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**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

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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**

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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.

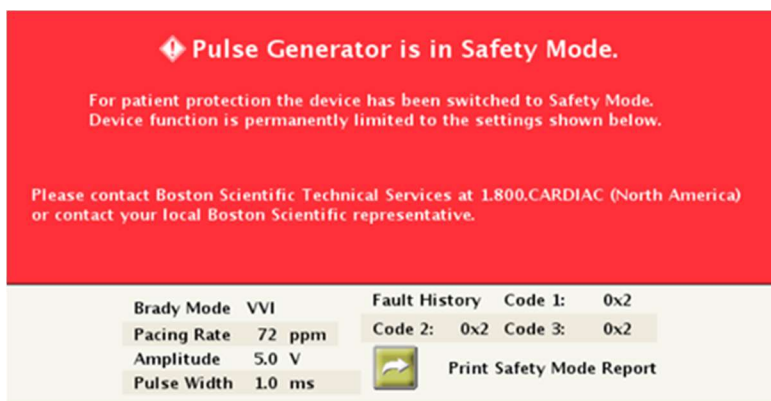


Figure 1. Programmer Warning Screen for Safety Mode

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,



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	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			00802526535956		
		00802526539619	INGENIO DR EL	K187	00802526543319		
		00802526539626			00802526543715		
		00802526539640	VITALIO DR EL	K274	00802526536557		
		00802526555619	VITALIO DR EL	K277	00802526528040		
		00802526566141	VITALIO DR EL	K284	00802526536571		
		00802526566158			00802526528071		
		ADVANTIO DR EL	J067	00802526496042	VITALIO DR EL	K287	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					
INGENIO DR EL	J174	00802526496073			00802526543784		
		00802526509339	INTUA CRT-P	V272	00802526536663		
		00802526509353	INTUA CRT-P	V273	00802526536670		
		00802526509360	INLIVEN CRT-P	V284	00802526543388		
		00802526509377	INLIVEN CRT-P	V285	00802526536717		
		00802526509391			00802526543395		
		00802526509407	INVIVE CRT-P	W172	00802526496530		
		00802526509414			00802526509896		
		00802526516511			00802526509919		
		00802526525629			00802526509926		
		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
		INGENIO DR EL			J177
00802526516542	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				
VITALIO DR EL	J274		00802526501531	INTUA CRT-P	
		00802526501548	00802526501609		
		00802526501555	00802526501616		
		00802526555718	00802526555787		
		00802526566592	00802526566752		
		00802526566608	00802526566769		
VITALIO DR EL	J277	00802526516627	INLIVEN CRT-P	W274	00802526526350
		00802526526022			00802526531446
					00802526531453
					00802526531460
					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			