Boston Scientific International S.A.
EMEA Headquarters
Siège social : Parc du Val Saint Quentin – 2 rue René Caudron
78960 Voisins le Bretonneux – France
Tel 33 (0)1 39 30 97 00
Fax 33 (0)1 39 30 97 99
www.bostonscientific.com

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Urgent Field Safety Notice
INGENIO EL and CRT-P Battery High Impedance Update

Subject: **Field Safety Notice –** Update to the June 2021 High Battery Impedance Advisory in INGENIO™, VITALIO™, and ADVANTIO™ dual chamber (DR) extended life (EL) pacemakers and INLIVEN™, INTUA™, and INVIVE™ cardiac resynchronization therapy pacemakers (CRT-Ps). Boston Scientific Field Action Reference: 92705305D-FA**.**

Summary

Since the original June 2021 communication, additional information is available about the potential for the approximately 38,000 remaining INGENIO family of DR EL pacemakers and CRT-Ps[1] to exhibit a high battery impedance later in device life and initiate Safety Mode. None of these affected devices remain available for implant.

- The occurrence rate for this behavior is up to 8% at 9 years, 12% at 10 years, and 49% at 11 years.
  - Most Safety Mode reports continue to be associated with telemetry operations. However, approximately 3.5% of reports are unrelated to interrogations by an external device, such as a programmer, LATITUDE Communicator, or LATITUDE Consult™[2].
  - There have been 15 reports of a pause in pacing in older devices with less battery capacity experiencing extended transitions into Safety Mode (up to approximately 20 seconds) during telemetry operations with an external device.
  - When Safety Mode is initiated due to high battery impedance, previously reported battery time remaining estimates are invalid because they were determined without accounting for Safety Mode's increased outputs or the battery's high impedance state.
- For patients who are at risk for harm related to this behavior, Boston Scientific continues to recommend replacement of affected DR EL pacemakers when the battery has 4 years (or less) remaining and in CRT-Ps when 3 years (or less) remain.
- There is a potential for life-threatening harm in patients whose cardiac condition may not be optimally supported via Safety Mode parameters. Recommendations from the June 2021 communication included a replacement interval for patients who are at risk for harm. There have been three (3) deaths in pacemaker-dependent patients associated with this behavior; all were within the recommended replacement interval. The potential for life-threatening harm for the affected population is 1 in 769 (0.13%) at 11 years, which may be mitigated if devices are replaced per the recommendations below.

[1]The INGENIO family of EL pacemakers/CRT-Ps includes: VITALIO™ dual-chamber rate response (DR) EL, INGENIO™ DR EL, and ADVANTIO™ DR EL pacemakers and INLIVEN™, INTUA™, and INVIVE™ CRT-Ps. (See Appendix A for list of affected devices).
[2]LATITUDE Consult is only available in the United States (US)

Dear Physician or Healthcare Professional (HCP),

This letter provides updated information about the June 2021 product advisory for INGENIO family of DR EL pacemakers and CRT-Ps. You are receiving this letter because our records indicate you may be following one or more of the approximately 38,000 remaining active, affected devices (Appendix A). No affected devices remain available for implant. Please distribute a copy of this letter to all other HCPs within your organization who need to be aware of this update.

Description:
In June 2021, Boston Scientific notified HCPs regarding reports of the INGENIO family of DR EL pacemakers and CRT-Ps (Appendix A) transitioning to Safety Mode during interrogation attempts by either a programmer or a LATITUDE Communicator. The INGENIO family of Standard Life (SL) devices are not affected by this advisory. The SL devices are built with a different battery and have not exhibited this behavior.

As previously shared in June 2021, investigation has shown that the battery impedance increases over time in affected devices, influenced by implant duration and power usage. This increased battery impedance may cause a device to exhibit transient voltage decreases during periods of high-power consumption (e.g., interrogation by a programmer). If the battery voltage drops below a minimum threshold during a high-power state, a system reset is automatically performed, and the conditions of the high-power state are interrupted. Subsequent high-power states 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 enter Safety Mode to maintain back-up pacing with pre-defined, non-programmable settings (Table 1). When a device is in Safety Mode, HCPs are directed to contact Boston Scientific via a programmer warning screen and LATITUDE alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available.

