Date: March 25 2026 (Original December 13 2024, Updates August 17 2025 & October 23 2025)

Canadian Heart Rhythm Society Device Committee

RE: ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 dual chamber (DR) standard life (SL) and extended life (EL) pacemakers; and VISIONIST and VALITUDE 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

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Nature of the Advisory:

A subset of devices from the ACCOLADE family has an increased potential to initiate Safety Mode during higher-power operations due to latent high battery impedance. During normal high-power operations (e.g. telemetry) high battery impedance may cause a device to exhibit transient voltage decreases, which may trigger a system reset. 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 [unipolar RV (or BiV) sensing/pacing at VVI @ 72.5 ppm with high output (5.0V at 1.0 msec)]. Although therapy is still provided, the reset to unipolar pacing and sensing when in Safety Mode may result in adverse effects via myopotential oversensing-associated pacing inhibition, loss of AV/VV synchrony, and muscle stimulation. Among patients at risk of harm, a 52% rate of major complications due to presyncope, syncope, fall with trauma, pauses/asystole, and death has been reported in those whose pacemaker initiates Safety Mode.

Scope of the problem:

The original advisory population at a higher risk of this malfunction constituted a subset of ACCOLADE family of devices built before Sep 2018. This population was manufactured with battery cathode processing practices that demonstrate higher concentration of lithium salts, which, over time, may lead to high battery impedance. 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. This population continues to have the highest occurrence rate for the behavior (up to ~3.3% at 117-158 months in the original advisory population vs. up to ~1.2% at 117-158 months in the October 2025 updated advisory population).

Following the August 2025 update, Boston Scientific released Brady software maintenance release 5 (SMR5; Model 3869 v2.04), which enables detection of an elevated battery impedance. When 4 out of 5 consecutive daily measurements are out of range, the device initiates a Code-1003 alert. When a single daily battery test measurement is <2.1V then wandless ZIP™ telemetry is disabled (wanded telemetry remains available). The intent was to prevent pacemakers in the ACCOLADE family from initiating Safety Mode in an ambulatory setting due to a high battery impedance state. However, Brady SMR5 only disables active ZIP telemetry. The ZIP wakeup state (short telemetry activations to determine if a LATITUDE communicator is trying to interrogate) remains enabled, which may still trigger safety mode.

A new software update, Brady SMR6 (Model 3869, v2.05), is now available in Canada to address this residual risk of safety mode being triggered. Furthermore, the new software update also addresses other identified issues, including false-positive high battery impedance results during magnet application, as well as rare occurrences of erroneously static battery voltage measurements.

Expansion of Advisory Population (2026)

ACCOLADE family CRT-P and EL devices have been associated with a higher than anticipated likelihood of requiring early replacement due to ZIP™ telemetry disablement, so Boston Scientific has expanded the advisory recommendations to include all CRT-P and DR-EL devices. While the majority (92.4%) of these CRT-P and DR-EL devices are expected to achieve anticipated longevity, it is estimated that 7.6% will require early replacement with a projected longevity reduction of 10.9% ± 9.6%. There is no expansion of the advisory for ACCOLADE DR-SL, and SR-SL devices, which continues to include those with a use-by-date on or before 30 June 2025.

Response of the CHRS Device Committee (*Updated*):

- As part of this formal advisory, we recommend that patients with a device affected by this advisory in the expanded population be notified about this potential issue.

- **For patients where a new implant of a device subject to advisory is being contemplated**, it is the recommendation of the CHRS Device committee that the following occur as part of the consent process:
    1. Patients must be informed of nature of the advisory **prior to device implantation**.
    2. Patients must be informed of the risks associated with implantation of an advisory device (as outlined above).
    3. Patients must be offered an alternate device not subject to advisory.
    4. Patients must be informed of the risks associated with implantation of an alternate device (e.g. lack of MRI conditionality in the case of mixed vendor systems at time of generator replacement).

