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<Reference: 97125289E-FA> 20 August 2025

Urgent Field Safety Notice

Subject: Field Safety Notice – Software to enhance Safety Architecture is available and designed to prevent initiation of Safety Mode in an ambulatory setting due to a high battery impedance state for the ACCOLADE™ family of devices which includes ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 dual chamber (DR) standard life (SL) and DR extended life (EL) pacemakers; and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps). (Boston Scientific Field Action Reference: 97125289E-FA).

Dear Physician or Healthcare Professional (HCP),

This notice provides an update to the December 2024 customer communication regarding the potential for the ACCOLADE family of pacemakers to initiate Safety Mode due to a high battery impedance state.

- A software upgrade (Model 3869 v2.04) is now available (CE Marked) for the LATITUDE™ Programming System, Model 3300 (programmer), which upon interrogation of a pacemaker from the ACCOLADE family enables detection of an elevated battery impedance by a Code-1003 alert and, after three (3) or more months of increasing battery impedance, disables wandless ZIP™ telemetry (i.e., radio frequency) before initiation of Safety Mode.
- By design, disablement of ZIP telemetry eliminates the potential for Safety Mode in an ambulatory setting for any device upgraded with this software that is experiencing a high battery impedance state.
- With the availability of this software, **prophylactic replacement is no longer recommended for patients at risk of harm due to the non-programmable parameters in Safety Mode**, see updated recommendations below in Table 1.
- All ACCOLADE pacemakers will benefit from this software upgrade. Boston Scientific is expanding our recommendations to all device types in the Accolade family. For precise details about the bounding of affected devices, see Appendix A.

Recommendations

These recommendations are intended to promote a risk-stratified, timely upgrade of pacemaker software to prevent the occurrence of Safety Mode in an ambulatory setting due to a high battery impedance state.

- Connect your LATITUDE programmer to the internet (e.g., via WiFi, ethernet, or cell adapter), select Utilities>Software Update>Easy Install, and wait for the programmer to install Model 3869 v2.04 software. Maintain internet connection and power until the installation is complete.
- If your programmer cannot be connected to the internet, contact your local Boston Scientific sales professional to arrange for your programmer's software to be upgraded.

Table 1 Recommendations for ACCOLADE pacemakers with availability of Model 3869 v2.04 software

<table>
<tr><td rowspan="2">Upgrade pacemaker or CRT-P software</td><td>For patients at risk of harm due to Safety Mode: If longevity remaining is four (4) years or less OR will reach four (4) years or less before the next scheduled follow-up, promptly schedule an in-person follow-up.</td><td>For all other patients: Schedule the next follow-up in-person.</td></tr>
<tr><td colspan="2">During the in-person follow-up, interrogate the device using a Model 3300 LATITUDE programmer installed with Model 3869 v2.04 software.</td></tr>
<tr><td>Follow-up Interval</td><td colspan="2">After device software has been upgraded by Model 3869 v2.04 software on a Model 3300 LATITUDE programmer, perform system follow-up in accordance with instructions for use (IFU).</td></tr>
<tr><td>Replace if high battery impedance state is detected</td><td colspan="2">If either an alert for voltage too low for remaining longevity (Code-1003) or wandless ZIP telemetry disablement warning message is observed, contact technical services for a customized recommended replacement interval.</td></tr>
<tr><td>LATITUDE not monitored list</td><td colspan="2">If a device upgraded with this software detects a high battery impedance state (e.g., Code-1003), remains in service, and the battery impedance continues rising, the device with this software, by design, will disable wandless ZIP telemetry to prevent Safety Mode initiation.
If wandless ZIP telemetry is disabled, the patient may be listed as not monitored in the LATITUDE Remote Patient Management System (RM) website after 14 days or more.
If all other causes for the patient not being monitored are ruled out (e.g., communicator connection/power is confirmed), schedule an in-person follow-up to assess wandless ZIP telemetry performance.</td></tr>
<tr><td>Replace the device if it enters Safety Mode before receiving the software upgrade</td><td>For patients at risk of harm:
Emergent/Urgent Replacement</td><td>All other patients:
Non-emergent Replacement</td></tr>
<tr><td></td><td colspan="2">When choosing a replacement interval, do not rely on previously reported battery time remaining estimates which do not account for Safety Mode's increased outputs nor the battery's high impedance state.
During replacement of a device in Safety Mode, pacing inhibition should be anticipated during electrocautery and when the device is removed from the pocket due to unipolar pacing and high sensitivity.</td></tr>
<tr><td>Prophylactic Replacement</td><td colspan="2">Not recommended for patients who have been interrogated with a Model 3300 LATITUDE programmer with Model 3869 v2.04 installed.</td></tr>
<tr><td>Medical Records</td><td colspan="2">For each patient with an affected device, append/update the patient's medical record with this letter to maintain awareness to all follow-up physicians of this topic for the remaining service life of the device.</td></tr>
</table>

