisory. Within 90 days, use the following algorithm to identify susceptible devices.



\* An alternative starting point is to review the post-op CXR to determine how the leads exit the generator. If they exist in a counter-clockwise direction, the device is not at risk, no matter what the location (subcutaneous or sub-pectoral) is.

If the operation or procedure note did not identify if the device was a sub-pectoral implantation, examination of the pocket in the clinic may be helpful in many cases. If the generator location still cannot be ascertained, it is best to treat it as a device at risk.

- Continue standard 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 (<https://icdpm.sanfrancisco.med.va.gov>). Most of the patients are already in the NISC database.
- However, in physically active patients or for patients who regularly need device therapy (tachy or brady), consider device repositioning or replacement.

**ATTACHMENT 2 (Continued)**

- Discuss this safety issue with your patients within 90 days of the issuance of this Alert, 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 to assist you to identify and track your actions steps in response to the recall. See Attachment 3 for instruction.
- For future implants of the involved models, consider subcutaneous implantation or orienting the device with the serial number facing away from the ribs for subpectoral implantation.
- These recommendations are only suggestions and are not binding. We have to evaluate individual patient's clinical conditions, advise the patients of the risks (especially infection associated with device replacement or repositioning) 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.

A handwritten signature in black ink that reads "Edmund Keung, MD". The signature is written in a cursive style with a large initial 'E'.

Ed Keung, MD  
Director, VA National ICD Surveillance Center  
Ph: 415-221-4810, extension 3182  
[Edmund.Keung@va.gov](mailto: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. Please note that you can use the same ICD and Pacemaker Web portal as your own device database.

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](mailto: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>. (See screen shot on the following page)
4. Select, in order: (See screen shot on the following page)
  - a. ICD/CRT-D from the Filter by Device Type dropdown list
  - b. Guidant from the Filter by Manufacturer dropdown list
  - c. Select GDT-Subpectoral implant: Loss of functions, second population (Vitality) (01/04/08) from the Filter by Alert dropdown list  
To retrieve the first population, select GDT-Subpectoral implant: Loss of functions (Vitality, Renewal) (05/21/06)
5. Click "Go" to obtain your list (See screen shot on the following page)

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. (See screen shot on the following page)

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.

The screenshot shows the 'Alert Management Utility' interface. On the left is a blue navigation menu with 'Safety Alerts and Recalls' circled in red and labeled '3'. The main area has a header 'DEPARTMENT OF VETERANS AFFAIRS INTRANET' and 'Alert Management Utility'. Below this are various filter options: 'Filter by Alert (\* Active)' with a dropdown menu labeled '4', 'Filter by Device Type' (set to ICD/CRT-D), 'Filter by Manufacturer' (set to Guidant), and 'Filter by Implant Date' (set to Jan 22 2008). There are also search fields for 'Search Model', 'Search Patient Name', and 'Search Social Security Number'. A 'Go' button is labeled '5'. Below the filters, there are options for 'Alert Status' (All, Y, N), 'Filter by Patient Location' (VA-San Francisco), and 'Filter by Patient Status' (- Select -). A text box on the right says 'Provides a spreadsheet containing a list of patients with the affected devices and a history of your action steps'. Below the filters, there are links for 'CSV Data Export', 'Printer-friendly Display', and 'View Alert Detail'. The 'Alert' section shows the current alert: 'GDT-Subpectoral implant: Loss of functions, second population (Vitality) (01/04/08)\*'. There are dropdowns for 'Action' (- Select -) and 'Action date' (Jan 22 2008), and a 'Comment' field. At the bottom, there is a table with columns: Patient Name, SSN, Status, Phone number, VAMC, Implant Date, Manufacturer, Model, Serial, and Alert. A red box labeled '6' points to the first row of the table.

