

Product Advisories

A Product Advisory is a voluntary letter issued to inform physicians of an anomalous device behavior identified by Boston Scientific's Quality System. A Product Advisory is issued when there is a material elevation in risk to patient safety with potential for compromised lifesaving therapy, or when Boston Scientific can provide meaningful guidance to improve patient outcomes or device performance. Boston Scientific considers many perspectives in the decision to issue a Product Advisory, including internal expertise and guidance from an independent Patient Safety Advisory Board (PSAB). The Board includes cardiac electrophysiology, engineering, statistics, risk management and bioethics experts. This report section includes summaries of Product Advisories for which significant, active U.S. device populations exist. In general, this includes advisories for which the estimated active U.S. advisory population

is at least 200. Physician and patient letters, as well as Advisory Updates, are available at www.bostonscientific.com. With respect to the number of reported events listed in the summaries below, Boston Scientific recognizes that the actual number of clinical malfunctions may be greater than the number actually reported. Additionally, rate projections are provided with the acknowledgment that predictive modeling is inherently uncertain due to its dependence on the device age distribution of reported events and resultant statistical approximations and assumptions. Advisory notifications may vary by geography, based upon local regulatory requirements. Please contact the local Boston Scientific office for more information. Not all products may be approved for use in all geographies, as product approval is geography specific.

PRODUCT	ORIGINAL COMMUNICATION July 2010— Magnetic Reed Switch 2010
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p> <p>CONTAK RENEWAL 3 Models H170/H175</p> <p>CONTAK RENEWAL 3 HE Models H177/H179</p> <p>CONTAK RENEWAL 3 RF Models H210/H215</p> <p>CONTAK RENEWAL 3 RF HE Models H217/H219</p> <p>CONTAK RENEWAL 4 Models H190/H195/H197/H199</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Some Boston Scientific defibrillators include a component referred to as a "magnetic reed switch," designed to sense the presence of a magnet. If Enable Magnet Use is programmed to On (nominally On) and a magnet is applied in emergent situations or during a medical/surgical procedure, the switch is designed to close and temporarily prevent delivery of undesired tachy therapy. When the magnet is removed, the magnetic switch is designed to open and thereby restore ability to deliver programmed tachy therapy.</p> <p>Magnetic reed switch technology has historically demonstrated a very low but non-zero rate of failing to open upon magnet removal. However, certain Boston Scientific CRT-Ds and ICDs manufactured between January 2006 and November 2007 have exhibited a somewhat higher rate of magnetic reed switch failure. Approximately 34,000 of these devices remain actively implanted; no devices in this population are available for implant. Devices manufactured after November of 2007 have returned to historic performance rates and are not included in this advisory.</p> <p>No patient deaths or injuries have been reported as a result of this issue, although some devices have been replaced. Most devices with a magnetic reed switch confirmed to be stuck in a closed position have remained implanted after "Enable Magnet Use" was programmed to Off (see Recommendations).</p> <p><i>Rate of Occurrence</i> A rate of one failure per 670 devices (0.0015) has been observed to date in the advisory population (average implant time of 38 months). However, with rapid identification and reprogramming, the probability of patient harm (therapy not available when needed due to a stuck magnetic reed switch) is estimated to be less than one in one million for a 60-month device service life.</p>
<p>CONTAK RENEWAL 4 AVT/AVT HE Models M170/M175/M177/M179</p> <p>CONTAK RENEWAL 4 RF Models H230/H235/H239</p>	<p>CURRENT STATUS 07-Oct-11</p> <p>There have been no reported patient deaths associated with this advisory.</p> <p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.</p>
<p>VITALITY DR HE Model T180</p>	<p>CURRENT RECOMMENDATION 07-Oct-11</p> <p>Consistent with physician instructions for use and patient manual labeling, physicians should continue routine follow-up sessions and patients should be reminded to contact their clinic or go to the hospital emergency room immediately if they hear tones/beeps from their device. In addition, Boston Scientific recommends:</p> <p>1) In a hospital/clinic/surgery setting, if tones are heard upon magnet application but do not cease upon magnet removal, the device should be interrogated with a programmer and checked per normal standard of care.</p>

Physician and patient
letters are available at
www.bostonscientific.com

2) In the United States, use of the LATITUDE remote patient monitoring system may help identify loss of daily measurements and thereby facilitate timely detection of a stuck reed switch. *[NOTE: A pop-up message and/or LATITUDE alert do not appear for missing Daily Measurements.]*

3) If a stuck magnetic switch is confirmed, program the Enable Magnet Use feature to Off, which ensures that programmed therapy will be provided to treat tachyarrhythmias. However, if Enable Magnet Use is programmed Off:

- A magnet will no longer inhibit tachy therapy.
- The Patient Triggered Monitor feature will no longer be available.

Contact Boston Scientific Technical Services (1-800-CARDIAC) for assistance to re-activate Daily Measurements for devices with a stuck magnetic switch.

4) After consultation with our Independent Patient Safety Advisory Board, **Boston Scientific does not recommend prophylactic explant.** We further advise that physicians **do not routinely program Enable Magnet Use to Off in the absence of a confirmed stuck magnetic reed switch** because the benefits of magnet use to disable tachy therapy in emergent situations outweigh the probability of patient harm associated with a stuck reed switch.

