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<Reference: 97125289F-FA>

September 2025

Urgent Field Safety Notice

Subject: Field Safety Notice – Update to December 2024 Field Safety Notice: Software designed to prevent initiation of Safety Mode in an ambulatory setting due to a high battery impedance state in ACCOLADE™ Pacemakers and CRT-Ps (Boston Scientific Reference: 97125289F-FA).

Dear Physician or Healthcare Professional (HCP),

This letter is a notification of the availability of enhanced software intended to detect high battery impedance and prevent initiation of Safety Mode in ACCOLADE™ devices¹ in an ambulatory setting; it also includes a description of possible unintended behaviors associated with this software and applicable recommendations for device management.

- Model 3869 v2.04 software is designed to detect high battery impedance and prevent initiation of Safety Mode in ACCOLADE devices in an ambulatory setting.
- Possible unintended behaviors have been observed with Model 3869 v2.04 software:
 - Incomplete disablement of wandless automatic telemetry after detecting a high battery impedance condition;
 - Potential for the new daily battery test to misinterpret measurements in the presence of a magnet, initiating a false positive response and disablement of wandless telemetry.
- Device sensing, therapy delivery, and all programmed functions remain unaffected, except for the noted changes to wandless telemetry operation described below.
- **Despite the possible occurrence of these unintended behaviors, the benefits of implementing the Model 3869 v2.04 software outweigh the risks associated with prophylactic replacement.**

Note: Appendices at the end of this letter provide further information regarding high battery impedance-related behaviors described in the original December 2024 Field Safety Notice (Appendix A) and precise details about the bounding of affected devices (Appendix B).

¹ACCOLADE family of devices include ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 single chamber (SR), dual chamber (DR) standard life (SL) and DR extended life (EL) pacemakers; and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps).

Model 3869 v2.04 Software Availability

This notice provides an update to December 2024 Field Safety Notice 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 v 2.04) is now available for the LATITUDE™ Programming System, Model 3300 (programmer). Upon interrogation and download of Model 3869 v2.04 to an ACCOLADE pacemaker, this software is intended to enable detection of an elevated battery impedance via an alert and disable wandless ZIP™ telemetry (i.e., wandless, two-way radiofrequency communication) in a device with high impedance to prevent initiation of Safety Mode in an ambulatory setting.
- When a pacemaker receives this enhanced 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, thus Boston Scientific recommends that patients have their devices interrogated by an upgraded programmer at their next in-person visit. 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 B.

Updated device management recommendations

These updated recommendations are intended to promote a risk-stratified, timely upgrade of pacemaker software to mitigate the occurrence of Safety Mode in an ambulatory setting due to a high battery impedance state. *[Note: until the Model 3869 v2.04 software is downloaded onto the ACCOLADE pacemaker, recommendations from the December 2024 Field Safety Notice still apply.]*

- 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. Verify successful installation.
- If your programmer cannot be connected to the internet, contact your local Boston Scientific sales professional or call Technical Services to arrange for your programmer’s software to be upgraded.

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

Actions	Recommendations	
Prophylactic Replacement	Not recommended for patients with any ACCOLADE device that has been interrogated with a Model 3300 LATITUDE programmer with Model 3869 v2.04 installed.	
Upgrade pacemaker or CRT-P firmware	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.	For all other patients: Schedule the next follow-up in-person.
	During the in-person follow-up, interrogate the device using a Model 3300 LATITUDE programmer installed with Model 3869 v2.04 software.	

