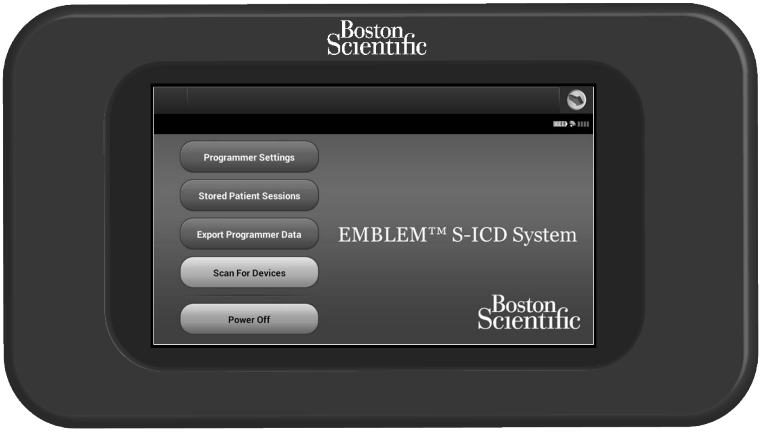
Boston Scientific

Model 3200

PROGRAMMER USER'S MANUAL

EMBLEM™ S-ICD Programmer



CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures

LIST OF ACRONYMS

AC	Alternating current	**IC**	Industry Canada
ATP	Anti-tachycardia pacing	**LCD**	Liquid crystal display
CRT	Cardiac resynchronization therapy	**MRI**	Magnetic resonance imaging
CPR	Cardiopulmonary resuscitation	**NSR**	Normal sinus rhythm
ECG	Electrocardiogram	**S-ECG**	Subcutaneous electrocardiogram
EMI	Elecromagnetic 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
FCC	Federal Communications Commission	**VT**	Ventricular tachycardia
GUI	Graphic user interface		

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Description

The EMBLEM™ S-ICD programmer (the "programmer") is a component of Boston Scientific's subcutaneous implantable cardioverter defibrillator system (the S-ICD System) which is prescribed for patients when cardiac arrhythmia management is warranted. Implantable components of the S-ICD System include the EMBLEM S-ICD pulse generator and the EMBLEM S-ICD subcutaneous electrode.

The programmer is a non–sterile, non–implantable, tablet computer controlled by a graphic user interface (GUI) displayed on a touchscreen. The programmer is powered by either AC line power or an internal lithium ion battery pack. The programmer uses a connected RF telemetry wand to communicate wirelessly with the EMBLEM S-ICD pulse generator in order to adjust programmable settings and to collect patient data. The EMBLEM S-ICD programmer is also compatible with the Cameron Health Model 1010 SQ-RX pulse generator. The programmer features and functions described in this manual apply to the EMBLEM S-ICD System as well as to the Cameron Health S-ICD System.

The S-ICD System is designed for ease of use and simplicity of patient management. The S-ICD System has a number of automatic functions designed to reduce the amount of time required for implantation, initial programming and patient follow-up.

Intended Use of Programmer

The programmer is intended to communicate with the implanted pulse generator using wireless telemetry. The programmer software controls all such telemetry functions.

Indications for Use

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

Contraindications

Unipolar pacing 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 and in the manuals for the other system components. Manuals for the other system components are listed below.

- EMBLEM S-ICD Pulse Generator User's Manual (or, for Cameron Health devices, SQ-RX Pulse Generator User's Manual)
- EMBLEM S-ICD Subcutaneous Electrode User's Manual
- EMBLEM S-ICD Subcutaneous Electrode Insertion Tool User's Manual

Programmer Warnings and Precautions

The following warnings and precautions apply specifically to the Model 3200 programmer component of the S-ICD System.

Programmer Warnings

General

Modifications. No modification of this equipment is allowed unless approved by Boston Scientific.

Programmer is MR Unsafe. The programmer is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[1]. Under no circumstances should the programmer be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

High temperatures. Do not subject the programmer to temperatures outside of the -10° C to 55° C (14° F to 131° F) storage range. Exposure to high temperatures may cause the programmer to overheat or ignite, and may possibly reduce its performance and service life.

Extreme temperatures. Do not discard the programmer in a fire, incinerate, or subject it to temperatures that exceed 100° C (212° F). This could cause the programmer to explode.

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

Do not immerse. Do not immerse the programmer in liquid of any kind. If the programmer does get wet, contact customer service for information about returning the programmer to Boston Scientific. Do not attempt to dry the programmer in an oven, microwave, or dryer because this poses a risk of overheating or explosion.

Conditions for Operation

Use only the supplied external power supply. Use the programmer only with the external power supply packaged with the programmer. Using other power supplies may cause damage to the programmer.

Electric shock. To avoid risk of electric shock, the programmer's external power supply must only be connected to a grounded electrical outlet.

Damaged programmer or power supply. Never use a damaged external power supply or a damaged programmer. Doing so could result in user injury, patient injury, or a lack of therapy delivery.

Interference with nearby equipment. By design, the programmer emits radio frequencies in the 402-405 MHz and 2.4 GHz bands. This may interfere with nearby medical or office equipment. When using the programmer, closely monitor equipment in the vicinity to verify normal operation. It may be necessary to take mitigation measures, such as reorienting or relocating the programmer or shielding the location.

Interference with programmer communication. The presence of other equipment operating in the same frequency bands used by the programmer (402-405 MHz for the pulse generator and 2.4 GHz for the printer) may interfere with communication. Interference can occur even if the other equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. This RF interference can be reduced by increasing the distance between the interfering device and the programmer and pulse generator or printer. If communication problems persist, refer to the Troubleshooting section of this manual.

Use of non-approved accessories. The use of any accessories with the programmer other than those specified by Boston Scientific in this manual may result in increased emissions or decreased immunity of the programmer and may cause decreased functionality or unintended operational behavior of the programmer. Anyone connecting such accessories to the programmer may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.

Programmer location. Do not use the programmer adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, check the programmer for normal operation in that configuration.

Programmer Precautions

General

Wand use. Use only the Model 3203 telemetry wand with the programmer.

Do not disassemble. Do not disassemble or alter any parts of the programmer.

Device communication. Use only the designated Boston Scientific programmer and appropriate software application to communicate with the S-ICD pulse generator.

Intended users. The programmer is intended for use by or under the direction of healthcare professionals only.

Storage and Handling

Mishandling. Mishandling (such as dropping or crushing) could damage the programmer. If you suspect damage to the programmer, contact your Boston Scientific representative or the customer service department for instructions and return packaging.

Broken or cracked screen. The display on the programmer is made of glass or acrylic and could break if the programmer is dropped or if it receives significant impact. Do not use if screen is broken or cracked as this could cause injury.

Magnet handling. Do not place a magnet on the programmer.

Implantation

Telemetry wand. The wand is a non-sterile device. Do not sterilize the wand. The wand must be contained in a sterile barrier before use in the sterile field.

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

Conditions for operation

Disconnecting the programmer. Mains isolation is achieved by disconnecting the external power supply power cord from the AC electrical outlet. Do not position the programmer or the external power supply in a manner that would make it difficult to disconnect that cord.

Programmer use. The programmer is not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures containing anesthetics, oxygen, or nitrous oxide.

Confirm communication. Confirm that the programmer is in communication with the intended implanted S-ICD pulse generator.

Electrostatic discharge. The programmer may be affected by ESD. If ESD occurs and the programmer's functionality is affected, attempt to reset the programmer or contact Boston Scientific for instructions. Do not touch or connect the telemetry wand to the programmer unless ESD precautionary procedures are used.

S-ICD System Warnings and Precautions

The following warnings and precautions apply to the S-ICD System as a whole. For additional warnings and precautions that are specific to other individual components of the system, and/or to the process of implanting the system, refer to the manual of the relevant system component (pulse generator, subcutaneous electrode, or electrode insertion tool [EIT]).

S-ICD System Warnings

General

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 will result in failure to deliver life-saving defibrillation therapy.

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

Pulse generator interaction. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. Test each system individually and in combination to help prevent undesirable interactions. Refer to the appropriate S-ICD pulse generator manual for more information.

Post-Implant

Magnet Response. Use caution when placing a magnet over the S-ICD pulse generator because it suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response.

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

Diathermy. Do not expose a patient with an implanted S-ICD System to diathermy. The interaction of diathermy therapy with an implanted S-ICD pulse generator or electrode can damage the pulse generator and cause patient injury.

Magnetic Resonance Imaging (MRI) exposure. Do not expose a patient to MRI scanning. Strong magnetic fields may damage the pulse generator and/or subcutaneous electrode, possibly resulting in injury to or death of the patient.

Protected environments. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator.

Sensitivity settings and EMI. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. Oversensing of noise due to this increased susceptibility could lead to inappropriate shocks and should be taken into consideration when determining the follow-up schedule for patients exposed to low frequency electromagnetic interference. The most common source of electromagnetic interference in this frequency range is the power system for some European trains which operate at 16.6 Hz. Particular attention should be given to patients with occupational exposure to these types of systems.

Clinical Considerations

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

Pediatric Use. The S-ICD System has not been evaluated for pediatric use.

Available Therapies. The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

Implantation

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

Device Programming

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

Patients hear tones coming from their devices. Patients should be advised to contact their physician immediately whenever they hear beeping tones coming from their device.

Programming for supraventricular tachyarrhythmias (SVTs). Determine if the device and programmed parameters are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy.

S-ICD System Precautions

Environmental and Medical Therapy Hazards

Avoid electromagnetic interference (EMI). Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Moving away from the source of the EMI or turning off the source usually allows the pulse generator to return to normal operation. Examples of potential EMI sources found in hospital and medical environments are:

- Radio transmitters
- Electronic surveillance or security systems
- Medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography,or nerve conduction studies

- Any externally applied device that uses an automatic lead detection alarm system (e.g., an EKG machine)

Hospital and Medical Environments

- **External defibrillation.** External defibrillation or cardioversion can damage the pulse generator or subcutaneous electrode. To help prevent damage to implanted system components, consider the following:
  > Avoid placing a pad (or paddle) directly over the pulse generator or subcutaneous electrode. Position the pads (or paddles) as far from the implanted system components as possible.
  > Set energy output of external defibrillation equipment as low as clinically acceptable.
  > Following external cardioversion or defibrillation, verify pulse generator function (“Post-Therapy Pulse Generator Follow-Up” on page 12).
- **Cardiopulmonary resuscitation.** Cardiopulmonary resuscitation (CPR) may temporarily interfere with sensing and may cause delay of therapy.
- **Electrical interference.** Electrical interference or “noise” from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another.
- **Ionizing Radiation.** It is not possible to specify a safe radiation dosage or guarantee proper pulse generator function following exposure to ionizing radiation. Multiple factors collectively determine the impact of radiation therapy on an implanted pulse generator, including proximity of the pulse generator to the radiation beam, type and energy level of the radiation beam, dose rate, total dose delivered over the life of the pulse generator, and shielding of the pulse generator. The impact of ionizing radiation will also vary from one pulse generator to another and may range from no changes in function to a loss of therapy. Sources of ionizing radiation vary significantly in their potential impact on an implanted pulse generator. Several therapeutic radiation sources are capable of interfering with or damaging an implanted pulse generator, including those used for the treatment of cancer, such as radioactive cobalt, linear accelerators, radioactive seeds, and betatrons. Prior to a course of therapeutic radiation treatment, the patient’s radiation oncologist and cardiologist or electrophysiologist should consider all patient management options, including increased follow-up and device replacement.

Other considerations include:

> Shield the pulse generator with a radiation-resistant material, regardless of the distance between the pulse generator and the radiation beam.

> Determining the appropriate level of patient monitoring during treatment

Evaluate pulse generator operation during and following the course of radiation treatment to exercise as much device functionality as possible (“Post-Therapy Pulse Generator Follow Up” on page 12). The extent, timing, and frequency of this evaluation relative to the radiation therapy regimen are dependent upon current patient health, and therefore should be determined by the attending cardiologist or electrophysiologist.

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

- **Electrocautery and Radio Frequency (RF) Ablation.** Electrocautery and RF ablation may induce ventricular arrhythmias and/or fibrillation, and may cause inappropriate shocks and inhibition of post-shock pacing. Additionally, exercise caution when performing any other type of cardiac ablation procedure in patients with implanted devices. If electrocautery or RF ablation is medically necessary, observe the following to minimize risk to the patient and device:

  > Program the pulse generator to Therapy Off mode.

  > Have external defibrillation equipment available.

  > Avoid direct contact between the electrocautery equipment or ablation catheters and the pulse generator and subcutaneous electrode.

  > Keep the path of the electrical current as far away as possible from the pulse generator and subcutaneous electrode.

  > If RF ablation and/or electrocautery is performed on tissue near the device or subcutaneous electrode, verify pulse generator function (“Post-Therapy Pulse Generator Follow Up” on page 12. For electrocautery, use a bipolar electrocautery system where possible and use short, intermittent, and irregular bursts at the lowest feasible energy levels.

