Medtronic

CareLink SmartSync[™] Azure[™] Astra[™] Application Help



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1 Introduction

1.1 Description

The CareLink SmartSync Azure Astra Application (referred to as the implantable device app) communicates with Azure MRI SureScan™ and Astra MRI SureScan pacemakers and allows you to program the device settings and view stored device data.

Use the implantable device app to perform the following tasks:

- Review the presenting rhythm
- · Verify the status of the implantable device
- Assess the clinical effectiveness of the implantable device
- View or enter patient information
- Program parameters
- · Save or export data

The implantable device app is a component of the CareLink SmartSync device manager.

This app help applies to a family of implantable device models. Not all features described in this app help are available in all the implantable device models in the family. To determine which features are available for a specific implantable device model, refer to the device manual

Note: The CareLink SmartSync Azure Astra Application model number is D00U003.

1.2 Intended use of the implantable device app

1.2.1 Intended use

The implantable device app is intended to be used as part of the device manager. Clinicians use the implantable device app with the patient connector to adjust programmable parameters and evaluate the performance of implantable Azure MRI SureScan and Astra MRI SureScan systems.

The implantable device app is intended for use by healthcare professionals or Medtronic representatives in a clinical or hospital environment.

For information about indications for the implantable devices that are compatible with the implantable device app, refer to the device manual.

1.2.2 Intended users

The implantable device app is intended for use by healthcare professionals or Medtronic representatives in a clinical or hospital environment.

1.2.3 Intended patient population

The implantable device app is intended for use with patients who either have or are receiving a supported implantable device.

1.2.4 Expected clinical benefits

The clinical benefit of the implantable device app is the ability to interrogate and program Medtronic implantable devices and test cardiac leads.

1.2.5 Indications for use

For information about the indications for the implantable devices that are compatible with the implantable device app, refer to the device manuals.

1.2.6 Contraindications

There are no known contraindications for the use of the implantable device app.

Note: For information about contraindications for the implantable devices that are compatible with the implantable device app, refer to the device manuals.

1.3 Warnings and precautions

These warnings and precautions apply when using the implantable device app in combination with the other device manager components.

Note: For warnings and precautions about the use of the implantable devices that are compatible with the implantable device app, refer to the device manuals.

Importance of instructions for use – Before using the implantable device app, Medtronic recommends that you do the following:

- · Read the implantable device instructions for use.
- Read the device manager instructions for use.
- Carefully assess the patient's condition and the implantable device system to determine the appropriate settings for tests and device programming.

Improper use of the implantable device app could result in erroneous programming, inadvertent pacing, improper operation of telemetry, or incorrect operation of measurement functions.

Tablet and app interaction – Due to the dynamic nature of the tablet environment, operating system events such as notifications, alarms, and messaging can take priority and, therefore, move the implantable device app to the background. Tapping, pressing buttons, and using gestures on the tablet can also result in moving the implantable device app to the background or closing the implantable device app. For example, the implantable device app moves to the background if you lock the tablet.

When the implantable device app moves to the background or closes, telemetry with the implantable device is paused or lost, which results in the following scenarios:

- If detection has been suspended and there is no magnet present, the implantable device resumes detection within a few seconds. For more information, see the section on suspending and resuming tachyarrhythmia detection in this app help.
- If a test is in progress, whether the test continues or stops depends on the type of test. For more information, refer to the section on performing system tests in this app help.

When you restore the implantable device app from the background, the implantable device app attempts to re-establish communication with the implantable device and displays the system status. If the implantable device app was closed, you must interrogate the implantable device to re-establish communication with the implantable device.

Electromagnetic interference – If electromagnetic interference (EMI) occurs during a telemetry session, EMI can prevent the proper programming or confirmation of values. For more information about EMI, refer to the medical procedure and EMI warnings and precautions manual.

1.4 Potential adverse events

There are no known potential adverse events related to the use of this implantable device app.

For information about potential adverse events related to the use of the implantable devices that are compatible with the implantable device app, refer to the device manuals.

1.5 Download or order the instructions for use

To view, download, or print a PDF version of this app help, go to www.medtronic.com/manuals or contact a Medtronic representative.

The PDF version of this app help can be viewed using a current version of any major internet browser. For best results, use Adobe™* Acrobat™* Reader software with the browser.

To order a paper copy of this app help free of charge, go to www.medtronic.com/manuals or contact a Medtronic representative. The paper copy should arrive in 3 to 7 days.

1.6 IT network, tablet, and data information

1.6.1 Required IT network characteristics and configuration

To use the implantable device app, the tablet must have Bluetooth®* wireless technology1. An Internet connection is optional.

Bluetooth wireless technology

You must enable Bluetooth wireless technology on the tablet. The Bluetooth connection allows the hardware components of the device manager to communicate with the device manager app that is installed on the tablet.

Failure to provide Bluetooth communication access prevents the device manager components from communicating with each other and with implantable devices. As a result, the device manager app is unable to establish a Bluetooth connection with the patient connector and, therefore, you are unable to interrogate and program the implantable device.

Internet

To configure your network, follow the processes and policies of your organization.

Internet access is not required to export and print reports. However, failure to provide access to an information technology (IT) network (for example, a Wi-Fi^{TM*} or cellular network) results in the inability to export and print reports using a wireless connection.²

¹ The Bluetooth^{®*} word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Medtronic is under license.

² Wi-Fi[™]* and Wi-Fi[™]* logo are trademarks of Wi-Fi Alliance[®].

1.6.2 Supported tablets and technical specifications

The tablet on which the device manager app is installed must meet the requirements in the CareLink SmartSync Tablet Compatibility Technical Manual. To download or order the CareLink SmartSync Tablet Compatibility Technical Manual, go to www.medtronic.com/manuals, or contact a Medtronic representative.

Note: The device manager app may not be compatible with the most current version of the tablet operating system.

1.6.3 Intended information flow

When you are exporting patient data from the implantable device app, the data flows to the IT network.

Note: You are responsible for the management of patient and device data that you export from the app. Examples of patient and device data include printed paper reports, data transferred to a hospital network, and emailed attachments.

1.7 Reporting errors and serious incidents

If a serious incident related to the CareLink SmartSync app occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

If you find information in this app help that is incorrect, contact a Medtronic representative.

2 Overview of the interface

2.1 Areas

The implantable device app is divided into 3 areas:

- The status bar at the top of the screen includes 2 rows of status information about the device manager components and the patient session. The status bar also includes the **SUSPEND**, **RESUME**, and **EMERGENCY** buttons, the **②** (Help) button, and the **Ⅎ** (Menu) button.
- The Live Rhythm Monitor, which appears below the status bar, displays real-time waveform traces.
- The work area, which is the largest area of the screen, displays the parameters, fields, and controls for the current window.

2.2 Status indicators

The status bar at the top of the screen displays the status of the base, the tablet, the patient connector, and the implantable device. For more information, tap on the status bar.

Table 1. Base status indicators

Indicator	Description
	The base is connected to the device manager app.
	The base is connected to the device manager app, and an analyzer session is in progress.
	There is no base connected to the device manager app.
	A base was recently connected to the device manager app but is not connected now. The device manager app is attempting to reconnect to the last used base.

Table 2. Tablet status indicators

Indicator	Description
	The tablet is connected to an IT network.
	Note: The status indicator shows the remaining percentage of the tablet battery.
((-))	The tablet is not connected to an IT network.
(**)	Note: The status indicator shows the remaining percentage of the tablet battery.
SessionSync Available	The device manager app is connected to the Paceart Optima™ System. Saved implantable device data and reports can be trans-

Table 2. Tablet status indicators (continued)

Indicator	Description
	ferred to the Paceart Optima System with the SessionSync™ software.
SessionSync	The device manager app is not connected to the Paceart Optima System. The indicator shows one of the following states:
	Disconnected — The SessionSync software is enabled, but the connection to the Paceart Optima System timed out.
	Not Available — The SessionSync software is enabled, but the connection to the Paceart Optima System is unavailable.
	 Not Connected — The SessionSync software is enabled, but a secure connection to the server could not be estab- lished due to a certificate error, CareLink SmartSync is not authorized by the Paceart Optima System, or the tablet is not connected to an IT network.
	Note: The Paceart Optima System is available only in supported regions.

Table 3. Patient connector status indicators

Indicator	Description
1	The patient connector is connected to the device manager app. The patient connector battery is good.
	The patient connector is connected to the device manager app. The patient connector is charging.
	The patient connector is connected to the device manager app. The patient connector battery is low. Recharge the patient connector.
	The patient connector is connected to the device manager app. The patient connector battery is critically low. Recharge the patient connector.
	There is no patient connector connected to the device manager app.
	A patient connector was recently connected to the device manager app but is not connected now. The device manager app is attempting to reconnect to the last used patient connector.

For information about improving and restoring the connections, see the section on maintaining reliable connections in this app help.

Table 4. Implantable device status indicators

Indicator	Description
	The implantable device is connected to the patient connector using low-frequency inductive telemetry. The connection is either strong or moderate.
*	The implantable device is connected to the patient connector using Bluetooth wireless technology. The connection is either strong or moderate.
	The implantable device is connected to the patient connector using low-frequency inductive telemetry. The connection is weak.
*	The implantable device is connected to the patient connector using Bluetooth wireless technology. The connection is weak.
	The connection with the implantable device has been lost. The device manager attempts to establish the connection and restore communication.

For information about improving and restoring the connections, see the section on maintaining reliable connections in this app help.

Table 5. Connection status indicators

Indicator	Description
	The Bluetooth connection between the device manager app and the base or the patient connector is strong.
••••	The Bluetooth connection between the device manager app and the base or the patient connector is moderate.
×	The connection between 2 system components has been lost. The device manager attempts to establish the connection and restore communication.
-	There is a USB connection between the base and the patient connector.
)))	The connection with the implantable device is strong.
)))	The connection with the implantable device is moderate.
)))	The connection with the implantable device is weak.

3 Maintaining reliable connections during a patient session

3.1 About the connection status

The status bar at the top of the screen displays the status of the connections among the device manager components. The connection status is indicated by the component icons and the icons that appear between each component. For more information, see the section about the status indicators in this app help.