<p>Follow-up</p>	<p>Consider enrolling/following patients via remote monitoring (RM) who are deemed at risk of harm due to Safety Mode and who are not currently followed remotely.</p> <p>After device firmware has been upgraded by Model 3869 v2.04 software on a Model 3300 LATITUDE programmer, perform system follow-up as described below:</p> <ul style="list-style-type: none"> • For patients followed via RM, continue monitoring. If the battery voltage is too low for projected remaining capacity (Code-1003 is detected), or wandless telemetry is disabled, a Red Alert will be displayed in LATITUDE. • For patients who cannot be monitored remotely: <ul style="list-style-type: none"> ○ For patients at risk of harm due to Safety Mode, perform system follow-up one week after pacemaker firmware has been upgraded to assess whether an elevated or high battery impedance has been detected. This provides the new software algorithm time to detect and declare a sufficiently high impedance state via a Code-1003 alert or disablement of wandless telemetry (in the event the device is very near entering Safety Mode at the time of the software upgrade). After that, perform device follow-ups at three (3) month intervals. ○ For all other patients, perform system follow-up at an interval in accordance with the Instructions for Use (IFU). 	
<p>Contact Technical Services if a high battery impedance state is detected after receiving the software upgrade</p>	<p>If either an alert for voltage too low for remaining longevity (Code-1003) and/or disablement of wandless telemetry is observed after device software has been upgraded by Model 3869 v2.04 software, contact Technical Services.</p> <ul style="list-style-type: none"> • Technical Services can provide a customized recommended replacement interval for high battery impedance conditions • Technical Services can assist in determining if disabled wandless telemetry is due to a false positive detection due to the presence of a magnet. 	
<p>Replace the device if it enters Safety Mode before receiving the software upgrade</p>	<p>For patients at risk of harm due to Safety Mode non-programmable parameters: Emergent/urgent replacement</p>	<p>All other patients: Non-emergent replacement</p>
<p>Replacement procedure considerations for a device in Safety Mode</p>	<ul style="list-style-type: none"> • When choosing a replacement interval, do not rely on previously reported battery time remaining estimates; these 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. 	
<p>Append Patient's Medical Records</p>	<ul style="list-style-type: none"> • For each patient with an affected device, append/update the patient's medical record with this letter to maintain physician awareness of this topic for the remaining service life of the device. • A patient letter is available upon request, which can be distributed to the patient. 	

Model 3869 v2.04 Software Unintended Behaviors

The Model 3869 v2.04 software was designed to prevent potential initiation of Safety Mode due to a high battery impedance condition in ACCOLADE pacemakers (originally described in the December 2024 Field Safety Notice). This software update introduces two separate mechanisms to mitigate risks associated with this battery condition. First, the software enables detection of an elevated battery impedance condition via a telemetry activated battery test, triggering a red alert (voltage is too low for projected remaining capacity, also known as Code-1003). Second, the software disables wandless telemetry when the battery reaches a high impedance state to prevent initiation of Safety Mode in an ambulatory setting.

Since the launch of Model 3869 v2.04 software in August 2025 and subsequent device firmware upgrades via the Model 3300 LATITUDE™ programmer, Boston Scientific has identified two unintended behaviors associated with the software. Device sensing, therapy delivery, and all programmed functions remain unaffected, except for the noted changes to wandless telemetry operation (described below). **Despite the possible occurrence of these unintended behaviors, the benefits of implementing the Model 3869 v2.04 software outweigh the risks associated with prophylactic replacement.** As such, Boston Scientific strongly recommends the continued installation of this software for **all devices** within the ACCOLADE family; all ACCOLADE pacemakers are intended to receive this software/firmware upgrade.

Although Model 3869 v2.04 software has significantly mitigated the initiation of Safety Mode associated with a high battery impedance condition, it does not fully eliminate this potential risk. Boston Scientific has identified two possible unintended behaviors associated with the Model 3869 v2.04 software design:

