

# 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, potential for compromised lifesaving therapy, or when Boston Scientific can provide meaningful guidance to improve patient outcomes or device performance. This report section lists in chronological order (from newest to oldest) the relevant Product Advisories for which significant, active device populations exist, current as of the date of report publication. In general, this includes advisories for which the estimated active device population is at least 200. Physician and patient letters, as well as Advisory Updates, are available at [www.bostonscientific.com](http://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	<b>ORIGINAL COMMUNICATION 23-Mar-09— Respiratory Sensor Oversensing</b>
<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 safety advisory is available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>COGNIS CRT-Ds and TELIGEN ICDs include a Respiratory Sensor that can be activated to monitor the patient's respiratory rate. For any implantable defibrillator, delivery of appropriate therapy is dependent upon lead system integrity. Conversely, if any component of the defibrillator system is compromised, appropriate therapy cannot be assured. For example, certain RV lead complications can cause inappropriate shocks or anti-tachycardia pacing, and/or inhibition of pacing. Boston Scientific has determined that if such RV lead complications were to occur with the Respiratory Sensor programmed On, additional oversensing may occur, thereby increasing the probability of inappropriate therapy. Five to eight successive inappropriate shocks could leave the device unable to treat an actual arrhythmia until the current episode ends.</p> <p>No patient deaths had been reported at the time of the Original Communication. Additional events can be prevented if recommendations are followed.</p> <p>Reported Events and Rate of Occurrence Boston Scientific estimates that the Respiratory Sensor has been programmed On in approximately 8,000 COGNIS and TELIGEN devices worldwide. Inappropriate therapy as described above has been reported 15 times (0.2%).</p>
<p><b>COGNIS</b> Models N106/N107/N118/N119 P106/P107</p>	<b>CURRENT STATUS 16-Oct-09</b>
<p><b>TELIGEN VR</b> Models E102/F102</p>	<p>Programmer software is available which automatically programs Respiratory Sensor Off. When the Respiratory Sensor is Off, this advisory does not apply and routine follow-up is indicated.</p> <p><i>Reported events (worldwide)</i> Twenty-four (24) reports of inappropriate therapy have been received from an estimated 12,500 COGNIS and TELIGEN devices in which the Respiratory Sensor had been programmed On.</p> <p>One death has been reported where inappropriate shocks were delivered in conjunction with a fractured non-BSC lead. Although the Respiratory Sensor was ON, its contribution to the patient outcome cannot be determined.</p> <p><i>Rate of Occurrence</i> For the estimated 12,500 devices which had the Respiratory Sensor programmed On worldwide, the rate of occurrence is 0.2%. Product Improvements have been implemented that will reduce the likelihood of future events. The Respiratory Sensor is Off in all new devices being shipped, and if a physician attempts to program the sensor On, there is a programmer software pop-up window to instruct users to check for noise when the Respiratory Sensor is turned On. In addition, recent improvements to the device header are designed to facilitate ease of lead connections to the device.</p>
<p><b>TELIGEN DR</b> Models E110/F110</p>	<b>CURRENT RECOMMENDATION 16-Oct-09</b>
<p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p><u>Patient management recommendations from the March 23, 2009 physician communication remain unchanged.</u></p>

Device programming records should be reviewed for each patient with a COGNIS CRT-D or TELIGEN ICD to determine if the Respiratory Sensor is programmed to On or Off.

- When the Respiratory Sensor is Off, this advisory does not apply and routine follow-up is indicated.
- If the Respiratory Sensor is On, Boston Scientific recommends that the Respiratory Sensor be programmed Off as follows:
- Select the SETTINGS tab
- Select the SETTINGS SUMMARY tab
- In the BRADY section, select the NORMAL SETTINGS details icon
- In the SENSORS AND TRENDING section, select the ACCELEROMETER details icon
- For RESPIRATORY SENSOR, select Off, and press PROGRAM

Physicians should review concurrent risks such as pacemaker dependency, historic lead fracture performance, patient age and activity level, etc. when considering the most appropriate management options for each patient.

