Boston Scientific International S.A.
ZAC Paris Nord II/Bât Emerson - 33 rue des Vanesses – 93420 Villepinte
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France
Tel 33 (0)1 48 17 47 00
Fax 33 (0)1 48 17 47 01
www.bostonscientific.com

«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country»

<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.

Alexandra Naughton
Vice President, Quality Assurance

Kenneth Stein, MD, FACC, FHRS
Senior Vice President and Chief Medical Officer, RM

Olaf Hedrich, MD, FACC, FHRS
Vice President, Medical Safety, RM

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

June 2021

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™ family[1] 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).

[1]The 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.

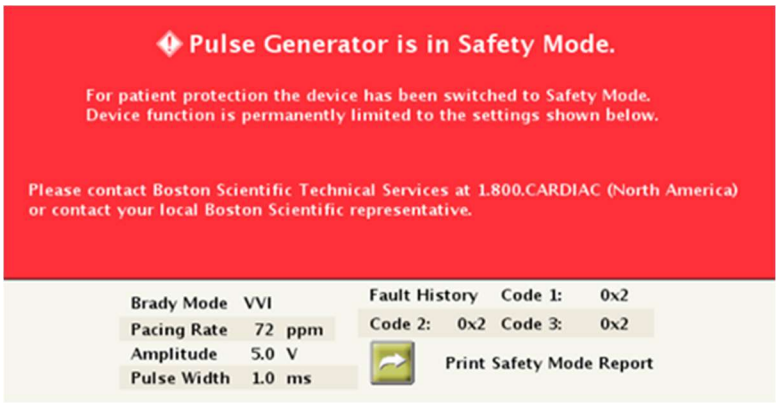

Figure 1. Programmer Warning Screen for Safety Mode

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,

Alexandra Naughton
Vice President, Quality Assurance

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
ADVANTIO DR EL	J064	00802526496011
		00802526508868
		00802526508912
		00802526508936
		00802526516429
		00802526525384
		00802526538643
		00802526538667
		00802526539619
		00802526539626
		00802526539640
		00802526555619
		00802526566141
		00802526566158
ADVANTIO DR EL	J067	00802526496042
		00802526516450
		00802526518140
		00802526518157
		00802526518171
		00802526518195
		00802526525506
		00802526538728
		00802526538742
		00802526538759
		00802526539817
		00802526539824
		00802526539831
		00802526539855
		00802526539862
		00802526555640
		00802526566233
		00802526566301
INGENIO DR EL	J174	00802526496073
		00802526509339
		00802526509353
		00802526509360
		00802526509377
		00802526509391
		00802526509407
		00802526509414
		00802526516511
		00802526525629
		00802526538810

Product Name	Model	GTIN
INGENIO DR EL	K184	00802526509698
		00802526509704
		00802526509711
		00802526536809
		00802526536915
		00802526543289
		00802526543685
INGENIO DR EL	K187	00802526535956
		00802526543319
		00802526543715
VITALIO DR EL	K274	00802526536557
VITALIO DR EL	K277	00802526528040
VITALIO DR EL	K284	00802526536571
VITALIO DR EL	K287	00802526528071
		00802526528170
		00802526543340
INVIVE CRT-P	V172	00802526496479
		00802526536625
INVIVE CRT-P	V173	00802526496486
		00802526536632
		00802526540387
INVIVE CRT-P	V182	00802526498121
		00802526509858
		00802526509865
		00802526536922
		00802526543364
		00802526543777
INVIVE CRT-P	V183	00802526498138
		00802526509872
		00802526509889
		00802526536656
		00802526536939
		00802526543371
		00802526543784
INTUA CRT-P	V272	00802526536663
INTUA CRT-P	V273	00802526536670
INLIVEN CRT-P	V284	00802526543388
INLIVEN CRT-P	V285	00802526536717
		00802526543395
INVIVE CRT-P	W172	00802526496530
		00802526509896
		00802526509919
		00802526509926

Product Name	Model	GTIN
INGENIO DR EL	J174	00802526538827
		00802526538834
		00802526538841
		00802526540028
		00802526540035
		00802526540042
		00802526540059
		00802526540066
		00802526540073
		00802526555657
		00802526563102
		00802526566356
		00802526566363
INGENIO DR EL	J177	00802526496103
		00802526516542
		00802526518423
		00802526518430
		00802526518454
		00802526518478
		00802526518485
		00802526525742
		00802526539022
		00802526539046
		00802526539053
		00802526539060
		00802526540233
		00802526540240
		00802526540257
		00802526540271
		00802526540288
		00802526543425
		00802526555688
		00802526563133
		00802526566516
		00802526566523
VITALIO DR EL	J274	00802526501531
		00802526501548
		00802526501555
		00802526555718
		00802526566592
		00802526566608
VITALIO DR EL	J277	00802526516627
		00802526526022