1. *Incomplete disablement of wandless automatic telemetry after detecting a high battery impedance condition.* If an ACCOLADE family device with an elevated battery impedance induced Code-1003 remains in service, the software's new telemetry activated battery test is designed to continue assessing battery impedance and disable all wandless telemetry operation before high impedance is achieved and device resets can initiate Safety Mode.
 - For devices exhibiting a high battery impedance condition, Safety Mode typically occurs during active LATITUDE programmer or communicator interrogation sessions, which draw the highest power. **The software's new telemetry activated battery test is operating as intended and is effective in disabling wandless telemetry operation before successive device resets can initiate Safety Mode associated with these active-telemetry scenarios.**
 - However, automatic low power telemetry wakeups are not disabled as intended in association with a high battery impedance condition. The software allows for continuation of automatic, low power telemetry wakeups used to initiate a Remote Monitoring session after a high battery impedance condition is detected in the device. As the battery impedance continues to increase, the telemetry wakeup power draws may trigger Safety Mode. The risk of automatic telemetry wakeups causing a device to enter Safety Mode increases as the battery nears its normal replacement time, albeit at a much lower observed occurrence than active telemetry-associated Safety Mode initiations.
2. *Potential for the software's new daily battery test to misinterpret measurements in the presence of a magnet, initiating a false positive response that results in disablement of wandless telemetry sessions.* For patients monitored via LATITUDE, an alert message will indicate an erroneous explant indicator (e.g., explant indicator was reached January 1, 2000) if the device had not previously reached replacement indication, stating that LATITUDE is no longer available, and prompting to contact Technical Services. **This false positive behavior is not possible if the device's magnet response is turned off.** Disabled wandless telemetry prevents subsequent Remote Monitoring and wandless telemetry sessions using a LATITUDE Programmer; note that wandless telemetry continues to operate as intended and will be required during programming sessions.

Boston Scientific is actively developing a software update to address these unintended behaviors associated with the Model 3869 v2.04 software design. Specifically, forthcoming updated software will fully disable the remaining wandless automatic telemetry wakeups after detecting a high battery impedance state, eliminate false positive detection of high battery impedance due to interaction with a magnet, and re-enable wandless telemetry in the case of a previous false positive response and telemetry inactivation due to interaction with a magnet. Until this updated software is available, please refer to the recommendations in Table 1.

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.

Please **complete the enclosed Acknowledgment Form** and **send it to Boston Scientific at «Customer_Service_Fax_Number» by 10 October 2025**. A completed form is required from every facility who receives this letter.

Boston Scientific requests that this notice is transferred (as appropriate) to other organizations impacted by this action. We also advise maintaining awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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 – Battery High Impedance Condition/Potential for Safety Mode and Software Update

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 (**Error! Reference source not found.**) may not provide optimal support of a patient’s cardiac condition; patients at risk of harm for Safety Mode include those with an inadequate underlying escape rhythm, a need for AV/VV pacing for cardiac synchrony, and/or a 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 a 52% rate of major complications due to presyncope, syncope, fall with trauma, pauses/asystole, and death.¹ Remote monitoring, a standard of care², 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. Details about the ACCOLADE subpopulations and lifetime occurrence rate for each device type are reported in Table 2. Occurrence rates for various device types are reported in Figures 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 SM Occurrence Rate
Dec 2024 Advisory Population	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

¹Caughron 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.

²In 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/LAHR 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>.

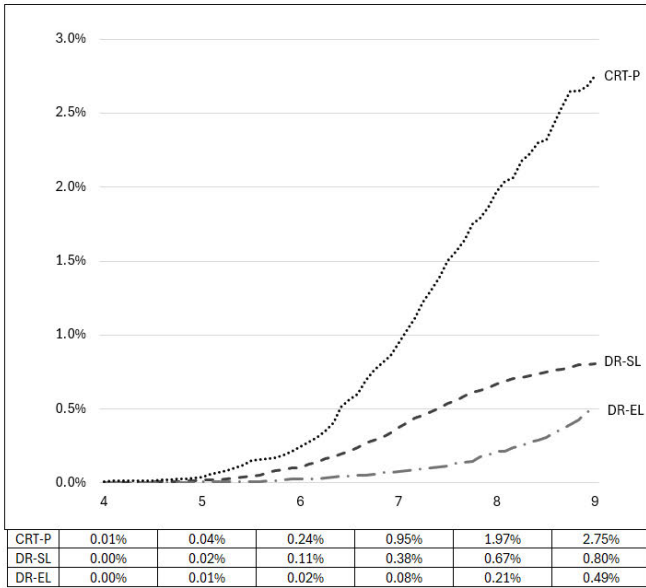


Figure 1 Occurrence rates for high battery impedance induced Safety Mode in the December 2024 advisory population

