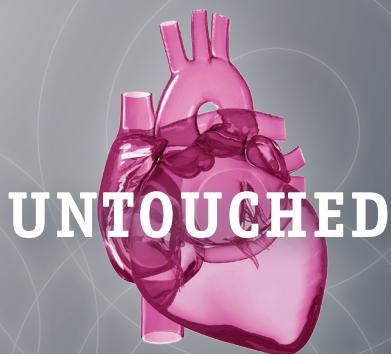
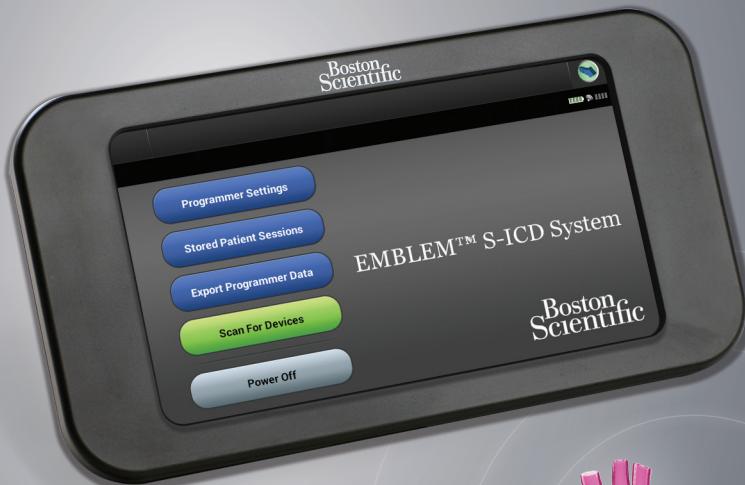


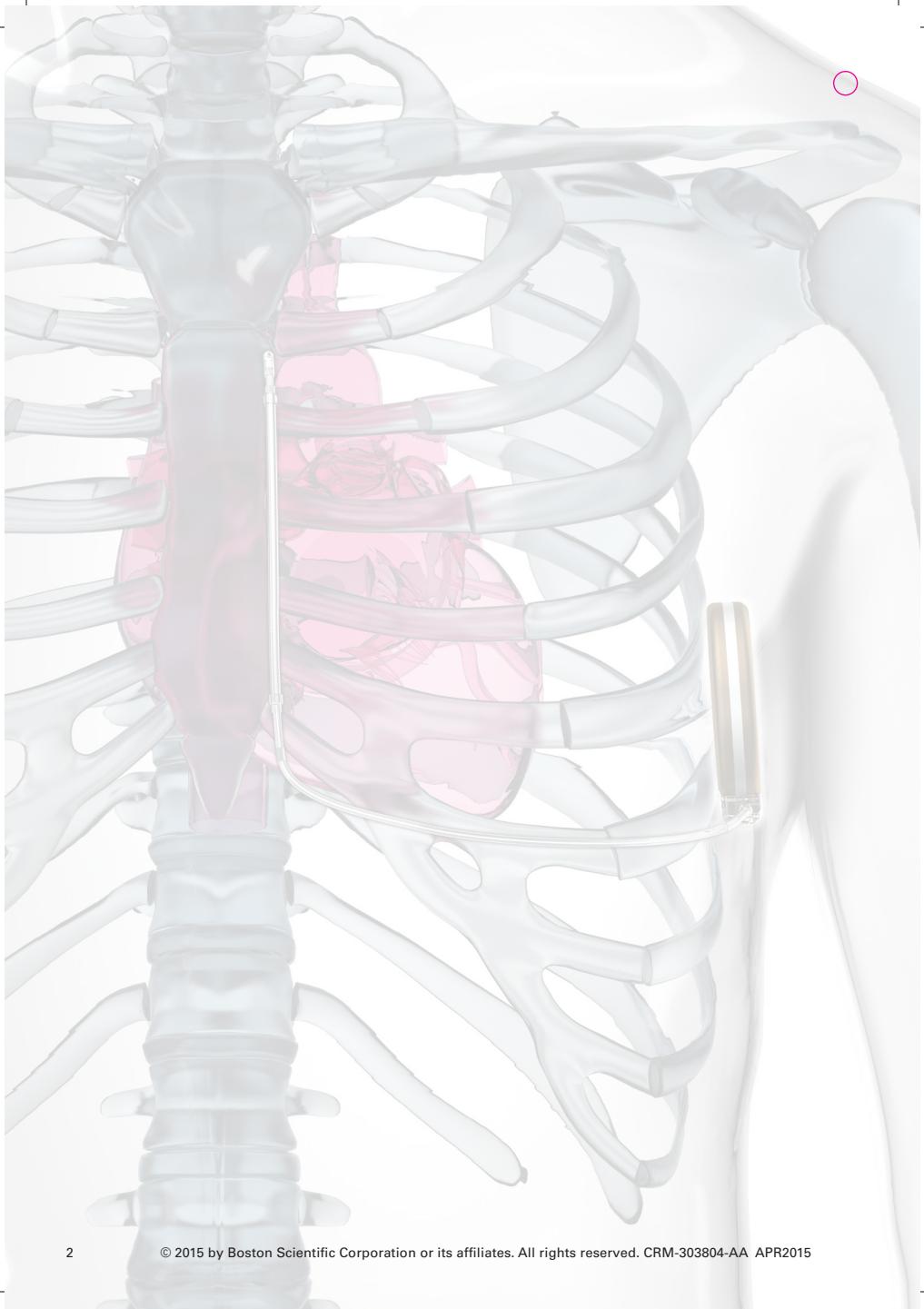


EMBLEM™ S-ICD SYSTEM

Programming at the Follow-up



UNTOUCHED





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11. Programmer Icons



1. Components

Programmer (Model #3200) – power button is located in the recess above and behind the left corner of the screen

Wand (Model #3203) – to connect, snap on the wand cable connector over the communication connector port located on the rear edge of the programmer

Power cord (Model #3204) – Boston Scientific's S-ICD System labeled 5.0 V transformer type power cord. Insert into the power receptacle located on the right side of the screen

Printer – configure Programmer Settings screen to select the printer (OfficeJet H470 or OfficeJet 100)

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.





2. Turn on Programmer and Printer

- Turn on Programmer – Power button is located in the recess above and behind the left corner of the screen
- Press and hold the Power button until the display screen becomes active

If unable to power on programmer while plugged in:

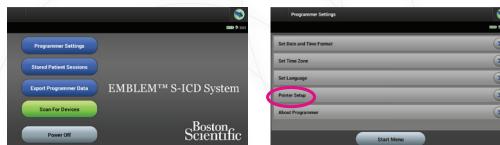
- First unplug the external power supply cord from the programmer
- Press and hold the programmer Power button until the display screen is active
- Finally, reconnect external power supply cord to the programmer

The volume button is located next to the Power button



To Set Up Printer:

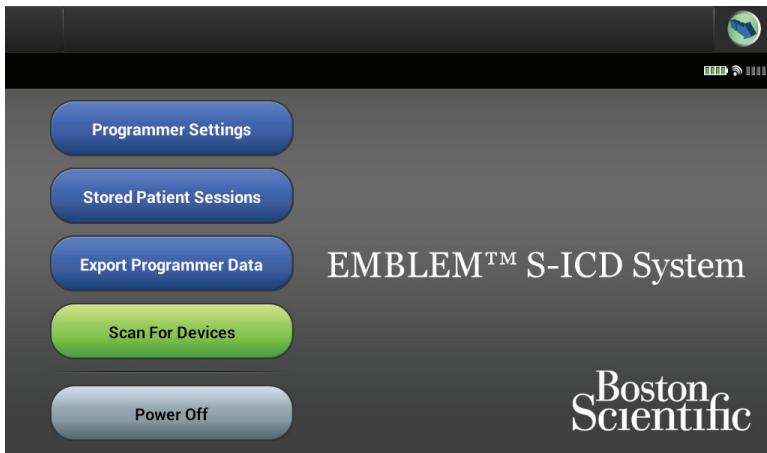
- Press Bluetooth button on the printer
 - Button will illuminate light blue when button is enabled on the printer
 - This setting will be remembered the next time the printer is turned on
- Select Printer Set up on the Programmer Settings screen
 - A previously configured printer becomes the default printer and will be displayed
 - If a default printer has not already been selected and configured, 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
- Select the printer of choice (Officejet H470 or Officejet 100)
 - If no printers are found, a window will appear stating that there are no printers
 - Note: A connection is established when Blue light is illuminated on Officejet 100 or the dongle is inserted for Officejet H470.
- Select the Scan Again or the Cancel button to return to the Programmer Settings screen





