

## SUMMARY

The Boston Scientific Q-TECH™ Programmer allows the user to save therapy history, programmed parameter values, and device diagnostic data files from an SQ-RX® pulse generator to an SD memory card.

This article provides an overview of how to save patient data from a programmer to an SD card.

*Definitions of terms used in this article:*

**S-ICD:** Subcutaneous Implantable Defibrillator

**Secure Digital (SD) Card:** A memory card with a non-volatile format

### Products Referenced

Model 1010 SQ-RX® Pulse Generator  
Model 2020 Q-TECH™ Programmer

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: [www.bsci.com/ifu](http://www.bsci.com/ifu).

**CAUTION:** Federal (U.S.) law restricts this device to sale by or on the order of a physician. Physician must be trained or experienced in device implant and follow-up procedures.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

### Contact Information

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## Saving Data from an SQ-RX® Pulse Generator to an SD Memory Card Using a Q-TECH™ Programmer

Patient and device data from a Boston Scientific SQ-RX® Pulse Generator can be downloaded from device memory and stored within a Q-TECH™ programmer. The information stored on the programmer can then be saved to a secure digital (SD) card upon completion of any programmer session.

The following types of data are saved when a Save to SD Card is performed:

- Current and start-of-session programmed values and patient data\*
- Battery and electrode status
- Therapy history and captured S-ECG episodes
- Device diagnostic data

To be saved within a session, desired episodes (treated and/or untreated) **must** be selected and viewed while in that programmer session. To view stored episodes:

1. Select the Follow Up button from the Main Menu.
2. Select the Captured and Stored Episodes S-ECG icon from the navigation bar.
3. Select the Episodes toggle switch to access the episodes pick list.
4. Select an episode from the list; the selected Episodes screen appears.
5. Select the Continue button to return to the pick list screen.
6. Once all desired sessions have been selected and viewed, choose “End Session” on the programmer screen.\*\*

Any episodes (other than S-ECGs from commanded therapy) that are not viewed while in the session will not be downloaded from the device and stored in the programmer. Thus, they cannot be saved to the SD card. Captured S-ECGs stored within a session will be available to save to an SD card whether or not they are viewed.

### Selecting and Initializing the SD Card

Once the session has ended, a Cameron Health validated Log Data SD card may be inserted for initialization. Table 1 contains Insertion and Initialization instructions.

### Copying Data

Once an SD card has been inserted and initialized, a series of pop-up windows will appear on the Programmer screen. Follow the instructions in Table 2 to copy data from the programmer to the card.

### Submitting Data to Boston Scientific Technical Services

Send the SD card contents to Technical Services using the programmer application (preferred) or e-mail the full contents of the SD card to Technical Services. Please contact Technical Services at the appropriate number for your region (listed in the sidebar) for e-mailing instructions.

\*Patient name is not exported due to HIPAA regulations; reports printed from an SD card will contain device serial number, follow-up date, and time in place of the patient's name. However, if the patient's name is listed within the notes section, the name will appear on the printed report.

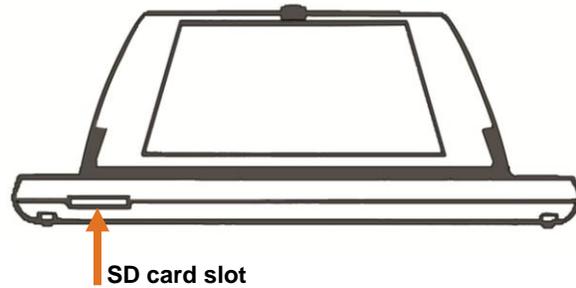
\*\* If “End Session” is not chosen before the SD card is inserted, a red screen directing users to call Customer Service will appear on the programmer. All current session data, including any downloaded episodes and captured S-ECGs will not be stored. They will need to be downloaded again to be saved to an SD card.