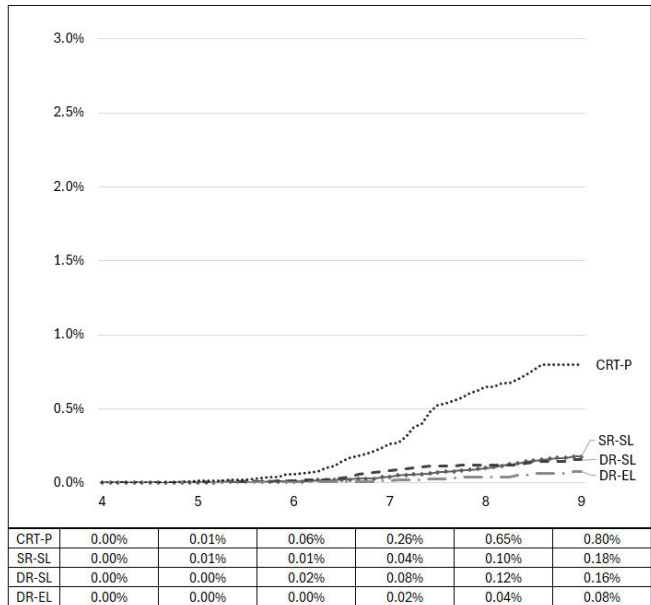


Figure 2 Occurrence rates for high battery impedance induced Safety Mode in remaining devices

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 associated with high battery impedance conditions. This software (Model 3869 v2.04) enhances Safety Architecture by adding a new daily wandless ZIP telemetry activated battery test¹ that assesses the battery’s response to short bursts (e.g., milliseconds) of telemetry, detects/alerts onset of a high battery impedance state, and intervenes to prevent Safety Mode initiation. Note that this time period may be shortened for devices that triggered a voltage alert within a week of the software upgrade.

This is accomplished in two separate 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 an elevated battery impedance condition 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 and disables wandless ZIP telemetry operation before a high impedance condition results in successive device resets leading to initiation of Safety Mode.

Note: In certain cases in which a device has a sufficiently high battery impedance at the time of receiving the software, the algorithm will disable ZIP wandless telemetry without first issuing a Code-1003.

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

By design, this daily wandless ZIP telemetry activated battery test enhances the ACCOLADE family’s Safety Architecture by mitigating 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 general 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.
- The earliest a Code-1003 alert will be initiated is four (4) days after the in-office programmer interrogation when the pacemaker’s software is upgraded.

Description of High Battery Impedance Behavior Without Software Upgrade

As described in the original December 2024 advisory, ACCOLADE devices have a potential to exhibit a high impedance condition because of an 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.

Table 3 Safety Mode Non-Programmable Settings

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.

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 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 (Figures 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

¹Caughron H., 2025 Apr 5:S0735-1097(25)05926-1. doi: <https://doi.org/10.1016/j.jacc.2025.03.501>.

