SUMMARY

Safety Mode provides back-up pacing and defibrillation therapy if certain non-recoverable or repeat fault conditions occur.

Products Referenced

- ACCOLADE™, PROPONENT™, ESSENTIO™, ALTRUA™ 2, INGENIO™, ADVANITO™, VITALIO™ pacemakers
- VISIONIST™, VALITUDE™, INVIVE™, INTUA™ CRT-P
- RESONATE™, VIGILANT™, MOMENTUM™, PERCIVA™, AUTOGEN™, DYNAGEN™, ORIGEN™, INCEPTA™, ENERGEN™ CRT-D and ICDs; COGNIS™ CRT-D; TELIGEN™ ICD

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
S-ICD: Subcutaneous Implantable Defibrillator
ICM: Implantable Cardiac Monitor

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Safety Mode Operations

Safety Mode provides back-up pacing and defibrillation therapy if certain non-recoverable or repeat fault conditions occur. Safety Mode parameters are not programmable, and Safety Mode is a permanent condition. Therefore, Boston Scientific recommends device replacement. Safety Mode parameters and settings should be understood and considered relative to some patients' cardiac conditions; for example, pacing may be paused due to Safety Mode's unipolar sensing configuration and a highly sensitive RV amplitude setting. Programmer warning messages and a LATITUDE Red Alert enable high detectability of a device that has entered Safety Mode.

What is Safety Mode?

Boston Scientific pulse generators are equipped with dedicated Safety Mode hardware that per product labeling, is intended to provide life-sustaining therapy if certain non-recoverable or repeat fault conditions occur that cause repeated system resets. These types of faults indicate a loss of component integrity in the pulse generator's central processing unit, including the pulse generator's microprocessor, program code and system memory. Safety Mode is designed to use minimal hardware, and operates independently, acting as a backup to these components, ensuring basic pacing and defibrillation functionality until the device can be replaced.

Safety Mode Operation

If a pulse generator experiences three resets within approximately 48 hours, the device reverts to Safety Mode permanently and device replacement should be considered. While in Safety Mode, the following will occur:

1. ZIP™ (Radio Frequency) telemetry is unavailable for communicating with the programmer; wanded telemetry must be used instead.
2. LATITUDETM NXT will issue a red alert that Safety Mode has been activated (Figure 1).
3. The programmer will display a warning screen indicating that the pulse generator is in Safety Mode, directing the clinician to contact Boston Scientific (Figure 2).
4. In ICDs and CRT-Ds, the pulse generator will emit 16 beeping tones every 6 hours. The beeping tones are disabled once a device is interrogated with a programmer.

When a device is in Safety Mode, Health Care Providers (HCPs) are directed to contact Boston Scientific via a LATITUDE programmer warning screen and a LATITUDE remote patient management system red alert, if applicable. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available.

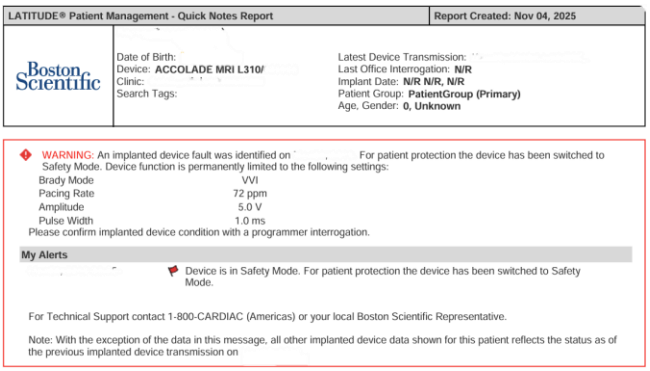


Figure 1. LATITUDE NXT Safety Mode activated

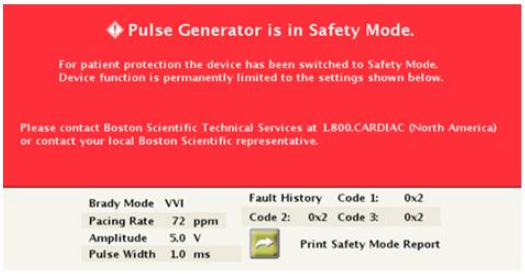


Figure 2. Programmer warning screen indicating Safety Mode

Safety Mode Parameters

Safety Mode is not intended to be a substitute for chronic pacing or defibrillation therapy as it acts as a backup pulse generator ensuring basic pacing and defibrillation functionality until the device can be replaced. Safety Mode parameters and settings should be understood and considered relative to some patients' cardiac conditions Safety Mode settings are non-programmable1 and when they differ from programmed settings, may not be optimal for a patients' cardiac condition. For example, pacing may be paused due to Safety Mode's unipolar sensing configuration and a highly sensitive RV amplitude setting.