Clinical Impact

Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. The non-programmable Safety Mode pacing parameters (Table 3) may not provide optimal support of a patient's cardiac condition (e.g., adequacy of underlying escape rhythm, the need for AV/VV pacing for cardiac synchrony, and/or the potential for pacing inhibition due to myopotential oversensing). Pacing inhibition due to myopotential oversensing for unipolar sensing configurations is well documented, however, provocative maneuvers, including isometric exercises, are not a reliable predictor of myopotential oversensing susceptibility for patients who may transition to Safety Mode.

The most common clinical outcome of this behavior is early device replacement. In certain patients, Safety Mode may result in unintended clinical impact such as pacing inhibition/pauses, muscle stimulation (e.g., skeletal muscle or phrenic nerve stimulation), or heart failure decompensation prior to device replacement. Among patients at risk of harm whose pacemaker initiates Safety Mode, Caughron et al. reported 52% rate of major complications due to presyncope, syncope, fall with trauma, pauses/asystole, and death.[1] Remote monitoring is a standard of care[2], is a critical device management capability, and is an important means to detect onset of high battery impedance with this software upgrade.

The worst case reported patient harm has been loss of pacing with serious injury or life-threatening outcome. There have been two (2) deaths in pacemaker dependent patients after initiating Safety Mode in an ambulatory setting and no additional deaths have been reported since that time. Details about the ACCOLADE subpopulations and projected lifetime occurrence rate for each device type are reported in Table 2. Occurrence rates for various device types are reported in Figure 1 and 2.

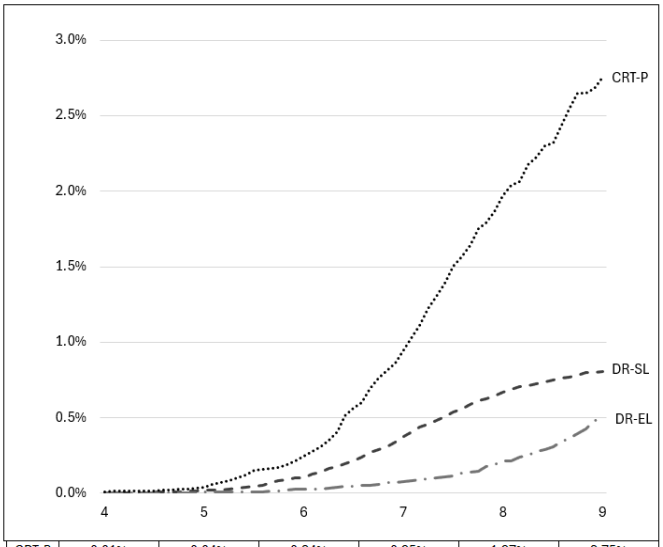
Table 2 ACCOLADE populations and occurrence rates for Safety Mode (SM) due to high battery impedance

