Early Removal of an ICD or CRT-D From Storage Mode

SUMMARY

All Boston Scientific ICDs and CRT-Ds should remain in Storage mode until an implanted lead has been attached. Doing so conserves battery life and in the case of ICDs and CRT-Ds prevents activation of daily diagnostic measurements, noise on electrograms during implant, and the storage of episodes prior to implant.

Boston Scientific ICDs and CRT-Ds are shipped in a power-saving Storage mode to conserve battery energy prior to implant. While in Storage mode all device features are inactive **except** telemetry support (interrogation and programming), the real-time clock, commanded capacitor re-formation, STAT SHOCK, and STAT PACE commands. If the Tachy Mode is programmed to Off, Monitor Only, or Monitor + Therapy, or a STAT function is commanded, the device will be removed from Storage mode.

Removing an ICD or CRT-D from Storage Mode

As described in the implant steps of defibrillator instructions for use (Table 1), the majority of the steps involved in an implant or replacement procedure can be conducted prior to removing a device from Storage mode.

Table 1. Summary of CRT-D Implant Steps

Step	Action
1	Verify the availability of equipment necessary for the implant procedure. This equipment includes the Boston Scientific programmer and instrumentation for cardiac monitoring, pacing, defibrillation, and lead signal measurements.
2	While the device is in sterile packaging: a. Perform an interrogation b. Verify Storage mode c. Perform a manual capacitor re-formation d. Review the current battery status
3	Implant the lead system.
4	Take baseline measurements—evaluate signal amplitudes, pacing thresholds, and impedances using a Pacing System Analyzer.
5	Form the implantation pocket.
6	Connect the leads to the device.
7	Take device out of Storage mode by programming the Tachy Mode to Off.*
8	Evaluate the pace/sense and defibrillation lead signals and impedances.
9	Program the device as appropriate.† a. Shocks intended for VR therapy should be programmed with a 10 Joule safety margin above the shock energy level that is required for successful VF conversion.
10	Complete device implant.

*CAUTION: To prevent inappropriate shocks, ensure that the device's Tachy Mode is programmed to Off when not in use and before handling the device. For tachyarrhythmia therapy, verify that the Tachy Mode is activated (Monitor + Therapy).

†Device programming can be done in parallel with Steps 3, 4, and 5. For pacemaker dependant patients in particular, consider appropriate programming and removal from Storage mode before attachment of the leads.

Upon removal from Storage mode:

- Pacing begins
- Device diagnostics are enabled
  - Certain diagnostics are automatically conducted on a daily basis as specified in defibrillator instructions for use, including daily lead impedance measurements
- Therapy history is enabled
  - Counters are activated
  - Arrhythmia Logbook is able to store data when an episode is declared

CRM PRODUCTS REFERENCED

All Boston Scientific ICDs and CRT-Ds, and LATITUDE® Patient Management System

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator

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Potential Consequences of Early Removal from Storage Mode

If an ICD or CRT-D is removed from Storage mode earlier than recommended in the defibrillator instructions for use (e.g., while in hospital shelf inventory or in sales representative consignment inventory), oversensing and/or beeping tones associated with an out-of-range shock lead impedance may occur.

Oversensing

Removal from Storage mode activates the device's sensing circuitry. Therefore, if one or more of the leads are **not** connected to a device when it exits Storage mode, external noise (i.e., environmental electromagnetic interference) may be "oversensed." This oversensing may be detected on either the atrial or ventricular channels or both (depending on which lead ports remain open) during the implant procedure and may lead to:

- Noise on electrograms
- Inhibition of atrial or ventricular pacing
- Inappropriate tracking of ventricular paced rate relative to atrial rate
- Inappropriate shock delivery into an open lead condition (when the leads are not connected), resulting in a warning message
- Brady and tachy episodes stored in the Arrhythmia Logbook—
  - Oversensing on the atrial channel may be stored as Atrial Tachycardia Response episodes
  - Oversensing on the right ventricular channel may be stored as Tachycardia or non-sustained episodes
  - All delivered shocks will be stored

Shock Lead Impedance Test

Daily measurements begin when the device is taken out of Storage mode. Therefore, if the device is removed from Storage mode earlier than recommended in the defibrillator instructions for use, a daily shock impedance measurement may occur before the device is attached to an implanted lead. When an out-of-range impedance measurement is detected (either less than 20 ohms [Ω] or greater than 125 Ω), the following will occur:

COGNIS® and TELIGEN® devices—

- Beeping tones will NOT be emitted.
- Upon device interrogation, the out-of-range impedance will be displayed in the Summary pop-up message appearing immediately upon interrogation.
  - The out-of-range measurement will be cleared automatically when device interrogation is complete.

VITALITY®HE, CONTAK RENEWAL®3 family, CONTAK RENEWAL 4 family, CONFIENT®, and LIVIAN® devices—

- 16 R-wave synchronous beeping tones will be emitted every six hours.
- Upon device interrogation, the out-of-range impedance will be displayed in the Clinical Events.
  - If the Clinical Event is not reset, beeping will continue post-implant.

All other ICDs and CRT-Ds—

- Beeping tones will NOT be emitted.
- Upon device interrogation, the out-of-range impedance will be displayed in the Clinical Events.
  - If the Clinical Event is not reset, it will remain post-implant.

Refer to the following **A Closer Look** articles for further information:

- *Beeping Tones Associated with "Out-of Range" Shock Lead Impedance*—to determine the root cause of the beeping tones heard from an ICD or CRT-D and prevent the recurrence of an out-of-range lead impedance measurement.
- *Investigate, Report, Print and Reset Clinical Event Messages in the System Summary Screen*—to learn the steps in resetting clinical events.
- *Shock Impedance Testing in COGNIS CRT-Ds and TELIGEN ICDs at Implant Procedures*—to understand how shock lead impedance testing is conducted with COGNIS and TELIGEN devices.

If beeps and/or out-of-range shock lead impedance measurements are detected in an implanted device, normal troubleshooting procedures should be followed to identify root cause and resolve the issue.

Prevention of Issues Related to Early Removal from Storage Mode

To avoid oversensing of noise or unnecessary out-of-range daily impedance measurements, the device should not be taken out of Storage mode until it has been attached to all implanted leads. **Pre-setting parameters, performing capacitor reformations and checking battery status are all possible without taking the device out of Storage mode.** If, however, an ICD or CRT-D is inadvertently removed from Storage mode, ensure that the Tachy Mode and Brady Mode are programmed to Off to prevent inappropriate pacing, shocks, and episode storage. Once implanted, verify that the Tachy Mode is activated (Monitor + Therapy), the Brady Mode is programmed to the preferred mode, and the clinical events and counters are reset.

For assistance, contact CRM Technical Services at 1.800.227.3422 or Technical Services – Europe at +32 2 416 7222.