Appendix A and **Appendix B** provide applicable Safety Mode parameters for Boston Scientific pulse generators (pacemakers, implantable cardioverter defibrillators, cardiac resynchronization therapy devices), the Safety Mode setting, and any applicable definitions or patient considerations related to the setting.

Product Performance

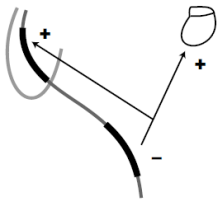
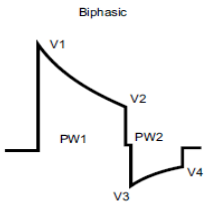
Every pacemaker, CRT-P, ICD, or CRT-D that is returned to Boston Scientific that has entered Safety Mode will be analyzed to determine the cause of the fault. If a pattern is detected, actions are taken to identify a common root cause, and changes intended to improve product reliability and/or performance may be implemented. Patterned events that result in Safety Mode operation can be found in the Boston Scientific Product Performance Report, which is published twice a year at www.bostonscientific.com/ppr.

[1] Safety Mode settings are non-programmable, with the exception of Tachy Mode which can be turned Off.

Appendix A – Safety Mode Non-Programmable Pacing Parameters in Tranvenous Pulse Generators

Parameter	Safety Mode Setting	Description and Patient Considerations
Brady Mode	VVI, Biventricular pacing for CRT	• In VVI mode, sensing and pacing occur only in the ventricle. • In the absence of sensed events, pacing pulses will be delivered to the ventricle at the LRL (VVI). • May be detrimental for heart failure patients. Potential loss of AV synchrony may lead to heart failure symptoms.
Lower Rate Limit	72.5 ppm	• LRL is the number of pulses per minute at which the pulse generator paces in the absence of sensed intrinsic activity. • Safety Mode set higher than nominal of 60 ppm (pacemakers and ICDs) or 45 ppm (CRTs). 72.5 ppm is not programmable by a clinician. • For patients with a sinus rate below LRL, loss of AV synchrony may result.
Pulse Amplitude	5.0 V	• Pulse amplitude is the voltage of the output pulse. • Safety Mode set higher than the nominal of 3.5 V. • Unipolar pacing at high outputs may result in muscle stimulation.
Pulse Width	1.0 ms	• Pulse Width or pulse duration determines how long the output pulse will be applied between the pacing electrodes. • Safety Mode set longer than the nominal of 0.4 ms. • Unipolar pacing at high outputs may result in muscle stimulation.
Right Ventricular Refractory Period (RVRP)	250 ms	• RVRP provides an interval following an RV pace event during which RV sensed events do not impact the timing of pacing delivery. • Safety Mode set to bradycardia Nominal (250).
RV Sensitivity	Automatic Gain Control (AGC) 0.25 mV	• AGC dynamically adjusts the sensitivity in the ventricle. • Safety Mode is set to an AGC floor of 0.25 mV which is lower than the nominal AGC of 2.5mV (bradycardia) and 0.6 mV (tachycardia). • When PG programmed to high sensitivity (low value), the PG may detect signals unrelated to cardiac depolarization (oversensing, such as sensing of myopotentials). • Oversensing can result in inhibition of pacing output. • Oversensing in ICDs can lead to inappropriate tachycardia therapy.
Lead Configuration	RV/LV unipolar sensing/pacing	• When the unipolar sensing configuration is programmed, the cardiac signals are detected between the lead tip and the PG case. The pacemaker can generally discern smaller intrinsic cardiac signals than in the bipolar configuration. • The unipolar configuration is more sensitive to myopotentials which can cause inhibition of pacing output. • Unipolar pacing at high outputs may result in muscle stimulation. • Since a bipolar lead is not always present, bipolar is not an optimal choice for Safety Mode.
Noise response	VOO	• The PG response (pace or inhibit) in the presence of noise. • Safety Mode is set to the same as nominal when the Brady Mode is VVI.
LV Offset (CRT-Ps only)	0 ms	• LV Offset allows for adjustment in the delay between delivery of the right and left ventricular pacing pulses. • Designed to enhance programming flexibility to coordinate the mechanical response of the ventricles. • Safety mode set same as nominal zero (0).
Magnet Response (PMs and CRT-Ps)	Disabled (Off)	• Controls the behavior of the pulse generator when a magnet is detected. • When Magnet Response is programmed to Off, application of the magnet will have no effect on the PG. The PG will not revert to asynchronous operation which may be clinically needed.
Post-Shock Pacing Delay (ICDs and CRT-Ds)	3 seconds	The earliest possible start of post-shock pacing following the delivery of a ventricular shock.

