Medtronic

AZURE MRI™ SURESCAN™ / ASTRA MRI™ SURESCAN™ SW030

Programmer software

Programming Guide

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

AZURE MRI™ SURESCAN™ / ASTRA MRI™ SURESCAN™ SW030

Programming Guide

A guide to programming the Azure™ MRI SureScan™ and Astra™ MRI SureScan™ pacemakers using the Medtronic SW030 application software on a Medtronic programmer

Contents

1 Software overview

1.1 Introduction

This manual describes the Medtronic Model SW030 programmer software and explains how to use a programmer to conduct a patient session.

Throughout this manual the word “device” refers to the implanted pacemaker. The names of screen titles and interactive screen elements are shown in **bold** type. Navigation paths to software screens or programmable parameters are shown with a “>” character between steps in the path (for example, **Data** > **Device/Lead Diagnostics** > **Lead Impedance Trends** > **Open Data**).

The software features described in this manual apply to the Azure XT DR MRI SureScan devices. To determine which features are available for another model in the Azure MRI SureScan or Astra MRI SureScan families, refer to the device reference manual. If this manual is supplied in its printed form and any part of it is illegible, contact a Medtronic representative to request a replacement manual.

Additional manuals and documents with information about the programmer and implanted device:

MRI technical manual – This manual provides MRI-specific procedures and warnings and precautions.

Reference manual – This manual contains information about device features. The reference manual applies to multiple models of IPG devices.

Programmer reference manual – This manual contains information about the features of the programmer. There are separate programmer reference manuals for the Medtronic CareLink 2090 programmer and the Medtronic CareLink Encore 29901 programmer.

Device manual – This manual contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

Explanation of symbols – This document defines the symbols that may appear on the device package. Refer to the package label to see which symbols apply specifically to this device.

Medical Procedure and EMI Warnings and Precautions Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on cardiac device patients. The manual also provides patient education information related to sources of electromagnetic interference (EMI) at home, at work, and in other environments.

Radio regulatory compliance information – This document provides compliance information related to the radio components of the device.

1.2 Software description

The Medtronic Model SW030 software runs on the Medtronic CareLink 2090 and Medtronic CareLink Encore 29901 programmers and communicates with an implanted device to program settings and view stored data. The software is compatible with implantable pacemakers from the Azure MRI SureScan and Astra MRI SureScan families.

The programmer and software should be used only by healthcare professionals or Medtronic personnel in a clinical or hospital environment.

1.3 Intended use

The Medtronic Model SW030 software is intended to be used to adjust programmable parameters and evaluate the performance of the implanted Azure MRI SureScan or Astra MRI SureScan pacemaker system. For information about indications for the implantable devices that are compatible with this software, refer to the appropriate device manual.

1.4 Contraindications

No contraindications related to the use of this software are known; however, contraindications related to the use of the implantable devices and programmers that are compatible with this software can be found in the appropriate manual for the compatible device.

1.5 Warnings and precautions

There are no general warnings or precautions related to the use of this software. Specific warnings and precautions are listed in the sections to which they pertain.

For information regarding warnings and precautions related to the use of the implantable devices and programmers that are compatible with this software, refer to the appropriate manual for the compatible device.

1.6 Potential adverse events

There are no known potential adverse events related to the use of this software.

For information regarding potential adverse events related to the use of the implantable devices and programmers that are compatible with this software, refer to the appropriate manual for the compatible device.

2 Patient session

2.1 Conducting a patient session

During a patient session, you can use the programmer to view or enter information about the patient and device, and to program the device.

Use the programmer to perform the following tasks:

- review the presenting rhythm
- verify the status and clinical effectiveness of the implanted system
- view or enter patient information
- program parameters
- print, save, or export data

2.2 Starting a patient session

To start a patient session, use a Medtronic programmer and a programming head that is appropriate for the programmer model.

Note: If you are using the Medtronic CareLink Programmer with Conexus telemetry, you must use the programmer in the nonwireless telemetry mode.

For information about setting up the programmer for a patient session, using the programming head, or compatible programming heads, refer to the programmer reference manual.

The programmer interrogates the patient's device at the start of a patient session. End the previous session before starting a session with another patient.

You can expect reliable telemetry between the implanted device and the programmer in a typical examination room or operating room.

Note: During an initial interrogation, only emergency programmer functions are available.

Caution: A programmer failure (for example, a faulty touch pen) could result in inappropriate programming or the inability to terminate an action or activity in progress. In the event of a programmer failure, immediately turn off the programmer power to deactivate telemetry and terminate any programmer-controlled activity in progress.

Use the following steps to start a patient session:

1. Turn on the programmer power.
2. Place the programming head over the device to establish telemetry between the device and the programmer.

   The amber light on the programming head turns off and 1 or more of the green indicator lights on the programming head illuminate when telemetry is established.
3. To ensure that reliable telemetry has been established, position the programming head so at least 2 of the green lights illuminate.

   To find the optimal position for the programming head, move it around the implanted device until the greatest number of green lights illuminate.

   Note: If the programming head slides off the patient, the session does not terminate. Place the programming head back over the device.
4. Press the "I" button on the programming head or tap **Find Patient…**.

   The patient session starts and the interrogation occurs. Successful interrogation or programming of the device verifies that the device and the programmer are communicating reliably.

For the device to transmit EGM traces and Marker Channel data, you must keep the programming head over the device during the patient session.

If you are having trouble maintaining consistent, reliable telemetry between a patient's implanted device and the programmer, remove any sources of electromagnetic interference (EMI) that may be affecting the telemetry signal. For more information about EMI, refer to the Medical Procedure and EMI Warnings and Precautions Manual for Health Care Professionals.

If programming is disrupted by EMI or loss of telemetry, you must reestablish telemetry and program the device again.

