

«Hospital_Name»
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<**References: 92705305 & 92289212-FA**>

June 2021

Cover letter

Urgent Field Safety Notices:

INGENIO™ Family DR EL Pacemakers and CRT-Ps (92705305-FA) And

Hydrogen Induced Accelerated Battery Depletion (92289212-FA)

Dear Healthcare Professional,

Boston Scientific is committed to vigilant monitoring of the performance of all our therapies. Our quality system allows us to maintain a clear picture of how our devices are performing and to identify opportunities for improvement. The system allows us to monitor multiple sources of information about our devices, including component suppliers, testing, manufacturing and field performance.

Product advisories are one way in which we communicate outcomes from our quality monitoring system. It is our practice to initiate product advisories whenever we can provide meaningful recommendations or guidance to improve patient outcomes or device performance, or when there is a material elevation in risk to patient safety with the potential for compromised lifesaving therapy. Beyond these criteria, Boston Scientific considers many perspectives in the decision to communicate, including feedback from healthcare professionals like you. We also solicit guidance from an independent, external Patient Safety Advisory Board, which is a globally represented, safety-specific physician and patient panel with deep expertise in the management of cardiac implantable electronic devices.

Recently, two separate and unrelated pacing system behaviors have been identified for which our standards prompt us to communicate to you. This packet contains two separate letters:

1. Pacemakers from the INGENIO™ EL family: INGENIO DR EL, VITALIO™ DR EL, ADVANTIO™ DR EL pacemakers and INLIVEN™, INTUA™, and INVIVE™ CRT-Ps – Potential for Safety Mode due to increase in battery impedance prior to replacement indicators.
2. Pacemakers from the ACCOLADE™ family: ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 pacemakers and VISIONIST™ and VALITUDE™ CRT-Ps (subset) – Elevated likelihood for early replacement due to accelerated battery depletion.

Instructions:

1. Please read carefully the 2 Field Safety Notices attached.
2. Then, complete and sign the enclosed Acknowledgement Form. Return the form to Boston Scientific at «Customer_Service_Fax_Number» by **25 June 2021**. It is mandatory for each customer to return this form to Boston Scientific.

No affected devices remain available for implant. Boston Scientific remains committed to continuous improvement in the interest of patient benefit, and patient safety remains our priority and our constant focus. Although we recognize the impact this information may have on both you and your patients, we believe transparent communication will ensure you have timely, relevant information for managing your patients.

If you have additional questions about these topics or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Attachments:

- Acknowledgment Form
- High Battery Impedance May Initiate Safety Mode in INGENIO™ Family DR EL Pacemakers and CRT-Ps (92705305-FA) Field Safety Notice
- Performance Update: Hydrogen Induced Accelerated Battery Depletion (92289212-FA) Field Safety Notice



Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Field Safety Notices:
INGENIO™ Family DR EL Pacemakers and CRT-Ps
And
Hydrogen Induced Accelerated Battery Depletion
92705305 & 92289212-FAs

By signing this form, I confirm that

**I have read and understood
the Boston Scientific Field Safety Notices**

dated June 2021 for the

INGENIO™ Family DR EL Pacemakers and CRT-Ps
And
Hydrogen Induced Accelerated Battery Depletion

NAME* _____ **Title** _____

Telephone _____ **Department** _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy

Urgent Field Safety Notice

Subject: Field Safety Notice – High Battery Impedance May Initiate Safety Mode in INGENIO™, VITALIO™, and ADVANTIO™ pacemakers and INLIVEN™, INTUA™, and INVIVE™ cardiac resynchronization therapy pacemakers (CRT-Ps) (Boston Scientific Field Action Reference: 92705305-FA).

