Boston Scientific

USER'S MANUAL

EMBLEM™ S-ICD, EMBLEM™ MRI S-ICD

SUBCUTANEOUS IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

REF A209, A219

Table of Contents

Description....1
About This Manual....1
Related Information....2
Indications for Use....3
Contraindications....3
Warnings....3
Precautions....6
Supplemental Precautionary Information....14
- Post-Therapy Pulse Generator Follow Up....14

Potential Adverse Events....15
Patient Screening....16
- Collecting the Surface ECG....17
- Evaluating the Surface ECG....18
- Determining an Acceptable Sense Vector....20

Operation....21
- General....21
- Modes of Operation....21
- Magnetic Resonance Imaging (MRI)....22
- Sensing Configuration and Gain Selection....23
- Sensing and Tachyarrhythmia Detection....24
- Therapy Zones....25
- Analysis in the Conditional Shock Zone....26
- Charge Confirmation....26
- Therapy Delivery....27
- SMART Charge....27
- Redetection....27
- Shock Waveform and Polarity....27
- Post-Shock Bradycardia Pacing Therapy....28
- Manual and Rescue Shock Delivery....28
- Additional Features of the S-ICD System....28
  - Auto Capacitor Reformation....28
  - Internal Warning System—Beeper Control....28
  - Arrhythmia Induction....30
- System Diagnostics....30
- Storing and Analyzing Data....31
- AF Monitor....34
- S-ICD System Magnet Use....34
- Bidirectional Torque Wrench....37

Using the S-ICD System....38
- Surgical Preparation....38

Items Included in Package 38
Implantation 39
Overview 39
Check Equipment 42
Interrogate and Check the Pulse Generator.....42
Creating the Device Pocket 43
Connect the Subcutaneous Electrode to the Device 43
Setting up the Pulse Generator using the Model 3200 S-ICD Programmer.....48
Defibrillation Testing 48
Complete and Return the Implantation Form 50
Patient Counseling Information 50
Post Implant Follow-Up Procedures 51
Explantation 52
Loosening Stuck Setscrews 53
Communication Compliance 54
Additional Information 54
Product Reliability 54
Pulse Generator Longevity 55
X-ray Identifier 56
Specifications.....57
Definitions of Package Label Symbols 62
S-ICD System and Pacemaker Interaction.....65
Warranty Information.....66

DESCRIPTION

The EMBLEM S-ICD family of pulse generators (the "device") are components of the Boston Scientific S-ICD System, which is prescribed for patients when cardiac arrhythmia management is warranted. The device accepts one EMBLEM S-ICD subcutaneous electrode with an SQ-1 S-ICD connector[1]. The device is also compatible with the Cameron Health Model 3010 Q-TRAK subcutaneous electrode.

The pulse generator and subcutaneous electrode constitute the implantable portion of the S-ICD System. The pulse generator can be used only with the EMBLEM S-ICD programmer Model 3200 and Model 3203 telemetry wand.

This guide may contain reference information for model numbers that are not currently approved for sale in all geographies. For a complete list of model numbers approved in your geography, consult with your local sales representative. Some model numbers may contain fewer features; for those devices, disregard descriptions of the unavailable features. Descriptions found within this manual apply to all device models unless otherwise noted.

NOTE: *EMBLEM S-ICD devices are considered MR Conditional. Refer to "Magnetic Resonance Imaging (MRI)" on page 22 and the ImageReady MR Conditional S-ICD System MRI Technical Guide for more information.*

NOTE: *Use of a Boston Scientific/Cameron Health electrode is required for an implanted system to be considered MR Conditional. Refer to the ImageReady MR Conditional S-ICD System MRI Technical Guide for model numbers of system components needed to satisfy the Conditions of Use.*

ABOUT THIS MANUAL

This product may be protected by one or more patents. Patent information can be obtained at www.bostonscientific.com/patents.

The following are trademarks of Boston Scientific Corporation or its affiliates: EMBLEM, IMAGEREADY, AF Monitor, LATITUDE.

The following acronyms may be used in this manual:

AC	Alternating Current
AF	Atrial Fibrillation
AST	Automated Screening Tool
ATP	Antitachycardia Pacing
BOL	Beginning of Life
CPR	Cardiopulmonary Resuscitation
CRM	Cardiac Rhythm Management
CRT	Cardiac Resynchronization Therapy
DFT	Defibrillation Threshold

1. SQ-1 is a non-standard connector unique to the S-ICD System.

EAS	Electronic Article Surveillance
ECG	Electrocardiogram
EGM	Electrogram
EIT	Electrode Insertion Tool
EKG	Electrocardiogram
EMI	Electromagnetic Interference
EOL	End of Life
ERI	Elective Replacement Indicator
ESWL	Extracorporeal Shock Wave Lithotripsy
HBOT	Hyperbaric Oxygen Therapy
ISO	International Standards Organization
MRI	Magnetic Resonance Imaging
NSR	Normal Sinus Rhythm
PVC	Premature Ventricular Contraction
RF	Radio Frequency
RFID	Radio Frequency Identification
S-ECG	Subcutaneous Electrocardiogram
S-ICD	Subcutaneous Implantable Cardioverter Defibrillator
SVT	Supraventricular Tachycardia
TENS	Transcutaneous Electrical Nerve Stimulation
VAD	Ventricular Assist Device
VF	Ventricular Fibrillation
VT	Ventricular Tachycardia

RELATED INFORMATION

Instructions in this manual should be used in conjunction with other resource material, including the applicable S-ICD subcutaneous electrode user's manual and electrode implant tools user's manual.

Refer to the ImageReady MR Conditional S-ICD System MRI Technical Guide (hereafter referred to as the MRI Technical Guide) for information about MRI scanning.

LATITUDE NXT is a remote monitoring system that provides pulse generator data for clinicians. All pulse generators described in this manual are designed to be LATITUDE NXT enabled; availability varies by region.

- Physicians/Clinicians—LATITUDE NXT enables you to periodically monitor both patient and device status remotely and automatically. The LATITUDE NXT system provides patient data that can be used as part of the clinical evaluation of the patient.
- Patients—A key component of the system is the LATITUDE Communicator, an easy-to-use, in-home monitoring device. The Communicator reads implanted device data from a compatible Boston Scientific pulse generator and sends this data to the LATITUDE NXT secure server. The LATITUDE NXT server displays the patient data on the LATITUDE NXT Web site, which is readily accessible over the Internet to authorized physicians and clinicians.

Refer to the LATITUDE NXT Clinician Manual for more information.

INTENDED AUDIENCE

This literature is intended for use by professionals trained or experienced in device implant and/or follow-up procedures.

INDICATIONS FOR USE

The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with antitachycardia pacing.

CONTRAINDICATIONS

Unipolar stimulation and impedance-based features are contraindicated for use with the S-ICD System.

WARNINGS

General

- **Co-implanted device interaction.** Concomitant use of the S-ICD System and implanted electro-mechanical devices (for example implantable neuromodulation/neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. The S-ICD is intended as lifesaving therapy and should be seen as priority in the decision and evaluation of concomitant system implants over non-lifesaving applications. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and/or compromise its functionality. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the S-ICD System when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Induction testing is recommended to ensure appropriate detection and time to therapy for the S-ICD and appropriate post-shock operation of the co-implanted device. Failure to ensure appropriate detection and time to therapy delivery of the S-ICD system could result in patient injury or death.

  Following completion of the interaction testing, thorough follow-up evaluation of all co-implanted devices should be performed to ensure that device functions have not been compromised. If operational settings of the co-implanted devices change or if patient conditions change which may affect S-ICD sensing and therapy performance, re-evaluation of the co-implanted devices may be required.

- **Labeling knowledge.** Read this manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death.

- **For single patient use only.** Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

- **Component compatibility.** All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific or Cameron Health S-ICD System only. Connection of any S-ICD System components to a non-compatible component has not been tested and could result in failure to deliver life-saving defibrillation therapy.
- **Backup defibrillation protection.** Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.
- **Pulse generator interaction.** Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Refer to "S-ICD System and Pacemaker Interaction" on page 65 for more information.

Handling

- **Proper handling.** Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Failure to do so may lead to injury, illness, or death of the patient.
- **Do not damage components.** Do not modify, cut, kink, crush, stretch, or otherwise damage any component of the S-ICD System. Impairment to the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
- **Handling the subcutaneous electrode.** Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. This could damage the connector. A damaged connector may result in compromised sealing integrity, possibly leading to compromised sensing, loss of therapy, or inappropriate therapy.

Implantation

- **Arm positioning.** Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing.
- **System migration.** Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgement and/or migration. Dislodgement and/or migration of the S-ICD System may result in an inappropriate shock or failure to deliver therapy to the patient.
- **Upper extremity injury.** During arrhythmia induction, the induction current and subsequent shock may result in forceful contraction of the pectoralis major muscle which can exert significant acute forces on the glenohumeral joint as well as on the clavicle. This, in conjunction with a tightly restrained arm, may result in injury to the clavicle, shoulder, and arm, including dislocation and fracture.

- **Do not implant in MRI site Zone III.** Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[2]. Some of the accessories used with pulse generators and electrodes, including the torque wrench and electrode implant tools, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

Post-Implant

- **Magnet response.** Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.
- **Magnet response with deep implant placement.** In patients with a deep implant placement (greater distance between the magnet and the pulse generator), magnet application may fail to elicit the magnet response. In this case the magnet cannot be used to inhibit therapy.
- **Diathermy.** Do not expose a patient with an implanted S-ICD System to diathermy. The interaction of diathermy therapy with an implanted S-ICD pulse generator or electrode can damage the pulse generator and cause patient injury.
- **Magnetic Resonance Imaging (MRI) exposure.** EMBLEM S-ICD devices are considered MR Conditional. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result.
- **Programmer is MR Unsafe.** The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[3]. Under no circumstances should the programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.
- **Tachycardia therapy suspended when programmed to MRI Protection Mode.** During MRI Protection Mode the Tachycardia therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady S-ICD System must be programmed to MRI Protection Mode using the programmer. MRI Protection Mode disables Tachycardia therapy. The system will not detect ventricular arrhythmias and the patient will not receive shock defibrillation therapy until the pulse generator resumes normal operation. Only program the device to MRI Protection Mode if the patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.
- **MRI scanning after ERI status.** MRI scanning after ERI status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. After performing an MRI scan on a device that has reached ERI status, verify pulse generator function and schedule device replacement.
- **Beeper volume after MRI.** The Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode.

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2. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007
3. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

- **Protected environments.** Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator.
- **Sensitivity settings and EMI.** The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. Oversensing of noise due to this increased susceptibility could lead to inappropriate shocks and should be taken into consideration when determining the follow-up schedule for patients exposed to low frequency electromagnetic interference. The most common source of electromagnetic interference in this frequency range is the power system for some European trains which operate at 16.6 Hz. Particular attention should be given to patients with occupational exposure to these types of systems.

PRECAUTIONS

Clinical Considerations

- **Longevity.** Battery depletion will eventually cause the S-ICD pulse generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.
- **Pediatric use.** The S-ICD System has not been evaluated for pediatric use.
- **Available therapies.** The S-ICD System does not provide long-term bradycardia pacing, cardiac resynchronization therapy (CRT), or antitachycardia pacing (ATP).

Sterilization and Storage

- **If package is damaged.** The blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator and/or subcutaneous electrode is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the pulse generator and/or subcutaneous electrode to Boston Scientific.
- **If device is dropped.** Do not implant a device which has been dropped while outside of its intact shelf package. Do not implant a device which has been dropped from a height of more than 24 inches (61 cm) while within its intact shelf package. Sterility, integrity, and/or function cannot be guaranteed under these conditions, and the device should be returned to Boston Scientific for inspection.
- **Use by date.** Implant the pulse generator and/or subcutaneous electrode before or on the USE BY date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 2.
- **Device storage.** Store the pulse generator in a clean area away from magnets, kits containing magnets, and sources of EMI to avoid device damage.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°C–50°C (32°F–122°F). Allow the device to reach a proper temperature before using telemetry communication capabilities, programming, or implanting the device because temperature extremes may affect initial device function.

Implantation

- **Avoid shock at implant.** Verify the device is in Shelf mode or Therapy Off to prevent the delivery of unwanted shocks to the patient or the person handling the device during the implant procedure.
- **Evaluate patient for surgery.** There may be additional factors regarding the patient's overall health and medical condition that, while not related to device function or purpose, could render the patient a poor candidate for implantation of this system. Cardiac health advocacy groups may have published guidelines that may be helpful in conducting this evaluation. Prior medical history of shoulder or clavicle injury (e.g., fracture or dislocation), or osteopenia/osteoporosis may predispose the patient to clavicle, shoulder, or arm injury during induction of VT/VF while testing the S-ICD.
- **Creating the subcutaneous tunnels.** Use Boston Scientific tools and accessories designed for use in implanting the subcutaneous electrode to create the subcutaneous tunnels when implanting and positioning the subcutaneous electrode. Avoid tunneling close to any other subcutaneously implanted medical devices or components, for example, an implantable insulin pump, drug pump, sternal wiring from previous sternotomy, or ventricular assist device.
- **Superior tunnel length.** Ensure the superior tunnel is long enough to accommodate the portion of the electrode from the distal tip to the suture sleeve without buckling or curving of the defibrillation coil. Buckling or curvature of the defibrillation coil within the superior tunnel could lead to compromised sensing and/or therapy delivery. After insertion of the electrode into the superior tunnel, X-ray or fluoroscopy may be used to confirm that no buckling or curvature is observed.
- **Suture location.** Suture only those areas indicated in the implant instructions.
- **Do not suture directly over subcutaneous electrode body.** Do not suture directly over the subcutaneous electrode body, as this may cause structural damage. Use the suture sleeve to prevent subcutaneous electrode movement.
- **Do not bend the subcutaneous electrode near the electrode-header interface.** Insert the subcutaneous electrode connector straight into the pulse generator header port. Do not bend the subcutaneous electrode near the subcutaneous electrode-header interface. Improper insertion can cause insulation or connector damage.
- **Subcutaneous electrode connections.** Do not insert the subcutaneous electrode into the pulse generator connector port without taking the following precautions to ensure proper insertion:
  - Insert the torque wrench into the preslit depression of the seal plug before inserting the subcutaneous electrode connector into the port, to release any trapped fluid or air.
  - Visually verify that the setscrew is sufficiently retracted to allow insertion. Use the torque wrench to loosen the setscrew if necessary.
  - Fully insert the subcutaneous electrode connector into the port and then tighten the setscrew onto the connector.
- **Sternal wires.** When implanting the S-ICD system in a patient with sternal wires, ensure that there is no contact between the sternal wires and the distal and proximal sense electrodes (for example, by using fluoroscopy). Compromised sensing can occur if metal-to-metal contact occurs between a sense electrode

and a sternal wire. If necessary, re-tunnel the electrode to ensure sufficient separation between the sense electrodes and the sternal wires.