Note: The programming head contains a magnet that suspends tachyarrhythmia detection and initiates magnet mode pacing until telemetry between the device and programmer is established.

2.3 Interrogating the device during a patient session

You can manually interrogate the device at any time during the patient session.

1. Tap **Interrogate…** or press the "I" button on the programming head.

   The **Interrogate How Much?** window is displayed.

2. Choose the data you would like to gather:
   - To gather information collected since the last patient session, tap **Since Last Session**.
   - To gather all the information stored in the device, tap **All**.
3. Tap **Start**.

2.4 Responding to device status indicator warnings

The device automatically monitors for internal conditions that affect device operation and require attention. If any such conditions occur, a device status indicator is recorded in memory, and a device status indicator warning is displayed on the programmer screen when the device is interrogated.

Device status indicator warnings are displayed both as a window on the programmer screen and in the Observations box on the Quick Look II screen.

Caution: Inform your Medtronic representative if a device status indicator warning is displayed.

- Take the following actions to respond to device status indicator messages:

Indicator warning	Action
Warning - Device Reset	If the device is not yet implanted, do not implant the device. Contact a Medtronic representative. If the device is implanted, follow the procedure in Section 2.4.1.
SERIOUS DEVICE MEMORY FAILURE	Contact a Medtronic representative. **Immediate replacement of the device is recommended.**
AT/AF Therapies Disabled	1. Contact a Medtronic representative. 2. Tap **Clear** to clear the device status indicator. 3. Review arrhythmia episode records and evaluate atrial lead integrity. 4. Adjust therapy parameters as needed.
Attention – Atrial Lead Not Detected During Implant	Tap **Clear**. If an atrial lead is not present, consider programming Atrial Sensitivity to Off and changing the pacing mode to VVI(R) to maximize longevity.

2.4.1 Responding to a device reset warning for an implanted device

A device reset is a safety feature that can automatically change parameter values or clear diagnostic data in response to a problem with device memory. If a device status indicator

warning for a reset is displayed, you must clear the device status indicator and may need to reprogram the device to desired parameters.

After a device reset, a device status indicator is recorded. For a device reset that requires attention, the device status indicator warning describes how data was affected by the reset. Read the message accompanying the indicator and follow the screen instructions carefully. If the message indicates that the device parameters were affected by the reset, you must reprogram the device to restore the previous settings.

If the programmer displays a device reset message for an implanted device, perform the following steps:

1. Remove any sources of electromagnetic interference (EMI).
2. Notify a Medtronic representative.
3. Tap **Clear** in the window to clear the device status indicator.

   A confirmation window appears indicating that all previously interrogated data in the programmer will be cleared.
4. 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.
5. Interrogate the device.
6. The time and date that the device reset occurred can be found in the CareAlert Events log.

   Note: If your device does not have a CareAlert Events log, the information can be found in the counter data.
7. Save your session data to a disk or a USB flash drive.

   You should give a copy of this saved data file to your Medtronic representative; it will be helpful in determining the events leading up to the reset.
8. Verify the programmed device parameters and reprogram them as necessary.

   Note: If the device parameters were affected by the reset, the device will automatically pace in VVI mode at 65 bpm until parameters are reprogrammed.
9. Verify that the device date and time are correct. If necessary, a Medtronic representative can reprogram the date and time.

10. Check the **Battery and Lead Measurements** screen to verify that the battery voltage is acceptable.
11. Conduct lead impedance and pacing threshold tests as desired.

2.5 Quick Look II screen

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

The Quick Look II screen provides the following information:

- Device and lead status information indicating whether the system is operating as expected.
- Information about arrhythmia episodes and provided therapies to help assess the patient's clinical status since the last follow-up appointment.
- System-defined observations alert you to unexpected conditions, providing suggestions of how to optimize the device settings.

Note: The **Quick Look II** screen shows information collected since the last patient session and stored in the device memory. Programming changes made during the current session may also affect the Quick Look II observations.

You can update the Quick Look II data during a session by reinterrogating the device.

The **Quick Look II** screen is automatically displayed after the patient session is started. To access the **Quick Look II** screen from another screen, tap **Data** > **Quick Look II**.

2.5.1 Information on the Quick Look II screen

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

Available information:

To view relevant details about a section of the screen, tap the » button.

Remaining Longevity – The Remaining Longevity estimate shows the estimated time remaining until Recommended Replacement Time (RRT).

To access the **Battery and Lead Measurements** screen, tap the » button next to the **Remaining Longevity** field.

Lead status and trends – Information about lead status allows you to assess the performance and integrity of leads and identify any unusual conditions. The "Last Measured" column shows the most recently measured lead impedance for each lead. To see more details, tap the ⏭ button in the "Last Measured" column.

The lead trend graphs show lead impedance, capture threshold, and sensing amplitude measurements recorded over the last 12 months. To see more details, tap the ⏭ button beside any of the lead trend graphs.

The graph legends contain the last measured values. To see more details about these values, tap the ⏭ button.

Pacing and sensing information – This information can help to assess the patient's AV conduction status and evaluate the effectiveness of programmed 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 session. If the 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 device. Some device features (for example, Ventricular Safety Pacing) affect the way events are counted. Also, due to rounding, percentages may not add up to 100%.

Arrhythmia episode information – This section shows the number of treated and monitored arrhythmia episodes that have occurred since the last patient session. To access the Arrhythmia Episodes data screen, tap the ⏭ button next to either the **Treated** or **Monitored** field.

Cardiac Compass trend data – The Cardiac Compass Trends screen provides a picture of the patient's condition during the last 14 months. The trend information can help to assess whether device therapies or antiarrhythmic drugs are effective. To access the Cardiac Compass Trends screen, tap the ⏭ button next to the **Cardiac Compass** field.

Rate Histograms data – The Rate Histograms screen provides information about heart rates recorded between patient sessions. This data can help you to monitor a patient's condition and assess the effectiveness of therapies. To access the Rate Histograms screen, tap the ⏭ button next to the **Rate Histograms** field.

Observations – Observations are based on an analysis of programmed parameters and data collected since the last session. Observations alert you to unexpected conditions related to device and lead status, parameter settings, arrhythmia episodes, and clinical status.

If you select one of the displayed observations, the ⏭ button becomes active if more information about the selected observation is available. You can use the ⏭ button to look at relevant details.

2.6 Programmer screen

The programmer screen is divided into areas to view information, navigate among screens, and perform tasks.

The screen includes the following areas:

- Task bar at the top of the screen (See the programmer reference manual for information about the task bar.)
- Status bar below the task bar
- Live Rhythm Monitor area
- Task area that changes according to the task or function you select
- Navigation icons on the right

2.6.1 Status bar

When the device has been interrogated, you can use the status bar at the top of the display screen (located immediately below the task bar) to perform some basic functions and to note the current status of the device.

The status bar displays the following items:

- Currently active pacing mode
- Programmed detection and therapy configuration
- **Resume** and **Suspend** buttons for resuming or suspending detection
- The word SUSPENDED when automatic detection is suspended
- An indicator (A) if an episode is in progress while AT/AF detection is On
- Either the current implant detection, episode, therapy, or manual operation status, or the device name and model number

2.6.2 Live Rhythm Monitor window

The **Live Rhythm Monitor** window displays ECG waveform traces, Marker Channel telemetry with marker annotations and intervals, and telemetered EGM waveform traces.

You can view live waveform traces, freeze waveform traces, record live waveform traces to the programmer's strip chart recorder or Electronic Strip chart (eStrip) recorder, whichever is available, and recall any saved waveform strips prior to ending a patient session. In addition to waveform traces, the **Live Rhythm Monitor** window shows the following information:

- If telemetry has been established with the device, heart rate and interval are displayed.
- If parameters are programmed, an annotation appears above the waveform trace showing the point at which programming occurred.

The **Live Rhythm Monitor** window appears in partial-screen view by default. You can expand this to full-screen view by tapping the small square button in the upper-right corner of the window or by tapping the **Adjust…** button. The display of waveform traces in the **Live Rhythm Monitor** window varies depending on which sources you select during data collection setup and how you arrange traces in the full-screen view.

2.6.2.1 Live waveform types

The Live Rhythm Monitor can display up to 6 different waveforms during a patient session.

Waveforms are available from ECG and EGM signals:

- The ECG Lead I, ECG Lead II, and ECG Lead III waveforms display ECG signals that are detected using skin electrodes attached to the patient. The ECG cable attached to these electrodes must be connected to the programmer.
- The EGM1, EGM2, and EGM3 signals are telemetered from the device and are selected from programmable EGM sources. You can choose the sources of EGM1, EGM2, and EGM3 when you set up data collection. The programmer cannot display or record an EGM waveform trace until the current EGM Range setting has been interrogated from the device.

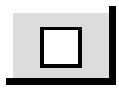
2.6.2.2 Adjusting the Live Rhythm Monitor display

Use the Live Rhythm Monitor **Adjust…** window selections to change the waveform display.

1. Tap **Adjust…**.

   The full-screen **Live Rhythm Monitor** window and the **Adjust…** window are displayed.

2. Adjust the size, source, and print selection options for each waveform trace using the waveform adjustment buttons to the left of each waveform trace.

Button	Description
	Increase the size of the waveform trace.
	Restore the waveform trace to its default size.
	Decrease the size of the waveform trace.
	Display a waveform trace, marker annotation, or marker intervals.
	Identifies a waveform trace selected for printing. Tap the button to clear the selection and choose a different trace.
	Select the waveform trace for printing. You can select up to 2 waveform traces for printing.
	Change the color of the waveform trace.

3. Adjust the appearance of all waveform traces by using the controls in the **Adjust…** window.

Optional adjustment	Steps
Truncate the tops and bottoms of waveform traces at a 22 mm boundary.	Tap **Clipping**.
Change the bandwidth of waveforms to improve the clarity of the displayed ECG in the presence of interference.	Tap **ECG Filter** and select the check box to set the bandwidth to 0.5 to 40 Hz, or clear the check box to set the bandwidth to 0.05 to 100 Hz.
Display pacing artifacts superimposed over waveform traces.	Tap **Show Artifacts**.
Control how quickly the waveform is drawn across the display.	Tap **Sweep Speed** and select a speed (12.5, 25, 50, or 100 mm/s). Selecting a fast **Sweep Speed** produces a wide waveform. Selecting a slow **Sweep Speed** produces a narrow waveform.

Optional adjustment	Steps
Equalize the spacing between the waveform traces and resize each trace to its default setting.	Tap **Normalize**.
Add a reference signal to the analog output, the screen, or the real-time strip recorder or Electronic Strip Chart (eStrip) recorder, whichever is available.	Tap (Calibrate).

4. Tap **OK**.

   The **Adjust…** window closes and the **Live Rhythm Monitor** window returns to its previous size.

2.6.2.3 Marker Channel data

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

The device continuously transmits Marker Channel data and supplementary marker data while telemetry is established and the programming head is positioned over the device. Marker Channel annotations appear as 2 characters above or below the Marker Channel waveform trace.

Real-time printed waveform recordings also display symbols that appear above or below their associated Marker Channel annotations. The symbols sometimes appear compressed, depending on the printout speed of the programmer strip chart recorder. The symbols do not appear on screens or in episode recordings.