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

PRODUCT	ORIGINAL COMMUNICATION 05-Apr-07 and 04-Mar-09— Shortened Replacement Window
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p>
<p><b>CONTAK RENEWAL 3</b> Models H170/H175</p>	<p>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.</p>
<p><b>CONTAK RENEWAL 3 AVT HE</b> Model M159</p>	<p>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.</p>
<p><b>CONTAK RENEWAL 3 AVT</b> Model M155</p>	<p>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.</p>
<p><b>CONTAK RENEWAL 3 RF HE</b> Model H239</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p>
<p><b>CONTAK RENEWAL 4 RF</b> Models H230/H235</p>	<p><i>Confirmed Malfunctions (worldwide)</i> <u>April 2007 Population</u> 1608 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices. 60 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).</p>
<p><b>CONTAK RENEWAL 4 RF HE</b> Models H197/H199</p>	<p><u>March 2009 Population</u> 81 malfunctions have been confirmed out of an advisory population of 856 active devices. One of those devices exhibited a shortened ERI to EOL replacement window (less than 90 days).</p>
<p><b>CONTAK RENEWAL 4</b> Models H190/H195</p>	<p>There have been no reported patient deaths associated with either advisory population.</p>
<p><b>CONTAK RENEWAL 4 AVT HE</b> Models M177/M179</p>	<p>No devices currently being distributed are susceptible to this malfunction mode.</p>
<p><b>CONTAK RENEWAL 4 AVT</b> Models M170/M175</p>	<p><i>Projected Rate of Occurrence</i> <u>April 2007 Population</u> The projected rate of occurrence for the April 2007 advisory population is 3–4% at 48 months.</p>
<p><b>CONTAK RENEWAL 3 RF HE</b> Models H217/H219</p>	<p><u>March 2009 Population</u> The cumulative failure rate for accelerated depletion for the March 2009 population is approximately 6% at 42 months and is projected to increase.</p>
<p><b>CONTAK RENEWAL 3 RF</b> Models H210/H215</p>	<p>Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.</p>
<p><b>CONTAK RENEWAL 3 HE</b> Models H177/H179</p>	<p><b>CURRENT RECOMMENDATION 16-Oct-09</b></p>
<p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p><u>Patient management recommendations from the April 5, 2007 physician communication remain unchanged.</u></p> <p>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:</p>

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.