When the procedure is finished, return the pulse generator to Therapy On mode.

- **Lithotripsy.** Extracorporeal shock wave lithotripsy (ESWL) may cause electromagnetic interference with or damage to the pulse generator. If ESWL is medically necessary, consider the following to minimize the potential for encountering interaction:
  - > Avoid focusing the lithotripsy beam near the pulse generator implant site.
  - > Program the pulse generator to Therapy Off mode to prevent inappropriate shocks.
- **Ultrasound energy.** Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.
- **Conducted electrical current**. Any medical equipment, treatment, therapy, or diagnostic test that introduces electrical current into the patient has the potential to interfere with pulse generator function. Medical therapies, treatments, and diagnostic tests that use conducted electrical current (e.g., TENS, electrocautery, electrolysis/thermolysis, electrodiagnostic testing, electromyography, or nerve conduction studies) may interfere with or damage the pulse generator. Program the device to Therapy Off mode prior to the treatment, and monitor device performance during the treatment. After the treatment, verify pulse generator function ("Post-Therapy Pulse Generator Follow Up" on page 12).
- **Transcutaneous Electrical Nerve Stimulation (TENS).** TENS involves passing electrical current through the body, and may interfere with pulse generator function. If TENS is medically necessary, evaluate the TENS therapy settings for compatibility with the pulse generator. The following guidelines may reduce the likelihood of interaction:
  - > Place the TENS electrodes as close together and as far away from the pulse generator and subcutaneous electrode as possible.
  - > Use the lowest clinically-appropriate TENS energy output.
  - > Consider cardiac monitoring during TENS use. Additional steps can be taken to help reduce interference during in-clinic use of TENS:
  - > If interference is suspected during in-clinic use, turn off the TENS unit.

  Do not change TENS settings until you have verified that the new settings do not interfere with pulse generator function.

  If TENS is medically necessary outside the clinical setting (at-home use), provide patients with the following instructions:

  - > Do not change the TENS settings or electrode positions unless instructed to do so.
  - > End each TENS session by turning off the unit before removing the electrodes.

> If the patient receives a shock during TENS use, they should turn off the TENS unit and contact their physician. Follow these steps to use the programmer to evaluate pulse generator function during TENS use:
>
> 1. Program the pulse generator to Therapy Off mode.
> 2. Observe real-time EGMs at prescribed TENS output settings, noting when appropriate sensing or interference occurs.
> 3. When finished, turn off the TENS unit and reprogram the pulse generator to Therapy On mode.

You should also perform a thorough follow-up evaluation of the pulse generator following TENS, to ensure that device function has not been compromised ("Post-Therapy Pulse Generator Follow Up" on page 12). For additional information, contact Boston Scientific using the information on the back cover.

- **Electronic Article Surveillance (EAS) and Security Systems.** Advise patients to avoid lingering near or leaning against antitheft and security gates or tag readers that include radio frequency identification (RFID) equipment. These systems may be found at the entrances and exits of stores, in public libraries, and in point-of-entry access control systems. These systems are unlikely to affect cardiac device function when patients walk through them at a normal pace. If the patient is near an electronic antitheft, security, or entry control system and experiences symptoms, they should promptly move away from nearby equipment and inform their doctor.
- **Elevated Pressures.** The International Standards Organization (ISO) has not approved a standardized pressure test for implantable pulse generators that experience hyperbaric oxygen therapy (HBOT). Elevated pressures due to HBOT may damage the pulse generator. Prior to starting an HBOT program, the patient's attending cardiologist or electrophysiologist should be consulted to fully understand the potential consequences relative to the patient's specific health condition. More frequent device follow-up may be warranted in conjunction with HBOT. Evaluate pulse generator operation following high pressure exposure ("Post-Therapy Pulse Generator Follow-Up" on page 12). The extent, timing, and frequency of this evaluation relative to the high pressure exposure are dependent upon current patient health, and should be determined by the attending cardiologist or electrophysiologist. Refer to the appropriate pulse generator manual for additional information about device-specific high pressure testing results. If you have additional questions, contact Boston Scientific using the information on the back cover.

Follow-up Testing

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

Explant and Disposal

- **Device handling at explant.** Before explanting, cleaning, or shipping the device, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:
  - > Program the pulse generator to Therapy Off mode
  - > If ERI or EOL has been reached, disable the beeper.
  - > Clean and disinfect the device using standard biohazard handling techniques.

Supplemental Precautionary Information

- **Post-Therapy Pulse Generator Follow Up.** Following any surgery or medical procedure with the potential to affect pulse generator function, you should perform a thorough follow up, which may include the following:
  - > Interrogating the pulse generator with a programmer
  - > Reviewing stored events, fault codes, and real-time S-ECGs prior to saving all patient data
  - > Testing the subcutaneous electrode impedance

> Verifying battery status
> Printing any desired reports
> Verifying the appropriate final programming prior to allowing the patient to leave the clinic
> Ending session

S-ICD System Clinical Investigation

A summary of the S-ICD System Clinical Investigation, including observed adverse events, is provided in the S-ICD pulse generator user's manual.

Potential Adverse Events

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

- Acceleration/induction of atrial or ventricular arrhythmia
- Adverse reaction to induction testing
- Allergic/adverse reaction to system or medication
- Bleeding
- Conductor fracture
- Cyst formation
- Death
- Delayed therapy delivery
- Discomfort or prolonged healing of incision
- Electrode deformation and/or breakage
- Electrode insulation failure
- Erosion/extrusion
- Failure to deliver therapy
- Fever
- Hematoma/seroma
- Hemothorax

- Improper electrode connection to the pulse generator
- Inability to communicate with the pulse generator
- Inability to defibrillate or pace
- Inappropriate post-shock pacing
- Inappropriate shock delivery
- Infection
- Keloid formation
- Migration or dislodgement
- Muscle/nerve stimulation
- Nerve damage
- Pneumothorax
- Post-shock/post-pace discomfort
- Premature battery depletion
- Random component failures
- Stroke
- Subcutaneous emphysema
- Surgical revision or replacement of the system
- Syncope
- Tissue redness, irritation, numbness or necrosis

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

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

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

Programmer Setup

Packaging

Programmer components include:

- Model 3200 Programmer with pre-loaded software
- Model 3203 Telemetry Wand
- External power supply and AC power cord

Visually inspect the packaging to ensure the contents are complete. Do not use if there is evidence of damage.

In case of damage return the product to Boston Scientific. For return packaging and instructions, contact Boston Scientific using the information on the back cover of this manual.

Programmer Controls and Connections

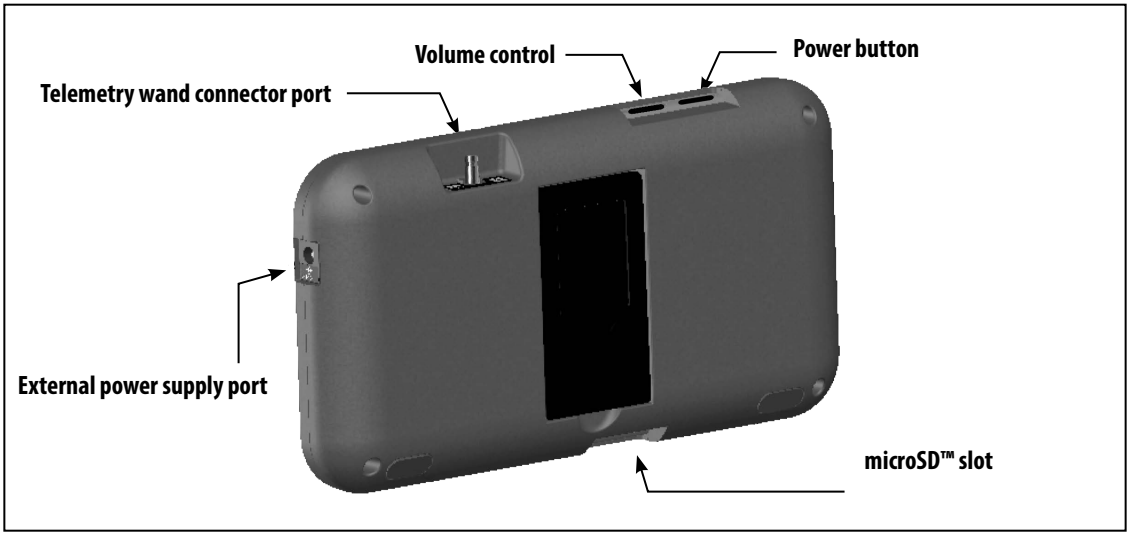


Figure 1: *Controls and external connections*

Charging the Programmer

The 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: *Current session data may be lost if a 45 minute period of inactivity occurs during an active telemetry session and the programmer is not connected to AC power.*

Typical charge time for a fully discharged battery is 5 hours. However, more time may be required if the programmer is in use while being recharged.

The Battery Status indicator located on the upper right corner of the screen displays the status of the main battery power when the unit is in use:

- 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 programmer displays one of the following alert screens as battery power gets progressively lower.

- Programmer Battery Low
- Programmer Battery Critical
- Out Of Power

To charge the programmer:

1. Connect the external power supply cable to the programmer (Figure 2).
2. Plug the external power supply cord into an AC power outlet.

Warning: *Use the programmer only with the external power supply packaged with the programmer. Using other power supplies may cause damage to the programmer.*

Warning: *To avoid risk of electric shock, the programmer's external power supply must only be connected to a grounded electrical outlet.*

Figure 2: *Connecting the external power supply*

Using the Programmer

Turning the Programmer On

The programmer power button is located in the recess above and behind the left corner of the screen. Press and hold the button until the display screen is active (Figure 3).

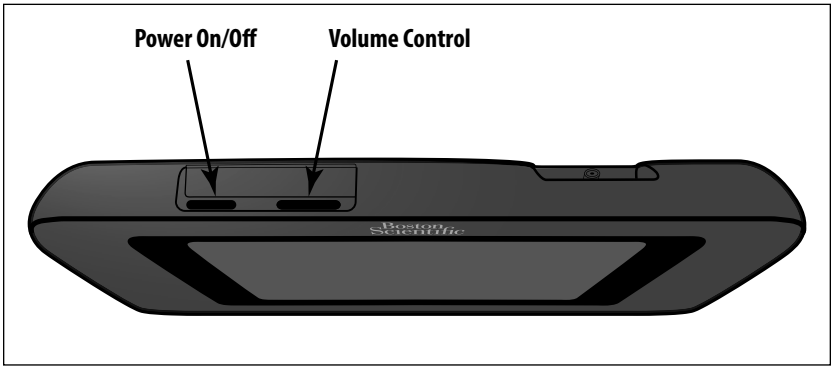


Figure 3: *Turning the programmer On/Off and changing the volume level*

Note: *If the programmer cannot be turned on while it is connected to AC power via the external power supply, first unplug the external power supply cord from the programmer. Press and hold the programmer power button until the display screen is active (Figure 3). AC power via the external power supply can then be reconnected.*

Changing the Programmer Volume Level

The volume level of programmer-generated sounds may be temporarily adjusted using the volume control (Figure 3). This level is automatically reset when the programmer is restarted.

Placing the Programmer in Suspend Mode

The programmer has a Suspend Mode which is activated automatically to conserve power. The display will be blank when this mode is in effect.

The programmer enters Suspend Mode whenever:

- The power button (Figure 3) is momentarily pressed and released
- The programmer is not connected to the external power supply, it is not in active communication with an S-ICD pulse generator, and no user activity has occurred for 15 minutes

Momentarily pressing the power button will resume normal operation.

Turning the Programmer Off

There are two ways to turn the programmer off:

1. Press and hold the power button (Figure 2) until the System shutdown menu appears. Select Power off from the popup and confirm by pressing OK.
2. From the on-screen Main Menu, press the Power Off button and select OK at the confirmation prompt.

Using the Programmer Touch Screen

The programmer is equipped with an LCD touch screen. The screen can be adjusted to the desired viewing angle by using the kick-stand located on the back of the programmer. 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 (Figure 4). An on-screen keyboard is presented whenever text entry is required.

Caution: *The display on the programmer is made of glass or acrylic and could break if the programmer is dropped or if it receives significant impact. Do not use if screen is broken or cracked as this could cause injury.*

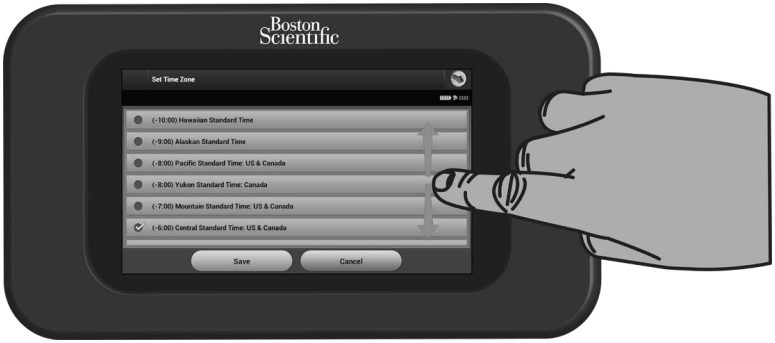


Figure 4: *Scrolling on-screen lists*

Using the Wand

The Model 3203 wand ("the wand") makes it possible for this programmer to communicate with the pulse generator.

Caution: *Use only the Model 3203 telemetry wand with the programmer.*

Caution: *The wand is a non-sterile device. Do not sterilize the wand. The wand must be contained in a sterile barrier before use in the sterile field*

Caution: *The programmer is non-sterile and cannot be sterilized. It must remain outside the sterile field.*

To connect the wand to the programmer, slide the wand cable connector over the communication connector port located on the rear edge of the programmer (Figure 5).

To disconnect the wand, grasp the wand cable connector and gently pull it straight off the communication connector port.

Note: *Do not pull or yank on the cable to disconnect the wand from the programmer. Such action could cause hidden damage to the cable. A damaged cable might reduce wireless communication capabilities and require a replacement wand.*

Figure 5: *Connecting the wand*

Optimal telemetry depends on the wand being placed directly over the implanted pulse generator. Although it may appear that the programmer is in communication with the pulse generator at greater distances, programming should always be performed with the wand placed directly over the implanted pulse generator.

Warning: *The presence of other equipment operating in the same frequency bands used by the programmer (402-405 MHz for the pulse generator and 2.4 GHz for the printer) may interfere with communication. Interference can occur even if the other equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. This RF interference can be reduced by increasing the distance between the interfering device and the programmer and pulse generator or printer. If communication problems persist, refer to the Troubleshooting section of this manual.*

When telemetry loss occurs, the display screen will turn yellow and a message will appear with the text "Communication Loss" to alert the user. Reposition the wand to establish communication. The programmer will return to the screen that was active before telemetry loss if the pulse generator is found and programming can continue.

Note: *If communication cannot be reestablished, the session should be ended and restarted by scanning for the pulse generator.*

Navigation

The programmer's graphic 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.

Screen Header

When the programmer is Offline (inactive communication), the screen header displays the Battery Status Indicator.

When viewing Offline Stored Sessions, the screen header displays:

- Patient name
- Therapy On/Off
- Battery status indicator

When the programmer 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

Navigation Bar

The Navigation Bar is the primary method for navigating the Online programmer screens. The bar is located along the top edge of the programmer screen and chosen screens appear with their selection icon highlighted.

Table 1 (page 24) provides a list of the programmer icons and their corresponding descriptions.

Restarting the Programmer

The programmer's operating system is self-monitoring and is generally able to sense many system error conditions and automatically initiate a restart sequence in response. Follow the on-screen instructions to complete the programmer-initiated restart sequence.

The programmer may need to be manually restarted if:

- You cannot exit a screen
- The operating system stops responding

A manual restart is accomplished by pressing and holding the power button until the system shutdown menu appears on the screen. Select Restart from the popup and confirm by pressing OK.

If the programmer does not respond to a restart process, contact Boston Scientific using the information on the back cover of this manual.

Table 1: *Icon descriptions*

Icon	Description	User 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.
	Patient View Icon	Allows user to access the patient chart screen.
	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
A B	Option Selection Slider Switch	Allows user to select one of two options, e.g. A or B

Configuring the Programmer

Configuring Programmer Settings

The programmer should be configured before communication with a pulse generator is attempted. This includes setting the date and time format, time zone, language and printer. Once these settings are configured during the initial setup process they become the default parameters and will not normally need to be changed with each session.

To configure the programmer settings:

1. Select the Programmer Settings button on the programmer start-up screen (Figure 6) to display the Programmer Settings screen (Figure 7).

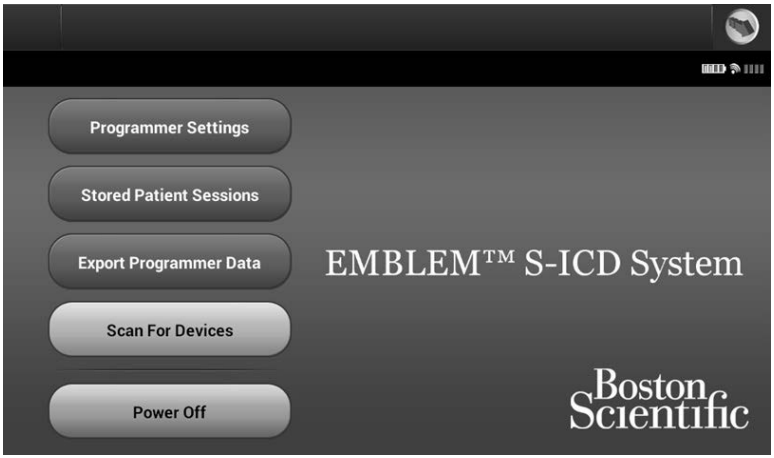


Figure 6: *Programmer start-up screen*

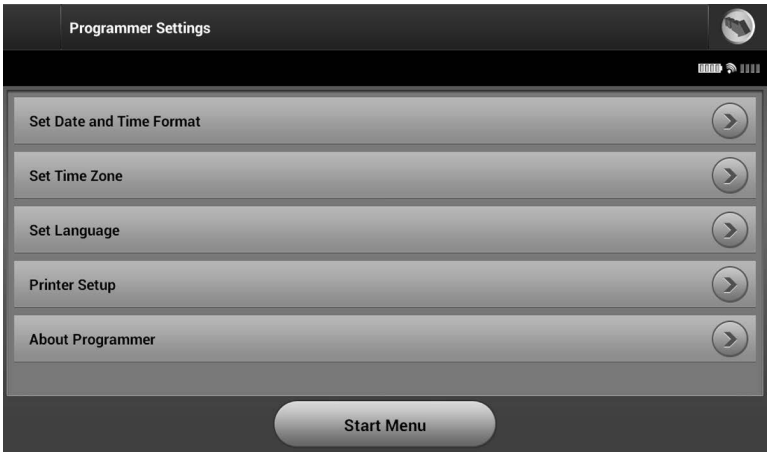


Figure 7: *Programmer Settings screen*

2. Select the corresponding line to access each setting. The settings that can be configured include:
   - Date and time format
   - Time zone
   - Language
   - Printer

Date and Time Format

To set the date and time format:

1. Select Set Date and Time Format on the Programmer Settings screen (Figure 7). The Date and Time Settings screen appears (Figure 8).
2. Select the desired date format.
3. 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.

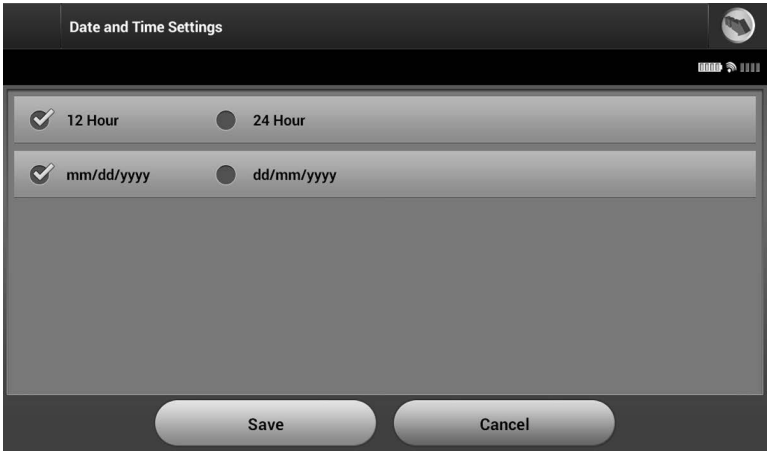


Figure 8: *Date and Time Settings screen*

Time Zone

The time zone setting controls two S-ICD System parameters, one for the programmer (the time shown on screens and printed reports), the other for pulse generators (the electronic filter that is intended to minimize electromagnetic interference {EMI}).

Choosing the correct time zone setting for the programmer will result in the electronic filter of interrogated pulse generators being set to the appropriate regional electrical power line frequency.

Specifically, the pulse generator line frequency filter is automatically programmed to either 50 Hz or 60 Hz, based on the time zone setting of the interrogating programmer.

To set the time zone

1. Select Set Time Zone on the Programmer Settings screen. The time zone selection screen appears (Figure 9).
2. Select the time zone button for the zone in which the programmer will be used. A checkmark will appear in the selected button.
3. 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.

In the rare cases where a single time zone setting includes regional power line frequency differences, two line frequency options are available. Choose the option with the correct frequency for the region where the programmer is located (for example see the top two rows in Figure 9.)

Because a programmer will set the time zone (and electronic frequency filter) of pulse generators it interrogates to match its own time zone setting, be aware that travelling patients whose devices are interrogated in time zones or countries other than the one in which they reside may need to have their pulse generator time zone reset upon returning home.

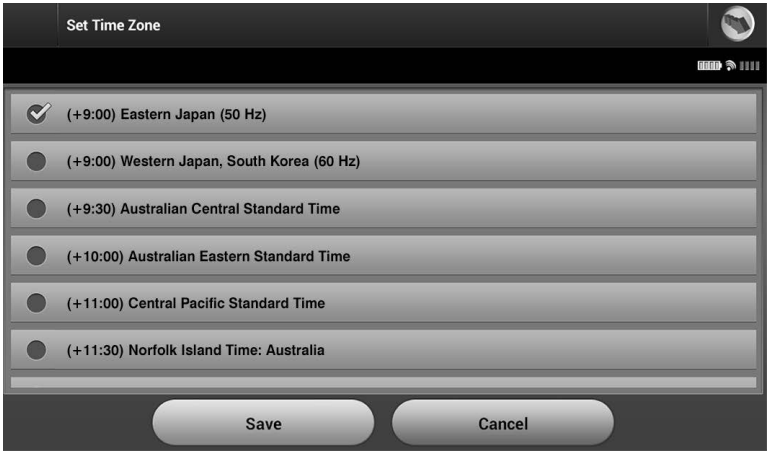


Figure 9: *Time Zone selection screen (scrollable list)*

Language Preference

To set the language preference:

1. Select Set Language on the Programmer Settings screen. The Language Settings screen appears. Scroll the list and select a language.
2. Select the Save button to save the changes or select Cancel to return to the Programmer Settings screen without saving the changes. If the language is changed the programmer will automatically restart and return to the Startup screen.

Printer Selection

The programmer communicates with the printer via *Bluetooth*® wireless technology. Only Boston Scientific-approved printers can be paired and used with the programmer. To select the printer to be paired and used with the programmer:

1. Ensure the printer is on and, depending on your specific printer, that the wireless function is enabled or the wireless adapter is in the printer's USB port.
2. Select Printer Setup on the Programmer Settings screen. A previously configured printer becomes the default printer and will be displayed at this time. If a default printer has not already been selected and configured, the Printer Setup screen (Figure 10) will be empty and the programmer will scan the area to locate wireless printers. A Scan Progress Bar will appear informing the user that the programmer is currently scanning for printers.
3. Select the printer of choice from among those found during the scan (Figure 10). If none were found, a window will appear stating that there are no printers. Select the Try Again button or the Cancel button to return to the Programmer Settings screen.

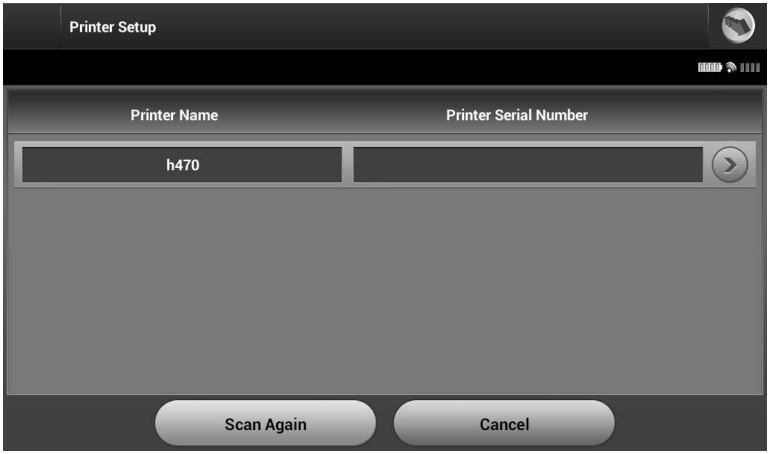


Figure 10: *Printer Setup screen*

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 (Figure 11).

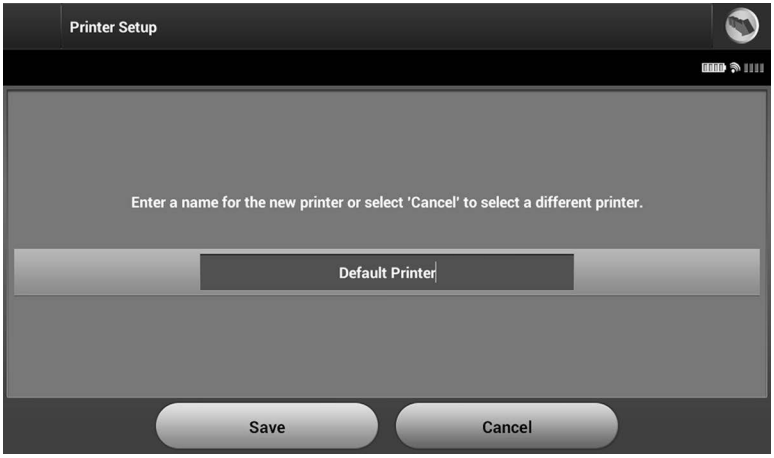


Figure 11: *Use the on-screen keyboard to enter a name for the selected printer*

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 will appear when the printer setup is completed (Figure 12).

   Note: *Refer to "Troubleshooting" section for information about printer problems.*

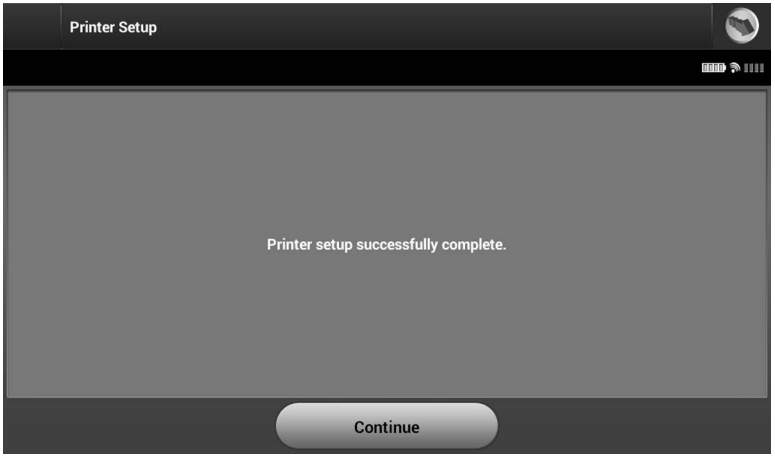


Figure 12: *Printer Setup confirmation screen*

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 smartphones.*

1. Since the programmer searches for nearby computers during the pairing process, the computer to be paired must first be made discoverable.

   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?"*

2. Once the target computer has been made discoverable, select the Export Programmer Data button on the programmer 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.

3. When the scan is complete the screen will list the discovered computers (the three computers having the strongest *Bluetooth®* signals) under the heading Unauthorized Computers Nearby (Figure 13). Choose the computer you wish to pair with and press the plus button next to it to complete the pairing process.
4. 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.
5. Successful pairing is indicated when the listing for the subject computer appears in the Authorized Computers column instead of the Unauthorized Computers Nearby column.
6. Authorized computers may be renamed if desired. Press and hold the listing for the computer until the Rename an Authorized Computer popup appears.

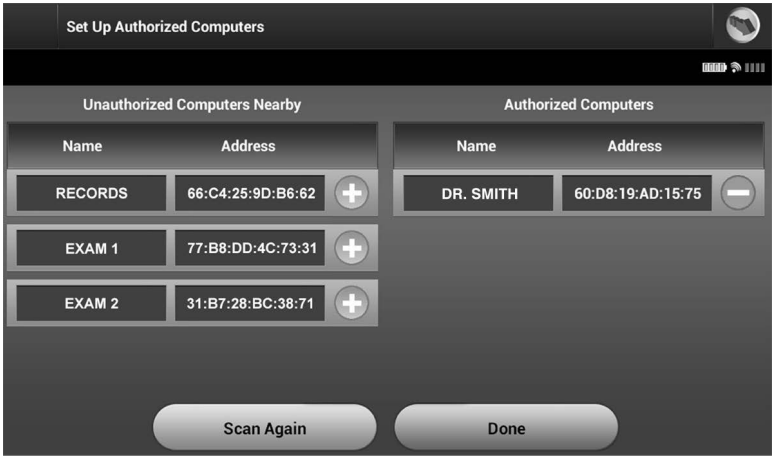


Figure 13: *Choosing a computer to authorize for* Bluetooth® *data transfer*

Programmer Software Version

To view the programmer's software version:

1. Select About Programmer on the Programmer Settings screen. The Programmer Software Version information screen appears (Figure 14).

Figure 14: *Programmer Software Version information screen*

2. This screen displays the current version of the programmer software. Select the Continue button to return to the Programmer Settings screen.

   Note: *The patient printed report also contains the programmer software version.*

Programmer Modes of Operation

Online Behavior

The programmer'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:** *Whenever the programmer is in active communication with a pulse generator, charging of the pulse generator in preparation for delivering a shock (whether commanded or in response to a detected arrhythmia) is indicated by an audible notification. The notification continues until the shock is 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. When the 51st session occurs, the programmer will automatically replace the oldest stored session with the new data. 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 programmer start-up screen, select Stored Patient Sessions.
2. Select the desired patient session.

Modes of Operation for the Pulse Generator

The pulse generator has three modes of operation:

- Shelf
- Therapy On
- Therapy Off

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 a programmer, it exits Shelf mode and defaults to Therapy Off mode. A full-energy capacitor reformation is performed and the pulse generator is prepared for set-up. Once the pulse generator is taken out of Shelf mode, it cannot be reprogrammed back into Shelf mode.

Therapy On Mode

The Therapy On mode is the primary operating mode of the 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 45.*

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.

Caution: *Use only the designated Boston Scientific S-ICD programmer and appropriate software application to communicate with and program the S-ICD pulse generator.*

Scanning for Pulse Generators

1. Select the Scan For Devices button on the programmer start-up screen (Figure 15). 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.

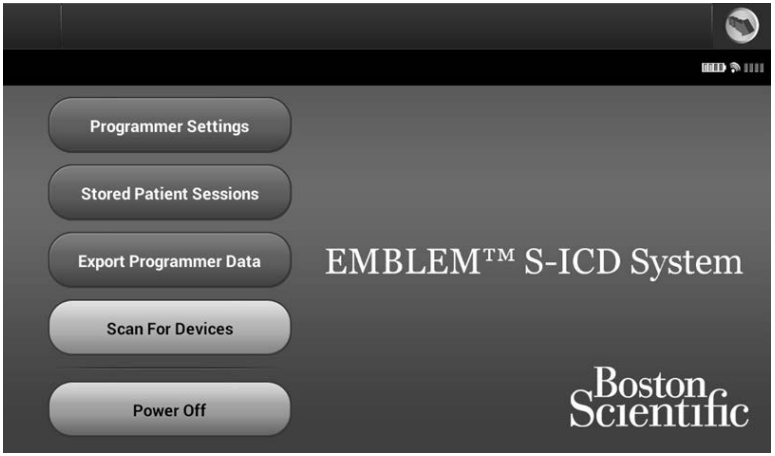


Figure 15: *Programmer start-up screen*

2. When the scanning process is complete, a list of all pulse generators detected (up to 16) will be displayed on the Device List screen (Figure 16). 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.

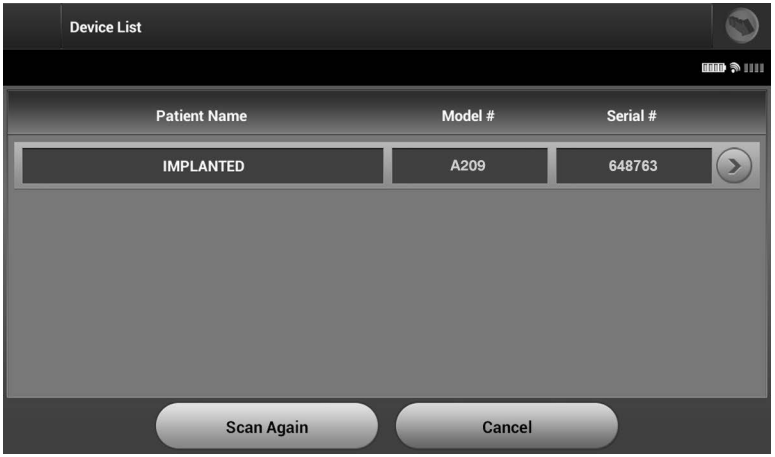


Figure 16: *Device List screen (scrollable list)*

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 programmer start-up screen.

   Note: *Refer to the* **Inability to Communicate With the Pulse Generator** *heading within the* **Troubleshooting** *section for further assistance.*

Connecting to a Pulse Generator

Select the desired pulse generator from the Device List screen (Figure 16) 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

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 appears once communication is established with the pulse generator (Figure 17).

Figure 17: *Device Identification screen*

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 Continue to remove the device from Shelf mode and prepare for implantation, or select Cancel to return to the Device List screen.

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.
2. The Device Status screen appears once communication is established with the pulse generator (Figure 36).

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 (Figure 18).

Figure 18: *Main Menu screen*

3. Warning messages (Figure 19) 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 has not been completed.
   - Optimization has not been completed. This message is displayed if Setup Optimization was not performed during the Automatic Setup process.

Figure 19: *Session incomplete message*

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, either automatically or manually, 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: *Use only the Model 3203 telemetry wand with the programmer.*

Caution: *The wand is a non-sterile device. Do not sterilize the wand. The wand must be contained in a sterile barrier before use in the sterile field.*

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 implanted 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. 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 20).
4. Select Set Electrode ID button.

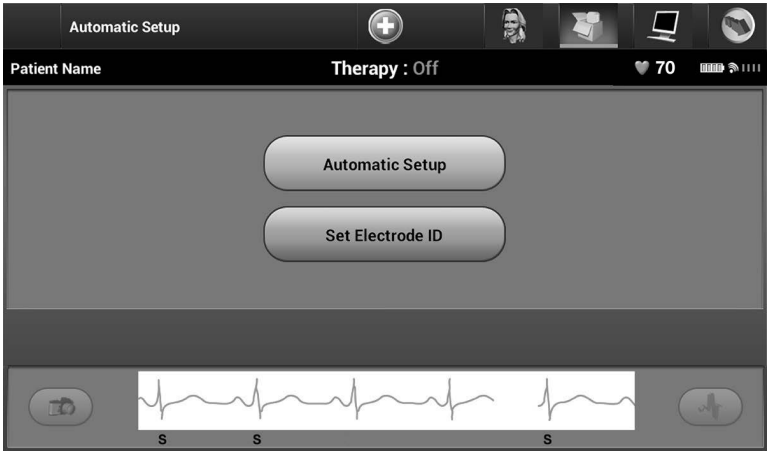


Figure 20: *Select the Set Electrode ID button to enter electrode information*

Note: *ECG and heart rate information is 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 (Figure 21).

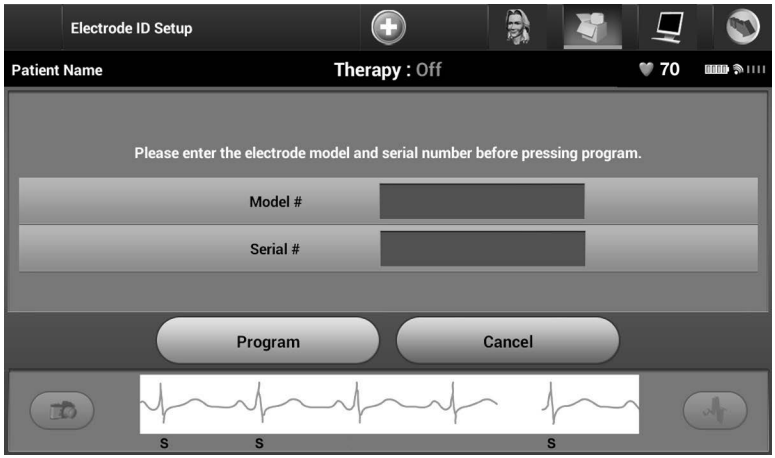


Figure 21: *Entering electrode information*

6. Select the Program button to save the information. A confirmation screen will appear during communication with the device (Figure 22). Select Cancel to cancel information storage and return to the Automatic Setup screen.

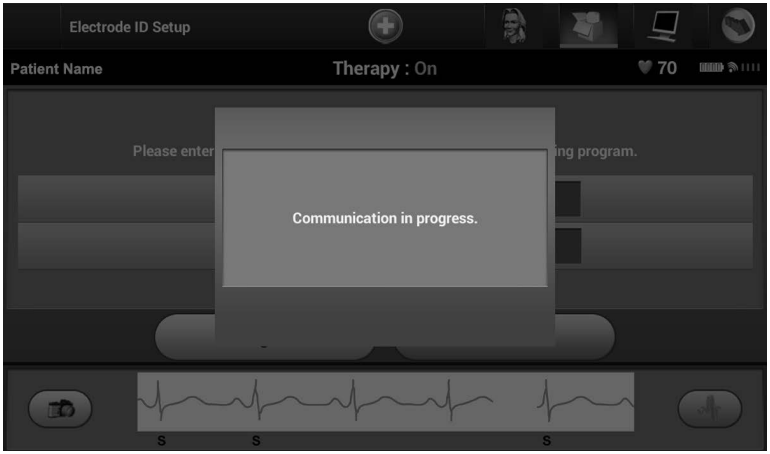


Figure 22: *Confirmation screen showing communication in progress*

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 (Figure 23).

Figure 23: *Select the Implant button to create a patient chart*

3. Select the Patient View icon to access the Patient View screen.
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 (Figure 24). 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 24: *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 bpm (Figure 25). For rates greater than 130 bpm, select the Cancel button and refer to the **Manual Setup** section on page 76.

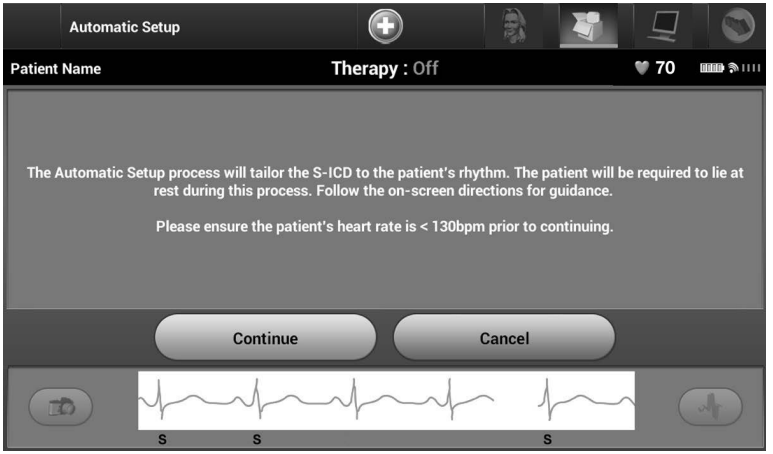


Figure 25: *Automatic Setup screen*

5. Once started the Automatic Setup will:
   - Perform the shock electrode integrity check to measure electrode impedance (Figure 26). Normal sub-threshold impedance range is < 400 Ohms.
   - Select the best sensing configuration. The sense electrode configuration appears on the printed report and can be viewed via the Manual Setup process.
   - Select the appropriate gain selection. The selected sense gain appears on the Printed Report and can be viewed via the Manual Setup process.

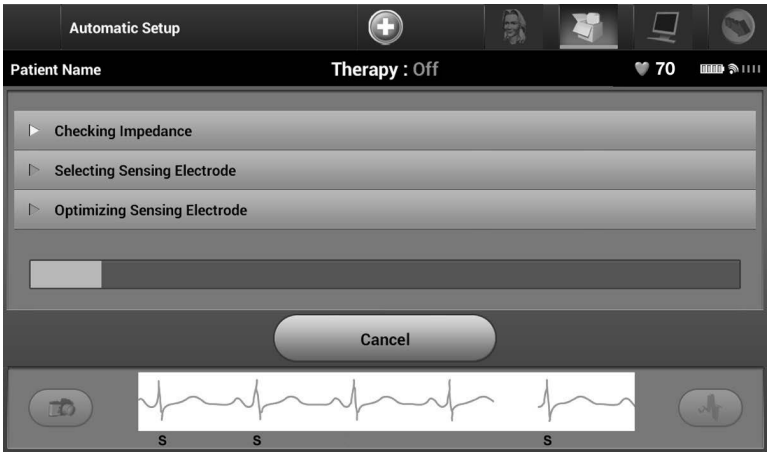


Figure 26: *Measuring electrode impedance*

The overall progress of the Automatic Setup process is shown in the status bar. 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 (Figure 27). If desired, Automatic Setup can be repeated during a follow-up session to include the optimization step.

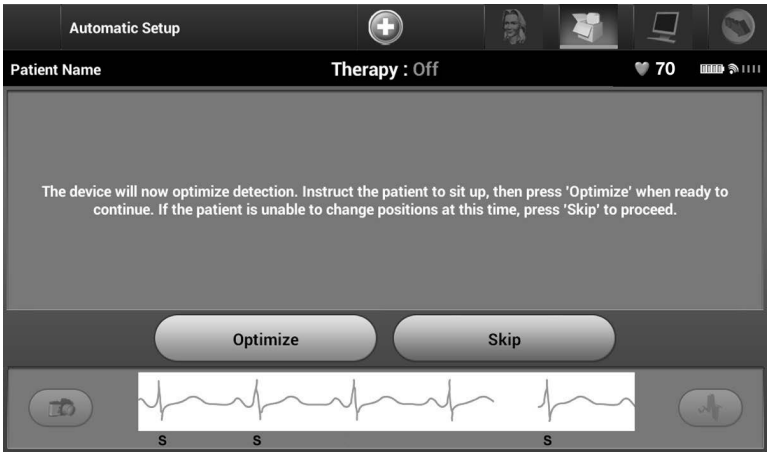


Figure 27: *Automatic Setup screen*

7. Select the Continue button to finish the Automatic Setup process. A confirmation screen will appear when Automatic Setup is complete (Figure 28).

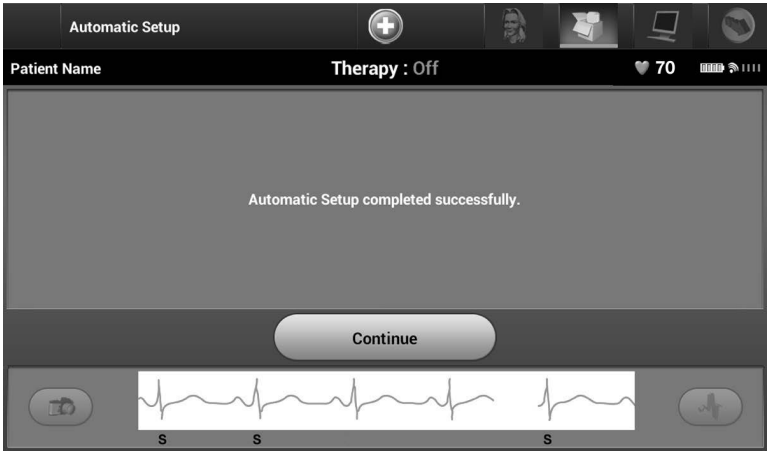


Figure 28: *Confirmation of successful Automatic Setup*

8. Following the optional optimization process, the Acquire Reference S-ECG screen is displayed (Figure 29). Select the Continue button to acquire a reference S-ECG.

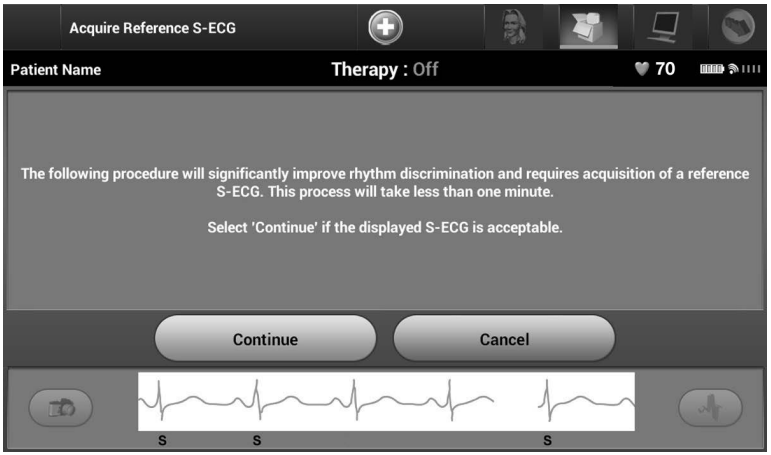


Figure 29: *Acquire Reference S-ECG screen*

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 30).

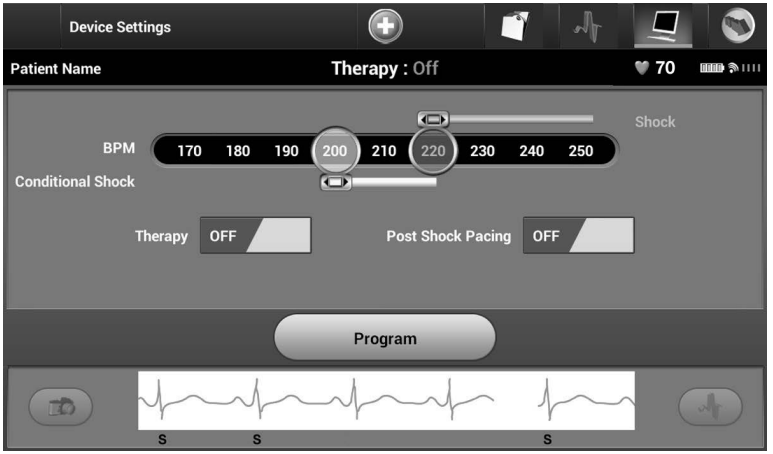


Figure 30: *Device Settings screen*

4. Select the On/Off Therapy switch to set the desired therapy mode (Figure 31).

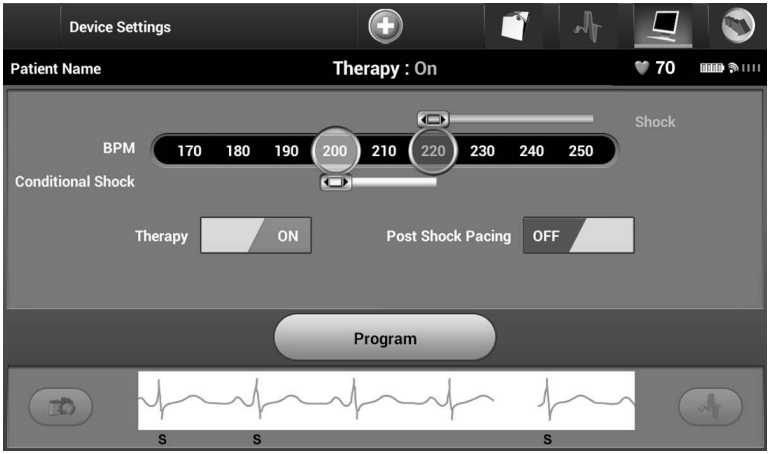


Figure 31: *Setting the On/Off Therapy switch*

5. Select and drag the Conditional Shock Zone (yellow) and Shock Zone (red) slider bars to set the desired zone configuration.

Note: *The IDE Study demonstrated a significant reduction in inappropriate therapy with the activation of the Conditional Shock Zone prior to hospital discharge (see S-ICD pulse generator user's manual).*

- The Shock Zone is programmable between 170 and 250 bpm in steps of 10 bpm.
- The Conditional Shock Zone is programmable between 170 and 240 bpm in steps of 10 bpm. 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 bpm 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, slide the Post Shock Pacing switch to the On position. (Post-shock bradycardia pacing occurs at a non-programmable rate of 50 bpm for up to 30 seconds. Pacing is inhibited if the intrinsic rate is greater than 50 bpm.)
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 (Figure 32) 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.

Warning: *The presence of other equipment operating in the same frequency bands used by the programmer (402-405 MHz for the pulse generator and 2.4 GHz for the printer) may interfere with communication. Interference can occur even if the other equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. This RF interference can be reduced by increasing the distance between the interfering device and the programmer and pulse generator or printer. If communication problems persist, refer to the Troubleshooting section of this manual.*

Figure 32: *Confirmation of programming*

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.

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 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 Capturing and viewing S-ECG Strips on page 70 and Captured S-ECG Report on page 62.)*

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 Patient Test button to setup the induction test (Figure 33).

Figure 33: *Select the Patient Test Button to access the Induction Test screen.*

3. Select either standard (STD) or reverse (REV) polarity (Figure 34).
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.

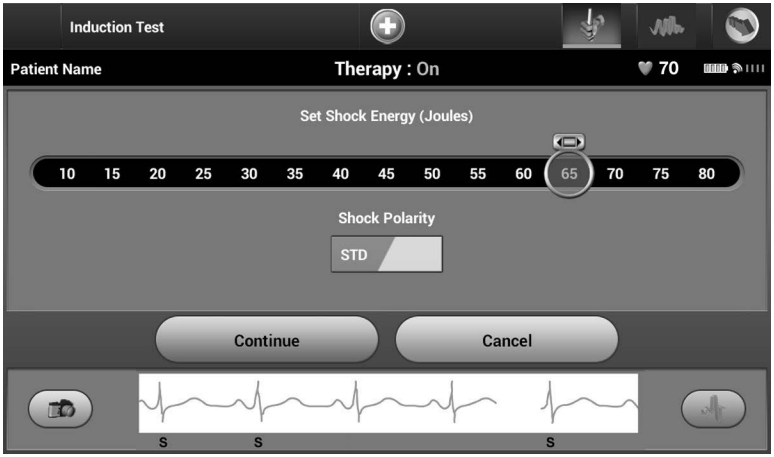


Figure 34: *Setting the desired first shock energy for defibrillation testing*

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. Select and hold the Hold To Induce button for the desired duration (Figure 35).

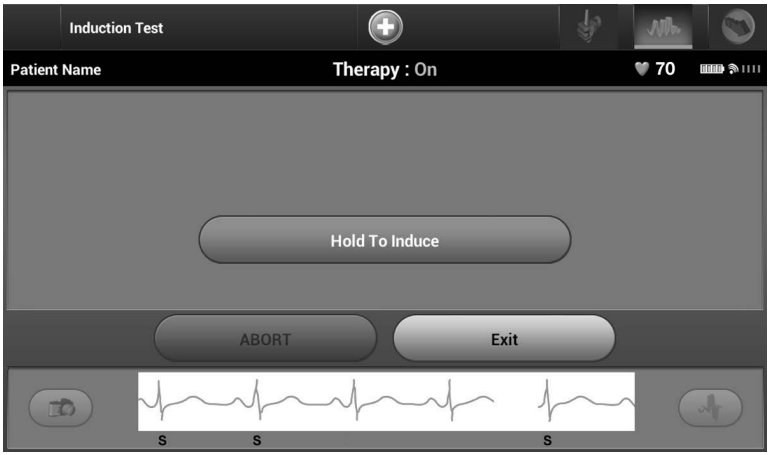


Figure 35: *Induction Test screen*

The following functions occur during the test:

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

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

- Arrhythmia detection and the Live S-ECG are suspended during 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 uses 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 ECG screen, labeled as "Induction S-ECG".

7. At any time prior to therapy delivery, the programmed energy may be aborted by selecting the red Abort button.
8. 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. After the setup process is complete, evaluate the streaming S-ECG during a pectoral exercise. Sensing performance during high rate exercises can also be performed. 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.

Caution: *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.
4. The Device Status screen will appear showing an overview of all pulse generator activity since the last communication session (Figure 36).

Figure 36: *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

  Note: *Choosing the "View" button in the Treated Episodes row allows navigation directly to the list of stored episodes (Figure 37).*

- Total number of untreated episodes since the last follow-up session
- Remaining pulse generator battery life

Viewing Stored Episodes

The pulse generator stores up to 25 treated and 20 untreated tachycardia episodes, which can be viewed during a patient's follow-up session. When the maximum number of episodes is exceeded, the most recent episode replaces the oldest stored episode; however, the first treated episode will not be 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.
5. Select an episode (treated or untreated) from the list (Figure 37). 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 37).*

Figure 37: *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 Programmer

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 Main Menu icon to display the Main Menu screen.
2. Select the Print Reports button to display the Print Reports screen (Figure 38).

Figure 38: *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:

- Patient Name
- Date of Current Follow-Up
- Date of Last Follow-Up
- Printed Report Date
- Pulse generator Model/Serial Number
- Electrode Model/Serial Number

- Implant Date
- Therapy Parameters
- Programmed Gain Settings and Sensing Configuration
- Initial Shock Polarity Configuration
- Episode Summary: Since Last Follow-Up and Since Initial Implant
- Battery Status
- Electrode Impedance Measurement
- Programmer Software Version
- Pulse generator Software Version
- Pulse generator Integrity Check, 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 (Figure 38).
2. A scrollable list containing both Captured S-ECG and Induction S-ECG strips is displayed (Figure 39). Select the desired S-ECG(s) to be printed by placing a checkmark next to the selection(s).

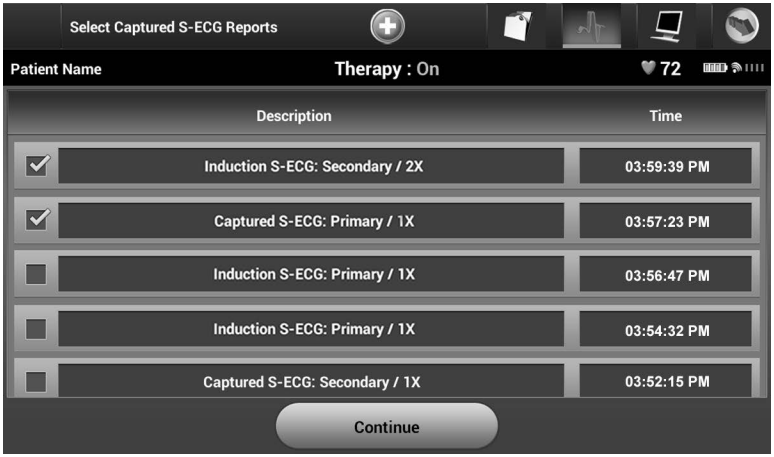


Figure 39: *Captured S-ECG list (scrollable)*

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 (Figure 38).
2. The Select Episode Reports screen appears showing a list of the stored episodes (Figure 40). 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 37).*

Figure 40: *Select Episode Reports screen (scrollable)*

3. Select Continue to return to the Print Reports screen (Figure 41). 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.

Figure 41: *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.

Export Patient Data

Patient data saved on the programmer may be exported to a desktop or notebook computer using either of two means: wirelessly, over a pre-configured *Bluetooth®* pairing, or with a Model 3205 microSD™ data card. For information about *Bluetooth®* pairing between the programmer and a desktop or laptop computer, see the **Bluetooth® Data Export** section on page 31 .

Export using Bluetooth® wireless technology

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

1. Select the Export Programmer Data button on the programmer 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 (Figure 42).

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

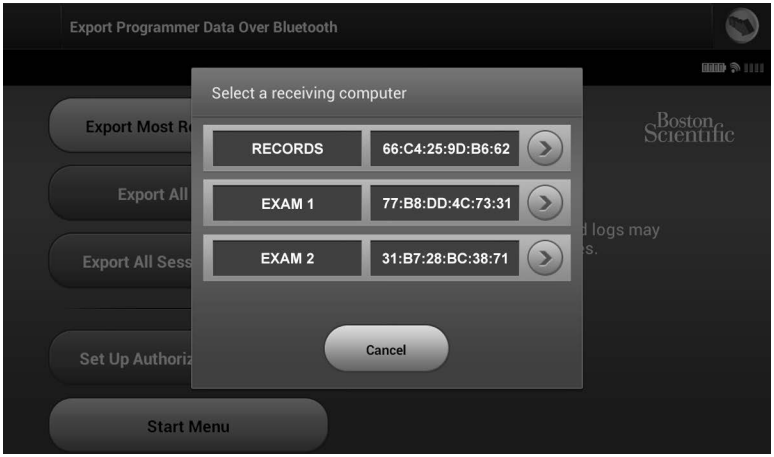


Figure 42: *Select a computer to receive the transfer*

3. The pop-up contains a scrollable list of all of the computers the programmer has been paired with. 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 programmer will prepare the file transfer package and attempt the wireless transfer. An error message will appear 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.*

Export using a microSD™ card

Data may also be exported using a microSD™ card. For security reasons, the programmer will only export data to Model 3205 microSD cards. Using any other microSD card will cause an error message (invalid card) to appear.

1. Navigate to the programmer start-up screen.
2. Insert the card into the microSD slot according to the instructions presented in ***Appendix A: Insertion and Removal of the microSD™ Card .*** The instructions are also provided with Model 3205 microSD Card. A Copy Data screen will appear when the microSD card has been properly inserted and recognized.

   Note: *An invalid card error message will appear if any card other than a Model 3205 card is inserted. The message may also appear if the programmer does not recognize the Model 3205 card after insertion. Should this occur, remove the card and select the OK button on the error screen. Wait for the programmer start-up screen to reappear and then reinsert the card.*
3. Select the Copy Data button on this screen and the next screen.
4. A confirmation screen is presented when the copy process is complete. Selecting the OK button will return the programmer to its start-up screen.
5. Remove the microSD card according to the instruction sheet (Appendix A).

Note: *Navigating away from and returning to the start-up screen with the microSD card still inserted will cause the export process to begin again.*

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

The system provides annotations to identify specific events on the S-ECG. These markers are shown in the S-ECG Markers on Programmer Display Screens and Printed Reports table (Table 2) and an example is shown in Figure 43.

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

Description	Marker
Charging [a]	C
Sensed Beat	S
Noisy Beat	N
Paced Beat	P
Tachy Detection	T
Discard Beat	•
Return to NSR[a]	
Shock	
Episode data compressed or not available	

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

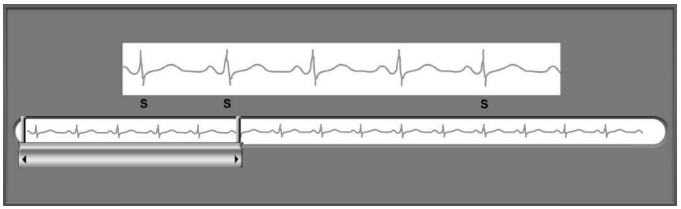


Figure 43: *Sample ECG markers*

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 44). 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.*

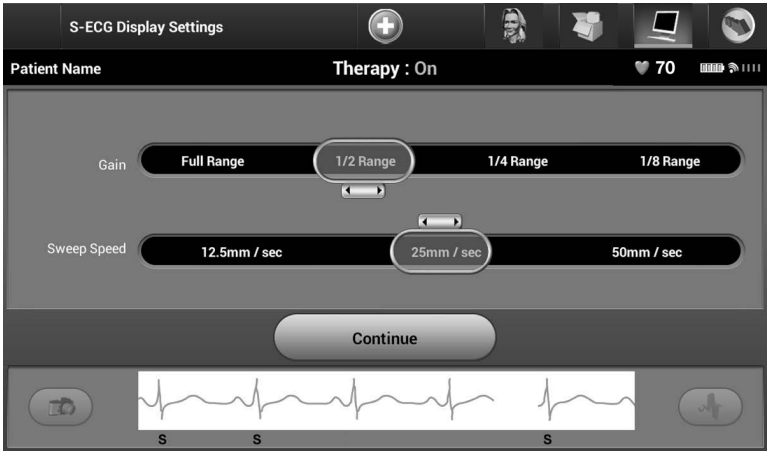


Figure 44: *Adjusting Gain and Sweep Speed*

Capturing and viewing S-ECG Strips

The programmer can display and store real-time S-ECG rhythm strips. The programmer saves a maximum of fifteen 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.

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 (Figure 45). The S-ECG will scroll across the display screen. Calipers appear below the Captured S-ECG rhythm strip (Figure 46). Each 12-second recording is date and time stamped according to the programmer's date and time setting.

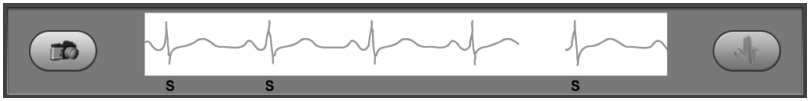


Figure 45: *Select the Capture S-ECG button*

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

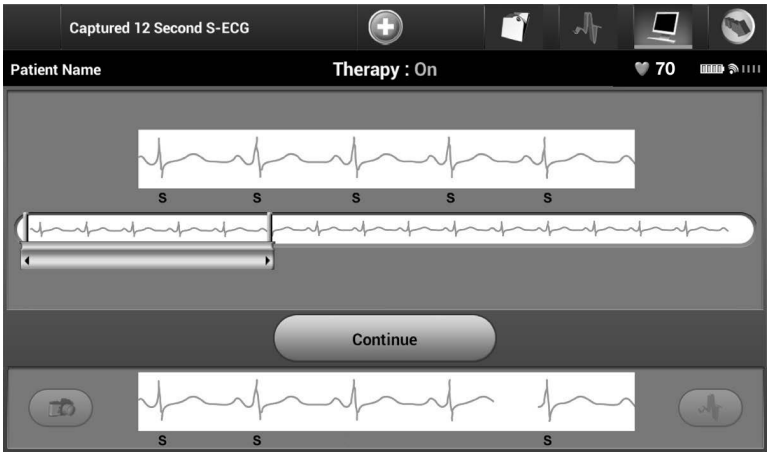


Figure 46: *Captured S-ECG rhythm strip*

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 47).

Viewing 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 Menu

The programmer Utilities menu provides access to additional device features. These include Acquire Reference S-ECG, Capture All Sense Vectors, Beeper Control, Manual Setup and Smart Charge.

To access the Utilities menu 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 (Figure 47).

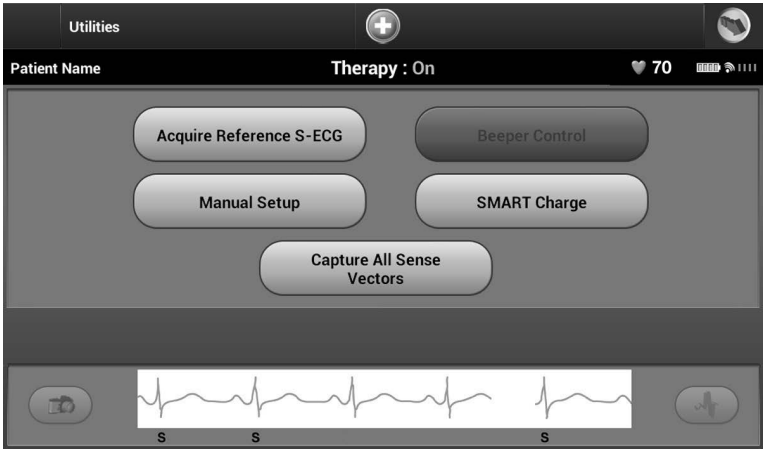


Figure 47: *Utilities screen*

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 programmer will begin acquiring the Reference S-ECG. A message will appear requesting that the patient remain still (Figure 48). The reference S-ECG QRS template is recorded and stored in the pulse generator.

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.

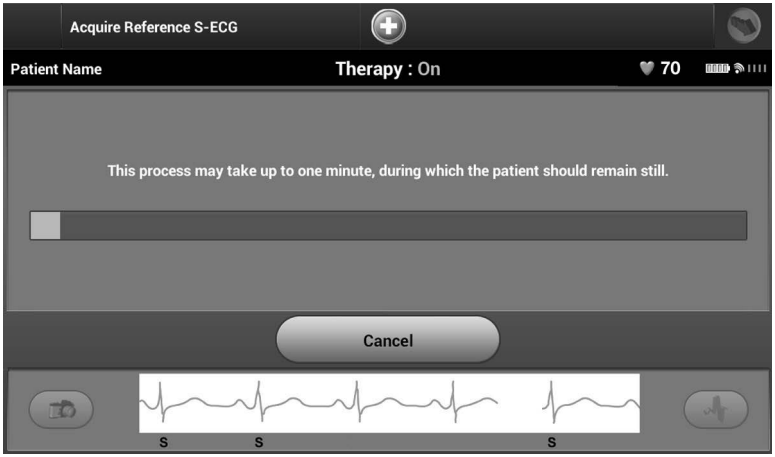


Figure 48: *The patient should remain still while the Reference S-ECG is acquired*

Capture All Sense Vectors

The Capture All Sense Vectors button on the Utilities screen configures temporary programmer 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 programmer returns to its original settings configuration 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 (Figure 49).

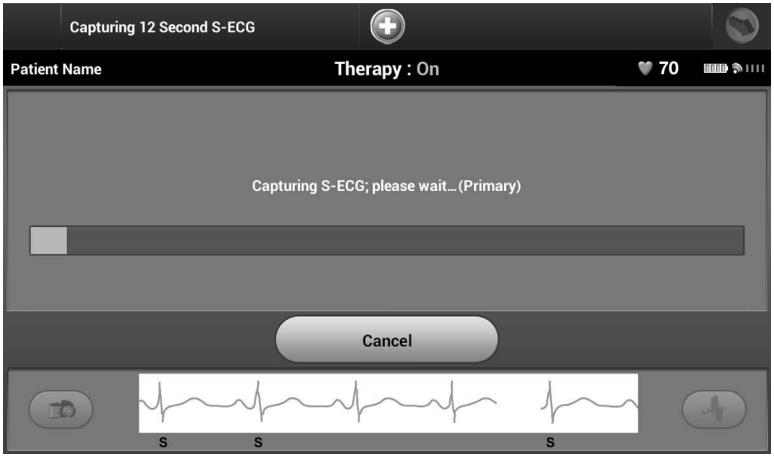


Figure 49: *Capture all sense vectors*

Once captured, the three S-ECGs can be viewed by following the steps outlined in **Viewing previously-captured S-ECGs** on page 71.

Beeper Control

The pulse generator has an internal alert system that emits an audible beeping tone when an alert condition occurs. Alert conditions may include Elective Replacement Indicator (ERI), End of Life (EOL), electrode impedance out of range, prolonged charge times, failed Device Integrity Check and irregular battery depletion.

Caution: *Patients should be advised to contact their physician immediately whenever they hear beeping tones coming from their device.*

Once an alert condition is triggered, audible tones beep for 16 seconds every nine hours until the alert condition is resolved. Beeper Control allows the beeper to be temporarily suspended (Reset Beeper) or permanently inactivated (Disable Beeper).

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

Reset Beeper

To reset the beeper, from the Utilities screen (accessible from the Main Menu screen), select the Beeper Control button. The Set Beeper Function screen will appear (Figure 50).

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.

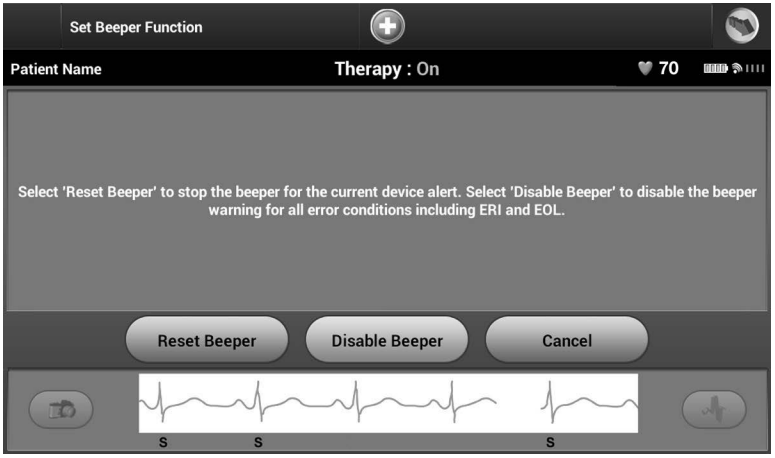


Figure 50: *Set Beeper Function*

Disable Beeper

The Disable Beeper feature option is enabled when ERI is reached or EOL occurs. If desired, select "Disable Beeper" from the Set Beeper function screen. Beeper tones are permanently disabled.

> ***Note:*** *If beeper is disabled alert conditions will not trigger audible tones*

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.

1. From the Utilities screen (accessible from the Main Menu screen), select the Manual Setup button. The Measure Impedance screen appears (Figure 51).
2. Select the Test button to perform the electrode integrity test.

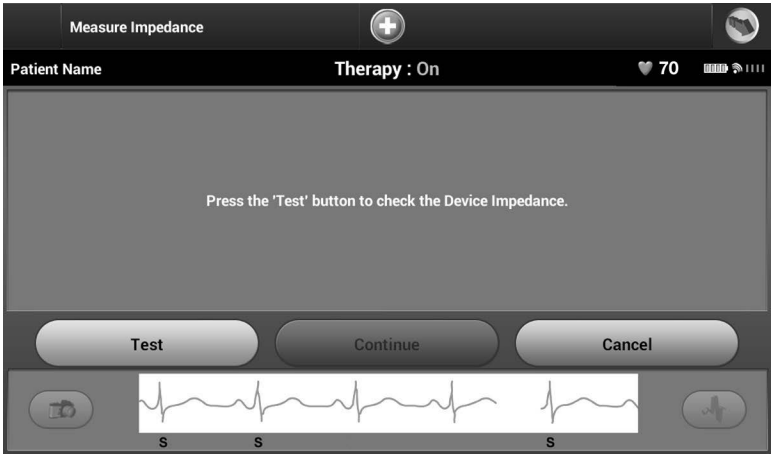


Figure 51: *Measure Impedance screen*

3. Select Continue to proceed or select Test to retry. The sensing configuration can be evaluated by temporarily activating any of the vectors or gain settings that are present on the Manual Setup screen (Figure 52). The Live S-ECG and markers will reflect the temporary selections for evaluation purposes.
4. There are three available sensing vectors that can be manually selected from the Manual Setup screen (Figure 52):
   - **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 slider switch on the Manual Setup screen (Figure 52).

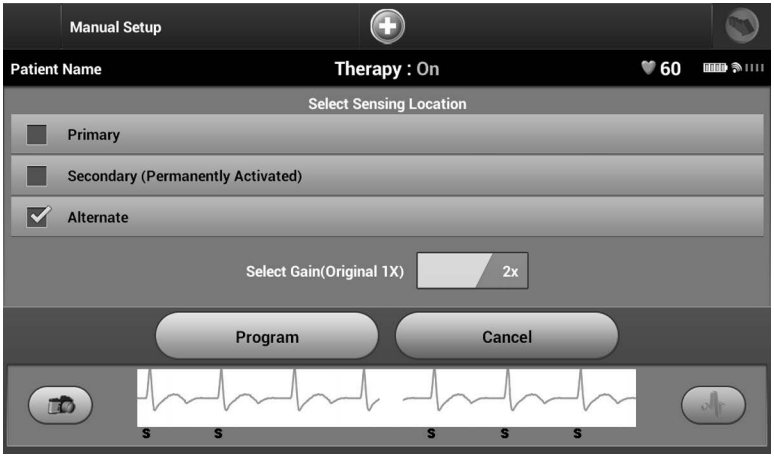


Figure 52: *Manual Setup screen with sensing vector and gain options*

- 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.

To program the manually selected sense configuration:

1. Select the Program button to save the sense vector and gain settings.
2. 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 (Figure 53).
3. Select the Continue button.

Figure 53: *Captured Reference S-ECG confirmation*

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. Refer to the pulse generator manual for further information about the Smart Charge feature.

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 Charge button. The Reset Smart Charge screen appears (Figure 54).

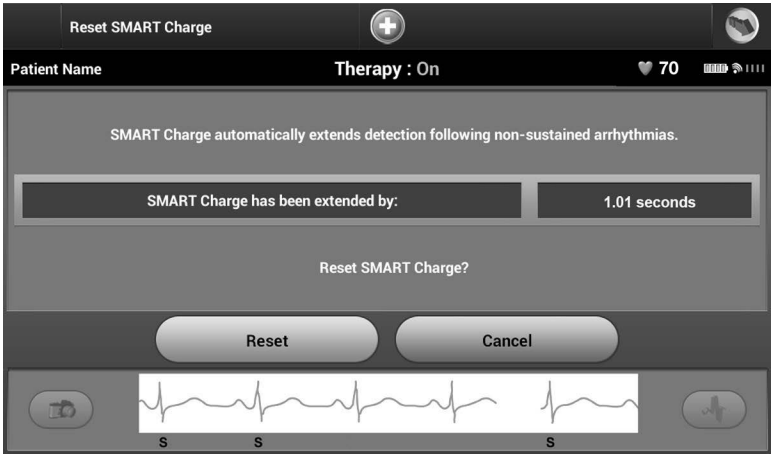


Figure 54: *Reset Smart Charge screen*

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.

Additional Programmer Functions

Rescue Shock

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

To deliver a rescue shock:

1. Select the red Rescue Icon at the top of the programmer screen. The Rescue Shock screen appears (Figure 55).

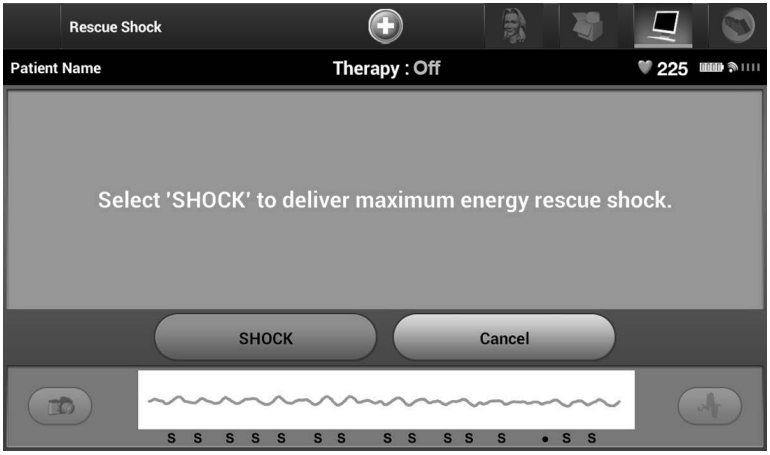


Figure 55: *Rescue Shock screen*

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 (Figure 56). Selecting the Abort button will prevent delivery of a rescue shock and will return to the Device Settings screen.

Figure 56: *Charging for rescue shock*

3. A confirmation screen will appear with notification that the shock was delivered successfully along with the corresponding shock impedance (Figure 57).

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.*

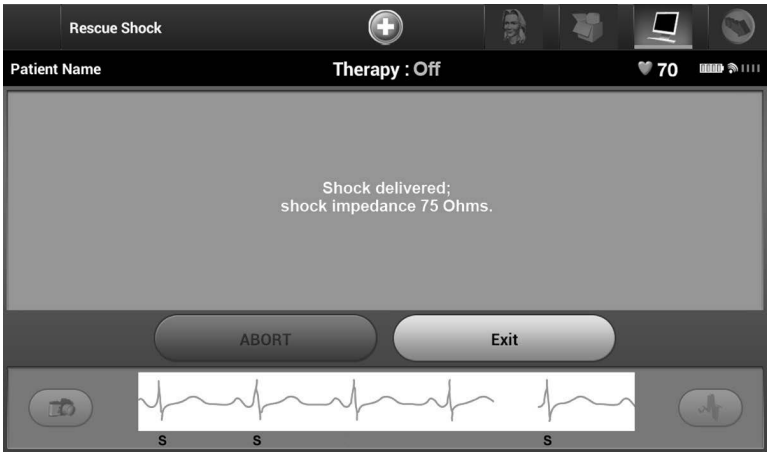


Figure 57: *Confirmation of Rescue Shock delivery*

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 58). 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.

