Provincial Triage Algorithm & Follow-Up Schedule for Patients Under Boston Scientific ACCOLADE Advisory

October 2025 release of SMR5 software upgrade

Group	Criteria	Action
High Risk Group 1	In Safety Mode AND PPM-dependent or at risk of deterioration with asynchronous pacing	Admission and urgent generator change.
High Risk Group 2	In Safety Mode AND Non-PPM-dependent and not at risk of deterioration with asynchronous pacing	Urgent outpatient generator change (within 2 weeks).
Moderate Risk	Less than 4 years of battery life remaining AND PPM-dependent or at risk of deterioration with asynchronous pacing, or CRT-P device	Prompt in-clinic follow-up: Software upgrade, enroll in remote monitoring (RM). If on RM, routine follow-up. If not on RM, see attached CHRS letter for guidance.
Low Risk	Greater than 4 years of battery life remaining OR Less than 4 years of battery life remaining AND Non-PPM-dependent and not at risk of deterioration with asynchronous pacing	Next scheduled clinic visit: Software upgrade, enroll in remote monitoring (RM). If on RM, routine follow-up. If not on RM, see attached CHRS letter for guidance.

Canadian Heart Rhythm Society
Société canadienne de rythmologie

Date: October 23 2025 (Original December 13 2024, Update August 17 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 phrenic nerve 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).

Since the previous August 2025 update, Boston Scientific had developed a software upgrade (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. This update is now available in Canada.

However, the initial iteration of the software (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) to address this residual risk of safety mode being triggered has been completed and submission to Regulatory Authorities is in progress.

It is anticipated that there is at least a 3-month warning between Code-1003 warning and the time of ZIP™ telemetry being disabled, however this timeline may be shorter for patients with abnormal impedance values at the time of software update.

The entire ACCOLADE family will benefit from this software update, so Boston Scientific has expanded the advisory recommendations to include CRT-P, DR-EL, DR-SL, and SR-SL devices 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.
- Patients with an ACCOLADE family pacemakers 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 v2.04 software.
    - Patients at risk of harm should promptly receive the software update (i.e. be prioritised to receive the software update) and be enrolled in remote monitoring
    - All other patients should receive the software update at their next 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
    - Patients on remote monitoring can receiving usual follow-up schedule
    - Patients not on remote monitoring should be brought back to clinic 1 week following the software update to assess for a Code-1003 alert.
        - If a Code-1003 alert is observed, please see below for further guidance
        - If no Code-1003 alert is observed, then follow-up can occur every three months (in person, in those at risk of harm) or routine follow-up (no risk of harm)
- If a device with enhanced software 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 wandless ZIP telemetry is disabled, a remote monitoring disabled alert will be presented in the LATITUDE Remote Patient Management System (RM) website with an Explant date of 1 Jan 2000.
- If an alert for voltage too low for remaining longevity (Code-1003) or wandless ZIP telemetry disablement warning message is observed, contact Boston Scientific technical services for a customized recommended replacement interval.
    - There is a possibility that the battery impedance warning may be a false positive due to a circumstance of concomitant magnet application during daily zip activated telemetry test.
    - If confirmed a true condition
        - For patients at risk of harm the generator should be replaced on an expedited basis since continued wandless ZIP telemetry wakeups can cause initiation of Safety Mode.
        - For patients not at risk of harm, then generator replacement can be performed on an elective basis, at the discretion of the treating team.
- The CHRS device committee may update these recommendations should more data become available.

CHRS Device Committee

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