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

PRODUCT	<b>ORIGINAL COMMUNICATION 10-Mar-07 — Product Update — Mid-Life Display of Replacement Indicators</b>	
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></p>	<p><b>CONTAK RENEWAL 3 AVT HE</b> Model M159</p>	<p>FDA Classification: Devices in Table 1, Column 1 of this <i>Product Update</i> were classified as Class II (27-November-07)</p>
<p><b>CONTAK RENEWAL 4 RF HE</b> Model H239</p>	<p><b>CONTAK RENEWAL 3 AVT</b> Model M155</p>	<p>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.</p>
<p><b>CONTAK RENEWAL 4 RF</b> Models H230/H235</p>	<p><b>VITALITY 2 EL VR/DR</b> Models T177/T167</p>	<p>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.</p>
<p><b>CONTAK RENEWAL 4 RF</b> Models H230/H235</p>	<p><b>VITALITY 2 VR/DR</b> Models T175/T165</p>	<p><i>Rate Projection</i> Certain devices, typically implanted prior to July 2005 (Table 1, Column 1 of the <i>Product Update</i>) are projected to exhibit Mid-Life Display of Replacement Indicators as indicated below:</p>
<p><b>CONTAK RENEWAL 4 HE</b> Models H197/H199</p>	<p><b>VITALITY DR HE</b> Model T180</p>	<ul style="list-style-type: none"> <li>– VITALITY AVT (Model A135), VITALITY VR/DR, VITALITY DR+ (<b>Projected rate: 8–10%</b>)</li> <li>– VITALITY AVT (Model A155), VITALITY DS VR/DR, VITALITY 2 VR/DR, ASSURE (<b>Projected rate: 4–7%</b>)</li> <li>– 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 (<b>Projected rate: 1–2%</b>)</li> </ul>
<p><b>CONTAK RENEWAL 4</b> Models H190/H195</p>	<p><b>VITALITY AVT A155</b> Model A155</p>	<p>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.</p>
<p><b>CONTAK RENEWAL 4 AVT HE</b> Models M177/M179</p>	<p><b>VITALITY AVT A135</b> Model A135</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p>
<p><b>CONTAK RENEWAL 4 AVT</b> Models M170/M175</p>	<p><b>VITALITY DS VR/DR</b> Models T135/T125</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 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.</p>
<p><b>CONTAK RENEWAL 3 RF HE</b> Models H217/H219</p>	<p><b>VITALITY EL</b> Model T127</p>	<p><i>Projected Rate of Occurrence</i> 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.”</p>
<p><b>CONTAK RENEWAL 3 RF</b> Models H210/H215</p>	<p><b>VITALITY VR/DR</b> Models 1871/1870</p>	<p><b>CURRENT RECOMMENDATION 16-Oct-09</b></p>
<p><b>CONTAK RENEWAL 3 HE</b> Models H177/H179</p>	<p><b>VITALITY DR+</b> Model 1872</p>	<p>Patient management recommendations from the March 10, 2007 Product Update remain unchanged.</p>
<p><b>CONTAK RENEWAL 3</b> Models H170/H175</p>	<p><b>ASSURE</b> Model B301</p>	<p><i>Patient Management Considerations</i></p>
<p><i>The Product Update and patient letter are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>		<ul style="list-style-type: none"> <li>– Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled.</li> <li>– Physicians can consider individual patient needs relative to the potential device behaviors associated with mid-life display of ERI or EOL.</li> <li>– Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the device reaches ERI.</li> <li>– 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.</li> </ul> <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</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><b>INSIGNIA Ultra SR</b> Models 1190/1390</p>	<p><b>INSIGNIA AVT</b> Models 0482/0882/0982 1192/12921392/1428/1432/1492</p>
<p><b>INSIGNIA Ultra DR (downsize)</b> Models 1290/1490</p>	<p><b>CONTAK RENEWAL TR 2</b> Models H140/H145</p>
<p><b>INSIGNIA Ultra DR</b> Models 1291/1491</p>	<p><b>CONTAK RENEWAL TR</b> Models H120/H125</p>
<p><b>INSIGNIA Entra SR</b> Models 1195/1198/1395/1398</p>	<p><b>VITALITY 2 EL VR/DR</b> Models T177/T167</p>
<p><b>INSIGNIA Entra DR (downsize)</b> Models 1296/1466</p>	<p><b>VITALITY 2 VR/DR</b> Models T175/T165</p>
<p><b>INSIGNIA Entra DR</b> Models 1294/1295/1494/1495</p>	<p><b>VITALITY DR HE</b> Model T180</p>
<p><b>INSIGNIA Entra SSI</b> Models 0484/0485/1325/1326</p>	<p><b>VITALITY DS VR/DR</b> Models T135/T125</p>
<p><b>INSIGNIA Entra DDD</b> Models 0985/0986/1426</p>	<p><b>VITALITY EL</b> Model T127</p>
<p><b>INSIGNIA Plus SR</b> Models 1194/1394</p>	<p><b>VITALITY VR/DR</b> Models 1870/1871</p>
<p><b>INSIGNIA Plus DR (downsize)</b> Models 1298/1468</p>	<p><b>VENTAK PRIZM 2 VR/DR</b> Models 1860/1861</p>
<p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p><b>INSIGNIA Plus DR</b> Models 1297/1467</p> <p><b>CURRENT STATUS 16-Oct-09</b></p> <p><i>Confirmed Malfunctions (worldwide)</i> 38 malfunctions have been confirmed from the advisory population. 27 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><b>CURRENT RECOMMENDATION 16-Oct-09</b></p> <p><u>Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.</u></p> <ul style="list-style-type: none"> <li>– Normal follow-up.</li> <li>– 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.</li> <li>– Should the device exhibit symptoms described below, please contact your local sales representative or Technical Services for assistance with device evaluation.</li> </ul> <p><b>Device Behavior</b></p> <p><b>Pacemakers: INSIGNIA/NEXUS</b></p> <ul style="list-style-type: none"> <li>– Intermittent or permanent loss of pacing output</li> <li>– Inability to interrogate</li> </ul>