Table 1: Per the Instructions For Use (IFU), Safety Mode is intended to provide life-sustaining therapy if repeated system resets occur with the following pre-defined, non-programmable parameters. A device that enters Safety Mode should be replaced.

Mode	VVI, biventricular pacing for CRT-Ps
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/LV Unipolar sensing/pacing
RVRP	250 ms
Noise response	VOO
LV Offset (CRT-Ps only)	0 ms
Magnet Response	Disabled

As previously shared in June 2021, the susceptibility of experiencing a high battery impedance and entering Safety Mode is increased when an affected device reaches approximately three or four years of remaining battery longevity. All INGENIO family of DR 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.

Since June 2021, the affected device population has aged, and additional post-market surveillance data has been collected.

- The occurrence rate for this behavior is up to 8% at 9 years, 12% at 10 years, and 49% at 11 years.
- Most Safety Mode reports continue to be associated with telemetry operations involving an external device. However, approximately 3.5% of reports are unrelated to telemetry operations with an external device and may occur in an ambulatory setting by transient voltage drops during normal, higher power device operations such as automatic radio frequency telemetry circuit enablement and automatic memory checks.
- There have been 15 reports of a pause in pacing in older devices with less battery capacity experiencing extended transitions into Safety Mode (up to approximately 20 seconds) during telemetry operations with an external device. Thirteen (13) were associated with in-person programmer/Consult interrogations, and two (2) were associated with a LATITUDE patient initiated interrogation (PII)[1].
- When Safety Mode is initiated due to this behavior, previously reported battery time remaining estimates are invalid because they were determined without accounting for Safety Mode's increased outputs or the battery's high impedance state.

Clinical Impact:

Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. The 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).

The most common clinical outcome of this behavior is early device replacement. In certain patients, Safety Mode may result in unintended clinical impact such as pacing inhibition/pauses, muscle stimulation (e.g., skeletal muscle or phrenic nerve stimulation), or heart failure prior to device replacement. The worst-case reported patient harm has been loss of pacing with serious injury or life-threatening outcome. There have been three (3) deaths in pacemaker dependent patients whose affected devices were within the recommended replacement interval. The potential for life-threatening harm for the affected population is 1 in 769 (0.13%) at 11 years, which may be mitigated if devices are replaced per the recommendations below.

Recommendations:

1- Individual patient evaluation. Identify patients who are at risk of harm due to Safety Mode's non-programmable parameters.

[1]A feature within the LATITUDE Patient Management System that allows non-scheduled patient initiated interrogations with the same data as a scheduled follow-up interrogation. Clinic users may enable or disable PIIs.

2- Replacement:

- If a device enters Safety Mode, perform emergent replacement for patients who are at risk of harm. For other patients, non-emergent replacement is recommended. When choosing a replacement interval, do not rely on previously reported battery time remaining estimates which do not account for Safety Mode's increased outputs nor the battery's high impedance state.
- General prophylactic replacement is not recommended. For patients who are at risk of harm, device replacement is recommended as follows:
  - For DR EL pacemakers, schedule replacement when the longevity remaining is 4 years or less.
  - For CRT-Ps, schedule replacement when the longevity remaining is 3 years or less.

Note: There is a potential for pacing pauses during in-person checks and LATITUDE PII in patients at risk of harm who remain implanted beyond the recommended replacement interval. During in-person device checks, consider patient recumbency and availability of resuscitation equipment with qualified personnel. Consider disabling PII for patients on LATITUDE.

3- Follow-up interval: Perform system follow-up in accordance with the instructions for use:

- Perform a system follow-up via remote or in-office interrogation at least every 12 months; and
- When longevity reaches One-Year-Remaining, follow-up every three (3) months thereafter until replacement is indicated.

