Medtronic

CareLink SmartSync™ Micra™ VR Application Help

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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Contents

1 Introduction

1.1 Description

The CareLink SmartSync Micra VR Application (referred to as the implantable device app) allows you to program the settings of a Micra VR transcatheter pacing device 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.

Note: The CareLink SmartSync Micra VR Application model number is D00U006.

1.2 Intended use of the implantable device app

1.2.1 Intended use

The intended purpose is to interrogate, program, or execute tests on a Medtronic cardiac device.

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.

1.2.5 Indications for use

For information about the indications for the implantable device, refer to the clinician manual for the implantable device.

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 device, refer to the clinician manual for the implantable device.

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 device, refer to the clinician manual for the implantable device.

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. 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 clinician manual for the implantable device.

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 device, refer to the clinician manual for the implantable device.

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 technology[1]. 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™* or cellular network) results in the inability to export and print reports using a wireless connection.[2]

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.

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[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®.

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 **EMERGENCY** button, the (Help) button, and the (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 transferred 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 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. **Note:** The Paceart Optima System is available only in supported regions.

Table 3. Patient connector status indicators

Indicator	Description
	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. The connection is either strong or moderate.
	The implantable device is connected to the patient connector. 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

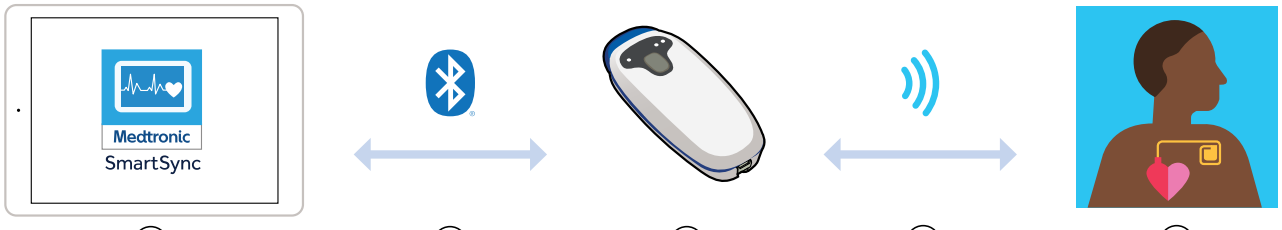
The status bar at the top of the screen displays the status of the connections among the device manager components. The connection status is indicated by the component icons and the icons that appear between each component. For more information, see the section about the status indicators in this app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

3.2 About the communication path

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.

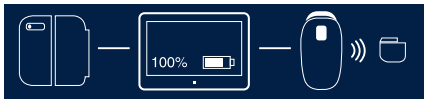
The following figure shows the communication path in a patient session:

Figure 1.



1 Implantable device app on the tablet
2 Bluetooth wireless technology
3 Patient connector
4 Low-frequency inductive telemetry
5 Implantable device

The following figure shows the connection status area of the status bar in a patient session:



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 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.

To reinterrogate the implanted device, tap ☰ > **INTERROGATE**.

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 WARNING – DEVICE ELECTRICAL RESET warning

Caution: If the implantable device app displays a **WARNING – DEVICE ELECTRICAL 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.
    c. 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, 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 implanted device is automatically programmed to either **Device Off** or VVI mode until the parameters are reprogrammed. In VVI mode, the implanted device paces at 65 bpm.
    b. Verify that the implantable device date and time are correct. If necessary, reprogram the date and time.

c. To verify that the battery voltage of the implantable device is acceptable, check the **BATTERY AND DEVICE MEASUREMENTS** window.
d. Conduct an electrode impedance test, a sensing test, and a pacing threshold test as desired.

5.3 Respond to the SERIOUS DEVICE ERROR warning

Caution: If the implantable device app displays a **SERIOUS DEVICE ERROR** status indicator warning, contact a Medtronic representative. An immediate new device implant is recommended.

To respond to the **SERIOUS DEVICE ERROR** status indicator warning, complete the following actions:

1. 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.
2. Tap **CONTINUE**.
3. To verify that the battery voltage of the implantable device is acceptable, check the **BATTERY AND DEVICE MEASUREMENTS** window.
4. Verify the programmed device parameters and reprogram them as necessary.
   Note: The implantable device is automatically programmed to **Device Off** until the parameters are reprogrammed.