Standard Warranty program available; please contact your local representative for terms and conditions.

PRODUCT

ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant 2009

A serialized search tool to determine if a specific device is affected by this safety advisory is available at www.bostonscientific.com.

Voluntary Physician Advisory
FDA Classification: Class II

This advisory is limited to devices identified in the product model list that were implanted subpectorally. Devices implanted subcutaneously are not included in this advisory.

This advisory is limited to those models listed below implanted subpectorally.

Boston Scientific has determined that the bond between the header and case could be weakened by significant forces associated with a subpectoral implant procedure or when a device in a subpectoral position is pushed against a rib during contraction of the pectoralis muscle. A weakened header bond may alter lead impedance and introduce noise that may inhibit pacing therapy or initiate inappropriate tachy therapy. Additional mechanical stress applied to a weakened bond may eventually cause header connection wires to fracture, resulting in loss of therapy.

COGNIS

Models
N106/N107/N108/N118/N119
P106/P107/P108

A weakened header bond can result in one or more of the following device behaviors:

- Significant changes in measured lead impedance
- Noise on real-time or stored electrograms
- Intermittent inhibition of pacing
- Inappropriate anti-tachy pacing or shock therapy
- Loss of pacing therapy
- Loss of anti-tachy pacing and shock therapy

TELIGEN VR

Models E102/F102

TELIGEN DR

Models E110/E111/F110/F111

No patient deaths related to this behavior have been reported. Patients have required early device replacement due to inappropriate shocks and/or noise induced by pocket manipulation or arm movement.

Physician and patient letters are available at www.bostonscientific.com

Rate of Occurrence

The implant orientation of devices is not reported to Boston Scientific, making it difficult to provide rate of occurrence and prediction information. Two (2) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 5% of approximately 77,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

The following factors may also impact the risk of failure if implanted in a subpectoral location:

- Exact location of the patient's ribs relative to the device
- Body size and/or muscle mass of the patient (risk may increase for larger/muscular patients)
- Activity level and/or occupation of the patient (risk may increase for more active patients)

CURRENT STATUS 07-Oct-11

COGNIS and TELIGEN devices are now available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired.

Reported events (worldwide)

Forty-one (41) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

There have been no reported patient deaths associated with this advisory.

Rate of Occurrence

The implant orientation of devices is not reported to Boston Scientific. For this reason, no rate of occurrence or rate projection is provided.

CURRENT RECOMMENDATION 07-Oct-11

If a patient's device was implanted subcutaneously, it is excluded from this advisory and no change to current patient management is recommended.

For affected devices implanted in a subpectoral location:

- Follow patient at least once every three months as recommended in device instructions for use.
- Consider advising patients to contact their physician or clinic if they receive shocks, in order to ensure timely review of associated electrograms and other device data via in-clinic or remote interrogation.
- Where available, consider using the LATITUDE® Patient Management System to facilitate remote device checks between in-clinic follow-ups.

COGNIS and TELIGEN devices are now available with improved header bond strength in the U.S. and the EU. The stronger bond allows physicians to position the devices in a subpectoral position, if desired.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT

A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.

CONTAK RENEWAL 4 RF HE
Model H239

CONTAK RENEWAL 4 RF
Models H230/H235

CONTAK RENEWAL 4 HE
Models H197/H199

CONTAK RENEWAL 4
Models H190/H195

CONTAK RENEWAL 4 AVT HE
Models M177/M179

CONTAK RENEWAL 4 AVT
Models M170/M175

CONTAK RENEWAL 3 RF HE
Models H217/H219

CONTAK RENEWAL 3 RF
Models H210/H215

CONTAK RENEWAL 3 HE
Models H177/H179

CONTAK RENEWAL 3
Models H170/H175

CONTAK RENEWAL 3 AVT HE
Model M159

CONTAK RENEWAL 3 AVT
Model M155

VITALITY 2 EL VR/DR
Models T177/T167

VITALITY 2 VR/DR
Models T175/T165

VITALITY DR HE
Model T180

VITALITY DS VR/DR
Model T135/T125

VITALITY EL
Model T127

VITALITY AVT A155
Model A155

Physician and patient letters are available at www.bostonscientific.com

ORIGINAL COMMUNICATION 05-Apr-07 and 04-Mar-09 – Shortened Replacement Window

Voluntary Physician Advisory
FDA Classification: Class II

Low-voltage capacitors may be subject to degradation. 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.

In April 2007, Boston Scientific CRM communicated with physicians regarding a population of devices subject to this failure mechanism. As of March 2009, the April 2007 advisory population has not experienced any clinically significant changes to either the rate of occurrence or patient management recommendations.

In March 2009, a second population was identified of 856 active ICDs and CRT-Ds manufactured with capacitors from the same supplier that may be subject to the same failure mechanism. The cumulative failure rate for accelerated depletion within this population is approximately 6% at 42 months and is projected to increase. Recommendations described in April 2007 have been 99.9% successful in identifying susceptible devices and ensuring replacement at ERI in the original population, and will minimize patient risk associated with a shortened replacement window when applied to this second population. No devices from this population have been registered as implanted after April 2007. No devices in this subset remain available for implant.