- Patients with an ACCOLADE family pacemaker or CRT-P should be brought into the clinic for an in person visit to receive the software update from a Model 3300 LATITUDE programmer installed with Model 3869 v2.05 software (Brady SMR6).
    - Patients who have not received the previous Brady SMR5 update and with ≤ 4 years of remaining battery longevity should promptly receive the software update (i.e. be prioritised to receive the software update) and be enrolled in remote monitoring. Priority should be especially given to those at increased risk of harm if they enter Safety Mode.
    - All other patients should receive the Brady SMR6 software update at their next routine follow-up

- Prophylactic device generator replacement is no longer recommended for individuals with a device affected by this advisory who receive the enhanced software.

- Following software update with Brady SMR6:
    - Patients on remote monitoring can receive their usual follow-up schedule
    - Patients not on remote monitoring should receive follow-up at 12 months, unless:
        - battery longevity 1 – 3 years *and* pacemaker dependent with CRT-P or DR-EL: follow-up at 6 months
        - If battery longevity ≤ 1 year: follow-up at 3 months

- If a device detects a high battery impedance state (e.g. Code-1003), and the battery impedance continues rising, the device will disable wandless ZIP telemetry to prevent Safety Mode initiation.

- If a Code-1003 alert or wandless ZIP telemetry disablement warning message is observed, or if patients being remotely monitored are found on the "Patients Not Monitored" list, contact Boston Scientific technical services for a customized recommended replacement interval.
    - *The appearance of a Code-1003 warning lacks specificity in predicting ZIP™ telemetry disablement, and technical support may advise further observation in this scenario prior to device replacement upon review of battery impedance trends.*

- *However, in patients where ZIP™ telemetry is found to have been disabled by the battery impedance test, device replacement is usually indicated. Remotely monitored patients with ZIP™ telemetry disablement can be identified under the LATITUDE NXT "Patient Not Monitored" page after 14 days of lack of remote communication with the affected device.*
- *If device replacement is recommended, then this should be expedited to reduce the risk of safety mode switches with in-clinic wanded telemetry, in addition to restoring full functionality of RF telemetry and remote monitoring.*

- The CHRS device committee may update these recommendations should more data become available.

CHRS Device Committee

Clarence Khoo, MD (Chair, CHRS Device Committee)
Jason Andrade, MD
Derek Chew, MD
Jaimie Manlucu, MD
Hugo-Pierre Racine, MD
Calum Redpath, MBChB
Martin Van Zyl, MD

Urgent Medical Device Correction

Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

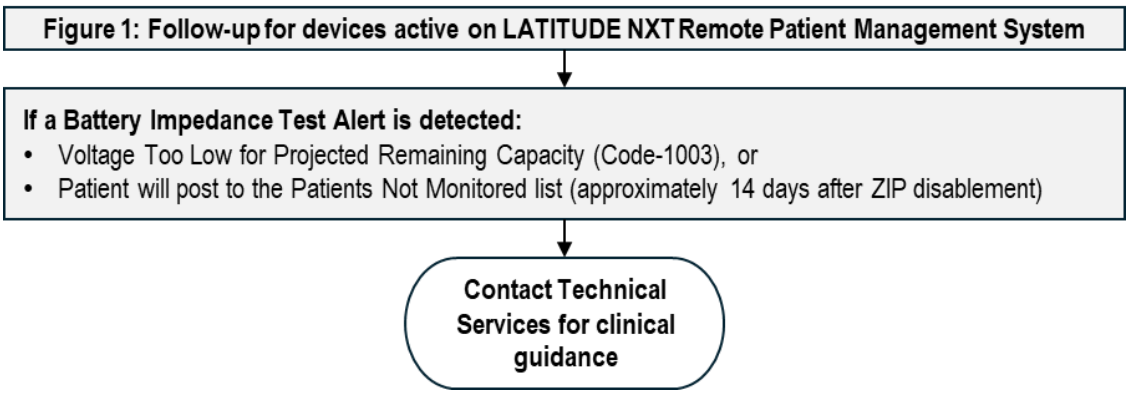
March 2026, Field Action Reference: 97125289H-1-FA.