Population	Device Type	Estimated WW Active Population	Estimated WW Distributed Population	SM Events	Lifetime Occurrence Rate
Dec 2024 Advisory Populations	CRT-P	8,500	21,300	281	3.27% at 117 months
	DR EL	34,300	58,600	183	3.27% at 158 months*
	DR SL	56,500	123,400	605	0.75% at 102 months
All other devices	CRT-P	92,500	124,100	83	1.16% at 117 months
	DR EL	444,300	534,200	23	1.16% at 158 months*
	DR SL	539,700	683,000	125	0.14% at 102 months
	SR SL	189,500	294,900	60	0.19% at 117 months
Total		1,365,300	1,839,400	1,360	

*DR-EL rate is projected based on the experience of CRT-P which uses the same EL battery

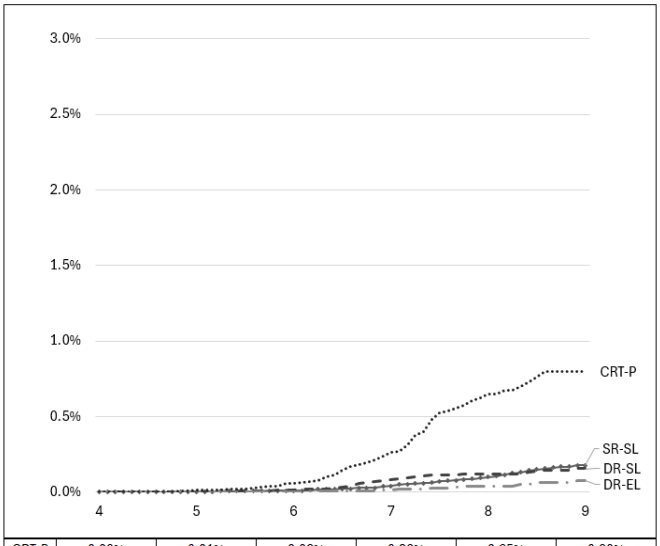
[1]Caughron H, Dhruva SS, Raitt MH. Complications Associated With Safety Mode Initiation in Recalled Boston Scientific Pacemakers. J Am Coll Cardiol. 2025 Apr 5:S0735-1097(25)05926-1. doi: 10.1016/j.jacc.2025.03.501. Epub ahead of print. PMID: 40202463.

[2]In patients with CIEDs, RM is recommended as part of the standard of care (COR-1/LOE-A) pg e99. Ferrick AM Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm, ISSN: 1547-5271, Vol: 20, Issue: 9, Page: e92-e144. https://doi.org/10.1016/j.hrthm.2023.03.1525.



CRT-P	0.01%	0.04%	0.24%	0.95%	1.97%	2.75%
DR-SL	0.00%	0.02%	0.11%	0.38%	0.67%	0.80%
DR-EL	0.00%	0.01%	0.02%	0.08%	0.21%	0.49%

Figure 1 Occurrence rates for high battery impedance induced Safety Mode in the December 2024 advisory population



CRT-P	0.00%	0.01%	0.06%	0.26%	0.65%	0.80%
SR-SL	0.00%	0.01%	0.01%	0.04%	0.10%	0.18%
DR-SL	0.00%	0.00%	0.02%	0.08%	0.12%	0.16%
DR-EL	0.00%	0.00%	0.00%	0.02%	0.04%	0.08%

Figure 2 Occurrence rates for high battery impedance induced Safety Mode in remaining devices

Description of Software Enhancement.

Wandless ZIP telemetry operations such as active telemetry sessions and automatic ZIP wakeups are the highest power operations performed in the ACCOLADE family of pacemakers and account for all confirmed instances of Safety Mode events. This software enhances Safety Architecture by adding a new daily wandless ZIP telemetry activated battery test[1] which assesses the battery's response to short bursts (e.g., milliseconds) of telemetry, detects/alerts onset of a high battery impedance state, and intervenes three (3) or more months later to prevent Safety Mode initiation. This is accomplished in two sequential stages.

1- If this telemetry activated battery test detects an elevated battery impedance state, the following alert: "Voltage too low for projected remaining longevity" (Code-1003) will be displayed via the LATITUDE programmer or LATITUDE RM. This first stage is designed to detect and alert users about a high battery impedance condition at least 3 months before pacemakers without this software would have initiated Safety Mode.