Product Name	Model	GTIN
INVIVE CRT-P	W172	00802526509933
		00802526509957
		00802526509964
		00802526509988
		00802526526206
		00802526536724
		00802526539220
		00802526539244
		00802526539251
		00802526539268
		00802526566714
		00802526566721
INVIVE CRT-P	W173	00802526496547
		00802526510007
		00802526510021
		00802526510038
		00802526510045
		00802526510069
		00802526510076
		00802526510083
		00802526510090
		00802526526237
		00802526536731
		00802526539275
		00802526539282
		00802526539299
		00802526539305
		00802526539312
		00802526555770
		00802526563140
		00802526566738
		00802526566745
INTUA CRT-P	W273	00802526501593
		00802526501609
		00802526501616
		00802526555787
		00802526566752
		00802526566769
INLIVEN CRT-P	W274	00802526526350
		00802526531446
		00802526531453
		00802526531460
		00802526531484

Product Name	Model	GTIN
VITALIO DR EL	J277	00802526528118
		00802526539138
		00802526539145
		00802526539152
		00802526539169
		00802526566653
		00802526566660
ADVANTIO DR EL	K064	00802526496233
		00802526516719
ADVANTIO DR EL	K084	00802526497926
		00802526509636
		00802526509643
		00802526536533
		00802526536908
		00802526543227
		00802526543623
ADVANTIO DR EL	K087	00802526535925
		00802526543258
		00802526543654
INGENIO DR EL	K174	00802526496295
		00802526536786
		00802526540363
		00802526552809

Product Name	Model	GTIN
INLIVEN CRT-P	W274	00802526531491
		00802526536762
		00802526539329
		00802526539336
		00802526539343
		00802526539350
		00802526543838
		00802526566776
		00802526566783
INLIVEN CRT-P	W275	00802526526404
		00802526531514
		00802526531521
		00802526531538
		00802526531552
		00802526531569
		00802526536779
		00802526539374
		00802526539381
		00802526539398
		00802526539404
		00802526555794
		00802526566790
		00802526566806

June 2021

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.

[1]Boston 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 tool[1], 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

[1]Available 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
ESSENTIO Pacemaker	L100	00802526558900
		00802526558917
		00802526571923
		00802526576300
		00802526576805
		00802526593109
ESSENTIO Pacemaker	L101	00802526558924
		00802526558931
		00802526576317
		00802526576812
ESSENTIO Pacemaker	L110	00802526558948
		00802526558955
		00802526571985
		00802526576324
		00802526576829
ESSENTIO Pacemaker	L111	00802526558962
		00802526558979
		00802526572012
		00802526576331
		00802526576836
ESSENTIO Pacemaker	L121	00802526558986
		00802526558993
		00802526572043
		00802526576348
		00802526576843
ESSENTIO Pacemaker	L131	00802526559006
		00802526559013
		00802526572081
		00802526576355
PROPONENT Pacemaker	L200	00802526559020
		00802526559037
		00802526572104
		00802526576362
		00802526578007
PROPONENT Pacemaker	L201	00802526559044
		00802526559051
		00802526576379
PROPONENT Pacemaker	L201	00802526576874
		00802526578014
PROPONENT Pacemaker	L209	00802526559068

Product Name	Model	GTIN
ACCOLADE Pacemaker	L310	00802526559204
		00802526559211
		00802526572364
		00802526576454
		00802526576959
		00802526578069
ACCOLADE Pacemaker	L311	00802526559228
		00802526559235
		00802526572395
		00802526576461
		00802526578076
ACCOLADE Pacemaker	L321	00802526559242
		00802526559259
		00802526572425
		00802526572432
		00802526576478
ACCOLADE Pacemaker	L331	00802526559266
		00802526559273
		00802526572456
		00802526576485
		00802526578083
		00802526592201
ALTRUA 2 Pacemaker	S701	00802526559327
		00802526559334
		00802526572487
		00802526576492
		00802526576997
		00802526578090
ALTRUA 2 Pacemaker	S702	00802526559341
		00802526559358
		00802526576508
		00802526577000
		00802526578106
		00802526593208
ALTRUA 2 Pacemaker	S722	00802526559365
		00802526559372
		00802526576515
ALTRUA 2 Pacemaker	S722	00802526577017
		00802526578113
VALITUDE CRT-P	U125	00802526559389

Product Name	Model	GTIN	Product Name	Model	GTIN
PROPONENT Pacemaker	L209	00802526576386	VALITUDE CRT-P	U125	00802526559396
PROPONENT Pacemaker	L210	00802526559082			00802526573101
		00802526572180			00802526577109
		00802526576393			00802526578793
		00802526576898	VALITUDE CRT-P	U128	00802526559402
		00802526578021			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			