

# URGENT MEDICAL DEVICE INFORMATION



## Cardiac Rhythm Management

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**Subject: Product Advisory** – Potential for reduced ERI to EOL time due to low-voltage capacitor degradation in a subset of ICDs and CRT-Ds

Dear Doctor,

This letter provides important patient management information regarding a subset of Guidant CRM ICDs and CRT-Ds. Our records indicate that you have implanted or are monitoring patients with one of these devices.

### Description of Issue

Boston Scientific has recently identified low-voltage capacitors from a former supplier that may be subject to degradation at a low rate of occurrence. These capacitors may cause accelerated battery depletion and may reduce the time between elective replacement indicator (ERI) and end of life (EOL) to less than three months. Device replacement indicators continue to function normally. Devices in this subset have been removed from distribution and are being retrieved from hospital inventory. There have been no patient deaths or serious injuries associated with this behavior.

### Rate of Occurrence

There have been no confirmed reports of shortened ERI to EOL time. However, 19 of approximately 73,000 devices in this population worldwide have been confirmed to have accelerated battery depletion, which could have resulted in shortened ERI to EOL time. While it is projected that less than 2% of this device population may exhibit a shortened ERI to EOL time, follow-up recommendations provided below will eliminate patient risk.

### Recommendations

If a patient has a device with a degraded capacitor, the time from implant to 2.65 volts (Middle of Life 2 / MOL2) will be reduced. To determine whether a patient may be at risk for a reduced ERI to EOL time, it is important to note when 2.65 volts (MOL2) was observed. For each patient:

1. Review patient records to assess battery voltage.
2. If battery voltage is **above** 2.65 volts (MOL2), continue to follow patient every three months per device labeling.
3. If battery voltage is **at or below** 2.65 volts (MOL2), determine the time between device implant and this observation.
4. If the time from implant to 2.65 volts (MOL2) is greater than 27 months (Note: For VITALITY<sup>®</sup> EL / 2 EL / HE devices, this value is 32 months), the patient is not at risk for a shortened ERI to EOL time, **and this advisory no longer applies.**
5. If the time from implant to 2.65 volts (MOL2) is 27 months or less (Note: for VITALITY EL / 2 EL / HE devices, this value is 32 months), **the patient should be followed monthly until ERI.** For devices that require monthly follow-up, replace the device within 30 days after ERI is displayed as ERI to EOL time may be shortened.

**Note: In geographies where available, the LATITUDE<sup>®</sup> Patient Management System can facilitate patient monitoring and also provide automatic notification when the device reaches a battery status of ERI.**

### Devices Affected

The potential for shortened ERI to EOL time due to low-voltage capacitor degradation is confined to a subset of devices within the CONTAK RENEWAL<sup>®</sup> 3 & 4, VITALITY and VITALITY 2 families. Enclosed is a list of patients at your clinic who were implanted with a device from this population. In addition, a model/serial search tool is available to determine if a specific device is subject to this product advisory (go to the Product Performance Resource Center located at [www.guidant.com/ppr/](http://www.guidant.com/ppr/)).

### Warranty Program

With certain terms and conditions, warranty and unreimbursed medical expense programs are available for this population.

### 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 9357.

Sincerely,

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