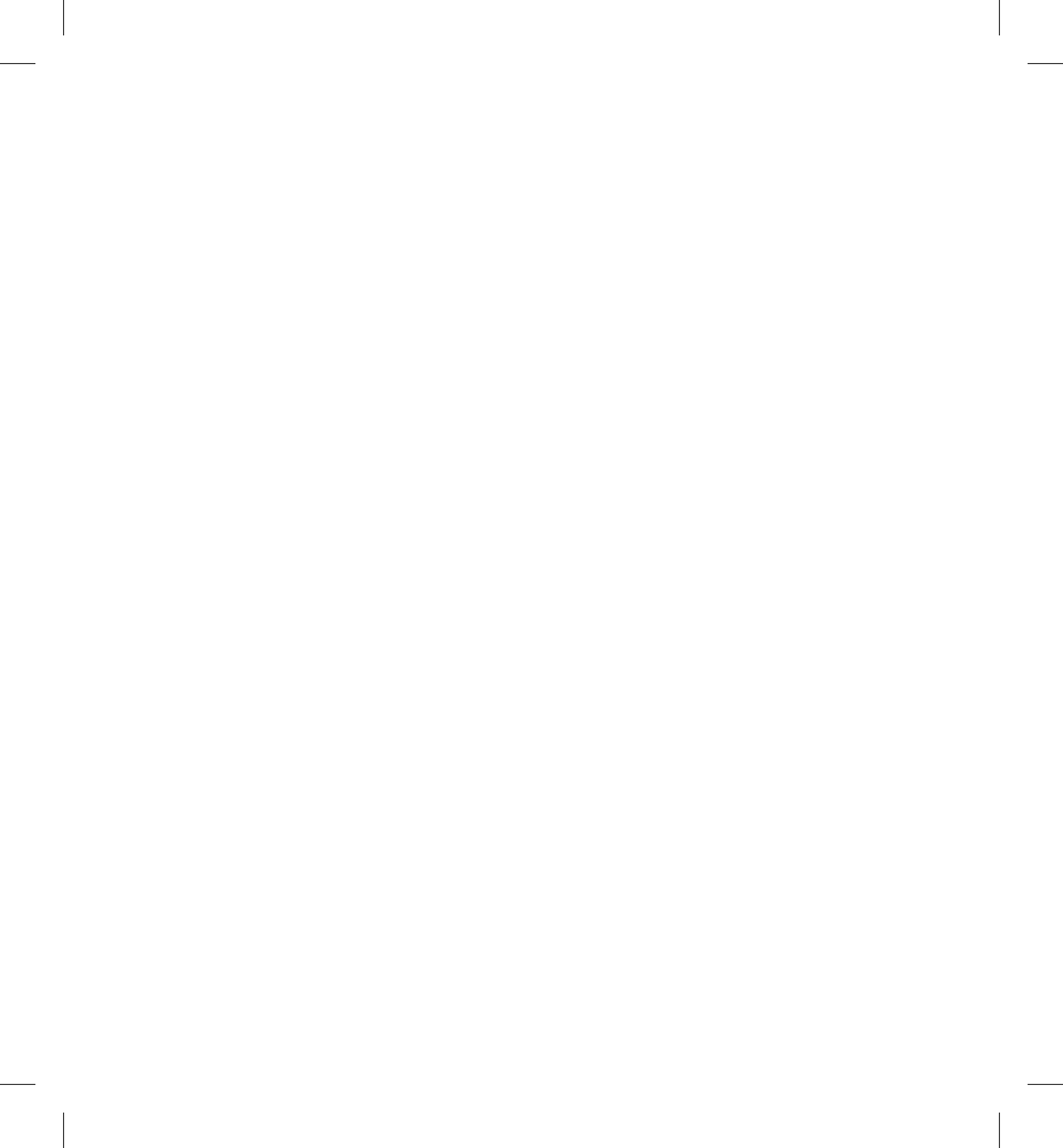




MODEL 3877 EMBLEM™ S-ICD SYSTEM APPLICATION*
SUPPLEMENT FOR PULSE GENERATOR MANUALS

S-ICD PHYSICIAN'S TECHNICAL MANUALS

***FOR THE LATITUDE™ PROGRAMMING SYSTEM, MODEL 3300**



This supplement provides a high-level overview of the key differences in the S-ICD software application software between the Model 3300 LATITUDE™ Programming System¹ (Programmer) and the Model 3200 EMBLEM™ S-ICD Programmer.

Current S-ICD pulse generator manuals describe features and functionalities when used with the Model 3200 EMBLEM S-ICD Programmer. This literature supplements the content in those manuals with information specific to the Model 3300 LATITUDE Programming System.