2- If a pacemaker from the ACCOLADE family with an elevated battery impedance induced Code-1003 remains in service, this telemetry activated battery test continues assessing the battery impedance (e.g., for three or more months) and disables wandless ZIP telemetry operation before the impedance achieves a level where Safety Mode has historically been initiated.

By design, this daily wandless ZIP telemetry activated battery test enhances the ACCOLADE family's Safety Architecture by eliminating the potential for Safety Mode initiation in an ambulatory setting due to a high battery impedance state. Please note the following:

- Code-1003 is a nonspecific alert condition that can be initiated for a high battery impedance state or detection of other anomalous system conditions. By contacting technical services when a Code-1003 is observed, an engineering analysis can determine a customized replacement interval.
- If wandless ZIP telemetry is disabled, the LATITUDE RM system will post the patient on the Not Monitored list in 14 or more days and an alert message will be displayed to the HCP upon interrogation by a LATITUDE programmer.
- Pacemaker longevity is not affected by a high battery impedance state when initiation of Safety Mode is prevented. In this circumstance, longevity is anticipated to be normal and battery status is extremely unlikely to initiate elective replacement before the labeled follow-up interval.
- After the device's software has been upgraded, the earliest a device experiencing a high battery impedance will initiate a Code-1003 alert is four (4) days later. Therefore, the software will not detect a high battery impedance state when device software is upgraded during an in-office programmer interrogation, rather the Code-1003 will be initiated four (4) or more days later.

[1]The daily wandless ZIP telemetry activated battery test is estimated to reduce device longevity by one (1) day for every 10 years of testing.

Description of High Battery Impedance Behavior Without Software Upgrade
As described in the original December 2024 advisory, ACCOLADE devices have a potential of exhibiting a high impedance condition because of unanticipated concentration of lithium salts resulting from variability of battery assembly techniques. This may result in a lack of available electrolyte between the battery anode and cathode.

High battery impedance may cause a device to exhibit transient voltage decreases during wandless ZIP telemetry operations. If the battery voltage drops below a minimum threshold during a high-power state (e.g., active ZIP telemetry), a system reset is automatically performed, and the conditions of the high-power state are interrupted. Subsequent high-power states may result in additional system resets due to the high battery impedance.

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 (Table 3). When a device is in Safety Mode, healthcare professionals (HCPs) are directed to contact Boston Scientific via a LATITUDE™ programmer warning screen and a LATITUDE remote patient management system red alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available. The susceptibility of experiencing a high battery impedance and entering Safety Mode has been observed when the device reaches approximately four (4) years or less of remaining battery longevity.

Per the IFU, Safety Mode is intended to provide life-sustaining therapy if repeated system resets occur with the following pre-defined, non-programmable parameters. A device that enters Safety Mode should be replaced.

Table 3 Safety Mode Non-Programmable Settings

Parameter	Setting
Mode	VVI, biventricular pacing for CRT-Ps
Rate	72.5 ppm
Sensitivity	Automatic Gain Control (AGC) 0.25 mV
Output	5.0 V at 1.0 ms RV (and LV for CRT-Ps)
Lead Configuration	RV/LV Unipolar sensing/pacing
RVRP	250 ms
Noise response	VOO
LV Offset (CRT-Ps only)	0 ms
Magnet Response	Disabled

When replacing a device in Safety Mode, the following conditions may interrupt pacing during the procedure:
- During applications of electrocautery, pacing may be inhibited due to Safety Mode's high sensitivity setting and unipolar sensing configuration.
- When removing the device from the pocket, loss of capture will occur due to Safety Mode's unipolar pacing configuration.

During normal operations when a device is indicated for replacement, the system is designed to reserve sufficient battery capacity to support device operations for three (3) months to allow for a replacement procedure to be scheduled. However, if a device without upgraded software enters Safety Mode due to the high battery impedance, the reserve battery capacity may not be sufficient to support device operations for three months and should be scheduled for replacement soon thereafter and emergently for patients at risk of harm from Safety Mode parameters.