CURRENT STATUS 07-Oct-11

Confirmed Malfunctions (worldwide)

April 2007 Population

2,464 malfunctions have been confirmed out of an advisory population of approximately 77,000 devices. 113 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).

March 2009 Population

116 malfunctions have been confirmed out of an advisory population of 856 active devices. Two of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).

There have been no reported patient deaths associated with either advisory population.

No devices currently being distributed are susceptible to this malfunction mode.

Projected Rate of Occurrence

April 2007 Population

The projected rate of occurrence for the April 2007 advisory population is 3–4% at 48 months.

March 2009 Population

The cumulative failure rate for accelerated depletion for the March 2009 population is approximately 6% at 42 months and is projected to increase.

Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.

CURRENT RECOMMENDATION 07-Oct-11

Patient management recommendations from the April 5, 2007 physician communication remain unchanged.

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, 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 (32 months for VITALITY® EL / 2 EL / HE devices), 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 (32 months for VITALITY® EL / 2 EL / HE devices), **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: If it is not clear when a battery voltage of less than 2.65 volts (MOL2) was reached, conduct a memory "Save to Disk" and return (mail or e-mail) to Boston Scientific CRM for prompt analysis. Contact your local Boston Scientific representative or Technical Services for further assistance.

In geographies where available, the LATITUDE® Patient Management System can facilitate remote patient monitoring and provide automatic notification when the device reaches a battery status of ERI.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT

A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com

CONTAK RENEWAL 4 RF HE
Model H239

CONTAK RENEWAL 4 RF
Models H230/H235

CONTAK RENEWAL 4 HE
Models H197/H199

CONTAK RENEWAL 4
Models H190/H195

CONTAK RENEWAL 4 AVT HE
Models M177/M179

CONTAK RENEWAL 4 AVT
Models M170/M175

CONTAK RENEWAL 3 RF HE
Models H217/H219

CONTAK RENEWAL 3 RF
Models H210/H215

CONTAK RENEWAL 3 HE
Models H177/H179

CONTAK RENEWAL 3
Models H170/H175

CONTAK RENEWAL 3 AVT HE
Model M159

CONTAK RENEWAL 3 AVT
Model M155

VITALITY 2 EL VR/DR
Models T177/T167

VITALITY 2 VR/DR
Models T175/T165

VITALITY DR HE
Model T180

VITALITY AVT A155
Model A155

VITALITY AVT A135
Model A135

VITALITY DS VR/DR
Models T135/T125

VITALITY EL
Model T127

VITALITY VR/DR
Models 1871/1870

VITALITY DR+
Model 1872

ASSURE
Model B301

The Product Update and patient letter are available at www.bostonscientific.com

ORIGINAL COMMUNICATION 10-Mar-07 — Product Update — Mid-Life Display of Replacement Indicators

FDA Classification: Devices in Table 1, Column 1 of this *Product Update* were classified as Class II (27-November-07)

Certain devices may display ERI or EOL during mid-life (typically 24–48 months), even though battery voltage (typically greater than or equal to 2.65 volts) and capacity remain available. This behavior is caused by high battery impedance rather than low battery voltage.

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 to continue to provide brady and LV pacing and maximum energy shocks. However, if ERI or EOL is triggered, device replacement should be scheduled.

Rate Projection

Certain devices, typically implanted prior to July 2005 (Table 1, Column 1 of the *Product Update*) are projected to exhibit Mid-Life Display of Replacement Indicators as indicated below:

- VITALITY AVT (Model A135), VITALITY VR/DR, VITALITY DR+ (**Projected rate: 8–10%**)
- VITALITY AVT (Model A155), VITALITY DS VR/DR, VITALITY 2 VR/DR, ASSURE (**Projected rate: 4–7%**)
- VITALITY EL; VITALITY 2 EL DR/VR; VITALITY DR HE; CONTAK RENEWAL 3/4/3HE/4HE; CONTAK RENEWAL 3 RF/4RF/3RF HE/4RF HE; CONTAK RENEWAL 3 AVT/4AVT/3AVT HE/4AVT HE (**Projected rate: 1–2%**)

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.

CURRENT STATUS 07-Oct-11

Confirmed Malfunctions (worldwide)

For confirmed malfunction counts related to a specific product family, refer to the Confirmed Malfunction Details section of the Product Performance Report and see pattern titled “Mid-life display of replacement indicators.” There have been no reported patient deaths associated with this advisory.

Projected Rate of Occurrence

For projected rates of occurrence see device-specific ranges listed above. Some performance differences have been observed between product families. For example, dual chamber devices have generally performed better than single chamber devices within the same product family. For current performance of a specific product family, refer to the U.S. Survival Probability section of the Product Performance Report and see population titled “10–Mar-07 Product Update — Mid-Life Display of Replacement Indicators.”

CURRENT RECOMMENDATION 07-Oct-11

Patient management recommendations from the March 10, 2007 Product Update remain unchanged.