3.2 About the communication paths

3.2.1 Communication paths and connection types

The communication paths among components vary depending on the type of patient session. To initiate an interrogation, you must always use the patient connector. Then the system uses 1 of 2 communication paths, depending on whether you selected the **Use** wireless telemetry for device interrogation checkbox on the device manager home screen when you initiated the interrogation.

3.2.2 Patient session using Bluetooth wireless technology

If you select the **Use wireless telemetry for device interrogation** checkbox before interrogating, the implantable device communicates with the patient connector using Bluetooth wireless technology.

The following figure shows the communication path in a patient session that uses Bluetooth wireless technology:

Figure 1.



- 1 Implantable device app on the tablet
- 2 Bluetooth wireless technology
- 3 Patient connector

- 4 Bluetooth wireless technology
- 5 Implantable device

The following figure shows the connection status area of the status bar in a patient session that uses Bluetooth wireless technology:



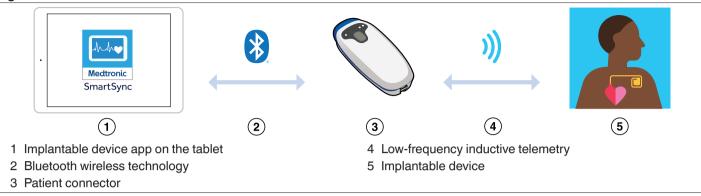
Note: The status of the base is shown in the status bar, even though the base is not involved in the communication with the implantable device.

3.2.3 Patient session using low-frequency inductive telemetry

If you clear the **Use wireless telemetry for device interrogation** checkbox before interrogating, the implantable device communicates with the patient connector using low-frequency inductive telemetry. You must leave the patient connector over the implantable device throughout the patient session.

The following figure shows the communication path in a patient session that uses low-frequency inductive telemetry:

Figure 2.



The following figure shows the connection status area of the status bar in a patient session that uses low-frequency inductive telemetry:



Note: The status of the base is shown in the status bar, even though the base is not involved in the communication with the implantable device.

3.3 Improve the connection

To improve the telemetry connection between the implantable device and the patient connector, take one or more of the following actions:

- Move the implantable device and the patient connector closer together.
- Move any possible source of electrical interference, such as a small portable electronic device, away from the implantable device and the patient connector.
- · Adjust the position of the patient connector.

To improve the Bluetooth connection between the tablet and the base or the patient connector, take one or more of the following actions:

- Move the tablet closer to the base or the patient connector.
- Move any possible source of electrical interference, such as a small portable electronic device, away from the tablet and the base or the patient connector.
- Turn off Wi-Fi™* in the tablet settings.
- Unpair other Bluetooth devices from the tablet.

3.4 Restore the connection

To restore a lost telemetry connection between the implantable device and the patient connector, take one or more of the following actions:

- Move the implantable device and the patient connector closer together.
- Move any possible source of electrical interference, such as a small electronic device, away from the implantable device and the patient connector.
- Move the tablet closer to the patient connector.

To restore a lost Bluetooth connection between the tablet and the base or the patient connector, take one or more of the following actions:

- Move the tablet closer to the base or the patient connector.
- Move any possible source of electrical interference, such as a small portable electronic device, away from the tablet and the base or the patient connector.

Note: Restore the Bluetooth connection between the tablet and the base or the patient connector within 2 min. After 2 min, Bluetooth wireless technology in the base or patient connector turns off. To attempt reconnecting the tablet to the base or patient connector, press the grey button. For information on reconnecting the tablet to the base or the patient connector, see the device manager app help.

4 Reinterrogating the implanted device

4.1 Reinterrogate the implanted device

During a device implant or a patient follow-up appointment, you can reinterrogate the implanted device.

Note: For information on how to perform an initial interrogation, refer to the device manager app help.

- 1. Tap **∃** > **INTERROGATE**.
- 2. If the INTERROGATE HOW MUCH? window appears, select one of the following options, then tap START:
 - To display all of the information stored on the implanted device, tap All.
 - To display only the information stored on the implanted device since the last patient session, tap Since Last Session.

5 Responding to device status indicator warnings

5.1 About device status indicator warnings

The implantable device automatically monitors for internal conditions that affect implantable device operation and require attention. If any such conditions occur, the implantable device saves the status indicator to its memory. The implantable device app displays the status indicator warning in a message window when you interrogate the implantable device. The status indicator warning is also displayed in the **OBSERVATIONS** area on the **Quick Look** screen.

5.2 Respond to the AT/AF THERAPIES DISABLED warning

Respond to the AT/AF THERAPIES DISABLED status indicator warning for the implantable device:

- 1. Complete one of the following actions:
 - If the status indicator warning has an **OK** button, tap **OK** to close the message.
 - If the status indicator warning has a CLEAR button, tap CLEAR to remove the status indicator.
- 2. Review the arrhythmia episode records and evaluate atrial lead integrity.
- 3. Adjust therapy parameters as needed.

5.3 Respond to the ATTENTION - ATRIAL LEAD NOT DETECTED DURING IMPLANT warning

To respond to the ATTENTION – ATRIAL LEAD NOT DETECTED DURING IMPLANT status indicator warning for the implantable device, tap **CLEAR**. If an atrial lead is not present, consider programming **Atrial Sensitivity** to **Off** and changing the pacing mode to VVI or VVIR to maximize longevity.

5.4 Respond to the WARNING - DEVICE RESET warning

Caution: If the implantable device app displays a **WARNING – DEVICE RESET** warning, contact a Medtronic representative. If the device is not yet implanted, do not implant the device.

A device reset is a safety feature that can automatically change parameter values or clear diagnostic data in response to a problem with the implantable device memory. If a device status indicator warning for a reset appears, you must clear the device status indicator. You may need to reprogram the implantable device to the desired parameters.

After a device reset, the device records a status indicator. For a device reset that requires attention, the status indicator warning for the implantable device describes how the reset affected device data. Read the message accompanying the indicator and follow the on-screen instructions carefully. If the message indicates that the reset affected implantable device parameters, you must reprogram the implantable device to restore the previous settings.

- 1. Respond to the status indicator warning:
 - a. Remove any sources of electromagnetic interference (EMI).
 - b. Notify a Medtronic representative.
 - To clear the status indicator, tap CLEAR in the window.
 A confirmation window appears, indicating that all previously interrogated data in the implantable device app will be cleared.
 - d. Tap CONTINUE.

Note: If a device reset occurred while the **MRI SureScan** parameter was programmed to **On**, the **MRI SureScan** window appears. Program the **MRI SureScan** parameter to **Off** before continuing with the next step.

- e. Interrogate the implantable device.
- 2. Determine the events leading up to the device reset:
 - a. To determine the time and date of the device reset, view the CareAlert EVENTS log.

Note: If the implantable device does not have a CareAlert EVENTS log, note the time and date when counter data was last cleared.

- b. If the device is implanted, determine what the patient was doing at the time and date of the device reset.
- c. Save the implantable device data.
- d. Send the implantable device data to a Medtronic representative.
- 3. Reprogram the implantable device:
 - a. Verify the programmed device parameters and reprogram them as necessary.

Note: If the reset affected the parameters, the implantable device operates with values that provide basic device functionality until the parameters are reprogrammed. Basic device functionality includes pacing in VVI mode at 65 bpm and, in some cases, disabled tachyarrhythmia detection and therapy.

- b. Verify that the implantable device date and time are correct. If necessary, a Medtronic representative can reprogram the date and time.
- c. To verify that the battery voltage of the implantable device is acceptable, check the BATTERY AND LEAD MEASUREMENTS window.
- d. Conduct lead impedance and pacing threshold tests as desired.

6 Using the Live Rhythm Monitor

6.1 About the Live Rhythm Monitor

The Live Rhythm Monitor displays markers, intervals, and telemetered EGM waveform traces from the implanted device. If the device manager app is connected to the base, the Live Rhythm Monitor also displays ECG waveform traces. In addition, the Live Rhythm Monitor displays annotations above the topmost waveform trace showing when programming or test events occur.

During patient sessions, you can view live waveform traces, freeze waveform traces, and access waveform strips.

The Live Rhythm Monitor displays the waveform traces on up to 6 channels. You can display any waveform trace on any channel.

6.2 Markers

Markers on the waveform trace indicate events such as pacing, sensing, detection, and delivered therapies.

Note: Any interruption in telemetry with the implanted device can result in missing markers on the waveform trace display.

Markers that indicate atrial events appear above the waveform trace. Markers that indicate ventricular events appear below the waveform trace.

Table 6. Pacing markers

Marker	Description
A	Atrial pace
AS	Atrial sense
A R	Atrial refractory sense
A b	Atrial blank sense
V P	Ventricular pace
V S	Ventricular sense
P	Proactive pace

Table 6. Pacing markers (continued)

Marker	Description
M S	Mode switch
ER	Unrecognized marker

Table 7. Detection and therapy markers

Marker	Description
T S	AT/AF sense
FS	Fast AT/AF sense
T _I	AT/AF detection
Бі	Fast AT/AF detection
T P	Tachycardia pace
Ϋ́I	VT monitor detection
Å I	Fast A&V detection

6.3 Adjust the Live Rhythm Monitor display

To change the size, order, and presentation of waveforms, complete the following actions:

- 1. To expand the Live Rhythm Monitor, tap X.
- 2. To change the settings for a channel, tap the waveform label, then complete the following actions in the channel settings window:
 - To display a different waveform trace on the channel, tap
 on the waveform list and select a waveform trace.

 Note: The Live Rhythm Monitor displays the waveform traces on up to 6 channels. You can display any waveform trace on any channel.
 - To decrease the size of the waveform trace, tap —.
 - To adjust the size of the waveform trace to its maximum size without clipping or overlapping other waveform traces, tap -√-.
 - To increase the size of the waveform trace, tap +.
 - To change the color of the waveform trace, tap and select a color.
 - To display markers on the channel, select the Markers checkbox.

Notes:

- You can display markers on only 1 channel at a time.
- If the currently selected channel already displays markers, the Markers checkbox is disabled.
- A channel that displays markers continues to display markers when you display a different waveform trace on that channel.
- To remove the display of markers from a channel, you must display markers on another channel.
- To display intervals on the channel, select the Intervals checkbox.

Notes:

- You can display intervals on only 1 channel at a time.
- If the currently selected channel already displays intervals, the Intervals checkbox is disabled.
- A channel that displays intervals continues to display intervals when you display a different waveform trace on that channel.
- · To remove the display of intervals from a channel, you must display intervals on another channel.

