

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

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 $10.9\% \pm 9.6\%$. 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

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