Patient Management Considerations

- Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled.
- Physicians can consider individual patient 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 device 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.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 23-Jun-06 and 24-Aug-06 – Low Voltage Capacitor
<p>Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Devices within a well-defined subset manufactured using low-voltage capacitors from a single component supplier may perform in a manner that leads to device malfunction, including intermittent or permanent loss of output or telemetry, or premature battery depletion. At the time of the original June 23, 2006 communication, approximately 49,800 devices had been distributed, and approximately 27,200 devices had been implanted worldwide. Boston Scientific initiated retrieval of all non-implanted devices within this subset from hospital and sales force inventory. An Advisory Update was issued on August 24, 2006, with a revised estimation of the implanted population to be approximately 31,000. All product currently being shipped and available for implant is not susceptible to this issue.</p>
<p>INSIGNIA Ultra SR Models 1190/1390</p>	<p>INSIGNIA AVT Models 0482/0882/0982 1192/12921392/1428/1432/1492</p>
<p>INSIGNIA Ultra DR (downsize) Models 1290/1490</p>	<p>CONTAK RENEWAL TR 2 Models H140/H145</p>
<p>INSIGNIA Ultra DR Models 1291/1491</p>	<p>CONTAK RENEWAL TR Models H120/H125</p>
<p>INSIGNIA Entra SR Models 1195/1198/1395/1398</p>	<p>VITALITY 2 EL VR/DR Models T177/T167</p>
<p>INSIGNIA Entra DR (downsize) Models 1296/1466</p>	<p>VITALITY 2 VR/DR Models T175/T165</p>
<p>INSIGNIA Entra DR Models 1294/1295/1494/1495</p>	<p>VITALITY DR HE Model T180</p>
<p>INSIGNIA Entra SSI Models 0484/0485/1325/1326</p>	<p>VITALITY DS VR/DR Models T135/T125</p>
<p>INSIGNIA Entra DDD Models 0985/0986/1426</p>	<p>VITALITY EL Model T127</p>
<p>INSIGNIA Plus SR Models 1194/1394</p>	<p>VITALITY VR/DR Models 1870/1871</p>
<p>INSIGNIA Plus DR (downsize) Models 1298/1468</p>	<p>VENTAK PRIZM 2 VR/DR Models 1860/1861</p>
<p><i>Physician and patient letters are available at www.bostonscientific.com</i></p>	<p>INSIGNIA Plus DR Models 1297/1467</p> <p>CURRENT STATUS 07-Oct-11</p> <p><i>Confirmed Malfunctions (worldwide)</i> 46 malfunctions have been confirmed from the advisory population. 35 of these were identified while implanted. There were an estimated 32,000 advisory devices implanted. 11 malfunctions were identified prior to implantation. There have been no reported patient deaths associated with this advisory. No devices currently being distributed are susceptible to this malfunction mode.</p> <p><i>Projected Rate of Occurrence</i> The rate of occurrence is projected to range between 0.10% and 0.22%.</p> <p>CURRENT RECOMMENDATION 07-Oct-11</p> <p><u>Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</u></p> <ul style="list-style-type: none"> – Normal follow-up. – Physicians should consider the low and declining failure rate in addition to the unique needs of individual patients when making medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness. – Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation. <p>Device Behavior</p> <p>Pacemakers: INSIGNIA/NEXUS</p> <ul style="list-style-type: none"> – Intermittent or permanent loss of pacing output – Inability to interrogate

- Erased values in Daily Measurements
- ERT or EOL indicator message displayed earlier than expected
- A gas gauge less than BOL within six months of implant

CRT-Ps: RENEWAL TR/TR2

- ERI or EOL indicator message displayed earlier than expected
- Fault Code 11 message (high current indicator)
- A gas gauge less than BOL within six months of implant

ICDs: VENTAK PRIZM 2, VITALITY and VITALITY 2

- ERI or EOL indicator message displayed earlier than expected
- A battery voltage **less than 3.10V** within six months of implant

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 12-May-06 and 04-Jan-08 Subpectoral Implant
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p> <p><i>This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs.</i></p> <p>CONTAK RENEWAL 4 HE Models H197/H199</p> <p>CONTAK RENEWAL 4 Models H190/H195</p> <p>CONTAK RENEWAL 4 AVT Models M170/M175</p> <p>CONTAK RENEWAL 4 AVT HE Models M177/M179</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Accelerated life testing has confirmed that 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:</p> <ul style="list-style-type: none"> – 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 <p><i>Reported Events</i> Two (2) reports of device malfunction associated with subpectoral implantation in an uncommon orientation (serial number facing ribs) were received. No patient deaths related to this advisory were reported. One patient required external pacing and immediate device replacement due to lack of pacing therapy. The vast majority of affected devices are implanted subcutaneously and are not subject to this failure mechanism.</p> <p><i>Rate of Occurrence</i> The implant orientation of devices is not reported. For this reason, no rate of occurrence or failure rate projection was provided. However, based on available information, it is estimated that the number of devices implanted in a susceptible orientation is likely less than 1% of the total population.</p>
<p>CONTAK RENEWAL 3 HE Models H177/H179</p> <p>CONTAK RENEWAL 3 Models H170/H173/H175</p> <p>CONTAK RENEWAL 3 AVT HE Model M159</p> <p>CONTAK RENEWAL 3 AVT Model M155</p> <p>VITALITY DR HE Model T180</p>	<p>CURRENT STATUS 07-Oct-11</p> <p><i>Confirmed Malfunctions (worldwide)</i> <u>May 12, 2006 Population</u> Eighteen (18) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation.</p> <p><u>January 4, 2008 Population</u> Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation.</p> <p>There have been no reported patient deaths associated with either advisory population.</p> <p><i>Projected Rate of Occurrence</i> The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.</p>
<p>VITALITY 2 EL VR/DR Models T167/T177</p> <p>VITALITY EL Model T127</p> <p>VITALITY DR+ Model 1872</p>	<p>CURRENT RECOMMENDATION 07-Oct-11</p> <p><u>Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication.</u></p> <ul style="list-style-type: none"> – For patients implanted with a model listed in the advisory, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory. – For subpectoral implants, use an AP radiograph to determine specific device orientation. <ul style="list-style-type: none"> • If the leads exit the pulse generator in a counter clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary. • If the device is in a susceptible orientation (serial number facing the ribs), <ul style="list-style-type: none"> – 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.