Summary

- Boston Scientific has determined that dual chamber INGENIO™ family¹ pacemakers or cardiac resynchronization therapy pacemakers (CRT-Ps) may initiate Safety Mode later in device life (i.e., prior to reaching the Explant battery indicator) when the device's battery exhibits high internal impedance. This latent battery condition puts a device at risk for system resets to occur due to temporary high-power consumption related to telemetry attempts and subsequent reversion to Safety Mode to maintain back-up pacing. Although therapy is still provided when a device is in Safety Mode, replacement is required.
 - Approximately 48,000 active dual chamber INGENIO family pacemakers and CRT-Ps built with the Extended Life (EL) battery are included within this advisory population (Appendix A).
 - No affected devices remain available for implant.
- Boston Scientific has received 65 reports of events associated with dual chamber INGENIO family EL pacemakers and CRT-Ps, in which devices transitioned to Safety Mode prior to reaching the Explant battery indicator during interrogation attempts by either a programmer or a LATITUDE™ communicator.
 - The most common clinical impact has been early device replacement.
 - Myopotential oversensing-associated pacing inhibition, as well as phrenic nerve stimulation have been reported in some patients prior to device replacement due to non-programmable Safety Mode pacing parameters.
 - No patient deaths have been reported.
 - It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator.
- If a device enters Safety Mode, schedule replacement. In situations where non-programmable Safety Mode pacing parameters (Table 1) may not provide optimal support of a patient's cardiac condition (e.g., adequacy of underlying escape rhythm, the need for AV/VV pacing for cardiac synchrony, and/or the potential for pacing inhibition due to myopotential oversensing), consider early device replacement per the following guidelines:
 - For dual chamber EL pacemakers, replace with a longevity remaining of 4 years (or less).
 - For CRT-Ps, replace with a longevity remaining of 3 years (or less).

¹The INGENIO family of DR EL pacemaker includes: VITALIO™ DR EL, INGENIO™ DR EL, and ADVANTIO™ DR EL pacemakers and INLIVEN™, INTUA™, and INVIVE™ CRT-Ps.

Dear Physician or Healthcare Professional,

This letter provides important information about dual chamber INGENIO™ family Extended Life (EL) pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps) and applies to approximately 48,000 active devices. You are receiving this letter because our records indicate you may be following one or more patients implanted with an affected device (Appendix A). The battery impedance within these devices increases over time, based on implant duration and power usage. This latent battery condition puts the device at risk for system resets to occur during telemetry attempts and may cause the device to enter Safety Mode prior to reaching the Explant battery indicator. Boston Scientific discontinued manufacturing dual chamber INGENIO EL pacemakers and CRT-Ps in 2018; these devices are no longer eligible for implant. The INGENIO devices built with the Standard Life (SL) battery, as well as all contemporary Boston Scientific pacemakers and CRT-Ps, have different batteries and have not exhibited this latent battery condition.

Please distribute a copy of this letter to all other physicians and healthcare professionals within your organization who need to be aware of this potential device behavior.

Description

Boston Scientific has received reports associated with dual chamber INGENIO family pacemakers and CRT-Ps built with the EL battery (Appendix A), in which the devices transitioned to Safety Mode during interrogation attempts by either a programmer or a LATITUDE™ communicator. Investigation has shown that the EL battery impedance increases over time, based on implant duration and power usage. This increased battery impedance may cause a device to exhibit transient voltage decreases during periods of high-power consumption associated with telemetry communication via a programmer or a LATITUDE communicator. If the battery voltage drops below a minimum threshold during communication attempts, the device will temporarily halt telemetry, and a system reset will be performed. The battery voltage recovers and pacing function resumes within one (1) second; however, subsequent telemetry attempts may result in additional system resets due to the high battery impedance. If three (3) system resets occur within a 48-hour period, the device is designed to immediately enter Safety Mode to maintain back-up pacing with pre-defined, non-programmable settings (Table 1). There is no delay in resumption of pacing when the device enters Safety Mode. When a device is in Safety Mode, replacement is required.