The ACCOLADE family of pacemakers includes a standard life (SL) battery for single chamber (SR) and dual chamber (DR) pacemakers and a larger, extended life (EL) battery for DR pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps). Because of disparate batteries (e.g., SL vs. EL) and therapies provided (e.g., SR/DR pacemakers vs. CRT-Ps), the occurrence rates vary (Figure 1 and 2). However, the susceptibility for a device to enter Safety Mode due to high battery impedance occurs when the device reaches approximately four (4) years or less of remaining battery longevity. A retrospective study of 121 US Department of Veterans Affairs (VA) Centers found that, of ACCOLADE and INGENIO devices initiating Safety Mode due to high battery impedance, 100% did so with 4 years or less time remaining and 92% with 2 years or less time remaining.[1]

[1]Caughron H,. 2025 Apr 5:S0735-1097(25)05926-1. doi: 10.1016/j.jacc.2025.03.501.

The Regulatory Authority of your country has been informed about this customer communication. Adverse events should be reported to Boston Scientific and Regulatory Authorities if appropriate.

A patient letter is available upon request, which can be distributed to the patient.

Please **complete the enclosed Acknowledgment Form** and **send it to Boston Scientific at «Customer_Service_Fax_Number» by 8 September 2025.** A completed form is required from every facility who receives this letter.

Additional Information
Patient safety remains Boston Scientific's highest priority, and we are committed to communicating up-to-date information with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. Product performance information, including this topic, a device lookup tool, and resources for returning product are available within our Product Performance Resource Center at www.bostonscientific.com/ppr.

If you have additional questions regarding this information, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

Attachment: Acknowledgement Form

Appendix A

Because of the latency associated with high battery impedance induced Safety Mode, the population has been expanded to include devices from the ACCOLADE family with a use-by-date (UBD) on or before 30 June 2025. All patients will benefit from this software update. This bounding is intended to prioritize pacemakers presently susceptible to Safety Mode due to a high battery impedance state with consideration for the additional in-clinic follow-up burden. Other pacemakers from the ACCOLADE family will not be susceptible for two years beyond this UBD and are therefore anticipated to receive this software through normal in-person follow-up scheduling. The expanded advisory population includes the following model numbers; however, these device attributes are not sufficient to precisely identify individual devices in the advisory population. Contact your local Boston Scientific sales professional for an affected serialized device list or enter a model/serial into the device lookup tool at www.BostonScientific.com/lookup.