*Physician and patient
letters are available at
www.bostonscientific.com*

– For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 22-Sep-05 — Crystal Timing Component
<p>Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p> <p>INSIGNIA Plus DR (downsize) Models 1298/1468</p> <p>INSIGNIA Plus DR Models 1297/1467</p> <p>INSIGNIA AVT Models 0482/0882/0982/1192/1292 1328/1428/1432/1392/1492</p> <p><i>Physician and patient letters are available at www.bostonscientific.com</i></p> <p>INSIGNIA Ultra SR Models 1190/1390</p> <p>INSIGNIA Ultra DR (downsize) Models 1290/1490</p> <p>INSIGNIA Ultra DR Models 1291/1491</p> <p>INSIGNIA Entra SR Models 1195/1198/1395/1398</p> <p>INSIGNIA Entra DR (downsize) Models 1296/1466</p> <p>INSIGNIA Entra DR Models 1294/1295/1494/1495</p> <p>INSIGNIA Entra SSI Models 0484/0485/1325/1326</p> <p>INSIGNIA Entra DDD Models 0985/0986/1425/1426</p> <p>INSIGNIA Plus SR Models 1194/1394</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Two separate failure modes were identified that may result in intermittent or permanent loss of pacing output without warning, intermittent or permanent loss of telemetry, and/or reversion to VVI mode or appearance of a Reset warning message upon interrogation. The root cause of the first failure mode is foreign material within a crystal timing component. As of September 22, 2005, the root cause of the second failure mode had not yet been determined and analysis was ongoing. As of the December 12, 2005 Advisory Update, root cause had been identified as a microscopic particle within the crystal timing component.</p> <p><i>Reported Events</i></p> <p>Failure Mode 1—As of September 6, 2005, 36 malfunctions have been confirmed out of 49,500 devices distributed worldwide (0.073%). The majority of malfunctions occurred early in life, with a mean implant time of seven (7) months. There were no reported patient deaths. The supplier of the crystal timing component used in this subset of devices has eliminated foreign material within the crystal chamber, and no malfunctions were observed in any devices shipped after March 12, 2004.</p> <p>Failure Mode 2—As of September 6, 2005, 16 malfunctions were confirmed out of 341,000 devices distributed worldwide (0.0047%). All 16 devices exhibited a no-output condition at the implant procedure or during pre-implant testing. There were no reported patient deaths.</p> <p><i>Rate Projection</i></p> <p>Failure Mode 1—As of the September 22, 2005 communication, Guidant’s modeling, based on field experience and statistical analysis, predicted the malfunction rate for the active device population of 41,000 to be between 0.017% to 0.037% over the remaining device lifetime.</p> <p>CURRENT STATUS 07-Oct-11</p> <p><i>Confirmed Malfunctions (worldwide)</i></p> <p>Failure Mode 1— 61 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory.</p> <p>Failure Mode 2— 26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory.</p> <p>None of the INSIGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode.</p> <p><i>Projected Rate of Occurrence</i></p> <p>Failure Mode 1— The rate of occurrence for the estimated worldwide active advisory device population of 12,000 is projected to range between 0.027% and 0.038%.</p> <p>CURRENT RECOMMENDATION 07-Oct-11</p> <p>Failure Mode 1—<u>Patient management recommendations from the September 22, 2005 physician communication remain unchanged.</u> Failure Mode 2—<u>Patient management recommendations supersede those originally communicated on September 22, 2005.</u></p> <ul style="list-style-type: none"> – Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices. – Specific to Failure Mode 1, physicians should consider the projected low and declining malfunction rate in addition to the unique needs of individual patients in their medical decisions regarding patient management. As always, advise patients to seek attention immediately if they experience syncope or lightheadedness.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component
<p>Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p>	<p>Voluntary Physician Advisory (18-Jul-05) FDA Classification: Class I</p>
<p>DISCOVERY DR (downsize) Model 1273</p>	<p>Voluntary Physician Advisory (21-Jan-06) FDA Classification: Class I</p>
<p>DISCOVERY DR Models 1274/1275</p>	<p>A hermetic sealing component utilized in a subset of pacemakers may experience a gradual degradation, resulting in higher than normal moisture content within the pacemaker case late in the device's service life; this could lead to a variety of inappropriate clinical behaviors.</p>
<p>PULSAR MAX SR (downsize) Model 1170</p>	<p>The original July 18, 2005 physician communication bounded the population to approximately 78,000 devices manufactured between November 25, 1997 and October 26, 2000; this number was further refined to 77,500 devices manufactured between October 27, 1997 and October 26, 2000.</p>
<p>PULSAR MAX SR Model 1171</p>	<p>The original July 18, 2005 communication predicted the rate of malfunction in the remaining active implanted devices (estimated at that time to be 28,000 worldwide) to be between 0.17% and 0.51% over the remaining device lifetime, based on field experience and statistical life-table analysis.</p>
<p>PULSAR MAX DR Model 1270</p>	<p>A Second Population of 54,000 devices was subsequently identified to be at risk of hermetic seal degradation (but at a much lower rate than the original population). This was communicated in the January 21, 2006 letter.</p>
<p>PULSAR Model 1272/0470/0870/0970/0972/1172</p>	<p>Original Population—<u>Patient management recommendations from the July 18, 2005 physician letter remain unchanged and are provided below under CURRENT RECOMMENDATION</u>; however, physicians should reassess patients in light of the increased projected rate of occurrence (detailed below).</p>
<p>MERIDIAN SSI Model 0476</p>	<p>Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.</p>
<p>MERIDIAN DDD Model 0976</p>	<p><i>Reported Events (worldwide)</i> Refined Original Population—A total of 145 devices that may have exhibited this malfunction mode were identified; 130 such malfunctions were confirmed out of the 77,500 devices manufactured (0.17%).</p>
<p>MERIDIAN SR Model 1176</p>	<p>Second Population—A total of five (5) devices that may have exhibited this malfunction mode were identified; two (2) such malfunctions were confirmed out of the 54,000 devices manufactured (0.004%).</p>
<p>MERIDIAN DR Model 1276</p>	<p><i>Rate Projection</i> Refined Original Population—The predicted failure rate for the estimated worldwide active device population of 16,000 had increased from the July 18, 2005 estimate as communicated in the January 21, 2006 letter and was projected to range between 0.31% and 0.88% over the remaining device lifetime.</p>
<p><i>Physician and patient letters are available at www.bostonscientific.com</i></p>	<p>Second Population—For the remaining lifetime of the estimated worldwide 19,300 active devices, the projected rate of occurrence for reported events was estimated to be between 0.02% and 0.06%.</p>
<p>DISCOVERY SR (downsize) Model 1174</p>	<p>CURRENT STATUS 07-Oct-11</p>
<p>DISCOVERY SR Model 1175</p>	<p><i>Reported Events (worldwide)</i> Refined Original Population— 339 malfunctions have been confirmed out of the 77,500 advisory population devices.</p> <p>Second Population— 13 malfunctions have been confirmed out of the 54,000 advisory population devices.</p>

