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Product Correction and Hazard Alert

ACCOLADE™ dual chamber (DR) standard life (SL) and DR extended life (EL) pacemakers; and VISIONIST™ cardiac resynchronization therapy pacemakers (CRT-Ps)

WAND: 141118-WAND-6IQY2P, 141118-WAND-6IQY0P, 141118-WAND-6IQYDZ, 141118-WAND-6IQYEK, 141118-WAND-6IQYF4

Medsafe Reference Number: 34338

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To: Physicians/Surgeons, Hospitals, Healthcare Professionals

Subject: Field Safety Notice – Boston Scientific has identified a subpopulation of ACCOLADE™ dual chamber (DR) standard life (SL) and DR extended life (EL) pacemakers; and VISIONIST™ cardiac resynchronization therapy pacemakers (CRT-Ps) with an increased potential to initiate Safety Mode during telemetry or other normal, higher-power operations due to high battery impedance (Boston Scientific Field Action Reference: 97125289C-FA).

Summary

- A subset of approximately 13% of devices from the ACCOLADE family[1], built before Sep 2018, are included in the advisory population and have an increased potential to initiate Safety Mode during telemetry or other normal, higher-power operations due to latent high battery impedance.
- The advisory population was defined based on battery cathode processing practices performed by a subset of manufacturing operators whose cathode processing techniques demonstrate higher concentration of lithium salts.
- Because the advisory devices were built before Sep 2018, there are no remaining devices within the advisory population available for implantation.
- 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).
- Occurrence rates are described below (Table 2).
- There have been two (2) reported deaths globally in pacemaker dependent patients implanted with devices from the advisory population that initiated Safety Mode in an ambulatory setting.

[1]The ACCOLADE™ family is composed of the ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 Standard Life (SL) and Extended Life (EL) pacemakers; and the VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-P). Please note that customers in New Zealand are impacted for ACCOLADE and VISIONIST models only, as per Appendix A of this letter.

- The recommendations contained herein are intended to mitigate risk for patients implanted with a device from the advisory population who are at risk of harm due to the non-programmable settings in Safety Mode.
- Refinement of operator processing techniques has reduced variability of lithium salt concentrations and improved the performance of batteries in the remaining population and contemporary devices.
- Boston Scientific is actively developing a software update for the ACCOLADE family of devices designed to detect the onset of a high impedance battery state and display a device-based alert via the LATITUDE™ programmer and remote patient management system prior to Safety Mode initiation.
- Please complete and return the attached mandatory acknowledgement form to Boston Scientific.

Dear Physician or Healthcare Professional (HCP),

This letter provides important information about a subset of pacemakers from the ACCOLADE™ family with an increased potential to initiate Safety Mode during telemetry or, in rare instances, other normal, higher-power operations due to latent, high battery impedance when the device reaches approximately four (4) years or less of remaining battery longevity. You are receiving this letter because our records indicate you have received or implanted an affected device. No devices within the advisory population 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 and complete and return the attached acknowledgement form.

Description

A subset of ACCOLADE devices, produced prior to Sep 2018, have an increased potential of exhibiting a high impedance condition because of unanticipated concentration of lithium salts resulting from variability of battery assembly techniques. This may result in a lack of available electrolyte between the battery anode and cathode.

High battery impedance may cause a device to exhibit transient voltage decreases, typically during telemetry operations or, in rare instances, during other normal high power device operations, such as automatic radio frequency telemetry circuit enablement and automatic memory checks. 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 backup 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 LATITUDE™ programmer warning screen and a LATITUDE remote patient management system red alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available. The susceptibility of experiencing a high battery impedance and entering Safety Mode has been observed when the device reaches approximately four (4) years or less of remaining battery longevity.

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

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Magnet Response	Disabled

Per the IFU, electrocautery may inhibit pacing due to oversensing and a unipolar pacing configuration applies pacing stimulus between lead tip and pacemaker case. During the replacement procedure, the Safety Mode non-programmable sensitivity setting, and unipolar pacing configuration make the system susceptible to pacing inhibition during electrocautery and removal of the device from the pocket.