Notes:

- Any interruption in telemetry with the device may result in missing marker annotations and symbols on the waveform trace display.
- The device stops transmitting marker data when you lift the programming head, unless the Holter telemetry feature is programmed to On. If Holter telemetry is programmed to On, the device transmits Marker Channel data and supplementary marker data regardless of the position of the programming head.

2.6.2.4 Live waveform trace recordings

At any time during a patient session, you can record a continuous, live waveform trace of the patient's ECG and EGM in one of two ways:

1. On an internal strip chart recorder, if available on your Medtronic programmer.

   Note: The printed waveform strip is of a higher resolution than the programmer display and may show artifacts and events that do not appear on the programmer display.

2. On an Electronic Strip Chart (eStrip) recorder, if available on your Medtronic programmer.

Depending on the Medtronic programmer model used, a printout of the live waveform trace includes the following information:

- ECG and EGM traces
- an indication of an executed command when confirmation of the command is received
- test values during system tests
- telemetry markers that show telemetry from the programmer to the device (programming the device) and telemetry from the device to the programmer (confirming the programming)
- Decision Channel annotations

EGM waveform trace

The programmer cannot display or record an EGM waveform trace until the current EGM Range setting has been interrogated from the device. If you program an EGM Range setting during a recording, the programmer marks the change with a vertical dotted line on the paper recording. EGM and Marker Channel telemetry can be momentarily interrupted during interrogation or programming.

Simultaneous report printing and live waveform trace recording

If you attempt to print a report to the strip chart printer while performing a live waveform trace recording, the report is sent to the print queue. Printing to an external printer is not affected.

2.6.2.5 Freezing live waveform traces

The Freeze feature enables you to freeze the last 15 s of all waveform traces displayed in the **Live Rhythm Monitor** window.

You can use controls in the frozen strip viewer to view earlier or later portions of the strip, see frozen waveform strips that are not visible in the window, and measure a time interval.

1. Tap **Freeze**.

   The live waveform trace is frozen and displayed in the frozen strip viewer.

2. To modify or navigate the frozen strip viewer, select from the following options in the frozen strip viewer:

Optional task	Steps
Open the **Adjust…** window for the frozen strip viewer.	Tap **Adjust…** to open the **Adjust…** window. The **Adjust…** window offers display options for the frozen strip viewer that are similar to the **Adjust…** window for the Live Rhythm Monitor.
Normalize or resize the trace, or change the waveform source.	Use the waveform adjustment buttons.
Measure time intervals on the waveform trace.	Use the **Caliper** controls. The caliper measurement is the time interval between the on-screen calipers. The arrow buttons move the on-screen calipers to show the beginning and the end of a time interval.
Open a list of other frozen strips.	Tap **Strips…** to open a list of other frozen strips. Tap a strip to view and tap **Open** to display the selected strip.
Delete the on-screen frozen strip (if it was previously saved).	Tap **Delete**.
Print the on-screen frozen strip.	Tap **Print…**.
View earlier or later portions of the strip.	Scroll horizontally using the horizontal scroll bar.
View frozen waveform strips that are not visible in the window.	Scroll vertically using the vertical scroll bar.
Save the on-screen frozen strip.	Tap **Save**.

3. To close the frozen strip viewer, tap **Close**.

2.6.2.6 Recalling saved waveform strips

Before ending a patient session, you can recall any waveform strip collected and saved during the session in order to view, adjust, and print the waveform strip.

1. Tap **Strips…** on the main screen or in the frozen strip viewer.

   The **Strips…** window is displayed.

2. Tap a strip to view.
3. Tap **Open**.

   The frozen strip viewer displays the selected strip.

2.6.3 Navigation icons

Navigation icons on the right side of the screen provide access to the main programmer screens.

After a patient session is started, the navigation icons are available on all but the **Emergency** or Live Rhythm Monitor **Adjust…** windows.

Table 1. Navigation icons

	Opens the **Checklist** screen for simplified navigation through a set of follow-up tasks.
	Navigates to the next task in the Checklist.
	Displays options for viewing device information and diagnostic data.
	Displays the **Parameters** screen for viewing and programming device parameters.
	Displays options for performing system tests and EP studies.
	Displays options for printing reports.
	Displays options for accessing the **TherapyGuide** or **Patient Information** screen.
	Displays options for adjusting preferences, viewing parameter changes made during the session, saving data, and ending the session.

2.7 Enabling emergency VVI pacing

Use emergency VVI pacing to quickly enable 70 bpm, high-output ventricular unipolar pacing to restore ventricular support in an emergency situation.

Note: MRI SureScan feature operation is disabled when emergency VVI pacing is programmed.

1. During a patient session, verify that telemetry is established between the device and the programmer.
2. Tap the on-screen **Emergency** button.

   Emergency VVI pacing is enabled, and the programmer displays the **Emergency** screen.

Note: You can also enable emergency VVI pacing by pressing the red mechanical emergency VVI button on the programmer.

To terminate emergency VVI pacing, you must reprogram pacing parameters from the **Parameters** screen.

2.8 Patient information

You can enter patient-related information and program it into device memory. This information can then be viewed and printed during a patient session.

Patient information is typically entered at the time of implant and can be revised at any time. After you enter the patient's information and program it into device memory, patient information is used in the following ways:

- Clinical conditions (Date of Birth and History) are available to the TherapyGuide feature.
- Clinical conditions are included in the Initial Interrogation Report and in the Save to Media file.
- Clinical conditions can be printed from the Patient Information screen.
- The patient's name and ID and the device serial number are included on all reports.

Some entries may appear shortened after they are entered. For example, the **Patient** field can display most but not all of the characters that can be entered. The full entry is provided on the Patient Information Report. When displayed or printed from other screens, the text entry may be shortened.

If you start a concurrent Medtronic analyzer session during the device session, you can export analyzer lead measurements. The exported measurements appear as pending parameter values in the **Implant** window, which is accessed from the **Patient Information** screen. You program these pending values from the **Patient Information** screen.

Note: The **Patient Information** screen should not be used in the place of the patient's medical chart. The **Patient Information** screen of the programmer software application 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.

2.8.1 Entering and viewing patient information

Enter information about the patient, the device, and the leads into the **Patient Information** screen.

1. Tap **Patient** > **Patient Information**.

   The **Patient Information** screen is displayed.

2. Tap each text field to enter or change its content:

Field	Description
Patient	Enter the patient's name (up to 29 characters).
ID	Enter the patient ID (up to 15 characters).
Date of Birth	Select the patient's date of birth.
Serial Number	Displays the serial number of the implanted device. This field is not selectable.
Lead 1…, **Lead 2…**	Enter detailed information for the lead or leads. If the lead information is not listed, tap **Modify List…** and add the information.
Implant…	Either export lead data from the Medtronic analyzer, or enter lead data using the fields. **Note:** If an implant procedure is in progress, consider making the measurements in a concurrent analyzer session. Measurements can be exported directly to the **Implant** window. Otherwise, select a value for each parameter.
MRI SureScan System/Other Hardware…	Select this field to access the MRI SureScan System/Other Hardware screen, which lets you enter information about leads and other hardware that may affect the decision to perform an MRI scan of this patient.
Notes	Enter notes about the patient or other information (up to 80 characters).

Field	Description
History…	Enter the patient's clinical conditions. This information is made available to the TherapyGuide feature. **Note:** Entering this information from either the **Patient Information** screen or the **TherapyGuide** screen updates the information on both screens.
EF, on	Select the ejection fraction from a table of values and select the measurement date.
Physician/Phone/Hospital	Select the physician's name, phone number, and hospital from a list. To add physician information to the list, tap **Modify List…** and add the information.
Last Update	Displays the last date that changes made to patient information were programmed into memory. This field is not selectable.

3. Tap **PROGRAM**.

2.8.2 Entering and viewing information about the MRI SureScan system and other implanted hardware

Enter information about the leads and other implanted hardware, such as abandoned devices and leads, lead extenders, or lead adaptors into the **MRI SureScan System/Other Hardware** screen.

1. Tap **Patient** > **Patient Information** > **MRI SureScan System/Other Hardware…**.

   The **MRI SureScan System/Other Hardware** screen is displayed.

2. Tap each text field to enter or change its content:

Field	Description
MR Conditional Device Implanted	Displays the MR conditional status of the implanted device. This field is not selectable.
MR Conditional Lead 1 Implanted	Specify whether Lead 1 is MR conditional by selecting Yes, No, or Unknown. **Note:** Selecting this parameter value from either the Patient Information screen or the MRI SureScan System/Other Hardware screen sets the parameters pending on both screens.
Lead 1 Model	Enter the model information for Lead 1.
MR Conditional Lead 2 Implanted	Specify whether Lead 2 is MR conditional by selecting Yes, No, or Unknown. **Note:** Selecting this parameter value from either the Patient Information screen or the MRI SureScan System/Other Hardware screen sets the parameters pending on both screens.
Lead 2 Model	Enter the model information for Lead 2.
Other Devices	Enter information to specify any other in-use or abandoned devices.

Field	Description
Other Leads	Enter information to specify any other in-use or abandoned leads.
Lead Extenders/Adaptors	Enter information to specify any in-use or abandoned lead extenders or adaptors.
Other Hardware Notes	Enter up to 50 characters of notes about other implanted hardware. **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 that changes made to patient information were programmed into memory. This field is not selectable.

3. Tap **OK**.

   The **Patient Information** screen is displayed.

4. Tap **PROGRAM**.

2.9 Parameters

Parameters are settings that control device functions and data collection. You view and program parameters from the **Parameters** screen.

All device 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. All permanent parameter changes can be programmed from the **Parameters** screen.

After you select new values for parameters, the new values are designated as pending values. A field containing a pending value has a dashed rectangle as its border. Values remain pending until you program them to device memory.

Parameter sets

Parameter sets are collections of parameter values that have been stored for quick retrieval. They include the following types:

Medtronic Nominals – Parameter values suggested for the device by Medtronic. The Medtronic Nominals cannot be customized or deleted.

Initial Interrogation Values – The permanently programmed parameter values as determined by the first interrogation of the device during the patient session. The Initial Interrogation Values cannot be customized or deleted.

Custom sets of values – 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 need to repeatedly program a particular set of parameters. The set of parameter values that you save can include both

programmed and pending values. To delete a custom parameter set, use the **Delete** button in the **Get Parameter Set** window.

2.9.1 Accessing and programming parameters

Use the **Parameters** screen to view and program parameters.

1. Tap the **Params** icon.

   The **Parameters** screen is displayed.

2. Make the desired parameter selections.

   New values are displayed as pending values.

3. Tap **PROGRAM**.

   The pending values are programmed to device memory.

2.9.2 Parameter symbols

Symbols can appear next to parameter values to convey their status or other information.

Table 2. Symbols that appear with parameter values

Symbol	Explanation
	**Interlock –** Indicates that 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 –** Indicates that a warning message is available regarding that value. The message can be viewed either by tapping the message button or by reselecting that parameter. In the latter case, the warning is displayed as a warning note in the selection window. These parameter values can be programmed.
	**Adaptive –** Indicates that the programmed value can be changed automatically by the 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 –** Indicates that the value is the Medtronic nominal value. **Note:** If the nominal value is also the programmed value, the Programmed symbol is displayed instead of the Nominal symbol.
	**Programmed –** Indicates that the value is the programmed value.

The programmer may display a message button next to the **PROGRAM** button that, when tapped, provides access to additional information about the pending parameters. The message button has one of the symbols described in the following table. When the message button is tapped, the programmer opens a second window displaying one or more messages. If there are multiple messages regarding the pending parameter values, the most significant message determines which symbol appears on the button.

Table 3. Symbols that appear on the message button

Symbol	Explanation
	**Interlock –** Indicates that a parameter interlock exists. Programming is restricted until you resolve the conflict. Tap this button for a message that describes the conflict.
	**Warning –** Indicates that there is a warning associated with programming one or more of the pending parameter values. Tap this button to view the warning message and recommendations.
	**Informational –** Indicates that there is an informational message regarding one or more of the parameter values. Tap this button to view the message.

2.9.3 Creating a custom parameter set

You can create and save sets of parameter values to the programmer and retrieve them either in the current patient session or in subsequent patient sessions.

This capability allows you to save and quickly 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 need to repeatedly program a particular set of parameters. The set of parameter values that you save can include both programmed and pending values.

1. Tap the **Params** icon.

   The **Parameters** screen is displayed.
2. Make the desired parameter selections.
3. Tap **Save…**.

   The **Parameter Set Name** window is displayed.
4. Enter a name for the parameter set, and tap either **OK** or **ENTER**.

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

The parameter set is saved for future retrieval and the parameter values appear as pending values on the **Parameters** screen.

2.9.4 Retrieving a parameter set

Use the **Get…** button to retrieve a Medtronic Nominals parameter set, an Initial Interrogation parameter set, or a custom parameter set.

1. Tap **Params** > **Get…**.

   The **Get Parameter Set** window opens.

2. Use the following optional tasks to manage parameter sets:

Optional task	Steps
Retrieve a parameter set.	Tap the parameter set you want to retrieve.
Program the selected parameter set.	Tap **Set Pending** to use the parameters from the selected set. The **Get Parameter Set** window closes and the new parameter values appear as pending values on the **Parameters** screen. Tap **PROGRAM** to program the pending values to device memory.
Remove an unneeded parameter set from the list.	Select the parameter set you want to remove and tap **Delete**.

2.9.5 Parameter values suggested by the TherapyGuide feature

The TherapyGuide feature provides a set of suggested parameter values based on the programmed information about the patient's clinical conditions. TherapyGuide suggestions are based on clinical studies, literature, current practice, and physician feedback.

Caution: The TherapyGuide feature does not replace a physician's expert judgment. The physician's knowledge of the patient's medical condition takes precedence over the set of inputs presented to the TherapyGuide feature. The physician is free to accept, reject, or modify any of the suggested parameter values.

When retrieved, suggested parameter values that are different than the programmed values appear as pending values on the **Parameters** screen. The suggested parameter values are stored in device memory only after you tap **PROGRAM** on the **Parameters** screen.

The clinical conditions can be entered in the **TherapyGuide** window or on the **Patient Information** screen. If the clinical conditions were previously entered using the **Patient Information** screen at implant or during a follow-up visit, they are displayed in the **TherapyGuide** window.

How programming suggestions are determined

The following table shows the clinical conditions that influence TherapyGuide suggestions. This table presents an overview, but the **Rationale** window shows how the suggested parameter values relate to specific settings for the clinical conditions. If a parameter is not influenced by the clinical conditions, the TherapyGuide feature may either recommend the Medtronic nominal value for that parameter or make no recommendation.

Table 4. Clinical conditions that influence TherapyGuide programming suggestions

Programming suggestions	Clinical condition parameters
Pacing Mode	Atrial Status, AV Conduction, Reflex Syncope
Lower Rate	Atrial Status, Date of Birth, Reflex Syncope
Upper Tracking Rate	Date of Birth
AV Intervals	Date of Birth
Rate Response (including Upper Sensor Rate)	Atrial Status, Heart Failure, Date of Birth, Activity Level
Rate Drop Response	Atrial Status, Reflex Syncope
VT Monitor	Date of Birth
AT/AF Detection	Date of Birth

2.9.5.1 Using the TherapyGuide feature

Use the **TherapyGuide** feature to obtain suggested parameter values.

1. Tap **Params** > **TherapyGuide…**.

   The **TherapyGuide** window is displayed.

2. Enter or change the clinical conditions as needed.

   Note: If the patient's clinical conditions have been previously entered, the information appears in this window, including the date the clinical conditions were last updated.

3. Tap **Get Suggestions**.

   The **TherapyGuide** window closes, and suggested changes to parameter values appear as pending values on the **Parameters** screen.

4. Review the pending parameter values and adjust them as needed using the following options:

Optional task	Steps
View rationale for TherapyGuide suggestions.	Tap **TherapyGuide** > **Rationale…**.
Clear all pending parameter values and pending clinical conditions.	Tap **Undo**.
Adjust specific pending values.	Tap the value you want to adjust. The parameter value window opens for that parameter. Tap **Undo Pending** or select a different parameter value. Tap **OK** to return to the **Parameters** screen.

5. Tap **PROGRAM** to program the pending parameter values and clinical conditions to device memory.

2.9.6 Setting data collection preferences

Use the **Data Collection Setup** screen to control the collection of EGM data for arrhythmia episodes, to adjust the device clock, to set Observation Conditions, and to enable telemetry features.

Notes:

- Data collection is automatic and cannot be turned off.
- The signal displayed on the Live Rhythm Monitor for EGM1, EGM2, and EGM3 sources is controlled by the **EGM Source** and **EGM Range** parameters on this **Data Collection Setup** screen.
- Pre-arrhythmia EGM storage works by keeping the EGM circuitry enabled at all times, and therefore it reduces device longevity. If you select **On – 1 month** or **On – 3 months**, Pre-arrhythmia EGM storage is automatically turned off after the time period expires. Refer to the reference manual for the implanted device for more information about the operation of Pre-arrhythmia EGM storage.