Projected Rate of Occurrence

Refined Original Population—The rate of occurrence for the estimated worldwide active device population of 4,000 is projected to range between 0.31% and 0.88% over the remaining device lifetime, as communicated in the January 21, 2006 Advisory Update letter.

Second Population—The rate of occurrence for the estimated worldwide active device population of 3,000 is projected to range between 0.02% and 0.06%, as communicated in the January 21, 2006 Advisory Update letter.

CURRENT RECOMMENDATION 07-Oct-11

Original Population—Patient management recommendations from the July 18, 2005 physician letter remain unchanged; however, physicians should reassess patients in light of the increased projected rate of occurrence communicated in the January 21, 2006 Advisory Update letter.

Second Population—Physicians should consider the Original Population recommendations while taking into account the lower projected rate of occurrence.

- Consider replacing devices for pacemaker-dependent patients.
- Advise patients to seek attention immediately if they notice a prolonged rapid heart rate, experience syncope or lightheadedness, or have new or increased symptoms of heart failure.
- Select a suitable Maximum Sensor Rate (MSR) setting, given the rare possibility that inappropriate sustained pacing at MSR can occur

OR

- Consider programming the accelerometer OFF to prevent inappropriate sustained pacing at MSR.
- Consider increasing the frequency of programmer follow-ups. This increases the likelihood of detecting a malfunction that has already occurred, but does not guarantee that the device will not exhibit this malfunction mode in the future. At each patient follow-up:
 - Evaluate for the clinical behaviors described in the July 18, 2005 letter.
 - Evaluate battery status for signs of early or rapid depletion between sequential follow-up visits.
 - Evaluate the accelerometer rate response (for devices with this feature).
 - Accelerometer ON:
 - Look for inappropriate MSR pacing or pacing higher than the programmed lower rate limit (LRL) while the patient is at rest.
 - Look for lack of rate response with activity (i.e., isometrics, short hall walk).
 - Accelerometer OFF:
 - *Temporarily* program the accelerometer ON and evaluate as described above
- Consider increasing the frequency of transtelephonic monitoring to detect inappropriate sustained MSR pacing and/or loss of pacing output.
- If any of these device behaviors are observed, contact your local representative or Technical Services for troubleshooting and recommendations.

Standard Warranty program available, please contact your local representative for terms and conditions.