**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). Clicking on the Alert will allow you to view the alert details and enter your actions in response to the alert. (See the screen shot on the following page)

## ATTACHMENT 3 (Continued)

Alerts:

Identifier	FDA Status	Issue date	Active
<a href="#">Shortened replacement window</a>	Alert	Apr 5, 2007	Yes
<a href="#">Mid-Life display of ERI/EOL: Long charge time</a>	FDA Recall Class II	Nov 27, 2007	No
<a href="#">Subpectoral implant: Loss of functions, second population</a>	Manufacturer Safety Alert	Jan 4, 2008	Yes

7

Click on Alert Identifier to view Alert details and to edit Action Tracking history

Other devices:

Device type	Description	Implant date	Removal date	Alert flag
<a href="#">Lead</a>	Guidant 4473 FINELINE II EZ STEROX	Nov 9, 2005		N
<a href="#">Lead</a>	Medtronic 5076 CapsureFix Novus	Nov 9, 2005		N
<a href="#">ICD/CRT-D</a>	Guidant 1850 Ventak Prizm VR	Jan 3, 2001	Apr 1, 2004	N
<a href="#">Lead</a>	Guidant 0147 Endotak Reliance	Jan 3, 2001		N

Click on Device Type for device and alert details

8. Click on the Action dropdown manual to select the alert action (see screen shot on the following page) accomplished and enter its appropriate Action date and Comment.
9. Click the [Add Action] button (see screen shot on the following page) to a link this action to the patient. Repeat #8 and #9 for each applicable action step.
10. Click the [Plain text summary] button (see screen shot on the following page) 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.

ATTACHMENT 3 (Continued)

Alert details:

**Identifier:** Subpectoral implant: Loss of functions, second population  
**FDA Status:** Manufacturer Safety Alert  
**Issue Date:** Jan 4, 2008  
**Description:** This product advisory is the same as that issued on May 12, 2006 except that additional models that are also subject to this failure mechanism have been identified. Repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction only if the device is implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion). An anterior/posterior (AP) radiograph can be used to determine device orientation. Due to component location, damage associated with this failure mode will not occur in a subcutaneous position or in a subpectoral position with the serial number facing up. This failure mechanism can result in one or more of the following device behaviors: (a) Loss of shock therapy, (b) Intermittent or permanent loss of pacing therapy, (c) Loss of telemetry communications, (d) Beeping (16 tones every six hours), and a programmer warning screen upon interrogation. To verify if a specific device is affected, go to <http://www.bostonscientific.com/webapp/emarketing/lookup.jsp>

**NCPS Issue Date:**  
**NCPS/Mfr Recommended Actions:**  
**US Physician Letter:** [\[View PDF\]](#)  
**Patient Safety Notification:** [\[View PDF\]](#)

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

Action tracking:

Description	Req	Action date	Entry date	By	Comment
Date alert status confirmed by NISC		Jan 21, 2008	Jan 21, 2008	Keung, Edmund	
Date patient first notified of alert	*				
Date of CPRS documentation of alert	*				
Date of next device clinic visit	*				
Date of last device clinic visit	*				
Date of last remote monitoring (if applicable)					
Unable to locate patient (enter last attempted contact date)					
Safeguard action: Increase frequency of/start remote monitoring (enter request/start date)					
Safeguard action: Increase clinic visit frequency (enter start date)					
Recall/alert does not apply to this device (enter today's date)					
Corrective action: Device replacement/abandonment (enter procedure date)					
Patient not followed by this VA facility (enter today's date)					
Patient expired (enter expired date, if known)					
Device not affected by the alert, confirmed by NISC					

A full display of recommended action steps and responses taken

Adding this action item turns the alert status to "N" (not affected)

8

Action:  [\[Add Action\]](#)  
 Action date: Jan 22 2008  
 Comment:

9

Other devices:

Device type	Description	Implant date	Removal date	Alert flag
<a href="#">Lead</a>	Guidant 4473 FINELINE II EZ STEROX	Nov 9, 2005		N
<a href="#">Lead</a>	Medtronic 5076 CapsureFix Novus	Nov 9, 2005		N
<a href="#">ICD/CRT-D</a>	Guidant 1850 Ventak Prizm VR	Jan 3, 2001	Apr 1, 2004	N
<a href="#">Lead</a>	Guidant 0147 Endotak Reliance	Jan 3, 2001		N

10

Click on Device Type for device and alert details

[\[ Plain text summary \]](#) [\[ Exit \]](#)