Appendix B – Advisory Population

Although high battery impedance induced Safety Mode occurs later in the life of the pacemaker, the population has been expanded to include recently implanted 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. 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	GTIN	Model	Product Name	GTIN	Model	Product Name
00802526558900	L100	ESSENTIO SR SL	00802526593246	L201	PROPONENT DR SL	00802526609015	L310	ACCOLADE MRI SR SL
00802526558917	L100	ESSENTIO SR SL	00802526611834	L201	PROPONENT DR SL	00802526611803	L310	ACCOLADE MRI SR SL
00802526571923	L100	ESSENTIO SR SL	00802526559068	L209	PROPONENT VDDR SL	00802526559228	L311	ACCOLADE MRI DR SL
00802526571930	L100	ESSENTIO SR SL	00802526572166	L209	PROPONENT VDDR SL	00802526559235	L311	ACCOLADE MRI DR SL
00802526571947	L100	ESSENTIO SR SL	00802526576386	L209	PROPONENT VDDR SL	00802526572395	L311	ACCOLADE MRI DR SL
00802526576300	L100	ESSENTIO SR SL	00802526576881	L209	PROPONENT VDDR SL	00802526572401	L311	ACCOLADE MRI DR SL
00802526576805	L100	ESSENTIO SR SL	00802526611889	L209	PROPONENT VDDR SL	00802526572418	L311	ACCOLADE MRI DR SL
00802526593109	L100	ESSENTIO SR SL	00802526559075	L210	PROPONENT MRI SR SL	00802526576461	L311	ACCOLADE MRI DR SL
00802526611605	L100	ESSENTIO SR SL	00802526559082	L210	PROPONENT MRI SR SL	00802526576966	L311	ACCOLADE MRI DR SL
00802526558924	L101	ESSENTIO DR SL	00802526572180	L210	PROPONENT MRI SR SL	00802526578076	L311	ACCOLADE MRI DR SL
00802526558931	L101	ESSENTIO DR SL	00802526576393	L210	PROPONENT MRI SR SL	00802526609008	L311	ACCOLADE MRI DR SL
00802526571961	L101	ESSENTIO DR SL	00802526576898	L210	PROPONENT MRI SR SL	00802526611896	L311	ACCOLADE MRI DR SL
00802526571978	L101	ESSENTIO DR SL	00802526578021	L210	PROPONENT MRI SR SL	00802526559242	L321	ACCOLADE DR EL
00802526576317	L101	ESSENTIO DR SL	00802526609077	L210	PROPONENT MRI SR SL	00802526559259	L321	ACCOLADE DR EL
00802526576812	L101	ESSENTIO DR SL	00802526611773	L210	PROPONENT MRI SR SL	00802526572425	L321	ACCOLADE DR EL
00802526593116	L101	ESSENTIO DR SL	00802526559099	L211	PROPONENT MRI DR SL	00802526572432	L321	ACCOLADE DR EL
00802526611629	L101	ESSENTIO DR SL	00802526559105	L211	PROPONENT MRI DR SL	00802526576478	L321	ACCOLADE DR EL
00802526558948	L110	ESSENTIO MRI SR SL	00802526572210	L211	PROPONENT MRI DR SL	00802526576973	L321	ACCOLADE DR EL
00802526558955	L110	ESSENTIO MRI SR SL	00802526576409	L211	PROPONENT MRI DR SL	00802526593260	L321	ACCOLADE DR EL
00802526571985	L110	ESSENTIO MRI SR SL	00802526576904	L211	PROPONENT MRI DR SL	00802526611766	L321	ACCOLADE DR EL
00802526572005	L110	ESSENTIO MRI SR SL	00802526578038	L211	PROPONENT MRI DR SL	00802526559266	L331	ACCOLADE MRI DR EL
00802526576324	L110	ESSENTIO MRI SR SL	00802526609022	L211	PROPONENT MRI DR SL	00802526559273	L331	ACCOLADE MRI DR EL
00802526576829	L110	ESSENTIO MRI SR SL	00802526611704	L211	PROPONENT MRI DR SL	00802526572456	L331	ACCOLADE MRI DR EL
00802526609039	L110	ESSENTIO MRI SR SL	00802526559112	L221	PROPONENT DR EL	00802526572463	L331	ACCOLADE MRI DR EL
00802526611636	L110	ESSENTIO MRI SR SL	00802526559129	L221	PROPONENT DR EL	00802526572470	L331	ACCOLADE MRI DR EL
00802526558962	L111	ESSENTIO MRI DR SL	00802526572265	L221	PROPONENT DR EL	00802526576485	L331	ACCOLADE MRI DR EL
00802526558979	L111	ESSENTIO MRI DR SL	00802526576416	L221	PROPONENT DR EL	00802526576980	L331	ACCOLADE MRI DR EL
00802526572012	L111	ESSENTIO MRI DR SL	00802526576911	L221	PROPONENT DR EL	00802526578083	L331	ACCOLADE MRI DR EL
00802526572029	L111	ESSENTIO MRI DR SL	00802526578045	L221	PROPONENT DR EL	00802526592201	L331	ACCOLADE MRI DR EL
00802526572036	L111	ESSENTIO MRI DR SL	00802526593307	L221	PROPONENT DR EL	00802526609084	L331	ACCOLADE MRI DR EL
