Boston Scientific Safety Alert: High Battery Impedance May Initiate Safety Mode in INGENIO™ Family DR EL Pacemakers and CRT-Ps

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

Urgent Implant Hazard Alert

High Battery Impedance INGENIO™, VITALIO™, and ADVANTIO™ dual chamber (DR) extended life (EL) pacemakers and INLIVEN™, and INVIVE™ cardiac resynchronization therapy pacemakers (CRT-Ps)

Wand listing: 120228-WAND-6CTVWA, 121115-WAND-6EDSPQ, 120228-WAND-6CTVYL, 121115-WAND-6EDSX0, 130829-WAND-6G3BQR, 120228-WAND-6CTVZ9, 120518-WAND-6DB010, 130829-WAND-6G3BSB, 130829-WAND-6G3BSS

Medsafe Reference Number 32199

December 2023

Subject Safety Alert: Update to the June 2021 High Battery Impedance Safety Alert Alert (Medsafe reference # 27824) in INGENIO™, VITALIO™, and ADVANTIO™ dual chamber (DR) extended life (EL) pacemakers and INLIVEN™, 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 worldwide of the 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 or 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-

[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)

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.

- Please complete and return the attached mandatory acknowledgement form to the following Boston Scientific email address: anz_incident_report@bsci.com

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Dear Physician or Healthcare Professional (HCP),

This letter provides updated information about the June 2021 Safety Alert 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. Please complete and return the attached acknowledgement form the following Boston Scientific email address: anz_incident_report@bsci.com.

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 Safety Alert. 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)[3].
- 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.

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

[3]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.

- 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.

Adverse events should be reported to Boston Scientific. Please complete and return the attached mandatory acknowledgement form to Boston Scientific. When completed, please return the form to the following Boston Scientific email address: anz_incident_report@bsci.com

Additional Information
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.

Please note, This recall action is being taken in consultation with Medsafe, Ministry of Health

Yours sincerely,

Seamus Gallagher

Quality Assurance Manager

Boston Scientific Pty Ltd Australia
and New Zealand

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Product Name	Model	GTIN
ADVANTIO DR EL	K084	00802526497926
		00802526509636
		00802526509643
		00802526536533
		00802526536908
		00802526543227
		00802526543623
ADVANTIO DR EL	K087	00802526535925
		00802526543258
		00802526543654
INGENIO DR EL	K184	00802526509698
		00802526509704
		00802526509711
		00802526536809
		00802526536915
		00802526543289
		00802526543685
INGENIO DR EL	K187	00802526535956
		00802526543319
		00802526543715
VITALIO DR EL	K287	00802526528071
		00802526528170
		00802526543340
INVIVE CRT-P	V182	00802526498121
		00802526509858
		00802526509865
		00802526536922
		00802526543364
		00802526543777
INVIVE CRT-P	V183	00802526498138
		00802526509872
		00802526509889
		00802526536656
		00802526536939
		00802526543371
		00802526543784
INLIVEN CRT-P	V284	00802526543388

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INLIVEN CRT-P	V285	00802526536717
		00802526543395