During normal operations when a device is indicated for replacement, the system is designed to reserve sufficient battery capacity to support device operations for three (3) months to allow for a replacement procedure to be scheduled. However, if a device enters Safety Mode due to the high battery impedance, the reserve battery capacity may not be sufficient to support device operations for three months and should be scheduled for replacement soon thereafter or emergently for patients at risk of harm from Safety Mode parameters.

The ACCOLADE family of pacemakers includes a standard life (SL) battery for single chamber (SR) and dual chamber (DR) pacemakers and a larger, extended life (EL) battery for DR pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps). Because of disparate batteries (e.g., SL vs. EL) and therapies provided (e.g., SR/DR pacemakers vs. CRT-Ps), the occurrence rates vary. However, the susceptibility for a device to enter Safety Mode due to high battery impedance occurs when the device reaches approximately four (4) years or less of remaining battery longevity. Furthermore, the ACCOLADE family of devices includes an advisory population with an elevated likelihood of high battery impedance-induced Safety Mode compared to the remaining (non-advisory) population.

Advisory population is composed of a subset of ACCOLADE devices (see Appendix A) manufactured prior to Sep 2018 with unanticipated concentrations of lithium salts during battery cathode processing.

Table 2: ACCOLADE High Battery Impedance Advisory Population and Performance

Therapy-Battery	Occurrence rate according to implant duration				Confirmed Malfunctions	~Population
	6yr	7yr	8yr	9yr		
DR-SL	0.1%	0.3%	0.6%	0.6%	436	123,000
DR-EL	0.02%	0.1%	0.2%	0.4%	83	59,000
CRT-P-EL	0.2%	0.9%	1.6%	2.0%	178	21,000
Total					697	203,000

Remaining (non-advisory) population includes batteries built with refined processing techniques which demonstrate reduced lithium salt concentration and a significantly lower malfunction rate of approximately 0.1% at 9 years.

These performance data will be updated within Boston Scientific's Product Performance Report (PPR), available online at www.BostonScientific.com/ppr. Boston Scientific is actively developing a software update for the ACCOLADE family of devices designed to detect the onset of a high impedance battery state and display a device-based alert via the LATITUDE programmer and remote patient management system prior to Safety Mode initiation.

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). Pacing inhibition due to myopotential oversensing for unipolar sensing configurations is well documented, however, provocative

manoeuvres, including isometric exercises, are not a reliable predictor of myopotential oversensing susceptibility for patients who may transition to Safety Mode.

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 decompensation 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 two (2) deaths in pacemaker dependent patients after initiating Safety Mode in an ambulatory setting.

Approximately 70% of Safety Mode events occurred during in-office interrogations from a LATITUDE programmer and the remaining in an ambulatory setting. The risk of harm may be greater when Safety Mode occurs in an ambulatory setting as patients are not in a monitored clinical environment. Given that remote monitoring is a standard of care[2], Boston Scientific's recommendations favor prophylactically replacing devices in patients at risk of harm due to non-programmable settings in Safety Mode versus discontinuing or altering remote monitoring schedules. Remote monitoring remains a critical device management capability and will be an important means to detect onset of high battery impedance when the future software update becomes available.

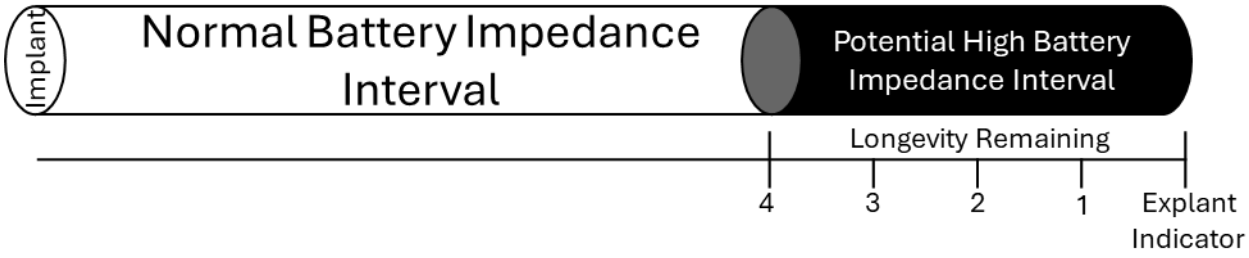
Recommendations.

