

Urgent Medical Device Correction Field Safety Notice

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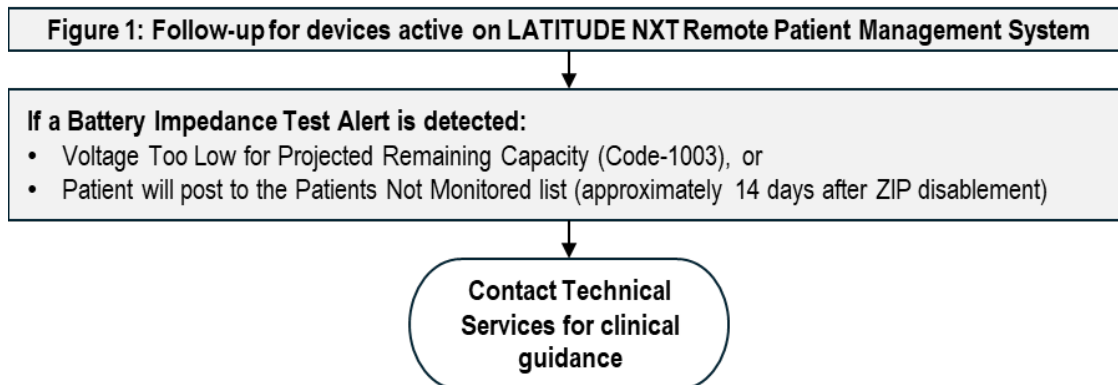
March 2026, Field Action Reference: 97125289H-1A-FA.

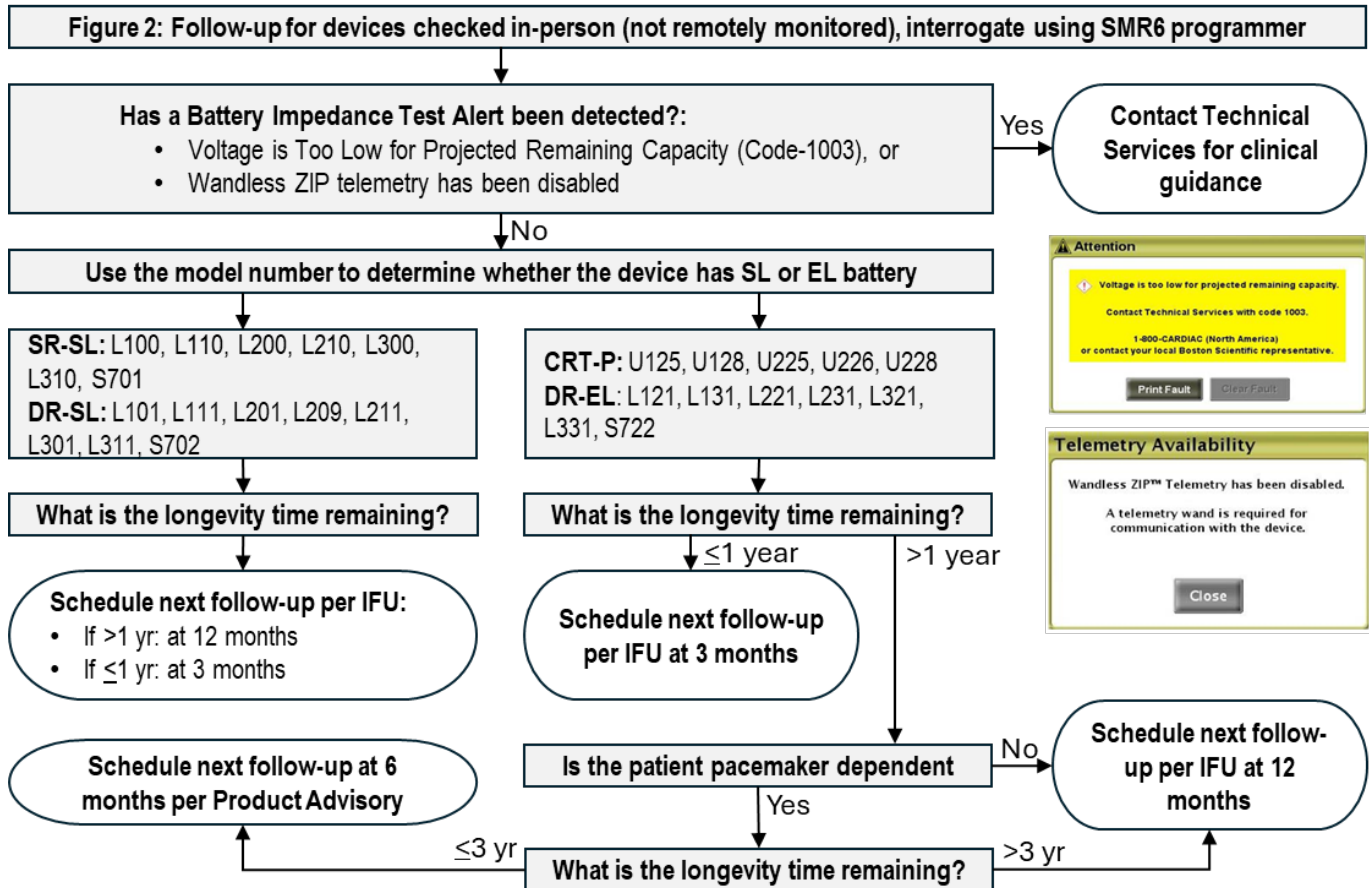
You are receiving this letter to inform you that updated software, Brady software maintenance release 6 (SMR6), is now available for the ACCOLADE™ family of pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps)¹ and the advisory population is expanding to include all CRT-P and dual-chamber 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 wandless 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.
- Complete and return the attached mandatory acknowledgement form to Boston Scientific at «Customer_Service_Fax_Number».





