Urgent Medical Device Correction

Rhythm Management
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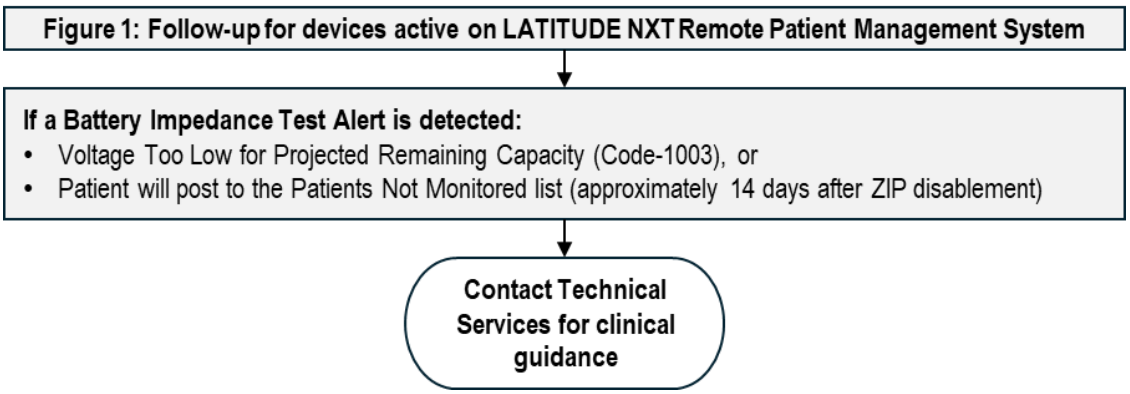
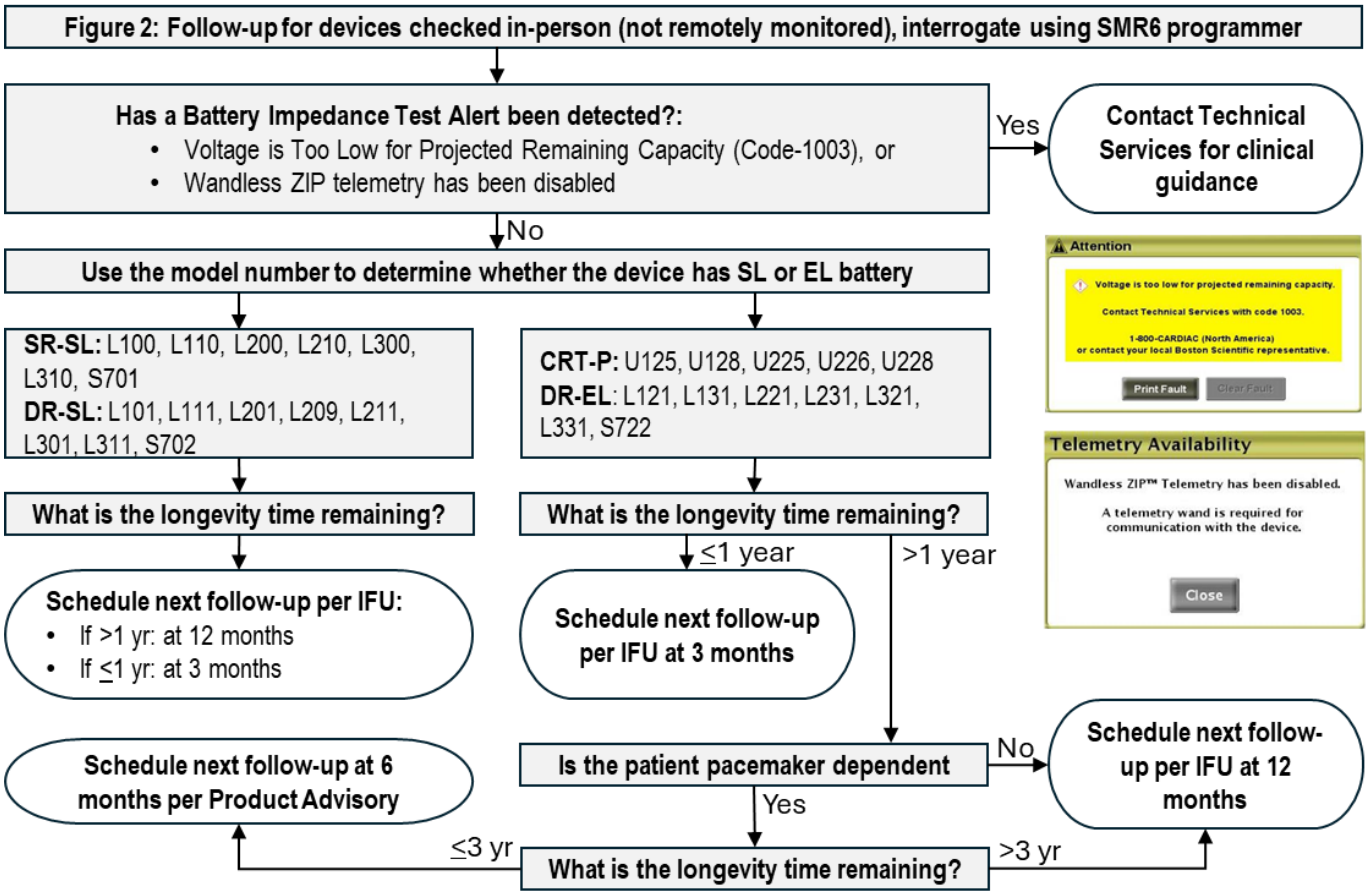
You are receiving this letter to inform you that updated software, Brady software maintenance release 6 (SMR6), is now available for the ACCOLADE™ family of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps)[1] and the advisory population is expanding to include all CRT-P and dual-chamber extended life (DR-EL) devices.