GTIN	Model	Product Name
00802526558900	L100	ESSENTIO SR SL
00802526558917	L100	ESSENTIO SR SL
00802526571923	L100	ESSENTIO SR SL
00802526571930	L100	ESSENTIO SR SL
00802526571947	L100	ESSENTIO SR SL
00802526576300	L100	ESSENTIO SR SL
00802526576805	L100	ESSENTIO SR SL
00802526593109	L100	ESSENTIO SR SL
00802526611605	L100	ESSENTIO SR SL
00802526558924	L101	ESSENTIO DR SL
00802526558931	L101	ESSENTIO DR SL
00802526571961	L101	ESSENTIO DR SL
00802526571978	L101	ESSENTIO DR SL
00802526576317	L101	ESSENTIO DR SL
00802526576812	L101	ESSENTIO DR SL
00802526593116	L101	ESSENTIO DR SL
00802526611629	L101	ESSENTIO DR SL
00802526558948	L110	ESSENTIO MRI SR SL
00802526558955	L110	ESSENTIO MRI SR SL
00802526571985	L110	ESSENTIO MRI SR SL
00802526572005	L110	ESSENTIO MRI SR SL
00802526576324	L110	ESSENTIO MRI SR SL
00802526576829	L110	ESSENTIO MRI SR SL
00802526609039	L110	ESSENTIO MRI SR SL
00802526611636	L110	ESSENTIO MRI SR SL
00802526558962	L111	ESSENTIO MRI DR SL
00802526558979	L111	ESSENTIO MRI DR SL
00802526572012	L111	ESSENTIO MRI DR SL
00802526572029	L111	ESSENTIO MRI DR SL
00802526572036	L111	ESSENTIO MRI DR SL
00802526576331	L111	ESSENTIO MRI DR SL
00802526576836	L111	ESSENTIO MRI DR SL
00802526609060	L111	ESSENTIO MRI DR SL
00802526611612	L111	ESSENTIO MRI DR SL
00802526558986	L121	ESSENTIO DR EL
00802526558993	L121	ESSENTIO DR EL
00802526572043	L121	ESSENTIO DR EL
00802526576348	L121	ESSENTIO DR EL
00802526576843	L121	ESSENTIO DR EL
00802526593277	L121	ESSENTIO DR EL
00802526611650	L121	ESSENTIO DR EL
00802526559006	L131	ESSENTIO MRI DR EL
00802526559013	L131	ESSENTIO MRI DR EL
00802526572074	L131	ESSENTIO MRI DR EL
00802526572081	L131	ESSENTIO MRI DR EL
00802526576355	L131	ESSENTIO MRI DR EL
00802526576850	L131	ESSENTIO MRI DR EL
00802526609053	L131	ESSENTIO MRI DR EL
00802526611643	L131	ESSENTIO MRI DR EL
00802526559020	L200	PROPONENT SR SL
00802526559037	L200	PROPONENT SR SL
00802526572104	L200	PROPONENT SR SL
00802526576362	L200	PROPONENT SR SL
00802526576867	L200	PROPONENT SR SL
00802526578007	L200	PROPONENT SR SL
00802526593338	L200	PROPONENT SR SL
00802526611827	L200	PROPONENT SR SL
00802526559044	L201	PROPONENT DR SL
00802526559051	L201	PROPONENT DR SL
00802526572135	L201	PROPONENT DR SL
00802526576379	L201	PROPONENT DR SL
00802526576874	L201	PROPONENT DR SL
00802526578014	L201	PROPONENT DR SL
00802526593246	L201	PROPONENT DR SL
00802526611834	L201	PROPONENT DR SL
00802526559068	L209	PROPONENT VDDR SL
00802526572166	L209	PROPONENT VDDR SL
00802526576386	L209	PROPONENT VDDR SL
00802526576881	L209	PROPONENT VDDR SL
00802526611889	L209	PROPONENT VDDR SL
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00802526559082	L210	PROPONENT MRI SR SL
00802526572180	L210	PROPONENT MRI SR SL
00802526576393	L210	PROPONENT MRI SR SL
00802526576898	L210	PROPONENT MRI SR SL
00802526578021	L210	PROPONENT MRI SR SL
00802526609077	L210	PROPONENT MRI SR SL
00802526611773	L210	PROPONENT MRI SR SL
00802526559099	L211	PROPONENT MRI DR SL
00802526559105	L211	PROPONENT MRI DR SL
00802526572210	L211	PROPONENT MRI DR SL
00802526576409	L211	PROPONENT MRI DR SL
00802526576904	L211	PROPONENT MRI DR SL
00802526578038	L211	PROPONENT MRI DR SL
00802526609022	L211	PROPONENT MRI DR SL
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00802526559129	L221	PROPONENT DR EL
00802526572265	L221	PROPONENT DR EL
00802526576416	L221	PROPONENT DR EL
00802526576911	L221	PROPONENT DR EL
00802526578045	L221	PROPONENT DR EL