NOTE: *The LATITUDE Programming System, Model 3300, has the same basic capabilities and intended use as the EMBLEM S-ICD Programmer, Model 3200.*

Primary Resources

Separate operator manuals are provided for the Model 3300 LATITUDE Programming System and the Model 3877 EMBLEM S-ICD Application. Please read these manuals first:

- LATITUDE Programming System Operator's Manual, Model 3300
- Network and Connectivity Operator's Manual, Model 3924
- EMBLEM S-ICD Application Operator's Manual, Model 3877

For electronic copies, go to www.bostonscientific-elabeling.com. For hard copies, contact Boston Scientific using the information on the back of this supplement.


GENERAL DIFFERENCES

Connecting to an S-ICD Device

- The required Model 3203 S-ICD Wand connects to a port on the right side of the Programmer (Figure 1 on page 3).
- The Model 3877 S-ICD Device Programmer application and Model 3889 Automated Screening Tool application are accessed from the main menu of the Model 3300 Programmer:
 - To access the Model 3877 S-ICD application, select S-ICD Applications icon from the Programmer Main Menu, then select S-ICD Device Programmer Application, as shown in Figure 2 on page 4. Press the Scan for Devices button to find and connect to an S-ICD device.
- The Model 3877 S-ICD Application loads about 30 seconds after the S-ICD Device Programmer Application button is pressed.
- The battery status for the Programmer is visible on the upper right of the S-ICD application main screen (Figure 3 on page 5).

¹ The Model 3300 Programmer may not yet be available in all geographies. For additional information, contact Boston Scientific using the information on the back of this supplement.

Rescue Shock

- To provide a rescue shock, interrogate the S-ICD pulse generator (PG), enable therapy on the S-ICD PG (Programmer screen displays "Therapy: On"), and press either the red STAT hard key at the upper right of the Model 3300 Programmer or the Rescue Shock button  from the S-ICD application.
- The STAT Operation is for defibrillation therapy only; there is no STAT pacing available.

Utilities

- **Programmer Language:** The programmer language is selected from the Model 3300 Utilities toolbar. Select the Setup tab and then the appropriate language.
- **Time Zone:** The time zone is selected from the Model 3300 Utilities toolbar. Select the Date and Time tab and then the appropriate time zone.
- **Noise Filter Configuration:** The noise filter configuration for the Model 3300 Programmer is now a separate selection (50 or 60 Hz) in the S-ICD application and is set at the factory according to the geography.²
- **Bluetooth® Communication:** *Bluetooth®* communication is enabled from the Model 3300 Utilities toolbar. Select the Network Setup tab and then the *Bluetooth®* tab to activate the *Bluetooth®* capability of the Model 3300 Programmer. This is necessary in order to have the S-ICD application use *Bluetooth®* printers and communicate with other *Bluetooth®* enabled computers.

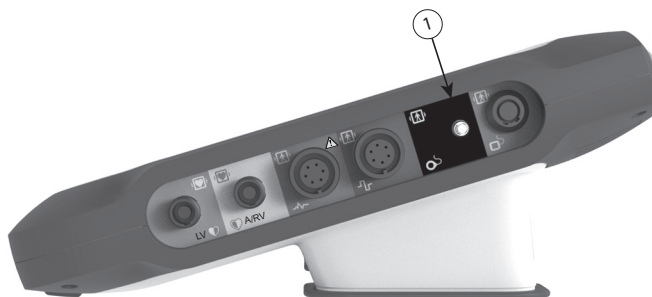
Patient Data

- The microSD™ card port on the Model 3200 Programmer has been replaced by USB ports on the Model 3300 Programmer.
- To save patient and device information, insert a USB drive³ while you are at the S-ICD application main screen (Figure 3 on page 5). After a short delay, the Copy Data screen displays, and data can be copied to the USB drive.
- To store patient and device data on the Model 3300 Programmer internal drive, the user must first interrogate the pulse generator. Then, pressing the End Session button from the S-ICD Main Menu (see Figure 4 on page 5) stores the patient data on the internal drive. To access stored S-ICD data, launch the S-ICD application, then select Stored Patient Sessions (see Figure 3 on page 5).
- Patient data on the Model 3300 hard drive is encrypted. When exporting patient data to a USB drive, the Model 3300 Programmer provides an option to create a password on the USB drive.
- The S-ICD software maintains a maximum of 50 patient files; the oldest is deleted and overwritten when the 51st patient file is created.

² The filter setting can be changed if the Programmer is moved to a different geography.

³ A USB storage device must be formatted to FAT32 to be recognized by the Programmer.

- Stored patient and device data older than 90 days is automatically purged without notification to the user.