- **Replacement device.** Implanting a replacement device in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Irrigating the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- **Telemetry wand.** The wand is a non-sterile device. Do not sterilize the wand or programmer. The wand must be contained in a sterile barrier before use in the sterile field.

Device Programming

- **Device communication.** Use only the designated programmer and software application to communicate with this pulse generator.
- **Sensing adjustment.** Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing.
- **Patients hear tones coming from their device.** Patients should be advised to contact their physician immediately if they hear tones coming from their device.
- **Programming for supraventricular tachyarrhythmias (SVTs).** Determine if the device and programmed parameters are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy.

Environmental and Medical Therapy Hazards

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

  Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation.

  Examples of potential EMI sources are:

  - Electrical power sources
  - Arc welding or resistance welding equipment (should remain at least 24 inches from the implant)
  - Robotic jacks
  - High voltage power distribution lines
  - Electrical smelting furnaces
  - Large RF transmitters such as radar
  - Radio transmitters, including those used to control toys
  - Electronic surveillance (antitheft) devices
  - An alternator on a car that is running

- Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies
- Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine)

Hospital and Medical Environments

- **External defibrillation.** External defibrillation or cardioversion can damage the pulse generator or subcutaneous electrode. To help prevent damage to implanted system components, consider the following:
  - Avoid placing a pad (or paddle) directly over the pulse generator or subcutaneous electrode. Position the pads (or paddles) as far from the implanted system components as possible.
  - Set energy output of external defibrillation equipment as low as clinically acceptable.
  - Following external cardioversion or defibrillation, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" on page 14).
- **Cardiopulmonary resuscitation.** Cardiopulmonary resuscitation (CPR) may temporarily interfere with sensing and may cause delay of therapy.
- **Electrical interference.** Electrical interference or “noise” from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. Electrical interference or “noise” from concomitant implanted devices such as ventricular assist device (VAD), drug pump, or insulin pump may interfere with establishing or maintaining telemetry for interrogating or programming the pulse generator. In the presence of such interference, place the wand over the pulse generator and shield both with a radiation-resistant material.
- **Ionizing radiation therapy.** It is not possible to specify a safe radiation dosage or guarantee proper pulse generator function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an implanted pulse generator, including proximity of the pulse generator to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the pulse generator, and shielding of the pulse generator. The impact of ionizing radiation will also vary from one pulse generator to another and may range from no changes in function to a loss of therapy.

  Sources of ionizing radiation vary significantly in their potential impact on an implanted pulse generator. Several therapeutic radiation sources are capable of interfering with or damaging an implanted pulse generator, including those used for the treatment of cancer, such as radioactive cobalt, linear accelerators, radioactive seeds, and betatrons.

  Prior to a course of therapeutic radiation treatment, the patient’s radiation oncologist and cardiologist or electrophysiologist should consider all patient management options, including increased follow-up and device replacement. Other considerations include:

  - Shield the Pulse Generator with a radiation-resistant material, regardless of the distance between the Pulse Generator and the radiation beam.

- Determining the appropriate level of patient monitoring during treatment.

Evaluate pulse generator operation during and following the course of radiation treatment to exercise as much device functionality as possible ("Post-Therapy Pulse Generator Follow Up" on page 14). The extent, timing, and frequency of this evaluation relative to the radiation therapy regimen are dependent upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist.

Pulse generator diagnostics are performed automatically once per hour, so pulse generator evaluation should not be concluded until pulse generator diagnostics have been updated and reviewed (at least one hour after radiation exposure). The effects of radiation exposure on the implanted pulse generator may remain undetected until some time following exposure. For this reason, continue to monitor pulse generator function closely and use caution when programming a feature in the weeks or months following radiation therapy.

- **Electrocautery and radio frequency (RF) ablation.** Electrocautery and RF ablation may induce ventricular arrhythmias and/or fibrillation, and may cause inappropriate shocks and inhibition of post-shock pacing. Additionally, exercise caution when performing any other type of cardiac ablation procedure in patients with implanted devices. If electrocautery or RF ablation is medically necessary, observe the following to minimize risk to the patient and device:
  - Have external defibrillation equipment available.
  - Program the pulse generator to Therapy Off mode.
  - Avoid direct contact between the electrocautery equipment or ablation catheters and the pulse generator and subcutaneous electrode.
  - Keep the path of the electrical current as far away as possible from the pulse generator and subcutaneous electrode.
  - If RF ablation and/or electrocautery is performed on tissue near the pulse generator or subcutaneous electrode, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" on page 14).
  - For electrocautery, use a bipolar electrocautery system where possible and use short, intermittent, and irregular bursts at the lowest feasible energy levels.

  When the procedure is finished, return the pulse generator to Therapy On mode.
- **Lithotripsy.** Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator. If ESWL is medically necessary, consider the following to minimize the potential for encountering interaction:
  - Avoid focusing the lithotripsy beam near the pulse generator implant site.
  - Program the pulse generator to Therapy Off mode to prevent inappropriate shocks.
- **Ultrasound energy.** Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.

- **Radio frequency (RF) interference.** RF signals from devices that operate at frequencies near that of the pulse generator may interrupt telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the programmer and pulse generator.
- **Conducted electrical current.** Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function. Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Therapy Off mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" on page 14).
- **Implanted medical devices with the potential to generate electromagnetic interference (EMI).** Electro-mechanical medical devices that are implanted near the S-ICD System (for example, implantable insulin pumps, drug pumps, or ventricular assist devices) have the potential to generate EMI and could interfere with S-ICD System function. Consider and/or test for potential effects of EMI if such devices are implanted near the S-ICD System.
- **Implanted medical devices with the potential to generate magnetic fields.** Some implanted medical devices, including ventricular assist devices and drug or insulin pumps, contain permanent magnets and motors which may create strong magnetic fields (greater than 10 gauss or 1 mTesla). Magnetic fields may suspend arrhythmia detection and therapy delivery if implanted in proximity to the S-ICD. Verify that S-ICD arrhythmia detection and therapy delivery functions appropriately when the S-ICD System is implanted concomitantly with such a device.
- **Transcutaneous electrical nerve stimulation (TENS).** TENS involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator. The following guidelines may reduce the likelihood of interaction:
  - Place the TENS electrodes as close together and as far away from the pulse generator and subcutaneous electrode as possible.
  - Use the lowest clinically-appropriate TENS energy output.
  - Consider cardiac monitoring during TENS use.

  Additional steps can be taken to help reduce interference during in-clinic use of TENS:
  - If interference is suspected during in-clinic use, turn off the TENS unit.
  - Do not change TENS settings until you have verified that the new settings do not interfere with pulse generator function.

  If TENS is medically necessary outside the clinical setting (at-home use), provide patients with the following instructions:
  - Do not change the TENS settings or electrode positions unless instructed to do so.
  - End each TENS session by turning off the unit before removing the electrodes.

- If the patient receives a shock during TENS use, they should turn off the TENS unit and contact their physician.

Follow these steps to use the programmer to evaluate pulse generator function during TENS use:

1. Program the pulse generator to Therapy Off mode.
2. Observe real-time S-ECGs at prescribed TENS output settings, noting when appropriate sensing or interference occurs.
3. When finished, turn off the TENS unit and reprogram the pulse generator to Therapy On mode.

You should also perform a thorough follow-up evaluation of the pulse generator following TENS to ensure that device function has not been compromised ("Post-Therapy Pulse Generator Follow Up" on page 14).

For additional information, contact Boston Scientific using the information on the back cover.

Home and Occupational Environments

- **Home appliances.** Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There have been reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.
- **Electronic Article Surveillance (EAS) and security systems.** Advise patients how to avoid impact to cardiac device function due to antitheft and security gates, tag deactivators, or tag readers that include radio frequency identification (RFID) equipment. These systems may be found at the entrances and exits of stores, at checkout counters, in public libraries, and in point-of-entry access control systems. Patients should avoid lingering near or leaning against antitheft and security gates and tag readers. In addition, patients should avoid leaning against checkout counter-mounted and handheld tag deactivation systems. Antitheft gates, security gates, and entry control systems are unlikely to affect cardiac device function when patients walk through them at a normal pace. If the patient is near an electronic antitheft, security, or entry control system and experiences symptoms, they should promptly move away from nearby equipment and inform their doctor.
- **Cellular phones.** Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone that is turned on in a breast pocket or on a belt within 15 cm (6 inches) of the implanted device since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.
- **Magnetic fields.** Advise patients that extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields may suspend arrhythmia detection. Examples of magnetic sources include:
  - Industrial transformers and motors
  - MRI scanners
    NOTE: *The magnet feature is disabled when the device is in MRI Protection Mode. Refer to "Magnetic Resonance Imaging (MRI)" on page 22 and the MRI Technical Guide for more information.*
  - Large stereo speakers
  - Telephone receivers if held within 1.27 cm (0.5 inches) of the pulse generator

- Magnetic wands such as those used for airport security and in the Bingo game

- **Elevated pressures.** The International Standards Organization (ISO) has not approved a standardized pressure test for implantable pulse generators that experience hyperbaric oxygen therapy (HBOT) or SCUBA diving. However, Boston Scientific developed a test protocol to evaluate device performance upon exposure to elevated atmospheric pressures. The following summary of pressure testing should not be viewed as and is not an endorsement of HBOT or SCUBA diving.

  Elevated pressures due to HBOT or SCUBA diving may damage the pulse generator. During laboratory testing, all pulse generators in the test sample functioned as designed when exposed to more than 300 cycles at a pressure up to 3.0 ATA. Laboratory testing did not characterize the impact of elevated pressure on pulse generator performance or physiological response while implanted in a human body.

  Pressure for each test cycle began at ambient/room pressure, increased to a high pressure level, and then returned to ambient pressure. Although dwell time (the amount of time under elevated pressure) may have an impact on human physiology, testing indicated it did not impact pulse generator performance. Pressure value equivalencies are provided in Table 1 Pressure Value Equivalencies on page 13.

Table 1. Pressure Value Equivalencies

Atmospheres Absolute	3.0 ATA
Sea water depth[a]	20 m (65 ft)
Pressure, absolute	42.7 psia
Pressure, gauge[b]	28.0 psig
Bar	2.9
kPa Absolute	290

a. All pressures were derived assuming sea water density of 1030 kg/m^3.
b. Pressure as read on a gauge or dial (psia = psig + 14.7 psi).

Prior to SCUBA diving or starting an HBOT program, the patient's attending cardiologist or electrophysiologist should be consulted to fully understand the potential consequences relative to the patient's specific health condition. A Dive Medicine Specialist may also be consulted prior to SCUBA diving.

More frequent device follow-up may be warranted in conjunction with HBOT or SCUBA diving. Evaluate pulse generator operation following high pressure exposure ("Post-Therapy Pulse Generator Follow Up" on page 14). The extent, timing, and frequency of this evaluation relative to the high pressure exposure are dependent upon current patient health and should be determined by the attending cardiologist or electrophysiologist. If you have additional questions, or would like more detail regarding the test protocol or test results specific to HBOT or SCUBA diving, contact Boston Scientific using the information on the back cover.

Follow-up Testing

- **Low shock impedance.** A reported shock impedance value of less than 25 ohms from a delivered shock could indicate a problem with the device. The delivered shock may have been compromised, and/or any future therapy from the device may be compromised. If a reported impedance value of less than 25 ohms is observed, correct functioning of the device should be verified.
- **Conversion testing.** Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the DFT, which may result in nonconversion of the arrhythmia post-operatively. Verify with a conversion test that the patient’s tachyarrhythmias can be detected and terminated by the pulse generator system if the patient’s status has changed or parameters have been reprogrammed.
- **Follow-up considerations for patients leaving the country.** Pulse generator follow-up considerations should be made in advance for patients who plan to travel or relocate post-implant to a country other than the country in which their device was implanted. Regulatory approval status for devices and associated programmer software configurations varies by country; certain countries may not have approval or capability to follow specific products.

  Contact Boston Scientific, using the information on the back cover, for help in determining feasibility of device follow-up in the patient's destination country.

Explant and Disposal

- **Handling at explant.** Before explanting, cleaning, or shipping the device, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:
  - Program the pulse generator to Therapy Off mode.
  - Disable the beeper, if available.
  - Clean and disinfect the device using standard biohazard handling techniques.
- **Incineration.** Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.

SUPPLEMENTAL PRECAUTIONARY INFORMATION

Post-Therapy Pulse Generator Follow Up

Following any surgery or medical procedure with the potential to affect pulse generator function, you should perform a thorough follow-up, which may include the following:

- Interrogating the pulse generator with a programmer
- Reviewing stored events, fault codes, and real-time S-ECGs prior to saving all patient data
- Testing the subcutaneous electrode impedance
- Verifying battery status
- Printing any desired reports

- Verifying the appropriate final programming prior to allowing the patient to leave the clinic
- Ending session

POTENTIAL ADVERSE EVENTS

Potential adverse events related to implantation of the S-ICD System may include, but are not limited to, the following:

- Acceleration/induction of atrial or ventricular arrhythmia
- Adverse reaction to induction testing
- Allergic/adverse reaction to system or medication
- Bleeding
- Conductor fracture
- Cyst formation
- Death
- Delayed therapy delivery
- Discomfort or prolonged healing of incision
- Electrode deformation and/or breakage
- Electrode insulation failure
- Erosion/extrusion
- Failure to deliver therapy
- Fever
- Hematoma/seroma
- Hemothorax
- Improper electrode connection to the device
- Inability to communicate with the device
- Inability to defibrillate or pace
- Inappropriate post-shock pacing
- Inappropriate shock delivery
- Infection
- Injury to or pain in upper extremity, including clavicle, shoulder, and arm
- Keloid formation
- Migration or dislodgement

- Muscle/nerve stimulation
- Nerve damage
- Pneumothorax
- Post-shock/post-pace discomfort
- Premature battery depletion
- Random component failures
- Stroke
- Subcutaneous emphysema
- Surgical revision or replacement of the system
- Syncope
- Tissue redness, irritation, numbness or necrosis

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

If any adverse events occur, invasive corrective action and/or S-ICD System modification or removal may be required.

Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following:

- Depression/anxiety
- Fear of device malfunction
- Fear of shocks
- Phantom shocks

PATIENT SCREENING

There are two options for patient screening.