Clinical Impact

Brady SMR6 resolves the previously described incomplete ZIP disablement behavior and magnet-induced false-positive battery impedance test³. 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

¹The ACCOLADE family includes ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 SR-SL, DR-SL, and DR-EL pacemakers; and VISIONIST™ and VALITUDE™ CRT-Ps

²Brady SMR6 Model 3869 v2.05 includes firmware revision “(3.24)” and Brady SMR5 Model 3869 v2.04 includes firmware revision “(3.10)”

³Boston Scientific will contact clinics with patients who have exhibited magnet-induced false positive disablement of ZIP and assist in resuming remote monitoring if desired

⁴Mean ± Standard Deviation

⁵Based on LATITUDE analysis of over 123,000 US devices in the ACCOLADE family upgraded to SMR5 for up to 3 months

Brady SMR6 Correction for ACCOLADE™ Family and DR-EL and CRT-P population expansion

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	Model	Product Name	Model	Product Name	Model	Product Name
L100	ESSENTIO SR-SL	L201	PROPONENT DR-SL	L301	PROPONENT MRI SR-SL	S722	ALTRUA 2 DR-EL
L101	ESSENTIO DR-SL	L209	PROPONENT VDDR-SL	L310	PROPONENT MRI DR-SL	U125	VALITUDE CRT-P IS-1
L110	ESSENTIO MRI SR-SL	L210	PROPONENT MRI SR-SL	L311	PROPONENT DR-EL	U128	VALITUDE X4 CRT-P
L111	ESSENTIO MRI DR-SL	L211	PROPONENT MRI DR-SL	L321	PROPONENT MRI DR-EL	U225	VISIONIST CRT-P
L121	ESSENTIO DR-EL	L221	PROPONENT DR-EL	L331	ACCOLADE SR-SL	U226	VISIONIST CRT-P
L131	ESSENTIO MRI DR-EL	L231	PROPONENT MRI DR-EL	S701	ACCOLADE DR-SL	U228	VISIONIST X4 CRT-P
L200	PROPONENT SR-SL	L300	ACCOLADE SR-SL	S702	ACCOLADE MRI SR-SL		

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Brady SMR6 Correction for ACCOLADE™ Family and DR-EL and CRT-P population expansion