Table 1. Safety Mode Non-Programmable Parameters

| | |
|-------------------------|--|
| Mode | VVI (for CRT-Ps: biventricular pacing) |
| Rate | 72.5 ppm |
| Sensitivity | Automatic Gain Control (AGC) 0.25 mV |
| Output | 5.0 V at 1.0 ms RV (and LV for CRT-Ps) |
| Lead Configuration | RV Unipolar sensing/pacing LV Unipolar (tip to can) |
| RVRP | 250 ms |
| Noise response | VOO |
| LV Offset (CRT-Ps only) | 0 ms |
| Magnet Response | Disabled |

Boston Scientific transvenous pulse generators contain dedicated hardware to support overall safety architecture. In pacemakers and CRT-Ps, this hardware is intended to provide back-up pacing if certain non-recoverable or repeat fault conditions occur. Safety Mode is not intended to be a substitute for chronic pacing therapy. There is a high degree of detectability when a device is operating in Safety Mode. A warning screen is displayed on the programmer upon device interrogation (Figure 1). For those devices monitored via LATITUDE, a red alert will also be issued, indicating the device has entered Safety Mode. If a device is unmonitored for a period of 14 days, it will show up on the 'not monitored' status page on LATITUDE. Whenever a device enters Safety Mode operation, users are instructed to contact Boston Scientific, and Technical Services will advise device replacement.

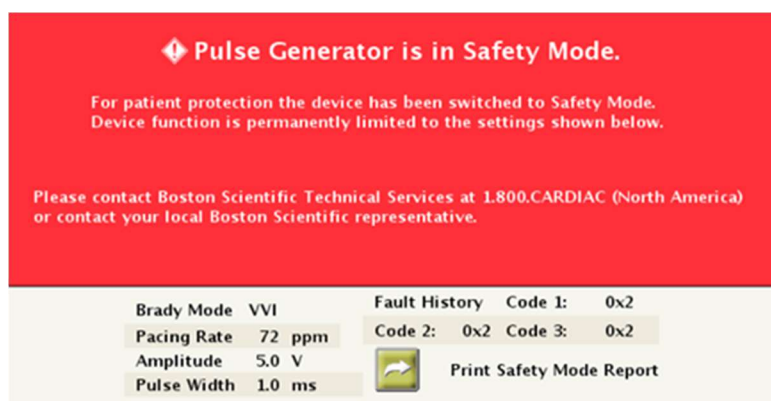


Figure 1. Programmer Warning Screen for Safety Mode

Clinical Impact

Investigation has shown that susceptibility of affected devices is increased when the device reaches approximately three (3) to four (4) years of remaining battery longevity. Based on the available information and subsequent modeling, all dual chamber INGENIO EL pacemakers and CRT-Ps are potentially susceptible to this latent battery condition and subsequent initiation of Safety Mode prior to reaching the Explant battery indicator. However, because implant duration and power usage vary and will impact the rate and degree of battery impedance increase over the lifetime of a device, not all affected devices will manifest in this manner. It is estimated that one third or more of affected devices will experience Safety Mode prior to reaching Explant battery indicator.

No deaths have been reported due to this latent battery condition causing devices to initiate Safety Mode prior to reaching the Explant battery indicator. The potential for life-threatening harm due to prolonged inhibition or loss of pacing over a device's lifetime is estimated to be less than 1 in 15,000; this has not been observed. Although the most common clinical outcome has been early device replacement, Safety Mode parameters may result in unintended clinical impact (e.g., myopotential oversensing-associated pacing inhibition, loss of AV/VV synchrony, phrenic nerve stimulation) for certain patients prior to device replacement. We have observed three instances where patients received external pacing after Safety Mode was initiated. The recommendations below can further reduce this risk.

Recommendations

1- Individual patient evaluation. As noted above, Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. When assessing potential risk for a patient if their device initiates Safety Mode prior to the Explant indicator, consider patient-specific physiological factors (which may vary over time), including: adequacy of underlying escape rhythm and/or the need for AV/VV pacing for cardiac synchrony and the potential for pacing inhibition due to myopotential oversensing..