PRODUCT	ORIGINAL COMMUNICATION 23-Jun-05 — Magnetic Switch
<p>Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>A magnetic switch inside affected CRT-Ds may stick in the closed position, potentially inhibiting tachyarrhythmia therapy (with no impact on bradycardia pacing) and affecting battery longevity. A total of four (4) occurrences out of approximately 46,000 devices sold worldwide were confirmed. A fifth occurrence was suspected but the device was not returned to Guidant for confirmation.</p>
<p>CONTAK RENEWAL 4 RF HE Model H239</p> <p>CONTAK RENEWAL 4 RF Models H230/H235</p> <p>CONTAK RENEWAL 4 HE Models H197/H199</p>	<p>CURRENT STATUS 07-Oct-11</p> <p><i>Confirmed Malfunctions (worldwide)</i> Ten (10) malfunctions out of approximately 46,000 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory. Approximately 3,000 advisory population devices remain implanted worldwide.</p> <p>A programmer software application upgrade that a) tests the position of the magnetic switch at the beginning of each interrogation session and displays a yellow pop-up dialogue box if the software detects the switch in the closed position, and b) provides various programmer screen alerts has been developed and is available worldwide.</p>
<p>CONTAK RENEWAL 4 Models H190/H195</p> <p>CONTAK RENEWAL 4 AVT HE Models M177/M179</p>	<p>CURRENT RECOMMENDATION 07-Oct-11</p> <p><u>Patient management recommendations from June 23, 2005 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> – Consider programming “Enable Magnet Use” to “OFF” – Patients should contact their physicians or go to the hospital emergency room <u>immediately</u> if they hear tones from their device.
<p>CONTAK RENEWAL 4 AVT Models M170/M175</p> <p>CONTAK RENEWAL 3 HE Models H177/H179</p> <p>CONTAK RENEWAL 3 Models H170/H173/H175</p> <p>CONTAK RENEWAL 3 AVT HE Model M159</p> <p>CONTAK RENEWAL 3 AVT Model M155</p> <p><i>Physician and patient letters are available at www.bostonscientific.com</i></p>	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

<p>PRODUCT</p>	<p>ORIGINAL COMMUNICATION 17-Jun-05 — Shorting Under Header</p>
<p>Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p> <p>CONTAK RENEWAL 2 Model H155</p> <p>CONTAK RENEWAL Model H135</p>	<p>Voluntary Physician Advisory FDA Classification: Class I</p> <p>CRT-Ds manufactured on or before August 26, 2004 may experience deterioration in a wire insulator surrounding a wire within the lead connector block which, in conjunction with other factors, could cause a short circuit and loss of device function. In all cases, device replacement is required if this short circuit occurs.</p> <p><i>Reported Events</i> Fifteen (15) reports were confirmed from approximately 16,000 devices implanted worldwide, including one associated patient death.</p> <p><i>Rate Projection</i> As of the June 17, 2005 communication, Guidant predicted that the reported rate of malfunctions may increase to between 0.20% and 0.59% over the device family lifetime, based on field experience and statistical life-table analysis.</p> <p>CURRENT STATUS 07-Oct-11</p>
<p><i>Physician and patient letters are available at www.bostonscientific.com</i></p>	<p><i>Confirmed Malfunctions (worldwide)</i> 83 malfunctions have been confirmed out of approximately 16,000 advisory population devices. There have been nine (9) reported patient deaths potentially associated with this advisory.</p> <p><i>Projected Rate of Occurrence (worldwide)</i> Approximately 600 advisory population devices remain implanted worldwide. The rate of occurrence is projected to range between 0.72% and 1.83% over the remaining device lifetime.</p> <p>CURRENT RECOMMENDATION 07-Oct-11</p>
	<p><u>Patient management recommendations from the June 17, 2005 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> – Physicians should reassess the balance of relative risks regarding device replacement as a result of the increased projected rate of occurrence as communicated in the September 12, 2005 Advisory Update. – Normal follow-up. – Patients should visit their follow-up clinic or doctor as soon as possible after receiving a shock. – Patients should go to their follow-up clinic or hospital emergency room immediately after hearing beeping tones. – If a patient has not recently received a high-voltage therapy, a commanded shock may be performed to confirm integrity of the high-voltage delivery circuit. While detailed statistical modeling and bench testing indicate that this cannot exclude the low likelihood of subsequent malfunction, a commanded shock may provide further confidence that high-voltage circuitry is working properly at the time of testing. – During every patient visit, verify normal device function using routine clinical follow-up procedures. – If a shock has been delivered since the last follow-up: <ul style="list-style-type: none"> • Examine the Last Delivered Shock impedance stored in device memory (displayed on the Battery Status screen) for evidence of out-of-range values. • If a yellow warning screen is observed, refer to the Shorted Shock Lead Warning Screen <i>A Closer Look</i>. <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT	ORIGINAL COMMUNICATION 17-Jun-05 — Shorting In Header
<p>Identifiable by serial number. Not all serial numbers are affected. A serialized search tool to determine if a specific device is affected by this product advisory is available at www.bostonscientific.com.</p> <p>VENTAK PRIZM 2 DR Model 1861</p>	<p>Voluntary Physician Advisory FDA Classification: Class I</p> <p>ICDs manufactured on or before April 16, 2002 may experience deterioration in a wire insulator within the lead connector block which, in conjunction with other factors, could result in an electrical short circuit that can prevent the delivery of shock and pacing therapy.</p> <p><i>Reported Events</i> Twenty-eight (28) malfunctions were reported worldwide from approximately 26,000 devices built prior to the April 2002 manufacturing change, including one event in which a device was returned after a patient death. No such malfunctions were observed in devices built after the April 2002 manufacturing change. Guidant recognizes that the actual number of clinical malfunctions may be greater than the number actually reported.</p> <p>CURRENT STATUS 07-Oct-11</p>
<p><i>Physician and patient letters are available at www.bostonscientific.com</i></p>	<p><i>Confirmed Malfunctions (worldwide)</i> 40 malfunctions out of approximately 27,000 advisory population devices have been confirmed. There have been five (5) reports of patient death potentially associated with this advisory. Four (4) malfunctions, detected during device interrogation and resulting in no clinical injury, have been identified among the 11,000 devices manufactured after April 16, 2002 and before November 13, 2002 (non-advisory population). No malfunctions of this type have been reported to Guidant out of approximately 22,000 devices built after November 13, 2002 (non-advisory population).</p> <p><i>Projected Rate of Occurrence (worldwide)</i></p> <ul style="list-style-type: none"> – Approximately 1,600 advisory population devices remain implanted worldwide. The rate of occurrence remains unchanged since the September 2005 Advisory Update communication, and is projected to range between 0.10% and 0.24% over the remaining device lifetime. – Approximately 700 VENTAK PRIZM 2 DR devices manufactured after April 16, 2002 and before November 13, 2002 (non-advisory population) remain implanted worldwide; engineering analysis and accelerated life testing suggest that the rate of occurrence is between 0.03% and 0.10% by the time all remaining devices complete their service life. Rate of occurrence predictions for this group are not statistically conclusive. <p>CURRENT RECOMMENDATION 07-Oct-11</p>
	<p><u>Patient management recommendations from the June 17, 2005 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> – Normal follow-up. – Patients should consult with their follow-up clinic after receiving a shock. – Guidant does not recommend device replacement prior to the appearance of normal elective replacement indicators. – Guidant does not recommend routinely using a commanded shock to detect the shorting problem, since we have insufficient data to indicate that such testing will be worthwhile for VENTAK PRIZM 2 DR devices. If a patient has not recently received high-voltage therapy, a commanded shock may be performed to confirm integrity of the high voltage delivery circuit. While detailed statistical modeling and bench testing indicate that this cannot exclude the low likelihood of subsequent malfunction, a commanded shock may provide further confidence that high voltage circuitry is working properly at the time of testing. <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