00802526576331	L111	ESSENTIO MRI DR SL	00802526611858	L221	PROPONENT DR EL	00802526611872	L331	ACCOLADE MRI DR EL
00802526576836	L111	ESSENTIO MRI DR SL	00802526559136	L231	PROPONENT MRI DR EL	00802526559327	S701	ALTRUA 2 SR SL
00802526609060	L111	ESSENTIO MRI DR SL	00802526559143	L231	PROPONENT MRI DR EL	00802526559334	S701	ALTRUA 2 SR SL
00802526611612	L111	ESSENTIO MRI DR SL	00802526572272	L231	PROPONENT MRI DR EL	00802526572487	S701	ALTRUA 2 SR SL
00802526558986	L121	ESSENTIO DR EL	00802526576423	L231	PROPONENT MRI DR EL	00802526576492	S701	ALTRUA 2 SR SL
00802526558993	L121	ESSENTIO DR EL	00802526576928	L231	PROPONENT MRI DR EL	00802526576997	S701	ALTRUA 2 SR SL
00802526572043	L121	ESSENTIO DR EL	00802526578052	L231	PROPONENT MRI DR EL	00802526578090	S701	ALTRUA 2 SR SL
00802526576348	L121	ESSENTIO DR EL	00802526609046	L231	PROPONENT MRI DR EL	00802526593222	S701	ALTRUA 2 SR SL
00802526576843	L121	ESSENTIO DR EL	00802526611780	L231	PROPONENT MRI DR EL	00802526611841	S701	ALTRUA 2 SR SL
00802526593277	L121	ESSENTIO DR EL	00802526559150	L300	ACCOLADE SR SL	00802526559341	S702	ALTRUA 2 DR SL
00802526611650	L121	ESSENTIO DR EL	00802526559167	L300	ACCOLADE SR SL	00802526559358	S702	ALTRUA 2 DR SL
00802526559006	L131	ESSENTIO MRI DR EL	00802526572302	L300	ACCOLADE SR SL	00802526572517	S702	ALTRUA 2 DR SL
00802526559013	L131	ESSENTIO MRI DR EL	00802526576430	L300	ACCOLADE SR SL	00802526576508	S702	ALTRUA 2 DR SL
00802526572074	L131	ESSENTIO MRI DR EL	00802526576935	L300	ACCOLADE SR SL	00802526577000	S702	ALTRUA 2 DR SL
00802526572081	L131	ESSENTIO MRI DR EL	00802526593321	L300	ACCOLADE SR SL	00802526578106	S702	ALTRUA 2 DR SL
00802526576355	L131	ESSENTIO MRI DR EL	00802526611810	L300	ACCOLADE SR SL	00802526593208	S702	ALTRUA 2 DR SL
00802526576850	L131	ESSENTIO MRI DR EL	00802526559174	L301	ACCOLADE DR SL	00802526611759	S702	ALTRUA 2 DR SL
00802526609053	L131	ESSENTIO MRI DR EL	00802526559181	L301	ACCOLADE DR SL	00802526559365	S722	ALTRUA 2 DR EL
00802526611643	L131	ESSENTIO MRI DR EL	00802526572333	L301	ACCOLADE DR SL	00802526559372	S722	ALTRUA 2 DR EL
00802526559020	L200	PROPONENT SR SL	00802526572340	L301	ACCOLADE DR SL	00802526573071	S722	ALTRUA 2 DR EL
00802526559037	L200	PROPONENT SR SL	00802526572357	L301	ACCOLADE DR SL	00802526576515	S722	ALTRUA 2 DR EL
00802526572104	L200	PROPONENT SR SL	00802526576447	L301	ACCOLADE DR SL	00802526577017	S722	ALTRUA 2 DR EL
00802526576362	L200	PROPONENT SR SL	00802526576942	L301	ACCOLADE DR SL	00802526578113	S722	ALTRUA 2 DR EL
00802526576867	L200	PROPONENT SR SL	00802526593215	L301	ACCOLADE DR SL	00802526593239	S722	ALTRUA 2 DR EL
00802526578007	L200	PROPONENT SR SL	00802526611865	L301	ACCOLADE DR SL	00802526611711	S722	ALTRUA 2 DR EL
00802526593338	L200	PROPONENT SR SL	00802526559204	L310	ACCOLADE MRI SR SL	00802526559389	U125	VALITUDE CRT-P EL IS-1
00802526611827	L200	PROPONENT SR SL	00802526559211	L310	ACCOLADE MRI SR SL	00802526559396	U125	VALITUDE CRT-P EL IS-1
00802526559044	L201	PROPONENT DR SL	00802526572364	L310	ACCOLADE MRI SR SL	00802526573101	U125	VALITUDE CRT-P EL IS-1
00802526559051	L201	PROPONENT DR SL	00802526572371	L310	ACCOLADE MRI SR SL	00802526573118	U125	VALITUDE CRT-P EL IS-1
00802526572135	L201	PROPONENT DR SL	00802526572388	L310	ACCOLADE MRI SR SL	00802526573125	U125	VALITUDE CRT-P EL IS-1
00802526576379	L201	PROPONENT DR SL	00802526576454	L310	ACCOLADE MRI SR SL	00802526577024	U125	VALITUDE CRT-P EL IS-1
00802526576874	L201	PROPONENT DR SL	00802526576959	L310	ACCOLADE MRI SR SL	00802526577109	U125	VALITUDE CRT-P EL IS-1
00802526578014	L201	PROPONENT DR SL	00802526578069	L310	ACCOLADE MRI SR SL	00802526578793	U125	VALITUDE CRT-P EL IS-1