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.

5- Adverse events should be reported to Boston Scientific.

6- Please **complete the enclosed Acknowledgment Form** and **send it to Boston Scientific at «Customer_Service_Fax_Number» by 22 December 2023.** A completed form is required from every facility who receives this letter.

Additional Information:
Your Competent Authority is being notified of this Field Safety Notice.
Patient safety remains Boston Scientific's highest priority, and we are committed to communicating up-to-date information with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. 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,

[redacted]

Appendix A: Affected Product Names/Models/Part Numbers (No changes from June 2021)

Product Name	Model	GTIN	Product Name	Model	GTIN	Product Name	Model	GTIN
ADVANTIO EL DR	J064	00802526566141	INGENIO DR EL	J174	00802526540073	ADVANTIO EL DR	K087	00802526543654
ADVANTIO EL DR	J064	00802526496011	INGENIO DR EL	J174	00802526555657	ADVANTIO EL DR	K087	00802526535925
ADVANTIO EL DR	J064	00802526508868	INGENIO DR EL	J174	00802526563102	ADVANTIO EL DR	K087	00802526543258
ADVANTIO EL DR	J064	00802526508912	INGENIO DR EL	J174	00802526566356	INGENIO DR EL	K174	00802526552809
ADVANTIO EL DR	J064	00802526508936	INGENIO DR EL	J174	00802526566363	INGENIO DR EL	K174	00802526496295
ADVANTIO EL DR	J064	00802526516429	INGENIO DR EL	J177	00802526496103	INGENIO DR EL	K174	00802526536786
ADVANTIO EL DR	J064	00802526525384	INGENIO DR EL	J177	00802526516542	INGENIO DR EL	K174	00802526540363
ADVANTIO EL DR	J064	00802526538643	INGENIO DR EL	J177	00802526518423	INGENIO DR EL	K184	00802526509698
ADVANTIO EL DR	J064	00802526538667	INGENIO DR EL	J177	00802526518430	INGENIO DR EL	K184	00802526509704
ADVANTIO EL DR	J064	00802526539619	INGENIO DR EL	J177	00802526518454	INGENIO DR EL	K184	00802526509711
ADVANTIO EL DR	J064	00802526539626	INGENIO DR EL	J177	00802526518478	INGENIO DR EL	K184	00802526536809
ADVANTIO EL DR	J064	00802526539640	INGENIO DR EL	J177	00802526518485	INGENIO DR EL	K184	00802526536915
ADVANTIO EL DR	J064	00802526555619	INGENIO DR EL	J177	00802526525742	INGENIO DR EL	K184	00802526543289
ADVANTIO EL DR	J064	00802526566158	INGENIO DR EL	J177	00802526539022	INGENIO DR EL	K184	00802526543685
ADVANTIO EL DR	J067	00802526538759	INGENIO DR EL	J177	00802526539046	INGENIO DR EL	K187	00802526535956
ADVANTIO EL DR	J067	00802526566233	INGENIO DR EL	J177	00802526539053	INGENIO DR EL	K187	00802526543319
ADVANTIO EL DR	J067	00802526496042	INGENIO DR EL	J177	00802526539060	INGENIO DR EL	K187	00802526543715
ADVANTIO EL DR	J067	00802526516450	INGENIO DR EL	J177	00802526540233	VITALIO DR EL	K274	00802526536557
ADVANTIO EL DR	J067	00802526518140	INGENIO DR EL	J177	00802526540240	VITALIO DR EL	K277	00802526528040
ADVANTIO EL DR	J067	00802526518157	INGENIO DR EL	J177	00802526540257	VITALIO DR EL	K284	00802526536571
ADVANTIO EL DR	J067	00802526518171	INGENIO DR EL	J177	00802526540271	VITALIO DR EL	K287	00802526528071