2- Replacement. If a device enters Safety Mode, schedule replacement. Boston Scientific does not recommend general prophylactic replacement for affected devices. However, for individual patients, factors such as those listed above and shared decision-making may support consideration of early device replacement to mitigate unintended clinical impact(s) due to potential entry into Safety Mode prior to the Explant indicator. In these cases, the following guidance should be considered:

- For EL pacemakers, if early replacement is planned, schedule replacement when the longevity remaining is 4 years (or less, if the device currently indicates fewer than 4 years longevity remaining).
- For CRT-Ps, if early replacement is planned, schedule replacement when the longevity remaining is 3 years (or less, if the device currently indicates fewer than 3 years longevity remaining).

3- Follow-up interval. Perform a system follow-up via remote or in-office interrogation at least every 12 months. For patients who may not require early device replacement, continue with existing follow-up protocols until the longevity reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated (in accordance with the device's instructions for use).

4- Medical records. For each patient with an affected device, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

Adverse events experienced with use of a dual chamber INGENIO EL pacemaker or CRT-P should be reported to Boston Scientific or the FDA's MedWatch Adverse Event Reporting program. Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

Please complete the attached acknowledgement form. It is mandatory for each customer to return this form to Boston Scientific. When completed, please return the Form to «Customer_Service_Fax_Number».

Additional Information

Patient safety remains Boston Scientific's highest priority. Although Boston Scientific recognizes the impact of advisory communications on both you and your patients, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. Up-to-date product performance information, including this topic, and a device lookup tool are available within our Product Performance Resource Center at www.bostonscientific.com/ppr.

If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely



**Appendix A: Affected Product Names/Models/Part Numbers for
High Battery Impedance May Initiate Safety Mode in INGENIO™ Family
DR EL Pacemakers and CRT-Ps (92705305-FA)**

| Product Name | Model | GTIN | Product Name | Model | GTIN |
|----------------|-------|----------------|---------------|-------|----------------|
| ADVANTIO DR EL | J064 | 00802526496011 | INGENIO DR EL | K184 | 00802526509698 |
| | | 00802526508868 | | | 00802526509704 |
| | | 00802526508912 | | | 00802526509711 |
| | | 00802526508936 | | | 00802526536809 |
| | | 00802526516429 | | | 00802526536915 |
| | | 00802526525384 | | | 00802526543289 |
| | | 00802526538643 | | | 00802526543685 |
| | | 00802526538667 | INGENIO DR EL | K187 | 00802526535956 |
| | | 00802526539619 | | | 00802526543319 |
| | | 00802526539626 | | | 00802526543715 |
| | | 00802526539640 | VITALIO DR EL | K274 | 00802526536557 |
| | | 00802526555619 | VITALIO DR EL | K277 | 00802526528040 |
| | | 00802526566141 | VITALIO DR EL | K284 | 00802526536571 |
| | | 00802526566158 | VITALIO DR EL | K287 | 00802526528071 |
| ADVANTIO DR EL | J067 | 00802526496042 | | | 00802526528170 |
| | | 00802526516450 | | | 00802526543340 |
| | | 00802526518140 | INVIVE CRT-P | V172 | 00802526496479 |
| | | 00802526518157 | | | 00802526536625 |
| | | 00802526518171 | INVIVE CRT-P | V173 | 00802526496486 |
| | | 00802526518195 | | | 00802526536632 |
| | | 00802526525506 | | | 00802526540387 |
| | | 00802526538728 | INVIVE CRT-P | V182 | 00802526498121 |
| | | 00802526538742 | | | 00802526509858 |
| | | 00802526538759 | | | 00802526509865 |
| | | 00802526539817 | | | 00802526536922 |
| | | 00802526539824 | | | 00802526543364 |
| | | 00802526539831 | | | 00802526543777 |
| | | 00802526539855 | INVIVE CRT-P | V183 | 00802526498138 |
| | | 00802526539862 | | | 00802526509872 |
| | | 00802526555640 | | | 00802526509889 |
| | | 00802526566233 | | | 00802526536656 |
| | | 00802526566301 | | | 00802526536939 |
| | | | | | 00802526543371 |
| | | | | | 00802526543784 |
| INGENIO DR EL | J174 | 00802526496073 | INTUA CRT-P | V272 | 00802526536663 |
| | | 00802526509339 | INTUA CRT-P | V273 | 00802526536670 |
| | | 00802526509353 | INLIVEN CRT-P | V284 | 00802526543388 |
| | | 00802526509360 | INLIVEN CRT-P | V285 | 00802526536717 |
| | | 00802526509377 | | | 00802526543395 |
| | | 00802526509391 | INVIVE CRT-P | W172 | 00802526496530 |
| | | 00802526509407 | | | 00802526509896 |
| | | 00802526509414 | | | 00802526509919 |
| | | 00802526516511 | | | 00802526509926 |
| | | 00802526525629 | | | |
| | | 00802526538810 | | | |