Close the channel settings window.

3. To change the size of a waveform trace without displaying the waveform settings window, complete the following actions:

- To increase or decrease the size of the waveform trace, swipe up or down on the waveform trace.
 A blue symbol appears momentarily to indicate that the size was adjusted. A white symbol appears momentarily when the maximum or minimum size has been reached.
- To adjust the size of the waveform trace to its maximum size without clipping or overlapping other waveform traces, double-tap on the waveform trace.
- 4. Configure the following additional adjustment options:

Option	Description
Clipping	When ON , truncates the tops and bottoms of waveforms that have high amplitudes.
ECG Filter	When ON , can improve the clarity of the ECG in the presence of interference.
Artifacts	When ON , displays line boundaries at the beginning and end of each wave. This feature is also known as pacing artifact enhancement.
Sweep Speed	Allows you to control how quickly the waveform trace is drawn across the screen. When you select a fast sweep speed, the waveform trace appears wide. When you select a slow sweep speed, the waveform trace appears narrow.
NORMALIZE	Adjusts the size of all displayed waveform traces to their maximum size without clipping or overlapping.
CALIBRATE	Adds a reference signal to the waveform trace of ECG.
ОК	Closes the adjustment options.

To minimize the Live Rhythm Monitor, tap X.

6.4 Freeze live waveform traces

To capture a waveform strip and to generate a report, complete the following actions:

- 1. From the Live Rhythm Monitor, tap 1.
- 2. To modify the waveform strip, use the options on the **FROZEN STRIP** window.
- 3. To generate a report of the waveform strip, complete the following actions:
 - a. Tap the PDF button.
 - b. Select the strips that you want to include in the report.
 - c. Tap **GENERATE REPORT > OK**.

7 Using the eStrip recorder

7.1 About the eStrip recorder

You can use the eStrip recorder to view waveform strips, add and modify waveform strips, and generate reports of waveform strips.

To open the eStrip recorder, tap ≡ > ESTRIP RECORDER. You can also open the eStrip recorder by freezing live waveform traces (⊚) from the Live Rhythm Monitor.

When you open the eStrip recorder, the **FROZEN STRIP** window appears and allows you to view the last 30 min for any of the waveform traces from the Live Rhythm Monitor. You can scroll horizontally along the waveform traces, or you can quickly navigate a waveform trace by using the Holter feature. Highlights on the waveform traces indicate waveform strips.

Waveform strips are available to view for the duration of the patient session, including strips that are older than 30 min. To view the waveform strips, use the strips list or the Holter feature.

7.2 Modify the display of waveform traces

Modify the display of waveform traces using the following options from the FROZEN STRIP window:

- To change the sweep speed for the waveform traces, tap
 on the sweep speed list and select a value.
 When you select a fast sweep speed, the waveform trace appears wide. When you select a slow sweep speed, the waveform trace appears narrow.
- To change the waveform source, tap

 on the waveform source list and select a source.
- To increase the size of the displayed waveform trace, tap +.
- To decrease the size of the displayed waveform trace, tap -.

7.3 Configure waveform strip preferences

To set clipping and artifacts options, or to set the default duration for new waveform strip highlights, configure waveform strip preferences:

- 1. From the FROZEN STRIP window, tap /.
- 2. Use the following options:

Option	Description
Clipping	When ON , truncates the tops and bottoms of waveforms that have high amplitudes.
Show Artifacts	When ON , displays line boundaries at the beginning and end of each wave. This feature is also known as pacing artifact enhancement.
HIGHLIGHT DURATION	Allows you to set the default duration for all new waveform strip highlights.

3. To save your preferences, tap OK.

7.4 Access waveform strips

To view, modify, and generate reports of waveform strips, complete the following actions in the FROZEN STRIP window:

- 1. To view waveform strips, perform one of the following actions:
 - To select a waveform strip, tap STRIPS, then tap a waveform strip from the list.
 Note: In the STRIPS list, the NOTES field displays
 \(\tilde{\text{N}} \) or
 \(\tilde{\text{w}} \) when the waveform strip includes a pinned caliper measurement or note.
 - To view the previous or next waveform strip, tap

 or

 .
- 2. To add or remove a waveform strip, perform one of the following actions:
 - To add a waveform strip, tap the following button:



• To remove a waveform strip, tap its green header, then tap the following button:



Note: You cannot remove test strips or the Presenting Rhythm strip.

- 3. To modify the waveform strip, use the options on the **FROZEN STRIP** window.
- 4. To generate a Strip Chart Report, complete the following actions:
 - a. Tap the PDF button.
 - b. Select the strips that you want to include in the report.
 - c. Tap GENERATE REPORT > OK.

7.5 Change the length of a waveform strip

To change the length of a waveform strip, complete the following actions:

Notes:

- You cannot change the length of test strips or the Presenting Rhythm strip.
- The waveform strips cannot overlap each other.
 - 1. From the **FROZEN STRIP** window, choose a strip, then tap its green header.
 - 2. Drag the vertical border of the waveform strip to make it longer or shorter.

If you want to move the waveform strip, drag the horizontal border to the right or left.

7.6 Measure time intervals

To measure time intervals on the waveform strip, use the caliper tool:

- 1. From the FROZEN STRIP window, tap A.
- 2. Use the following options:
 - To adjust the caliper, drag
 - To walk the caliper, tap ①.

- To pin the caliper measurement and include the caliper measurement in a strip report that you generate, tap ...
- To undo or redo a pinned caliper measurement, tap or •.
- 3. To close the caliper tool, tap A.

7.7 Draw notes

To annotate the waveform strip, draw notes on the waveform strip. If you generate a report of the strip, the notes that you draw on the waveform strip are included in the report.

- 1. From the **FROZEN STRIP** window, tap ...
- 2. Draw on the waveform strip.
- 3. Optionally, tap **⊙** or **⊙** to remove or reinsert drawings.
- 4. To disable the drawing mode, tap ...

7.8 Edit the title of a waveform strip

To edit the title of a waveform strip, complete the following actions:

Note: You cannot edit the titles of test strips or the Presenting Rhythm strip.

- 1. From the FROZEN STRIP window, choose a strip if the desired strip is not already displayed.
- 2. To open the keyboard, take one of the following actions:
 - If the strip is highlighted with a wide, green border on all sides, tap the strip title.
 - If the strip is not highlighted with a wide, green border on all sides, tap the strip title to highlight it, then tap the strip title
 again.
- 3. Enter a new title and tap OK.

7.9 Use the Holter feature

To navigate quickly along a waveform trace, use the Holter feature in the FROZEN STRIP window:

- 1. To select the waveform trace that you want to view, tap on the top waveform source list and select a source.
- 2. Tap HOLTER.

The blue rectangle indicates the section of the waveform trace that is displayed in the **FROZEN STRIP** window. A green rectangle indicates a waveform strip.

- 3. Use the following options:

 - Tap an area of the waveform trace to display that area in the FROZEN STRIP window.

8 Viewing summary data using the Quick Look™ screen

8.1 About the Quick Look screen

The **Quick Look** screen provides a summary of the most important indicators of the implanted system's operation and the patient's condition since the last patient session. The screen includes links to more detailed status and diagnostic information stored in the implanted device.

Use the Quick Look screen to view the following information:

- Device and lead status information that indicates whether the implanted system is operating as expected
- Information about arrhythmia episodes and provided therapies, which helps to assess the patient's clinical status since the last follow-up appointment
- System-defined observations about unexpected conditions, along with suggestions on how to optimize the implanted device settings

Note: The **Quick Look** screen displays the information collected and stored in the implanted device memory since the last patient session. However, the **OBSERVATIONS** section can also reflect programming changes made during the current patient session.

To update the Quick Look data during a patient session, reinterrogate the implanted device.

8.2 View the Quick Look screen

To view the Quick Look screen, tap E > Quick Look. You can view the following information:

Section	Description
REMAINING LONGEVITY	Displays the estimated time remaining until Recommended Replacement Time (RRT).

Section	Description
	To view more details, tap REMAINING LONGEVITY .
IMPEDANCE (Ω) THRESHOLD (V @ ms) AMPLITUDE (mV)	Displays information about the lead status, which allows you to assess the performance and integrity of leads and identify any unusual conditions. The graphs display lead impedance, capture threshold, and sensing amplitude measurements recorded over the last 12 months. The graph legends show the most recent measurements for each lead. Use the following options: To view detailed lead trend data, tap LEAD TRENDS . To view more details about the most recent measurements, tap LAST MEASURED . Where applicable, to hide or show the atrial or RV lead data on the graphs, tap A or RV .
% OF TIME	Displays information that helps you to assess the patient's AV conduction status and to evaluate the effectiveness of programmed implanted device settings.
	Notes:
	• MVP On and MVP Off refer to the currently programmed pacing mode, not the usage of MVP™ mode pacing since the last patient session. If the implanted device was programmed to an MVP mode during the reporting period, a high percentage of ventricular pacing may indicate that the patient has heart block.
	 The paced and sensed event counters do not count all events recorded by the implanted device. Some device features (for example, Ventricular Safety Pacing) affect the way events are counted. Also, due to rounding, the percentages may not add up to 100%.
TREATED	Displays the number of treated arrhythmia episodes that occurred since the last patient session. To view more details, tap TREATED .
MONITORED	Displays the number of monitored arrhythmia episodes that occurred since the last patient session. To view more details, tap MONITORED .
Cardiac Compass	Opens the Cardiac Compass TRENDS window, which provides a picture of the patient's condition during the last 14 months. The trend information can help you assess whether the implanted device therapies or antiarrhythmic drugs are effective.
RATE HISTOGRAMS	Opens the RATE HISTOGRAMS window, which displays information about heart rates recorded between patient sessions. The data can help you to monitor the patient's condition and assess the effectiveness of therapies.
	Note: The recording time spans from the start of a session to the start of the next session.
OBSERVATIONS	Displays observations that are based on an analysis of programmed parameters and data collected since the last patient session. The OBSERVATIONS section can also reflect programming changes made during the current patient session. Observations alert you to unexpected conditions related to implanted device and lead status, parameter settings, arrhythmia episodes, and clinical status. When you select one of the displayed observations, the arrow next to the OBSERVATIONS section title becomes active if more information about the selected observation is available. To view the relevant details, tap OBSERVATIONS .

9 Using emergency VVI pacing

9.1 Enable emergency VVI pacing

To quickly enable high-output ventricular pacing, program emergency VVI pacing:

Note: When you program emergency VVI pacing, the implantable device app disables MRI SureScan operation.

- 1. Verify that telemetry is established between the implanted device and the patient connector.
- 2. Tap **EMERGENCY**.
- 3. Tap **PROGRAM**.

The implanted device delivers emergency VVI pacing and the EMERGENCY PROGRAM - SUCCESSFUL window appears.

- 4. Close the EMERGENCY PROGRAM SUCCESSFUL window.
- 5. When the emergency is resolved, tap **EXIT EMERGENCY** to close the **EMERGENCY VVI PACING** window.
- 6. Reprogram the implanted device settings to values appropriate for the patient.

10 Suspending and resuming tachyarrhythmia detection

10.1 Suspend and resume tachyarrhythmia detection during a patient session

To suspend tachyarrhythmia detection temporarily during a patient session, tap **SUSPEND**. The second row of the status bar turns vellow and replaces the patient name with **SUSPENDED**.

To resume tachyarrhythmia detection, tap **RESUME**.

Note: The presence of a magnet has no effect on tachyarrhythmia detection unless telemetry is lost.

Loss of telemetry during a patient session

If telemetry is lost, the state of tachyarrhythmia detection is affected by whether or not a magnet is present. On the screen, the second row of the status bar displays a status message.

Table 8. States of tachyarrhythmia detection

Magnet present	State prior to a loss of telemetry	State when telemetry is lost or re- gained
Yes	Suspended	Suspended ^a
Yes	Resumed	Resumed
No	Suspended	Resumed ^b
No	Resumed	Resumed ^b

^a If you remove the magnet while telemetry is lost, tachyarrhythmia detection resumes.

10.2 Suspend and resume tachyarrhythmia detection outside of a patient session

To suspend tachyarrhythmia detection temporarily outside of a patient session, place a magnet over the implantable device.

To resume tachyarrhythmia detection, remove the magnet.

11 Programming patient information

11.1 Program the patient information

To store information about the patient, the implantable device, and the leads for later use, enter and program the patient information into the implantable device memory. When you program the patient information, the status bar displays the patient name. Also, the implantable device app includes the patient name, the patient ID, and the serial number of the implantable device on reports.

Typically, you enter the patient information at the time of implant, but you can revise it at any time.

Note: The PATIENT INFORMATION screen should not be used in place of the patient's medical chart. The PATIENT INFORMATION screen is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the patient information that end users enter into the PATIENT INFORMATION screen. MEDTRONIC SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

1. Tap **∃** > **PATIENT INFORMATION**.

2. On the **PATIENT INFORMATION** screen, tap each field, then enter or select the information.

Field	Description	
Patient	Opens the Patient window, which allows you to enter the patient's name.	
	Note: There is a limit of 29 characters.	
ID	Opens the ID window, which allows you to enter the patient ID.	
	Note: There is a limit of 15 characters.	
Date of Birth	Opens the Date of Birth window, which allows you to select the patient's date of birth.	
Serial Number	Displays the serial number of the implantable device.	
Lead 1	Opens the LEAD 1 window, which allows you to select the patient lead information. If the desired value for a lead parameter is not listed when you tap the field, tap MODIFY LIST and add the value.	
Lead 2	Opens the LEAD 2 window, which allows you to select the patient lead information. If the desired value for a lead parameter is not listed when you tap the field, tap MODIFY LIST and add the value.	

^b If you place a magnet over the implanted device after telemetry is lost, tachyarrhythmia detection is suspended. However, when telemetry is regained, tachyarrhythmia detection resumes.

Field	Description
Implant	Opens the IMPLANT window, which allows you to enter the implant date and lead measurements. Alternatively, you can take the measurements in a concurrent analyzer session and then export the measurements to the IMPLANT window.
History	Opens the HISTORY window, which allows you to select the patient's clinical conditions.
EF, on	Opens the Ejection Fraction window, which allows you to select the ejection fraction value. Also allows you to select the measurement date.
Physician	Opens the PHYSICIAN NAME/PHONE window, which allows you to select the physician's name and phone number from a list. To add physician information to the list, tap MODIFY LIST and add the information.
Phone	Opens the PHYSICIAN NAME/PHONE window, which allows you to select the physician's name and phone number from a list. To add physician information to the list, tap MODIFY LIST and add the information.
Hospital	Opens the HOSPITAL window, which allows you to select the hospital. To add hospital information to the list, tap MODIFY LIST and add the information.
Last Update	Displays the last date on which changes to patient information were programmed into the implantable device memory.
MRI SureScan System/Other Hardware	Opens the MRI SureScan SYSTEM/OTHER HARDWARE window, which allows you to enter the information about leads and other hardware that affect the decision to perform an MRI scan on the patient.
Notes	Opens the Notes window, which allows you to enter notes about the patient or other information.
	Note: There is a limit of 80 characters.

Note: When the entries are too long to display in the fields, the implantable device app displays truncated versions of the entries. For example, the **Patient** field displays a truncated version of the patient name if the name does not fit in the display field. The Patient Information Report displays the full entry.

- 3. Tap PROGRAM.
- 4. To create the Patient Information Report, tap the PDF button.

11.2 Program MRI SureScan system and other implanted hardware information

Enter and program information about leads and other implanted hardware, such as abandoned implanted devices and leads, lead extenders, or lead adaptors:

- 1. Tap **∃ > PATIENT INFORMATION > MRI SureScan System/Other Hardware...**.
- 2. Tap MRI SureScan System, then tap each field and enter the information.

Field	Description
MR Conditional Device Implant-	Displays the MR Conditional status of the implanted device.
ed	
MR Conditional Lead 1 Implant-	Allows you to specify whether Lead 1 is MR Conditional.
ed	
Lead 1 Model	Allows you to select the model information for Lead 1.
MR Conditional Lead 2 Implant-	Allows you to specify whether Lead 2 is MR Conditional.
ed	
Lead 2 Model	Allows you to select the model information for Lead 2.
Last Update	Displays the last date on which changes to the MRI SureScan SYSTEM/OTHER
	HARDWARE window were programmed into the implantable device memory.

On the MRI SureScan SYSTEM/OTHER HARDWARE window, tap Other Hardware, then tap each field and enter the information.

Field	Description
Other Devices	Allows you to specify whether any other in-use or abandoned implanted devices are present.
Other Leads	Allows you to specify whether any other in-use or abandoned leads are present.
Lead Extenders/Adaptors	Allows you to specify whether any in-use or abandoned lead extenders or adaptors are present.
Other Hardware Notes	Opens the Other Hardware Notes window, which allows you to enter up to 50 characters of notes about other implanted hardware.

Field	Description
	Note: The presence of other hardware in the patient may have an impact on whether the patient can have an MRI scan.
Last Update	Displays the last date on which changes to the MRI SureScan SYSTEM/OTHER HARDWARE window were programmed into the implantable device memory.

4. Tap **OK > PROGRAM**.

12 Programming implantable device settings

12.1 Parameter symbols

The implantable device app can display symbols next to parameter values to convey their status or other information.

Table 9. Symbols that appear with parameter values

Symbol	Name	Description
0	Interlock	The parameter value conflicts with the setting of another present or pending value. Select another value or resolve the conflicting parameter value before programming the parameter.
A	Warning	A warning message exists regarding that value. To view the message, tap the message symbol next to the PROGRAM button or reselect that parameter.
2	Adaptive	The programmed value can be changed automatically by the implantable device. The symbol does not necessarily indicate that the parameter value has been adapted from a previously programmed value, only that it is able to be adapted.
⟨n̂⟩	Nominal	The value is the Medtronic nominal value. Note: If the nominal value is also the programmed value, the Programmed symbol appears instead of the Nominal symbol.
p	Programmed	Indicates that the value is the programmed value.

The implantable device app displays message symbols next to the **PROGRAM** button. When you tap the message symbol, additional parameter information appears.

If there are multiple messages about the pending parameter values, the symbol for the most significant message appears.

Table 10. Message symbols

Symbol	Name	Description
\bigcirc	Interlock	A parameter interlock exists. Programming is restricted until the interlock conflict is resolved.
A	Warning	There is a warning associated with programming 1 or more of the pending parameter values.
0	Informational	There is an informational message regarding 1 or more of the parameter values.

12.2 Program the parameters

To control the implantable device functions and data collection capabilities, program the parameters.

The parameters that you can view and program appear as active fields. Some active fields pertain to only 1 parameter, while other fields provide access to groups of parameters. If a parameter cannot be programmed, no active field appears next to its name.

- 1. Tap **∃** > **PARAMETERS**.
- 2. Tap each field and change the value.

The implantable device app displays the new values with a dashed border. The dashed border signifies that the values are pending.

3. Tap PROGRAM.

The pending values are programmed to the implantable device memory.

12.3 Create custom parameter sets

Create and save sets of parameter values for retrieval in either the current patient session or in subsequent patient sessions.

You can save and access a custom set of parameter values for a particular clinical situation. For example, you may want to save a set of parameter values for an initial implant setting, for a specific disease state, or for situations in which you must repeatedly program a particular set of parameters. The set of parameter values that you save can include both programmed and pending values.

- 1. Tap **∃** > **PARAMETERS**.
- 2. On the **PARAMETERS** screen, make the desired parameter selections.
- 3. Tap SAVE & GET... > ADD NEW.
- 4. Enter a name for the parameter set.
- 5. Tap **OK** > **SAVE**.

If a parameter set exists with that name, either confirm that you want to replace the existing set with a new set or change the name of the new parameter set.

Note: You cannot customize or delete the **Medtronic Nominals** or the **Initial Interrogation Values** parameter set.

12.4 Retrieve parameter sets

Parameter sets are collections of parameter values.

The implantable device app includes 3 types of parameter sets:

- Medtronic Nominals Parameter values that Medtronic suggests for the implantable device. You cannot customize or delete the
 Medtronic Nominals parameter set.
- Initial Interrogation Values Permanently programmed parameter values as determined by the first interrogation of the implantable device during the patient session. You cannot customize or delete the Initial Interrogation Values parameter set.
- **Custom** Sets of parameter values that you create for a particular clinical situation. For example, you may want to save a set of parameter values for an initial implant setting, for a specific disease state, or for situations in which you must repeatedly program a particular set of parameters.
- 1. Tap **∃** > **PARAMETERS** > **SAVE & GET....**
- 2. Tap the parameter set you want to retrieve, then tap SET PENDING.
- 3. On the PARAMETERS screen, review and change the parameter settings as needed for the patient.
- 4. Tap PROGRAM.

The pending values are programmed to the implantable device memory.

12.5 Program data collection preferences

To control how the implantable device collects and transmits data, program the data collection preferences:

- 1. Tap **∃** > PARAMETERS > Data Collection Setup....
- 2. Configure the following options.

Note: Data collection is automatic and you cannot turn it off.

Option	Description		
SOURCE	For EGM 1 , EGM 2 , and EGM 3 , allows you to select the source electrodes that the implantable device uses to record EGM signals. The SOURCE parameters control the signal that appears on the Live Rhythm Monitor.		
	Note: The cardiac interval measurements of the implantable device are based on the signals sensed through the programmed sensing polarity (not the stored diagnostic EGM). Your EGM source selection does not affect bradycardia pacing or tachyarrhythmia detection.		
RANGE	For EGM 1 , EGM 2 , and EGM 3 , allows you to select the range of the EGM signal. The lower the setting, the higher the resolution. When the EGM signal is illegible or clipped, change the range selection. The RANGE parameters control the signal that appears on the Live Rhythm Monitor.		
Monitored Sources	Allows you to select the 2 waveform traces to be stored with the episode records.		
Pre-arrhythmia EGM	Allows you to choose if you want to store the EGM data that the implantable device collects before an episode begins. Pre-arrhythmia EGM storage keeps the EGM circuitry enabled at all times, which reduces implantable device longevity. When you select On – 1 months or On – 3 months , the implantable device		
	automatically turns off pre-arrhythmia EGM storage when the time period expires.		
Device Date/Time	Allows you to select the time zone offset from Coordinated Universal Time (UTC).		

Option	Description		
	Current Device Date/Time – Displays the date and time that the implantable device currently uses.		
	New Device Date/Time – Displays the new date and time that the implantable device will use based on your selection for Time Zone.		
	Time Zone – Allows you to select the time zone offset to adjust the implantable device time.		
	Note: The implantable device app expresses time in the 24-hour format or in the 12-hour format, depending on your tablet settings.		
Holter Telemetry Duration	Allows you to either enter the duration for Holter telemetry or disable Holter telemetry. When you enable Holter telemetry, the implanted device continuo transmits EGM and marker data for the selected duration, regardless of the presence of the patient connector.		
Wireless Telemetry with Monitor	Allows you to turn the wireless telemetry for remote monitoring on and off.		
	Notes:		
	 You can use wireless telemetry for remote monitoring and Medtronic CareAlert™ Monitoring (if available) only when Wireless Telemetry with Monitor is programmed to On. 		
	When important clinical management and system performance events occur between scheduled patient sessions, a CareAlert notification is elicited when Wireless Telemetry with Monitor is programmed to On.		
	When Wireless Telemetry with Monitor is programmed to Off, you are still able to use wireless telemetry with the device manager.		
AT/AF Settings	Allows you to select the thresholds for the following Quick Look observations:		
	AT/AF Daily Burden		
	Avg. V. Rate During AT/AF		
	Notes:		
	AT/AF observations are only available for certain implantable devices.		
	 If Wireless Telemetry with Monitor is programmed to On, the AT/AF settings are shown instead in the Medtronic CareAlert Setup window (PARAME- TERS > Alert). 		

3. Tap **OK > PROGRAM**.

12.6 View parameter changes

Review the list of parameter changes that you made during the patient session:

- 1. Tap **∃** > SESSION > CHANGES THIS SESSION.
- 2. Review the list of parameter changes.
- 3. To create a report, tap the PDF button.

13 Viewing and analyzing diagnostic data

13.1 View CareAlert events

13.1.1 About CareAlert events

Important clinical management and system performance events may occur between scheduled patient sessions, eliciting a CareAlert notification (if remote monitoring is available). You can program notifications for certain CareAlert events.

You can program CareAlert notifications for clinical management events and lead and device integrity events. The CareAlert notification for a device reset occurs automatically and is not programmable. CareAlert notification settings can be programmed during implant, at patient discharge, or during a patient follow-up appointment. Changes to CareAlert notification settings take effect immediately in the implanted device upon successful completion of programming.

13.1.2 View CareAlert event logs

View the logs of **CareAlert EVENTS** that are stored in the implanted device:

- Tap > DATA > CareAlert EVENTS.
- 2. To create a report, tap the PDF button.

13.2 View clinical diagnostic data

13.2.1 About clinical diagnostic data

The implanted device collects and stores diagnostic data, which you can use to assess the patient's clinical conditions and the effectiveness of therapies.

13.2.2 View arrhythmia episode data

View summary and detailed diagnostic data for arrhythmia episodes:

1. Tap ■ > DATA > ARRHYTHMIA EPISODES.

Note: The implantable device app is unable to display the data for an episode that is in progress. These episodes are labeled **(Episode in progress)** and cannot be viewed in the episode records until the episode terminates and an interrogation is performed. However, if flashback data is available for an episode in progress, you can view the flashback data.

- 2. Optionally, tap the PDF button to create a report that includes data for all arrhythmia episodes.
- 3. On the ARRHYTHMIA EPISODES window, use the following options:
 - To filter the list by episode type, tap VT/VF, AT/AF, or Fast A&V.
 - To filter the data by type, tap the **View** list, then select the data type.
 - To display episodes that are longer than a specific amount of time, tap the box next to > and choose the minimum episode duration.
- Tap the episode you want to view, then tap [⊕].
- 5. To change the display of the episode data, use the available options:

Option	Description			
FLASHBACK	Displays a graph of atrial and ventricular intervals, including any stored flashback data, that the implanted device captured. In the FLASHBACK view, use the available options:			
	To switch the y-axis, tap Rate or Interval.			
	To show or hide interval data, tap V-V or A-A.			
	 To select a portion of the data to view in PLOT format, tap □ and □ to position the yellow box. 			
PLOT	Displays a graph of cardiac events. In the PLOT view, use the available options:			
	To switch the y-axis, tap Rate or Interval.			
	To show or hide interval data, tap V-V or A-A.			
	To select a portion of the data to view in EGM format, scroll horizontally to position the yellow box.			
EGM	Displays the stored EGM data.			
	To choose an interval to display, tap the atrial interval list.			
TEXT	Displays a text summary of the episode.			

6. To create a report that includes data for the episode that you are viewing, tap the PDF button.

Note: If the PDF button is disabled in the current tab, tap **FLASHBACK**, then tap the PDF button.

- 7. Optionally, complete the following actions:
 - To view the previous or next episode in the list, tap û or ♥.
 - To minimize the view of episode details, tap ⊆.

13.2.3 View rate drop response episode data

View and analyze rate drop episodes and the events that cause rate drop episodes:

- 1. Tap **∃** > **DATA** > **RATE DROP RESPONSE EPISODES**.
- 2. Optionally, tap the PDF button to create a report that includes data for all rate drop response episodes.
- 3. Tap the episode you want to view, then tap ⊕.
- 4. To change the display of the episode data, use the available options:

Option	Description
PLOT	Displays a graph of cardiac events. In the PLOT view, use the available options:
	To switch the y-axis, tap Rate or Interval .
	To show or hide interval data, tap V-V or A-A.
	 To select a period for which to view markers, tap and to position the yellow box.
MARKERS	Displays markers for the episode.

Option	Description
	To choose an interval to display, tap the atrial interval list.
TEXT	Displays the Rate Drop Response settings that were in effect at the start of the programming session.

- 5. To create a report that includes data for the episode that you are viewing, tap the PDF button.
- 6. Optionally, complete the following actions:
 - To view the previous or next episode in the list, tap û or ♥.
 - To minimize the view of episode details, tap ⊆.

13.2.4 View interrogation flashback data

View a graph that shows atrial and ventricular intervals that occurred before the most recent interrogation. The interrogation flashback data allows you to assess the patient's heart rhythm and performance of other features, such as Rate Response.

- 1. Tap **∃ > DATA > INTERROGATION FLASHBACK**.
- 2. Use the available options:

Option	Description
FLASHBACK	Displays a graph of atrial and ventricular intervals, including any stored flashback data, that the implanted device captured. In the FLASHBACK view, use the available options:
	To switch the y-axis, tap Rate or Interval .
	To show or hide interval data, tap V-V or A-A.
	 To select a portion of the data to view in PLOT format, tap and to position the yellow box.
PLOT	Displays a graph of cardiac events. In the PLOT view, use the available options:
	To switch the y-axis, tap Rate or Interval .
	To show or hide interval data, tap V-V or A-A.
	To view more of the data, scroll horizontally.

3. To generate a report, tap **FLASHBACK**, then tap the PDF button.

13.2.5 View Cardiac Compass™ trend data

To assess the effectiveness of implanted device therapies and antiarrhythmia drugs, view the data about the patient's conditions:

- 1. Tap **∃** > **DATA** > **Cardiac Compass TRENDS**.
- 2. To create a report, tap the PDF button.

13.2.6 View rate histogram data

View the heart rate data that the implanted device records between patient sessions. Use the heart rate data to monitor the patient's condition and the effectiveness of therapies.

Note: The recording time spans from the start of a session to the start of the next session.

- 1. Tap **= > DATA > RATE HISTOGRAMS**.
- 2. To create a report, tap the PDF button.

13.2.7 View MVP mode switch data

View the 10 most recent MVP mode switches to DDD(R):

- 1. Tap **∃** > **DATA** > **MVP MODE SWITCHES**.
- 2. To create a report, tap the PDF button.

13.2.8 View counter data

View the counter data, which allows you to analyze information about VT/VF episodes, AT/AF episodes, and therapy occurrences:

- 1. Tap => DATA > COUNTERS.
- 2. Select one of the following data types:
 - VT/VF EPISODES
 - AT/AF EPISODES
 - AT/AF RX
- 3. To create a report, tap the PDF button.

13.3 View device and lead diagnostic data

13.3.1 About device and lead diagnostic data

The implanted device automatically measures and records daily device and lead performance data.

13.3.2 View battery and lead measurement data

To assess the most recent measurements and trended measurements of implanted device and lead performance, view the battery and lead measurement data.

Warning: Replace the implanted device immediately if the implantable device app displays an End of Service (EOS) indicator. The implanted device may lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears.

Note: If the implantable device app displays the Recommended Replacement Time (RRT) indicator, contact a Medtronic representative and the patient to schedule a replacement procedure.

- 1. Tap **∃ > DATA > BATTERY AND LEAD MEASUREMENTS**.
- 2. Select the type of data you want to view:
 - Remaining Longevity / Battery Voltage
 - Sensing Integrity Counter
 - Atrial Lead Position Check
 - Lead Impedance
 - Sensing
- 3. To create a report, tap the PDF button.

13.3.3 View lead impedance trend data

To analyze the automatic daily lead impedance measurements, view the lead impedance trend data:

- Tap > DATA > LEAD IMPEDANCE TRENDS.
- 2. Configure the display options:
 - · Select a measurement trend.
 - If applicable, tap the polarity type you want to view.
- 3. To create a report, tap the PDF button.

The graph displays up to 15 daily measurements and up to 60 weekly summary measurements. Gaps in the graph occur when the implanted device fails to complete automatic lead impedance measurements.

Note: Significant and sudden changes in lead impedance can indicate a problem with the lead.

13.3.4 View capture threshold trend data

To evaluate Capture Management™ operations and the effectiveness of the pacing output values, view and analyze the capture threshold trend data:

- 1. Tap **∃ > DATA > CAPTURE THRESHOLD TRENDS**.
- 2. Configure the display options:
 - Select the chamber data you want to view.
 - To view the last 15 days of threshold measurement data, tap LAST 15 DAYS DETAIL.
- 3. To create a report, tap the PDF button.

The graph displays up to 15 daily measurements and up to 60 weekly summary measurements. Gaps in the graph occur when the implanted device fails to complete daily capture threshold measurement.

The implanted device measures the capture threshold data only when the **Capture Management** parameter is configured as **Adaptive** or **Monitor**.

Note: Significant and sudden changes in the pacing threshold can indicate a problem with the lead.

13.3.5 View P/R wave amplitude trend data

View and analyze the daily sensing amplitude measurements:

- 1. Tap => DATA > P/R WAVE AMPLITUDE TRENDS.
- 2. Select the amplitude measurement type that you want to view.
- 3. To create a report, tap the PDF button.

The graph displays up to 15 daily measurements and up to 60 weekly summary measurements. The daily measurements are the median values of the amplitudes of 9 normal intrinsic sensed events. Gaps in the graph occur when the implanted device is unable to collect 9 amplitude measurements on a given day.

Note: Significant and sudden changes in the sensing amplitude can indicate a problem with the lead.

14 Performing system tests

14.1 Configure the test preferences for the Live Rhythm Monitor

To view the EGM for the heart chamber you test, configure the test preferences for the Live Rhythm Monitor:

- 1. Tap => SESSION > PREFERENCES > TESTS.
- 2. Select one of the following options:
 - To display the EGM for the heart chamber you test, tap Auto-arrange waveforms.
 - To leave the waveform display unchanged during a test, tap **Do not auto-arrange waveforms**.
- 3. Tap **OK**.

14.2 Perform an Underlying Rhythm Test

To evaluate the patient's intrinsic heart rhythm by temporarily inhibiting the pacing output of the implanted device, use the Underlying Rhythm Test.

Caution: While the Underlying Rhythm Test is in progress, patients are not receiving pacing support because the implanted device is temporarily programmed to a nonpacing mode. Pacing is inhibited as long as you press and hold **INHIBIT Press and Hold**. Carefully consider the implications of performing this test on pacemaker-dependent patients.

Notes:

- If telemetry between the implantable device app and the implanted device is paused or lost during an Underlying Rhythm Test, the test stops and the implanted device parameters revert to permanently programmed values.
- During system tests, tachyarrhythmia detection is suspended.
 - 1. Tap **∃** > **TESTS** > **UNDERLYING RHYTHM**.
 - 2. Verify the permanent values for **Mode** and **Lower Rate**.
 - 3. To help avoid sudden changes in ventricular rate, consider lowering the programmed lower rate:
 - a. Tap > PARAMETERS > Lower Rate.
 - b. Select an appropriate rate.
 - c. To program any pending changes, tap PROGRAM.
 - d. To return to the UNDERLYING RHYTHM screen, tap 囯 > TESTS > UNDERLYING RHYTHM.
- 4. Press and hold INHIBIT Press and Hold.
- 5. Observe the display of the heart's intrinsic rhythm.

Note: Pacing is inhibited until you release INHIBIT Press and Hold.

- 6. Release INHIBIT Press and Hold.
- 7. If the **Lower Rate** value was changed before conducting the Underlying Rhythm Test, return to the **PARAMETERS** screen to return the rate to its original value.

14.3 Perform a Sensing Test

To assess lead integrity and sensing performance, perform the Sensing Test, which measures P-wave and R-wave amplitudes.

The Sensing Test allows you to temporarily program pacing parameters to increase the likelihood that sensed events will occur. Sensing amplitude measurements taken during a Sensing Test may include events that are atypical or a result of oversensing (for example, PVCs or far-field R-waves). These events are excluded from the daily automatic sensing amplitude measurements that the implanted device collects and reports in the sensing amplitude trends. Because of the difference in measurement operations, Sensing Test results can differ from the measurements reported in the sensing amplitude trend data.

Caution: Use caution when selecting temporary settings for pacemaker-dependent patients. These patients may not receive adequate pacing support while sensing amplitude measurements are being obtained.

Notes:

- The Sensing Test does not function when the device is operating in an asynchronous pacing mode, such as VOO. Program the device to a pacing mode other than an asynchronous pacing mode before performing a Sensing Test.
- The Sensing Test does not function when polarity parameters are set to **Configure**. Program polarity parameter values manually or allow implant detection to complete before performing a Sensing Test.

- During a Sensing Test, reduce the pacing rate gradually to minimize patient symptoms associated with abrupt changes in heart rate.
- If telemetry between the implantable device app and the implanted device is paused or lost during a Sensing Test, the test stops and the implanted device parameters revert to permanently programmed values.
- During system tests, tachyarrhythmia detection is suspended.
 - 1. Tap **∃** > **TESTS** > **SENSING**.
 - 2. Verify or change the **TEST VALUE** parameter values for **Mode** and **AV Delay**.
- 3. Tap START Measurement.
- 4. Observe the Live Rhythm Monitor for an intrinsic rhythm. If consistent pacing continues to occur, tap ▼ to decrease the Lower Rate.

The implanted device measures amplitudes only for intrinsic events. The maximum amplitude value that the Sensing Test measures is 20 mV. When the amplitude measures over 20 mV, the implantable device app displays the results as >20 mV. When there are no intrinsic events and the pacing rate remains the same, the Sensing Test automatically stops.

When the Sensing Test successfully completes, it automatically stops. The implantable device app displays the measurements and the pacing settings return to their programmed values. To stop the test manually before it completes, tap **STOP and Restore**.

- To compare the Sensing Test measurements with the automatic daily sensing amplitude measurements, tap P/R WAVE AMPLITUDE TRENDS.
- 6. To create a report, tap the PDF button.

Note: Do not adjust the **A. Sensitivity** and **RV Sensitivity** values based on the results of the Sensing Test. For more information, refer to the reference manual for the implanted device.

14.4 Perform a Pacing Threshold Test

To determine the patient's pacing thresholds, use the Pacing Threshold Test. Use the test results to help you select amplitude and pulse width settings that ensure capture while minimizing output to maximize battery longevity.

Notes:

- If telemetry between the implantable device app and the implanted device is paused or lost during a Pacing Threshold Test, the test stops and the implanted device parameters revert to permanently programmed values.
- During system tests, tachyarrhythmia detection is suspended.
 - 1. Tap => TESTS > PACING THRESHOLD.
- 2. Verify or change the values:
 - To change how the test operates, tap **Test Type**, select new values, then tap **OK**.
 - To change the pacing parameters applied during the test, select new values in the TEST VALUE column.
 - To change the sensing parameters applied during the test, tap Additional Settings..., select new values in the TEST VALUE column, then tap OK.

Note: The programmable and default values depend on the programmed values for bradycardia pacing therapy.

- 3. Press and hold **TEST Press and Hold**, then observe the Live Rhythm Monitor for loss of capture.
- 4. When loss of capture occurs, release TEST Press and Hold.
- 5. On the results window, verify the detected pacing threshold for the loss of capture:
 - To update the detected pacing threshold, tap the value in the THRESHOLD column.
 - To view the test strip from the most recent pacing threshold test, tap the **Test Strip** icon.
- 6. Ensure that the amplitude and pulse width values provide an adequate safety margin above the pacing threshold.
- 7. To change the programmed pace polarity value, tap the pace polarity value in the **PERMANENT** column, select the desired value, then tap **PROGRAM**.
- 8. To change the programmed amplitude or pulse width values, complete the following actions:
 - a. In the **PERMANENT** column, tap the value.
 - b. On the **CAPTURE** window, select the desired values, then tap **OK**.
 - c. Tap **PROGRAM**.
- 9. To view the ending value and permanent value for the **V. Pace Blanking**, **A. Pace Blanking**, or **PVARP** parameters, complete the following actions:
 - a. Tap Additional Settings....
 - b. To return to the results window, tap **OK**.
- 10. To view a test strip from the most recent pacing threshold test, complete the following actions:

- a. Tap the **Test Strip** icon.
- b. Close the window to return to the results window.

14.5 Perform a Lead Impedance Test

To test the integrity of the implanted lead system by measuring the impedance of the atrial and ventricular pacing electrodes, use the Lead Impedance Test.

Notes:

- If telemetry between the implantable device app and the implanted device is paused or lost during a Lead Impedance Test, the
 implanted device continues to measure impedance values. When the test completes, the implanted device parameters revert to
 permanently programmed values.
- During system tests, tachyarrhythmia detection is suspended.
 - 1. Tap **∃** > **TESTS** > **LEAD IMPEDANCE**.
 - 2. Tap START Measurement.

When the Lead Impedance Test completes, the implantable device app displays the measured impedance values for the tested polarities.

To stop the test manually before it completes, tap **STOP**.

- 3. Optionally, complete 1 or more of the following actions:
 - To view the measurements for all lead polarities, tap ALL MEASURED POLARITIES.
 - To compare the test results to daily automatic lead impedance measurements, tap LEAD IMPEDANCE TRENDS.
 - To save the Lead Impedance Test Report, tap the PDF button.

14.6 Perform a Magnet Test

To observe and document magnet mode operation while the implantable device is in a telemetry session, use the Magnet Test.

During magnet mode operation, the implantable device provides asynchronous pacing at a fixed rate. While the implantable device is in a telemetry session, you cannot initiate magnet mode operation by placing a magnet over the device. The Magnet Test can automatically record Live Rhythm Monitor strips showing magnet mode and non-magnet mode operation.

Notes:

- If telemetry between the implantable device app and the implanted device is paused or lost during a Magnet Test, the test stops
 and the implanted device parameters revert to permanently programmed values.
- During system tests, tachyarrhythmia detection is suspended.
 - 1. Tap **∃** > **TESTS** > **MAGNET**.
 - 2. To automatically record a strip that shows non-magnet operation, select the Non-Magnet Strip checkbox.
 - 3. To select a strip duration value for the automatically collected strips, tap **Strip Durations** and select a value.
 - 4. Tap START Test.

Note: To stop the test manually before it completes, tap **STOP Test**.

- 5. Tap the Magnet Strip icon or the Non-Magnet Strip icon to view the collected strip in the FROZEN STRIP window.
- 6. To create a report, tap the PDF button.

14.7 Perform EP Study tests to induce arrhythmias

14.7.1 About arrhythmia inductions

You can use electrophysiology study (EP Study) test functions to induce arrhythmias in order to evaluate the effectiveness of tachyarrhythmia therapies.

The available arrhythmia induction methods are 50 Hz Burst, Fixed Burst, and Programmed Electrical Stimulation (PES).

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Tachyarrhythmia detection is automatically suspended during all EP Study tests. If you manually suspend detection before the induction, detection is not resumed automatically when the induction is delivered. All EP study inductions provide the option to resume detection automatically after the induction is delivered.

The EP study functions use test values that do not change the programmed parameters of the implanted device. The test values take effect when the induction or therapy begins. After the induction or therapy, the implanted device reverts to its programmed parameter values for bradycardia pacing and tachyarrhythmia therapy.

14.7.2 Induce AT/AF with an atrial 50 Hz Burst

Use a 50 Hz Burst to induce AT/AF by delivering a rapid burst of AOO pacing pulses to the atrium.

You can also use an atrial 50 Hz Burst to treat AF episodes manually.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Note: If telemetry between the implantable device app and the implanted device is paused or lost during the test, the test stops and the implanted device parameters revert to permanently programmed values.

- 1. Ensure that telemetry is established between the implanted device and the patient connector.
 - **Note:** Successful interrogation or programming confirms proper communication between the implanted device and the patient connector.
- 2. Tap => TESTS > EP STUDY > 50 Hz Burst.
- 3. Set up the test using the following options:
 - To maintain automatic detection and therapy during the test, select the Resume at BURST checkbox.
 - To treat the induced episode with a manual therapy, clear the Resume at BURST checkbox, then tap SUSPEND to
 prevent automatic detection.
- 4. Verify or change the displayed test values.
 - Note: To provide VOO Backup pacing during the pacing burst, tap VOO Backup... and set the VOO Backup pacing parameters.
- 5. Press and hold **50 Hz BURST Press and Hold**. As long as you hold **50 Hz BURST Press and Hold**, the implanted device continues delivering the induction (up to a maximum of 10 s). To end the induction, release the button.

Notes:

- To abort a therapy, tap ABORT.
- To resume detection after a manual therapy or after an induction that was delivered with the Resume at BURST checkbox cleared, tap RESUME.

14.7.3 Induce AT or VT with Fixed Burst

Use Fixed Burst to induce AT or VT by delivering a set of asynchronous AOO or VOO pacing pulses.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Note: If telemetry between the implantable device app and the implanted device is paused or lost during the test, the test stops and the implanted device parameters revert to permanently programmed values.

- 1. Ensure that telemetry is established between the implanted device and the patient connector.
 - **Note:** Successful interrogation or programming confirms proper communication between the implanted device and the patient connector.
- 2. Tap ∃ > TESTS > EP STUDY > Fixed Burst.
- 3. If applicable, select the chamber in which to perform the test.
- 4. Set up the test using the following options:
 - To maintain automatic detection and therapy during the test, select the Resume at BURST checkbox.
 - To treat the induced episode with a manual therapy, clear the Resume at BURST checkbox, then tap SUSPEND to
 prevent automatic detection.
- 5. Verify or change the displayed test values.
 - **Note:** To provide VVI Backup pacing during an atrial Fixed Burst induction, tap **VVI Backup...** and set the VVI Backup pacing parameters. If the test value for atrial **Amplitude** is greater than **6 V**, crosstalk can inhibit VVI Backup pacing.
- 6. Press and hold **Fixed BURST Press and Hold**. To end the induction, release the button.

Notes:

- To abort a therapy, tap ABORT.
- To resume detection after a manual therapy or after an induction that was delivered with the Resume at BURST checkbox cleared, tap RESUME.

14.7.4 Induce AT or VT with PES

Use Programmed Electrical Stimulation (PES) to induce AT or VT by delivering a selectable number of pacing pulses and individually selectable intervals. PES delivers a selectable number of pacing pulses at the **S1S1** interval and then delivers up to 3 asynchronous pacing pulses at **S1S2**, **S2S3**, and **S3S4** intervals.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Note: If telemetry between the implantable device app and the implanted device is paused or lost during the test, the implanted device continues the test. When the test completes, the implanted device parameters revert to permanently programmed values.

1. Ensure that telemetry is established between the implanted device and the patient connector.

Note: Successful interrogation or programming confirms proper communication between the implanted device and the patient connector.

- 2. Tap => TESTS > EP STUDY > PES.
- 3. If applicable, select the chamber in which to perform the test.
- 4. Set up the test using the following options:
 - To maintain automatic detection and therapy during the test, select the Resume at DELIVER checkbox.
 - To treat the induced episode with a manual therapy, clear the **Resume at DELIVER** checkbox, then tap **SUSPEND** to prevent automatic detection.
- 5. Verify or change the displayed test values.

Note: To provide VVI Backup pacing during an atrial PES induction, tap **VVI Backup...** and set the VVI Backup pacing parameters. If the test value for atrial **Amplitude** is greater than **6 V**, crosstalk can inhibit VVI Backup pacing.

6. Tap **DELIVER PES**.

Notes:

- To abort a therapy, tap ABORT.
- To resume detection after a manual therapy or after an induction that was delivered with the Resume at DELIVER checkbox cleared, tap RESUME.

14.8 Perform EP Study tests to deliver manual therapies

14.8.1 Perform manual therapies

You can use manual therapies to provide backup therapy during EP testing and to assess therapy effectiveness during follow-up appointments.

The available manual therapies include Atrial Burst+, Atrial Ramp, Ventricular Ramp, Ventricular Burst, and Ventricular Ramp+ pacing therapies.

Warning: Monitor the patient carefully when delivering a manual therapy. Have an external defibrillator nearby and ready for immediate use. Potentially harmful tachyarrhythmias may occur during device testing.

Notes:

- If the test value for atrial **Amplitude** is greater than **6 V**, VVI Backup pacing during a manual atrial ATP therapy may be inhibited by crosstalk.
- When a manual therapy is delivered, the device automatically aborts any induction or automatic therapy already in progress.
- If telemetry between the implantable device app and the implanted device is paused or lost during a manual therapy, the implanted device continues the manual therapy. When the manual therapy completes, the implanted device parameters revert to permanently programmed values.
- During system tests, tachyarrhythmia detection is suspended. Once a test is completed, detection remains suspended until you tap **RESUME**.

The EP Study functions use test values that do not change the programmed parameters of the device. The test values take effect when the induction or therapy begins. After the induction or therapy, the device reverts to its programmed parameter values for bradycardia pacing and tachyarrhythmia therapy.

1. Ensure that telemetry is established between the implanted device and the patient connector.

Note: Successful interrogation or programming confirms proper communication between the implanted device and the patient connector.

- Tap > TESTS > EP STUDY.
- 3. Tap the desired manual therapy from the list of inductions and therapies.
- 4. If applicable, select the chamber in which to perform the test.
- 5. Verify or change the displayed test values.
- 6. Tap the appropriate button: DELIVER Ramp, DELIVER Burst, DELIVER Ramp+, or DELIVER Burst+.

Notes:

- To abort a therapy, tap ABORT.
- To resume detection after a manual therapy, tap **RESUME**.

14.8.2 Operation of manual therapies

In general, each manual therapy with a corresponding automatic therapy operates the same as its automatic counterpart.

Note: Manual ATP therapies deliver 1 sequence of the selected therapy.

Atrial Burst+ pacing therapy – Manual Atrial Burst+ pacing therapy delivers the selected number of initial atrial pulses, followed by up to 2 additional pulses in AOO mode. All the initial atrial pulses are delivered at the same pacing interval, which is determined as a percentage of the atrial tachycardia cycle length using the selected **%AA Interval** value. If the **S1S2** option is selected, an additional atrial pulse is delivered at an interval determined using the selected percentage. If the **S2S3 Dec** option is also selected, another atrial pulse is delivered at an interval that is calculated by subtracting the selected decrement value from the previous interval.

Atrial Ramp pacing therapy – Manual Atrial Ramp pacing therapy delivers the selected number of pacing pulses to the atrium in AOO mode. The pacing interval for the first pulse of the Ramp sequence is determined as a percentage of the atrial tachycardia cycle length using the selected **%AA Interval** value. Each subsequent pulse in the sequence is delivered at progressively shorter intervals by subtracting the selected interval decrement (**Dec/Pulse**) from each pulse.

Ventricular Ramp pacing therapy – Manual Ventricular Ramp pacing therapy delivers the selected number of pacing pulses in VVI mode. The pacing interval for the first pulse of the Ramp sequence is determined as a percentage of the ventricular tachycardia cycle length using the selected **%RR Interval** value. Each subsequent pulse in the sequence is delivered at progressively shorter intervals by subtracting the selected interval decrement (**Dec/Pulse**) from each pulse.

Ventricular Burst pacing therapy – Manual Ventricular Burst pacing therapy delivers the selected number of pacing pulses in VOO mode. The pacing interval for the Burst sequence is determined as a percentage of the ventricular tachycardia cycle length using the selected **%RR Interval** value. The pulses within the sequence are delivered at the same pacing interval.

Ventricular Ramp+ pacing therapy – Manual Ventricular Ramp+ pacing therapy delivers the selected number of pacing pulses in VOO mode. The pacing interval for the first pulse of the Ramp+ sequence is determined as a percentage of the ventricular tachycardia cycle length using the selected **R-S1(%RR)** value. The second pulse is delivered at an interval determined using the selected **S1S2(%RR)** percentage. Any remaining pulses in the sequence are delivered at the selected **S2SN(%RR)** percentage.

15 Using the SessionSync software

15.1 View the SessionSync connection status

If your clinic uses a Paceart Optima System, the SessionSync software enables you to transfer saved implantable device data and reports to that system.

To view the SessionSync connection status, use the DATA SYNCHRONIZATION STATUS window.

Notes:

- The SessionSync connection status is visible only if you configure the SessionSync software. To configure the SessionSync software, refer to the device manager app help.
- The Paceart Optima System is available only in supported regions.
 - On the status bar, tap
- 2. From DATA EXPORT STATUS, tap DETAILS....
- 3. On the DATA SYNCHRONIZATION STATUS window, view the SessionSync connection status:
 - Available The SessionSync software is enabled and there is a connection between the device manager app and the Paceart Optima System.
 - Disconnected The SessionSync software is enabled, but the connection to the Paceart Optima System timed out.
 - Not Available The SessionSync software is enabled, but the connection to the Paceart Optima System is unavailable.
 - Not Connected The SessionSync software is enabled, but a secure connection to the server could not be
 established due to a certificate error, CareLink SmartSync is not authorized by the Paceart Optima System, or the
 tablet is not connected to an IT network.

The DATA SYNCHRONIZATION STATUS window also shows the following information:

Field	Description
Clinic Name	Name of the clinic that receives SessionSync transfers.
Gateway address	IP address or hostname of the SessionSync gateway.
Transfers	The implantable device data and reports that the SessionSync software transfers to the Paceart Optima System. The Transfers table displays the most recent transfer at the top of the table.
	GENERATED – Date and time of the transfer
	RECEIVING CLINIC – Name of the clinic that receives the transfer
	STATUS – Status of the transfer

15.2 Send device data and reports to the Paceart Optima System

If your clinic uses a Paceart Optima System, the SessionSync software enables you to transfer implanted device data and reports to that system without ending the patient session:

- 1. Tap **∃** > SESSION > SessionSync > TRANSFER.
- 2. To close the message, tap **OK**.

15.3 End the patient session with the automatic SessionSync feature

If your clinic uses a Paceart Optima System, end the current session and use the automatic SessionSync feature to transfer implantable device data and reports from the device manager to the Paceart Optima System:

- 1. Tap **∃ > END SESSION**.
- 2. Ensure that the Automatic SessionSync checkbox is selected.
- 3. Tap END NOW > TRANSFER.
- 4. On the transfer message window, tap END NOW.

16 Managing the patient session

16.1 Turn on standby mode for the implantable device

When you need a period of inactivity during a patient session, turn on standby mode for the implantable device.

Note: Standby mode is only available when the implantable device is connected to the patient connector using Bluetooth wireless technology.

When standby mode is on for the implantable device, the following implantable device app functions are limited:

- · Emergency VVI pacing is unavailable.
- · System tests are unavailable.
- EGM waveform traces and markers from the implantable device are unavailable.
- You are unable to program parameters.
- You are unable to reinterrogate the implantable device.

Note: When standby mode is on for the implantable device, the implantable device app prompts you to turn off standby mode when you attempt to enable emergency VVI pacing, perform tests, program parameters, or reinterrogate the implantable device.

To turn on standby mode for the implantable device, complete the following actions:

- On the status bar, tap
- 2. Set STANDBY MODE to ON.

16.2 Turn off standby mode for the implantable device

To turn off standby mode for the implantable device, complete the following actions:

- On the status bar, tap
- 2. Set STANDBY MODE to OFF.

16.3 Connect the device manager app to the base

The device manager app must be connected to the base before you can start an analyzer session or view ECG waveforms during a patient session. If the device manager app is not already connected to the base, complete the following actions:

- 1. Plug in the base to the AC power outlet (AC mains).
- 2. On the status bar, tap

 ✓.
- 3. Near the base status indicator, tap SELECT.
- 4. Tap **CONTINUE**.
- 5. From the device manager app, follow the prompts to complete the base connection. For more information, refer to the device manager app help.

For information on connecting the surgical cable or patient cable and ECG cable to the base, refer to the base technical manual, the patient cable or surgical cable instructions for use (IFU), and the ECG cable IFU.

16.4 Start or return to a concurrent analyzer session

To assess the correct placement and electrical performance of implanted leads, start or return to a concurrent analyzer session:

1. Verify that the base is on and connected to the app.

- 2. Tap \equiv , then tap one of the following:
 - To start an analyzer session, tap LAUNCH ANALYZER.
 - To return to a concurrent analyzer session, tap ANALYZER.

To return to the concurrent patient session from the analyzer, tap \equiv then tap the name of the implantable device.

16.5 Save the implantable device data

Save the interrogated device data from a patient session to the **SAVED REPORTS** window. The save operation generates a PKG file that includes the implantable device data (PDD file) and any reports that you generated during the session.

Implantable device data automatically saves when you end the patient session. However, implantable device data does not save when the implantable device app closes from the tablet operating system. To avoid permanent loss of implantable device data, save the implantable device data.

Note: During the save operation, the **EMERGENCY** button is available. However, if an error occurs during a save operation, there may be a delay in initiating the **EMERGENCY - VVI PACING** window. Do not save implantable device data while performing a system test or when it is possible that the Emergency function will be needed immediately. If the Emergency function is used during a save operation, the implantable device app aborts the save operation.

- 1. Tap **∃** > **INTERROGATE**.
- 2. If the INTERROGATE HOW MUCH? window appears, tap AII > START.

Note: Selecting All provides more data for future analysis.

- 3. When the interrogation is complete, tap **∃** > SESSION > SAVE SESSION. The implantable device data saves to the SAVED REPORTS window.
- 4. On the SESSION DATA SAVED window, tap OK.

16.6 About Read From File sessions

Use a Read From File session to view saved implantable device data, to save and export reports, and to display all programmed parameter values.

To start a Read From File session, end the patient session and refer to the device manager app help.

Warning: A Read From File session is designed only for viewing saved implantable device data while no patient session is in progress. You cannot program an implantable device or deliver emergency therapies from a Read From File session.

A Read From File session presents implantable device data in a slightly different way than what is seen during a patient session. Because you are not in a live patient session, the Live Rhythm Monitor is replaced with the device model and the words **Read From File**.

When you generate reports during a Read From File session, the retention of those reports is the same as the saved implantable device data.

16.7 Extend the patient session

To keep the patient session open during a period of inactivity, extend the patient session.

Note: After 45 min of inactivity, the implantable device app displays a message that prompts you to extend or end the patient session. If you do not respond within 15 min, the patient session ends automatically and any unsaved data is lost.

To reset the inactivity timer in order to extend the patient session, complete one of the following actions:

- If the **NO ACTIVITY DETECTED** window appears, tap **EXTEND**.
- If the NO ACTIVITY DETECTED window has not yet appeared, tap anywhere on the screen.

16.8 End the patient session

When you finish with the patient session, end the session.

- 1. Tap ∃ > END SESSION.
- 2. On the END SESSION? window, tap END NOW.

Note: Ending the patient session does not end a concurrent analyzer session.

17 Working with reports and saved device data

17.1 Configure the report preferences

17.1.1 Configure the Initial Interrogation Report preferences

Enable the Initial Interrogation Report, then select the reports that you want to include in the Initial Interrogation Report:

- 1. Tap 🗏 > SESSION > PREFERENCES > INITIAL REPORT.
- 2. Complete the following actions:
 - a. Select the Automatically generate initial interrogation report after first interrogation checkbox.
 - b. Select the reports to include in the Initial Interrogation Report.

Note: The Quick Look Report is always included in the Initial Interrogation Report.

c. Tap OK.

To generate an Initial Interrogation Report for a patient session that is in progress, end and restart the patient session.

17.1.2 Configure the Final Report preferences

Select the reports that you want to include in the Final Report:

- 1. Tap **∃** > SESSION > PREFERENCES > FINAL REPORT.
- 2. Complete the following actions:
 - a. Select the reports to include in the Final Report. If you are configuring Final Report preferences for the first time, select **All Settings** in the **PARAMETERS** section.

Note: The Session Summary Report is always included in the Final Report.

b. Tap OK.

17.2 Generate reports

17.2.1 Generate a report using the PDF button

A PDF button appears on many windows and screens throughout the implantable device app. To generate a report from one of these screens or windows, tap the PDF button.

17.2.2 Generate a final report

To view summaries of selected data at the end of a session, generate the Final Report.

Tap **∃ > SESSION > FINAL REPORT**.

17.2.3 Generate a set of reports

To generate available reports, select a set of reports:

- 1. Tap > SESSION > AVAILABLE REPORTS.
- 2. Select the reports that you want to generate, then tap **GENERATE REPORTS**.

17.3 View or export saved reports and implantable device data

When you generate a report, you can view or export it directly from the **REPORT SAVED** window.

Also, you can access generated reports and saved implantable device data from the SAVED REPORTS window:

- 1. Tap **∃ > SAVED REPORTS / DATA**.
- 2. On the SAVED REPORTS window, view reports or export reports and device data:
 - To view a report, tap VIEW next to the report.
 - To export reports, select the reports, tap SEND TO..., then select the export option or location.
 - To export device data and the reports associated with the device data, select the PKG file, tap **SEND TO...**, then select the export option or location.

Notes:

- To select all files, tap the checkbox at the top of the list.
- When you select multiple reports to export, the reports export as a single PDF file.

Notes:

- The export options depend on the email, network, and printing apps or connections set up on the tablet.
- You are responsible for the management of patient and device data that you export from the app. Examples of patient and device data include printed paper reports, data transferred to a hospital network, and emailed attachments.

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