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
A serialized search tool to determine if a specific device is affected by this product advisory is available here:

Device Lookup Tool

ORIGINAL COMMUNICATION  Aug 2013 and Sep 2014 — Low Voltage Capacitor 2014

Voluntary Physician Advisory
FDA Classification August 2013: Class II
FDA Classification September 2014: Class II

In August 2013, a physician communication discussed a subset of COGNIS CRT-Ds and TELIGEN ICDs that had experienced an increased rate of premature battery depletion due to compromised performance of a low voltage (LV) capacitor. A second subset of devices was identified in September 2014 that may exhibit compromised LV capacitor performance at a rate that is similar to the August 2013 advisory subset.

The performance of an LV capacitor may be compromised in some devices after two or more years of implant time, which will increase battery use and may eventually initiate one or more Safety Architecture alerts and patient-audible beeping.

COGNIS
Models N106/N107/N108/N118/N119/N120/P106/P107/P108

TELIGEN VR
Models E102/E103/F102/F103

TELIGEN DR
Models E110/E111/F110/F111

The most common alert is a yellow programmer screen that states, “Voltage is too low for projected remaining capacity. Contact Technical Services with Code 1003”. LATITUDE issues a corresponding yellow alert (nominally configured “On”). In other instances, diminished LV capacitor performance can result in an early “Explant” battery status indicator (ERI) and a replacement window that may be less than 3 months. Devices that experience a low voltage alert require replacement. If not replaced, increased current drain could deplete the battery and impact therapy delivery and telemetry.

Advisory population
Approximately 22,800 devices identified in the August 2013 communication remain in service. In September 2014, Boston Scientific identified an additional 27,300 active devices that may exhibit diminished LV capacitor performance at a rate that is similar to the August 2013 advisory population. The projected cumulative rate of occurrence for LV capacitor malfunction within the total advisory population is approximately 2.9% at 60 months. Due to Safety Architecture alerts and timely physician response, the potential for life-threatening harm from loss of therapy is estimated to be less than 1 in 125,000 (0.0008%) at 60 months.

Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013

Current Status
07-Oct-16

Advisory devices have not been available for implant for more than three years.

Confirmed Malfunctions (worldwide)
3,997 malfunctions have been confirmed from the advisory population. Approximately 39,000 devices from the advisory population remain in service.

There has been one reported patient death associated with this advisory.

Projected Rate of Occurrence
The rate of occurrence for advisory population devices is 5.9% at 72 months. The projected rate of occurrence at 84 months is approximately 9.1%.

Current Recommendation
07-Oct-16

Updated Software
In 2014 BSC released software that enhances the effectiveness of the Safety Architecture tools later in device life. When the software was introduced, BSC recommended an in-clinic follow-up with an updated programmer at first opportunity, but within 3 months for patients within the advisory population. In-clinic interrogation with a current programmer automatically downloads Safety Architecture software upgrades from the programmer into individual patient devices, enhancing detection of a compromised LV capacitor before therapy delivery is impacted.

LATITUDE Patient Management System
Boston Scientific recommends that advisory patients utilize the LATITUDE Patient Management System (remote monitoring), which offers additional/supplemental device checks between office visits. Use of LATITUDE may accelerate detection of Safety Architecture alerts, and can notify if when scheduled checkups have not occurred. Verify that the yellow alert "Voltage was too low for projected remaining capacity“ is configured “On”.

Additional Recommendations
- After a device has been upgraded with new software, Boston Scientific recommends normal device monitoring as described in device labeling.
- Device replacement is not recommended for advisory devices displaying normal behavior.
- Promptly investigate alerts, device beeping, and unanticipated replacement indicator messages.
- Following a Safety Architecture alert, contact Boston Scientific Technical Services as directed on programmer screens. Technical Services can facilitate an evaluation of device information downloaded from a recent in-clinic or remote LATITUDE interrogation, which may help to clarify available replacement time. Note that “Approximate time to Explant” and “Time Remaining” estimates displayed on the programmer are not accurate following a low voltage alert.