- 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

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

PRODUCT	ORIGINAL COMMUNICATION 12-May-06 — Premature Battery Depletion
<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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p>	<p>Voluntary Physician Advisory FDA Classification: Class II</p> <p>Devices manufactured using a single lot of low-voltage capacitors from a single supplier may experience premature battery depletion due to compromised capacitor function. With the accelerated battery use seen in some devices in this population, device replacement indicators continue to function as expected and the device continues to operate normally. However, longevity and time between Elective Replacement Indicator (ERI) and End of Life (EOL) may be significantly shortened. At the time of the original communication, there were no patient deaths or serious injuries other than device replacement associated with the confirmed premature depletions. Only devices manufactured with capacitors from this supplier's lot (996 devices implanted which is less than 1% of all implants from these device families) had exhibited an increased probability of premature battery depletion. No devices manufactured with components from this lot remain available for implant.</p>
<p><b>CONTAK RENEWAL 4 HE</b> Model H199</p>	<p><i>Reported Events</i> As of May 8, 2006, a total of 76 devices that may have exhibited this failure mode were reported. Of those, thirty (30) such failures were confirmed.</p>
<p><b>CONTAK RENEWAL 4</b> Models H190/H195</p>	<p><i>Rate of Occurrence</i> A total of 76 reported events represented 7.6% of the 996 devices implanted worldwide that utilized a capacitor from this single manufacturing lot. Fourteen (14) devices were identified at implant, while the average age of implanted devices at the time of detection was 9.3 months and ranged from 5 to 12 months.</p>
<p><b>CONTAK RENEWAL 4 AVT HE</b> Model M177</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p>
<p><b>CONTAK RENEWAL 4 AVT</b> Models M170/M175</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 587 malfunctions have been confirmed out of the 996 implanted advisory population devices. There have been no reported patient deaths associated with this advisory. To date, 21 devices were identified at implant, while the average age of implanted devices at the time of detection was 12 months and ranged from 2 to 50 months. No devices currently being distributed are susceptible to this malfunction mode.</p>
<p><b>CONTAK RENEWAL 3 HE</b> Models H177/H179</p>	<p><i>Rate of Occurrence</i> A total of 587 confirmed malfunctions represents 59% of the 996 implanted advisory population devices worldwide.</p>
<p><b>CONTAK RENEWAL 3</b> Models H170/H175</p>	<p><b>CURRENT RECOMMENDATION 16-Oct-09</b></p>
<p><b>VITALITY 2 VR/DR</b> Models T175/T177</p>	<p><u>Patient management recommendations from the May 12, 2006 physician communication remain unchanged.</u></p>
<p><b>VITALITY DS VR</b> Model T135</p>	<p>– An in-clinic follow-up should have happened for all patients with implanted devices in this subset.</p>
<p><b>VITALITY DS DR</b> Model T125</p>	<p>– In addition to normal follow-up, physicians should have contacted Technical Services at 1-800-CARDIAC (227-3422) for instructions on performing a baseline Save To Disk. Data from this interrogation allow Boston Scientific to analyze device memory data, estimate remaining longevity, and provide individualized follow-up and replacement guidelines. Physicians will be notified of disk analysis findings and provided with specific recommendations for individual devices.</p>
<p><b>VITALITY AVT A155</b> Model A155</p>	<p>– For devices in which Save To Disk data analysis shows <i>normal</i> battery depletion:</p> <ul style="list-style-type: none"> <li>• Normal three month follow-up per labeling</li> <li>• Activation of the programmable feature “Beep When ERI is Reached”</li> <li>• Continued Save To Disk operations at each patient follow-up visit to facilitate continuous assessment of battery performance for that device</li> </ul>
<p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p>– For devices in which Save To Disk data analysis shows <i>premature</i> battery depletion:</p> <ul style="list-style-type: none"> <li>• Monthly follow-up visits</li> <li>• Activation of the programmable feature “Beep When ERI is Reached”</li> <li>• Continued Save To Disk operations at each patient follow-up visit to facilitate continuous assessment of battery performance for that device. Some variation in estimates can be expected due to variation in device usage from follow-up to follow-up.</li> <li>• Device replacement upon appearance of ERI</li> </ul>

- Consideration for device replacement any time prior to ERI based on individual patient condition.