GTIN	Model	Product Name	GTIN	Model	Product Name	GTIN	Model	Product Name
00802526558900	L100	ESSENTIO SR-SL	00802526576874	L201	PROPONENT DR-SL	00802526572371	L310	ACCOLADE MRI SR-SL
00802526558917	L100	ESSENTIO SR-SL	00802526578014	L201	PROPONENT DR-SL	00802526572388	L310	ACCOLADE MRI SR-SL
00802526571923	L100	ESSENTIO SR-SL	00802526593246	L201	PROPONENT DR-SL	00802526576454	L310	ACCOLADE MRI SR-SL
00802526571930	L100	ESSENTIO SR-SL	00802526611834	L201	PROPONENT DR-SL	00802526576959	L310	ACCOLADE MRI SR-SL
00802526571947	L100	ESSENTIO SR-SL	00802526559068	L209	PROPONENT VDDR-SL	00802526578069	L310	ACCOLADE MRI SR-SL
00802526576300	L100	ESSENTIO SR-SL	00802526572166	L209	PROPONENT VDDR-SL	00802526609015	L310	ACCOLADE MRI SR-SL
00802526576805	L100	ESSENTIO SR-SL	00802526576386	L209	PROPONENT VDDR-SL	00802526611803	L310	ACCOLADE MRI SR-SL
00802526593109	L100	ESSENTIO SR-SL	00802526576881	L209	PROPONENT VDDR-SL	00802526559228	L311	ACCOLADE MRI DR-SL
00802526611605	L100	ESSENTIO SR-SL	00802526611889	L209	PROPONENT VDDR-SL	00802526559235	L311	ACCOLADE MRI DR-SL
00802526558924	L101	ESSENTIO DR-SL	00802526559075	L210	PROPONENT MRI SR-SL	00802526572395	L311	ACCOLADE MRI DR-SL
00802526558931	L101	ESSENTIO DR-SL	00802526559082	L210	PROPONENT MRI SR-SL	00802526572401	L311	ACCOLADE MRI DR-SL
00802526571954	L101	ESSENTIO DR-SL	00802526572180	L210	PROPONENT MRI SR-SL	00802526572418	L311	ACCOLADE MRI DR-SL
00802526571961	L101	ESSENTIO DR-SL	00802526576393	L210	PROPONENT MRI SR-SL	00802526576461	L311	ACCOLADE MRI DR-SL
00802526571978	L101	ESSENTIO DR-SL	00802526576898	L210	PROPONENT MRI SR-SL	00802526576966	L311	ACCOLADE MRI DR-SL
00802526576317	L101	ESSENTIO DR-SL	00802526578021	L210	PROPONENT MRI SR-SL	00802526578076	L311	ACCOLADE MRI DR-SL
00802526576812	L101	ESSENTIO DR-SL	00802526609077	L210	PROPONENT MRI SR-SL	00802526609008	L311	ACCOLADE MRI DR-SL
00802526593116	L101	ESSENTIO DR-SL	00802526611773	L210	PROPONENT MRI SR-SL	00802526611896	L311	ACCOLADE MRI DR-SL
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00802526558948	L110	ESSENTIO MRI SR-SL	00802526559105	L211	PROPONENT MRI DR-SL	00802526559259	L321	ACCOLADE DR-EL
00802526558955	L110	ESSENTIO MRI SR-SL	00802526572210	L211	PROPONENT MRI DR-SL	00802526572425	L321	ACCOLADE DR-EL
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00802526576829	L110	ESSENTIO MRI SR-SL	00802526609022	L211	PROPONENT MRI DR-SL	00802526593260	L321	ACCOLADE DR-EL
00802526609039	L110	ESSENTIO MRI SR-SL	00802526611704	L211	PROPONENT MRI DR-SL	00802526611766	L321	ACCOLADE DR-EL
00802526611636	L110	ESSENTIO MRI SR-SL	00802526559112	L221	PROPONENT DR-EL	00802526619403	L321	ACCOLADE DR-EL
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00802526572029	L111	ESSENTIO MRI DR-SL	00802526576416	L221	PROPONENT DR-EL	00802526572463	L331	ACCOLADE MRI DR-EL
00802526572036	L111	ESSENTIO MRI DR-SL	00802526576911	L221	PROPONENT DR-EL	00802526572470	L331	ACCOLADE MRI DR-EL
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00802526576836	L111	ESSENTIO MRI DR-SL	00802526593307	L221	PROPONENT DR-EL	00802526576980	L331	ACCOLADE MRI DR-EL
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00802526576348	L121	ESSENTIO DR-EL	00802526576928	L231	PROPONENT MRI DR-EL	00802526559334	S701	ALTRUA 2 SR-SL
00802526576843	L121	ESSENTIO DR-EL	00802526578052	L231	PROPONENT MRI DR-EL	00802526572487	S701	ALTRUA 2 SR-SL
00802526593277	L121	ESSENTIO DR-EL	00802526609046	L231	PROPONENT MRI DR-EL	00802526576492	S701	ALTRUA 2 SR-SL
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00802526559013	L131	ESSENTIO MRI DR-EL	00802526559150	L300	ACCOLADE SR-SL	00802526593222	S701	ALTRUA 2 SR-SL
00802526572074	L131	ESSENTIO MRI DR-EL	00802526559167	L300	ACCOLADE SR-SL	00802526611841	S701	ALTRUA 2 SR-SL
00802526572081	L131	ESSENTIO MRI DR-EL	00802526572302	L300	ACCOLADE SR-SL	00802526559341	S702	ALTRUA 2 DR-SL
00802526576355	L131	ESSENTIO MRI DR-EL	00802526576430	L300	ACCOLADE SR-SL	00802526559358	S702	ALTRUA 2 DR-SL
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00802526609053	L131	ESSENTIO MRI DR-EL	00802526593321	L300	ACCOLADE SR-SL	00802526576508	S702	ALTRUA 2 DR-SL
00802526611643	L131	ESSENTIO MRI DR-EL	00802526611810	L300	ACCOLADE SR-SL	00802526577000	S702	ALTRUA 2 DR-SL
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00802526576362	L200	PROPONENT SR-SL	00802526572340	L301	ACCOLADE DR-SL	00802526559365	S722	ALTRUA 2 DR-EL
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00802526611827	L200	PROPONENT SR-SL	00802526593215	L301	ACCOLADE DR-SL	00802526577017	S722	ALTRUA 2 DR-EL
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00802526559051	L201	PROPONENT DR-SL	00802526559204	L310	ACCOLADE MRI SR-SL	00802526593239	S722	ALTRUA 2 DR-EL
00802526572135	L201	PROPONENT DR-SL	00802526559211	L310	ACCOLADE MRI SR-SL	00802526611711	S722	ALTRUA 2 DR-EL
00802526576379	L201	PROPONENT DR-SL	00802526572364	L310	ACCOLADE MRI SR-SL	00802526559389	U125	VALITUDE CRT-P IS-1