ADVANTIO EL DR	J067	00802526518195	INGENIO DR EL	J177	00802526540288	VITALIO DR EL	K287	00802526528170
ADVANTIO EL DR	J067	00802526525506	INGENIO DR EL	J177	00802526543425	VITALIO DR EL	K287	00802526543340
ADVANTIO EL DR	J067	00802526538728	INGENIO DR EL	J177	00802526555688	INVIVE CRT-P	V172	00802526496479
ADVANTIO EL DR	J067	00802526538742	INGENIO DR EL	J177	00802526563133	INVIVE CRT-P	V172	00802526536625
ADVANTIO EL DR	J067	00802526539817	INGENIO DR EL	J177	00802526566516	INVIVE CRT-P	V173	00802526496486
ADVANTIO EL DR	J067	00802526539824	INGENIO DR EL	J177	00802526566523	INVIVE CRT-P	V173	00802526536632
ADVANTIO EL DR	J067	00802526539831	VITALIO DR EL	J274	00802526566592	INVIVE CRT-P	V173	00802526540387
ADVANTIO EL DR	J067	00802526539855	VITALIO DR EL	J274	00802526566608	INVIVE CRT-P	V182	00802526498121
ADVANTIO EL DR	J067	00802526539862	VITALIO DR EL	J274	00802526501531	INVIVE CRT-P	V182	00802526509858
ADVANTIO EL DR	J067	00802526555640	VITALIO DR EL	J274	00802526501548	INVIVE CRT-P	V182	00802526509865
ADVANTIO EL DR	J067	00802526566301	VITALIO DR EL	J274	00802526501555	INVIVE CRT-P	V182	00802526536922
INGENIO DR EL	J174	00802526496073	VITALIO DR EL	J274	00802526555718	INVIVE CRT-P	V182	00802526543364
INGENIO DR EL	J174	00802526509339	VITALIO DR EL	J277	00802526516627	INVIVE CRT-P	V182	00802526543777
INGENIO DR EL	J174	00802526509353	VITALIO DR EL	J277	00802526526022	INVIVE CRT-P	V183	00802526498138
INGENIO DR EL	J174	00802526509360	VITALIO DR EL	J277	00802526528118	INVIVE CRT-P	V183	00802526509872
INGENIO DR EL	J174	00802526509377	VITALIO DR EL	J277	00802526539138	INVIVE CRT-P	V183	00802526509889
INGENIO DR EL	J174	00802526509391	VITALIO DR EL	J277	00802526539145	INVIVE CRT-P	V183	00802526536656
INGENIO DR EL	J174	00802526509407	VITALIO DR EL	J277	00802526539152	INVIVE CRT-P	V183	00802526536939
INGENIO DR EL	J174	00802526509414	VITALIO DR EL	J277	00802526539169	INVIVE CRT-P	V183	00802526543371
INGENIO DR EL	J174	00802526516511	VITALIO DR EL	J277	00802526566653	INVIVE CRT-P	V183	00802526543784
INGENIO DR EL	J174	00802526525629	VITALIO DR EL	J277	00802526566660	INTUA CRT-P	V272	00802526536663
INGENIO DR EL	J174	00802526538810	ADVANTIO EL DR	K064	00802526496233	INTUA CRT-P	V273	00802526536670
INGENIO DR EL	J174	00802526538827	ADVANTIO EL DR	K064	00802526516719	INLIVEN CRT-P	V284	00802526543388
INGENIO DR EL	J174	00802526538834	ADVANTIO EL DR	K084	00802526497926	INLIVEN CRT-P	V285	00802526536717
INGENIO DR EL	J174	00802526538841	ADVANTIO EL DR	K084	00802526536533	INLIVEN CRT-P	V285	00802526543395
INGENIO DR EL	J174	00802526540028	ADVANTIO EL DR	K084	00802526536908	INVIVE CRT-P	W172	00802526526206
INGENIO DR EL	J174	00802526540035	ADVANTIO EL DR	K084	00802526509636	INVIVE CRT-P	W172	00802526566714
INGENIO DR EL	J174	00802526540042	ADVANTIO EL DR	K084	00802526509643	INVIVE CRT-P	W172	00802526496530
INGENIO DR EL	J174	00802526540059	ADVANTIO EL DR	K084	00802526543227	INVIVE CRT-P	W172	00802526509896
INGENIO DR EL	J174	00802526540066	ADVANTIO EL DR	K084	00802526543623	INVIVE CRT-P	W172	00802526509919