The Model 2889 EMBLEM S-ICD Automated Screening Tool (AST) is software used on the Model 3120 programmer to screen patients prior to implant of the S-ICD System. The AST is an alternative to the model 4744 Patient Screening Tool. The two screening tools serve the same purpose and may be used independently or together. Refer to the EMBLEM S-ICD Automated Screening Tool (AST) Instructions for Use for more information.

The patient screening tool, Model 4744 (Figure 1 Patient Screening Tool on page 17) is a customized measurement tool made of transparent plastic printed with colored profiles. Each colored profile is assigned a letter (A,B,C,D,E,F) for ease of reference. The profiles are designed to ensure appropriate device performance by identifying signal characteristics that may lead to unsatisfactory detection outcomes for a patient before implant. The patient screening process is completed in three steps: (1) Collecting the surface ECG, (2) Evaluating the surface ECG and (3) Determining an acceptable sense vector.

The patient screening tool can be obtained from any Boston Scientific representative or by contacting Boston Scientific using the information on the back cover.

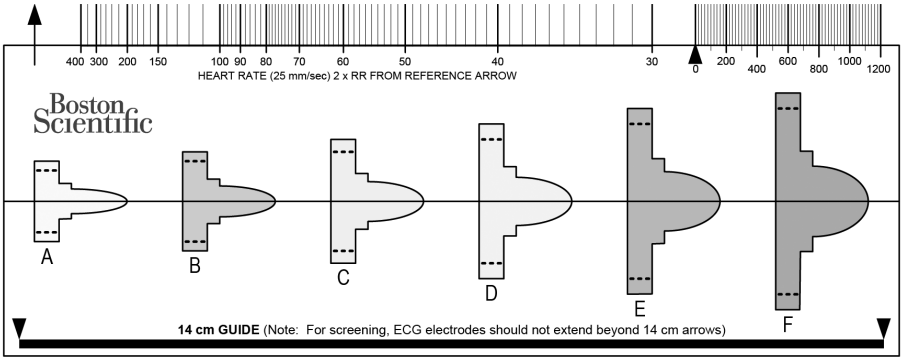


Figure 1. Patient Screening Tool

Collecting the Surface ECG

1. In order to perform the patient screening process, a surface equivalent of the subcutaneous sensing vectors must be obtained. It is important to collect the surface ECG in the location that represents the intended position of the implanted S-ICD System. When placing the S-ICD System in the typical implant location, the surface ECG electrode should be positioned as follows (Figure 2 Typical Placement of Surface ECG Electrodes for Patient Screening on page 18). If a non-standard S-ICD System subcutaneous electrode or pulse generator placement is desired, the surface ECG electrode locations should be modified accordingly.
   - **ECG Electrode LL** should be placed in a lateral location, at the 5th intercostal space along the mid-axillary line to represent the intended location of the implanted pulse generator.
   - **ECG Electrode LA** should be placed 1 cm left lateral of the xiphoid midline to represent the intended location of the proximal sensing node of the implanted subcutaneous electrode.
   - **ECG Electrode RA** should be placed 14 cm superior to the ECG Electrode LA, to represent the intended position of the distal sensing tip of the implanted subcutaneous electrode. A 14 cm guide is located at the bottom of the transparent screening tool.

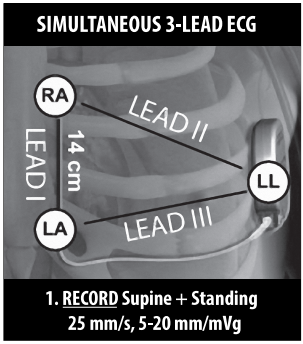


Figure 2. Typical Placement of Surface ECG Electrodes for Patient Screening

2. Using a standard ECG machine, record 10-20 seconds of ECG using Leads I, II, and III with a sweep speed of 25 mm/sec and ECG gain between 5-20 mm/mV. Use the largest ECG gain that does not result in clipping.

   NOTE: *It is important to establish a stable baseline when collecting the surface ECG. If a wandering baseline is noted, ensure that the appropriate ground electrodes from the ECG machine are attached to the patient. To yield an acceptable signal for testing, the gain may be adjusted for each ECG lead independently.*

3. Record ECG signals in at least two postures: (1) Supine and (2) Standing. Other postures may be collected including: Seated, Left Lateral, Right Lateral, and Prone.

   NOTE: *If the S-ICD System is to be implanted with a concomitant pacemaker, all ventricular morphologies (paced and intrinsic, if normal conduction is expected) should be collected.*

Evaluating the Surface ECG

Each surface ECG should be evaluated by analyzing at least 10 seconds of QRS complexes. If multiple morphologies are noted (e.g., bigeminy, pacing, etc.), all morphologies should be tested as described below before the vector is deemed acceptable.

Each QRS complex is evaluated as follows:

1. **Select** the colored profile from the Patient Screening Tool that best matches the amplitude of the QRS (Figure 3 Selecting the Colored Profile on page 19). For biphasic or notched signals, the larger peak should be used to determine the appropriate colored profile. The QRS peak must fall within the window bounded by the dotted line and the peak of the colored profile.

NOTE: *ECG gains >20 mm/mV are not permitted. If, when printed at the maximum 20 mm/mV gain, the QRS peak does not reach the minimum boundary (dotted line) of the smallest colored profile, that QRS complex is deemed unacceptable.*

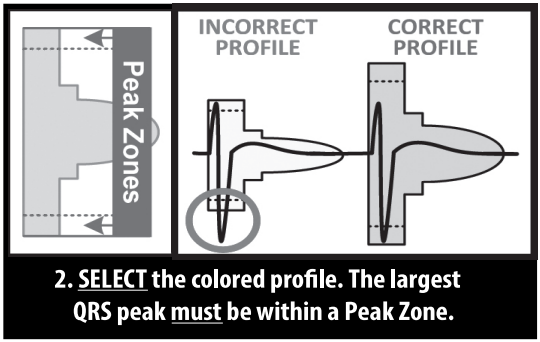


Figure 3. Selecting the Colored Profile

2. **Align** the left edge of the selected colored profile with the onset of the QRS complex. The horizontal line on the colored profile should be used as a guide for isoelectric baseline alignment.
3. **Evaluate** the QRS complex. If the entire QRS complex and trailing T-wave are contained within the colored profile, the QRS is deemed acceptable. If any portion of the QRS complex or trailing T-wave extends outside of the colored profile, the QRS is deemed unacceptable (Figure 4 Evaluating the QRS Complex on page 20). Multiple colored profiles may be used to evaluate the same surface ECG if varying QRS amplitudes are observed.

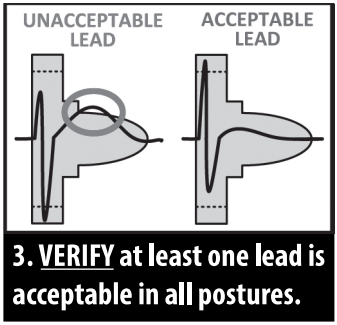


Figure 4. Evaluating the QRS Complex

4. **Repeat** the above steps with all QRS complexes collected with all surface ECG leads in all collected postures.

Determining an Acceptable Sense Vector

Each collected surface ECG lead represents a sense vector of the S-ICD System. Evaluate each surface ECG lead independently for acceptability. A surface ECG lead (sense vector) should be deemed acceptable only if all of the following conditions are met:

- All tested QRS complexes and morphologies from the surface ECG lead (sense vector) must pass the QRS evaluation. Exceptions can be made for a large morphology change associated with an occasional ectopic beat (e.g., PVC).
- The morphology of the intrinsic/paced QRS complex is stable across postures (similar positive/negative peak amplitudes and QRS widths). No significant change to the QRS complex is noted as a result of postural changes. For notched signals, ensure that the location of the larger peak is consistent in relation to the smaller peak.
- The surface ECG lead (sense vector) must be deemed acceptable in all tested postures.

A patient is considered suitable for implant of the S-ICD System if at least one surface ECG lead (sense vector) is acceptable for all tested postures.

NOTE: *Special circumstances may present in which the physician elects to proceed with the implantation of the S-ICD System despite failing the screening process. In this case, careful attention should be applied to the device setup process of the S-ICD System as the risk of poor sensing and/or inappropriate shock is increased.*

OPERATION

General

The S-ICD System is designed for ease of use and simplicity of patient management. The arrhythmia detection system employs up to two rate zones, and the device has a single automatic response to a detected ventricular tachyarrhythmia—a nonprogrammable, maximum-energy, biphasic shock of 80 J. The device has a number of automatic functions designed to reduce the amount of time required for implantation, initial programming, and patient follow-up.

Modes of Operation

The device has the following modes of operation:

- Shelf
- Therapy On
- Therapy Off
- MRI Protection Mode

Shelf Mode

The Shelf mode is a low-power consumption state intended for storage only. When communication is initiated between the device and the programmer, a full-energy capacitor reformation is performed and the device is prepared for setup. Once the device is taken out of Shelf mode, it cannot be reprogrammed back into Shelf mode.

Therapy On Mode

The Therapy On mode is the primary operating mode of the device, allowing automatic detection of and response to ventricular tachyarrhythmias. All device features are active.

NOTE: *The device must be programmed out of Shelf mode before being programmed to Therapy On.*

Therapy Off Mode

The Therapy Off mode disables automatic therapy delivery while still allowing manual control of shock delivery. Programmable parameters may be viewed and adjusted via the programmer. Also, the subcutaneous electrogram (S-ECG) may be displayed or printed.

The device automatically defaults to Therapy Off when taken out of Shelf mode.

NOTE: *Manual and rescue shock therapy are available when the device is set to Therapy On or Therapy Off mode, but only after the initial setup process is complete. Refer to "Setting up the Pulse Generator using the Model 3200 S-ICD Programmer" on page 48.*

MRI Protection Mode

See "Magnetic Resonance Imaging (MRI)" on page 22.

Magnetic Resonance Imaging (MRI)

MRI Protection Mode modifies certain pulse generator functions in order to mitigate risks associated with exposing the S-ICD system to the MRI environment. Choosing MRI Protection Mode will initiate a sequence of screens to assess the patient's eligibility and readiness to undergo an MR Conditional MRI scan. Refer to the Summary Report to find out whether the device has been in MRI Protection Mode. For a complete description of MRI Protection Mode, a list of MR Conditional devices, and additional information about the ImageReady S-ICD System, refer to the MRI Technical Guide.

Prior to the patient undergoing an MRI scan, an ImageReady S-ICD System must be programmed to the MRI Protection Mode using the programmer. In MRI Protection Mode:

- Tachycardia therapy is suspended
- A Time-out feature is nominally set to 6 hours, with programmable values of 6, 9, 12, and 24 hours
- Beeper is disabled

MRI Protection Mode is terminated by manual exit or through the user-programmed automatic MRI Protection Time-out period (refer to the MRI Technical Guide for MRI Protection Mode programming instructions.) Rescue Shock will also terminate MRI Protection Mode. When MRI Protection Mode is exited, all parameters (except for the Beeper) return to the previously programmed settings.

NOTE: *The Beeper can be reenabled after exiting MRI Protection Mode ("Internal Warning System—Beeper Control" on page 28).*

The following Warnings and Precautions, and Conditions of Use are applicable to MRI scanning of patients implanted with an ImageReady S-ICD System. For additional warnings, precautions, Conditions of Use, and potential adverse events applicable when the Conditions of Use are met or not met, refer to the MRI Technical Guide.

MR Conditional S-ICD System Warnings and Precautions

WARNING: EMBLEM S-ICD devices are considered MR Conditional. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and/or damage to the implanted system may result.

WARNING: The Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

WARNING: The Programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[4]. Under no circumstances should the programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

4. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007.

WARNING: Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[5]. Some of the accessories used with pulse generators and electrodes, including the torque wrench and electrode implant tools, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

WARNING: During MRI Protection Mode the Tachycardia therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady S-ICD System must be programmed to MRI Protection Mode using the programmer. MRI Protection Mode disables Tachycardia therapy. The system will not detect ventricular arrhythmias and the patient will not receive shock defibrillation therapy until the pulse generator resumes normal operation. Only program the device to MRI Protection Mode if the patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

MRI Conditions of Use

The following subset of the MRI Conditions of Use pertains to implantation and must be met in order for a patient with an ImageReady S-ICD System to undergo an MRI scan. Adherence to the Conditions of Use must be verified prior to each scan to ensure that the most up-to-date information has been used to assess the patient's eligibility and readiness for an MR Conditional scan. Refer to the MRI Technical Guide at www.bostonscientific-elabeling.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady S-ICD System.

Cardiology

1. Patient is implanted with an ImageReady S-ICD System
2. No other active or abandoned implanted devices, components, or accessories present such as lead adaptors, extenders, leads, or pulse generators
3. At least six (6) weeks have elapsed since implantation and/or any electrode revision or surgical modification of the ImageReady S-ICD System
4. No evidence of a fractured electrode or compromised pulse generator-electrode system integrity

SENSING CONFIGURATION AND GAIN SELECTION

During the Automatic Setup process, the device automatically selects an optimal sensing vector based on an analysis of cardiac signal amplitude and signal-to-noise ratio. This analysis is performed on the three available vectors:

- **Primary:** Sensing from the proximal electrode ring on the subcutaneous electrode to the active surface of the device.
- **Secondary:** Sensing from the distal sensing electrode ring on the subcutaneous electrode to the active surface of the device.
- **Alternate:** Sensing from the distal sensing electrode ring to the proximal sensing electrode ring on the subcutaneous electrode.

5. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

The sensing vector can also be selected manually. The EMBLEM S-ICD Programmer User's Manual provides additional information about sensing vector selection.

The SMART Pass feature activates an additional high-pass filter designed to reduce oversensing while still maintaining an appropriate sensing margin. Internal bench testing of the SMART Pass feature, using a standard arrhythmia dataset, demonstrated it maintained the overall S-ICD system sensitivity and specificity. In addition, the SMART Pass feature reduced inappropriate therapy by greater than 40%. The system automatically evaluates if SMART Pass should be enabled whenever a sensing vector is selected via automatic or manual setup. SMART Pass will be enabled when the measured amplitudes of ECG signals during setup are ≥ 0.5 mV. The status of SMART Pass (On/Off) is displayed on the SMART Settings programmer screen, Summary Report, Captured S-ECG Reports, and Episode Reports.

The device continuously monitors the ECG signal amplitude and disables SMART Pass if under-sensing is suspected. It can be manually disabled if under-sensing is suspected by selecting the Disable button on the SMART Settings screen. If SMART Pass is disabled, another automatic or manual setup must be performed to re-enable the feature.

Additional SMART Pass diagnostic information can be retrieved from the device. For assistance, contact Boston Scientific using the information on the back cover.

The device automatically selects an appropriate gain setting during the Automatic Setup process. The gain also can be manually selected, as further explained in the EMBLEM S-ICD Programmer User's Manual. There are two gain settings:

- **1x Gain (±4 mV):** Selected when the signal amplitude is clipped at the 2x gain setting.
- **2x Gain (±2 mV):** Selected when the signal amplitude is not clipped at this setting.

SENSING AND TACHYARRHYTHMIA DETECTION

The device is designed to prevent inappropriate therapy delivery as a result of noise sensing or multiple counting of individual cardiac cycles. This is accomplished by an automatic analysis of sensed signals, which includes event detection, certification, and decision phases.

Detection Phase

During the Detection Phase, the device uses a detection threshold to identify sensed events. The detection threshold is automatically adjusted continuously using amplitudes of recently detected electrical events. In addition, detection parameters are modified to increase sensitivity when rapid rates are detected. Events detected during the Detection Phase are passed on to the Certification Phase.

Certification Phase

The Certification Phase examines the detections and classifies them as certified cardiac events or as suspect events. Certified events are used to ensure that an accurate heart rate is passed to the Decision Phase. A suspect event can be one whose pattern and/or timing indicates the signal is caused by noise, such as a muscle artifact or some other extraneous signal. Events are also marked as suspect if they appear to derive from double or triple detections of single cardiac events. The device is designed to identify and correct multiple detections of wide QRS complexes and/or erroneous detections of a T-wave.

Decision Phase

The Decision Phase examines all certified events and continuously calculates a running four R-to-R interval average (4 RR average). The 4 RR average is used throughout the analysis as an indicator of the heart rate.

WARNING: During MRI Protection Mode the Tachycardia therapy is suspended. Prior to the patient undergoing an MRI scan, an ImageReady S-ICD System must be programmed to MRI Protection Mode using the programmer. MRI Protection Mode disables Tachycardia therapy. The system will not detect ventricular arrhythmias and the patient will not receive shock defibrillation therapy until the pulse generator resumes normal operation. Only program the device to MRI Protection Mode if the patient is judged to be clinically capable of tolerating no Tachycardia protection for the entire duration in which the pulse generator is in MRI Protection Mode.

THERAPY ZONES

The device allows the selection of rate thresholds that define a Shock Zone and an optional Conditional Shock Zone. In the Shock Zone, rate is the only criterion used to determine if a rhythm will be treated with a shock. The Conditional Shock Zone has additional discriminators used to determine if a shock is warranted to treat an arrhythmia.

The Shock Zone is programmable from 170–250 bpm in increments of 10 bpm. The Conditional Shock Zone must be lower than the Shock Zone, with a range of 170–240 bpm in increments of 10 bpm.

NOTE: *To ensure proper detection of VF, program the Shock Zone or Conditional Shock Zone to 200 bpm or less.*

NOTE: *Clinical testing of the first generation S-ICD System demonstrated a significant reduction in inappropriate therapy with the activation of the Conditional Shock Zone prior to hospital discharge.*[6]

Graphically, the use of a Shock Zone and Conditional Shock Zone is shown in Figure 5 Shock Zone Rate Detection Diagram on page 25:

Figure 5. Shock Zone Rate Detection Diagram

The device declares a Tachycardia when the 4RR average enters either therapy zone.

6. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, Rashtian M, Kremers M, Crozier I, Lee KI, Smith W, Burke MC. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013;128:944–953

Once a Tachycardia is declared, the 4RR average must become longer (in ms) than the lowest rate zone plus 40 ms for 24 cycles for the device to consider the episode to have ended. In the Shock Zone, treatable arrhythmias are determined by rate alone.

ANALYSIS IN THE CONDITIONAL SHOCK ZONE

In contrast, rate and morphology are analyzed in the Conditional Shock Zone. The Conditional Shock Zone is designed to discriminate between treatable and other high-rate events such as atrial fibrillation, sinus tachycardia, and other supraventricular tachycardias.

A normal sinus rhythm template (NSR Template) is formed during device initialization. This NSR template is used during analysis in the Conditional Shock Zone to identify treatable arrhythmias. In addition to morphology comparison with the NSR template, other morphologic analysis is used to identify polymorphic rhythms. Morphology and QRS width are used to identify monomorphic arrhythmias such as ventricular tachycardia. If the Conditional Shock Zone is enabled, then an arrhythmia is found to be treatable according to the decision tree (Figure 6 Decision Tree for Determining Treatable Arrhythmias in the Conditional Shock Zone on page 26).

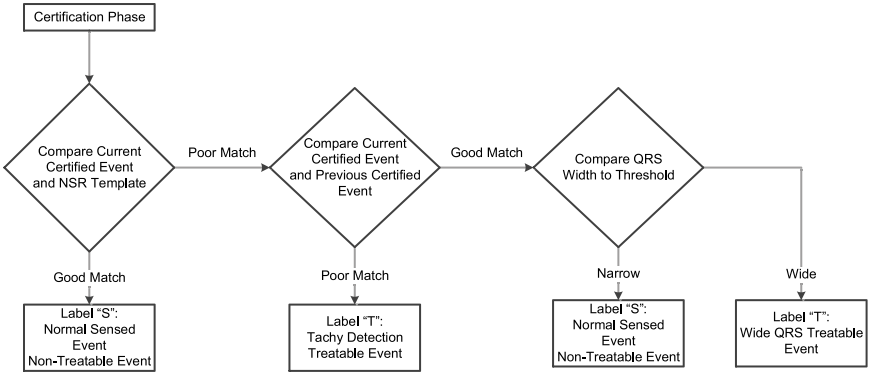


Figure 6. Decision Tree for Determining Treatable Arrhythmias in the Conditional Shock Zone

For some patients, an NSR Template may not be formed during device initialization as a result of variability in their cardiac signal at resting heart rates. For such patients, the device uses beat-to-beat morphology and QRS width analysis for arrhythmia discrimination.

CHARGE CONFIRMATION

The device must charge the internal capacitors before shock delivery. Confirmation of the ongoing presence of a tachyarrhythmia requires monitoring a moving window of the 24 most recent intervals defined by certified events. Charge confirmation employs an X (treatable interval) out of Y (total intervals in the window) strategy to accomplish this. If 18 of the 24 most recent intervals are found to be treatable, the device begins to analyze

rhythm persistence. Persistence analysis requires the X out of Y condition be maintained or exceeded for at least two consecutive intervals; however, this value may be increased as a result of SMART Charge, as explained below.

Capacitor charging is initiated when the following three conditions are met:

1. X of Y criterion is satisfied.
2. Persistence requirement is satisfied.
3. The last two certified intervals are in the treatable zone.

THERAPY DELIVERY

Rhythm analysis continues throughout the capacitor charging process. Therapy delivery is aborted if the 4 RR average interval becomes longer (in ms) than the lowest rate zone plus 40 ms for 24 intervals. When this occurs, an untreated episode is declared and a SMART Charge extension is incremented, as explained below.

Capacitor charging continues until the capacitor has reached its target voltage, at which time reconfirmation is performed. Reconfirmation is used to ensure that the treatable rhythm did not spontaneously terminate during the charging cycle. Reconfirmation requires the last three consecutive detected intervals (regardless of whether the intervals are certified or suspect) to be faster than the lowest therapy zone. If non-treatable events are detected during or after the charging sequence, reconfirmation is automatically extended, one interval at a time, up to a maximum of 24 intervals.

Reconfirmation is always performed and shock delivery is non-committed until reconfirmation is complete. Once the criteria for reconfirmation are met, the shock is delivered.

SMART CHARGE

SMART Charge is a feature that automatically increases the Persistence requirement by three intervals each time an untreated episode is declared, up to a maximum of five extensions. Thus, after an untreated episode, the requirement to start capacitor charging becomes more stringent. The SMART Charge extension value can be reset to its nominal value (zero extensions) using the programmer. The SMART Charge feature cannot be disabled, though it is not used for the second and later shocks that occur during any given episode.

REDETECTION

A blanking period is enabled following delivery of a high-voltage shock. After delivery of the first shock, up to four additional shocks will be delivered if the episode does not terminate. Rhythm analysis for delivering shocks 2–5 generally follows the detection steps described above, with the following exceptions:

1. Following the first shock delivery, the X/Y criterion is modified to require 14 treatable intervals in the last 24 (14/24), rather than 18.
2. The Persistence Factor is always set to two intervals (i.e., not modified by the SMART Charge feature).

SHOCK WAVEFORM AND POLARITY

The shock waveform is biphasic, with a fixed tilt of 50%. The shock is delivered synchronously unless a 1000 ms time out expires without an event being detected for synchronization, at which time the shock is delivered in an asynchronous manner.

The device is designed to automatically select the appropriate polarity for therapy. Both standard and reversed polarity shocks are available. If a shock fails to convert the arrhythmia and subsequent shocks are required, polarity is automatically reversed for each successive shock. The polarity of the successful shock is then retained as the starting polarity for future episodes. Polarity can also be selected during the Induction and Manual Shock process to facilitate device-based testing.

POST-SHOCK BRADYCARDIA PACING THERAPY

The device provides optional post-shock, on-demand bradycardia pacing therapy. When enabled via the programmer, bradycardia pacing occurs at a non-programmable rate of 50 bpm for up to 30 seconds. The pacing output is fixed at 200 mA and uses a 15 ms biphasic waveform.

Pacing is inhibited if the intrinsic rate is greater than 50 bpm. In addition, post-shock pacing is terminated if a tachyarrhythmia is detected or a magnet is placed over the device during the post-shock pacing period.

MANUAL AND RESCUE SHOCK DELIVERY

Upon programmer command, the device can deliver manual and rescue shocks. Manual shocks are programmable from 10 to 80 J delivered energy in 5 J steps. Rescue shocks are non-programmable, delivering the maximum output of 80 J.

NOTE: *A rescue shock that is commanded when the magnet is already in place will be delivered, but if the magnet is applied after the rescue shock is commanded, the shock will be aborted. Refer to "S-ICD System Magnet Use" on page 34 for complete information.*

NOTE: *Rescue shock will terminate MRI Protection Mode.*

Additional Features of the S-ICD System

This section presents descriptions of several additional features available in the S-ICD System.

Auto Capacitor Reformation

The device automatically performs a full-energy (80 J) capacitor reformation when taken out of Shelf mode and every four months until the device reaches Elective Replacement (ERI). The energy output and reformation time interval are non-programmable. The Auto Capacitor Reformation interval is reset after any 80 J capacitor charge is delivered or aborted.

Internal Warning System—Beeper Control

The device has an internal warning system (beeper) that may emit an audible tone to alert the patient to certain device conditions that require prompt consultation with the physician. These conditions include:

- Elective Replacement (ERI) and End of Life (EOL) indicators (see "Storing and Analyzing Data" on page 31)
- Electrode impedance out of range
- Prolonged charge times

- Failed Device Integrity Check
- Irregular battery depletion

This internal warning system is automatically activated at time of implant. Once triggered, if the beeper is enabled, tones beep for 16 seconds every nine hours until the trigger condition has been resolved. If the triggering condition reoccurs, then the tones will once again alert the patient to consult the physician.

CAUTION: Patients should be advised to contact their physician immediately if they hear tones coming from their device.

The Beeper may be activated for demonstration purposes or to evaluate its audibility in the clinic by using the programmer to test the Beeper, described as follows.

Perform the following steps to program the Beeper:

1. From the Utilities screen, select Beeper Control.
2. Select the Test Beeper button from the Set Beeper Function screen.
3. Evaluate if the Beeper is audible. Use a stethoscope.
4. If the Beeper is audible, select the Yes, Enable Beeper button. If the Beeper is not audible, select the No, Disable Beeper button.

If the Beeper is not audible to the patient, it is strongly recommended that the patient has a follow-up schedule of every three months either on LATITUDE NXT or in-clinic to monitor device performance.

When the Beeper is disabled, upon subsequent interrogations, a notification that it is disabled will be provided on the Device Status Since Last Follow-up screen.

When the Beeper is disabled, the device will not beep when any of the following occur:

- The programmer connects to the device
- A system error occurs
- A magnet is held over the device

WARNING: The Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

The system proactively disables the Beeper when MRI Protection Mode is programmed. The Beeper will remain off upon exiting MRI Protection Mode. The Beeper can be reenabled using the Beeper Control option.

The Beeper will emit tones due to a device reset even when the Beeper is disabled. However, following an MRI scan, the Beeper volume in the device will be decreased and may be inaudible.

For additional information regarding the Beeper, refer to the MRI Technical Guide or contact Boston Scientific using the information on the back cover.

Arrhythmia Induction

The device facilitates testing by providing the capability to induce a ventricular tachyarrhythmia. Via the programmer, the implanted system can deliver a 200 mA output at a frequency of 50 Hz. The maximum length of stimulation is 10 seconds.

NOTE: *Induction requires that the device be programmed to Therapy On.*

WARNING: Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

System Diagnostics

The S-ICD System automatically performs a diagnostic check at scheduled intervals.

Subcutaneous Electrode Impedance

A subcutaneous electrode integrity test is performed once a week using a sub-threshold energy pulse. The Summary report indicates whether the measured impedance is in range by reporting "Ok" for values below 400 ohms. Values above 400 ohms will result in activation of the internal warning system (beeping tones).

NOTE: *If the device is taken out of Shelf mode, but not implanted, the internal warning system will be activated due to the weekly automatic measurements of impedance. Device beeping due to this mechanism is normal behavior.*

In addition, subcutaneous electrode impedance is measured each time a shock is delivered, and the shock impedance values are stored and displayed in the episode data and reported on the programmer screen just after the shock is delivered. Reported shock impedance values should be within 25–200 ohms. A reported value of greater than 200 ohms will activate the internal warning system.

CAUTION: A reported shock impedance value of less than 25 ohms from a delivered shock could indicate a problem with the device. The delivered shock may have been compromised, and/or any future therapy from the device may be compromised. If a reported impedance value of less than 25 ohms is observed, correct functioning of the device should be verified.

NOTE: *Measurement of electrode impedance either by the sub-threshold measurement or during shock delivery may not detect a loose setscrew due to the location of the setscrew at the electrode tip.*

Device Integrity Check

The Device Integrity Check is automatically performed daily by the implanted system, and also each time the programmer communicates with an implanted device. This test scans for any unusual conditions in the device and, if any are detected, the system provides a notification either via the pulse generator's internal warning system or on the programmer screen.

Battery Performance Monitoring System

The device automatically monitors battery status to provide notice of impending battery depletion. Two indicators are provided via messages on the programmer, each activated by declining battery voltage. ERI and EOL are also signaled by activation of the device's beeper.

- **Elective Replacement Indicator (ERI):** When the ERI is detected, the device will provide therapy for at least three months, if no more than six maximum energy charges/shocks occur. The patient should be scheduled for replacement of the device.
- **End of Life (EOL):** When the EOL indicator is detected, the device should be replaced immediately. Therapy may not be available when EOL is declared.
  NOTE: *A LATITUDE alert is generated, after which LATITUDE NXT ceases remote interrogations of the device.*

WARNING: MRI scanning after ERI status has been reached may lead to premature battery depletion, a shortened device replacement window, or sudden loss of therapy. After performing an MRI scan on a device that has reached ERI status, verify pulse generator function and schedule device replacement.

Storing and Analyzing Data

EMBLEM S-ICD (Model A209) stores S-ECGs for up to 25 treated and 20 untreated tachyarrhythmia episodes.

EMBLEM MRI S-ICD (Model A219) stores S-ECGs for up to 20 treated and 15 untreated tachyarrhythmia episodes, as well as up to 7 AF episodes.

For all EMBLEM S-ICD devices, a treated or untreated episode is stored only if it progresses to the point where charging is initiated. The number of episodes and the therapy shocks delivered since the last follow-up procedure and initial implant are recorded and stored. Through wireless communication with the programmer, the stored data is retrieved for analysis and report printouts.

NOTE: *Episode data associated with programmer-commanded rescue shocks, manual shocks, induction testing, or episodes that occur while communicating with the programmer are not stored by the pulse generator. Episode data associated with induction testing commanded by the programmer using the Hold to Induce button is captured by the programmer and is available as a captured S-ECG. (Refer to the EMBLEM S-ICD Programmer User's Manual for more information.)*

NOTE: *SVT episodes with heart rates lower than or within the Conditional Shock Zone are not stored.*

Treated Episodes

Up to 128 seconds of S-ECG data is stored for each treated episode:

- **First Shock:** 44 seconds prior to capacitor charging, up to 24 seconds prior to shock delivery and up to 12 seconds of post-shock S-ECG.
- **Subsequent Shocks:** A minimum of 6 seconds of pre-shock and up to 6 seconds post-shock S-ECG.

Untreated Episodes

For untreated episodes, 44 seconds of pre-episode and up to 84 seconds of episode S-ECG are stored. A return to normal sinus rhythm during an untreated episode halts S-ECG storage.

AF Episodes

EMBLEM MRI S-ICD (Model A219) with AF Monitor stores up to one AF episode for each day in which an atrial arrhythmia is detected. Up to seven of the most recent AF Episode S-ECGs (44 seconds in length) can be stored.

Captured S-ECG

The S-ECG can be captured in real time on rhythm strips when the device is actively linked via wireless telemetry to the programmer. Refer to the EMBLEM S-ICD Programmer User's Manual for more information.

S-ECG Rhythm Strip Markers

The system provides S-ECG annotations (Table 2 S-ECG Markers on Programmer Display Screens and Printed Reports on page 32) to identify specific events during a recorded episode. Sample annotations are shown for the programmer display (Figure 7 Programmer Display Markers on page 33) and the printed report (Figure 8 Printed Report Markers on page 33).

Table 2. S-ECG Markers on Programmer Display Screens and Printed Reports

Description	Marker
Charging[a]	C
Sensed Beat	S
Noisy Beat	N
Paced Beat	P
Tachy Detection	T
Discard Beat	•
Return to NSR[a]	

Table 2. S-ECG Markers on Programmer Display Screens and Printed Reports (continued)

Description	Marker
Shock	
Episode data compressed or not available	

a. Marker present on printed report but not on programmer display screen.

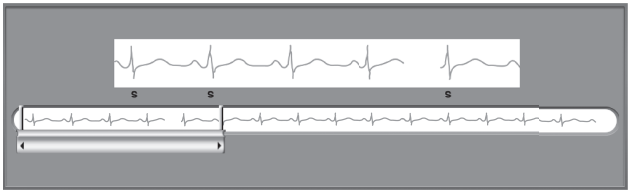


Figure 7. Programmer Display Markers

Figure 8. Printed Report Markers

Patient Data

The device can store the following patient data, which can be retrieved and updated through the programmer:

- Patient's name
- Physician's name and contact information

- Device and subcutaneous electrode identification information (model and serial numbers) and implant date
- Patient Notes (displayed upon connection to the device)

AF MONITOR

The AF Monitor feature is available in EMBLEM MRI S-ICD (Model A219) and is designed to assist in the diagnosis of atrial fibrillation. Internal bench testing, using a subset of data from the Physiobank public domain database, demonstrated a sensitivity of greater than or equal to 87% and a positive predictive value of greater than or equal to 90% for AF Monitor.

AF Monitor is designed to notify a clinician when at least six minutes of atrial fibrillation has been detected within a day. The six minutes is cumulative and could include a single arrhythmia or multiple shorter arrhythmias. AF is detected using 192-beat windows; greater than 80% of the beats in a window must be AF for the entire window to be accumulated. Based on this, AF Monitor may underreport total time in AF for patients with certain AF arrhythmias or episodes that are short in duration.

Once AF has been detected, the clinician should consider other clinical information and diagnostic test results, such as Holter monitoring, to confirm the diagnosis of AF. Consider turning the AF Monitor feature to Off once the diagnosis of AF has been confirmed.

The following statistics are available on the programmer screen by selecting the AF Monitor button:

1. Days with measured AF: provides the number of days within the last 90 where AF was detected.
2. Estimate of measured AF: provides the total percent of detected AF within the last 90 days.

Additionally, the device stores one AF episode S-ECG for each day in which atrial fibrillation is detected. The S-ECG should be used in conjunction with other AF statistics to confirm the presence of atrial fibrillation. Up to seven of the most recent AF episode S-ECGs (44 seconds in length) can be stored.

AF Monitor statistics are included on the Summary Report, and AF episode S-ECGs can be printed via the Episode Reports print option. AF Monitor information, as well as a trend, is also available on LATITUDE NXT along with a programmable alert.

NOTE: *Print desired reports and/or save session data (via End Session) prior to programming AF Monitor Off. When AF Monitor is programmed Off, currently stored AF Monitor statistics are cleared and can no longer be printed or saved.*

S-ICD System Magnet Use

The Boston Scientific magnet Model 6860 (the magnet) is a non-sterile accessory that may be used to temporarily inhibit the delivery of therapy from the device if necessary. The Cameron Health magnet Model 4520 may be used interchangeably with the Boston Scientific magnet for this purpose.

NOTE: *When long duration therapy suspension is desired, it is recommended to modify pulse generator behavior with the programmer rather than the magnet whenever possible.*

NOTE: *The magnet feature is suspended when the pulse generator is in MRI Protection Mode.*

To suspend therapy using a magnet:

1. APPLY the magnet over the device header or over the lower edge of the device as illustrated in Figure 9 Starting Position of the Magnet for Suspension of Therapy on page 35.
2. LISTEN for beeping tones (use a stethoscope if necessary). Therapy is not suspended until beeping tones are heard. If no beeping is heard, try other positions within the target zones illustrated in grey shaded areas of figure until beeping tones are heard (Figure 10 Zone within Which Magnet Placement is Most Likely to Suspend Therapy on page 36). Sweep the magnet vertically and horizontally across the target zone as indicated by the arrows. Maintain the magnet in each tested position for one second (it takes approximately one second for the pulse generator to respond to the magnet).

   NOTE: *If the Beeper is disabled or if the patient has been through an MRI scan, the Beeper may be inaudible. It may be necessary to use the programmer to suspend therapy in these patients.*

3. HOLD the magnet in place to keep therapy suspended. Beeping will continue for 60 seconds while the magnet is held in place. After 60 seconds, beeping stops, but therapy continues to be inhibited unless the magnet has been moved.

NOTE: *If it is necessary to confirm therapy is still being inhibited after beeping has stopped, remove and replace the magnet to reactivate the beeping tones. This step can be repeated as necessary.*

4. REMOVE the magnet to resume normal pulse generator operation.

Figure 9. Starting Position of the Magnet for Suspension of Therapy

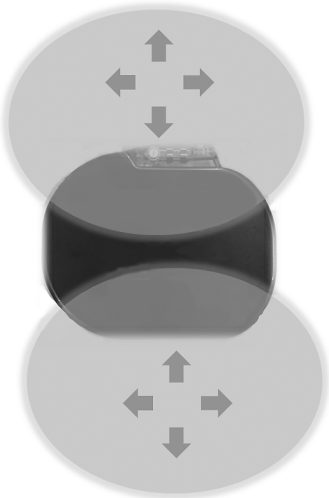


Figure 10. Zone within Which Magnet Placement is Most Likely to Suspend Therapy

Magnet Use for Patients with Deep Implant Placement

Consider the following when using the magnet on patients with deep implant placement:

- If the exact location of the pulse generator is not evident, the magnet may need to be tested across a broader region of the body surrounding the anticipated pulse generator location. Unless beeping tones are heard, therapy has not been suspended.
- Beeping from a device with a deep implant location may be difficult to hear. Use a stethoscope if necessary. Correct magnet placement can be confirmed only by detection of the beeping tones.
- Multiple magnets may be used in a stacked configuration to increase the likelihood of eliciting the beeping and associated inhibition of therapy.
- If beeping tones cannot be detected, it may be necessary to use the programmer to suspend therapy in these patients.

WARNING: In patients with a deep implant placement (greater distance between the magnet and the pulse generator), magnet application may fail to elicit the magnet response. In this case the magnet cannot be used to inhibit therapy.

Magnet Response and Pulse Generator Mode

The effect of the magnet on the pulse generator varies depending on the mode the pulse generator is programmed to as shown in Table 3 Magnet Response on page 37.

Table 3. Magnet Response

Pulse Generator Mode	Magnet Response
Shelf Mode	• A single beep sounds when the magnet is detected
Therapy On	• Arrhythmia detection and therapy response are suspended until the magnet is removed • The beeper sounds with each detected QRS complex for 60 seconds or until the magnet is removed, whichever occurs first • Programmer-commanded rescue shocks and manual shocks are aborted if the magnet is applied after the shock is commanded[a] • Post-shock pacing is terminated • Arrhythmia induction testing is prohibited
Therapy Off	• The beeper sounds with each detected QRS complex for 60 seconds or until the magnet is removed, whichever occurs first • Programmer commanded rescue shocks and manual shocks are aborted if the magnet is applied after the shock is commanded[a] • Post-shock pacing is terminated
MRI Protection Mode	• Magnet response is disabled

a. Programmer commanded rescue shocks and manual shocks are delivered if they are commanded with the magnet already in place.

NOTE: *If the magnet is applied during a treated or untreated episode, the episode will not be stored in the device memory.*

NOTE: *Magnet application does not affect wireless communication between the device and the programmer.*

NOTE: *If the Beeper is disabled or if the patient has been through an MRI scan, the Beeper may be inaudible.*

Bidirectional Torque Wrench

A torque wrench (model 6628) is included in the sterile tray with the pulse generator, and is designed for tightening and loosening #2-56 setscrews, captured setscrews, and setscrews on this and other Boston Scientific pulse generators and lead accessories that have setscrews that spin freely when fully retracted (these setscrews typically have white seal plugs).

The torque wrench is bidirectional, is preset to apply adequate torque to the setscrew, and will ratchet when the setscrew is secure. The ratchet release mechanism prevents overtightening that could result in device damage. To facilitate the loosening of tight extended setscrews, this wrench applies more torque in the counterclockwise direction than in the clockwise direction.

NOTE: *As an additional safeguard, the tip of the torque wrench is designed to break off if used to overtighten beyond preset torque levels. If this occurs, the broken tip must be extracted from the setscrew using forceps.*

This torque wrench may also be used for loosening setscrews on other Boston Scientific pulse generators and lead accessories that have setscrews that tighten against a stop when fully retracted (these setscrews typically have clear seal plugs). However, when retracting these setscrews, stop turning the torque wrench when the setscrew has come in contact with the stop. The additional counterclockwise torque of this wrench may cause these setscrews to become stuck if tightened against the stop.

USING THE S-ICD SYSTEM

Surgical Preparation

Consider the following prior to the implantation procedure:

The S-ICD System is designed to be positioned using anatomical landmarks. However, it is recommended to review a pre-implant chest X-ray in order to confirm that a patient does not have notably atypical anatomy (e.g., dextrocardia). Consider marking the intended position of the implanted system components and/or incisions prior to the procedure, utilizing anatomical landmarks or fluoroscopy as a guide. Additionally, if deviations from the implant instructions are required to accommodate for physical body size or habitus, it is recommended that a pre-implant chest X-ray has been reviewed.

WARNING: Attention is required to placement of the arm ipsilateral to the device implant to avoid injury of the ulnar nerve and brachial plexus while the patient is in the supine position during device implantation and before VF induction or shock delivery. The patient should be positioned with the arm abducted to an angle of no more than 60° with the hand in a supinated (palm up) position during the implant phase of the procedure. Securing the arm to an arm board is standard practice to maintain positioning of the arm during device implantation. Do not strap the arm too tightly during defibrillation testing. Elevation of the torso through use of a wedge may also add stress to the shoulder joint and should be avoided during defibrillation testing.

Items Included in Package

Store in a clean, dry area. The following pre-sterilized items are included with the pulse generator:

- One bidirectional torque wrench

Additionally, product literature is included.

NOTE: *Accessories (e.g., wrenches) are intended for one-time use only. They should not be resterilized or reused.*

Implantation

Overview

This section presents the information necessary for implanting and testing the S-ICD System, including:

- Implanting the pulse generator (the “device”)
- Implanting the subcutaneous electrode (the “electrode”) using the electrode implant tools
- Setting up and testing the device using the programmer.

WARNING: All Boston Scientific S-ICD implantable components are designed for use with the Boston Scientific or Cameron Health S-ICD System only. Connection of any S-ICD System components to a non-compatible component has not been tested and could result in failure to deliver life-saving defibrillation therapy.

WARNING: Implant of the system cannot be performed in an MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[7]. Some of the accessories used with pulse generators and electrodes, including the torque wrench and electrode implant tools, are not MR Conditional and should not be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

NOTE: *If the electrode terminal will not be connected to a pulse generator at the time of electrode implantation, you must cap the electrode terminal before closing the pocket incision. The lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.*

NOTE: *Use of a Boston Scientific/Cameron Health electrode is required for an implanted system to be considered MR Conditional. Refer to the MRI Technical Guide for model numbers of system components needed to satisfy the Conditions of Use.*

The device and subcutaneous electrode are typically implanted subcutaneously in the left thoracic region. The electrode implant tools are used to create the subcutaneous tunnels in which the electrode is inserted. The defibrillation coil must be positioned parallel to the sternum, in close proximity to or in contact with the deep fascia, below adipose tissue, approximately 1-2 cm from the sternal midline (Figure 11 Placement of the S-ICD System (Model 3501 Electrode shown) on page 40 and Figure 12 Subcutaneous Tissue Layers on page 41).

7. Kanal E, et al., American Journal of Roentgenology 188:1447-74, 2007

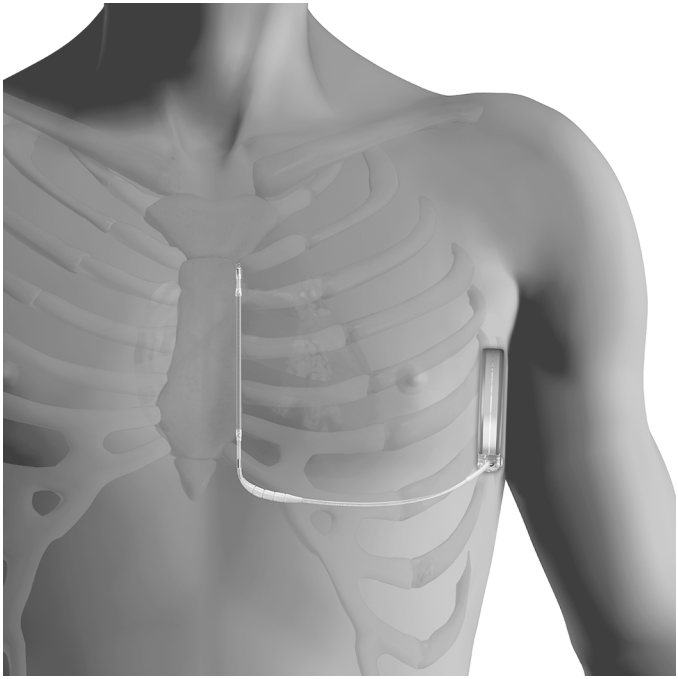
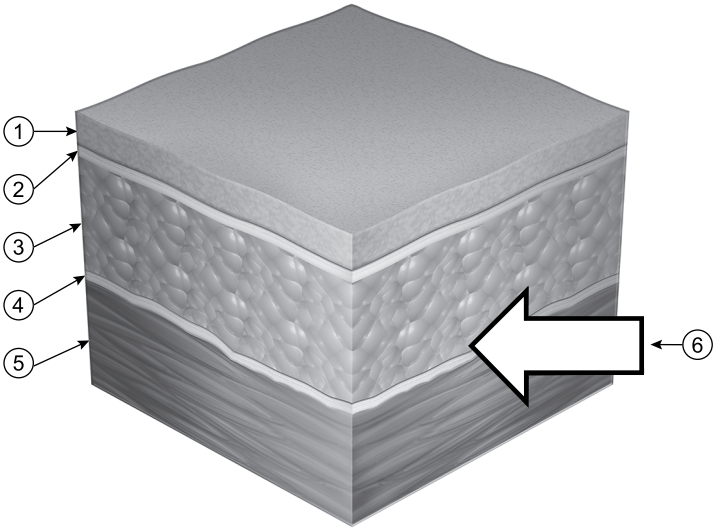


Figure 11. Placement of the S-ICD System (Model 3501 Electrode shown)



[1] Skin, [2] Hypodermal layer, [3] Adipose tissue, [4] Deep fascia, [5] Sub-fascial tissue (muscle or bone), [6] Correct location for subcutaneous tunnels and the S-ICD Subcutaneous Electrode

Figure 12. Subcutaneous Tissue Layers

Placement of the pulse generator and electrode can be achieved using various techniques. To ensure optimal placement of the subcutaneous electrode at the fascial plane, physician preference and patient assessment should be considered when choosing the implant method.

Care should be taken to position both the electrode and device directly on the fascia without underlying adipose tissue. High shocking electrode impedance may be associated with adipose tissue under the coil of the electrode, which may require repositioning of the electrode so that it is on the fascia.

In order to maximize the heart mass between the pulse generator and electrode, while maintaining acceptable sensing parameters, transthoracic defibrillation is achieved through the positioning of an anterior electrode and a device in the mid-axillary line or posterior axillary line.

In case of failure to convert VT/VF without adequate safety margin, either during defibrillation testing or later spontaneous ambulatory episode(s), the physician should review the position of both the electrode and device by use of anatomical landmarks or X-ray/fluoroscopy. A more posterior device location may reduce the defibrillation threshold.

Depending on patient body habitus and anatomy, the physician may choose to position the device between the serratus anterior muscle and the latissimus dorsi muscle. Device fixation to the musculature is needed to secure its position, ensure performance, and to minimize wound complications.

Good tissue contact with the electrode and pulse generator is important to optimize sensing and therapy delivery. Use standard surgical techniques to obtain good tissue contact. For example, keep the tissue moist and flushed with sterile saline, expel any residual air out through the incisions prior to closing and, when closing the skin, take care not to introduce air into the subcutaneous tissue.

Check Equipment

It is recommended that instrumentation for cardiac monitoring and defibrillation be available during the implant procedure. This includes the S-ICD System Programmer with its related accessories and the software application. Before beginning the implantation procedure, become completely familiar with the operation of all the equipment and the information in the respective user's manuals. Verify the operational status of all equipment that may be used during the procedure. In case of accidental damage or contamination, the following should be available:

- Sterile duplicates of all implantable items
- Wand in a sterile barrier
- Torque and non-torque wrenches

During the implantation procedure, always have a standard transthoracic defibrillator with external pads or paddles available for use during defibrillation threshold testing.

Interrogate and Check the Pulse Generator

To maintain sterility, test the pulse generator as described below before opening the sterile blister tray. The pulse generator should be at room temperature to ensure accurately measured parameters.

1. Place the wand directly over the pulse generator.
2. From the programmer startup screen, select the Scan for Devices button.
3. Identify the pulse generator being implanted from the Device List screen and verify that the status of the pulse generator is reported as Not Implanted. This indicates the pulse generator is in Shelf mode. If otherwise, contact Boston Scientific using the information on the back cover.
4. From the Device List screen, select the pulse generator being implanted to initiate a communication session.
5. Upon connection with the pulse generator, the programmer will display an alert if the pulse generator battery status is below the appropriate level for a device at implant. If a battery alert appears, contact Boston Scientific using the information on the back cover.

Creating the Device Pocket

The device is typically implanted in the left lateral thoracic region. To create the device pocket, make an incision such that the device can be placed in the vicinity of the left 5th and 6th intercostal spaces and near the mid-axillary line (Figure 13 Creating the Device Pocket on page 43) and secured to the fascial plane covering the serratus anterior muscle. Depending on patient body habitus and anatomy, the physician may choose to position the device between the serratus anterior muscle and the latissimus dorsi muscle, in which case the device should be secured to the musculature. Creating the device pocket can be accomplished by making an incision along the inframammary crease.

The instructions for implanting the device describe two techniques: the subcutaneous and the intermuscular techniques. For information on how the device is secured depending on the implant technique, see "Connect the Subcutaneous Electrode to the Device " on page 43. Alternate surgical approaches could be considered if system placement requirements can be achieved. The physician determines which tools and surgical technique are used to implant and position the device based on the patient’s anatomical features.

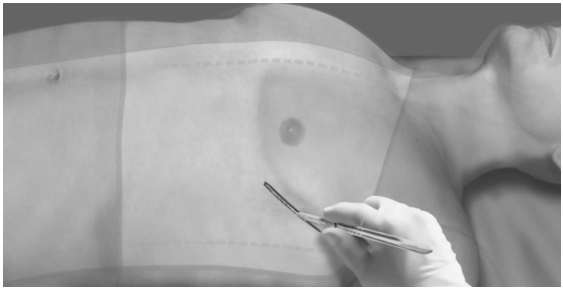


Figure 13. Creating the Device Pocket

Implant the EMBLEM S-ICD Subcutaneous Electrode

The pulse generator requires an electrode for sensing and delivering shocks. Electrode implant tools are used to create the subcutaneous tunnels in which the electrode is inserted. For information on implanting the subcutaneous electrode using the electrode implant tools, refer to the applicable S-ICD implant tools user's manual.

Connect the Subcutaneous Electrode to the Device

When connecting the subcutaneous electrode to the device, use only the tools provided in the device tray. Failure to use the supplied tools may result in damage to the setscrew. Retain the tools until all testing procedures are complete and the device is implanted.

CAUTION: Verify the device is in Shelf mode or Therapy Off to prevent the delivery of unwanted shocks to the patient or the person handling the device during the implant procedure.

NOTE: *Avoid allowing blood or other body fluids to enter the connector port in the device header. If blood or other body fluids inadvertently enter the connector port, flush with sterile water.*

NOTE: *Do not implant the device if the setscrew seal plug appears to be damaged.*

NOTE: *If the electrode terminal will not be connected to a pulse generator at the time of electrode implantation, you must cap the electrode terminal before closing the pocket incision. The lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.*

1. If applicable, remove and discard the tip protection before using the torque wrench.
2. Gently insert the torque wrench blade into the setscrew by passing it through the preslit, center depression of the seal plug at a 90° angle (Figure 14 Inserting the Torque Wrench on page 45). This will open up the seal plug, relieving any potential pressure build-up from the connector port by providing a pathway to release trapped fluid or air.

   NOTE: *Failure to properly insert the torque wrench in the preslit depression of the seal plug may result in damage to the plug and its sealing properties.*

   CAUTION: Do not insert the subcutaneous electrode into the pulse generator connector port without taking the following precautions to ensure proper insertion:

   - Insert the torque wrench into the preslit depression of the seal plug before inserting the subcutaneous electrode connector into the port, to release any trapped fluid or air.
   - Visually verify that the setscrew is sufficiently retracted to allow insertion. Use the torque wrench to loosen the setscrew if necessary.
   - Fully insert the subcutaneous electrode connector into the port and then tighten the setscrew onto the connector.

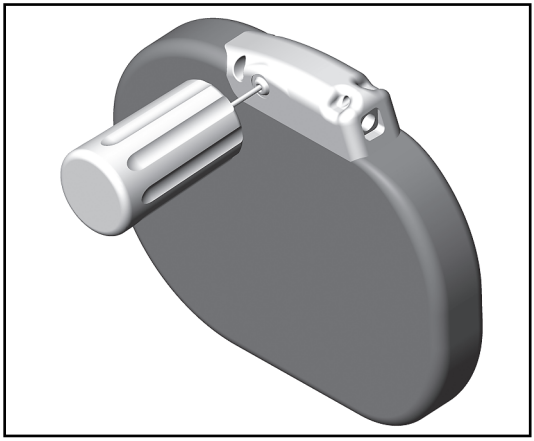
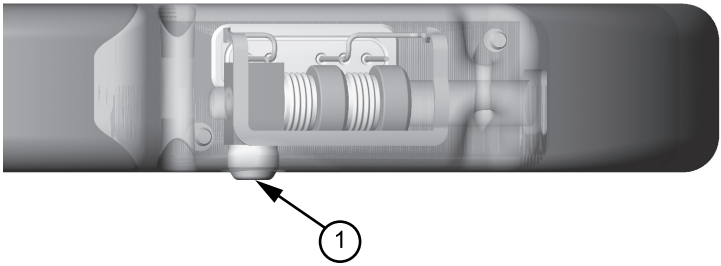


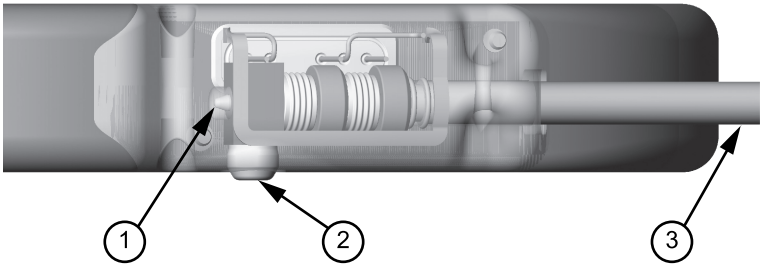
Figure 14. Inserting the Torque Wrench

3. With the torque wrench in place, fully insert the subcutaneous electrode terminal into the electrode port. Grip the subcutaneous electrode close to the connector and insert it straight into the connector port. The electrode is fully inserted when the tip of the connector is visible beyond the connector block when viewed from the top. Refer to figures for illustrations of the header connector block with no electrode inserted (Figure 15 Subcutaneous Electrode Connector with No Electrode Inserted (Top View) on page 46) and with the electrode fully inserted (Figure 16 Subcutaneous Electrode Connector with Electrode Fully Inserted (Top View) on page 46). Place pressure on the subcutaneous electrode to maintain its position and ensure that it remains fully inserted in the connector port.



[1] Setscrew

Figure 15. Subcutaneous Electrode Connector with No Electrode Inserted (Top View)



[1] Tip of connector, [2] Setscrew, [3] Electrode

Figure 16. Subcutaneous Electrode Connector with Electrode Fully Inserted (Top View)

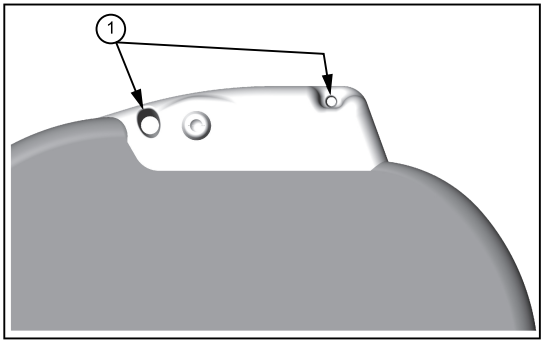
WARNING: Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. This could damage the connector. A damaged connector may result in compromised sealing integrity, possibly leading to compromised sensing, loss of therapy, or inappropriate therapy.

CAUTION: Insert the subcutaneous electrode connector straight into the pulse generator header port. Do not bend the subcutaneous electrode near the subcutaneous electrode-header interface. Improper insertion can cause insulation or connector damage.

NOTE: *If necessary, lubricate the connector sparingly with sterile water to make insertion easier.*

4. Apply gentle downward pressure on the torque wrench until the blade is fully engaged within the setscrew cavity, taking care to avoid damage to the seal plug. Tighten the setscrew by slowly turning the torque wrench clockwise, until it ratchets once. The torque wrench is preset to apply the proper amount of force to the captive setscrew; additional rotation and force is unnecessary.

5. Remove the torque wrench.
6. Apply gentle traction to the subcutaneous electrode to ensure a secure connection.
7. If the subcutaneous electrode terminal is not secure, attempt to reseat the setscrew. Reinsert the torque wrench as described above, and loosen the setscrew by slowly turning the wrench counterclockwise, until the subcutaneous electrode is loose. Then repeat the sequence above.
8. Insert the device into the subcutaneous pocket, with any excess subcutaneous electrode placed underneath the device.
9. Anchor the device to prevent possible migration using conventional 0- silk or similar non-absorbable suture material. Two suture holes are provided in the header for this purpose (Figure 17 Header Suture Holes for Anchoring the Device on page 47).
   - **For subcutaneous implant technique:** Secure the device to the fascial plane covering the serratus anterior muscle.
   - **For intermuscular implant technique:** Secure the device to the musculature.
10. Flush the pulse generator pocket with sterile saline solution and ensure there is good contact between the pulse generator and the surrounding tissue of the pocket prior to closing the first layer of tissue and prior to performing Automatic Setup of the device.



[1] Suture holes

Figure 17. Header Suture Holes for Anchoring the Device

11. Perform Automatic Setup as described in "Setting up the Pulse Generator using the Model 3200 S-ICD Programmer" on page 48 of this manual.
12. After performing Automatic Setup, and with the device mode still set to Therapy Off, palpate the subcutaneous electrode while monitoring the real-time S-ECG on the programmer screen for evidence of inappropriate sensing. If inappropriate sensing is observed, do not proceed until it is resolved. Contact

Boston Scientific for assistance if necessary. Once the baseline is stable and appropriate sensing is observed, set the device mode to Therapy On and conduct defibrillation testing if desired. (See "Defibrillation Testing" on page 48 for defibrillation testing instructions.)

13. After device setup and defibrillation testing, close all incisions. Use standard surgical techniques to achieve good tissue contact with both the subcutaneous electrode and pulse generator, for example avoiding any air entrapment in the subcutaneous tissue.

Setting up the Pulse Generator using the Model 3200 S-ICD Programmer

A brief setup process must be completed before the device can deliver manual or automatic therapy. Additional details can be found in the EMBLEM S-ICD Model 3200 Programmer User's Manual. This process can be performed automatically or manually during the implant procedure, although Automatic Setup is recommended. During setup, the system automatically:

- Confirms entry of the subcutaneous electrode model and serial numbers.
- Measures the shock electrode impedance.
- Optimizes the sense electrode configuration (and automatically enables SMART Pass if appropriate).
- Optimizes the gain selection.
- Acquires a reference NSR template.

To initiate the Automatic Setup process:

1. After using the programmer to scan for devices, choose the device being implanted from the Device List screen.
2. The programmer will connect to the chosen pulse generator and the Device Identification screen will appear. Choosing the Continue button from this screen removes the pulse generator from Shelf mode and causes the Automatic Setup screen to appear.
3. Select the Automatic Setup button to initiate Automatic Setup.
4. Follow the on-screen instructions to complete the Automatic Setup sequence.

If the patient’s heart rate is greater than 130 bpm, you will be instructed to complete the Manual Setup process instead. To initiate the Manual Setup process:

1. From the Main Menu screen, select the Utilities button.
2. From the Utilities screen, select the Manual Setup button.

You will be guided through a manual impedance test, selection of sensing vector, selection of gain setting, and acquisition of a reference S-ECG. During Manual Setup, the system will also automatically enable SMART Pass if appropriate.

Defibrillation Testing

Once the device is implanted and programmed to Therapy On, defibrillation testing may be conducted. A 15 J safety margin is recommended for defibrillation testing. Prior to arrhythmia induction during implant procedure,

the following recommendations for arm positioning are intended to reduce the potential for injury of the clavicle, arm and shoulder in the event of forceful muscle contraction:

- Avoid tight strapping of the arm to the arm board, and consider loosening arm restraints.
- Remove any wedge elevation below the torso, if used during the implant procedure, taking care to preserve the sterile field.
- Create a smaller angle of arm abduction from the torso, by adducting the arm as close to the torso as feasible, taking care to preserve the sterile field. Temporarily place the hand in a neutral position while the arm is in a more adducted position, reverting to a supinated position if the arm needs to be abducted again.

WARNING: During arrhythmia induction, the induction current and subsequent shock may result in forceful contraction of the pectoralis major muscle which can exert significant acute forces on the glenohumeral joint as well as on the clavicle. This, in conjunction with a tightly restrained arm, may result in injury to the clavicle, shoulder, and arm, including dislocation and fracture.

NOTE: *Defibrillation testing is recommended at implant, replacement, and concomitant device implants to confirm the ability of the S-ICD System to sense and convert VF.*

WARNING: Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

To induce VF and test the S-ICD System using the Model 3200 S-ICD programmer:

1. Select the Main Menu icon (arrow within a circle) in the Navigation bar, in the top right corner of the screen.
2. From the Main Menu screen, select the Patient Test button to set up the induction test.
3. Follow the on-screen instructions to set shock energy and polarity and to induce an arrhythmia.

   NOTE: *Ensure that noise markers ("N") are not present on the S-ECG prior to induction. The presence of noise markers may delay detection and therapy delivery.*

4. At any time prior to therapy delivery, the programmed energy may be aborted by selecting the red Abort button.
5. Select the Exit button to exit the induction process and return to the Main Menu screen.

The following functions occur during the test:

- The S-ICD System induces ventricular fibrillation using 200 mA alternating current (AC) at 50 Hz. Induction continues until the Hold To Induce button is released (up to a maximum of 10 seconds per attempt).

  NOTE: *If necessary, the induction can be terminated by disconnecting the wand from the programmer.*

- Arrhythmia detection and the Live S-ECG are suspended during AC induction. Once the Hold to Induce button is released, the programmer displays the patient's rhythm.

- Upon detection and confirmation of an induced arrhythmia, the S-ICD System automatically delivers a shock at the programmed energy output and polarity.

  NOTE: *Whenever the programmer is in active communication with an S-ICD pulse generator, charging of the pulse generator in preparation for delivering a shock (whether commanded or in response to a detected arrhythmia) is indicated by an audible notification. The notification continues until the shock is delivered or aborted.*

- If the shock fails to convert the arrhythmia, re-detection occurs and subsequent shocks are delivered at the pulse generator's maximum energy output (80 J).

  NOTE: *The pulse generator can deliver a maximum of five shocks per episode. At any time, an 80 J rescue shock can be delivered by pressing the Rescue Shock button.*

  NOTE: *Following the release of the Hold To Induce button, evaluate the sensing markers during the induced rhythm. The S-ICD System uses a lengthened rhythm detection period. Consistent tachy "T" markers indicate that tachyarrhythmia detection is occurring, and that capacitor charging is imminent. If a high degree of amplitude variation is noted during the arrhythmia, a slight delay may be expected prior to capacitor charging or shock delivery.*

If appropriate sensing or VF conversion cannot be demonstrated with adequate safety margin, the physician should consider changing the selected sense configuration or review the position of both the electrode and device by use of anatomical landmarks or X-ray/fluoroscopy, reposition if necessary, and then retest. A more posterior device location may reduce the defibrillation threshold. VF conversion testing can be conducted in either polarity.

Complete and Return the Implantation Form

Within ten days of implantation, complete the Warranty Validation and Lead Registration form and return the original to Boston Scientific along with copies of the Summary Report, Captured S-ECG Reports, and Episode Reports printed from the programmer. This information enables Boston Scientific to register each implanted pulse generator and subcutaneous electrode, and provide clinical data on the performance of the implanted system. Keep a copy of the Warranty Validation and Lead Registration form and programmer printouts for the patient's file.

Patient Counseling Information

The following topics should be discussed with the patient prior to discharge.

- External defibrillation—the patient should contact their physician to have their pulse generator system evaluated if they receive external defibrillation
- Beeping tones—the patient should contact their physician immediately if they hear tones coming from their pulse generator
- Signs and symptoms of infection
- Symptoms that should be reported (e.g., lightheadedness, palpitations, unexpected shocks)
- Protected environments—the patient should seek medical guidance before entering areas protected by a warning notice that prevents entry by patients who have a pulse generator

- MRI scanning—the physician following the patient's device must be consulted to determine eligibility for an MRI scan. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper.

WARNING: The Beeper may no longer be usable following an MRI scan. Coming in contact with the strong magnetic field of an MRI scanner may cause a permanent loss of the Beeper volume. This cannot be recovered, even after leaving the MR scan environment and exiting MRI Protection Mode. Before an MRI procedure is performed, a physician and patient should weigh the benefit of the MR procedure against the risk of losing the Beeper. It is strongly recommended that patients are followed on LATITUDE NXT after an MRI scan if they are not already. Otherwise, an in-clinic follow-up schedule of every three months is strongly recommended to monitor device performance.

- Avoiding potential sources of EMI in home, work, and medical environments
- Persons administering CPR—the presence of voltage (tingling) on the patient's body surface may be experienced when the pulse generator delivers a shock
- Reliability of their pulse generator ("Product Reliability" on page 54)
- Activity restrictions (if applicable)
- Frequency of follow up
- Travel or relocation—Follow-up arrangements should be made in advance if the patient is leaving the country of implant
- Patient ID card—a patient ID card is packaged with the device, and the patient should be advised to carry it at all times

NOTE: *Patients should present their patient ID card before entering protected environments such as for MRI scanning.*

Patient Handbook

A copy of the Patient Handbook is available for the patient, patient's relatives, and other interested people.

It is recommended that you discuss the information in the Patient Handbook with concerned individuals both before and after implantation so they are fully familiar with pulse generator operation.

In addition, an ImageReady MR Conditional S-ICD System MRI Patient Guide for MRI Scans is available.

For additional copies, contact Boston Scientific using the information on the back cover.

Post Implant Follow-Up Procedures

It is recommended that device functions be evaluated with periodic follow-up testing by trained personnel to enable review of device performance and associated patient health status throughout the life of the device.

WARNING: Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient’s death.

Immediately following the implant procedure, it is recommended that the following procedures be performed:

1. Interrogate the pulse generator and review the Device Status screen (refer to the EMBLEM S-ICD Programmer User's Manual for additional information).
2. Perform sensing optimization (refer to "Setting up the Pulse Generator using the Model 3200 S-ICD Programmer" on page 48 for instructions on performing Automatic Setup including sensing optimization).
3. Follow the on-screen instructions to capture a reference S-ECG.
4. Print the Summary Report, Captured S-ECG Report, and Episode Reports to retain in the patient's files for future reference.
5. End session.

During a follow-up procedure, it is recommended that the location of the subcutaneous electrode be periodically verified by palpation and/or X-ray. When device communication with the programmer is established, the programmer automatically notifies the physician of any unusual conditions. Refer to the EMBLEM S-ICD Programmer User's Manual for more information.

Patient management and follow-up are at the discretion of the patient's physician, but are recommended one month after implant and at least every 3 months to monitor the condition of the patient and evaluate device function. Scheduled remote follow-ups with the LATITUDE Communicator, where available, may replace some in-office visits according to the physician's judgement and patient's medical condition.

NOTE: *Because the duration of the device replacement timer is three months (starting when ERI is reached), three month follow-up frequency or remote device monitoring with the LATITUDE Communicator is particularly important to ensure timely replacement of the device if necessary.*

CAUTION: Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the DFT, which may result in nonconversion of the arrhythmia post-operatively. Verify with a conversion test that the patient's tachyarrhythmias can be detected and terminated by the pulse generator system if the patient's status has changed or parameters have been reprogrammed.

Explantation

NOTE: *Return all explanted pulse generators and subcutaneous electrodes to Boston Scientific. Examination of explanted pulse generators and subcutaneous electrodes can provide information for continued improvement in system reliability and warranty considerations.*

WARNING: Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Contact Boston Scientific when any of the following occur:

- When a product is removed from service.
- In the event of patient death (regardless of cause), along with an autopsy report, if performed.

- For other observation or complication reasons.

NOTE: *Disposal of explanted pulse generators and/or subcutaneous electrodes is subject to applicable laws and regulations. For a Returned Product Kit, contact Boston Scientific using the information on the back cover.*

CAUTION: Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.

CAUTION: Before explanting, cleaning, or shipping the device, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:

- Program the pulse generator to Therapy Off mode.
- Disable the beeper, if available.
- Clean and disinfect the device using standard biohazard handling techniques.

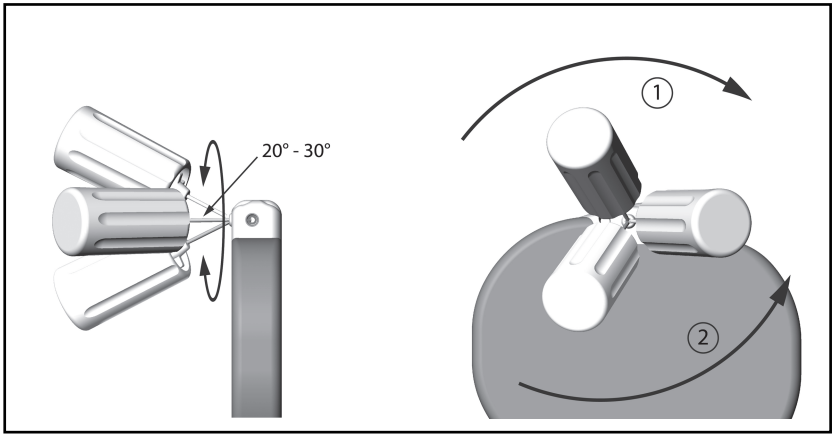
Consider the following items when explanting and returning the pulse generator and/or subcutaneous electrode:

- Interrogate the pulse generator and print all reports.
- Deactivate the pulse generator before explantation.
- Disconnect the subcutaneous electrode from the pulse generator.
- If subcutaneous electrode is not explanted and terminal will not be connected to a pulse generator, cap the electrode terminal before closing the pocket incision. The lead cap is designed specifically for this purpose. Place a suture around the lead cap to keep it in place.
- If subcutaneous electrode is explanted, attempt to remove it intact, and return it regardless of condition. Do not remove the subcutaneous electrode with hemostats or any other clamping tool that may damage it. Resort to tools only if manual manipulation cannot free the subcutaneous electrode.
- Wash, but do not submerge, the pulse generator and subcutaneous electrode to remove body fluids and debris using a disinfectant solution. Do not allow fluids to enter the pulse generator's connector port.
- Use a Boston Scientific Returned Product Kit to properly package the pulse generator and/or subcutaneous electrode, and send it to Boston Scientific.

Loosening Stuck Setscrews

Follow these steps to loosen stuck setscrews:

1. From a perpendicular position, tilt the torque wrench to the side 20º to 30º from the vertical center axis of the setscrew (Figure 18 Rotating the Torque Wrench to Loosen a Stuck Setscrew on page 54).
2. Rotate the wrench clockwise (for retracted setscrew) or counterclockwise (for extended setscrew) around the axis three times, such that the handle of the wrench orbits the centerline of the screw (Figure 18 Rotating the Torque Wrench to Loosen a Stuck Setscrew on page 54). The torque wrench handle should not turn or twist during this rotation.



[1] Clockwise rotation to free setscrews stuck in the retracted position, [2] Counterclockwise rotation to free setscrews stuck in the extended position

Figure 18. Rotating the Torque Wrench to Loosen a Stuck Setscrew

3. As needed, you may attempt this up to four times with slightly more angle each time. If you cannot fully loosen the setscrew, use the #2 torque wrench from Wrench Kit Model 6501.
4. Once the setscrew has been freed, it may be extended or retracted as appropriate.
5. Discard the torque wrench upon completion of this procedure.

COMMUNICATION COMPLIANCE

This transmitter operates in the 402–405 MHz band using FSK modulation with radiated power conforming to the applicable 25 µW limit. The purpose of the transmitter is to communicate with the S-ICD System programmer to transfer data and to receive and respond to programming commands.

ADDITIONAL INFORMATION

Product Reliability

It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. These malfunctions may include the following:

- Premature battery depletion
- Sensing or pacing issues

- Inability to shock
- Error codes
- Loss of telemetry

Refer to Boston Scientific's CRM Product Performance Report on www.bostonscientific.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products.

Sometimes device malfunctions result in the issuance of product advisories. Boston Scientific determines the need to issue product advisories based on the estimated malfunction rate and the clinical implication of the malfunction. When Boston Scientific communicates product advisory information, the decision whether to replace a device should take into account the risks of the malfunction, the risks of the replacement procedure, and the performance to date of the replacement device.

Pulse Generator Longevity

Based on simulated studies, it is anticipated that these pulse generators have average longevity to EOL as shown in Table 4 Device Longevity on page 55. At the time of manufacture, the device has the capacity for over 100 full energy charges/shocks. The average projected longevity, which accounts for the energy used during manufacture and storage, assumes the following conditions:

- Two maximum energy charges at implant and six maximum energy charges/shocks in the final three-month period between ERI and EOL
- The pulse generator spends six months in Shelf mode during shipping and storage
- Telemetry use for one hour at implant and 30 minutes annually for in-clinic follow-up checks
- Standard use of the LATITUDE Communicator as follows: Weekly Device Check, monthly Full Interrogations (scheduled remote follow-ups, and quarterly patient-initiated interrogations)
- With stored Episode Report Onset EGM

Table 4. Device Longevity

Annual Full Energy Charges	Average Projected Longevity (years)
3 (Normal Use[a])	7.3
4	6.7
5	6.3

a. The median number of annual full energy charges seen in clinical testing of the first generation S-ICD system was 3.3.

NOTE: *The energy consumption in the longevity table is based upon theoretical electrical principles and verified via bench testing only.*

Full energy charges result from capacitor reformations, non-sustained episodes, and delivered shocks.

CAUTION: Battery depletion will eventually cause the S-ICD pulse generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity.

Longevity is also affected in the following circumstances:

- A decrease in charging frequency may increase longevity
- An additional maximum energy shock reduces longevity by approximately 29 days
- One hour of additional telemetry reduces longevity by approximately 14 days
- Five patient-initiated LATITUDE Communicator interrogations per week for a year reduces longevity by approximately 31 days
- Upload of 100 AF episodes to the LATITUDE Communicator reduces longevity by approximately six days (EMBLEM MRI S-ICD Model A219 only)
- An additional six months in Shelf mode prior to implant reduces longevity by 103 days
- Six hours in MRI Protection Mode reduces longevity by approximately two days

Device longevity may also be affected by tolerances of electronic components, variations in programmed parameters, and variations in usage as a result of patient condition.

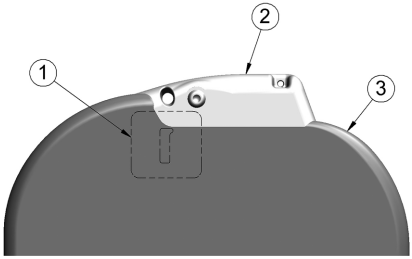
Refer to the Patient View or Device Status screen on the programmer or refer to the printed Summary Report for an estimate of remaining battery capacity specific to the implanted device.

X-ray Identifier

The pulse generator has an identifier that is visible on X-ray film or under fluoroscopy. This identifier provides noninvasive confirmation of the manufacturer and consists of the following:

- The letters, BSC, to identify Boston Scientific as the manufacturer
- The number, 507, to identify the device as an EMBLEM or EMBLEM MRI pulse generator

The X-ray identifier is located in the pulse generator case, just below the header (Figure 19 Location of the X-ray ID on page 57), and is read vertically.



[1] X-ray identifier location, [2] header, [3] pulse generator case

Figure 19. Location of the X-ray ID

Specifications

Specifications provided at 37° C ± 3° C, and assume a 75 Ohm (± 1%) load unless noted otherwise.

Table 5. Mechanical Specifications

Model	Dimensions W x H x D (mm)	Mass (g)	Volume (cm^3)	Connector Type[a]
A209, A219	83.1 x 69.1 x 12.7	130	59.5	SQ-1 S-ICD connector (non-standard)

a. The pulse generator is compatible with all Boston Scientific/Cameron Health electrodes.

The pulse generator has a case electrode surface area of 111.0 cm^2.

Material Specifications

- Case: hermetically sealed titanium, coated with titanium nitride
- Header: implantation-grade polymer
- Power Supply: lithium-manganese dioxide cell; Boston Scientific; 400530

Table 6. Programmable Parameters

Parameter	Programmable Values	Nominal (as shipped)
Shock Zone	170–250 bpm (steps of 10 bpm)	220 bpm
Conditional Shock Zone	Off, 170–240 bpm (If On, at least 10 bpm less than Shock Zone)	200 bpm
S-ICD Pulse Generator Mode	Shelf, Therapy On, Therapy Off, MRI Protection Mode	Shelf
Post-shock Pacing	On, Off	Off
Sensing Configuration	Primary: Proximal electrode ring to device Secondary: Distal electrode ring to device Alternate: Distal electrode ring to proximal electrode ring	Primary
Max Sensing Range	x1 (± 4 mV) x2 (± 2 mV)	x1
Manual Shock	10–80 J (in steps of 5 J)	80 J
SMART Charge	Resets to nominal	0 extensions
Polarity	Standard: Phase 1 Coil (+) Reverse: Phase 1 Coil (-)	Standard
AF Monitor[a]	On, Off	On
MRI Protection Time-out (hours)	6, 9, 12, 24	6
Set Beeper Function	Enable Beeper, Disable Beeper	Enable Beeper

a. Available in EMBLEM MRI S-ICD (Model A219).

Table 7. Non-Programmable Parameters (Shock Therapy)

Parameter	Value
SHOCK THERAPY	
Delivered Energy	80 J
Peak Shock Voltage (80 J)	1328 V
Shock Tilt (%)	50%
Waveform Type	Biphasic
Maximum Number of Shocks per episode	5 shocks
Charge Time to 80 J (BOL/ERI)[a]	≤10 sec / ≤15 sec[b]
Sync Time Out	1 sec
Shock Sync Delay	100 ms
Post-Shock Blanking Period	1600 ms

a. Charge time is one portion of the overall time-to-therapy. BOL refers to beginning of life.
b. Under typical conditions.

Table 8. Non-Programmable Parameters (Post-Shock Pacing)

Parameter	Value
POST-SHOCK PACING	
Rate	50 ppm
Pacing Output	200 mA
Pulse Width (each phase)	7.6 ms
Waveform	Biphasic
Polarity (first phase)	Standard: Phase 1 Coil (+)
Mode	Inhibited Pacing

Table 8. Non-Programmable Parameters (Post-Shock Pacing) (continued)

Parameter	Value
POST-SHOCK PACING	
Duration	30 sec
Post-Pace Blanking Period/ Refractory Period	750 ms (first pace pulse) 550 ms (subsequent pace pulses)
Runaway Protection	120 ppm

Table 9. Non-Programmable Parameters (Detection/Rhythm Discrimination, Fibrillation Induction, Sensing, Capacitor Reform Schedule, Internal Warning System)

Parameter	Value
DETECTION/RHYTHM DISCRIMINATION	
X/Y for Initial Detection	18/24 intervals
X/Y for Redetection	14/24 intervals
Confirmation Before Shock	3–24 consecutive tachy intervals
Refractory Period	Fast 160 ms, Slow 200 ms
FIBRILLATION INDUCTION	
Frequency	50 Hz
Output	200 mA
Time out After Activation	10 sec
SENSING	
Minimum Sensing Threshold[a]	.08 mV
CAPACITOR REFORM SCHEDULE	
Automatic Capacitor Reformation Interval	Approximately 4 months[b]

Table 9. Non-Programmable Parameters (Detection/Rhythm Discrimination, Fibrillation Induction, Sensing, Capacitor Reform Schedule, Internal Warning System) (continued)

Parameter	Value
INTERNAL WARNING SYSTEM	
High Impedance (sub-threshold)	> 400 Ohms
High Impedance (delivered shock)	> 200 Ohms
Maximum Charge Time out	44 sec

a. With 10 Hz sine wave.
b. Reform can be delayed if capacitor was charged due to sustained/non-sustained arrhythmia in past 4 months.

Table 10. Episode Data Parameters

Parameter	Value
Treated Episodes	25 stored (A209), 20 stored (A219)
Untreated Episodes	20 stored (A209), 15 stored (A219)
AF Episodes[a]	7 stored
Maximum Length per S-ECG Episode	128 sec

a. Available in EMBLEM MRI S-ICD (Model A219).

Table 11. Stored Patient Information

Patient Information (Stored Data)
Patient Name
Physician Name
Physician Contact Information
Device Model Number

Table 11. Stored Patient Information (continued)

Patient Information (Stored Data)
Device Serial Number
Electrode Model Number
Electrode Serial Number
Patient Notes

Table 12. Magnet Specifications (Model 6860)

Component	**Specification**
Shape	Circular
Size	Approximate Diameter: 2.8 in (7.2 cm) Thickness: 0.5 in (1.3 cm)
Content	Ferrous alloys coated with epoxy
Field Strength	90 gauss minimum when measured at a distance of 1.5 in (3.8 cm) from magnet surface

NOTE: *Specifications are also applicable to the Cameron Health magnet Model 4520.*

Definitions of Package Label Symbols

The following symbols may be used on packaging and labeling.

Table 13. Packaging Symbols

Symbol	**Description**
STERILE EO	Sterilized using ethylene oxide
	Date of manufacture
EC REP	Authorized Representative in the European Community

Table 13. Packaging Symbols (continued)

Symbol	Description
	Dangerous voltage
	Use by
SN	Serial number
LOT	Lot number
REF	Reference number
	Temperature limitation
	Open here
www.bostonscientific-elabeling.com	Consult instructions for use on this website: www.bostonscientific-elabeling.com
	Literature enclosed
	Package contents

Table 13. Packaging Symbols (continued)

Symbol	Description
2 STERILIZE	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	Manufacturer
MR	MR Conditional
SQ-1	SQ-1 S-ICD connector (non-standard)
R–NZ	New Zealand radio communications standards compliance mark
	Australian Communication and Media Authority (ACMA) – Radio Communications Standards compliance mark
RF	RF telemetry
	Uncoated device
	Pulse generator

Table 13. Packaging Symbols (continued)

Symbol	Description
	Torque wrench
CE0086	CE mark of conformity with the identification of the notified body authorizing use of the mark
AUS	Australian Sponsor Address

S-ICD System and Pacemaker Interaction

WARNING: Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Refer to "S-ICD System and Pacemaker Interaction" on page 65 for more information.

Interaction between the S-ICD System and a temporary or permanent pacemaker is possible and can interfere with the identification of tachyarrhythmias in several ways.

- If the pacing pulse is detected, the S-ICD System may not adjust sensitivity appropriately, fail to sense a tachyarrhythmia episode, and/or not deliver therapy.
- Pacemaker sensing failure, lead dislodgment, or failure to capture could result in the sensing of two asynchronous sets of signals by the S-ICD System, causing the rate measurement to be faster, and may result in delivery of unnecessary shock therapy.
- Conduction delay may cause the device to oversense the evoked QRS and T-wave, resulting in unnecessary shock therapy.

Unipolar stimulation and impedance-based features can interact with the S-ICD. This includes bipolar pacemakers that revert or reset to the unipolar pacing mode. Refer to the manufacturer's pacemaker manual for considerations when configuring a bipolar pacemaker for compatibility with an S-ICD.

Prior to implantation, follow the patient screening tool procedure to assure that the patient’s paced S-ECG signal passes the criteria.

The following test procedure aids in determining S-ICD System and pacemaker interaction after implantation:

WARNING: Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient’s death.

NOTE: *If implanting a pacemaker with an existing S-ICD System, program the S-ICD System to Therapy Off during the implantation and initial testing of the pacemaker.*

During the testing procedure, program the pacemaker output to maximum and asynchronously pace in the pacing mode to which the pacemaker will be permanently programmed (e.g., DOO for most dual-chamber modes and VOO for single-chamber modes).

1. Complete the S-ICD System setup procedure.
2. Observe the S-ECG for any pacing artifacts. If any pacing artifacts are present and larger in amplitude than the R-wave, use of the S-ICD System is not recommended.
3. Induce the tachyarrhythmia and observe the S-ECG markers to determine appropriate detection and delivery of therapy.
4. If inappropriate sensing is observed as a result of the device sensing the pacing artifact, reduce the pacemaker's pacing output and retest.

In addition, pacemaker operation may be affected by the S-ICD System therapy delivery. This could alter the pacemaker's programmed settings or damage the pacemaker. In this situation, most pacemakers will conduct a memory check to determine if the parameters for safe operation were affected. Further interrogation will determine if programmed pacemaker parameters are altered. Refer to the manufacturer's pacemaker manual for implantation and explantation considerations.

Warranty Information

A limited warranty certificate for the pulse generator is available at www.bostonscientific.com. For a copy, contact Boston Scientific using the information on the back cover.

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