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.

### Voluntary Physician Advisory - AUTOGEN RVAT November 2014

**PRODUCT**

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

**AUTOGEN CRT-D**

Models G172/G173/G175/G177/G179

**AUTOGEN ICD MINI DR**

Models D046/D047

**AUTOGEN ICD EL DR**

Models D176/D177

**ORIGINAL COMMUNICATION**  17-Nov-2014 - AUTOGEN RVAT November 2014

**CURRENT STATUS**  17-Nov-14

- **Reported events (worldwide)**
  - Three (3) reports have been received worldwide of ineffective pacing support during an RVAT test.

- **Current recommendation**  17-Nov-14
  - The RVAT test can be used in-clinic to run an automatic threshold test (nominally enabled) or it can be enabled for ambulatory use (nominally not enabled). Until a software solution can be implemented, Boston Scientific recommends the following:

  1. For ambulatory RVAT tests, we recommend that the RVAT test feature is not enabled in AUTOGEN DR ICDs and CRT-Ds, due to the potential risk of asystole occurring during the RVAT test. If the ambulatory RVAT test feature has been enabled, Boston Scientific recommends disabling the RVAT feature at the first opportunity, but within three months. To ensure the RVAT test feature is not enabled for ambulatory use:

     - Select the SETTINGS tab
     - Select the SETTINGS SUMMARY tab
     - In the BRADY section, select the NORMAL SETTINGS details icon
     - In the PACING and SENSING section, select the desired pacing RV Amplitude (do not select Auto)
     - Ensure that DAILY TREND is not selected
     - Press PROGRAM to implement the selected fixed amplitude pacing output.

  2. For in-clinic/commanded RVAT tests, we recommend that physicians test thresholds manually, rather than utilizing the automatic RVAT test. Under the Test Type field, select Amplitude (do not select Auto Amplitude).

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

Boston Scientific CRM Product Performance Report, Q4 2014
Current Advisories, Published November 18, 2014
CURRENT RECOMMENDATION 10-Oct-14

Updated Software
Boston Scientific introduced updated programmer software (Model 2868, version 3.04) that enhances the effectiveness of the Safety Architecture tools later in device life. Patients with a device in the advisory population should be scheduled for an in-clinic follow-up at first opportunity, but within 3 months, using a programmer with the new software. In-clinic interrogation with an updated programmer will automatically download 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.

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.

Projected Rate of Occurrence
The projected rate of occurrence for advisory population devices is approximately 2.9% at 60 months.

Low Voltage Capacitor 2014 Physician Letter, Sep 17, 2014
Low Voltage Capacitor 2014 Patient Letter, Sep 17, 2014
Low Voltage Capacitor 2013 Physician Letter, Aug 29, 2013

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

**Rate of Occurrence**

Cameron Health has confirmed one (1) occurrence of a device experiencing premature battery depletion due to this condition.

Cameron Health conducted a systematic analysis of all implanted devices worldwide and identified two populations at risk for premature battery depletion due to this condition:

- Population I consists of 18 devices that were confirmed through manufacturing records to contain the condition within a battery cell. 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 consists of 386 devices for which manufacturing records cannot exclude the possibility of the condition existing within a battery cell. 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 STATUS 10-Oct-14**

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.

- 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.

**CURRENT RECOMMENDATION 10-Oct-14**

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

**Device Lookup Tool**

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.

**CONTAK RENEWAL 3**
Models H170/H175

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.

**CONTAK RENEWAL 3 HE**
Models H177/H179

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).

**CONTAK RENEWAL 3 RF**
Models H210/H215

Rate of Occurrence
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.

**CONTAK RENEWAL 3 RF HE**
Models H217/H219

**CONTAK RENEWAL 4**
Models H190/H195/H197/H199

**CONTAK RENEWAL 4 RF**
Models H230/H235/H239

**VITALITY DR HE**
Model T180

**CURRENT STATUS  10-Oct-14**

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

**Projected Rate of Occurrence**

The projected rate of occurrence for the advisory device population is 0.0029 at 60 months.

**CURRENT RECOMMENDATION  10-Oct-14**

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:

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.

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.]
July 2010— Magnetic Reed Switch 2010, continued…

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.
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.

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

TELIGEN VR
Models E102/F102

TELIGEN DR
Models E110/E111/F110/F111

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

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

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

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

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

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

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.

Reported events (worldwide)
Eighty-seven (87) reports have been received worldwide of subpectoral implants with weakened header bonds. An estimated 10% of approximately 104,000 COGNIS and TELIGEN devices worldwide have been implanted in a subpectoral location.

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

Rate of Occurrence
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 0.6% at 60 months.
01-Dec-09 — Subpectoral Implant 2009, continued…

CURRENT RECOMMENDATION 10-Oct-14

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.
Voluntary Physician Advisory

Low-voltage capacitors may be subject to degradation. These capacitors may cause accelerated battery depletion and may reduce the time between Elective Replacement Indicator (ERI) and End Of Life (EOL) to less than three months. Device replacement indicators continue to function normally.

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

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

2,565 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.

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Following monitoring recommendations below will minimize patient risk associated with a shortened replacement window.
VITALITY EL
Model T127

VITALITY AVT A155
Model A155

Shortened Replacement Window
Physician Letter, Mar 04, 2009

Shortened Replacement Window
Patient Letter, Mar 04, 2009

Shortened Replacement Window
Physician Letter, Apr 5, 2007

Shortened Replacement Window
Patient Letter, Apr 5, 2007

05-Apr-07 and 04-Mar-09— Shortened Replacement Window, continued…

CURRENT RECOMMENDATION 10-Oct-14

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

**PRODUCT**

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

**CONTAK RENEWAL 4 RF HE**

- Model H230

**CONTAK RENEWAL 4 RF / HE**

- Models H230/H235/H197/H199

**CONTAK RENEWAL 4 and 4 AVT / AVT HE**

- Models H190/H195/M170/M175/M177/M179

**CONTAK RENEWAL 3 RF HE**

- Models H217/H219

**CONTAK RENEWAL 3 RF / HE**

- Models H210/H215/H177/H179

**CONTAK RENEWAL 3 and 3 AVT / AVT HE**

- Models H170/H175/M155/M159

**VITALITY 2 EL VR/DR**

- Models T177/T167

**VITALITY 2 VR/DR**

- Models T175/T165

**VITALITY DR HE and EL**

- Model T180 and Model T127

**VITALITY DS VR/DR**

- Model T135/T125

**VITALITY AVT A135 / A155**

- Models A135/A155

**VITALITY VR/DR and DR+**

- Models 1871/1870/1872

**ASSURE**

- Model B301

**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 10-Oct-14**

**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 10-Oct-14**

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

- **Patient Management Considerations**
  - Normal follow-up. If ERI or EOL is triggered, device replacement should be scheduled.
  - Physicians can consider individual patient needs relative to the potential device behaviors associated with mid-life display of ERI or EOL.
  - Activating the programmable feature “Beep When ERI is Reached” (nominally ON) will provide audible tones when the device reaches ERI.
  - Last measured charge time and date are stored in device memory and are available during device interrogation. Commanding amanual capacitor reform may be helpful in characterizing the current charge time.

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

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

**ORIGINAL COMMUNICATION** 23-Jun-06 and 24-Aug-06—Low Voltage Capacitor

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.

**INSGNIA Ultra SR**
Models 1190/1390

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

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

**INSGNIA Entra DR (downsize)**
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 1194/1394

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

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

**CONTAK RENEWAL TR / TR2**
Models H120/H125/H140/H145

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

**VITALITY 2 VR/DR**
Models T175/T125

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

**CURRENT STATUS 10-Oct-14**

**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.

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

**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 RECOMMENDATION 10-Oct-14**

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

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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.

**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

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Boston Scientific CRM Product Performance Report, Q4 2014

Current Advisories, Published November 18, 2014
23-Jun-06 and 24-Aug-06— Low Voltage Capacitor, continued…

CURRENT RECOMMENDATION, continued…

CRT-Ps: RENEWAL TR/TR2
– ERI or EOL indicator message displayed earlier than expected
– Fault Code 11 message (high current indicator)
– A gas gauge less than BOL within six months of implant

ICDs: VENTAK PRIZM 2, VITALITY and VITALITY 2
– ERI or EOL indicator message displayed earlier than expected
– A battery voltage less than 3.10V within six months of implant

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

CONTAK RENEWAL 4
Models H190/H195
- Beeping (16 tones every six hours), and a programmer warning screen upon interrogation

CONTAK RENEWAL 4
AVT / AVT 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
Models H170/H175
- 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 RECOMMENDATION 10-Oct-14
Patient management recommendations for both populations remain unchanged from the May 12, 2006 physician communication.

Subpectoral Implant, Physician Letter, Jan 04, 2008
- 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.
- If the leads exit the pulse generator in a clockwise direction (serial number facing away from the ribs), this advisory does not apply and no change to current patient management is necessary.
12-May-06 and 04-Jan-08 Subpectoral Implant, continued...

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.
PRODUCT

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 here: Device Lookup Tool

ORIGINAL COMMUNICATION  22-Sep-05 — Crystal Timing Component

Voluntary Physician Advisory
FDA Classification: Class II

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.

INSGNIA Ultra SR
Models 1190/1390

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

INSGNIA Entra SR
Models 1195/1198/1395/1398

INSGNIA Entra DR (downsize)
Models 1296/1466

INSGNIA Entra DR
Models 1294/1295/1494/1495

INSGNIA Entra SSI
Models 1296/1467/1298/1468

INSGNIA Entra DDD
Models 1192/12921392/1428/1432/1492

INSGNIA Plus SR
Models 1194/1394

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

INSGNIA AVT
Models 0482/0882/0982
1192/12921392/1428/1432/1492

Device Lookup Tool

Reported Events

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.

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.

Rate Projection

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.

Confirmed Malfunctions (worldwide)

Failure Mode 1—62 malfunctions out of approximately 49,500 advisory population devices have been confirmed. There have been no reported patient deaths associated with this advisory.

Failure Mode 2—26 malfunctions out of approximately 257,000 (0.010%) devices distributed have been confirmed. Twenty-two (22) malfunctions were identified before or during the implant procedure and four (4) were identified after implant. There have been no reported patient deaths associated with this advisory.

None of the INSGNIA or NEXUS devices currently being distributed are susceptible to this malfunction mode.

Projected Rate of Occurrence

Failure Mode 1—The rate of occurrence for the estimated worldwide active advisory device population of 6,000 is projected to range between 0.027% and 0.038%.

CURRENT RECOMMENDATION  10-Oct-14

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.

Standard Warranty program available, please contact your local representative for terms and conditions.
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 here: Device Lookup Tool

**CONTAK TR**
Model 1241

**DISCOVERY II SR (downsize)**
Models 1186/1187/1385

**DISCOVERY II DR (downsize)**
Models 1283/1483

**DISCOVERY II SR**
Models 1186/1187/1385

**DISCOVERY II DR**
Models 1284/1286/1484/1485

**DISCOVERY II SSI (downsize)**
Models 0481/1349

**DISCOVERY II DDD**
Models 0981/1285/1499

**PULSAR MAX II SR (downsize)**
Models 1180/1380

**PULSAR MAX II SR / DR**
Models 1181/1290/1480

**DISCOVERY SR/SR (downsize)**
Models 1174/1175

**DISCOVERY DR/DR (downsize)**
Models 1274/1275/1273

**PULSAR MAX SR (downsize)**
Model 1170

**PULSAR MAX SR / DR**
Model 1171/1270

**PULSAR**
Models 1272/0470/0870/0970/0972/1172

**MERIDIAN SSI / DDD**
Models 0476/0976

**MERIDIAN SR / DR**
Models 1176/1276

**ORIGINIAL COMMUNICATION** 18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component

Voluntary Physician Advisory (18-Jul-05)
FDA Classification: Class I

Voluntary Physician Advisory (21-Jan-06)
FDA Classification: Class I

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.

**Device Lookup Tool**

**CURRENT STATUS** 10-Oct-14

**Reported Events (worldwide)**

Refined Original Population—342 malfunctions have been confirmed out of the 77,500 advisory population devices.

Second Population—13 malfunctions have been confirmed out of the 54,000 advisory population devices.

**Projected Rate of Occurrence**

Refined Original Population—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.
18-Jul-05 and 21-Jan-06 — Hermetic Sealing Component, continued…

**CURRENT RECOMMENDATION 10-Oct-14**

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 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.