Boston Scientific Corporation Building 1,
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Mascot NSW 2020

Update – Critical Product Correction and Product Alert

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

ARTG Numbers: 400400, 400396, 400399, 400403, 400404 and 400405

TGA Ref: RC-2024-RN-001116-1

March 2026

Dear Physician or Healthcare Professional (HCP),

Subject: Update to December 2024 and September 2025 Product Correction and Product Alert (TGA Ref: RC-2024-RN-001116-1) and availability of Brady software (SMR6).

You are receiving this letter to inform you

- of an update to the December 2024 Urgent Product Defect Correction and Implant Hazard Alert and September 2025 Critical Product Correction and Product Alert (TGA Ref: RC-2024-RN-001116-1) communications
- that updated software, Brady software maintenance release 6 (SMR6), is now available for the ACCOLADE™ family of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps)[1]
- that the market action population is expanding to include all CRT-P and dual-chamber extended life (DR-EL) devices.

Summary

- Brady SMR6 effectively mitigates the previously reported risk of Safety Mode in an ambulatory setting due to high battery impedance and corrects all unintended behaviours from Brady SMR5 as communicated in September 2025 (see Clinical Impact).
- However, the market action population is expanding to include all ACCOLADE CRT-P and DR-EL devices (see Appendix A) because there is a 7.6% probability of early device replacement due to high battery impedance induced wandless ZIP™ telemetry (ZIP) disablement. As a result, some devices may not achieve original, projected longevity. Early performance data for the SMR5/6 RF Disablement suggests devices with the extended life battery (DR EL and CRT-P) may be at increased risk of early explant.
- Prophylactic replacement before confirming high battery impedance is not recommended.

- Remote follow-up interval is unchanged from the Instructions For Use (IFU) and most devices followed in-person may resume normal follow-up interval after being upgraded to SMR6 (see Figure 1 and 2).
- There is a residual risk of in-clinic Safety Mode being induced by wanded telemetry. This risk applies to patients who are not monitored on the LATITUDE™ NXT Remote Patient Management System, are pacemaker dependent, and have a CRT-P or DR-EL device with three years or less longevity time remaining.

Clinical Impact

Brady SMR6 resolves the incomplete ZIP disablement behaviour and magnet-induced false-positive battery impedance test[3] previously described in the September 2025 update. For remotely monitored patients, if ZIP becomes disabled due to high battery impedance, the device will post to the LATITUDE NXT "Patient Not Monitored" page after 14 days, rather than generating a "Remote Monitoring Disabled" alert. Brady SMR6 also resolves a third unintended behaviour of SMR5 not previously described where under specific circumstances related to an interaction between competing battery diagnostics, the battery test to determine battery status and longevity time remaining can become frozen until the next programmer interrogation.

Device Longevity Impact

Any ACCOLADE device experiencing ZIP disablement by the battery impedance test due to detection of high battery impedance requires replacement before normal battery replacement is indicated. There is a 7.6% likelihood that an individual CRT-P or DR-EL device will need to be replaced early due to high battery impedance-induced ZIP disablement. For those devices, the projected reduction in longevity is 10.9% ± 9.6%[4]. 92.4% of CRT-P and DR-EL devices are expected to achieve anticipated longevity, thus the overall weighted longevity impact of high battery impedance is 1%.[5]

Given this longevity impact, Boston Scientific is expanding the market action population to include all CRT-P and DR-EL devices (see Appendix A) until additional battery impedance test refinements and updated longevity projections are available. Single-chamber (SR) and DR standard life (SL) devices are performing within anticipated longevity expectations; therefore, no population expansion is required for these devices.

Boston Scientific is developing a software update and corresponding IFU revision to improve battery impedance test performance and address the longevity impact.