Standard Warranty program available, please contact your local representative for terms and conditions.
**ORIGINAL COMMUNICATION 01-Jun-11 — High Cathode Condition**

Voluntary Physician Advisory

**PRODUCT**

A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool

**SQ-RX S-ICD**
Model1010

**Rate of Occurrence**

Boston Scientific has determined that a specific subset of SQ-RX pulse generators may not achieve the five (5) year typical longevity due to premature battery depletion. Although the longevity of these devices may be shortened, therapy remains available through the onset of the Elective Replacement Indicator (ERI). This subset of devices also has the potential for the time between the onset of the ERI and End of Life (EOL) indicators to be less than the nominal three (3) months. The risk for premature battery depletion is due to a specific condition within an individual battery cell. No affected devices remain available for implant.

**CURRENT STATUS 07-Oct-16**

No devices in the advisory population remain available for implant.

**Confirmed Malfunctions (worldwide)**

Three (3) malfunctions have been confirmed worldwide of devices experiencing High Cathode Condition. There have been no reported patient deaths associated with this advisory.

**Projected Rate of Occurrence**

– Population I - Bench testing and engineering analysis estimate that 33.1% [+20.8/-19.5] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There has been one (1) confirmed occurrence in this population to date.

– Population II - Bench testing and engineering analysis estimate that 3.3% [+2.2/-1.8] of devices in this population may experience premature battery depletion due to this condition over the five (5) year typical device longevity. There have been zero (0) confirmed occurrences in this population to date.

**CURRENT RECOMMENDATION 07-Oct-16**

– If a device experiences an unexpected decline in battery voltage leading to ERI, schedule replacement as soon as possible.

– Communicate to patients that, consistent with device labeling, an emitted audible tone requires immediate follow-up by their physician. Once triggered, the audible tone will sound for 16 seconds every 9 hours until the trigger condition has been resolved. As a reminder, a Cameron Health Model 4520 magnet placed over the device may be used to demonstrate the audible tone.

For patients implanted with devices in Population I, Cameron Health recommends this communication occurs as soon as practical. For patients implanted with devices in Population II, Cameron Health recommends this communication occurs at the next follow-up.

Standard Warranty program available, please contact your local representative for terms and conditions.
<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>ORIGINAL COMMUNICATION</th>
<th>July 2010— Magnetic Reed Switch 2010</th>
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</thead>
<tbody>
<tr>
<td>A serialized search tool to determine if a specific device is affected by this product advisory is available here:</td>
<td>Voluntary Physician Advisory</td>
<td></td>
</tr>
<tr>
<td>Device Lookup Tool</td>
<td>FDA Classification: Class II</td>
<td></td>
</tr>
<tr>
<td>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.</td>
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<table>
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<tr>
<th>CONTROL RENEAL 3</th>
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<tbody>
<tr>
<td>Models H170/H175</td>
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<tr>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTROL RENEAL 3 HE</th>
</tr>
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<tbody>
<tr>
<td>Models H177/H179</td>
</tr>
<tr>
<td>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).</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>CONTROL RENEAL 3 RF</th>
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<tbody>
<tr>
<td>Models H210/H215</td>
</tr>
<tr>
<td>Rate of Occurrence</td>
</tr>
<tr>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTROL RENEAL 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Models H190/H195/H197/H199</td>
</tr>
<tr>
<td>CURRENT STATUS</td>
</tr>
<tr>
<td>07-Oct-16</td>
</tr>
<tr>
<td>There have been no reported patient deaths associated with this advisory.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTROL RENEAL 4 RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Models H230/H235/H239</td>
</tr>
<tr>
<td>CURRENT RECOMMENDATION</td>
</tr>
<tr>
<td>07-Oct-16</td>
</tr>
<tr>
<td>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:</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>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.]</td>
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<table>
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<tr>
<th>VITALITY DR HE</th>
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<tbody>
<tr>
<td>Model T180</td>
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<tr>
<td>Magnetic Reed Switch 2010, Physician Letter, Jul 22, 2010</td>
</tr>
<tr>
<td>Magnetic Reed Switch 2010, Patient Letter, Jul 22, 2010</td>
</tr>
</tbody>
</table>
CURRENT RECOMMENDATION, continued…