00802526593307	L221	PROPONENT DR EL
00802526611858	L221	PROPONENT DR EL
00802526559136	L231	PROPONENT MRI DR EL
00802526559143	L231	PROPONENT MRI DR EL
00802526572272	L231	PROPONENT MRI DR EL
00802526576423	L231	PROPONENT MRI DR EL
00802526576928	L231	PROPONENT MRI DR EL
00802526578052	L231	PROPONENT MRI DR EL
00802526609046	L231	PROPONENT MRI DR EL
00802526611780	L231	PROPONENT MRI DR EL
00802526559150	L300	ACCOLADE SR SL
00802526559167	L300	ACCOLADE SR SL
00802526572302	L300	ACCOLADE SR SL
00802526576430	L300	ACCOLADE SR SL
00802526576935	L300	ACCOLADE SR SL
00802526593321	L300	ACCOLADE SR SL
00802526611810	L300	ACCOLADE SR SL
00802526559174	L301	ACCOLADE DR SL
00802526559181	L301	ACCOLADE DR SL
00802526572333	L301	ACCOLADE DR SL
00802526572340	L301	ACCOLADE DR SL
00802526572357	L301	ACCOLADE DR SL
00802526576447	L301	ACCOLADE DR SL
00802526576942	L301	ACCOLADE DR SL
00802526593215	L301	ACCOLADE DR SL
00802526611865	L301	ACCOLADE DR SL
00802526559204	L310	ACCOLADE MRI SR SL
00802526559211	L310	ACCOLADE MRI SR SL
00802526572364	L310	ACCOLADE MRI SR SL
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00802526578076	L311	ACCOLADE MRI DR SL
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00802526559242	L321	ACCOLADE DR EL
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00802526593260	L321	ACCOLADE DR EL
00802526611766	L321	ACCOLADE DR EL
00802526559266	L331	ACCOLADE MRI DR EL
00802526559273	L331	ACCOLADE MRI DR EL
00802526572456	L331	ACCOLADE MRI DR EL
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00802526592201	L331	ACCOLADE MRI DR EL
00802526609084	L331	ACCOLADE MRI DR EL
00802526611872	L331	ACCOLADE MRI DR EL
00802526559327	S701	ALTRUA 2 SR SL
00802526559334	S701	ALTRUA 2 SR SL
00802526572487	S701	ALTRUA 2 SR SL
00802526576492	S701	ALTRUA 2 SR SL
00802526576997	S701	ALTRUA 2 SR SL
00802526578090	S701	ALTRUA 2 SR SL
00802526593222	S701	ALTRUA 2 SR SL
00802526611841	S701	ALTRUA 2 SR SL
00802526559341	S702	ALTRUA 2 DR SL
00802526559358	S702	ALTRUA 2 DR SL
00802526572517	S702	ALTRUA 2 DR SL
00802526576508	S702	ALTRUA 2 DR SL
00802526577000	S702	ALTRUA 2 DR SL
00802526578106	S702	ALTRUA 2 DR SL
00802526593208	S702	ALTRUA 2 DR SL
00802526611759	S702	ALTRUA 2 DR SL
00802526559365	S722	ALTRUA 2 DR EL
00802526559372	S722	ALTRUA 2 DR EL
00802526573071	S722	ALTRUA 2 DR EL
00802526576515	S722	ALTRUA 2 DR EL
00802526577017	S722	ALTRUA 2 DR EL
00802526578113	S722	ALTRUA 2 DR EL
00802526593239	S722	ALTRUA 2 DR EL
00802526611711	S722	ALTRUA 2 DR EL
00802526559389	U125	VALITUDE CRT-P EL IS-1
00802526559396	U125	VALITUDE CRT-P EL IS-1
00802526573101	U125	VALITUDE CRT-P EL IS-1
00802526573118	U125	VALITUDE CRT-P EL IS-1
00802526573125	U125	VALITUDE CRT-P EL IS-1
00802526577024	U125	VALITUDE CRT-P EL IS-1
00802526577109	U125	VALITUDE CRT-P EL IS-1
00802526578793	U125	VALITUDE CRT-P EL IS-1

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Acknowledgement Form – Urgent Field Safety Notice

Software available to prevent initiation of Safety Mode for ACCOLADE™ Family of Pacemakers and CRT-Ps launch Software

97125289E-FA

By signing this form, I confirm that

I have read and understood the Boston Scientific Field Safety Notice dated 20 August 2025 for:

Software available to prevent initiation of Safety Mode for ACCOLADE™ Family of Pacemakers and CRT-Ps launch Software

NAME* _____ Title _____

Telephone _____ Email _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy