

OPERATOR'S MANUAL

EMBLEM™ S-ICD

REF 3877, 3300

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud version. Äрге kasutaga.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Versione obsoleta. No utilitzar.
Úreilt útgáfa. Notið ekki.
Novecojsi verzija. Nenaudokite.
Pasenusi versija. Ne naudokite.
Elavult verzió. Ne használjal.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaraná verzija. Nepoužívat.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud version. Må ekki notuð.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreilt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Novecojsi versija. Nenaudokite.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használjal.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaraná verzija. Nepoužívať.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Table of Contents

INFORMATION FOR USE	1
Trademark Statement	1
Description and Use	1
Intended Use	1
Intended Audience	1
Required Expertise and Knowledge	1
Medical Product Operator's Ordinance	1
List of Acronyms	2
Contraindications	2
Related Information	2
Warnings	3
S-ICD Precautions	5
Adverse Effects	7
USING THE S-ICD APPLICATION	7
S-ICD Application Setup Overview	7
Powering the Model 3300 Programmer	8
Powering the Programmer On and Off	10
Using the Programmer Touch Screen	10
S-ICD Application Navigation	11
S-ICD Application Screen Header	11
S-ICD Application Navigation Bar	11
Configuring the S-ICD Application	12
Starting the Model 3300 Programmer	12
Set the Language and Time Zone	13
Enable Bluetooth® Communications	14
Start the S-ICD Application	15
Date and Time Format	17
Set Noise Filter Configuration	18
Printer Selection	19
Model 3877 S-ICD Application Software Version	20
Bluetooth® Data Export	21
Application Modes of Operation	22
Online Behavior	22
Offline Behavior	22
Stored Patient Sessions	22
Modes of Operation for the Pulse Generator	23
Shelf Mode	23
Therapy On Mode	23
Therapy Off Mode	23
MRI Protection Mode	23

Connecting and Disconnecting from the S-ICD Pulse Generator	25
Scanning for Pulse Generators	25
Connecting to a Pulse Generator	26
Connecting to a Pulse Generator in Shelf Mode	26
Connecting to an Implanted Pulse Generator	26
Ending a Patient Session	26
Programming the Pulse Generator at Implant	28
Entering Electrode Information	29
Creating the Patient Chart	29
Automatic Setup	30
Programming Therapy Parameters	32
Defibrillation Testing	34
Performing a Follow-up	37
Sensing Configuration and Automatic Setup	37
Viewing Pulse Generator Status	37
Viewing Stored Episodes	38
Printing Reports from the S-ICD Application	40
Printing Reports	40
Summary Report	40
Captured S-ECG Report	41
Episode Reports	42
Export Patient Data	43
S-ECG Features	44
S-ECG Rhythm Strip Markers, Indicators, and Discontinuities	44
S-ECG Scale Settings	45
Capture and View S-ECG Strips	46
View previously-captured S-ECGs	47
Utilities Screen	47
Acquire Reference S-ECG	48
Capture All Sense Vectors	48
Beeper Control	49
Manual Setup	50
SMART Settings	51
AF Monitor	52
Additional S-ICD Application Features	53
Rescue Shock	53
Manual Shock	54
S-ICD System Magnet Use	55
MAINTENANCE, TROUBLESHOOTING, HANDLING, STANDARDS, AND SPECIFICATIONS	56
WARRANTY INFORMATION	56

INFORMATION FOR USE

Trademark Statement

The following are trademarks of Boston Scientific Corporation or its affiliates: AF Monitor, EMBLEM, ImageReady, LATITUDE, LATITUDE NXT, Quick Start, ZIP, and ZOOM.

Bluetooth® is a registered trademark of Bluetooth SIG.

DisplayPort is a trademark of the Video Electronics Standards Association (VESA).

Description and Use

The following Operator's Manuals describe the LATITUDE Programming System for use with S-ICD pulse generators:

1. *LATITUDE™ Programming System Operator's Manual (Model 3300)*
2. *EMBLEM™ S-ICD Application Operator's Manual (Model 3877)*

These manuals are also available online at:
www.bostonscientific-elabeling.com.

The Model 3300 Programmer is the programming device of the LATITUDE Programming System, which is a portable cardiac rhythm management system designed to be used with specific Boston Scientific systems, i.e., implantable pulse generators (PGs), electrodes, and leads.

Intended Use

The LATITUDE Programming System is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. The software in use controls all communication functions for the PG. For detailed software application instructions, refer to the associated product literature for the PG being interrogated.

Intended Audience

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

Required Expertise and Knowledge

Users must be thoroughly familiar with electrotherapy of the heart. Only qualified medical specialists having the special knowledge required for the proper use of the device are permitted to use it.

Physician Supervision

The LATITUDE Programming System may only be operated under the constant supervision of a physician. During a procedure, the patient must be continuously monitored by medical personnel with the aid of a surface ECG monitor.

Medical Product Operator's Ordinance

National regulations may require that the user, manufacturer or manufacturer representative perform and document safety checks of the device during installation. They

may also require that the manufacturer or its representative provide training to users on the proper use of the device and its accessories.

If you do not know the national regulations in your country, please contact your local Boston Scientific representative.

List of Acronyms

The following list of acronyms is used throughout this manual.

AC	Alternating current	MRI	Magnetic resonance imaging
AF	Atrial Fibrillation	NSR	Normal sinus rhythm
ATP	Anti-tachycardia pacing	RF	Radio Frequency
CRT	Cardiac resynchronization therapy	RFI	Radio Frequency Interference
CPR	Cardiopulmonary resuscitation	RFID	Radio Frequency Identification
ECG	Electrocardiogram	S-ECG	Subcutaneous electrocardiogram
EMI	Electromagnetic interference	S-ICD	Subcutaneous implantable cardioverter defibrillator
EOL	End of life	USB	Universal serial bus
ERI	Elective replacement indicator	VAC	Voltage alternating current
ESD	Electrostatic discharge	VF	Ventricular fibrillation
GUI	Graphic user interface	VT	Ventricular tachycardia
LCD	Liquid crystal display		

Contraindications

The LATITUDE Programming System is contraindicated for use with any PG other than a Boston Scientific PG. For contraindications for use related to the PG, refer to the associated product literature for the PG being interrogated.

The Model 3877 S-ICD application is contraindicated for use with any programming system other than the Boston Scientific Model 3300 LATITUDE Programming System.

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

Related Information

Before using the S-ICD system, read and follow all instructions, warnings, and precautions provided in this manual, the *LATITUDE Programming System Operator's Manual* (Model 3300), and in the manuals for the other system components, including the applicable S-ICD pulse generator, subcutaneous electrode, and electrode implant tools user's manuals.

This manual may contain reference information for pulse generator 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 tiers unless otherwise noted.

Refer to the *ImageReady™ MR Conditional S-ICD System - MRI Technical Guide* (hereafter referred to as the S-ICD MRI Technical Guide) for information about MRI scanning. This manual is also available online at www.bostonscientific-elabeling.com.

WARNINGS

Additional warnings specific to the Model 3300 Programmer are described in the *LATITUDE Programming System Operator's Manual*, Model 3300.

Additional warnings specific to the S-ICD pulse generator are described in the S-ICD Physician Technical Manuals.

S-ICD System Warnings General

- **Connector contacts.**



Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor.

- **Physiological signals.**



Operation of the LATITUDE Programming System with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results.

- **LATITUDE Programming System must remain outside sterile field.**



The Programmer is non-sterile and cannot be sterilized. Do not allow the device to enter a sterile zone in an implant environment.

- **LATITUDE Programming System location.**



Use of the Model 3300 Programmer adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- **LATITUDE Programming System is MR unsafe.**



The LATITUDE Programming System 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 Practices¹. Under no circumstances should the LATITUDE Programming System be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

- **Backup defibrillation protection.**

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



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.

- **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.

- **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 the appropriate S-ICD pulse generator manual for more information.

Clinical Considerations

- **Myopotentials.**



The S-ICD System may sense myopotentials which may result in over/under sensing.

Implantation

- **High shocking electrode impedance.**



High shocking electrode impedance may reduce VT/VF conversion success.

- **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.

- **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.

Device Programming

- **Sensing adjustment.**



Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing.

- **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.

Post-Implant

- **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. 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 (a remote patient management system) 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.

- **Magnet Response with Deep Implant Placement (S-ICD only).**



In patients with an S-ICD pulse generator 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 (S-ICD only).**



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.

PRECAUTIONS

Additional precautions specific to the Model 3300 Programmer are described in the *LATITUDE Programming System Operator's Manual*, Model 3300.

Additional precautions specific to the S-ICD pulse generator are described in the S-ICD Physician Technical Manuals.

- Implantation
 - **Operating temperature.** Allow the pulse generator to reach an operating temperature range of 25° C - 45° C (77° F - 113° F) before using telemetry communication capabilities, programming, or implanting the pulse generator because temperature extremes may affect initial device function.
 - **At implant, confirm communication with the PG.** Confirm that the Programmer is in communication with the intended S-ICD pulse generator.
- Device Programming
 - **Programming System.** Use only the appropriate LATITUDE Programming System equipped with the appropriate software to program specific Boston Scientific PGs.

- **Programmer must remain outside the sterile field.** The Programmer is non-sterile and cannot be sterilized. It must remain outside the sterile field.
- **Model 3203 S-ICD Telemetry Wand use.** For S-ICD PG telemetry, use only the Model 3203 S-ICD Telemetry Wand with the LATITUDE Programming System.
- **Date and time accuracy.** Inability to access a remote time server could lead to discrepancies in the Programmer time. As a backup, contact your Boston Scientific representative to have the time and date set manually.
- **Patient data (S-ICD).** Data files for up to fifty (50) patients may be stored on the Programmer and appropriate precautions should be taken to secure the Programmer from unauthorized access.
 - Delete all S-ICD patient data from the Programmer by selecting the Purge All Data button on the Stored Patient Sessions screen before shipping the Programmer or at any time when the Programmer leaves your direct control.
 - Only connect to known Bluetooth® devices to reduce the potential of transmitting patient data to inappropriate printers or devices.
- **Stylus use.** If you want to use a stylus, ensure that it is a projected capacitance stylus. The use of any other object could damage the touchscreen.
- **USB devices.** USB devices connected to the Programmer should be encrypted and controlled to limit the potential introduction of malware.
- **Software.** Ensure that you have the latest software versions installed. Refer to the *LATITUDE Programming System Operator's Manual (Model 3300)* for information about performing a software update. As a backup, your local Boston Scientific representative can provide software updates using a USB pen drive.
- **Wi-Fi.** Wi-Fi connectivity is not permitted in Indonesia due to specific configuration requirements.
- **Magnet handling.** Do not place a magnet on the Programmer.
- **Patients hear tones coming from their S-ICD device.** Patients should be advised to contact their physician immediately whenever they hear tones coming from their S-ICD device.
- **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.
- **High shock impedance.** A reported shock impedance value of greater than 110 ohms from a delivered shock could indicate sub-optimal system placement. Care should be taken to place both the pulse generator and electrode directly on the fascia without underlying adipose tissue. Adipose tissue can add significant impedance to the high voltage shock current pathway.
- **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.

- Environmental and Medical Therapy Hazards
 - **Electrocautery.** Electrocautery may induce ventricular arrhythmias and/or fibrillation and may cause inappropriate shocks and inhibition of post-shock pacing and may produce unexpected behavior in the Programmer display or operation. If electrocautery is medically necessary, maintain a distance of at least 30 cm (12 in) between electrocautery equipment and the Programmer and its associated components. Similarly, maintain this distance between the Programmer and its associated components and the patient during these procedures.
 - **Model 3203 S-ICD Telemetry Wand shipped non-sterile.** The Model 3203 S-ICD Telemetry Wand is shipped non-sterile. Remove the wand from all packaging material before use. If the wand is to be used in a sterile field, it must be enclosed in a sterile intraoperative probe cover (Model 3320) during use. Refer to the *LATITUDE™ Programming System Operator's Manual* (Model 3300) for cleaning information.

Adverse Effects

The following are the possible adverse effects associated with programming the pulse generators described in this manual.

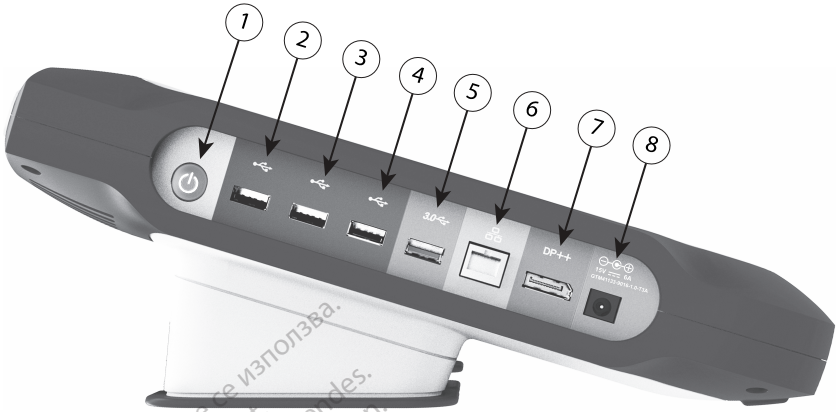
- Asystole
- Atrial arrhythmia
- Bradycardia
- Tachycardia
- Ventricular arrhythmia

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

USING THE S-ICD APPLICATION

S-ICD Application Setup Overview

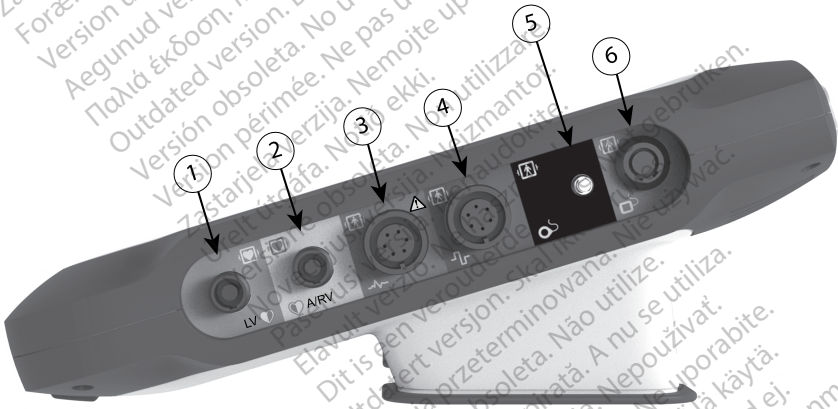
This section describes the wand and power connections to the Model 3300 Programmer and basic navigation of the S-ICD Application.



[1] Power (on/off) button (light gray) [2-4] USB 2.0 ports (dark gray) [5] USB 3.0 port (blue) [6] Ethernet port (orange) [7] DisplayPort Out (red-orange) [8] DC power connection for Model 6689 power adapter (green)

Figure 1. Left Side Panel of the Programmer

In Figure 1 Left Side Panel of the Programmer on page 8, callout 8 identifies the DC power connection, and callout 1 identifies the Programmer On/Off power button.



[1] Model 6763 PSA Cable for LV (green) [2] Model 6763 PSA Cable for A/RV (light gray) [3] Model 3154/3153 ECG Cable (dark gray) [4] connection port for future use (brown) [5] Model 3203 S-ICD Telemetry Wand (black) [6] Model 6395 Telemetry Wand (blue)

Figure 2. Right Side Panel of the Programmer

In Figure 2 Right Side Panel of the Programmer on page 8, callout 5 identifies the Model 3203 S-ICD Telemetry Wand connection.

Powering the Model 3300 Programmer

The Model 3300 Programmer is primarily intended to be operated while connected to the AC-powered external power supply, but may also be operated on battery power provided

that the internal battery is adequately charged. The Programmer is recharged whenever it is connected to the AC-powered external power supply. When not in use, it is recommended that the Programmer remain connected to the external power supply in order to maintain an adequate battery charge.

NOTE: Refer to the LATITUDE™ Programming System Operator's Manual (Model 3300) for complete startup and battery charging information.

NOTE: Current S-ICD session data may be lost if a 45 minute period of inactivity occurs and the Programmer is not connected to AC power.

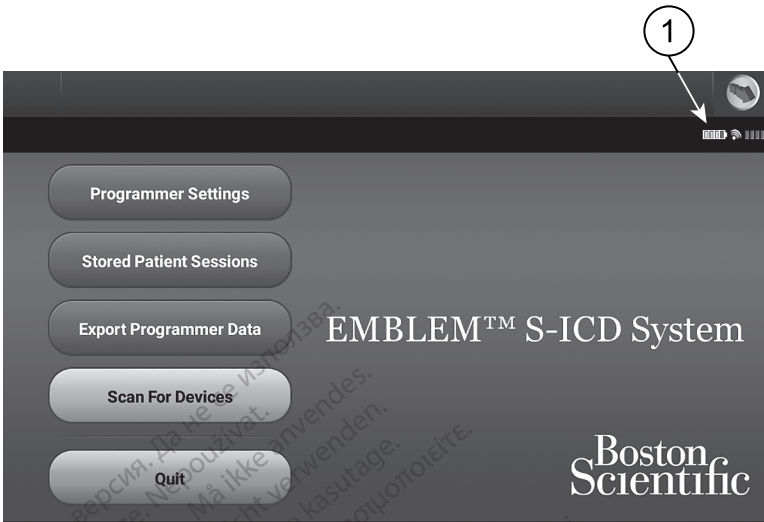
When the Programmer is powered On and the S-ICD Application is running, the battery status indicator displays in the upper right corner of the screen indicating the approximate charge status of the Programmer battery. See Figure 3 S-ICD Application start up screen with battery status icon on page 10.

- All four bars are illuminated (green) – The battery is 100% charged
- Three bars are illuminated (green) – The battery is 75% charged
- Two bars are illuminated (yellow) – The battery is 50% charged
- One bar is illuminated (red) – The battery is 25% charged

The S-ICD Application displays the following alert screens and text as the Programmer battery power gets progressively lower.

- Programmer Battery Caution Screen – “Programmer Battery \leq 25% – Battery capacity is at xx%.² It is recommended you find an AC Power source.”
- Programmer Battery Warning Screen – “Programmer Battery \leq 10% – Battery capacity is at xx%. Plug the Programmer into AC Power immediately to ensure system functionality.”
- Programmer Battery Critical Screen – “Programmer Battery \leq 5% – Battery capacity is at xx%. Plug the Programmer into AC Power immediately to ensure system functionality. Programmer will automatically shut off within 60 seconds.”

2. “xx” is replaced by the actual battery charge remaining percentage.



[1] Battery Status (bars visible when on battery power).

Figure 3: S-ICD Application start up screen with battery status icon

Powering the Programmer On and Off

The Programmer's power button is located on the left side of the Programmer (see Figure 1 Left Side Panel of the Programmer on page 8). Press the button and release it to power the Programmer On or Off.³

NOTE: To end the S-ICD application, select the Quit button from the S-ICD main application screen (Figure 3 S-ICD Application start up screen with battery status icon on page 10). This returns the user to the Programmer main menu Figure 4 Model 3300 Programmer Main Menu on page 13.

NOTE: The Model 3300 Programmer can operate on battery or AC power. Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for instructions on charging the battery and operating only on battery power.

Using the Programmer Touch Screen

The Programmer is equipped with an LCD touch screen. All interaction with the programmer is conducted using the fingers to touch the appropriate areas on the screen. Scroll on-screen lists by sliding a finger up and down the list. An on-screen keyboard is presented whenever text entry is required.

NOTE: Use only fingers or a projected capacitance stylus on the Programmer touch screen.

3. End the S-ICD session before powering off the Programmer.

S-ICD Application Navigation

The application's graphical user interface (GUI) facilitates management and control of the S-ICD System. The Navigation Bar and on-screen icons at the top of the screen allow the user to navigate programming software screens. In addition, a continuous subcutaneous electrocardiogram (S-ECG) is displayed along the bottom of the screen during Online (active) communication with the pulse generator.

S-ICD Application Screen Header

When the S-ICD Application is Offline (inactive communication), the screen header displays the Programmer battery status indicator.

When viewing Offline Stored Sessions, the screen header displays:

- Patient name
- Therapy On/Off
- Programmer battery status indicator

When the S-ICD Application is Online (active communication), the screen header displays:

- Therapy On/Off
- Patient name
- Patient heart rate
- Programmer battery and telemetry status indicator
- Screen title
- Rescue shock icon

S-ICD Application Navigation Bar

The Navigation Bar is the primary method for navigating the Online application screens. The bar is located along the top edge of the application screen and chosen screens appear with their selection icon highlighted. The following table provides a list of the icons and their corresponding descriptions.

Table 1. Icon descriptions















Icon	Description	User Application
	S-ICD Application Main Menu Icon	Allows user to return to the main menu.
	Automatic Setup Icon	Allows user to access the Automatic Setup menu.
	Device Settings Icon	Allows user to access the S-ICD device settings screen.
	Device Status Icon (open folder and closed folder)	Allows user to access the S-ICD device status screen. User can view number of shocks delivered since the last update as well as the S-ICD device battery life.

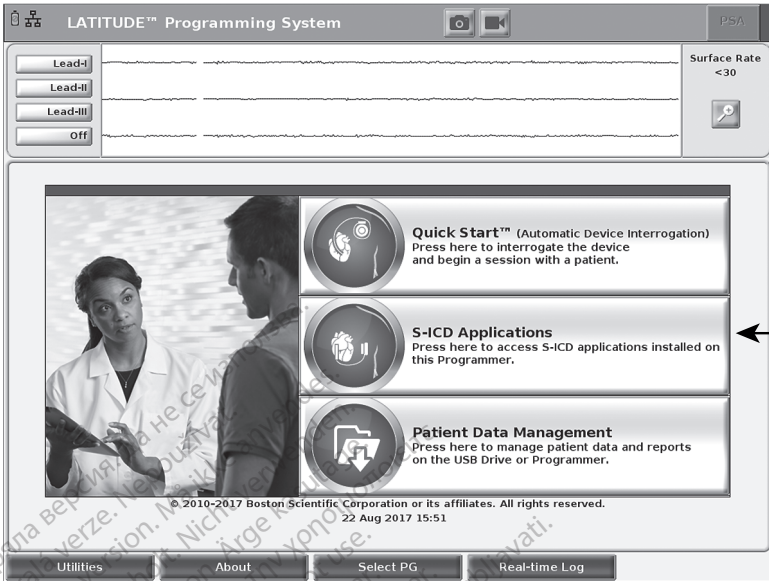
Table 1. Icon descriptions (continued)

Icon	Description	User Application
	Patient View Icon	Allows user to access the patient chart screen. User can view information on the S-ICD device battery life.
	Captured and Stored Episodes S-ECG Icon	Allows user to access captured S-ECG and stored episode screens.
	Induction Test Icon	Allows user to access induction screen.
	Manual Shock Icon	Allows user to access the manual shock screen.
	Battery & Telemetry Meter	Left side of the meter allows user to view the Programmer's battery status. The right side of the meter allows viewing of telemetry signal strength
	Capture S-ECG	Allows user to capture a live S-ECG.
	S-ECG Display Settings	Allows user to modify the zoom and sweep speed on the live S-ECG.
	Heart Rate Icon	Allows user to view current heart rate.
	Rescue Shock Icon	Allows user to administer a rescue shock.
	Option Selection Switch	Allows user to select one of two options, e.g. A or B.

Configuring the S-ICD Application

Starting the Model 3300 Programmer

Power on the Programmer to display the Main Menu



[1] S-ICD Applications button [2] Utilities button

Figure 4. Model 3300 Programmer Main Menu

Set the Language and Time Zone

Before starting the S-ICD Application, the language and time zone are set. These settings are persistent and do not need to be re-entered for subsequent S-ICD programming sessions or uses of the Model 3300 Programmer.

NOTE: The formats for the date (mm/dd/yyyy or dd/mm/yyyy) and the time (12 hour or 24 hour) are set in the S-ICD Application itself. See "Date and Time Format" on page 17.

1. Set the Language

- a. From the Model 3300 Programmer Main Menu, select the Utilities button in the lower left of the screen.
- b. Select the Setup tab.
- c. Select the language bar, then select the desired language, as illustrated in the following figure.

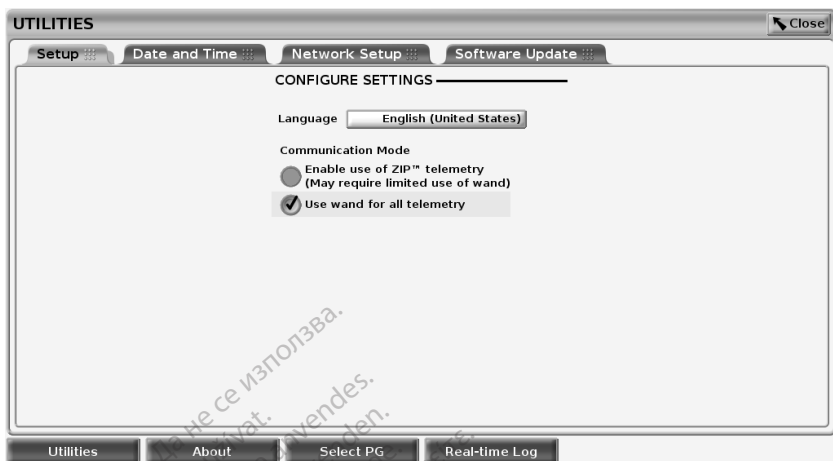


Figure 5. Utilities

2. Set the Time Zone

- From the Model 3300 Programmer Main Menu, select the Utilities button in the lower left of the screen.
- Select the Data and Time tab.
- Select the time zone bar, then select the desired time zone as illustrated in the following figure.

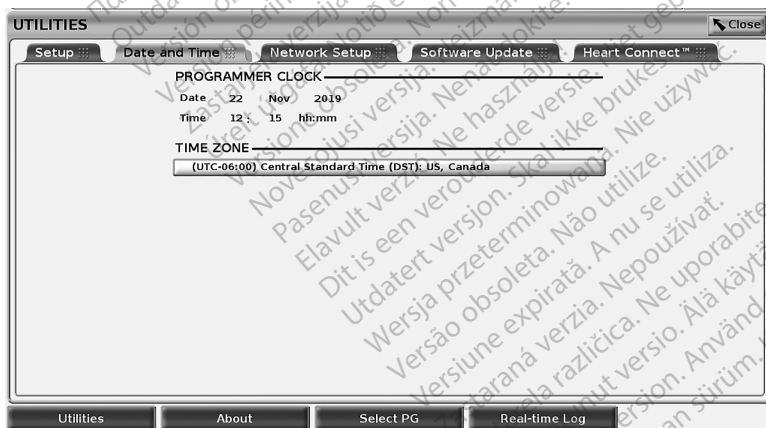


Figure 6. Utilities – Setup time zone

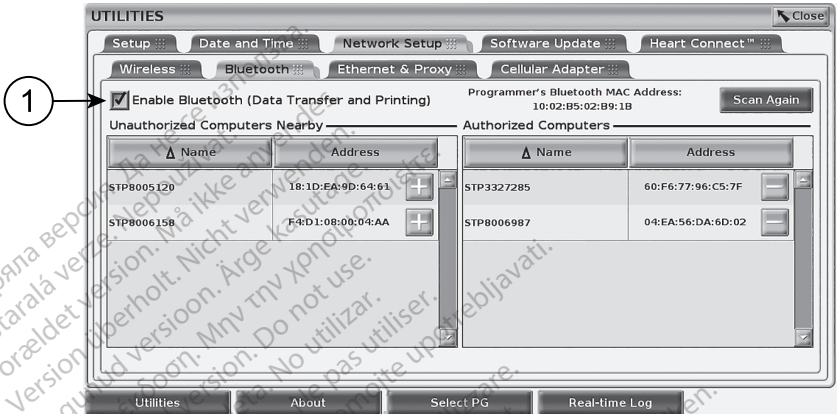
Enable Bluetooth® Communications

To use Bluetooth® communications for printing or exporting patient data, it must be enabled using the Utilities menu of the Model 3300 Programmer.

NOTE: Printers that are directly connected to the Programmer by a USB cable do not require Bluetooth® communications.

NOTE: Exporting patient data using Bluetooth® requires that Bluetooth® communications be enabled.

1. Select the Utilities tab from the main menu of the Programmer.
2. From the Utilities menu, select the Bluetooth® tab and then select the Enable Bluetooth check box as illustrated in Figure 7 Utilities menu - Enable Bluetooth® check box selected on page 15.



[1] Enable Bluetooth® checkbox selection

Figure 7. Utilities menu - Enable Bluetooth® check box selected

3. The Programmer begins a scan of Bluetooth® enabled computers⁴ within range and lists them in the Unauthorized Computers Nearby column.

These steps enable Bluetooth® communications and allow you to configure a Bluetooth printer and export patient data from within the S-ICD Application.

Refer to "Printer Selection" on page 19 to configure a Bluetooth® printer. Refer to "Bluetooth® Data Export" on page 21 to authorize a computer to receive exported patient data using Bluetooth®.

NOTE: Printers can be configured from either the Programmer Utilities tab or from the S-ICD Printer Setup screen.

Start the S-ICD Application

1. With the Model 3203 Telemetry Wand connected and the Model 3300 Programmer powered on, select the S-ICD Applications button from the main menu. See Figure 4 Model 3300 Programmer Main Menu on page 13.
2. When the S-ICD Applications panel displays, select the S-ICD Device Programmer Application icon.
4. The 3300 Programmer only recognizes Bluetooth® enabled computers and printers.

3. A Start Application dialogue displays while the application loads, then the EMBLEM™ S-ICD System start-up screen displays.

NOTE: It can take approximately 30 seconds for the S-ICD Application to load. During this time, the screen displays the Start Application message and hourglass icon followed by a large text display of Boston Scientific.

The following figure illustrates the startup sequence.

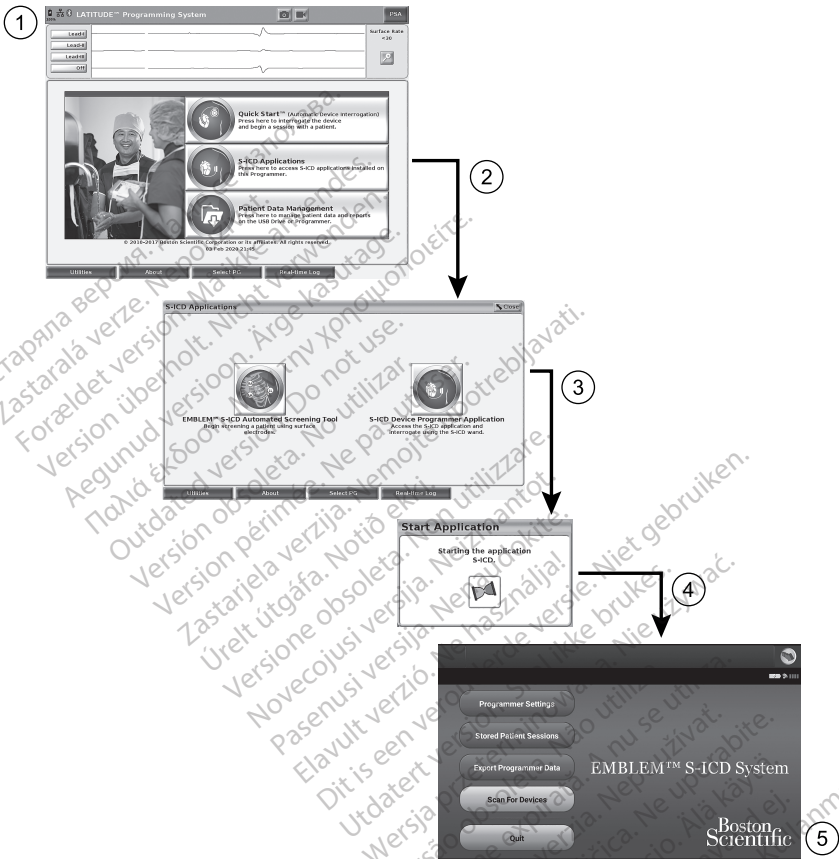


Figure 8. S-ICD Application startup sequence

To configure the S-ICD Application settings:

1. Select the Programmer Settings button on the EMBLEM S-ICD start-up screen (Figure 9 S-ICD programming application start-up screen on page 17) to display the Programmer Settings screen (Figure 10 S-ICD Programmer Settings screen on page 17).

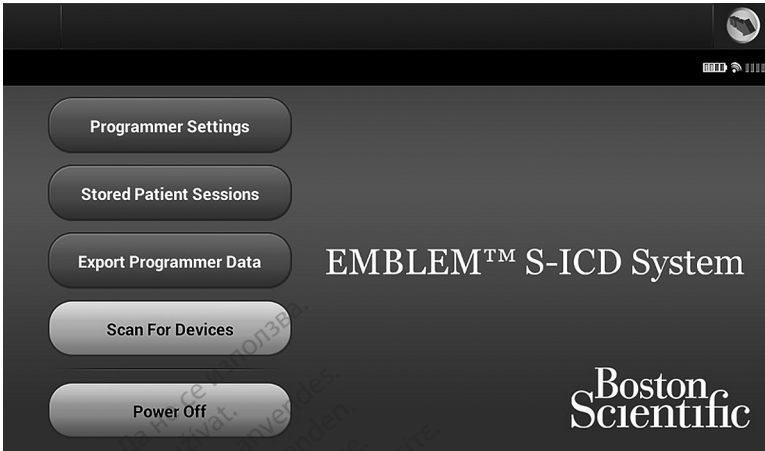


Figure 9. S-ICD programming application start-up screen

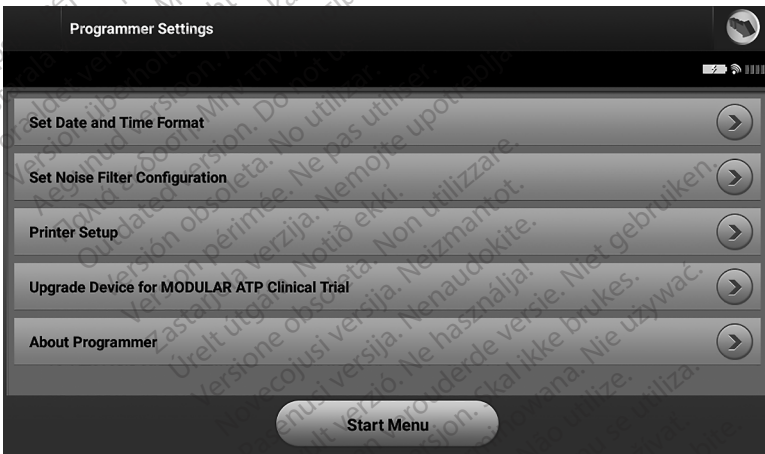


Figure 10. S-ICD Programmer Settings screen

2. Select the corresponding line to access each setting. The settings that can be configured include:
 - Date and Time format
 - Noise Filter Configuration
 - Printer Setup

Date and Time Format

NOTE: Before setting the date and time formats, ensure that the Time Zone has been set for the Programmer. See "Set the Language and Time Zone" on page 13.

To set the date and time format:

1. Select Set Date and Time Format on the Programmer Settings screen (Figure 11 Set Date and Time Format screen on page 18). The Date and Time Settings screen appears.
2. Select the desired time format (12 or 24 hour).⁵
3. Select the desired date format (mm/dd/yyyy or dd/mm/yyyy).
4. Select the Save button to save the changes and return to the Programmer Settings screen, or select Cancel to return to the Programmer Settings screen without saving the changes.

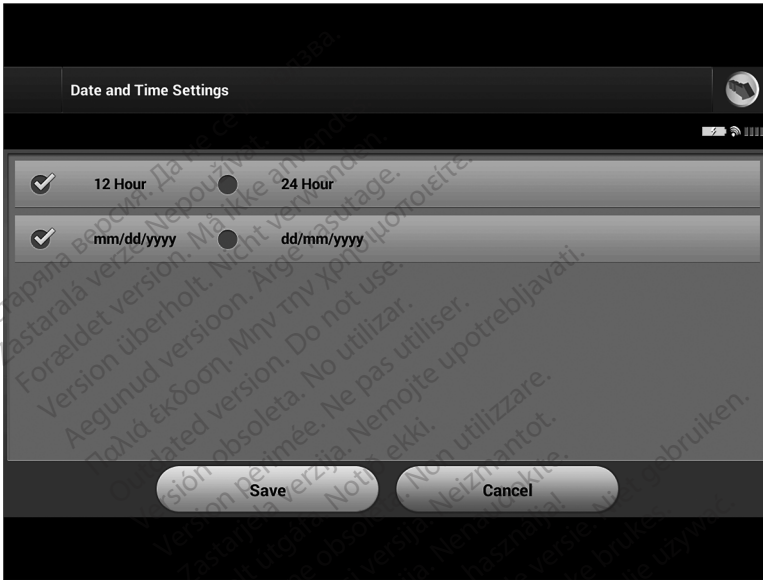


Figure 11. Set Date and Time Format screen

Set Noise Filter Configuration

The Noise Filter Configuration setting controls the electronic filter in the pulse generator that is intended to minimize electromagnetic interference (EMI). Specifically, the pulse generator line frequency filter is automatically programmed to either 50 Hz or 60 Hz, based on the Noise Filter setting.

The Noise Filter is factory set to match your country's electrical grid. So, do not change it unless you change countries.

NOTE: *Changing the Noise Filter Configuration setting on the Programmer will result in the 50/60 Hz line frequency filter being configured to the chosen setting (50 Hz or 60 Hz) in all subsequent pulse generators interrogated.*

To set the S-ICD application Noise Filter:

5. This only affects the S-ICD application date and time format. The Model 3300 Programmer date and time format is not affected.

1. Select Set Noise Filter Configuration on the S-ICD Programmer Settings screen (Figure 12 Set Noise Filter Configuration screen on page 19). to display the noise filter configuration screen.
2. Select either 50 Hz or 60 Hz.
3. Select the Save button to save the changes and return to the S-ICD Programmer Settings screen, or select Cancel to return to the Programmer Settings screen without saving the changes.

In the rare cases where there are regional power line frequency differences, choose the option with the correct frequency for the region where the Programmer is located. Be aware that travelling patients whose devices are interrogated in regions or countries other than the one in which they reside may need to have their Noise Filter reset upon returning home.

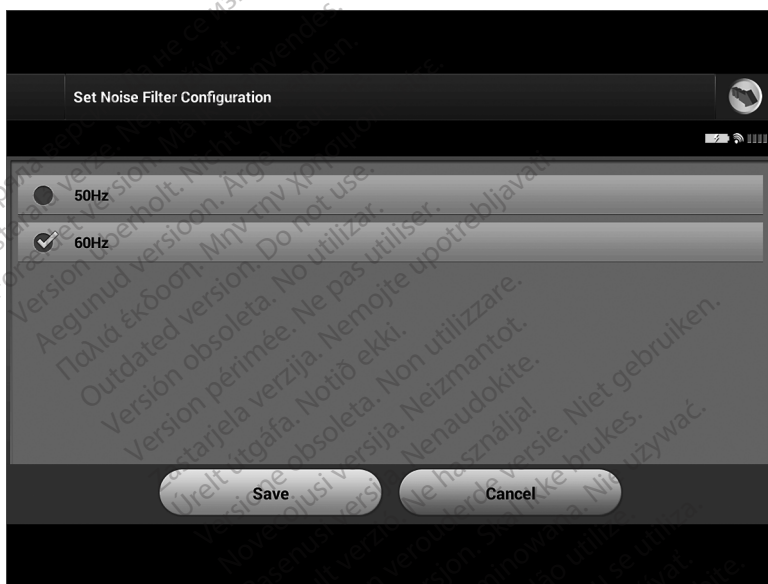


Figure 12. Set Noise Filter Configuration screen

Printer Selection

The Model 3300 Programmer provides USB and Bluetooth® support for printers.

1. Ensure the printer is on and, depending on your specific printer, connect it to the Programmer via USB cable or Bluetooth®.
 - For a USB printer, connect the printer to a USB port on the left side of the Programmer.
 - Bluetooth® communications must be enabled before selecting a Bluetooth® printer in the S-ICD application. See "Enable Bluetooth® Communications" on page 14 to enable Bluetooth® communications.
2. Select Printer Setup on the Programmer Settings screen. The Printer Setup screen (Figure 13 Printer Setup screen on page 20) displays with a USB printer whether one

is configured or not. If a default printer has already been selected and configured, the screen will display it. Select the Scan Again button and the Programmer scans the area to locate Bluetooth® printers. A Scan Progress Bar displays informing the user that the Programmer is currently scanning for printers.

Additionally, when the printer setup screen is loaded, all printers already paired will be displayed.

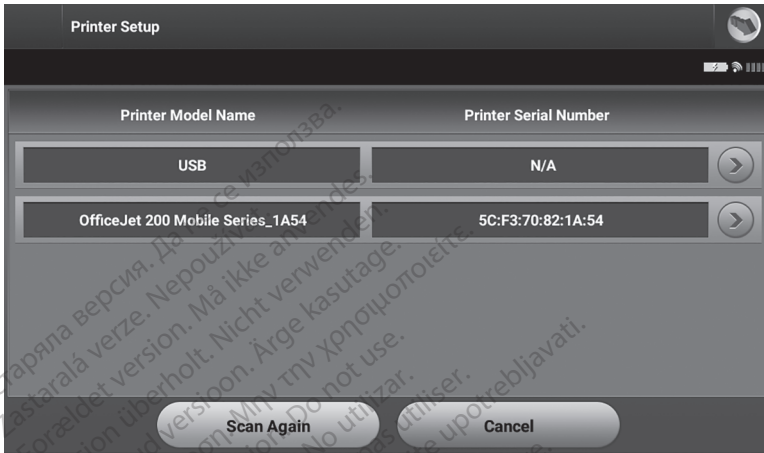


Figure 13. Printer Setup screen

3. Select the printer of choice from among those found during the scan. If none were found, a window displays stating that there are no printers. Select the Scan Again button or the Cancel button to return to the Programmer Settings screen.
4. Select the desired printer from the list and enter the name using the on-screen keyboard (up to 15 characters). A unique printer identifier should appear with the printer selection.
5. Select the Save button to save the changes and return to the Programmer Settings screen, or select Cancel to return to the Programmer Settings screen without saving the changes. A confirmation screen displays when the printer setup is completed.

NOTE: Refer to the "Troubleshooting" section of the Model 3300 Operator's Manual for information about printer problems.

Model 3877 S-ICD Application Software Version

To view the S-ICD Application's software version:

1. Select About Programmer on the Programmer Settings screen. The Programmer Software Version information screen appears.
2. The Programmer Software Version information screen displays the current version of the Programmer software. Select the Close button to return to the Programmer Settings screen.

NOTE: The printed reports also contain Programmer software version information.

Bluetooth® Data Export

The Programmer can be configured to wirelessly export patient data to desktop or notebook computers that are equipped with Bluetooth® wireless technology. The Programmer and each computer must be individually paired in order to use the wireless data export function. The procedure for pairing the Programmer with a computer is different from the procedure used to pair the Programmer with the printer.

NOTE: Data transfer is supported for computers running Windows. The data transfer feature is not available for tablets or smart phones.

NOTE: In Windows 10, the Bluetooth® "Receive a File" window must be open to transfer files to that PC.

1. Bluetooth® communications must be enabled in the Model 3300 Programmer before the S-ICD application can export patient data. See "Enable Bluetooth® Communications" on page 14 for instructions to enable Bluetooth® communications.
2. Ensure the computer to be paired has been made discoverable, since the Programmer searches for nearby computers during the pairing process.

NOTE: Detailed instructions for accomplishing this are found in the Microsoft Windows help files under the general heading of "Why can't I connect my Bluetooth device to my computer?"

3. Once the target computer has been made discoverable, select the Export Programmer Data button on the S-ICD application start-up screen. The Export Programmer Data Over Bluetooth screen will appear. Select the Set Up Authorized Computers button to scan for nearby computers and begin the pairing process.
4. While scanning, discovered computers display under the heading Unauthorized Computers Nearby as illustrated in Figure 14 Choosing a computer to authorize for Bluetooth® data transfer on page 22. Choose the computer you wish to pair with and press the plus button next to it to complete the pairing process. You can cancel any time after you see the PC you wish to pair.
5. During the pairing process, both the Programmer and the computer will present identical numeric passkeys and both machines will ask you to confirm that the two numbers are the same. The passkey is only presented while pairing and is used to verify that the correct machines are being paired.
6. Successful pairing is indicated when the listing for the subject computer appears in the Authorized Computers column instead of the Unauthorized Computers Nearby column.
7. Authorized computers may be renamed if desired. Press and hold the listing for the computer until the Rename an Authorized Computer popup appears.



Figure 14. Choosing a computer to authorize for Bluetooth® data transfer

Application Modes of Operation

Online Behavior

The application's interface varies according to whether the Programmer is Online (actively communicating) or Offline (not communicating) with a selected pulse generator.

An Online session begins when the Programmer establishes a telemetry link with a specific pulse generator. A yellow alert screen is displayed if the telemetry signal is lost between the Programmer and the pulse generator for more than five seconds during active communication. This may occur if the wand is moved out of the telemetry communications range or if noise or interfering objects inhibit communication. Programming commands, including Rescue Shocks, will not be available until telemetry is reestablished.

Telemetry reconnection may occur automatically if the reason for the telemetry loss has been remedied, e.g. moving the wand back into telemetry range of the pulse generator or removing the source of interference or noise. Restart the session if the telemetry link does not resume within one minute.

NOTE: *When in active communication with a pulse generator, the Programmer emits an audible notification to indicate that the pulse generator is preparing to deliver a shock, whether that shock is commanded or is in response to a detected arrhythmia. The notification continues until the shock is either delivered or aborted.*

Offline Behavior

The Programmer is Offline when it is not actively communicating with a pulse generator. Programmer settings can be accessed and stored patient sessions can be viewed and/or printed during Offline sessions.

Stored Patient Sessions

During a patient follow-up visit, the Programmer will retrieve data from the pulse generator memory. The Programmer can store up to 50 patient sessions or 90 days of patient session data. When the 51st session occurs, the Programmer will automatically

replace the oldest stored session with the new data. Additionally, when the 90th day passes after a patient session was stored, the Programmer will automatically delete that patient session when the S-ICD application is started. A stored session includes the following information:

- Captured S-ECG Reports (including Induction S-ECGs)
- Episode History (including any downloaded episodes)
- Patient Data
- Programmed Device Settings

To view stored patient sessions:

1. From the S-ICD application start-up screen, select Stored Patient Sessions.
2. Select the desired patient session.

Modes of Operation for the Pulse Generator

The pulse generator 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 a pulse generator in Shelf mode is interrogated by the Programmer, a full-energy capacitor reformation is performed and the pulse generator is prepared for set-up. When Shelf mode is exited, the S-ICD application defaults to Therapy Off mode. The pulse generator cannot be reprogrammed back into Shelf mode.

Therapy On Mode

The Therapy On mode is the primary operating mode of the pulse generator, allowing automatic detection of, and response to, ventricular tachyarrhythmias.

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. The subcutaneous electrogram (S-ECG) may be displayed or printed from this mode.

The pulse generator defaults to Therapy Off mode when it is 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 and is actively communicating with a pulse generator, but only after the initial Setup process is complete. Refer to "Automatic Setup" on page 30.

MRI Protection Mode

MRI Protection Mode is available in EMBLEM S-ICD devices.

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 S-ICD 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

NOTE: *The Beeper remains disabled until the user reprograms it On ("Beeper Control" on page 49).*

Monitor the patient continuously by pulse oximetry and electrocardiography (ECG) until scan is completed and for the entire duration in which the system is in MRI Protection Mode. External defibrillator and medical personnel must be present.

MRI Protection Mode is terminated by manual exit using the Programmer or through the user-programmed automatic MRI Protection Time-out period (refer to the S-ICD 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.

WARNING:



The LATITUDE Programming System 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 Practices⁶. Under no circumstances should the LATITUDE Programming System be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

WARNING:



The S-ICD pulse generator Beeper may no longer be usable following an MRI scan. Exposure to 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 (a remote patient management system) 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.

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

Connecting and Disconnecting from the S-ICD Pulse Generator

This section provides the information necessary for selecting, connecting to, and disconnecting from the pulse generator.

Scanning for Pulse Generators

1. Select the Scan For Devices button on the Programmer start-up screen (Figure 9 S-ICD programming application start-up screen on page 17). The Scan Progress Bar is displayed during the scanning process, at the conclusion of which the Device List screen appears. Select the Cancel button at any time to end the scanning process.
2. When the scanning process is complete, a list of all S-ICD pulse generators detected (up to 16) will be displayed on the Device List screen (Figure 15 Device List screen (scrollable list) on page 25). The devices that are in Shelf mode will be displayed as "NOT IMPLANTED". Any devices that were previously taken out of Shelf mode are displayed either as "IMPLANTED" or with the stored patient name.

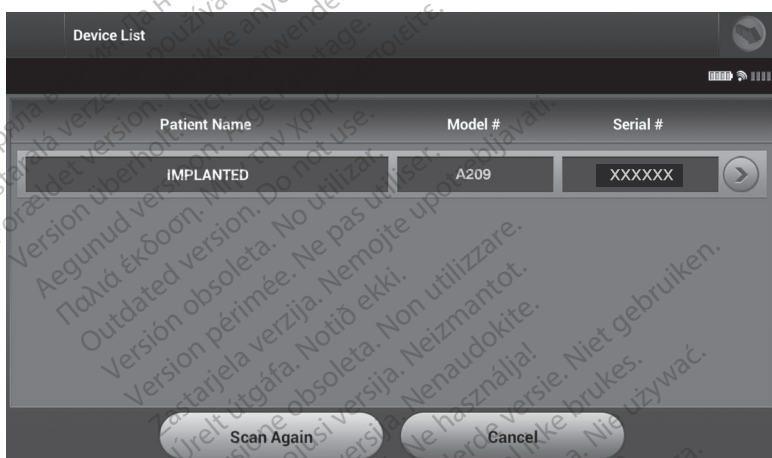


Figure 15. Device List screen (scrollable list)

3. If the desired pulse generator is not listed, select the Scan Again button to re-initiate the scanning process. Select the Cancel button to return to the S-ICD Programming application start-up screen.

If the Programmer is unable to communicate with the pulse generator, follow the steps below:

1. Ensure the Programmer is connected to AC power, which improves telemetry performance.
2. Attempt to reposition the wand.
3. Select Scan For Devices from the S-ICD Programming application start-up screen or select Scan Again from the Device List screen to locate the desired device.
4. Move any equipment and associated cables that may be interfering with RF communication.
5. If available, attempt to communicate using a different Programmer and/or wand.

6. Apply a pulse generator magnet to the pulse generator to elicit beeper tones.
Remove the magnet and re-attempt communication.

Connecting to a Pulse Generator

Select the desired pulse generator from the Device List screen (Figure 15 Device List screen (scrollable list) on page 25) to initiate the communication session.

NOTE: *Regardless of how many pulse generators are located by a scan, the user must select a specific pulse generator from the list in order to begin active communication.*

Connecting to a Pulse Generator in Shelf Mode

If a pulse generator in shelf mode is chosen from the Device List screen, the following connection sequence occurs:

1. The Programmer connects to the selected pulse generator after the selection is made. A window will appear indicating connection is in process.
2. The Device Identification screen displays once communication is established with the pulse generator.

NOTE: *The Device Identification screen is visible only while connecting to a pulse generator in Shelf mode.*

3. The device model and serial numbers are automatically acquired and displayed during the initial scanning process. Select Exit Shelf Mode to remove the device from Shelf mode and prepare for implantation, or select Cancel to return to the Device List screen.

NOTE: *When a pulse generator is taken out of shelf mode, it cannot be reprogrammed back into Shelf mode.*

NOTE: *Each time a pulse generator in shelf mode is interrogated, a full-energy capacitor reformation is performed.*

Connecting to an Implanted Pulse Generator

If an implanted pulse generator is chosen from the Device List screen, the following connection sequence occurs:


1. The Programmer connects to the selected pulse generator after the selection is made. A window will appear indicating connection is in process.

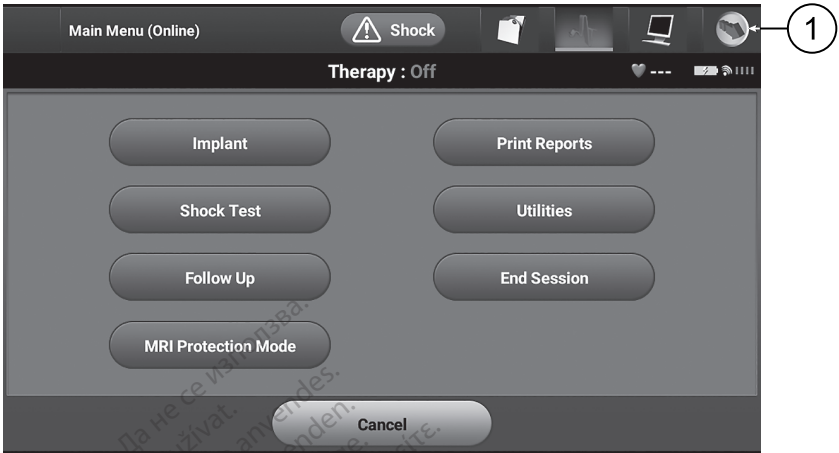
During the connection process, informational messages and warning messages may display, e.g. SMART Pass has been disabled.

2. The Device Status screen appears once communication is established with the pulse generator (Figure 25 Device Status screen on page 38).

Ending a Patient Session

To end an Online patient session and return the Programmer to its Offline operation mode:

1. Select the Main Menu icon  on the Navigation Bar. The Main Menu screen appears.
2. Select the End Session button.



[1] Return to Main Menu icon

Figure 16. S-ICD Online – Main Menu screen

3. Warning messages (Figure 17 Session Incomplete message examples on page 28) will be displayed to the user if any of the following conditions exists:

- Therapy mode is programmed to Off
- Reference S-ECG has not been acquired
- Automatic Setup or Manual Setup has not been completed
- Optimization has not been completed. This message is displayed if Automatic Setup Optimization was not performed during the Automatic Setup process
- SMART Pass is not enabled



Figure 17. Session Incomplete message examples

4. Select the Continue button to end the patient session and return to the Programmer start-up screen, or select Cancel to remain Online and return to the Main Menu screen.

NOTE: Once the Continue button is selected, the session is stored and communication is terminated.

NOTE: A telemetry session must be terminated using the End Session process as described in steps 1 through 4 above in order for data obtained during that session to be saved. If the Programmer is powered off during a session, session data will not be saved.

NOTE: In order to confirm that Therapy Mode is set to On upon disconnection, always use the End Session process and review all displayed warning messages.

Programming the Pulse Generator at Implant

This section provides the information necessary for programming the pulse generator during an implant.

CAUTION: Allow the pulse generator to reach an operating temperature range of 25° C - 45° C (77° F - 113° F) before using telemetry communication capabilities, programming, or implanting the pulse generator because temperature extremes may affect initial device function.

CAUTION: For S-ICD PG telemetry, use only the Model 3203 S-ICD Telemetry Wand with the LATITUDE Programming System.

CAUTION: The Model 3203 S-ICD Telemetry Wand is shipped non-sterile. Remove the wand from all packaging material before use. If the wand is to be used in a sterile field, it

must be enclosed in a sterile intraoperative probe cover (Model 3320) during use. Refer to the *LATITUDE™ Programming System Operator's Manual* (Model 3300) for cleaning information.

CAUTION: The Programmer is non-sterile and cannot be sterilized. It must remain outside the sterile field.

CAUTION: Confirm that the Programmer is in communication with the intended S-ICD pulse generator.

Entering Electrode Information

The Programmer maintains information on the implanted electrode. To record this information for a patient's new or replacement electrode:

1. With the Programmer connected to an S-ICD pulse generator, select the Main Menu icon.
2. Select the Implant button.
3. Select the Automatic Setup icon in the Navigation Bar. The Automatic Setup screen appears (Figure 21 Measuring electrode impedance on page 32).
4. Select Set Electrode ID button.

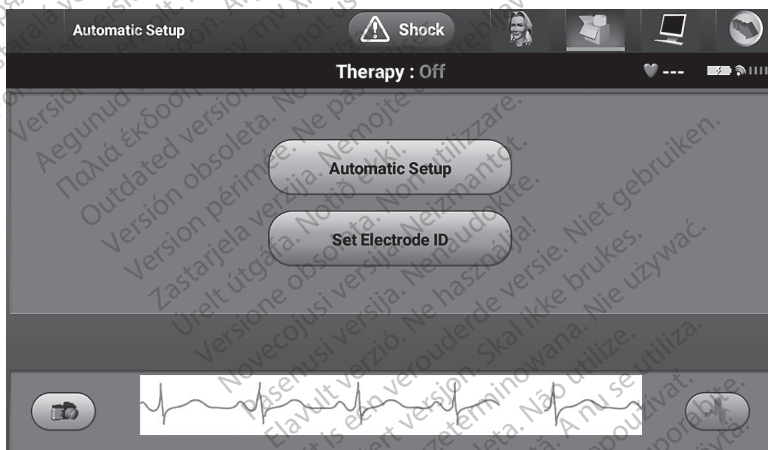


Figure 18. Select the Set Electrode ID button to enter electrode information

NOTE: ECG and heart rate information are not present on the Automatic Setup and Electrode ID setup screens until the electrode has been connected to the pulse generator.

5. Enter the electrode model and serial number.
6. Select the Program button to save the information. A confirmation screen will appear during communication with the device. Select Cancel to cancel information storage and return to the Automatic Setup screen.

Creating the Patient Chart

This chart contains reference information for the patient. To set up the patient chart:

1. Select the Main Menu icon on the Navigation Bar.
2. Select the Implant button.
3. Select the Patient View icon to access the Patient View screen (Figure 19 Patient View screen on page 30).
4. The pulse generator model and serial numbers appear on the first line of the chart. The electrode model and serial numbers appear on the second line of the chart. The implant date appears on the third line of the chart. Using the on-screen keyboard, enter the following patient information:
 - Patient Name: up to 25 characters
 - Doctor Name: up to 25 characters
 - Doctor Info: up to 25 characters
 - Notes: up to 100 characters



Figure 19. Patient View screen

NOTE: The Notes field will automatically wrap the text with the presence of a space between any characters within the first line.

5. Select the Save button to update the pulse generator with the patient information.

NOTE: Failure to save the new patient information will result in loss of the entered data.

Automatic Setup

Before the S-ICD device can be activated, it must go through an initial Automatic Setup process at the time of the implant.

The Automatic Setup process is initiated as follows:

1. Select the Main Menu icon.
2. Select the Implant button.

3. Select the Automatic Setup icon on the navigation bar. The Automatic Setup screen appears. Select the Automatic Setup button on this screen to advance to the next screen.
4. Select Continue if the patient's heart rate is less than 130 min^{-1} (Figure 20 Automatic Setup screen on page 31). For rates greater than 130 min^{-1} , select the Cancel button and refer to "Manual Setup" on page 50.

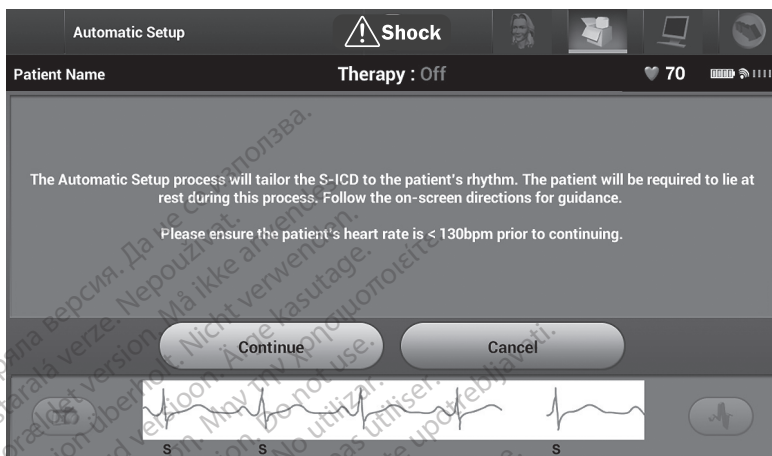


Figure 20. Automatic Setup screen

5. Once started the Automatic Setup will:
 - Perform the shock electrode integrity check to measure electrode impedance. Normal sub-threshold impedance range is $< 400 \text{ Ohms}$.
 - Select the best sensing configuration. SMART Pass will be automatically configured based on the amplitude of the ECG signals in the selected vector. The sense electrode configuration appears on the printed report and can be viewed via the Manual Setup process. The status of SMART Pass (On/Off) is displayed on the SMART Settings Programmer screen and Summary Report (for more information on SMART Charge and SMART Pass, see "SMART Settings" on page 51).
 - Select the appropriate gain setting. The selected sense gain appears on the Printed Report and can be viewed via the Manual Setup process.

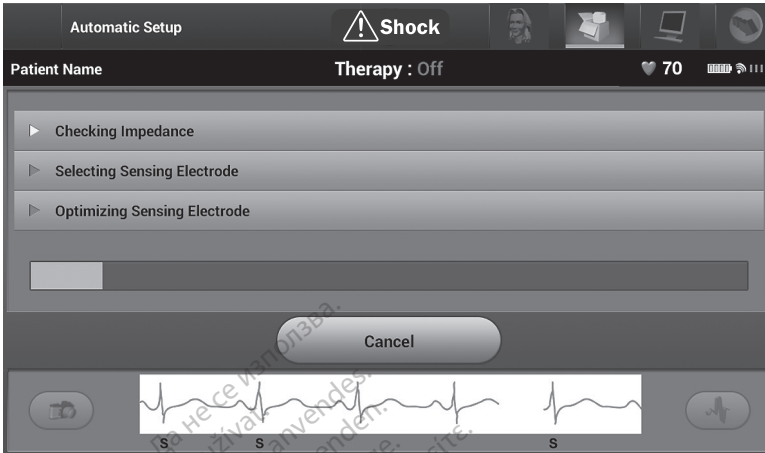


Figure 21. Measuring electrode impedance

The overall progress of the Automatic Setup process is shown in the status bar (Figure 21 Measuring electrode impedance on page 32). When each function is complete, the arrow next to the function moves to a down position.

6. The Automatic Setup optimization process will be initiated. The Programmer will display a message requesting that the patient sit up. If Automatic Setup is being performed during implant, or if the patient is unable to sit up for some other reason, this step can be omitted by selecting the Skip button. If desired, Automatic Setup can be repeated during a follow-up session to include the optimization step.
7. Select the Continue button to finish the Automatic Setup process. A confirmation screen will appear when Automatic Setup is complete.
8. Following the optional optimization process, the Acquire Reference S-ECG screen is displayed. Select the Continue button to acquire a reference S-ECG.

NOTE: When the Continue button is pressed, if a Reference S-ECG is currently stored in the pulse generator, it will be deleted and cannot be recovered.

9. Once the Reference S-ECG acquisition process begins, a status screen appears. The process may take up to one minute, during which the patient should remain still. During this process, a template of the patient's baseline QRS complex is stored in the pulse generator. Select Cancel at any time to end Reference S-ECG acquisition. When acquisition is complete, select the Continue button.

Programming Therapy Parameters

Once Automatic Setup has been completed, the pulse generator therapy parameters may be selected.

To set the therapy parameters:

1. Select the Main Menu icon on the Navigation Bar.
2. Select the Implant button.
3. Select the Device Settings icon on the Navigation Bar to display the Device Settings screen (Figure 22 Device Settings screen on page 33).

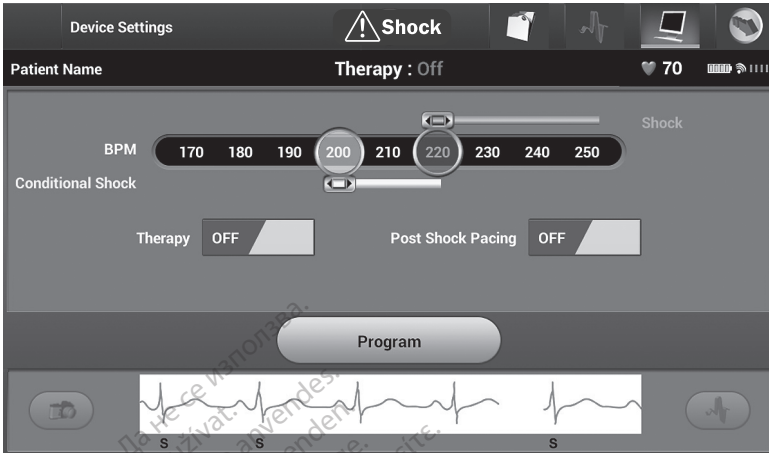


Figure 22. Device Settings screen

4. Select the desired therapy mode using the On/Off Therapy toggle button.
5. Select and drag the Conditional Shock Zone (yellow) and Shock Zone (red) slider bars to set the desired zone configuration.

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.⁷

- The Shock Zone is programmable between 170 and 250 min^{-1} in steps of 10 min^{-1}
 - The Conditional Shock Zone is programmable between 170 and 240 min^{-1} in steps of 10 min^{-1} . Enhanced detection criteria are automatically enabled when the Conditional Shock Zone is programmed.
 - When programming both the Shock Zone and Conditional Shock Zone, maintain at least a 10 min^{-1} difference between the two zones. If the Conditional Shock Zone slider (yellow) is dragged over the Shock Zone slider (red), the two sliders will merge to create a single Shock Zone.
6. If post-shock pacing is desired, set the Post Shock Pacing toggle button to the ON position. (Post-shock bradycardia pacing occurs at a non-programmable rate of 50 min^{-1} for up to 30 seconds. Pacing is inhibited if the intrinsic rate is greater than 50 min^{-1} .)
 7. Select the Program button to apply the changes and program the pulse generator. A message confirming that the pulse generator settings were successfully programmed will appear. Select the Continue button to return to the Device Settings screen.
 8. If the pulse generator does not accept the programming, a message with instructions will appear on the Device Settings screen. Press the Continue button after following the instructions.

7. 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.

9. Once programming is confirmed, select the Continue button to proceed to the next operation.

NOTE: *The Pending Program Changes screen will appear if changes made to pulse generator settings on the Device Settings screen were not successfully applied to the pulse generator. Select Cancel to return to the Device Settings screen and save all settings changes, or Continue to abandon all pulse generator setting changes.*

Defibrillation Testing

Once the pulse generator is implanted and Therapy Mode is programmed On, defibrillation testing may be conducted. 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 with S-ICD pulse generators, 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.

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.

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.

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.*

NOTE: *When the Hold to Induce button is pressed during defibrillation testing, the Programmer begins capturing the episode data generated during the test. This data*

is available for viewing and printing (see "Capture and View S-ECG Strips" on page 46 and "Captured S-ECG Report" on page 41.)

To induce VF and test the S-ICD System:

1. Select the Main Menu icon on the Navigation Bar to access the Main Menu.
2. Select the Shock Test button to set up the induction test (Figure 23 Setting the desired first shock energy for defibrillation testing on page 35).
3. Select either standard (STD) or reverse (REV) polarity.
4. Select and drag the red marker to set the desired shock energy for the first delivered shock. The shock energy may be programmed from 10 to 80 J. A 15 J safety margin is recommended for defibrillation testing.

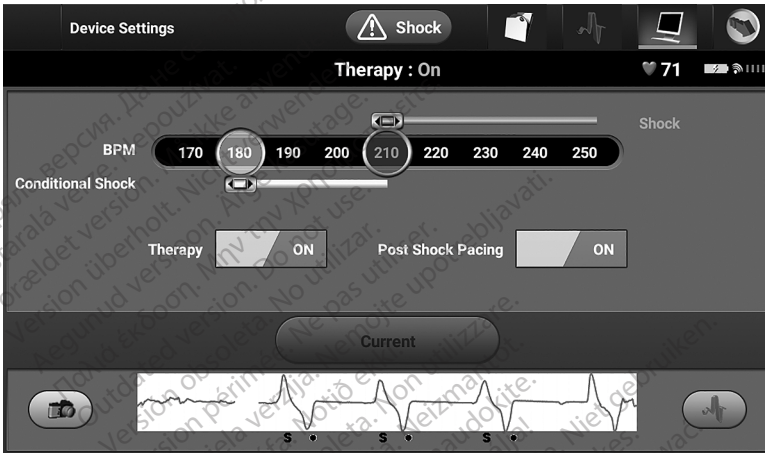


Figure 23. Setting the desired first shock energy for defibrillation testing

5. Select the Continue button to display the next Induction Test screen or select the Cancel button to return to the Main Menu screen.

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.

6. On the Induction Test screen, select the check box to enable the Hold to Induce button.

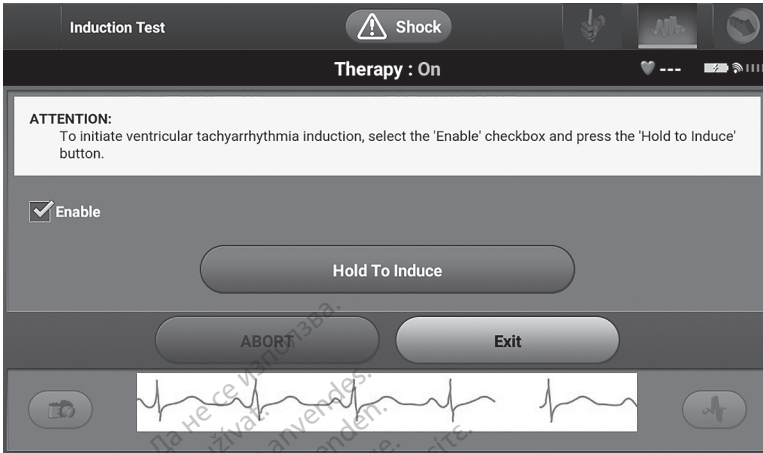


Figure 24. Induction Test – Hold to Induce screen

7. Select and hold the Hold To Induce button for the desired duration.

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 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: When in active communication with a pulse generator, the Programmer emits an audible notification to indicate that the pulse generator is preparing to deliver a shock, whether that shock is commanded or is in response to a detected arrhythmia. The notification continues until the shock is either 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: Evaluate the sensing markers during the induced rhythm that follows the release of the Hold To Induce button. 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.

NOTE: The pulse generator can deliver a maximum of five shocks per episode. An 80 J rescue shock can be delivered at any time prior to therapy delivery by pressing the Rescue Shock icon.

- The Programmer will start capturing S-ECG data when the Hold to Induce button is pressed. The Captured S-ECG will cover the time period six seconds before the button is pressed and up to 102 seconds afterwards, for a maximum total of 108 seconds. The Induction S-ECGs will be viewable and printable from the Captured S-ECG screen, labeled as "Induction S-ECG".
8. At any time prior to therapy delivery, the programmed energy may be aborted by selecting the red ABORT button.
 9. Select the Exit button to return to the Main Menu screen.

Performing a Follow-up

Sensing Configuration and Automatic Setup

It is not necessary to perform Automatic Setup at each follow-up. If Sensing Optimization was skipped during the original implant setup, it may be performed during a follow-up.

Sensing should be re-evaluated if Automatic Setup is performed and results in a vector change or if the S-ECG signal quality indicates any progressive or sudden changes in sensing amplitude or morphology since implant or last follow-up exam which could impact the device's performance. After the setup process is complete, evaluate the streaming S-ECG during a pectoral exercise. Sensing performance while bending at the waist or during high-rate exercises can also be evaluated. Acceptable sensing will yield "S" markers synchronous to all QRS complexes. If other markers are noted, use the Manual Setup process to evaluate other sensing configurations.

WARNING:



The S-ICD System may sense myopotentials which may result in over/under sensing.

WARNING:



Following any sensing parameter adjustment or any modification of the subcutaneous electrode, always verify appropriate sensing.

NOTE: If Manual Setup was previously used to override a sensing configuration, careful consideration should be taken when selecting Automatic Setup.

If an update to the reference S-ECG is desired due to a change in the patient's resting ECG, follow the Acquire Reference S-ECG instructions.

Viewing Pulse Generator Status

Once communication is established, the Programmer displays the Device Status screen which contains information regarding the current episodes and battery status of the pulse generator.

To navigate to this screen from another location:

1. Select the Main Menu icon.
2. Select the Follow Up button.

3. Select the Device Status icon on the Navigation Bar to display the Device Status screen.
4. The Device Status screen will appear showing an overview of all pulse generator activity since the last communication session (Figure 25 Device Status screen on page 38).

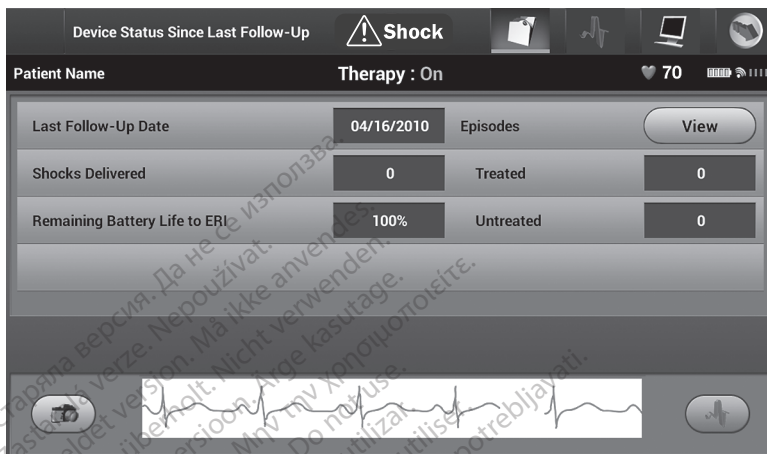


Figure 25. Device Status screen

The Device Status overview reports:

- Date of the last follow-up session
 - Total number of shocks delivered since the last follow-up session
 - Total number of treated episodes since the last follow-up session
 - Total number of untreated episodes since the last follow-up session
 - Total number of Stored AF episodes since the last follow-up session that are available for review (Model A219 only)
- NOTE:** Choosing the "View" button in the Episodes row allows navigation directly to the list of stored episodes (Figure 26 Episodes screen (scrollable list) on page 39).
- Remaining pulse generator battery life

Viewing Stored Episodes

The pulse generator stores episodes, which can be viewed during a patient's follow-up session. EMBLEM S-ICD (Model A209) and Cameron Health (Model 1010) pulse generators store up to 25 treated and 20 untreated tachycardia episodes. EMBLEM MRI S-ICD (Model A219) pulse generators store S-ECGs for up to 20 treated and 15 untreated tachycardia episodes, as well as up to 7 AF episodes. When the maximum number of episodes is reached, the most recent episode replaces the oldest stored episode of the same type. The first treated episode is never overwritten.

NOTE: Spontaneous episodes that occur while the pulse generator is communicating with the Programmer will not be stored.

To view stored episodes:

1. Select the Main Menu icon.
2. Select the Follow Up button.
3. Select the Captured and Stored Episodes S-ECG icon from the Navigation Bar.
4. Select the Episodes option to access the Episodes screen (Figure 26 Episodes screen (scrollable list) on page 39).
5. Select an episode from the list. The selected episode will be downloaded from the pulse generator and displayed.

NOTE: In order to be available for printing, episodes must first be individually selected and viewed from the Episodes screen.

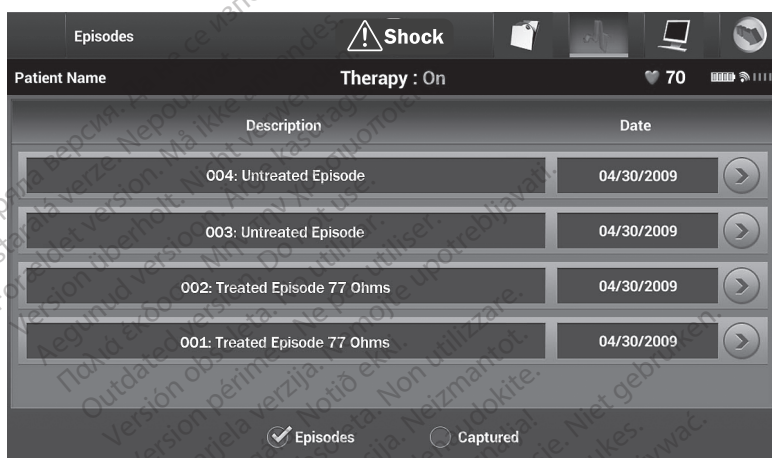


Figure 26. Episodes screen (scrollable list)

6. The display screen for each selected episode also displays the programmed parameters and the stored S-ECG data at the time of episode declaration.
7. Select the Continue button on the display screen for the selected episode to return to the Episodes screen.

The following details are available for each episode:

Treated Episodes

Up to 128 seconds of S-ECG data is stored for each Treated Episode:

- **Pre-episode S-ECG:** Up to 44 seconds
- **First shock:** Up to 24 seconds of pre-shock S-ECG and up to 12 seconds of post-shock S-ECG
- **Subsequent shocks:** 6 seconds of pre-shock and 6 seconds post-shock S-ECG

Untreated Episodes

An Untreated Episode is defined as any high-rate episode that spontaneously terminates during the charging process, before a shock is delivered.

Up to 128 seconds of S-ECG data is stored for each Untreated Episode:

- **Pre-episode S-ECG:** 44 seconds of pre-episode S-ECG
- **Episode S-ECG:** Up to 84 seconds of tachycardia S-ECG data

Printing Reports from the S-ICD Application

Printing Reports

Patient reports can be printed before or after a patient session is ended. It is recommended that a final report be printed immediately following the implant procedure. There are three patient reports:

- Summary Report
- Captured S-ECG Report
- Episode Reports

To print patient reports from either an Online or Offline session:

1. Select the S-ICD Main Menu icon to display the Main Menu screen.
2. Select the Print Reports button to display the Print Reports screen (Figure 27 Print Reports screen on page 40).

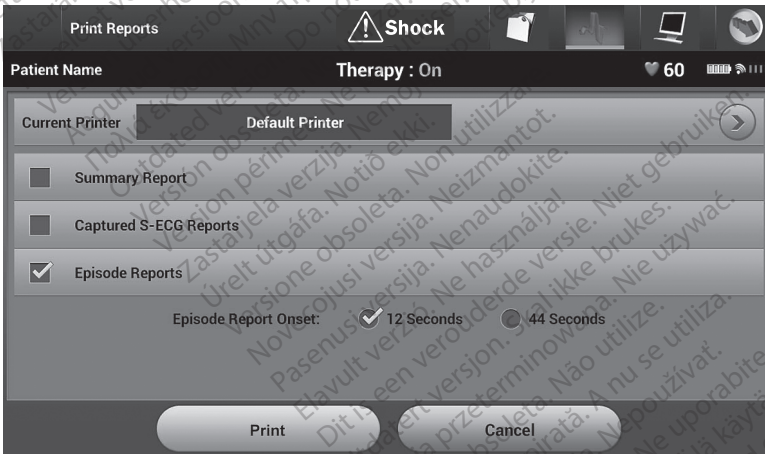


Figure 27. Print Reports screen

3. Select the desired report type. A checkmark will appear next to the selected report. Report types are described below.
4. Select the Print button to print the selected report.
5. Select the Cancel button to return to the previously accessed screen.

Summary Report

To print a summary report, select the Summary Report option on the Print Reports screen and press the Print button. The report will print for either the current active session (if the Programmer is Online) or for the chosen stored session (if the Programmer is Offline.)

The Summary Report includes the following information:

- Printed Report Date
- Programmer Software Version
- Pulse generator Software Version
- Patient Name
- Date of Last Follow-Up
- Date of Current Follow-Up
- Implant Date
- Pulse generator Model/Serial Number
- Electrode Model/Serial Number
- Therapy Parameters
- SMART Charge Delay
- SMART Pass status (On/Off) [Models A209 and A219 only]
- Programmed Gain Settings and Sensing Configuration
- Pulse generator Integrity Check, if applicable
- Initial Shock Polarity Configuration
- Days with measured AF [Model A219 only]
- Estimate of measured AF [Model A219 only]
- Beeper Status (if disabled)
- MRI Information
- Episode Summary: Since Last Follow-Up and Since Initial Implant
- Pulse generator Battery Status
- Electrode Impedance Measurement
- System alerts, if applicable

Captured S-ECG Report

To print a Captured S-ECG Report:

1. Select the Captured S-ECG Reports option from the Print Reports screen.
2. A scrollable list containing both Captured S-ECG and Induction S-ECG strips is displayed (Figure 28 Captured S-ECG list (scrollable) on page 42). Select the desired S-ECG(s) to be printed by placing a checkmark next to the selection(s).

Select Captured S-ECG Reports		Shock	
Patient Name		Therapy : On	
Description		Time	
<input checked="" type="checkbox"/>	Induction S-ECG: Secondary / 2X	03:59:39 PM	
<input checked="" type="checkbox"/>	Captured S-ECG: Primary / 1X	03:57:23 PM	
<input type="checkbox"/>	Induction S-ECG: Primary / 1X	03:56:47 PM	
<input type="checkbox"/>	Induction S-ECG: Primary / 1X	03:54:32 PM	
<input type="checkbox"/>	Captured S-ECG: Secondary / 1X	03:52:15 PM	
Continue			

Figure 28. Captured S-ECG list (scrollable)

3. Select Continue to return to the Print Reports screen.
4. Select the Print button to print the selected report and return to the previously accessed screen.
5. Select the Cancel button to return to the previously accessed screen without printing the report.

Episode Reports

To print an Episode Report:

1. Select the Episode Reports option on the Print Reports screen.
2. The Select Episode Reports screen appears showing a list of the stored episodes (Figure 29 Select Episode Reports screen (scrollable) on page 43). Select the episode (s) to be printed. A checkmark appears next to the selected episode(s).

NOTE: In order to be available for printing, episodes must have been individually selected and viewed from the Episodes Screen (Figure 26 Episodes screen (scrollable list) on page 39).

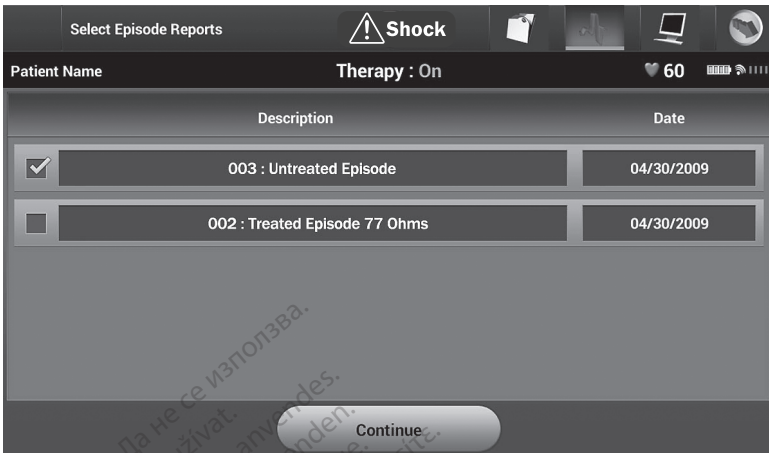


Figure 29. Select Episode Reports screen (scrollable)

3. Select Continue to return to the Print Reports screen. Either 12 seconds or 44 seconds of pre-episode S-ECG data may be selected using the radio buttons below the Episode Reports row. The default value for Episode Report Onset is 12 seconds.
4. Select the Print button to print the selected report and return to the previously accessed screen.
5. Select the Cancel button to return to the previously accessed screen without printing the report.

Export Patient Data

Patient data saved in the S-ICD application may be exported to a desktop or laptop computer using a pre-configured Bluetooth® pairing. For information about Bluetooth® pairing between the S-ICD application and a desktop or laptop computer, see "Bluetooth® Data Export" on page 21.

Before configuring Bluetooth® capable printers and computers, Bluetooth® connectivity must be turned on using the Utilities function of the Programmer. Refer to the LATITUDE Programming System, *Network and Connectivity Operator's Manual* (Model 3924) for complete instructions.

Ensure that the Programmer and the intended recipient computer are within 10 meters (33 feet) of each other before attempting a Bluetooth® wireless data transfer.

1. Select the Export Programmer Data button on the S-ICD application start-up screen. The Export Programmer Data Over Bluetooth® screen will appear.
2. Select one of the three export options (Export Today's Data, Export Last Seven Days, Export All). The "Select a receiving computer" pop-up window will appear.

NOTE: *The Export Today's Data and Export Last Seven Days options typically take less time to complete than the Export All option.*

3. The pop-up contains a scrollable list of all computers paired to the Programmer. Select the intended receiving computer from the list to begin the transfer.

NOTE: Although every paired computer is listed in the scrollable box, only those within 10 meters (33 feet) of the Programmer can participate in a file transfer. Once one of the three export options has been selected, the S-ICD application prepares the file transfer package and attempts the wireless transfer. An error message appears if the transfer cannot be completed. Should this occur, move the Programmer to within 10 meters of the intended receiving computer or choose another computer within that distance. Restart the export process by selecting one of the three export options on the Export Programmer Data Over Bluetooth screen.

S-ECG Features

The Programmer provides the capability to view, adjust, and capture the streaming S-ECG from the pulse generator.

S-ECG Rhythm Strip Markers, Indicators, and Discontinuities



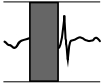
The system provides annotations to identify specific events on the S-ECG. These markers, indicators, and discontinuities are described in the following tables:

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

Description	Marker
Charging ^a	C
ATP (clinical devices only)	A
Sensed Beat	S
Noisy Beat	N
Paced Beat	P
Tachy Detection	T
Discard Beat	•
Return to NSR ^a	

a. Marker is present on printed report but not on the Programmer display screen.

Table 3. S-ECG Indicators and Discontinuities on Programmer Display Screens and Printed Reports

Description	Indicator / Discontinuity
ATP discontinuity (clinical devices only)	
Shock discontinuity	
Episode data compressed or not available (display only)	

S-ECG Scale Settings

To adjust the real-time S-ECG amplitude and display speed scale settings:

1. Select the S-ECG Display Settings icon located to the right of the Live S-ECG window. The S-ECG Settings screen is displayed.
2. Select and drag the Gain or Sweep Speed Scale bars as desired (Figure 30 Adjusting Gain and Sweep Speed on page 46). The S-ECG scale will change according to the selected setting. The gain setting controls the visual gain. The Programmer defaults to Full Range for pulse generators with a gain setting of 1x and to 1/2 Range for pulse generators with a gain setting of 2x. The Sweep Speed slider controls the display speed of the scrolling Live S-ECG. The nominal sweep speed setting is 25 mm/sec.

NOTE: Amplitude settings and display speed adjustments on scrolling real-time S-ECG and Captured S-ECGs affect the display screen settings only and have no impact on the pulse generator settings for sensing.

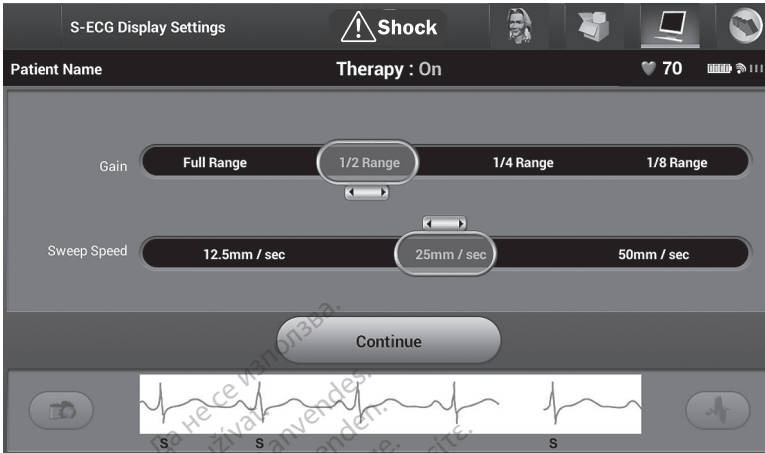


Figure 30. Adjusting Gain and Sweep Speed

Capture and View S-ECG Strips

The Programmer can display and store real-time S-ECG rhythm strips. The Programmer saves a maximum of 50 recordings generated by:

1. Manually-captured twelve-second S-ECGs using the Capture S-ECG button which include:
 - 8.5 seconds before activation of the Capture S-ECG button
 - 3.5 seconds after activation of the Capture S-ECG button
2. S-ECGs captured automatically during induction testing which include:
 - 6 seconds before the induce button is pressed
 - up to 102 seconds after the induce button is pressed

NOTE: The S-ICD suspends detection of sensed events for 1.6 seconds after a shock has been delivered. As a result, the S-ECG rhythm strip will not contain event markers during this 1.6 second post-shock interval.

If an additional recording is required, then the oldest previous recording is replaced with the new recording.

Manually Capture New S-ECG Rhythm Strips

To manually capture a new S-ECG rhythm strip:

1. Select the Capture S-ECG button located to the left of the Live S-ECG window. The S-ECG will scroll across the display screen. Calipers appear below the Captured S-ECG rhythm strip. Each 12-second recording is date and time stamped according to the Programmer's date and time setting.

NOTE: Induction S-ECGs are automatically generated during induction testing without additional user input.

2. Select and move the calipers across the S-ECG strip to measure intervals as desired.
3. Select the Continue button to return to the previously accessed screen.

It is also possible to capture S-ECGs corresponding to all three sense vectors (Primary, Secondary, and Alternate) by using the Capture All Sense Vectors button on the Utilities screen (Figure 31 Utilities screen on page 48).

View previously-captured S-ECGs

When the Programmer is online:

1. Select the Main Menu icon.
2. Select the Follow Up button.
3. Select the Captured and Stored Episode S-ECG icon. The Captured S-ECG screen appears.
4. Select one Captured S-ECG or Induction S-ECG from the list. The S-ECG details screen appears.
5. Select and drag the calipers to view details.
6. Select the Continue button to return to the Captured S-ECG list screen.

When the Programmer is offline:

1. Select the Stored Patient Sessions button from either the Programmer start-up screen or the Main Menu.
2. Select the desired stored patient session.
3. Select one Captured S-ECG from the list. The Captured S-ECG Details screen appears.

NOTE: *Not all stored patient sessions contain captured S-ECGs. A message to that effect is presented when such patient sessions are opened. In this event select the Main Menu icon, then select the End Session button. This action returns you to the Programmer start-up screen.*

4. Select and drag the calipers to view details.
5. Select the Continue button to return to the Captured S-ECG list screen.

Utilities Screen

The S-ICD application Utilities screen provides access to additional device features. These may include Acquire Reference S-ECG, Capture All Sense Vectors, Beeper Control, Manual Setup, SMART Settings, and AF Monitor.

To access the Utilities screen during an Online session:

1. Select the Main Menu icon to display the Main Menu screen.
2. Select the Utilities button. The Utilities screen appears as illustrated in the following figure.

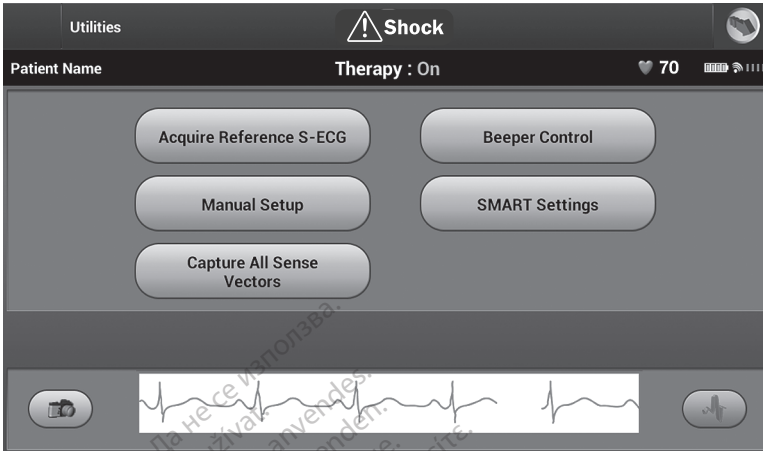


Figure 31. Utilities screen

Acquire Reference S-ECG

To acquire a manual Reference S-ECG:

1. From the Utilities screen (accessible from the Main Menu screen), select the Acquire Reference S-ECG button to access the Acquire Reference S-ECG screen.
2. Select Continue to acquire a Reference S-ECG. The S-ICD application will begin acquiring the Reference S-ECG. A message will appear requesting that the patient remain still. The reference S-ECG QRS template is recorded and stored in the pulse generator.

NOTE: When the Continue button is pressed, if a Reference S-ECG is currently stored in the pulse generator, it will be deleted and cannot be recovered.

3. Select the Continue button to complete the process and return to the Utilities screen. The Cancel button can be used at any time to end S-ECG acquisition and return to the Utilities screen.

Capture All Sense Vectors

The Capture All Sense Vectors button on the Utilities screen configures temporary settings that allow you to capture S-ECGs generated from each of the three sense vectors (Primary, Secondary, and Alternate). This process takes approximately one minute. The original settings configuration is returned after all S-ECGs have been captured.

To capture the three sense vectors:

1. From the Utilities screen (accessible from the Main Menu screen), select the Capture All Sense Vectors button.
2. The Capturing 12 Second S-ECG screen will appear and display the status of the sense vector capture process.

Once captured, the three S-ECGs can be viewed by following the steps outlined in "View previously-captured S-ECGs" on page 47.

Beeper Control

The pulse generator 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 may include:

- 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 whenever they hear tones coming from their S-ICD device.

NOTE: Access to the Reset Beeper display screen is enabled only when an alert condition occurs. If an alert condition is activated, a notification screen will appear upon connection.

WARNING:



The S-ICD pulse generator Beeper may no longer be usable following an MRI scan.

Exposure to 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 (a remote patient management system) 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.

Reset Beeper

To reset the Beeper, select the Beeper Control button from the Utilities screen (accessible from the Main Menu) to open the Set Beeper Function screen.

Select the Reset Beeper button to suspend audible beeping tones triggered by an alert condition. If the alert condition is not corrected, the audible beeping tones will be reactivated during the next automatic S-ICD System self-check.

Disable Beeper (SQ-Rx devices)

In SQ-Rx devices, Beeper Control allows for the deactivation of beeping on alert conditions (Disable Beeper). Perform the following steps to disable the Beeper:

NOTE: The Disable Beeper function is only available once device ERI or EOL is reached.

1. From the Utilities screen, select Beeper Control to open the Set Beeper Function screen.
2. Select Disable Beeper to disable the Beeper for the device.

NOTE: This will permanently disable all beeping on alert conditions for the SQ-Rx device. However, this will not affect Beeper functionality for when a magnet is placed on the device or when the S-ICD Device Programmer Application connects to the device.

Enable/Disable Beeper (EMBLEM S-ICD devices)

In EMBLEM S-ICD devices, the Beeper must be tested before being enabled or disabled. Perform the following steps to test the Beeper:

NOTE: For EMBLEM S-ICD devices, the Test Beeper function is available only when beeping for an alert condition is not active.

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 using a stethoscope.
4. If the Beeper is audible, select the Yes, Enable Beeper button. If the Beeper is not audible or you wish to permanently disable beeping functionality, select the No, Disable Beeper button.

NOTE: This will disable beeping functionality for alert conditions, for when a magnet is placed over the device, and for when the S-ICD application connects to the device.

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

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

Manual Setup

Manual Setup enables the user to perform the electrode integrity test and select the electrode sensing configuration and gain setting in the pulse generator. During Manual Setup, the system will also automatically enable SMART Pass if appropriate.

1. From the Utilities screen (accessible from the Main Menu screen), select the Manual Setup button. The Measure Impedance screen appears.
2. Select the Test button to perform the electrode integrity test.
3. Select the Continue button.
4. There are three available sensing vectors that can be manually selected from the Manual Setup screen (Figure 32 Manual Setup screen with sensing vector and gain options on page 51).
 - **Primary:** Sensing from the proximal electrode ring on the subcutaneous electrode to the surface of the active pulse generator
 - **Secondary:** Sensing from the distal sensing electrode ring on the subcutaneous electrode to the surface of the active pulse generator
 - **Alternate:** Sensing from the distal sensing electrode ring to the proximal sensing electrode ring on the subcutaneous electrode

The gain setting adjusts the sensed S-ECG signal sensitivity. It may be manually selected with the Select Gain switch on the Manual Setup screen.

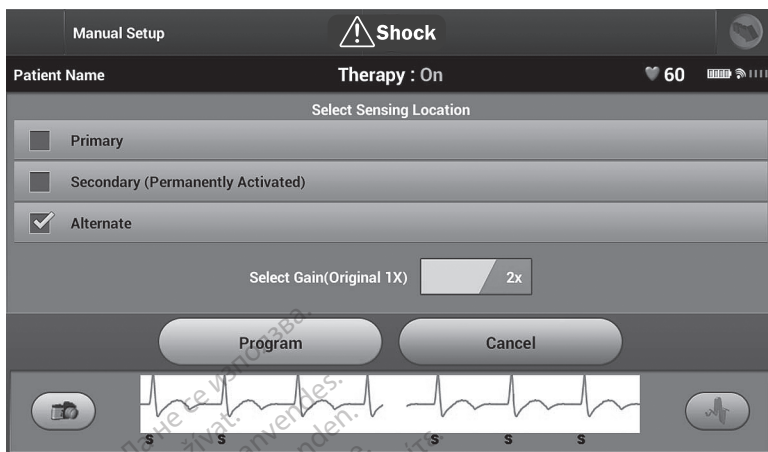


Figure 32. Manual Setup screen with sensing vector and gain options

- 1x Gain (± 4 mV): 1x Gain should be selected when the signal amplitude is large enough to cause clipping when the 2x gain is selected.
- 2x Gain (± 2 mV): 2x Gain should be selected when the signal amplitude is small enough to allow use of a more sensitive setting without causing clipping of the captured signal. The 2x gain selection amplifies the signal twice as much as the 1x gain selection.

NOTE: The gain setting may affect certification phase performance. Specifically, using 2x gain may improve identification of noise.

To program the manually selected sense vector and gain settings:

1. Select the Program button to save the sense vector and gain settings.
2. Select the Continue button. When the continue button is selected, the device will automatically evaluate if SMART Pass should be enabled. Refer to the S-ICD User's Manual for additional information about SMART Pass. For assistance, contact Boston Scientific using the information on the back cover.
3. The Acquire Reference S-ECG process is automatically enabled during the Manual Setup Process. Select the Continue button to acquire a reference S-ECG. A confirmation screen will appear when the captured reference S-ECG is acquired.

SMART Settings

The SMART Settings screen allows the user to access information and functions for the SMART Charge and SMART Pass features.

SMART Charge

Through the SMART Charge feature, the pulse generator charge initiation sequence adapts to the occurrence of non-sustained ventricular arrhythmia episodes by delaying capacitor charging. This conserves battery life and may prevent unnecessary shocks for non-sustained arrhythmias. For further information about the SMART Charge feature, refer to the EMBLEM™ S-ICD, EMBLEM™ MRI S-ICD User's Manual available online at www.bostonscientific-elabeling.com.

SMART Charge is enabled automatically when an untreated ventricular arrhythmia episode is recorded. Resetting returns the SMART Charge value to zero. To reset the SMART Charge feature:

1. From the Utilities screen (accessible from the Main Menu screen), select the SMART Settings button. The SMART Settings screen appears as shown below.

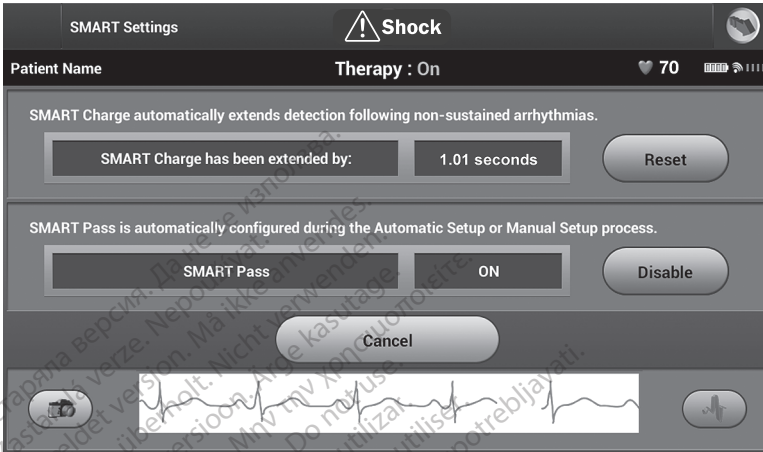


Figure 33. SMART Settings screen

2. Select the Reset button to reset the SMART Charge to zero or press Cancel to return to the Utilities Menu without resetting the SMART Charge.
3. A confirmation window will appear with the message: “SMART Charge successfully reset.”
4. Press the Continue button to return to the Utilities screen.

Disabling SMART Pass

The SMART Pass feature is designed to reduce oversensing while still maintaining an appropriate sensing margin. The device continuously monitors the ECG signal amplitude and automatically disables SMART Pass if under-sensing is suspected.

SMART Pass can be manually disabled if under-sensing is suspected by selecting the Disable button on the SMART Settings screen.

NOTE: If SMART Pass is disabled, another automatic or manual setup must be performed to re-enable the feature.

AF Monitor

The AF Monitor feature is designed to assist in the diagnosis of atrial fibrillation.

The AF Monitor feature can be enabled/disabled using the On/Off switch accessed through the AF Monitor button on the Utilities screen.

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.

Select the Program button to apply the changes and program the pulse generator.

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

- Days with measured AF: Provides the number of days within the last 90 where AF was detected
- Estimate of measured AF: Provides the total percent of detected AF within the last 90 days


For further information about AF Monitor, refer to the EMBLEM™ S-ICD, EMBLEM™ MRI S-ICD User's Manual available online at www.bostonscientific-elabeling.com.

Additional S-ICD Application Features

Rescue Shock

The Rescue Shock icon is available in the navigation bar on the S-ICD application display when the Setup Process is complete, and a pulse generator is actively communicating with the S-ICD application. During active communication, a maximum (80 J) rescue shock can be delivered upon command.

To deliver a rescue shock:

1. Select either the red Rescue Shock Icon at the top of the programmer screen or the red STAT button  on the Programmer. The Rescue Shock screen appears (Figure 34 Rescue Shock screen on page 53).

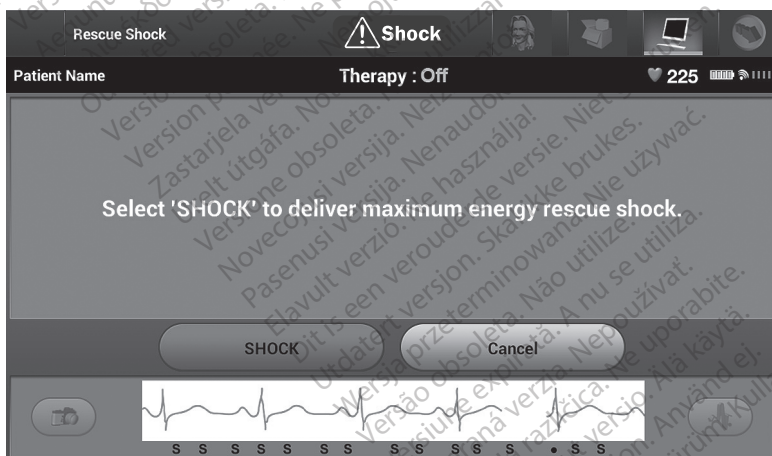


Figure 34. Rescue Shock screen

2. Select the Shock button to begin charging the pulse generator for a rescue shock. A red background screen with the word "Charging" will appear and a siren tone will be heard from the Programmer. Selecting the Abort button will prevent delivery of a rescue shock and will return to the Device Settings screen.
3. A confirmation screen will appear with notification that the shock was delivered successfully along with the corresponding shock impedance.

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.

WARNING:



High shocking electrode impedance may reduce VT/VF conversion success.

CAUTION: A reported shock impedance value of greater than 110 ohms from a delivered shock could indicate sub-optimal system placement. Care should be taken to place both the pulse generator and electrode directly on the fascia without underlying adipose tissue. Adipose tissue can add significant impedance to the high voltage shock current pathway.

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.

If for any reason the shock could not be delivered, a red background screen will appear with a message stating, "The shock could not be delivered."

NOTE: *In the event telemetry is lost, pulse generator commands— including Rescue Shocks— will not be available until telemetry is reestablished.*

Manual Shock

Manual Shock allows the user to deliver a synchronized shock during a sinus rhythm, an atrial rhythm, or a ventricular rhythm. The shock energy level is user-configured in the 10 to 80 joule range and the polarity is also user-configured (Figure 35 Manual Shock on page 55). Manual shock may also be utilized at a low energy to assess system impedance/integrity either at implant or as warranted by patient condition. A manual shock may be administered with the Therapy Mode set to On or Off.

To access Manual Shock, select the Shock Test button on the main menu. The Induction Test screen will appear. Select the Manual Shock icon in the navigation bar at the top of the screen to view the Manual Shock Test screen.

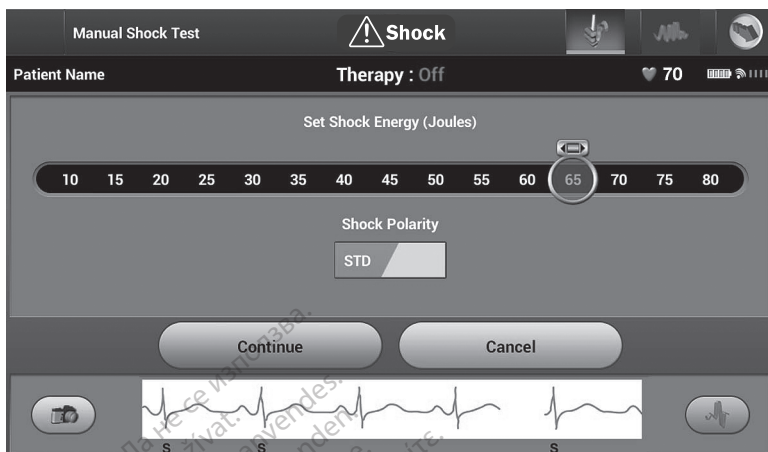


Figure 35. Manual Shock

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.

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 pulse generator if necessary. The Cameron Health magnet Model 4520 may be used interchangeably with the Boston Scientific magnet for this purpose.

For detailed information about using the magnet, refer to the appropriate S-ICD User's Manual.

Other behaviors of magnet application:

- Inhibit shock therapy delivery
- Terminate post-shock pacing therapy
- Prohibit arrhythmia induction testing
- Activate the pulse generator's beeper with each detected QRS complex for 60 seconds if beeper is turned on and is audible

WARNING:



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.

WARNING:



In patients with an S-ICD pulse generator 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.

CAUTION: Do not place a magnet on the Programmer.

NOTE: A programmer commanded Rescue Shock can override the use of the magnet as long as the magnet was in place prior to the initiation of the programming command. If the magnet is applied after the initial command, the Rescue Shock will be terminated.

NOTE: Magnet application does not affect wireless communication between the pulse generator and the Programmer.

MAINTENANCE, TROUBLESHOOTING, HANDLING, STANDARDS, AND SPECIFICATIONS

Refer to the *LATITUDE Programming System Operator's Manual*, Model 3300 for maintenance, troubleshooting, handling (including symbols on devices and packaging), standards, and specifications information for the Model 3300 Programmer device.

WARRANTY INFORMATION

A warranty card is packaged with the LATITUDE Programming System. Unless otherwise agreed, the LATITUDE Programming System remains the property of Boston Scientific and Boston Scientific must perform all necessary servicing and repair work. For additional warranty information, contact Boston Scientific using the warranty information on the card.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud version. Må ekki notuð.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreilt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Novcojusi versija. Nenaudokite.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használjal.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaraná verzija. Nepoužívať.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud version. Må ekki notuð.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreilt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Novcojusi versija. Nenaudokite.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használjal.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaraná verzija. Nepoužívať.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.

Остаряла версия. Да не се използва.
Zastaralá verze. Nepoužívat.
Forældet version. Må ikke anvendes.
Version überholt. Nicht verwenden.
Aegunud version. Må ekki notuð.
Παλιά έκδοση. Μην την χρησιμοποιείτε.
Outdated version. Do not use.
Version obsolete. Ne pas utiliser.
Zastarjela verzija. Nemojte upotrebljavati.
Úreilt útgáfa. Notið ekki.
Versione obsoleta. Non utilizzare.
Novcojusi versija. Nenaudokite.
Pasenusi versija. Neizmantot.
Elavult verzió. Ne használjal.
Dit is een verouderde versie. Niet gebruiken.
Utdatert versjon. Skal ikke brukes.
Wersja przeterminowana. Nie używać.
Versão obsoleta. Não utilize.
Versiune expirată. A nu se utiliza.
Zastaraná verzija. Nepoužívať.
Zastarela različica. Ne uporabite.
Vanhentunut versio. Älä käytä.
Föråldrad version. Använd ej.
Güncel olmayan sürüm. Kullanmayın.



Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

EC REP

Guidant Europe NV/SA; Boston Scientific
Green Square, Lambroekstraat 5D
1831 Diegem, Belgium

www.bostonscientific.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

© 2020 Boston Scientific Corporation or its affiliates

All rights reserved.

92123952-001 EN OUS 2020-03



CE 2797

