



## URGENT MEDICAL DEVICE SAFETY INFORMATION & CORRECTIVE ACTION

May 12, 2006

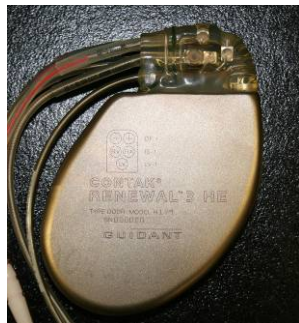
Subject: VITALITY<sup>®</sup> HE implantable cardioverter defibrillators (ICDs) and CONTAK RENEWAL<sup>®</sup> 3 and 4 cardiac resynchronization therapy defibrillators (CRT-Ds) implanted beneath the pectoral muscle in an uncommon orientation.

Dear Doctor,

This letter provides important safety information regarding VITALITY HE ICDs, and CONTAK RENEWAL 3 and 4 CRT-Ds (model numbers listed in Table 1 below). Guidant has received two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs). While implant orientation is not reported to Guidant, our records indicate that your health care facility may have implanted or is currently monitoring devices that may be at risk. This advisory is limited to those implanted **subpectorally with the serial number facing the ribs** (see Figure 2 below). You are encouraged to review the implant positioning for each patient to determine if any of your patients are affected. The vast majority of devices are implanted subcutaneously and are not subject to this failure mechanism. The United States Food and Drug Administration (FDA) may classify this communication as a recall.

### Description of Issue

Two reports of malfunction were associated with subpectoral implantation of devices in certain families of ICDs and CRT-Ds (see Table 1). Accelerated life testing has shown that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction. This can occur **only if the device is implanted subpectorally with the serial number facing the ribs**. As shown in Figure 2, an anterior/posterior (AP) radiograph can be used to determine device orientation.



Anterior  
view



**Figure 1.** Optimal orientation for subpectoral implants. Leads exit in a counter clockwise direction. Serial number is visible at implant.

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

### Clinical Implications

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

- Loss of shock therapy
- Loss of pacing therapy (intermittent or permanent)
- Loss of telemetry communications
- Beeping (16 tones every six hours) and a programmer warning screen upon interrogation

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

## Devices Impacted

The following model numbers are affected by this communication. Only device families listed in Table 1 that have been implanted subpectorally with the serial number facing the ribs (Figure 2) are subject to this issue.

**Table 1.** Model numbers potentially affected\*

Device Family	Models	Device Family	Models
CONTAK RENEWAL 3	H170/H173/H175	CONTAK RENEWAL 4	H190/H195
CONTAK RENEWAL 3 HE	H177/H179	CONTAK RENEWAL 4 HE	H197/H199
CONTAK RENEWAL 3 AVT	M150/M155	CONTAK RENEWAL 4 AVT	M170/M175
CONTAK RENEWAL 3 AVT HE	M157/M159	CONTAK RENEWAL 4 AVT HE	M177/M179
VITALITY HE	T180		

\*Not all devices are approved in all geographies

Due to component location, damage associated with this failure mode will not occur in a subcutaneous position. Similarly, the failure will not occur in devices implanted in a subpectoral position with the serial number facing up (Figure 1).

## Rate of Occurrence

The implant orientation of devices is not reported to Guidant. For this reason, no rate of occurrence or failure rate projection can be provided. However, based on available information, Guidant estimates that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.

The following factors may also impact the risk of failure:

- Exact location of the patient's ribs relative to the pulse generator case
- Body size or muscle mass of the patient (risk increases for larger patients)
- Activity level or occupation of the patient (risk increases for more active patients)
- Duration of implant (the risk of component damage increases as devices age, due to repetitive rib stress)

## Recommendations

For patients implanted with a model listed in Table 1, review records to determine if the device is subpectoral.

1. For patients with a subpectoral implant, use an AP radiograph to determine device orientation. If the device is in a susceptible orientation, the patient should be advised of the potential for device failure, and patient follow-up at least once per quarter is recommended in accordance with device labeling. Consider device replacement for muscular or active patients or for patients who regularly need device therapy.

If the patient's device was implanted subpectorally and leads exit the pulse generator in a **counter clockwise** direction as shown in Figure 1, no change to your current patient management is necessary.

A list of devices specific to your clinic that may be at risk if implanted in a susceptible subpectoral orientation is available from your local Guidant sales representative. A device model and serial number search tool, available at [www.guidant.com](http://www.guidant.com) in the Product Safety Information section, will be updated as soon as possible.

2. For future implants, when using 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, as shown in Figure 1.

## Warranty Supplement Program

Guidant's warranty supplement program, subject to certain conditions, provides a no cost replacement device and up to \$2500 in unreimbursed medical expenses.

## Further Information

Guidant will provide additional information as it becomes available. We recognize the impact of this communication on both you and your patients, and want to reassure you that patient safety remains our primary concern. As always, if you have any questions regarding this communication, please contact your local Guidant representative or Guidant Technical Services at 1.800.CARDIAC (227-3422).

Sincerely,



Renold J. Russie  
Director, Product Performance Reporting  
Guidant Cardiac Rhythm Management