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Warranty Supplement 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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p> <p><i>This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs.</i></p> <p><b>CONTAK RENEWAL 4 HE</b> Models H197/H199</p> <p><b>CONTAK RENEWAL 4</b> Models H190/H195</p> <p><b>CONTAK RENEWAL 4 AVT</b> Models M170/M175</p> <p><b>CONTAK RENEWAL 4 AVT HE</b> 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 <b>implanted subpectorally with the serial number facing the ribs (leads exiting the pulse generator in a clockwise fashion)</b>. 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"> <li>– Loss of shock therapy</li> <li>– Loss of pacing therapy (intermittent or permanent)</li> <li>– Loss of telemetry communications</li> <li>– Beeping (16 tones every six hours), and a programmer warning screen upon interrogation</li> </ul> <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><b>CONTAK RENEWAL 3 HE</b> Models H177/H179</p> <p><b>CONTAK RENEWAL</b> Models H170/H173/H175</p> <p><b>CONTAK RENEWAL 3 AVT HE</b> Model M159</p> <p><b>CONTAK RENEWAL 3 AVT</b> Model M155</p> <p><b>VITALITY DR HE</b> Model T180</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p> <p><i>Confirmed Malfunctions (worldwide)</i> <u>May 12, 2006 Population</u> Seventeen (17) 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><b>VITALITY 2 EL VR/DR</b> Models T167/T177</p> <p><b>VITALITY EL</b> Model T127</p> <p><b>VITALITY DR+</b> Model 1872</p>	<p><b>CURRENT RECOMMENDATION 16-Oct-09</b></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"> <li>– 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.</li> <li>– 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 away 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> </li> </ul>

*Physician and patient  
letters are available at  
[www.bostonscientific.com](http://www.bostonscientific.com)*

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

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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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p> <p><b>INSIGNIA Plus DR (downsize)</b> Models 1298/1468</p> <p><b>INSIGNIA Plus DR</b> Models 1297/1467</p> <p><b>INSIGNIA AVT</b> Models 0482/0882/0982/1192/1292 1328/1428/1432/1392/1492</p> <p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p> <p><b>INSIGNIA Ultra SR</b> Models 1190/1390</p> <p><b>INSIGNIA Ultra DR (downsize)</b> Models 1290/1490</p> <p><b>INSIGNIA Ultra DR</b> Models 1291/1491</p> <p><b>INSIGNIA Entra SR</b> Models 1195/1198/1395/1398</p> <p><b>INSIGNIA Entra DR (downsize)</b> Models 1296/1466</p> <p><b>INSIGNIA Entra DR</b> Models 1294/1295/1494/1495</p> <p><b>INSIGNIA Entra SSI</b> Models 0484/0485/1325/1326</p> <p><b>INSIGNIA Entra DDD</b> Models 0985/0986/1425/1426</p> <p><b>INSIGNIA Plus SR</b> 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><b>CURRENT STATUS 16-Oct-09</b></p> <p><i>Confirmed Malfunctions (worldwide)</i></p> <p>Failure Mode 1— 55 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— 24 malfunctions out of approximately 257,000 (0.009%) devices distributed have been confirmed. Twenty-one (21) malfunctions were identified before or during the implant procedure and three (3) 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 21,000 is projected to range between 0.027% and 0.038%.</p> <p><b>CURRENT RECOMMENDATION 16-Oct-09</b></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"> <li>– Normal follow-up for both Failure Mode 1 and Failure Mode 2 devices.</li> <li>– 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.</li> </ul>

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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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p>	<p>Voluntary Physician Advisory (18-Jul-05) FDA Classification: Class I</p>
<p><b>DISCOVERY DR (downsize)</b> Model 1273</p>	<p>Voluntary Physician Advisory (21-Jan-06) FDA Classification: Class I</p>
<p><b>DISCOVERY DR</b> 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><b>PULSAR MAX SR (downsize)</b> 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><b>PULSAR MAX SR</b> 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><b>PULSAR MAX DR</b> 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><b>PULSAR</b> 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><b>MERIDIAN SSI</b> 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><b>MERIDIAN DDD</b> 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><b>MERIDIAN SR</b> 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><b>MERIDIAN DR</b> 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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></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><b>DISCOVERY SR (downsize)</b> Model 1174</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p>
<p><b>DISCOVERY SR</b> Model 1175</p>	<p><i>Reported Events (worldwide)</i> Refined Original Population— 331 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 5,000 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 4,000 is projected to range between 0.02% and 0.06%, as communicated in the January 21, 2006 Advisory Update letter.