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.
<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>ORIGINAL COMMUNICATION 01-Dec-09 — Subpectoral Implant 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRODUCT</strong></td>
<td>A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool</td>
</tr>
<tr>
<td><strong>ORIGINAL COMMUNICATION</strong></td>
<td>Voluntary Physician Advisory</td>
</tr>
<tr>
<td><strong>FDA Classification</strong></td>
<td>Class II</td>
</tr>
<tr>
<td><strong>Device Lookup Tool</strong></td>
<td></td>
</tr>
<tr>
<td><strong>This advisory is limited to those models listed below implanted subpectorally.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>COGNIS</strong></td>
<td>A weakened header bond can result in one or more of the following device behaviors:</td>
</tr>
<tr>
<td>Models</td>
<td>– Significant changes in measured lead impedance</td>
</tr>
<tr>
<td>N106/N107/N108/N118/N119</td>
<td>– Noise on real-time or stored electrograms</td>
</tr>
<tr>
<td>P106/P107/P108</td>
<td>– Intermittent inhibition of pacing</td>
</tr>
<tr>
<td><strong>TELIGEN VR</strong></td>
<td>– Inappropriate anti-tachy pacing or shock therapy</td>
</tr>
<tr>
<td>Models E102/F102</td>
<td>– Loss of pacing therapy</td>
</tr>
<tr>
<td><strong>TELIGEN DR</strong></td>
<td>– Loss of anti-tachy pacing and shock therapy</td>
</tr>
<tr>
<td>Models E110/E111/F110/F111</td>
<td></td>
</tr>
<tr>
<td><strong>CURRENT STATUS 07-Oct-16</strong></td>
<td>COGNIS and TELIGEN devices are 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.</td>
</tr>
<tr>
<td><strong>Reported events (worldwide)</strong></td>
<td>Ninety-five (95) 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.</td>
</tr>
<tr>
<td><strong>There have been no reported patient deaths associated with this advisory.</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Rate of Occurrence</strong></td>
<td>An estimated 10% of COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral position. The rate of occurrence for subpectoral implants of COGNIS advisory devices is 1.95% at 60 months. The rate of occurrence for subpectoral implants of TELIGEN advisory devices is 0.53% at 60 months.</td>
</tr>
</tbody>
</table>
CURRENT RECOMMENDATION 07-Oct-16

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.
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool.

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 April 2007, 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.

2,566 malfunctions have been confirmed out of an advisory population of approximately 75,000 devices. 115 of these devices exhibited a shortened ERI to EOL replacement window (less than 90 days).

Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.
05-Apr-07 and 04-Mar-09— Shortened Replacement Window, continued…

CURRENT RECOMMENDATION 07-Oct-16

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 here: [Device Lookup Tool]

**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.

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-16

**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.”

**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-16

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

**ASSURE**

Model B301

**Product Update - Mid-Life Display of Replacement Indicators, Mar 10, 2007**

**Mid-Life Display of Replacement Indicators, Patient Letter, Nov 27, 2007**
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool.

INSGNIA Ultra SR
Models 1190/1390

INSGNIA Ultra DR and Ultra DR Dowsnize
Models 1291/1491/1290/1490

INSGNIA Entra SR
Models 1195/1198/1395/1398

INSGNIA Entra DR (dowsize)
Models 1296/1466

INSGNIA Entra DR
Models 1294/1295/1494/1495

INSGNIA Entra SSI
Models 0484/0485/1325/1326

INSGNIA Entra DDD
Models 0985/0986/1426

INSGNIA Plus SR
Models 1194/1194

INSGNIA Plus DR and Plus DR Dowsnize
Models 1297/1467/1298/1468

INSGNIA AVT
Models 0482/0882/0982
1192/1292/1392/1428/1432/1492

CUNIAK RENEWAL 1K / 1KZ
Models H120/H125/H140/H145

VITALITY 2 EL VR/DR
Models T177/T167

VITALITY 2 VR/DR
Models T175/T165

VITALITY DR HE
Model T180

VITALITY DS VR/DR
Models T135/T125

VITALITY VR/DR and EL
Models 1870/1871/T127

Voluntary Physician Advisory
FDA Classification: Class II

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.

Reported Events (worldwide)

At the time of the original June 23, 2006 communication, a total of five (5) devices had been confirmed to have malfunctioned. As reported in the August 24, 2006 Advisory Update, five (5) additional malfunctions were confirmed since the original June 23, 2006 communication. A total of 10 confirmed malfunctions represented 0.032% of the implanted population of approximately 31,000 devices. Seven (7) of 10 malfunctions were identified while implanted, and three were identified prior to the implant procedure. There were no reports of patient death associated with this issue. There were a total of three (3) reports of patients experiencing syncope associated with loss of pacing.