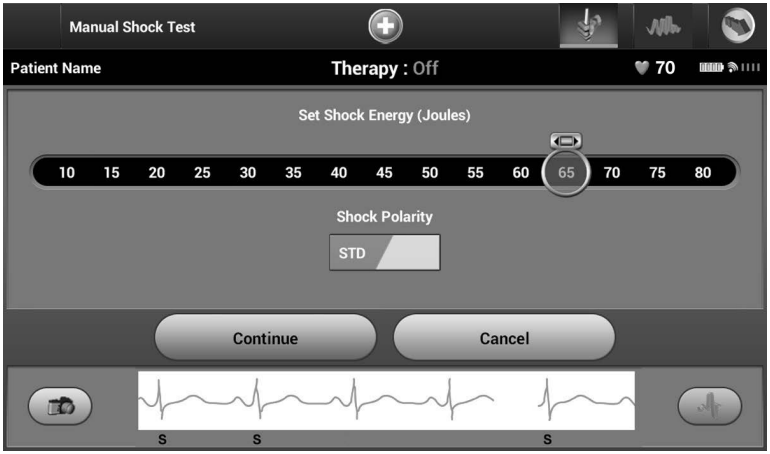


Figure 58: *Manual shock*

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 pulse generator 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

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

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

Charging the Programmer

When not in use, it is recommended that the programmer remain connected to the external power supply, which in turn is connected to the AC mains. This will ensure that the internal battery is adequately charged.

Cleaning the Programmer

Keep the programmer away from dust and dirt. Do not use harsh chemicals, cleaning solvents, or strong detergents to clean the programmer and wand.

To clean the programmer and wand as needed:

1. Turn the programmer off.
2. Gently wipe the programmer screen with a soft, clean, dry cloth.
3. Clean the programmer plastic case and the wand by wiping them with an isopropyl alcohol-moistened cloth.
4. Dry the programmer immediately to remove residue.

Service

There are no user-accessible or user-serviceable parts or components in the programmer. If any service, repair, or replacement of internal components is needed, the programmer must be returned to Boston Scientific. For instructions and return packaging, contact Boston Scientific using the information on the back cover of this manual.

When requesting service, please provide information concerning the nature of the failure and the manner in which the equipment was used when the failure occurred. The model number and serial number should also be provided.

Maintenance Check

Prior to each use, you should perform a visual inspection and verify the following:

- Mechanical and functional integrity of the programmer, cables, and accessories.
- Legibility and adherence of the programmer labels.

- That the programmer start-up screen appears a few seconds after you turn on the programmer. (The normal power-up process verifies that the programmer has passed its internal checks and is ready for use.)

Safety Measurements

National regulations may require that the user, manufacturer, or manufacturer representative periodically perform and document safety tests of the programmer. If such testing is required in your country, follow the testing interval and extent of testing as regulated in your country. If you do not know the national regulations in your country, please contact Boston Scientific using the information on the back cover of this manual. If IEC/EN 62353 is a required standard in your country, but no specific testing or interval is specified, it is recommended that you perform these safety tests using the direct method as specified in IEC/EN 62353 at an interval of every 24 months. Test values are shown in the Nominal Specifications table (Table 11).

Programmer End of Life

The programmer and accessories are designed to provide years of service under typical use. To dispose of, return, or exchange a programmer, contact Boston Scientific using the information on the back cover of this manual. Do not dispose of the programmer in the trash or at electronics recycling facilities.

TROUBLESHOOTING

This section presents potential programmer issues and the possible solutions. Of note, restarting the programmer can often resolve many of the issues listed below. The programmer can be restarted by pressing and holding the power button until the system shutdown menu appears and then choosing the "Restart" option.

Contact Boston Scientific using the information on the back cover of this manual for additional assistance.

Inability to Print

If unable to print, follow the steps below:

1. Ensure that the printer is turned On and that it contains paper and a sufficient ink supply.
2. Check printer feed for paper jam.
3. Ensure, as applicable, that the wireless function is enabled on the printer or that the *Bluetooth®* wireless adapter is fully inserted into the USB slot on the printer.

No Printer Available

The No Printer Available screen will appear if a printer was not set up. Select the Try Again button or refer to the Printer Selection section for instructions.

Touch Screen Inactive while Connected to AC Power

If the touch screen does not function while the programmer is connected AC power via the external power supply, disconnect and reconnect the external power supply and restart the programmer.

Loss of Communication with Printer

When communication between the programmer and the printer fails, a Printing Error screen will appear with a message stating "Error while printing reports. Press 'Continue' to try printing any remaining reports, or 'Cancel' to cancel the current print job."

If this occurs:

1. Select the Try Again button to reconnect to the printer.
2. Ensure, as applicable, that the wireless function is enabled on the printer or that the *Bluetooth®* wireless adapter is fully inserted into the USB slot on the printer.
3. Move the programmer closer to the printer.
4. Move any devices and the associated cables that may be interfering with the RF communication.

Inability to Communicate With the Pulse Generator

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

1. Attempt to reposition the wand.
2. Select Scan For Devices from the Main Menu or select Scan Again from the Device List screen to locate the desired device.
3. Move any equipment and associated cables that may be interfering with RF communication.
4. If available, attempt to communicate using a different S-ICD System programmer and/or wand.
5. Apply a pulse generator magnet to the pulse generator to elicit beeper tones. Remove the magnet and re-attempt communication.

COMPLIANCE STATEMENTS

EMI/RFI

This equipment has been tested and found to comply with the applicable limits for medical devices, IEC 60601-1-2:2007 or Active Implantable Medical Device Directive 90/385/EEC.

Although this testing shows the device to provide reasonable protection against harmful interference in a typical medical installation, there is no guarantee that interference will not occur in a particular installation. If the device does cause harmful interference the user is encouraged to try and correct the interference by the following measures:

- Reorient or relocate the device
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Contact Boston Scientific using the information on the back cover of this manual.

Essential Performance

In order for the Model 3200 Programmer to meet its intended use, it must interrogate and maintain a communications link with an S-ICD pulse generator as well as being able to appropriately detect touch screen button presses. Therefore those functions that pertain to communications with the implanted cardioverter defibrillator and detection of touch screen presses are considered essential performance.

Federal Communications Commission (FCC) Compliance

FCC ID: ESCCRM320014

Contains: FCC ID ESCCRM70514

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired operation

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

CAUTION: Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment.

Industry Canada (IC) Compliance

IC 4794A-CRM32004
Contains: IC 4794A-CRM7054

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

CAUTION: Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment.

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services, and must accept any interference received, including interference that may cause undesired operation.

Table 3: Declaration Electromagnetic Emission

The Model 3200 programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3200 programmer should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment Guidance**
RF Emissions CISPR 11	Group 1	The Model 3200 programmer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The Model 3200 programmer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Table 4: Declaration Electromagnetic Immunity Part 1

The Model 3200 programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3200 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, then the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips, Short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T 30% dip in U_T) or 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Model 3200 programmer requires continued operation during power mains interruptions, it is recommended that the Model 3200 programmer be powered from an uninterruptible power supply or a battery.
Power Frequency (50/60 Hz) Magnetic Fields IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table 5: Declaration Electromagnetic Immunity Part 2

The Model 3200 programmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 3200 programmer should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Model 3200 programmer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ 150 KHz to 80 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2.5GHz	3 V/m	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 3200 programmer is used exceeds the applicable RF compliance level above, the Model 3200 programmer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 3200 programmer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table 6: Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Model 3200 programmer			
The programmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the programmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the programmer as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Table 7: EMI/RFI Information: Programmer-to-Pulse Generator Communication

Specification	Medical Implant Communications Service (MICS)
Frequency band	402-405 MHz
Modulation type	FSK
Radiated Power	<25 µW
Bandwidth	< 300 KHz

Table 8: EMI/RFI Information: *Bluetooth*® Wireless Printing and Data Transfer

Specification	*Bluetooth*® 4.0 wireless technology
Frequency band	2.402-2.480 GHz
Modulation type	GFSK, π/4-DQPSK, 8DPSK
Radiated power	<100 mW
Bandwidth	< 1 MHz

Table 9: Product Guidelines

Component	**Requirement**	
DC Power		
Battery pack type	4000 mAh 3.7 volt lithium-ion battery pack	
Charge time	Approximately 5 hours	
Power Supply		
Input	100 – 240 VAC, 50 – 60 Hz, 0.5A	
Output	5.5 VDC, 3.64A Power: 20 W	
Manufacturer/Model	Elpac Power Systems MWA020005A	
Environment	**Operating**	**Storage and Transport**
Temperature	15° C to +38° C (+59° F to +100° F)	-10° C to +55° C (+14° F to +131° F)
Relative humidity	5% to 93% maximum at 40° C, non-condensing	5% to 93% maximum at 40° C, non-condensing
Atmospheric pressure	50 kPa to 106 kPa (7.252 psi to 15.374 psi)	50 kPa to 106 kPa (7.252 psi to 15.374 psi)

Table 10: Specifications

Parameter	**Specification**
Dimensions Width x Depth x Height	24.0 cm x 12.7 cm x 2.6 cm 9.4 in x 5.0 in x 1.0 in
Weight	.6 kg, 1.3 lbs
Standard Screen Display	WVGA, 1024 x 600 pixels, 16M TFT

Table 11: Nominal Specifications (with device connected to external power supply)	
Characteristic	**Nominal**
Electrical Safety Testing – IEC 60601-1:2005 / ANSI/AAMI ES60601-1:2005 allowed values	
Earth resistance	Not accessible
Earth leakage current	5 mA Normal Condition (NC)
	10 mA Single Fault Condition (SFC)
Patient leakage current	100 µA Normal Condition (NC)
	500 µA Single Fault Condition (SFC) (mains on applied parts)
Electrical Safety Testing – IEC 62353:2008 allowed values	
Protective Earth Resistance	Not accessible
Equipment leakage — direct method	500 µA
Patient leakage current — direct method (Wand, BF)	<= 5000 µA
Insulation resistance	Not accessible
Safety Features	
Defibrillator protection	to 5000 V, 400 J

Table 12: Packaging and Device Symbols: Model 3200 Programmer

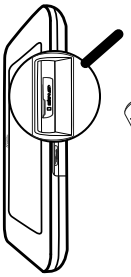
The following symbols may be used on the Model 3200 programmer, its accessories, and their packaging.

Symbol	Specification	Symbol	Specification
	Follow instructions for use		**Type BF Applied Part**
	Electrostatic discharge		**Non-ionizing electromagnetic radiation**
	Temperature limitations		**Humidity limitations**
	Atmospheric pressure limitations		**Manufacturer**
SN	**Serial Number**		**Date of Manufacture**
REF	**Reference Number**	EC REP	**Authorized Representative in the European Community**
LOT	**Lot number**	NON STERILE	**Non-sterile**
	ACMA Compliance Mark	AUS	**Australian Sponsor Address**
	Power plug storage		**Door, open**
	Consult instructions for use		**Proper insertion of microSD™ card**
	WEEE – Waste, Electrical, and Electronic Equipment (WEEE). Indicates separate collection for electrical and electronic equipment (i.e., do not throw this device in the trash).	CE0086	**CE mark of conformity with the identification of the notified body authorizing use of the mark**
		TÜV SÜD NRTL C US	**Mark for Nationally Recognized testing for safety standards**

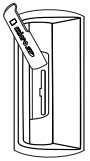
Boston Scientific

Model 3200 Programmer

microSD™

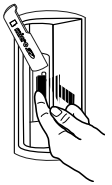


Insert microSD

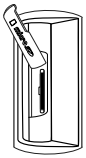


Lift the microSD slot cover and swing it away. Confirm that there is no card in the slot.

Place the microSD card into the empty slot with the lettering facing the the same direction as the programmer screen.



Gently press the card into the slot until it latches into place. There will be increasing spring resistance followed by a softly audible click which indicates that the latch is activated.



The properly mounted card will be flush with the slot opening surface.

Close the microSD slot cover.

Remove microSD

Lift the microSD slot cover and swing it away. Verify that a card is in the slot.

Press the edge of the card with your fingernail until the latch releases and you hear a click. Let the card gradually come out until you hear a second click, then remove your finger.

At this point it is safe to remove the card, although it may be difficult to grasp the card with your fingers. In this case the spring tensioner inside the slot can be used to eject the card.

Use a fingertip to slightly press the card back into the slot, then quickly slide your finger away before the card latches back into place. Note that the card may travel some distance when it is ejected.

Repeat this procedure as needed until card is ejected.

Close the microSD slot cover.

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