1. Tap **Params** > **Data Collection Setup…**.
2. Set your preferences using the following fields and controls:

Field	Description
EGM Source	For each EGM channel, define the source electrodes between which the device records EGM signals. **Note:** The cardiac interval measurements of the device are always based on the signals sensed through the programmed sensing polarity (not the stored diagnostic EGM). Therefore, your selection of EGM sources does not affect bradycardia pacing or tachyarrhythmia detection.
EGM Range	For each EGM channel, select a range. The EGM range setting affects the resolution of the EGM signal; the lower the setting, the higher the resolution. If the EGM signal is illegible or clipped, consider changing the range selection.
Monitored	Select a set of 2 sources to be used for monitored episode record storage.
Pre-arrhythmia EGM	Indicate whether you want to store EGM data collected prior to an episode.
AT/AF Settings…	Select the thresholds for AT/AF Daily Burden and Avg. V. Rate During AT/AF that will trigger QuickLook II Observations. **Note:** The **AT/AF Settings…** field will not appear on the screen if **Wireless Telemetry with Monitor** is programmed to **On**.
Device Date/Time… > **Time Zone**	Select the appropriate Time Zone offset from Coordinated Universal Time (UTC) to adjust the device time.
Holter Telemetry	Select a duration for the Holter telemetry feature to operate, or disable Holter telemetry. When Holter telemetry is enabled, the device continuously transmits EGM and Marker Channel data for the selected duration regardless of the presence of the programming head.
Wireless Telemetry with Monitor	Turn the Wireless Telemetry with Monitor feature on or off. **Note:** Wireless telemetry and Medtronic CareAlert Monitoring (if available) can only be used when Wireless Telemetry with Monitor is programmed to **On**.

3. Tap **OK**.

   The **Data Collection Setup** window closes and new values are displayed as pending values.

4. Tap **PROGRAM**.

2.10 Using a checklist to complete tasks

Use the Checklist feature to cycle through common tasks that are performed during an implant session or a follow-up session. You can use Medtronic standard checklists or your own custom checklists.

When you select a task from a checklist, the associated programmer screen for that task appears. Once you complete a task, you can either go back to the **Checklist** screen or continue on to the screen associated with the next task.

1. Tap the **Checklist** icon.

   The **Checklist** screen is displayed.

2. Tap a checklist from the **Checklist** field to display the tasks associated with that checklist. You can choose from the following checklists:

   - Medtronic Standard Followup Checklist
   - Medtronic Standard Implant Checklist
   - Custom checklists you have created

   The tasks included in that checklist appear in the Task list.

   Check marks appear next to the names of any programmer screens that were visited during a session.

3. Advance through the checklist tasks using the following actions:

Action	Steps
Begin the first checklist task.	Tap **Go to Task** or tap the ▸ button next to the **Checklist** icon. The screen for the first task appears. Complete the task on the screen.
Advance through the tasks.	Use the ▸ button to continue from one task to the next.
Return to the Task list.	Tap the **Checklist** icon.
Repeat a Task.	Tap the task in the checklist, then tap **Go To Task** or tap the ▸ button next to the **Checklist** icon.
Perform a task out of order.	Tap the task in the checklist, then tap **Go To Task** or tap the ▸ button next to the **Checklist** icon.

Once you have completed the last task on the Task list, the ▸ button and the **Go To Task** button become inactive. However, if you select a task in the list, both buttons become active again and you can use them to move among the task screens.

2.10.1 Creating and editing a custom checklist

Use the **Checklist** screen to create customized checklists that reflect your personal workflow.

To create a new checklist, use the following steps:

1. Tap the **Checklist** icon.

   The **Checklist** screen is displayed.

2. Tap **New…**.

   The **Checklist - New** window opens.

3. Use the following options to add and modify tasks on your custom checklist:

Optional task	Steps
Add a task to your checklist.	Tap the task you want to add in the box on the left. The selected task appears in the box on the right.
Add the same task more than once.	Tap the task again in the box on the left. The task appears again in the box on the right.
Add a task between other tasks.	Highlight the task on your checklist that the new task should follow. Tap the new task in the box on the left. The new task appears in the box on the right.
Delete a task from your checklist.	Highlight the task you want to delete on your checklist and tap **Delete**.

4. Tap the **Checklist name** field and enter a name.
5. Tap **Save**.

   Your new custom checklist is saved. The **Checklist – New** window closes and returns to the **Checklist** screen. Your new custom checklist is available to select in the **Checklist** field.

Use the following options to manage custom checklists:

Optional task	Steps
Edit a custom checklist.	Tap the checklist in the **Checklist** field and tap **Edit…**. Add or delete tasks as needed, then tap **Save**.
Rename a custom checklist.	Tap the checklist in the **Checklist** field and tap **Edit…**. Change the name and tap **Save**.
Delete a custom checklist.	Tap the checklist in the **Checklist** field and tap **Delete**. **Note:** After a custom checklist has been deleted, it cannot be restored.

Note: The Medtronic Standard Followup Checklist and the Medtronic Standard Implant Checklist cannot be edited or deleted.

2.11 Printing reports

You can print reports at the beginning of a session, during a session, at the end of a session, and after a session. By setting printing preferences, you can identify the reports to print, whether to print them now or later, and which printer to use.

During a patient session, you can print a report on a specific programmer screen by selecting the **Print…** button or the **Print** icon. If the printing preferences window appears, select printing preferences as desired. If the printing preferences window does not appear, the report prints according to the previously set printing preferences.

2.11.1 Setting printing preferences

Use the **Preferences** window to select print options, such as number of copies, printer type, and whether to print now or later.

