Field Safety Notice

Rhythm Management
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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.

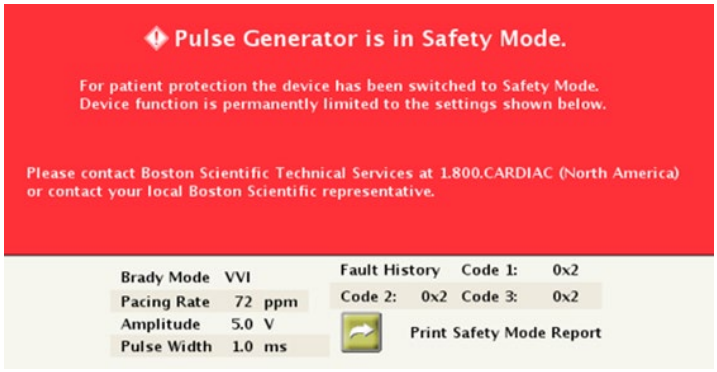

Figure 1. Programmer Warning Screen for Safety Mode

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

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
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

Appendix A: Affected Product Names/Models/Part Numbers

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
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

Appendix A: Affected Product Names/Models/Part Numbers

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
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

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