3. Scan for Devices

- Place wand over implanted device
- Select Scan for Devices





4. Information Screen and Review Episodes

- Note if any episodes occurred since last follow-up
- Select View to review stored episodes



- Individually select each episode to be downloaded and reviewed



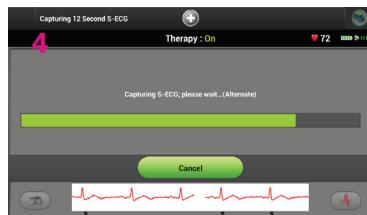
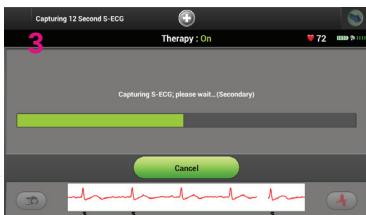
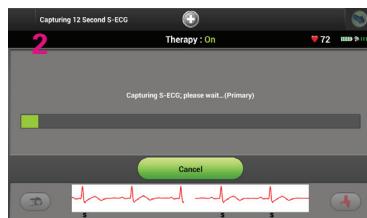
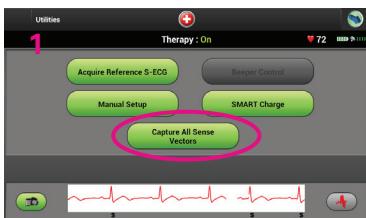
You must select and download each episode that you wish to review and print



5. Capture S-ECG

Capture All Sense Vectors button is located in the Utilities screen

- Select Capture Sense Vectors button to capture and store a 12-second strip of the live S-ECG of each vector. It will take approximately a minute to automatically capture all vectors.
- Ensure that sensing and markers are appropriate



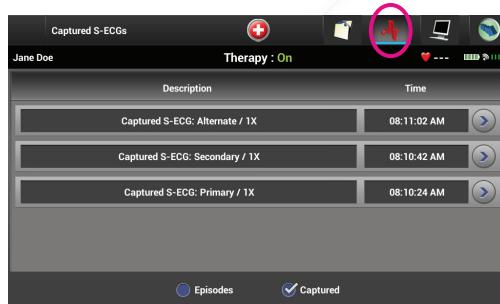
Note: You can also select the Camera icon to capture and store the live S-ECG (8.5 seconds of onset and 3.5 seconds post)

6. Review Captured S-ECG & Device Settings

- Select the ECG icon: This allows the real-time scaling/viewing of the live streaming ECG and does not alter the sensing setup of the PG



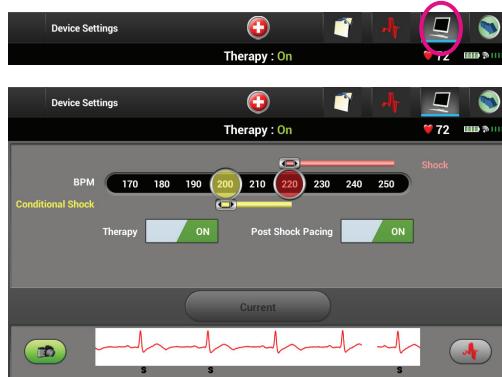
- After capturing the S-ECGs, select the ECG button to review captured S-ECGs





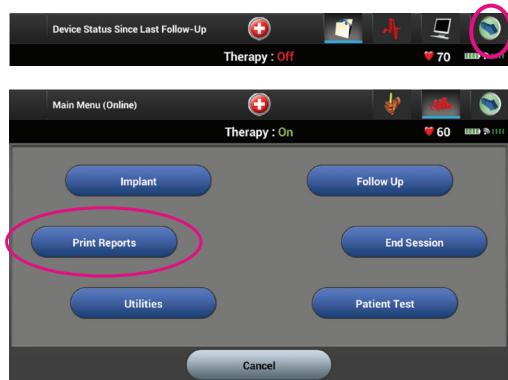
6. Review Captured S-ECG and Device Settings

- Select the Computer icon to view current Device Settings

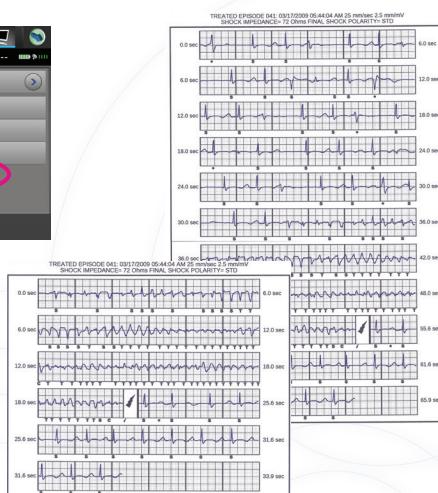


7. Print Reports

- After reviewing episodes and stored S-ECGs, and after viewing Device Settings, select the Blue Arrow Back button to return to the Main screen



- Select Print Reports
 - Remember you must view each episode before you can print
 - Print either a 12-second onset ECG or a 44-second onset ECG





8. End Session

- Select End Session on Main Menu



A warning message will be displayed to the user if any of the following conditions exist:

- AutomaticTherapy is programmed to OFF
- Reference S-ECG has not been acquired
- Setup is not complete
- Setup optimization is not complete

Note: Remember to turn programmer off after End Session.

Plug in to keep charged





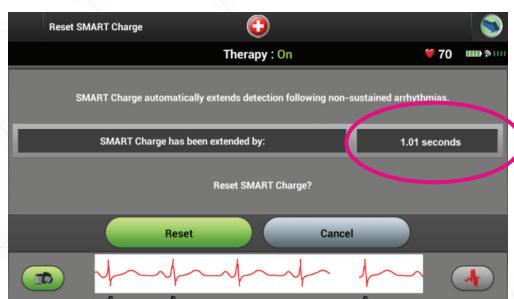
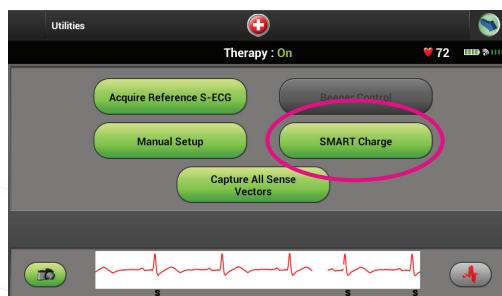
9. Resources

- a. Review SMART Charge
- b. Review Each Vector
- c. Automatic Setup
- d. How to Save a New Template
- e. Save Patient Sessions to Log Data Card
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9.a. Review SMART Charge

- From the Main screen select Utilities, select SMART Charge
 - Note time extension



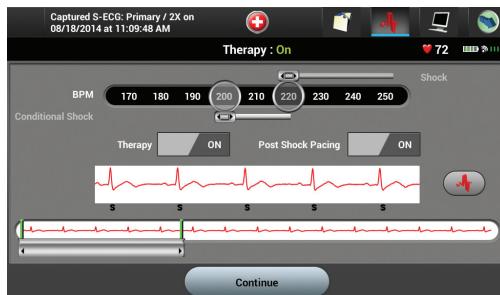
It is generally NOT recommended to reset SMART Charge



9.b. Review Each Vector

It is recommended to view each vector and snapshot at follow-up

- Select S-ECG icon
- Select each vector to review, Continue when done





9.c. Automatic Setup

- From the Main Menu select Implant
- Select the Box icon on upper screen
- Select Automatic Setup – you will receive a confirmation screen when setup is complete





9.d. How to Save a New Template

- From the Utilities screen – Select Acquire Reference S-ECG – you will receive a confirmation screen when complete
- Note: check patient notes prior to updating the template
- Select Continue to take you back to the Utilities screen

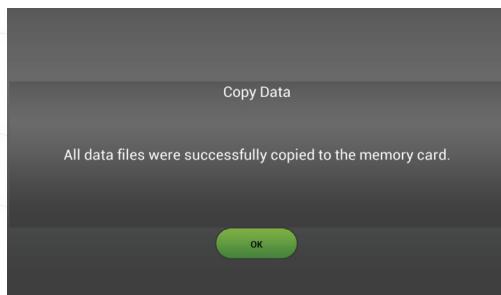
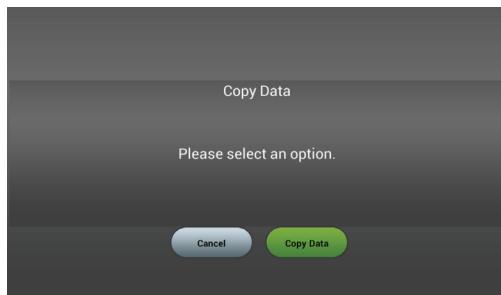




9.e. Save Patient Sessions to Log Data Card

To save patient sessions to Log Data Card:

- End Session before inserting Log Data Card
- Insert Log Data Card (Model #3205)
- Select appropriate prompts
- Remove card and store (Log Data Card can be left in tablet – you may receive a dialog window to save sessions every time you power up the tablet)



9.f. Viewing Stored Sessions

A stored session includes the following information:

- Captured S-ECG Reports (from within that session)
- Downloaded episodes
- Patient Data
- Programmed Device Settings

To view stored patient sessions:

- From the Startup screen, select Stored Patient Sessions
- Select the desired Patient Session





9.g. Reset the Programmer

The programmer's operating system is self-monitoring and is 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 if required

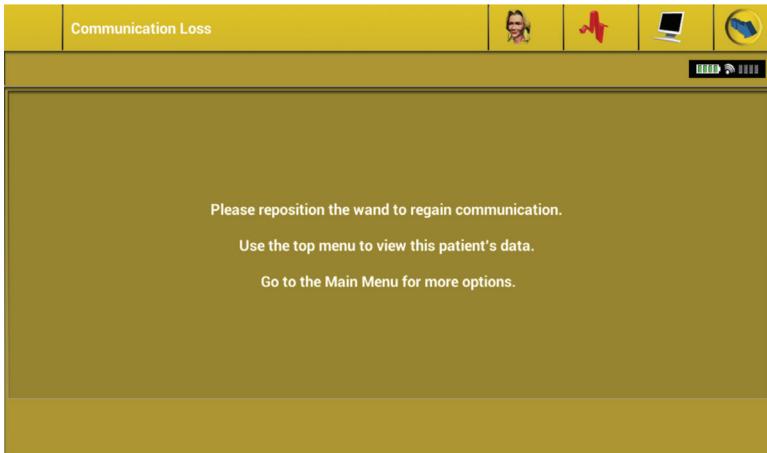
The programmer may need to be manually restarted if:

- You cannot exit a screen
- The operating system stops responding
- To manually restart: press and hold the Power button until the system shutdown menu appears on the screen. Select Restart from the popup and confirm by pressing OK



9.h. Yellow Screen

A Yellow screen warns that telemetry has been lost between the programmer and device