**CURRENT RECOMMENDATION 16-Oct-09**

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	<b>ORIGINAL COMMUNICATION 23-Jun-05 — Magnetic Switch</b>
<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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</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><b>CONTAK RENEWAL 4 RF HE</b> Model H239</p> <p><b>CONTAK RENEWAL 4 RF</b> Models H230/H235</p> <p><b>CONTAK RENEWAL 4 HE</b> Models H197/H199</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p> <p><i>Confirmed Malfunctions (worldwide)</i> Nine (9) malfunctions out of approximately 46,000 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory. 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><b>CONTAK RENEWAL 4</b> Models H190/H195</p> <p><b>CONTAK RENEWAL 4 AVT HE</b> Models M177/M179</p>	<p><b>CURRENT RECOMMENDATION 16-Oct-09</b></p> <p><u>Patient management recommendations from June 23, 2005 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> <li>– Consider programming “Enable Magnet Use” to “OFF”</li> <li>– Patients should contact their physicians or go to the hospital emergency room <u>immediately</u> if they hear tones from their device.</li> </ul>
<p><b>CONTAK RENEWAL 4 AVT</b> Models M170/M175</p> <p><b>CONTAK RENEWAL 3 HE</b> Models H177/H179</p> <p><b>CONTAK RENEWAL 3</b> Models H170/H173/H175</p> <p><b>CONTAK RENEWAL 3 AVT HE</b> Model M159</p> <p><b>CONTAK RENEWAL 3 AVT</b> Model M155</p> <p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT	ORIGINAL COMMUNICATION 17-Jun-05 and 22-Jul-05 — Functional Latching
<p>A serialized search tool to determine if a specific device is affected by this product advisory is available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p>	<p>Voluntary Physician Advisory (17-Jun-05) FDA Classification: Class II</p> <p>Voluntary Physician Advisory (22-Jul-05) FDA Classification: Class I</p>
<p><b>CONTAK RENEWAL 4 AVT HE</b> Models M177/M179</p>	<p>Memory error leads to “functional latching” that limits available therapy in affected ICDs and CRT-Ds. Recommendations issued in the June 17, 2005 product advisory letter (programming Atrial Tachy Episode Data Storage to 0%) exposed a second latching mechanism, which increased the risk of malfunction. For this reason, original recommendations were revised in a July 22, 2005 product advisory letter.</p>
<p><b>CONTAK RENEWAL 4 AVT</b> Models M170/M175</p>	<p><b>CURRENT STATUS 16-Oct-09</b></p>
<p><b>CONTAK RENEWAL 3 AVT HE</b> Model M159</p>	<p>Software is available worldwide to prevent functional latching. The risk of functional latching as described in the advisories is eliminated immediately upon initial interrogation of an implanted device by a programmer with new software installed. Note that all AVT devices currently available for implant already contain the new software and no further upgrade actions are necessary.</p>
<p><b>CONTAK RENEWAL 3 AVT</b> Model M155</p>	<p><i>Confirmed Malfunctions (worldwide)</i> 46 malfunctions have been confirmed out of approximately 25,000 implanted advisory population devices. Three (3) malfunctions (0.01%) are as described in the original June 17, 2005 physician letter.</p>
<p><b>VITALITY AVT A155</b> Model A155</p>	<p>Forty-three (43) malfunctions (0.18%) are related to programming Atrial Tachy Episode Data Storage to 0% in a device that contained previously-stored atrial episode data.</p>
<p><b>VITALITY AVT A135</b> Model A135</p>	<p>No malfunctions have occurred with Atrial Tachy Episode Data Storage programmed to 20% (as recommended in the July 22, 2005 communication).</p> <p><b>CURRENT RECOMMENDATION 16-Oct-09</b></p>
<p><b>VENTAK PRIZM AVT</b> Model 1900</p>	<p>Programming recommendations to eliminate functional latching were communicated to U.S. physicians in a May 1, 2007 advisory update letter. Physicians in other geographies were notified as software received regulatory approval.</p>
<p><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<ul style="list-style-type: none"> <li>– Confirm the ZOOM / ZOOM LATITUDE programmer has been upgraded with new software. (See table in the advisory update letter.)</li> <li>– Interrogate each patient’s AVT device using the new software.</li> <li>– Resume normal programming.</li> </ul> <p><i>Important note:</i> For implanted devices that are not interrogated with new software, the probability of functional latching and programming recommendations remain as described in the July 22, 2005 product advisory letter. The probability of functional latching also applies to VENTAK PRIZM AVT devices for which new software was not developed.</p>
	<p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