Product Name	Model	GTIN	Product Name	Model	GTIN
INVIVE CRT-P	W172	802526509926	INLIVEN CRT-P	W275	802526555794
INVIVE CRT-P	W172	802526509933	INLIVEN CRT-P	W275	802526526404
INVIVE CRT-P	W172	802526509957	INLIVEN CRT-P	W275	802526531514
INVIVE CRT-P	W172	802526509964	INLIVEN CRT-P	W275	802526531521
INVIVE CRT-P	W172	802526509988	INLIVEN CRT-P	W275	802526531538
INVIVE CRT-P	W172	802526536724	INLIVEN CRT-P	W275	802526531552
INVIVE CRT-P	W172	802526539220	INLIVEN CRT-P	W275	802526531569
INVIVE CRT-P	W172	802526539244	INLIVEN CRT-P	W275	802526536779
INVIVE CRT-P	W172	802526539251	INLIVEN CRT-P	W275	802526539374
INVIVE CRT-P	W172	802526539268	INLIVEN CRT-P	W275	802526539381
INVIVE CRT-P	W172	802526566721	INLIVEN CRT-P	W275	802526539398
INVIVE CRT-P	W173	802526566738	INLIVEN CRT-P	W275	802526539404
INVIVE CRT-P	W173	802526496547	INLIVEN CRT-P	W275	802526566790
INVIVE CRT-P	W173	802526510007	INLIVEN CRT-P	W275	802526566806
INVIVE CRT-P	W173	802526510021			
INVIVE CRT-P	W173	802526510038			
INVIVE CRT-P	W173	802526510045			
INVIVE CRT-P	W173	802526510069			
INVIVE CRT-P	W173	802526510076			
INVIVE CRT-P	W173	802526510083			
INVIVE CRT-P	W173	802526510090			
INVIVE CRT-P	W173	802526526237			
INVIVE CRT-P	W173	802526536731			
INVIVE CRT-P	W173	802526539275			
INVIVE CRT-P	W173	802526539282			
INVIVE CRT-P	W173	802526539299			
INVIVE CRT-P	W173	802526539305			
INVIVE CRT-P	W173	802526539312			
INVIVE CRT-P	W173	802526555770			
INVIVE CRT-P	W173	802526563140			
INVIVE CRT-P	W173	802526566745			
INTUA CRT-P	W273	802526555787			
INTUA CRT-P	W273	802526566752			
INTUA CRT-P	W273	802526566769			
INTUA CRT-P	W273	802526501593			
INTUA CRT-P	W273	802526501609			
INTUA CRT-P	W273	802526501616			
INLIVEN CRT-P	W274	802526566776			
INLIVEN CRT-P	W274	802526566783			
INLIVEN CRT-P	W274	802526526350			
INLIVEN CRT-P	W274	802526531446			
INLIVEN CRT-P	W274	802526531453			
INLIVEN CRT-P	W274	802526531460			
INLIVEN CRT-P	W274	802526531484			
INLIVEN CRT-P	W274	802526531491			
INLIVEN CRT-P	W274	802526536762			
INLIVEN CRT-P	W274	802526539329			
INLIVEN CRT-P	W274	802526539336			
INLIVEN CRT-P	W274	802526539343			
INLIVEN CRT-P	W274	802526539350			
INLIVEN CRT-P	W274	802526543838			

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

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

Acknowledgement Form – Urgent Field Safety Notice

INGENIO EL and CRT-P Battery High Impedance Update

92705305D-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 30 November 2023 for

INGENIO EL and CRT-P Battery High Impedance Update.

NAME* _____ Title _____

Telephone _____ Email _____

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