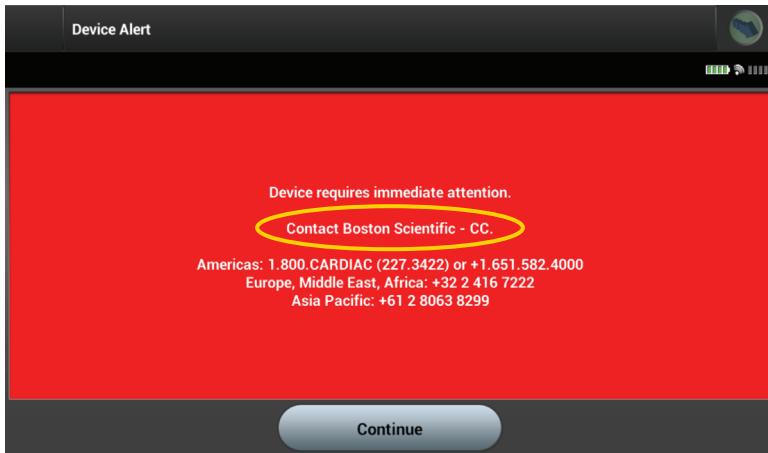




9.i. Red Screen

A Red screen depicts an error state. Please note the letter codes if presented with a Red screen

Report all Red screens to Tech Services and note the code(s) displayed –
Code CC is displayed here





10. Log Data Card

- The tablet programmer is designed to utilize a Log Data Card (Model #3205)
- Once a session is complete, patient log files/sessions can be downloaded and saved to the Log Data Card
 - 50 patient sessions are stored on the programmer
 - Oldest session is overwritten when a new session is completed
- Log Data Card receptacle is located at the bottom of the screen





10. Log Data Card

Correct Placement of the Log Data Card



Insert label up and notch to the right

Upon proper insertion of the Log Data Card, you will feel it click into place

- To remove, push in the Log Data Card and it will eject
- To remove the card once ejected, grasp by the sides and pull out

Incorrect Placement of the Log Data Card

Log Data Card can jam in the receptacle and render the tablet programmer unusable.





11. Programmer Icons

Icons	Description	User Application
	Main Menu Icon	Allows user to return to 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 State 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 the induction screen.
	Manual Shock Icon	Allows user to access the manual shock screen.
	Battery and Telemetry Meter Icon	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 Icon	Allows user to capture a live S-ECG.
	S-ECG Display Settings Icon	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 Icon	Allows user to administer a rescue shock.
	Option Selection Slider Switch Icon	Allows user to select one of two options, e.g. A or B.

EMBLEM™ S-ICD System from Boston Scientific CRM

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.

Warnings: Read this manual thoroughly before using the S-ICD System to avoid damage to the pulse generator and/or subcutaneous electrode. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or re-sterilize. 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. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow-up testing.

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.

Concomitant use of the S-ICD System and implanted electromechanical devices (for example a ventricular assist device, VAD; or implantable insulin pump or drug pump) can result in interactions that could compromise the function of the S-ICD, the co-implanted device, or both. Electromagnetic (EMI) or therapy delivery from the co-implanted device can interfere with S-ICD sensing and/or rate assessment, resulting in inappropriate therapy or failure to deliver therapy when needed. In addition, a shock from the S-ICD pulse generator could damage the co-implanted device and compromise its functionality. To help prevent undesirable interactions, test the S-ICD system when used in combination with the co-implanted device, and consider the potential effect of a shock on the co-implanted device. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. Do not modify, cut, kink, crush, stretch or otherwise damage any component of the S-ICD System. Use caution handling the subcutaneous electrode connector. Do not directly contact the connector with any surgical instruments such as forceps, hemostats, or clamps. Use appropriate anchoring techniques as described in the implant procedure to prevent S-ICD System dislodgment and/or migration. Use caution when placing a magnet over the SICD pulse generator because it suspends arrhythmic detection and therapy response. 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. Do not expose a patient with an implanted S-ICD System to diathermy. Do not expose a patient to MRI scanning. 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. The pulse generator may be more susceptible to low frequency electromagnetic interference at induced signals greater than 80 uV. The S-ICD System has not been evaluated for pediatric use.

Precautions: For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow-up testing, explant and disposal and supplemental precautionary information.

Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

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, hem thorax, improper electrode connection to the device, inability to communicate with the device, inability to defibrillate or pace, inappropriate post shock pacing, inappropriate shock delivery, infection, keloid formation, migration or dislodgment, 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.

Patients who receive an S-ICD System may develop psychological disorders that include, but are not limited to, the following: depression/anxiety, fear of device malfunction, fear of shocks, phantom shocks.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. A)

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CRM-303804-AA APR2015

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