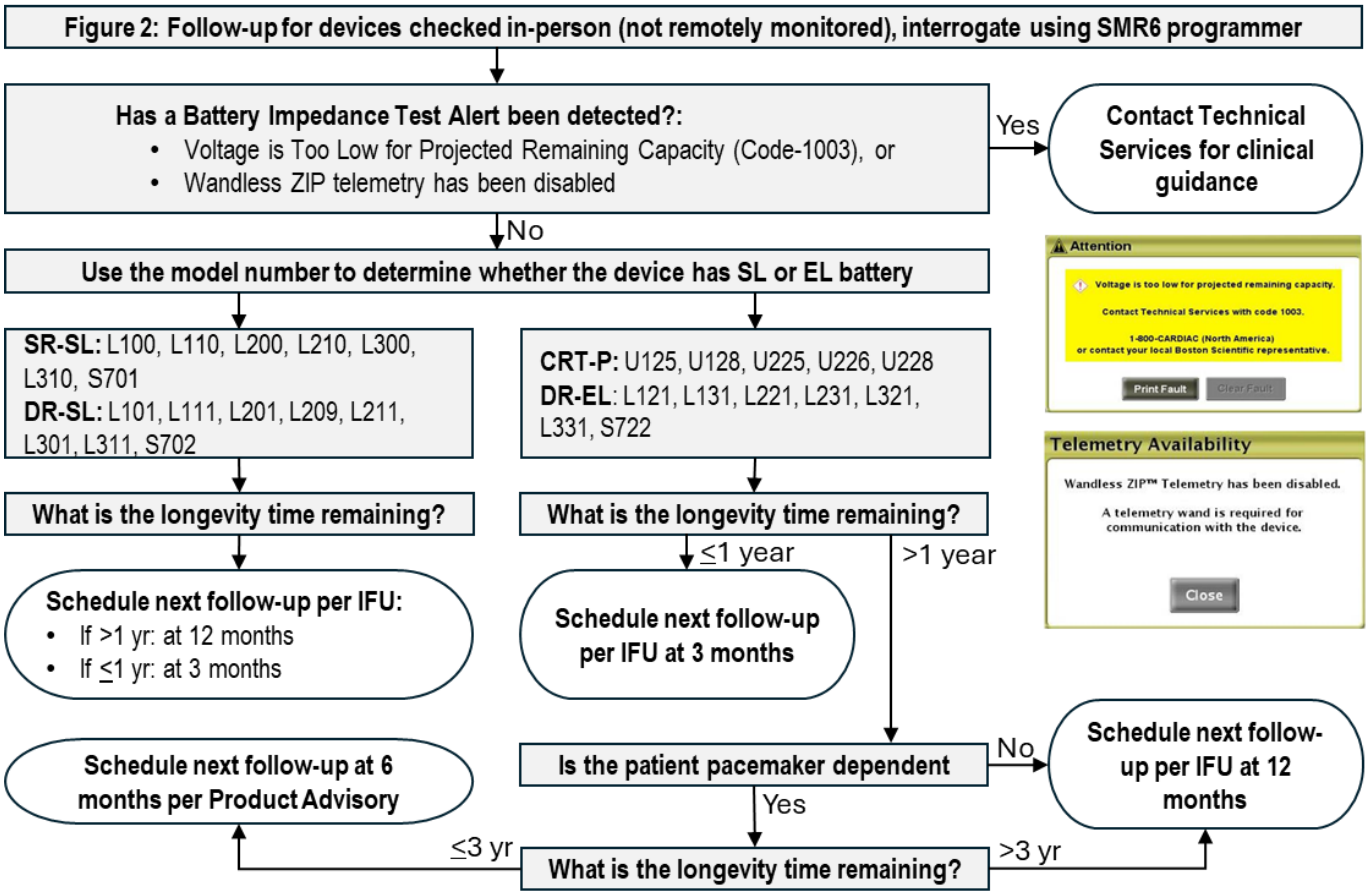
You are receiving this letter to inform you that updated software, Brady software maintenance release 6 (SMR6), is now available for the ACCOLADE™ family of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps)[1] and the advisory population is expanding to include all CRT-P and dual-chamber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