Appendix B – Safety Mode Defibrillation Parameters in Transvenous ICDs and CRT-Ds

Parameter	Safety Mode Setting	Description and Patient Considerations
Tachy Mode	Monitor + Therapy	• Tachy Mode controls the availability of the detection and therapy functions in the ventricle. • Monitor + Therapy enables the full range of ventricular detection and ventricular therapy options. • Programmability in Safety Mode to Off. Off disables ventricular tachycardia detection and therapy delivery. • Useful during explant or if therapy is not clinically desired.
Zone	Single Zone	• A zone is a range of heart rates defined by a programmed ventricular tachycardia rate threshold. Nominally, three tachycardia zones can be prescribed. • When Safety Mode is activated, Tachy Mode is automatically set provide single zone tachycardia therapy and detection. Single zone supports therapy supports a single lead connected to the RV. • Safety Mode set to same as Nominal (1-Zone).
Shocks per Episode	5 maximum-energy committed	• A maximum number of shocks are delivered per ventricular episode. • Safety Mode is set to five (5) maximum-energy committed shocks per episode. • Safety Mode set less than Nominal in VF Zone (8 shocks).
VF Rate Threshold	165 ppm	• Initial ventricular detection criteria consist of programmed Rate and Duration. • PG compares each sensed RV cardiac cycle interval against the programmed Ventricular Rate Threshold. • Safety Mode set to lower than Nominal 1-Zone (200 ppm).
Duration	1 second	• Duration is a timer that measures the length of time in a zone that a rhythm must be sustained before therapy is delivered. • Safety Mode is set lower than the Nominal initial duration (2.5 seconds).
Shock Polarity	Initial	Waveform polarity reflects the relationship between the leading-edge voltages on the defibrillating output electrodes. Polarity is either Initial or Reverse. Safety Mode set to same as Nominal (Initial).  Initial polarity
Shock Waveform	Biphasic	All shocks delivered using biphasic waveform. Safety Mode set to same as Nominal (Biphasic).  PW = Pulse Width PW2 = PW1 x 0.66 V2 = V3
Shock Vector	RV Coil to RA Coil and Can (V-TRIAD)	• RV Coil to RA Coil and Can, also known as V-TRIAD vector. Uses the housing of the PG as an active electrode combined with a two-electrode defibrillation lead. Energy is sent via dual-current pathway from the distal shocking coil electrode to the proximal electrode and the PG case. • For single coil lead, this is effectively RV Coil to Can. Used for single coil lead. Uses the housing of the PG as an active electrode. Energy is sent from the distal shocking coil electrode to the PG case. • Safety Mode is set to the same as nominal RV Coil to RA Coil and Can.
Magnet Response (ICDs and CRT-Ds)	Inhibit Therapy	• Magnet application will immediately inhibit therapy, charging may continue. After the magnet has been applied for 1 second, therapy is diverted, and detection is inhibited. The magnet must then be removed for 2 seconds to allow detection to continue. • Safety Mode disables normal beeping behavior following magnet application. • Safety Mode is set to the same as Nominal (Inhibit).

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