6 Using the Live Rhythm Monitor

6.1 About the Live Rhythm Monitor

The Live Rhythm Monitor displays markers, intervals, and the telemetered EGM waveform trace 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 and sensing.

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

Table 6. Pacing markers

Marker	Description
VP	Ventricular pace
VS	Ventricular sense
VR	Ventricular refractory sense
VC	Ventricular capture
VL	Ventricular loss of capture
ER	Unrecognized marker

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 ⤫.
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.
OK	Closes the adjustment options.

5. To minimize the Live Rhythm Monitor, tap .

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 .
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 A or ✎ 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 .
2. Use the following options:
    - To adjust the caliper, drag .
    - To walk the caliper, tap .
    - 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 .

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:
    - To navigate along the waveform trace, tap and .
    - 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 device'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 status information that indicates whether the implanted device is operating as expected
- Information about 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 ☰ > **Quick Look**. You can view the following information:

Section	Description
REMAINING LONGEVITY	Displays the estimated time remaining until Recommended Replacement Time (RRT). To view more details, tap **REMAINING LONGEVITY**.
IMPEDANCE (Ω) **THRESHOLD (V @ ms)** **AMPLITUDE (mV)**	Displays information about the implanted device status, which allows you to assess the performance and integrity of the device electrode and identify any unusual conditions. The graphs display electrode impedance, capture threshold, and sensing amplitude measurements recorded over the last 12 months. The graph legends show the most recent measurement for each device performance variable. Use the following options: • To view detailed device trend data, tap **TRENDS**. • To view more details about the most recent measurements, tap **LAST MEASURED**.
% OF TIME	Displays information that helps you to evaluate the effectiveness of programmed implanted device settings.
RATE HISTOGRAM	Opens the **RATE HISTOGRAM** 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 status, parameter settings, 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 Programming patient information

10.1 Program the patient information

To store information about the patient and the implantable device 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 30 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.
Implant…	Opens the **IMPLANT** window, which allows you to enter or select the test values for **R-Wave Amplitude (mV)**, **Electrode Impedance (Ω)**, and **Threshold**. Also allows you to select the **Pulse Width** value.
History…	Opens the **HISTORY** window, which allows you to select the patient's clinical conditions.
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.
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 Programming implantable device settings

11.1 Parameter symbols

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

Table 7. Symbols that appear with parameter values

Symbol	Name	Description
	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.
	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.
	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.
	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.
	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 8. Message symbols

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

11.2 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.

11.3 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.

11.4 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.

11.5 Program data collection preferences

To adjust the date and time of the implantable device and to enable the Holter telemetry feature, program the data collection preferences:

1. Tap ☰ > **PARAMETERS** > **Data Collection Setup…**.
2. Configure the following options:

Option	Description
Device Date/Time…	Allows you to program the date and time of the implantable device to the date and time of your tablet. • **Device Date/Time** – Displays the date and time that the implantable device currently uses. • **Tablet Date/Time** – Displays the date and time that the tablet currently uses. • **SET TO TABLET TIME** – Allows you to program the new date and time that the implantable device will use based on the date and time of your tablet. **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 continuously transmits EGM and marker data for the selected duration, regardless of the presence of the patient connector. **Note:** Enabling Holter telemetry results in a higher consumption of the implanted device battery. Use of a customized Holter monitor (provided by Medtronic) is required for monitoring the device markers and EGM.

3. To program any pending changes, tap **OK** > **PROGRAM**.

11.6 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.

12 Viewing and analyzing diagnostic data

12.1 View clinical diagnostic data

12.1.1 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.

12.1.2 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 HISTOGRAM**.
2. To create a report, tap the PDF button.

12.2 View device diagnostic data

12.2.1 About device diagnostic data

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

12.2.2 View battery and device measurement data

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

Warning: The implantable device app displays an End of Service (EOS) indicator when the device battery no longer has adequate capacity to provide therapy to the patient and the device has reached the EOS condition. When the battery reaches the EOS condition, the device deactivates pacing permanently.

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

1. Tap ☰ > **DATA** > **BATTERY AND DEVICE MEASUREMENTS**.
2. Select the type of data you want to view:
    - **Remaining Longevity / Battery Voltage**
    - **Sensing Integrity Counter**
    - **Electrode Impedance**
    - **Capture Threshold**
    - **Sensing**
3. To create a report, tap the PDF button.

12.2.3 View electrode impedance trend data

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

1. Tap ☰ > **DATA** > **ELECTRODE IMPEDANCE TREND**.
2. To create a report, tap the PDF button.

The graph displays up to 15 daily measurements and up to 80 weekly summary measurements. Gaps in the graph occur when the implanted device fails to complete automatic electrode impedance measurements.

Note: Significant and sudden changes in electrode impedance can indicate a problem with the implanted device fixation or the electrode.

12.2.4 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 TREND**.
2. 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 80 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 implanted device fixation or the electrode.

12.2.5 View R-wave amplitude trend data

View and analyze the daily R-wave sensing amplitude measurements:

1. Tap ☰ > **DATA** > **R-WAVE AMPLITUDE TREND**.
2. To create a report, tap the PDF button.

The graph displays up to 15 daily measurements and up to 80 weekly summary measurements. The daily measurements are the median values of the amplitudes of 5 normal intrinsic ventricular sensed events. Gaps in the graph occur when the implanted device is unable to collect 5 amplitude measurements on a given day.

Note: Significant and sudden changes in the R-wave amplitude can indicate a problem with the implanted device fixation or the electrode.

13 Performing system tests

13.1 Configure the test preferences for the Live Rhythm Monitor

To view the EGM waveform, 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 waveform, tap **Auto-arrange waveforms**.
    - To leave the waveform display unchanged during a test, tap **Do not auto-arrange waveforms**.
3. Tap **OK**.

13.2 Perform the Device Measurements Tests

The implantable device app provides 3 assessment tools to measure device electrical performance for your patient. These tests, the Sensing Test, the Impedance Test, and the Threshold Test, can be performed individually or in an automated sequence.

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

To select the tests you wish to perform in an automated sequence, complete the following actions:

1. Tap ☰ > **TESTS** > **DEVICE MEASUREMENTS**.
2. Select each test that you wish to perform.
3. Make your pre-test parameter changes for the Sensing Test or the Threshold Test. The Impedance Test has no parameters.
4. Tap **START Tests** to perform the selected device measurements tests.
5. Optionally, complete 1 or more of the following actions:
    - To create a report, tap the PDF button.
    - To save the test values to the implanted device memory, tap **SAVE… > PROGRAM**. The test values appear when you open the **IMPLANT** window.

      Note: SAVE... only appears within 10 days of implant.
    - To clear the test results, tap **CLEAR… > CONTINUE**.

13.3 Perform a Sensing Test

To assess sensing performance, perform the Sensing Test, which measures 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, noise interference). These events are excluded from the daily automatic sensing amplitude measurements that the implanted device collects and reports in the R-wave amplitude trend. Because of the difference in measurement operations, Sensing Test results can differ from the measurements reported in the R-wave amplitude trend data.

Warning: Before you start the Sensing Test, select a temporary pacing rate that allows intrinsic sensed events that can be well tolerated by the patient. If the patient shows poor tolerance to the selected pacing rate during the test, tap **STOP**. To complete the Sensing Test, the device must detect 2 consecutive ventricular sensed events, and the interval between them must be at least 500 ms (120 bpm). If after 30 s this interval is not detected between 2 consecutive ventricular sensed events, the Sensing Test stops. If you cannot select a pacing rate that is well tolerated by the patient, consider withholding the Sensing Test.

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:

- If you need to conduct consecutive Sensing Tests to collect data, reduce the pacing rate gradually to avoid or 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.

1. Tap ☰ > **TESTS** > **DEVICE MEASUREMENTS**.
2. Clear the **Impedance Test** and **Threshold Test** checkboxes.

3. Verify or change the **TEST VALUE** parameter values for **Mode** and **Lower Rate**.
4. Tap **START Tests**.
5. Observe the Live Rhythm Monitor for an intrinsic rhythm.
    - If the patient shows poor tolerance to the test pacing rate, tap **STOP** to stop the test manually before it completes.
    - If you see an intrinsic rhythm at a rate that is within the normal rate range for the patient, the test is successful. When the test successfully completes, it automatically stops. The implantable device app displays the R-wave measurement value and the pacing settings return to their programmed values.
6. Optionally, complete 1 or more of the following actions:
    - To compare the Sensing Test R-wave measurement value with the automatic daily sensing R-wave amplitude measurements, tap ☰ **> DATA > R-WAVE AMPLITUDE TREND**.
    - To view the test strip, tap the test strip icon next to the **R-Wave** measurement value.
    - To create a report, tap the PDF button.
    - To save the test value to the implanted device memory, tap **SAVE… > PROGRAM**.
    - To clear the test results, tap **CLEAR… > CONTINUE**.

Note: Do not adjust the **RV Sensitivity** value based on the results of the Sensing Test. For more information, refer to the clinician manual for the implantable device.

13.4 Perform an Impedance Test

To test the integrity of the implanted device by measuring the impedance of the pacing electrode, use the Impedance Test.

Impedance measurements are made by delivering a pacing pulse. If the intrinsic heart rate is faster than the programmed pacing rate, the implanted device increases the pacing rate to be slightly faster than the intrinsic rate for 1 interval.

Notes:

- The upper limit for the pacing rate can vary depending on the programmed pacing mode.
- During a sequence of electrode impedance measurements, the implanted device may pace at a rate faster than the programmed value for the lower rate for 1 or more pacing cycles.
- If telemetry between the implantable device app and the implanted device is paused or lost during an Impedance Test, the test stops and the implanted device parameters revert to permanently programmed values.

1. Tap ☰ **> TESTS > DEVICE MEASUREMENTS**.
2. Clear the **Sensing Test** and **Threshold Test** checkboxes.
3. Tap **START Tests**.

    When the Impedance Test completes, the implantable device app displays the measured impedance value.

    To stop the test manually before it completes, tap **STOP**.
4. Optionally, complete 1 or more of the following actions:
    - To compare the test result to daily automatic impedance measurements, tap ☰ **> DATA > ELECTRODE IMPEDANCE TREND**.
    - To create a report, tap the PDF button.
    - To save the test value to the implanted device memory, tap **SAVE… > PROGRAM**.
    - To clear the test results, tap **CLEAR… > CONTINUE**.

13.5 Perform a pacing Threshold Test

13.5.1 Perform an automatic pacing Threshold Test

To determine the patient's pacing thresholds, use the automatic (Capture Management) Threshold Test. The Capture Management test checks the pacing stimulation thresholds at different pacing amplitude settings. Use the test results to help you select amplitude and pulse width settings that ensure capture while minimizing output to maximize battery longevity.

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

1. Tap ☰ **> TESTS > DEVICE MEASUREMENTS**.
2. Clear the **Sensing Test** and **Impedance Test** checkboxes.
3. Select **Capture Management** from the **Threshold Test** list.
4. Tap **START Tests**.

    When the test completes, the implantable device app displays the **Threshold** measurement value.

    To stop the test manually before it completes, tap **STOP**.
5. Ensure that the amplitude and pulse width values provide an adequate safety margin above the pacing threshold.

6. Optionally, complete 1 or more of the following actions:
    - To compare the **Threshold** measurement value to the automatic daily threshold measurement values, tap ☰ **> DATA > CAPTURE THRESHOLD TREND**.
    - To view the test strip, tap the test strip icon next to the **Threshold** measurement value.
    - To create a report, tap the PDF button.
    - To save the test values to the implanted device memory, tap **SAVE… > PROGRAM**.
    - To clear the test results, tap **CLEAR… > CONTINUE**.

13.5.2 Perform a manual pacing Threshold Test

To determine the patient's pacing thresholds, use the manual pacing Threshold Test. The manual pacing Threshold Test allows you to program your own mode and pacing settings to identify the pacing stimulation thresholds. Use the test results to help you select amplitude and pulse width settings that ensure capture while minimizing output to maximize battery longevity.

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

1. Tap ☰ **> TESTS > DEVICE MEASUREMENTS**.
2. Clear the **Sensing Test** and **Impedance Test** checkboxes.
3. Select **Amplitude - Auto Decrement** from the **Threshold Test** list.
4. Tap **START Tests** to display the **TESTS - PACING THRESHOLD - AMPLITUDE - AUTO DECREMENT** window.
5. Verify or change the values:
    - Verify or change the value for **Decrement After**.
    - To change the parameters applied during the test, select new values in the **TEST VALUE** column.

    Note: The programmable and default values depend on the programmed values for pacing therapy.
6. Press and hold **TEST Press and Hold**, then observe the Live Rhythm Monitor for loss of capture.
7. When loss of capture occurs, release **TEST Press and Hold**.