<p>PRODUCT</p>	<p>ORIGINAL COMMUNICATION 19-Jul-99 – "Long" IS-1 Terminal Pin</p>
<p>Identifiable by serial number (serial numbers less than 230,000). Not all serial numbers are affected.</p> <p>ENDOTAK DSP Passive Fixation Models 0095/0125</p> <p><i>Physician letter is available at www.bostonscientific.com</i></p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>The integrity of affected defibrillation leads with "long" IS-1 terminal pins (serial numbers less than 230,000) can be compromised if the lead is bent sharply away from the terminal header block. Excessive bending of the lead could compromise lead insulation or conductor integrity and may occur when the system is placed in the implant pocket or if the pulse generator migrates from the implant site.</p> <p>A shorter version of the ENDOTAK DSP IS-1 terminal pin was implemented in 1997. This shorter version reduces the likelihood of damage caused by excessively sharp bends during implant and/or lead positioning. No confirmed malfunctions were identified in leads with short terminal pins. In addition, Guidant device lead barrels were lengthened to provide additional assurance that the terminal pin-conductor coil transition remains within the header.</p> <p>CURRENT STATUS 07-Oct-11</p>
	<p><i>Reported Events (worldwide)</i></p> <ul style="list-style-type: none"> – 638 "long" pin ENDOTAK DSP leads that may have exhibited this malfunction have been reported to Guidant from an advisory population of approximately 29,100 leads. – 226 leads have been removed and confirmed to have exhibited this malfunction while clinically implanted. – Six (6) occurrences were reported in the last six months among the estimated 6,000 active population advisory devices. – There have been two (2) reported patient deaths potentially associated with this advisory. <p>In addition, Guidant has confirmed 98 similar malfunctions out of approximately 320,000 leads of other models with long IS-1 terminal pins, including one reported patient death potentially associated with these non-advisory leads. Damage related to the use of "long" IS-1 pins is most common when implanted in pulse generators with "short" lead barrels, as is the case with ENDOTAK DSP leads. All IS-1 leads currently manufactured and distributed by Guidant have "short" terminal pins.</p> <p>CURRENT RECOMMENDATION 07-Oct-11</p>
	<p><u>Patient management recommendations from the July 19, 1999 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> – Ensure that sensing is not affected when patient performs upper-arm movements. If warranted, inspect the lead-to-device connection on X-ray for sharp bends or device migration. – For ICD replacement procedures, visually check the implanted lead to verify insulation integrity at the terminal pin connection. Perform routine lead threshold and impedance measurements. If issues are identified, consider implanting a new ENDOTAK lead system and/or separate rate-sensing lead. Avoid stressing the lead at the lead-to-pulse generator connection when implanting a new system. <p>A shorter version of the IS-1 terminal pin was implemented in 1997. This shorter version reduces the likelihood of damage caused by excessively sharp bends during implant and/or lead positioning.</p>