1. Individual patient evaluation. Promptly identify patients within the advisory population who are at risk of harm due the non-programmable parameters in Safety Mode.

2. Replacement.
   Safety Mode. 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.

   Note: During replacement of a device in Safety Mode, pacing inhibition should be anticipated during electrocautery and when the device is removed from the pocket due to unipolar pacing and high sensitivity.

   Prophylactic. General prophylactic replacement is not recommended. For patients with a device from the advisory population AND who are at risk of harm due to non-programmable parameters in Safety Mode, schedule device replacement promptly when the longevity remaining reaches four (4) years or if the longevity remaining is already less than 4 years.



[2]In patients with Cardiovascular Implantable Electronic Devices (CIEDs), Remote Monitoring (RM) is recommended as part of the standard of care (COR-1/LOE-A) pg e99. Ferrick AM Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm, ISSN: 1547-5271, Vol: 20, Issue: 9, Page: e92-e144. https://doi.org/10.1016/j.hrthm.2023.03.1525.

If the device reaches the potential high battery impedance interval before the next scheduled follow-up, schedule an appointment with your patient prior to that interval to discuss management options using a shared decision-making approach.

Note: There is a potential for pacing pauses during in-person checks and LATITUDE patient-initiated interrogation (PII) in patients at risk of harm who remain implanted beyond the recommended replacement interval. During in-person device checks for such patients in the advisory population, consider patient recumbency and availability of resuscitation equipment with qualified personnel. Consider disabling PII for such 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 remaining 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/update the patient's medical record with this letter to maintain awareness to all follow-up physicians of this topic for the remaining service life of the device.

Boston Scientific will communicate when the software update is available to detect the onset of a high impedance battery state.

Additional Information
This action is being conducted following consultation with Medsafe, Ministry of Health.

Patient safety remains our highest priority. Although we recognize the impact of this type of communication 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. 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 an adverse event, please contact your Boston Scientific representative or Technical Services or email ANZ_Incident_Report@bsci.com.

Yours sincerely,

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Appendix A: Advisory Population Product Part Number, Model Number, and Product Names

GTIN	Model	Product Name
00802526559228	L311	ACCOLADE DR SL MRI
00802526559235	L311	ACCOLADE DR SL MRI
00802526572395	L311	ACCOLADE DR SL MRI
00802526576461	L311	ACCOLADE DR SL MRI
00802526578076	L311	ACCOLADE DR SL MRI
00802526559266	L331	ACCOLADE DR EL MRI
00802526559273	L331	ACCOLADE DR EL MRI
00802526572456	L331	ACCOLADE DR EL MRI
00802526576485	L331	ACCOLADE DR EL MRI
00802526578083	L331	ACCOLADE DR EL MRI
00802526592201	L331	ACCOLADE DR EL MRI
00802526559433	U225	VISIONIST CRT-P EL
00802526572630	U225	VISIONIST CRT-P EL
00802526577048	U225	VISIONIST CRT-P EL
00802526577116	U225	VISIONIST CRT-P EL
00802526578809	U225	VISIONIST CRT-P EL
00802526559457	U226	VISIONIST CRT-P EL
00802526559464	U226	VISIONIST CRT-P EL
00802526577062	U226	VISIONIST CRT-P EL
00802526577123	U226	VISIONIST CRT-P EL
00802526559488	U228	VISIONIST CRT-P EL MRI
00802526572692	U228	VISIONIST CRT-P EL MRI
00802526577130	U228	VISIONIST CRT-P EL MRI
00802526578830	U228	VISIONIST CRT-P EL MRI

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