GTIN	Model	Product Name	GTIN	Model	Product Name	GTIN	Model	Product Name
00802526593291	U125	VALITUDE CRT-P EL IS-1	00802526559433	U225	VISIONIST CRT-P EL IS-1	00802526577123	U226	VISIONIST CRT-P EL IS-1/LV-1
00802526611735	U125	VALITUDE CRT-P EL IS-1	00802526572630	U225	VISIONIST CRT-P EL IS-1	00802526578816	U226	VISIONIST CRT-P EL IS-1/LV-1
00802526559402	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526572647	U225	VISIONIST CRT-P EL IS-1	00802526611728	U226	VISIONIST CRT-P EL IS-1/LV-1
00802526559419	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526577048	U225	VISIONIST CRT-P EL IS-1	00802526559471	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526572609	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526577116	U225	VISIONIST CRT-P EL IS-1	00802526559488	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526572616	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526578809	U225	VISIONIST CRT-P EL IS-1	00802526572692	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526572623	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526593253	U225	VISIONIST CRT-P EL IS-1	00802526572708	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526576522	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526611742	U225	VISIONIST CRT-P EL IS-1	00802526572715	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526577031	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526559457	U226	VISIONIST CRT-P EL IS-1/LV-1	00802526577055	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526578120	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526559464	U226	VISIONIST CRT-P EL IS-1/LV-1	00802526577130	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526593284	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526572661	U226	VISIONIST CRT-P EL IS-1/LV-1	00802526578830	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526611797	U128	VALITUDE X4 CRT-P EL IS-1/IS4	00802526572678	U226	VISIONIST CRT-P EL IS-1/LV-1	00802526593314	U228	VISIONIST X4 CRT-P EL IS-1/IS4
00802526559426	U225	VISIONIST CRT-P EL IS-1	00802526577062	U226	VISIONIST CRT-P EL IS-1/LV-1	00802526611902	U228	VISIONIST X4 CRT-P EL IS-1/IS4



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Acknowledgement Form – Urgent Field Safety Notice

Software designed to prevent initiation of Safety Mode in an ambulatory setting due to a high battery impedance state in ACCOLADE™ Pacemakers and CRT-Ps

97125289F-FA

By signing this form, I confirm that

**I have read and understood
the Boston Scientific Field Safety Notice dated
September 2025 for:**

Software designed to prevent initiation of Safety Mode in an ambulatory setting due to a high battery impedance state in ACCOLADE™ Pacemakers and CRT-Ps

NAME* _____ **Title** _____

Telephone _____ **Email** _____

SIGNATURE* _____ **DATE*** _____

* Required field

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