| Product Name | Model | GTIN | Product Name | Model | GTIN |
|---------------|-------|----------------|---------------|-------|----------------|
| INGENIO DR EL | J174 | 00802526538827 | INVIVE CRT-P | W172 | 00802526509933 |
| | | 00802526538834 | | | 00802526509957 |
| | | 00802526538841 | | | 00802526509964 |
| | | 00802526540028 | | | 00802526509988 |
| | | 00802526540035 | | | 00802526526206 |
| | | 00802526540042 | | | 00802526536724 |
| | | 00802526540059 | | | 00802526539220 |
| | | 00802526540066 | | | 00802526539244 |
| | | 00802526540073 | | | 00802526539251 |
| | | 00802526555657 | | | 00802526539268 |
| | | 00802526563102 | | | 00802526566714 |
| | | 00802526566356 | | | 00802526566721 |
| | | 00802526566363 | | | 00802526496547 |
| | | 00802526496103 | | | 00802526510007 |
| INGENIO DR EL | J177 | 00802526516542 | INVIVE CRT-P | W173 | 00802526510021 |
| | | 00802526518423 | | | 00802526510038 |
| | | 00802526518430 | | | 00802526510045 |
| | | 00802526518454 | | | 00802526510069 |
| | | 00802526518478 | | | 00802526510076 |
| | | 00802526518485 | | | 00802526510083 |
| | | 00802526525742 | | | 00802526510090 |
| | | 00802526539022 | | | 00802526526237 |
| | | 00802526539046 | | | 00802526536731 |
| | | 00802526539053 | | | 00802526539275 |
| | | 00802526539060 | | | 00802526539282 |
| | | 00802526540233 | | | 00802526539299 |
| | | 00802526540240 | | | 00802526539305 |
| | | 00802526540257 | | | 00802526539312 |
| | | 00802526540271 | | | 00802526555770 |
| | | 00802526540288 | | | 00802526563140 |
| | | 00802526543425 | | | 00802526566738 |
| | | 00802526555688 | | | 00802526566745 |
| | | 00802526563133 | INTUA CRT-P | W273 | 00802526501593 |
| | | 00802526566516 | | | 00802526501609 |
| | | 00802526566523 | | | 00802526501616 |
| | | 00802526501531 | | | 00802526555787 |
| VITALIO DR EL | J274 | 00802526501548 | INLIVEN CRT-P | W274 | 00802526566752 |
| | | 00802526501555 | | | 00802526566769 |
| | | 00802526555718 | | | 00802526526350 |
| | | 00802526566592 | | | 00802526531446 |
| | | 00802526566608 | | | 00802526531453 |
| VITALIO DR EL | J277 | 00802526516627 | | | 00802526531460 |
| | | 00802526526022 | | | 00802526531484 |

| Product Name | Model | GTIN | Product Name | Model | GTIN |
|----------------|-------|----------------|---------------|-------|----------------|
| VITALIO DR EL | J277 | 00802526528118 | INLIVEN CRT-P | W274 | 00802526531491 |
| | | 00802526539138 | | | 00802526536762 |
| | | 00802526539145 | | | 00802526539329 |
| | | 00802526539152 | | | 00802526539336 |
| | | 00802526539169 | | | 00802526539343 |
| | | 00802526566653 | | | 00802526539350 |
| | | 00802526566660 | | | 00802526543838 |
| ADVANTIO DR EL | K064 | 00802526496233 | | | 00802526566776 |
| | | 00802526516719 | | | 00802526566783 |
| ADVANTIO DR EL | K084 | 00802526497926 | INLIVEN CRT-P | W275 | 00802526526404 |
| | | 00802526509636 | | | 00802526531514 |
| | | 00802526509643 | | | 00802526531521 |
| | | 00802526536533 | | | 00802526531538 |
| | | 00802526536908 | | | 00802526531552 |
| | | 00802526543227 | | | 00802526531569 |
| | | 00802526543623 | | | 00802526536779 |
| ADVANTIO DR EL | K087 | 00802526535925 | | | 00802526539374 |
| | | 00802526543258 | | | 00802526539381 |
| | | 00802526543654 | | | 00802526539398 |
| INGENIO DR EL | K174 | 00802526496295 | | | 00802526539404 |
| | | 00802526536786 | | | 00802526555794 |
| | | 00802526540363 | | | 00802526566790 |
| | | 00802526552809 | | | 00802526566806 |

Urgent Field Safety Notice

Subject: Field Safety Notice – Hydrogen-Induced Accelerated Battery Depletion in ACCOLADE™, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 pacemakers and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps) originally communicated in September 2018 (Boston Scientific Field Action Reference: 92289212-FA).¹

Table 1. The model numbers by population within the subset of devices affected by the hydrogen-induced accelerated battery depletion advisory. Additional model numbers since 2018 are in bold.

| | 2018 Affected Models | 2021 Affected Models |
|---------------------|------------------------------------|--|
| ACCOLADE Pacemaker | L300, L301, L310, L311, L321, L331 | L300, L301, L310, L311, L321, L331 |
| PROPONENT Pacemaker | L200, L210, L211, L221, L231 | L200, L201, L209 , L210, L211, L221, L231 |
| ESSENTIO Pacemaker | L100, L101, L110, L111, L121, L131 | L100, L101, L110, L111, L121, L131 |
| ALTRUA 2 Pacemaker | No Affected Models | S701, S702, S722 |
| VISIONIST CRT-P | U228 | U225, U226 , U228 |
| VALITUDE CRT-P | U128 | U125 , U128 |

Dear Physician or Healthcare Professional,

Description

In September 2018, Boston Scientific advised physicians about a population of pacemakers and CRT-Ps (collectively pacemakers) exhibiting hydrogen-induced accelerated battery depletion. Since that time, additional confirmed depletion events have been reported and described within Boston Scientific's Product Performance Report (PPR) for both the 2018 advisory and the non-advisory population. Latent release of small amounts of hydrogen within the pacemaker may cause a low voltage capacitor to become electrically compromised over time resulting in accelerated battery depletion of the battery and associated progression of displayed battery depletion indicators. Boston Scientific's **ongoing investigation has determined that any pacemaker built with a specific, discontinued low voltage capacitor is potentially susceptible to this behavior**. Therefore, Boston Scientific is expanding the advisory population to make customers aware of all potentially susceptible pacemakers to this behavior (Appendix A). The production of pacemakers from these advisory populations ceased in November 2017, and therefore they are no longer available for implantation. Pacemakers built with contemporary low voltage capacitors have not exhibited this behavior and are not included in this expansion.

Clinical Impact

Ongoing monitoring, aligned with labeled instructions for use, has continued to validate the high degree of detectability and low risk of life-threatening harm due to this behavior. To date, 99.5% of the total 1,776 pacemakers confirmed to have exhibited this behavior were replaced before the battery reached a depleted state. The likelihood of this behavior occurring in the 2021 expanded population is an order of magnitude lower which contributes to a proportionally lower potential for life-threatening harm of a battery reaching a depleted state: 1 in 500,000 at 5 years for the approximate 2,100 active devices in the 2018 population and 1 in 5,000,000 at 5 years for the approximate 125,000 active devices in the expanded 2021 population. As communicated in the 2018 advisory, the most common clinical impact of this behavior is early device replacement. There have been no reported deaths associated with this behavior.