**TABLE 1. Inserting and Initializing the SD Card**

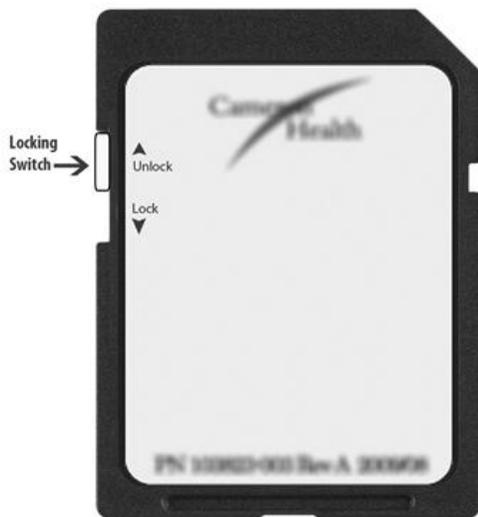
**Step 1:** Navigate to the Start Menu



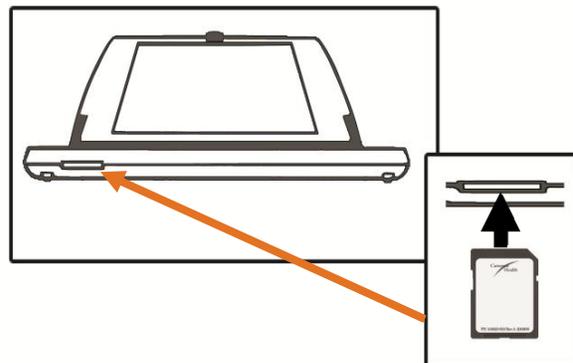
**Step 2:** Locate the SD card slot positioned in the lower left front of the programmer just below the keyboard.



**Step 3:** Verify that the locking switch on the SD card is in the unlocked (up) position.



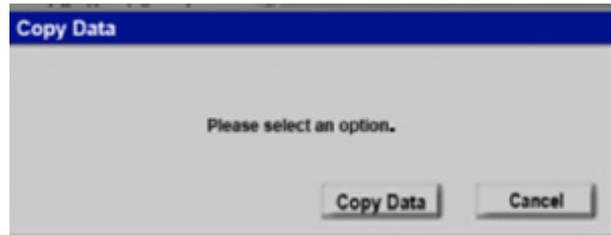
**Step 4:** Insert the SD card into the programmer. Ensure that the Cameron Health logo is facing up and oriented as shown; the metal contacts on the card will be facing down and will enter the SD card slot first.



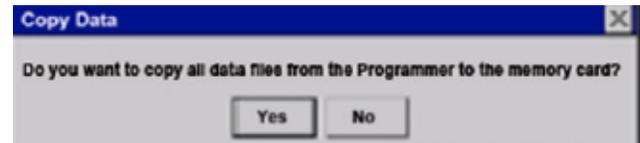
**TABLE 2. Copying Data from the Q-TECH Programmer to the SD Card**

Once the SD card has been successfully inserted, a series of pop-up windows will appear on the Programmer screen.

**Step 1:** Select Copy Data



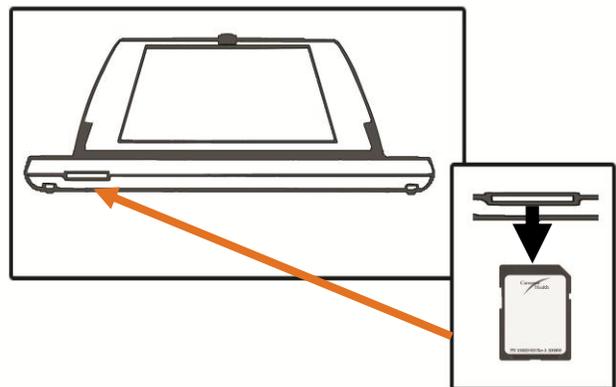
**Step 2:** Select Yes to save Programmer data to the memory card. It will take approximately 15 seconds for the Copy Data process to complete.



**Step 3:** Once the Copy Data process is complete, select the OK button located in the upper right hand corner of the dialog box.



**Step 4:** Remove the SD card by pressing briefly on it so it ejects. Original "Copy Data" window will close upon SD card removal.



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## The S-ICD® System from Boston Scientific CRM

### Indications

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 pacemakers are contraindicated for use with the S-ICD System.

### Warnings and Cautions

The S-ICD System contains sterile products for single use only. Do not resterilize. Handle the components of the S-ICD System with care at all times and maintain proper sterile technique. All Cameron Health implantable components are designed for use with the Cameron Health S-ICD System only. Connection of any S-ICD System components to any other ICD system will result in failure to deliver lifesaving defibrillation therapy. External defibrillation equipment should be available for immediate use during the implantation procedure and follow-up. Placing a magnet over the SQ-RX Pulse Generator suspends arrhythmia detection and therapy response. Removing the magnet resumes arrhythmia detection and therapy response. Battery depletion will eventually cause the SQ-RX Pulse Generator to stop functioning. Defibrillation and excessive numbers of charging cycles shorten the battery longevity. The S-ICD System has not been evaluated for pediatric use. The S-ICD System does not provide long-term bradycardia pacing, Cardiac Resynchronization Therapy (CRT) or Anti-Tachycardia Pacing (ATP).

### Potential Adverse Events

Potential adverse events from 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; Hemothorax; Improper electrode connection to the device; Inability to communicate with the device; Inability to defibrillate or pace; Inappropriate post-shock pacing; Inappropriate shock delivery; Infection; Keloid formation; Migration or dislodgement; Muscle 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.

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

*(Rev. A) NOTE: Most Current Revision Found @ <http://www.bostonscientific.com/cardiac-rhythm-resources/index.html>? > Product Information > View Featured Products > Prescriptive Information*

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