Projected Rate of Occurrence

While a statistically significant projection of expected failures for implanted devices was not possible, testing suggested that the frequency of new malfunctions would continue to decrease in the future.

CURRENT STATUS 07-Oct-16

Confirmed Malfunctions (worldwide)

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.

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

Projected Rate of Occurrence

The rate of occurrence is projected to range between 0.10% and 0.22%.

CURRENT RECOMMENDATION 07-Oct-16

Patient management recommendations from the August 24, 2006 Advisory Update remain unchanged.

– 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.

Device Behavior

Pacemakers: INSGNIA/NEXUS

– 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
23-Jun-06 and 24-Aug-06—Low Voltage Capacitor, continued...

CURRENT RECOMMENDATION, continued...

**VENTAK PRIZM 2 VR/DR**
Models 1860/1861

- 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

**CRT-Ps: RENEWAL TR/TR2**

**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.
A serialized search tool to determine if a specific device is affected by this product advisory is available here: Device Lookup Tool.

**This advisory is limited to those models listed below implanted subpectorally with the serial number facing the ribs.**

### CONTAK RENEWAL 4 HE
Models H197/H199

This failure mechanism can result in one or more of the following device behaviors:
- Loss of shock therapy
- Loss of pacing therapy (intermittent or permanent)
- Loss of telemetry communications
- Beeping (16 tones every six hours), and a programmer warning screen upon interrogation

### CONTAK RENEWAL 4 HE
Models M170/M175/M177/M179

**Reported Events**

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.

### CONTAK RENEWAL 3 HE
Models H177/H179

**Rate of Occurrence**

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.

### CONTAK RENEWAL 3 HE
Models H170/H175

### VITALITY 2 EL VR/DR
Models T177/T167

**Confirmed Malfunctions (worldwide)**

May 12, 2006 Population

Nineteen (19) malfunctions have been confirmed from an estimated 700 devices implanted in the susceptible orientation.

### VITALITY DR HE
Model T180

January 4, 2008 Population

Seven (7) malfunctions have been confirmed from an estimated 330 devices implanted in the susceptible orientation.

### VITALITY EL
Model T127

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

### VITALITY DR+
Model 1872

**Projected Rate of Occurrence**

The projected rate of occurrence for devices implanted in the susceptible orientation is estimated to be 3% to 4% at 60 months.

**CURRENT STATUS** 07-Oct-16

Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication.

- 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.
  - 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.
CURRENT RECOMMENDATION, continued…
If the device is in a susceptible orientation (serial number facing the ribs):
   – 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.
   – 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.
Voluntary Physician Advisory

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.

A serialized search tool to determine if a specific device is affected by this product advisory is available here: [Device Lookup Tool](#).

**INSIGNIA Ultra SR**
Models 1190/1390

**INSIGNIA Ultra DR and Ultra DR Downsize**
Models 1291/1491/1290/1490

**INSIGNIA Entra SR**
Models 1195/1198/1395/1398

**INSIGNIA Entra DR (downsize)**
Models 1296/1466

**INSIGNIA Entra DR**
Models 1294/1295/1494/1495

**INSIGNIA Entra SSI**
Models 0484/0485/1325/1326

**INSIGNIA Entra DDD**
Models 0985/0986/1426

**INSIGNIA Plus SR**
Models 1194/1394

**INSIGNIA Plus DR and Plus DR Downsize**
Models 1297/1467/1298/1468

**INSIGNIA AVT**
Models 0482/0882/0982
1192/12921392/1428/1432/1492

**CURRENT STATUS** 07-Oct-16

**CURRENT RECOMMENDATION** 07-Oct-16

Failure Mode 1 — Patient management recommendations from the September 22, 2005 physician communication remain unchanged.

Failure Mode 2 — Patient management recommendations supersede those originally communicated on September 22, 2005.

— 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.

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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.

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.

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.

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.

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

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%.

The rate of occurrence for the estimated worldwide active device population of 3,000 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 2,000 is projected to range between 0.02% and 0.06%, as communicated in the January 21, 2006 Advisory Update letter.
CURRENT RECOMMENDATION 07-Oct-16

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.

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