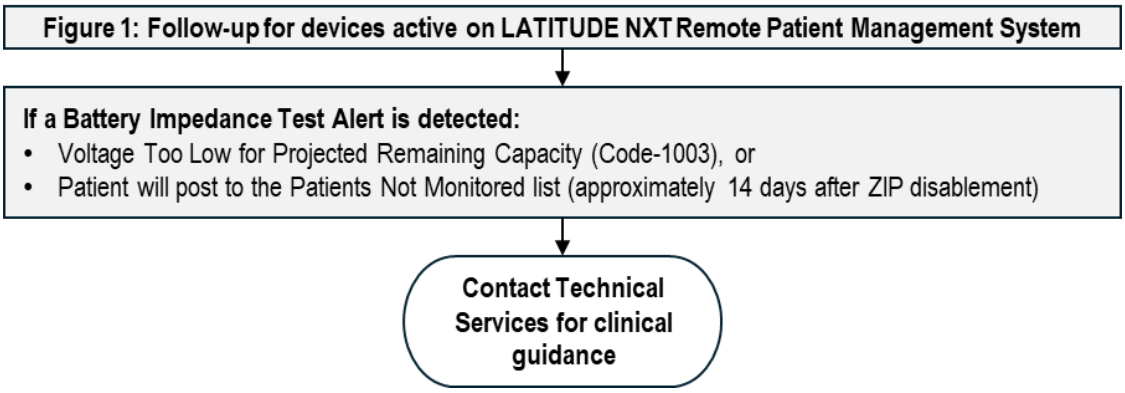
Recommendations

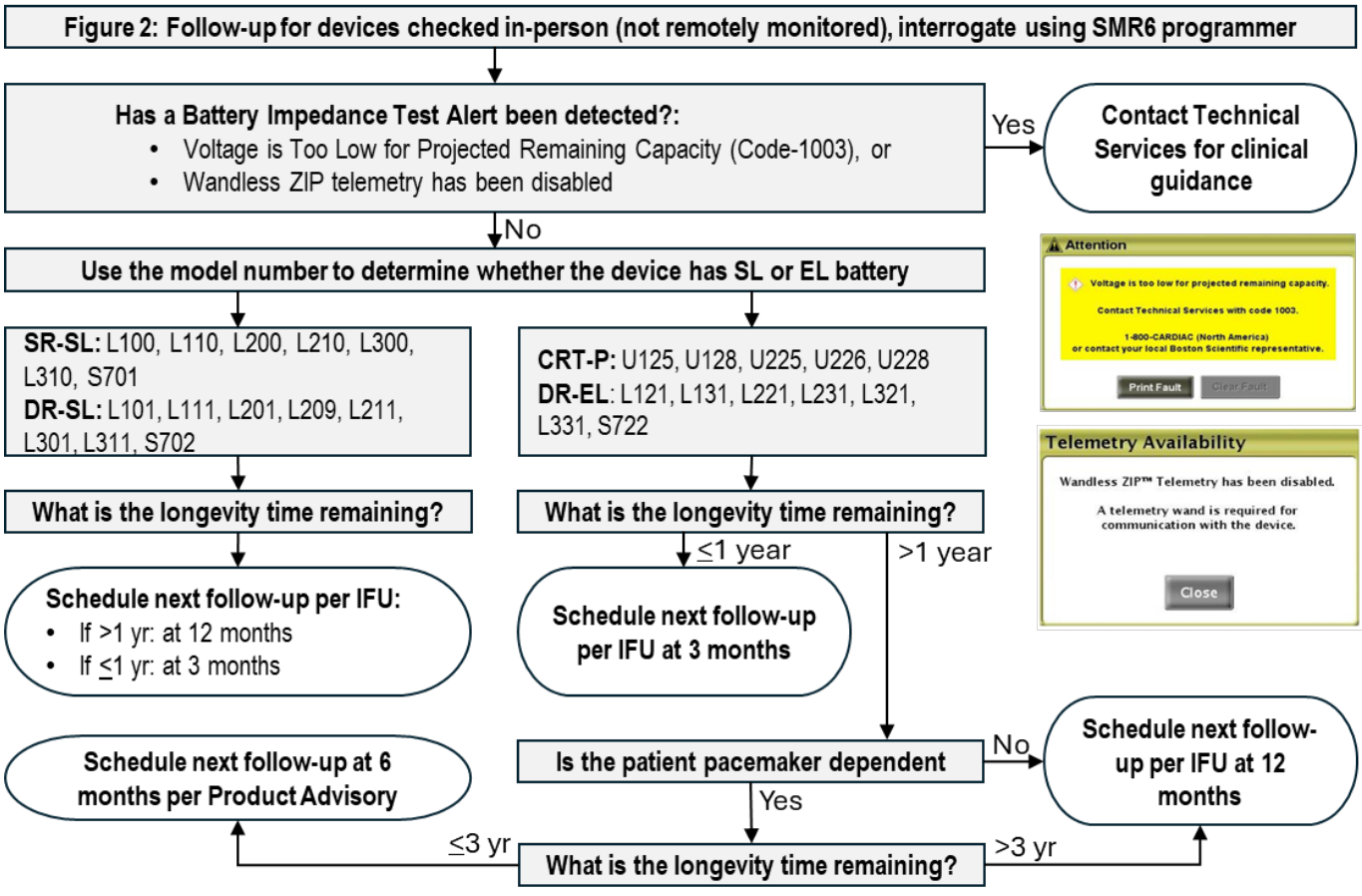
- Upgrade LATITUDE™ Model 3300 programmers with Model 3869 v2.05 software (Brady SMR6).
- Upgrade pacemaker software in-clinic by interrogating the device with a programmer upgraded with Brady SMR6 (Model 3869 v2.05).
  - Patients at risk of harm from Safety Mode who haven't already received Brady SMR5: Promptly schedule an in-person follow-up if four (4) or less years of longevity time remaining OR will reach four (4) years or less before the next scheduled follow-up.
  - Note, the footer of the device

follow-up report identifies the device firmware version. If the parenthetical at the end of the reported Firmware Version is "(3.10)" or greater, the device has been updated to either Brady SMR5 or SMR6.[2]

  - All other patients: Schedule the next in-person follow up at a frequency described in the IFU: every 12 months or every 3 months if the battery status reaches One-Year-Remaining.

- Once pacemaker software has been upgraded, follow devices using the applicable flow chart below, based on the remote monitoring status (Figure 1 and 2).
- Update the medical record for each patient with an affected device (see Appendix A) by appending this letter to ensure continuous awareness throughout the device's remaining service life.
- Complete and email your Customer Response Form(s) to ANZ_Incident_Report@bsci.com.





Additional Information

This action is being conducted following consultation with the Therapeutic Goods Administration (TGA). Please report any adverse events through the TGA website "**Reporting adverse events for medical devices | Therapeutic Goods Administration (TGA)**" and follow the prompts for health professionals.

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, a device lookup tool, and resources for returning product 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 call Technical Services (+61 2 8063 8299) or email ANZ_Incident_Report@bsci.com.

We appreciate your understanding as we take action to address this matter. At Boston Scientific, patient safety and customer satisfaction are our priority. We are committed to continuing to offer products that meet the quality standards that you expect from Boston Scientific.

Sincerely,

Seamus Gallagher

Seamus Gallagher
Senior Quality Assurance Manager | Boston Scientific Pty Ltd Australia and New Zealand

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[1]The ACCOLADE family includes ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 SR-SL, DR-SL, and DR-EL pacemakers; and VISIONIST™ and VALITUDE™ CRT-Ps
[2]Brady SMR6 Model 3869 v2.05 includes firmware revision "(3.24)" and Brady SMR5 Model 3869 v2.04 includes firmware revision "(3.10)"
[3]Boston Scientific will contact clinics with patients who have exhibited magnet-induced false positive disablement of ZIP and assist in resuming remote monitoring if desired
[4]Mean ± Standard Deviation
[5]Based on LATITUDE analysis of over 123,000 US devices in the ACCOLADE family upgraded to SMR5 for up to 3 months

Appendix A

The market action population includes all models listed below; however, the bounding differs by battery type:

- All serialised DR-EL pacemakers and CRT-Ps from the ACCOLADE family are included in the market action population.
- ACCOLADE DR-SL and SR-SLs with a use-by-date (UBD) on or before 30 June 2025 are included in the market action population. Model number alone will not precisely identify individual DR-SL or SR-SL devices in the market action population.

To determine if a device is affected, enter a model/serial into the device lookup tool at www.BostonScientific.com/lookup.

GTIN	Model	Product Name
00802526559204	L310	ACCOLADE SR SL MRI
00802526559211	L310	ACCOLADE SR SL MRI
00802526572364	L310	ACCOLADE SR SL MRI
00802526572371	L310	ACCOLADE SR SL MRI
00802526572388	L310	ACCOLADE SR SL MRI
00802526576454	L310	ACCOLADE SR SL MRI
00802526576959	L310	ACCOLADE SR SL MRI
00802526578069	L310	ACCOLADE SR SL MRI
00802526609015	L310	ACCOLADE SR SL MRI
00802526611803	L310	ACCOLADE SR SL MRI
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