¹Boston Scientific's Product Performance Report (PPR) includes advisory information at www.BostonScientific.com/ppr

Based on the high degree of early detectability of this behavior, normal battery assessment during labeled 12-month follow-ups has been effective and is recommended for the 2018 and 2021 advisory populations. If you are following Boston Scientific pacemakers every 12-months in person or via remote monitoring, there are no new actions for you to take. Continue to evaluate battery performance at each follow-up and contact Boston Scientific if you observe accelerated battery depletion.

Recommendations

1- Follow-up interval. Per labeling, perform a system follow-up via remote or in-office interrogation at least every 12 months until One-Year-Remaining and then 3 months thereafter until replacement is indicated. Note: this is a change to the recommendations originally communicated for the 2018 population.

2- During follow-ups. Assess battery for accelerated depletion by comparing the device's 'Approximate Time to Explant' between two follow-up intervals. If the change in longevity significantly exceeds the interval between follow-ups, the device may be exhibiting accelerated depletion. Contact Boston Scientific Technical Services for assistance verifying if there is accelerated depletion or if the observed change in longevity remaining is expected based on changes in device power usage.

3- Replacement. Replace and return to Boston Scientific any affected pacemakers suspected of exhibiting accelerated battery depletion within 90 days of the Explant battery status indicator. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. Prophylactic replacement is not recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated battery depletion.

4- Medical records. For each patient with an affected pacemaker, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the pacemaker.

Please distribute this update to all other physicians and healthcare professionals within or outside your organization who need to be aware of this topic. Enclosed is a list of affected pacemakers. Adverse reactions or quality problems experienced with the use of these or any devices should be reported to Boston Scientific and your local and your local regulatory authority, as applicable.

Please complete the attached acknowledgement form. It is mandatory for each customer to return this form to Boston Scientific. When completed, please return the Form to «Customer_Service_Fax_Number».

Up-to-date product performance information about this topic, including a device lookup tool¹, is available within our Product Performance Resource Center at www.bostonscientific.com/ppr.

If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,



Alexandra Naughton
Vice President, Quality Assurance

¹Available at www.BostonScientific.com/lookup

Appendix A: Affected Product Names/Models/Part Numbers for Hydrogen Induced Accelerated Battery Depletion (92289212-FA)

Affected product models/GTIN numbers that compose the subset of hydrogen-induced accelerated battery depletion advisory populations: Sep 2018 advisory population composed of ~2,100 active pacemakers and Jun 2021 advisory population composed of ~125,000 active pacemakers.

| Product Name | Model | GTIN | Product Name | Model | GTIN |
|----------------------|-------|----------------|--------------------|-------|----------------|
| ESSENTIO Pacemaker | L100 | 00802526558900 | ACCOLADE Pacemaker | L310 | 00802526559204 |
| | | 00802526558917 | | | 00802526559211 |
| | | 00802526571923 | | | 00802526572364 |
| | | 00802526576300 | | | 00802526576454 |
| | | 00802526576805 | | | 00802526576959 |
| | | 00802526593109 | | | 00802526578069 |
| ESSENTIO Pacemaker | L101 | 00802526558924 | ACCOLADE Pacemaker | L311 | 00802526559228 |
| | | 00802526558931 | | | 00802526559235 |
| | | 00802526576317 | | | 00802526572395 |
| | | 00802526576812 | | | 00802526576461 |
| ESSENTIO Pacemaker | L110 | 00802526558948 | ACCOLADE Pacemaker | L321 | 00802526578076 |
| | | 00802526558955 | | | 00802526559242 |
| | | 00802526571985 | | | 00802526559259 |
| | | 00802526576324 | | | 00802526572425 |
| | | 00802526576829 | | | 00802526572432 |
| ESSENTIO Pacemaker | L111 | 00802526558962 | ACCOLADE Pacemaker | L331 | 00802526576478 |
| | | 00802526558979 | | | 00802526559266 |
| | | 00802526572012 | | | 00802526559273 |
| | | 00802526576331 | | | 00802526572456 |
| ESSENTIO Pacemaker | L121 | 00802526576836 | ALTRUA 2 Pacemaker | S701 | 00802526576485 |
| | | 00802526558986 | | | 00802526578083 |
| | | 00802526558993 | | | 00802526592201 |
| | | 00802526572043 | | | 00802526559327 |
| | | 00802526576348 | | | 00802526559334 |
| ESSENTIO Pacemaker | L131 | 00802526576843 | ALTRUA 2 Pacemaker | S702 | 00802526572487 |
| | | 00802526559006 | | | 00802526576492 |
| | | 00802526559013 | | | 00802526576997 |
| | | 00802526572081 | | | 00802526578090 |
| PROPOSITOR Pacemaker | L200 | 00802526576355 | ALTRUA 2 Pacemaker | S722 | 00802526559341 |
| | | 00802526559020 | | | 00802526559358 |
| | | 00802526559037 | | | 00802526576508 |
| | | 00802526572104 | | | 00802526577000 |
| | | 00802526576362 | | | 00802526578106 |
| PROPOSITOR Pacemaker | L201 | 00802526578007 | ALTRUA 2 Pacemaker | S722 | 00802526593208 |
| | | 00802526559044 | | | 00802526559365 |
| | | 00802526559051 | | | 00802526559372 |
| PROPOSITOR Pacemaker | L201 | 00802526576379 | ALTRUA 2 Pacemaker | S722 | 00802526576515 |
| | | 00802526576874 | | | 00802526577017 |
| PROPOSITOR Pacemaker | L209 | 00802526578014 | VALITUDE CRT-P | U125 | 00802526578113 |
| | | 00802526559068 | | | 00802526559389 |

| Product Name | Model | GTIN | Product Name | Model | GTIN |
|---------------------|-------|----------------|-----------------|-------|----------------|
| PROPONENT Pacemaker | L209 | 00802526576386 | | | 00802526559396 |
| PROPONENT Pacemaker | L210 | 00802526559082 | VALITUDE CRT-P | U125 | 00802526573101 |
| | | 00802526572180 | | | 00802526577109 |
| | | 00802526576393 | | | 00802526578793 |
| | | 00802526576898 | | | 00802526559402 |
| | | 00802526578021 | VALITUDE CRT-P | U128 | 00802526559419 |
| PROPONENT Pacemaker | L211 | 00802526559105 | | | 00802526572609 |
| | | 00802526572210 | | | 00802526572616 |
| | | 00802526576409 | | | 00802526576522 |
| | | 00802526576904 | | | 00802526577031 |
| | | 00802526578038 | | | 00802526578120 |
| PROPONENT Pacemaker | L221 | 00802526559129 | VISIONIST CRT-P | U225 | 00802526559433 |
| | | 00802526576416 | | | 00802526572630 |
| | | 00802526576911 | | | 00802526577048 |
| | | 00802526578045 | | | 00802526577116 |
| | | 00802526593307 | | | 00802526578809 |
| PROPONENT Pacemaker | L231 | 00802526559136 | VISIONIST CRT-P | U226 | 00802526559457 |
| | | 00802526559143 | | | 00802526559464 |
| | | 00802526572272 | | | 00802526577062 |
| | | 00802526576423 | | | 00802526577123 |
| | | 00802526576928 | VISIONIST CRT-P | U228 | 00802526559471 |
| | | 00802526578052 | | | 00802526559488 |
| ACCOLADE Pacemaker | L300 | 00802526559150 | | | 00802526572692 |
| | | 00802526559167 | | | 00802526577055 |
| | | 00802526572302 | | | 00802526577130 |
| ACCOLADE Pacemaker | L301 | 00802526559174 | | | 00802526578830 |
| | | 00802526559181 | | | |
| | | 00802526572333 | | | |
| | | 00802526572340 | | | |
| | | 00802526576447 | | | |
| | | 00802526576942 | | | |