PRODUCT	ORIGINAL COMMUNICATION 17-Jun-05 – Shorting Under 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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p> <p><b>CONTAK RENEWAL 2</b> Model H155</p> <p><b>CONTAK RENEWAL</b> 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><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p><b>CURRENT STATUS 16-Oct-09</b></p> <p><i>Confirmed Malfunctions (worldwide)</i> 82 malfunctions have been confirmed out of approximately 16,000 advisory population devices. There have been eight (8) reported patient deaths potentially associated with this advisory.</p> <p><i>Projected Rate of Occurrence (worldwide)</i> Approximately 900 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><b>CURRENT RECOMMENDATION 16-Oct-09</b></p> <p><u>Patient management recommendations from the June 17, 2005 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> <li>– 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.</li> <li>– Normal follow-up.</li> <li>– Patients should visit their follow-up clinic or doctor as soon as possible after receiving a shock.</li> <li>– Patients should go to their follow-up clinic or hospital emergency room immediately after hearing beeping tones.</li> <li>– 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.</li> <li>– During every patient visit, verify normal device function using routine clinical follow-up procedures.</li> <li>– If a shock has been delivered since the last follow-up: <ul style="list-style-type: none"> <li>• Examine the Last Delivered Shock impedance stored in device memory (displayed on the Battery Status screen) for evidence of out-of-range values.</li> <li>• If a yellow warning screen is observed, refer to the Shorted Shock Lead Warning Screen <i>A Closer Look</i>.</li> </ul> </li> </ul> <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

<p>PRODUCT</p>	<p><b>ORIGINAL COMMUNICATION 17-Jun-05 — Shorting In Header</b></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 <a href="http://www.bostonscientific.com">www.bostonscientific.com</a>.</p> <p><b>VENTAK PRIZM 2 DR</b> 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><i>Physician and patient letters are available at <a href="http://www.bostonscientific.com">www.bostonscientific.com</a></i></p>	<p><b>CURRENT STATUS 16-Oct-09</b></p> <p><i>Confirmed Malfunctions (worldwide)</i> 39 malfunctions out of approximately 27,000 advisory population devices have been confirmed. There have been four (4) 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 23,000 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"> <li>– Approximately 2,100 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.</li> <li>– Approximately 1,700 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.</li> </ul> <p><b>CURRENT RECOMMENDATION 16-Oct-09</b></p>
	<p><u>Patient management recommendations from the June 17, 2005 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> <li>– Normal follow-up.</li> <li>– Patients should consult with their follow-up clinic after receiving a shock.</li> <li>– Guidant does <b>not</b> recommend device replacement prior to the appearance of normal elective replacement indicators.</li> <li>– Guidant does <b>not</b> 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.</li> </ul> <p>Standard Warranty program available, please contact your local representative for terms and conditions.</p>

<p>PRODUCT</p>	<p><b>ORIGINAL COMMUNICATION 19-Jul-99 – "Long" IS-1 Terminal Pin</b></p>
<p>Identifiable by serial number (serial numbers less than 230,000). Not all serial numbers are affected.</p> <p><b>ENDOTAK DSP Passive Fixation</b> 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><b>CURRENT STATUS 16-Oct-09</b></p>
	<p><i>Reported Events (worldwide)</i></p> <ul style="list-style-type: none"> <li>– 617 "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.</li> <li>– 226 leads have been removed and confirmed to have exhibited this malfunction while clinically implanted.</li> <li>– Two (2) occurrences were reported in the last six months among the estimated 8,000 active population advisory devices.</li> <li>– There have been two (2) reported patient deaths potentially associated with this advisory.</li> </ul> <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><b>CURRENT RECOMMENDATION 16-Oct-09</b></p>
	<p><u>Patient management recommendations from the July 19, 1999 physician communication remain unchanged.</u></p> <ul style="list-style-type: none"> <li>– 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.</li> <li>– 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.</li> </ul> <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>