GTIN	Model	Product Name	GTIN	Model	Product Name	GTIN	Model	Product Name
00802526559396	U125	VALITUDE CRT-P IS-1	00802526578120	U128	VALITUDE X4 CRT-P	00802526572678	U226	VISIONIST CRT-P
00802526573101	U125	VALITUDE CRT-P IS-1	00802526593284	U128	VALITUDE X4 CRT-P	00802526577062	U226	VISIONIST CRT-P
00802526573118	U125	VALITUDE CRT-P IS-1	00802526611797	U128	VALITUDE X4 CRT-P	00802526577123	U226	VISIONIST CRT-P
00802526573125	U125	VALITUDE CRT-P IS-1	00802526559426	U225	VISIONIST CRT-P	00802526578816	U226	VISIONIST CRT-P
00802526577024	U125	VALITUDE CRT-P IS-1	00802526559433	U225	VISIONIST CRT-P	00802526611728	U226	VISIONIST CRT-P
00802526577109	U125	VALITUDE CRT-P IS-1	00802526572630	U225	VISIONIST CRT-P	00802526559471	U228	VISIONIST X4 CRT-P
00802526578793	U125	VALITUDE CRT-P IS-1	00802526572647	U225	VISIONIST CRT-P	00802526559488	U228	VISIONIST X4 CRT-P
00802526593291	U125	VALITUDE CRT-P IS-1	00802526577048	U225	VISIONIST CRT-P	00802526572692	U228	VISIONIST X4 CRT-P
00802526611735	U125	VALITUDE CRT-P IS-1	00802526577116	U225	VISIONIST CRT-P	00802526572708	U228	VISIONIST X4 CRT-P
00802526559402	U128	VALITUDE X4 CRT-P	00802526578809	U225	VISIONIST CRT-P	00802526572715	U228	VISIONIST X4 CRT-P
00802526559419	U128	VALITUDE X4 CRT-P	00802526593253	U225	VISIONIST CRT-P	00802526577055	U228	VISIONIST X4 CRT-P
00802526572609	U128	VALITUDE X4 CRT-P	00802526611742	U225	VISIONIST CRT-P	00802526577130	U228	VISIONIST X4 CRT-P
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00802526572623	U128	VALITUDE X4 CRT-P	00802526559464	U226	VISIONIST CRT-P	00802526593314	U228	VISIONIST X4 CRT-P
00802526576522	U128	VALITUDE X4 CRT-P	00802526572661	U226	VISIONIST CRT-P	00802526611902	U228	VISIONIST X4 CRT-P
00802526577031	U128	VALITUDE X4 CRT-P						

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