[1] Model 3203 S-ICD Wand Connection Port

Figure 1. Right-hand (Patient) Side of the Model 3300 Programmer

DESCRIPTION

The pulse generator and subcutaneous electrode constitute the implantable portion of the S-ICD System. The pulse generator can be used only with the Model 3203 Telemetry Wand and either a) the Model 3200 EMBLEM S-ICD programmer or b) the Model 3300 LATITUDE Programming System.

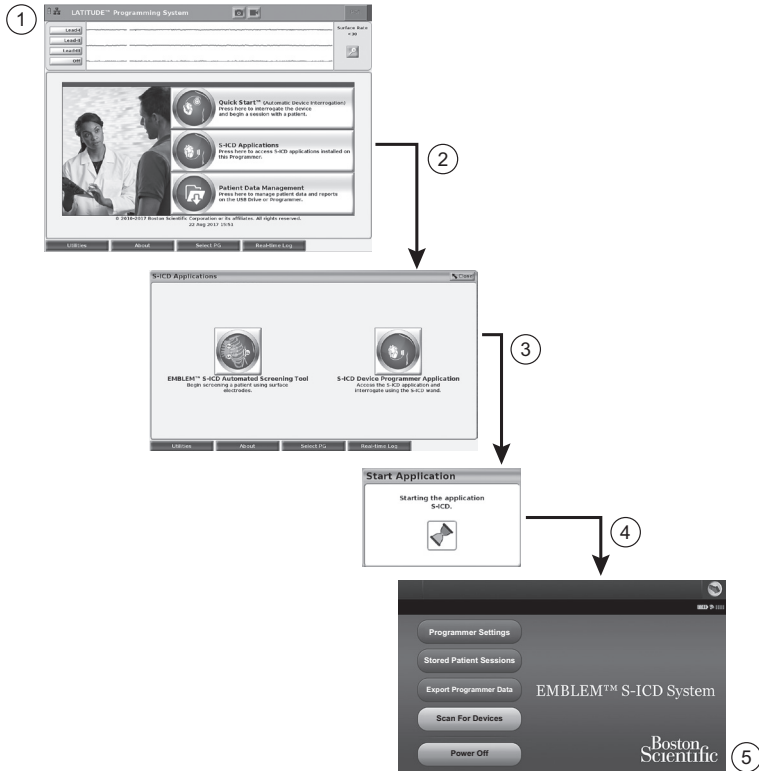
SETTING UP THE PULSE GENERATOR USING THE MODEL 3300 PROGRAMMER

A brief setup process must be completed before the device can deliver therapy. Additional details can be found in the *EMBLEM™ S-ICD Application Operator's Manual, Model 3877*.

To initiate the process: (see Figure 2 on page 4)

1. From the main screen of the 3300 Programmer, press the S-ICD Applications button.
2. The S-ICD Applications window displays.
3. Press the S-ICD Device Programmer Application button.
4. Wait until the application loads (about 30 seconds) and displays the S-ICD application main screen.
5. From the S-ICD application main screen, begin a programming session for the S-ICD PG by pressing the Scan For Devices button.

6. Select an S-ICD PG from the list.
7. If the S-ICD PG selected is still in shelf mode, press the Continue button to exit shelf mode.
8. Start the manual or automatic setup process.



[1] Model 3300 Main Menu [2] S-ICD Applications button [3] S-ICD Applications [4] Start S-ICD Application dialog [5] S-ICD Application main screen

Figure 2. Accessing the S-ICD Application (representative images)

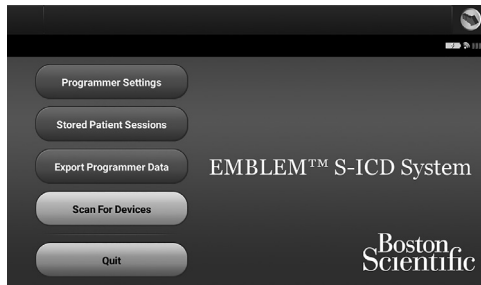


Figure 3. S-ICD Application main screen



Figure 4. S-ICD Main Menu

TRADEMARK STATEMENT

The following are trademarks of Boston Scientific Corporation or its affiliates: LATITUDE and EMBLEM.

The *Bluetooth®* word mark and logos are registered trademarks owned by Bluetooth SIG, Inc., and any use of such marks is under license.

microSD (secure digital) is a trademark of the SD Association (SD-3C, LLC)



92123954-001 en 2020-01



MANUFACTURER

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

MANUFACTURED AT

Cardiac Pacemakers Incorporated
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

1.800.CARDIAC (227.3422)
+1.651.582.4000

www.bostonscientific.com

EC

REP

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

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

AUS

AUSTRALIAN SPONSOR ADDRESS

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY NSW 1455 Australia

Free Phone 1 800 676 133
Free Fax 1 800 836 666

© 2020 Boston Scientific Corporation or its affiliates.

All Rights Reserved.