- Brady SMR6 effectively mitigates the previously reported risk of Safety Mode in an ambulatory setting due to high battery impedance and corrects all unintended behaviors from Brady SMR5 (see Clinical Impact).
- However, the advisory 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.
- 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.

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. 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.
- 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.





Clinical Impact

Brady SMR6 resolves the previously described incomplete ZIP disablement behavior and magnet-induced false-positive battery impedance test[3]. 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.

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 advisory 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.

Additional Information

The Regulatory Authority of your country has been informed of this communication. Adverse events should be reported to Boston Scientific or the FDA's MedWatch Adverse Event Reporting program.

Patient safety remains Boston Scientific's highest priority, and we are committed to communicating with physicians and healthcare professionals to ensure timely, relevant information for managing your patients. Our Product Performance Resource Center at www.bostonscientific.com/ppr, includes information on this topic, a device lookup tool, and instructions for returning explanted products. If you have additional questions, or would like to report on a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

[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 advisory population includes all models listed below; however, the bounding differs by battery type:

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

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

Model	Product Name
L100	ESSENTIO SR SL
L101	ESSENTIO DR SL
L110	ESSENTIO MRI SR SL
L111	ESSENTIO MRI DR SL
L121	ESSENTIO DR EL
L131	ESSENTIO MRI DR EL
L200	PROPONENT SR SL

Model	Product Name
L201	PROPONENT DR SL
L209	PROPONENT VDDR SL
L210	PROPONENT MRI SR SL
L211	PROPONENT MRI DR SL
L221	PROPONENT DR EL
L231	PROPONENT MRI DR EL
L300	ACCOLADE SR SL

Model	Product Name
L301	ACCOLADE DR SL
L310	ACCOLADE MRI SR SL
L311	ACCOLADE MRI DR SL
L321	ACCOLADE DR EL
L331	ACCOLADE MRI DR EL
S701	ALTRUA 2 SR SL
S702	ALTRUA 2 DR SL

Model	Product Name
S722	ALTRUA 2 DR EL
U125	VALITUDE CRT-P EL IS-1
U128	VALITUDE X4 CRT-P EL IS-1/IS4
U225	VISIONIST CRT-P EL IS-1
U226	VISIONIST CRT-P EL IS-1/LV-1
U228	VISIONIST X4 CRT-P EL IS-1/IS4