    The implanted device resumes its original pacing values.
8. In the **ENDING VALUE** column, verify the detected **RV Amplitude** at which loss of capture occurred.
9. In the **THRESHOLD** column, adjust the RV Amplitude threshold value as needed.
10. Ensure that the amplitude and pulse width values in the **PERMANENT** column provide an adequate safety margin above the pacing threshold.
11. To change the programmed **RV Amplitude** or **RV Pulse Width** values, complete the following actions:
    a. In the **PERMANENT** column, tap the value.
    b. On the **RV Amplitude** or **RV Pulse Width** window, select the desired value.
    c. Tap **PROGRAM**.
12. View the ending value and permanent value for the **V. Pace Blanking** parameter.
13. To view a test strip from the Threshold Test, complete the following actions:
    a. Tap the **Test Strip** icon.
    b. Close the window to return to the results window.
14. When you have finished viewing or changing data on the **RV AMPLITUDE THRESHOLD TEST - RESULTS** window, tap **CLOSE** to return to the **DEVICE MEASUREMENTS** screen.
15. Optionally, complete 1 or more of the following actions:
    - To compare the **Threshold** measurement value to the automatic daily threshold measurement values, tap ☰ **> DATA > CAPTURE THRESHOLD TREND**.
    - To view the test strip, tap the test strip icon next to the **Threshold** measurement value.
    - To create a report, tap the PDF button.
    - To save the test values to the implanted device memory, tap **SAVE… > PROGRAM**.
    - To clear the test results, tap **CLEAR… > CONTINUE**.

13.6 Perform a Temporary Test

The Temporary Test evaluates device operation during temporary changes to parameter settings. The changes are in effect only while the test is in progress.

The Temporary Test allows you to evaluate changes to these parameters:

- **Mode**
- **Lower Rate**

- **Amplitude**
- **Pulse Width**
- **Refractory**
- **Sensitivity**

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

1. Tap ☰ > **TESTS** > **TEMPORARY**.
2. To change the parameters applied during the test, select new values in the **TEST VALUE** column.

   Note: Be aware of temporary parameter values that can inhibit pacing in pacemaker-dependent patients.

   Warning: High-rate stimulation of the ventricle could result in ventricular tachycardia or fibrillation. Apply temporary high-rate pacing under careful patient monitoring and control.
3. Press and hold **TEST Press and Hold**.
4. Observe changes in the waveform.
5. Release **TEST Press and Hold**.
6. To view a test strip from the most recent Temporary Test, tap the **Test Strip** icon.
7. To create a report, tap the PDF button.

13.7 Perform an Exercise Test

13.7.1 About the Exercise Test

When the pacing mode is programmed to VVIR, the Exercise Test helps you to assess the patient's settings for rate response. The rate-response settings are applied when the implanted device is operating in VVIR mode.

As an alternative to automatic Rate Profile Optimization, you can perform an Exercise Test from the implantable device app to set the rate-response values for the **Lower Rate**, **ADL Rate**, and **Upper Sensor Rate**. If **Rate Profile Optimization** is programmed to **Off**, the rate-response parameters remain at their programmed values. When **Rate Profile Optimization** is programmed to **On**, this feature adjusts the 3 rate-response parameters once each day. For more information about rate-responsive pacing, see the clinician manual for the implantable device.

The Exercise Test allows you to evaluate the rate-response settings for the patient and optimize the rate-response control parameters:

- The **LR Setpoint** (lower rate setpoint) value determines the activity counts required to pace at a rate higher than the lower rate.
- The **ADL Setpoint** (activities of daily living setpoint) value determines the minimum sensor response to pace at the **ADL Rate**, which falls within the ADL rate range.
- The **UR Setpoint** (upper rate setpoint) value determines the minimum sensor response to pace at the **Upper Sensor Rate**, which is at the upper limit of the exertion rate range.
- The **Activity Vector** value determines the accelerometer vector used for rate response. For more information about choosing the **Activity Vector**, see the clinician manual for the implantable device.

Note: The programmed **LR Setpoint** setting must be lower than the **ADL Setpoint** setting, and the **ADL Setpoint** setting must be lower than the **UR Setpoint** setting.

13.7.2 Performing an Exercise Test

Perform an Exercise Test to help you assess the patient's settings for rate response.

Note: If telemetry between the implantable device app and the implanted device is paused or lost during an Exercise Test, the implanted device continues to record test data. The test completes when the test duration is reached.

1. Program the pacing mode to VVIR.
2. Tap ☰ > **TESTS** > **EXERCISE**.
3. Tap **Duration** and select the test duration.
4. Tap **Activity Vector**, select a value, and tap **PROGRAM**.

   Note: Do not change the currently programmed values for **LR Setpoint**, **ADL Setpoint**, and **UR Setpoint**. These values provide a baseline to determine the necessity to adjust the patient's rate-response setpoints in consideration of the results of the Exercise Test.
5. Tap **START Test**.

   If test data from a previous Exercise Test is in the device memory, the WARNING - DATA WILL BE LOST message appears. The message warns you that the current test results will be overwritten if you start the Exercise Test.

   Note: Create a report or otherwise record the current values if you want to compare them to the test values.
6. To start the test, tap **CONTINUE**.

When the test completes, the **EXERCISE** window displays the Test Complete message.

To stop the test manually before it completes, tap **Stop and Retrieve**. The data recorded up to that point will be saved.

7. Re-establish telemetry between the implanted device and the patient connector.

   The test results appear.

13.7.3 Interpreting Exercise Test data and adjusting rate-response setpoints

The implanted device collects the Exercise Test data. You can view the test data on the **EXERCISE** screen to interpret the test data and adjust rate-response setpoints.

1. From the **EXERCISE** screen, view the test data. The test data is displayed as the **Activity Counts** graph.
2. To view the patient's heart rate, sensor rate, and the device activity that was recorded during the Exercise Test, tap **Activity Counts** and select **Rate Graph**.
3. Examine the Exercise Test results shown on the **Activity Counts** graph. Compare the patient activity count data to the programmed values for **LR Setpoint**, **ADL Setpoint**, and **UR Setpoint**.

   To determine if you need to adjust the rate-response setpoint values, consider the activity that the patient was engaged in during the Exercise Test:

   - The **LR Setpoint** (the lower rate set point) corresponds to when the patient is at rest at the beginning of the test. Following the test, tap **LR Setpoint** and select a value slightly higher than the highest activity count for when the patient is at rest.
   - The **ADL Setpoint** (the activities of daily living set point) corresponds to when the patient is engaged in moderate activity. Following the test, tap **ADL Setpoint** and select the average activity count for when the patient is engaged in moderate activity.
   - The **UR Setpoint** (the upper rate setpoint) corresponds to when the patient is engaged in vigorous activity. Following the test, tap **UR Setpoint** and select a value slightly lower than the average activity count for when the patient is engaged in vigorous activity.
4. Tap **PROGRAM** to program the updated rate-response values.
5. To create a report, tap the PDF button.

14 Using the SessionSync software

14.1 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.

1. 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.

Field	Description
	• **GENERATED** – Date and time of the transfer • **RECEIVING CLINIC** – Name of the clinic that receives the transfer • **STATUS** – Status of the transfer

14.2 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**.

14.3 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**.

15 Managing the patient session

15.1 Connect the device manager app to the base

Connect to the base to view ECG waveforms during a patient session:

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 ECG cable to the base, refer to the base technical manual and the ECG cable IFU.

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

15.3 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.

15.4 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.

15.5 End the patient session

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

1. Tap ☰ > **END SESSION**.
2. To change the setting for clearing the session data, select one of the following options from the **Pacemaker Data** list:
    - Select **Clear Now** to immediately clear the session data at the end of the session.
    - Select **1 hour after session end** to clear session data 1 hour after the end of the session.
    - Select **Do not clear** if you want data collection to continue as if there were no device interrogation. Data collection ends when the session data is cleared.
3. Tap **END NOW**.

16 Working with reports and saved device data

16.1 Configure the report preferences

16.1.1 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.

16.1.2 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**.

16.2 Generate reports

16.2.1 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.

16.2.2 Generate a final report

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

Tap ☰ > **SESSION** > **FINAL REPORT**.

16.2.3 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**.

16.3 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.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

Medtronic USA, Inc.
Toll-free in the USA (24-hour technical consultation for physicians and medical professionals)
Bradycardia: +1 800 505 4636
Tachycardia: +1 800 723 4636

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