1. After starting a patient session, tap **Reports** > **Preferences…** > **Printing**.
2. Select or deselect the check box next to **Pop up these options when any Print button is selected**:
   - To apply the printing preferences automatically whenever you print a report, leave the check box blank.
   - To be prompted to set printing preferences each time you print a report, select the check box.
3. Select the number of copies, choose a printer, and tap **OK**.

   Note: You can save reports as PDF files by choosing **Save to PDF File**. Reports are saved to an attached USB flash drive (or to a disk, if the programmer has a disk drive, a disk is inserted in the disk drive, and a USB flash drive is not connected).

Your preferences take effect immediately.

2.11.2 Enabling printing of an Initial Interrogation Report

You can set a preference to have the software application print an Initial Interrogation Report automatically after the first interrogation in a patient session. You can also specify the data to include in the report.

Initial Report preferences take effect at the start of a new session and remain in effect until you change them and start a new session.

1. After starting a patient session, tap **Reports** > **Preferences…** > **Initial Report**.
2. Select the check box next to **Print Initial Interrogation Report after first interrogation**.

3. Select the reports to include in the Initial Interrogation Report, if desired, and tap **OK**.

   Notes:

   - The Quick Look II Report is always included in the Initial Interrogation Report and cannot be deselected.
   - To print an Initial Interrogation Report for a patient session that is in progress, end and restart the patient session.

   The selected preferences are stored and the **Preferences** window closes. The Initial Interrogation Report prints automatically after interrogation.

2.11.3 Printing a set of reports during a patient session

Use the **Available Reports** window to specify a customized set of reports for printing.

1. Tap **Reports** > **Available Reports…**.
2. Select the reports you want to print.

   Note: A report can be printed only if its data has been collected. If no data has been collected, the name of the report appears gray.

3. Tap **Print Options…** if it is available, and select printing preferences as desired.
4. Tap one of the following buttons:
   - **Print Now** prints the reports immediately.
   - **Print Later** adds the print request to the print queue.

2.11.4 Printing a Final Report for the patient session

You can print a Final Report summarizing selected data at the end of a patient session.

The Session Summary Report is always included in the Final Report. You can select additional reports to include in the Final Report using the **Preferences** window.

- Tap **Reports** > **Final Report…**.

  The result depends on the following print preference you have specified in the **Preferences** window.

Print Preference	Result
Pop up these options when any Print button is selected box is checked	The **Final Report** window is displayed • Specify the number of copies to print and select the printer. If you select **Full Size** for the printer, select the file format from the list of available options. • Tap **Print Now** to print the Final Report immediately. • Tap **Print Later** to add the Final Report to the print queue.
Pop up these options when any Print button is selected box is unchecked	The Final Report prints immediately.

2.11.4.1 Setting Final Report preferences

Use the **Preferences** window to select the reports you want printed as part of the Final Report.

Your Final Report preferences remain in effect between sessions and across all applications.

Note: The Session Summary is always included in the Final Report and cannot be deselected.

1. Before ending a patient session, tap **Reports** > **Preferences…** > **Final Report**.
2. Select the reports to include in the Final Report.
3. If this is the first time you are establishing Final Report preferences, select **All Settings** in the Parameters section.
4. Select **OK**.

2.11.5 Print Queue window

The **Print Queue** window indicates the status of print jobs. It is available during a patient session and outside of a patient session.

The Print Queue window during a patient session

The **Print Queue** window indicates the printing status of reports that you select to print as you progress through a patient session. To display the **Print Queue** window during a patient session, select **Reports** > **Print Queue**.

The Print Queue window outside of a patient session

When you end a patient session, the **Print Queue** window is still available. It lists any reports held from that session and other sessions. To display the **Print Queue** window when you are not in a patient session, select the **Print Queue** icon from the **Select Model** screen.

Printing or deleting a print job

You can print or delete a print job from the queue. A report cannot be deleted if its status is “Printing” or “Waiting”.

A status of “Hold-Later” indicates one of the following situations:

- A report is on hold until you request that it be printed (using the **Print** button).
- The printing of a report was interrupted by the start of a recording.
- The printer is not operational (because it is out of paper, for example).

2.12 Exporting data to the Paceart system

The SessionSync feature provides network connectivity between the programmer and the Medtronic Paceart data management system. Using your clinic’s network, the programmer can send downloaded device data through the SessionSync feature to the data management system for later analysis and patient management.

For information about the SessionSync feature, see the programmer reference manual.

2.13 Saving and retrieving device data

You can save interrogated device data from a patient session to a disk or to a USB flash drive. Later, while no patient session is in progress, you can use the Read From Media application on the programmer to retrieve, view, and print previously saved data.

The Save to Media feature stores session data in a format that can only be retrieved using the Read from Media application.

Note: You can also save reports and frozen waveform strips as PDF files by checking the **Save to PDF File** option when printing.

The Medtronic CareLink 2090 programmer has a disk drive for 90 mm (3.5 inch) disks plus a USB port for USB flash drives, and the Medtronic CareLink Encore 29901 programmer has a USB port only. If your programmer has a USB port only, please disregard the information about using a disk drive.

Any programmer equipped with a disk drive can read device data from or write device data to a disk. However, if a USB flash drive is inserted into the programmer, it overrides the disk drive for saving and retrieving device data. Disks may be used only when no USB flash drive is inserted.

Interrogate the device before saving data to a USB flash drive or a disk because the programmer saves only the data it has interrogated. If the **Interrogate How Much?** window is displayed, select **All** to save a record of all the information from the device. If an issue needs to be investigated, selecting the **All** option provides more data for analysis.

During the save operation, the **Emergency** button remains displayed, and the Emergency function is available. If an error occurs during a save operation, there may be a delay in initiating the Emergency screen. Do not save to media during EP studies or when it is possible that the Emergency function will be needed immediately. If the Emergency function is used during a save operation, the device aborts the save operation.

Do not insert or remove a USB flash drive during the following operations:

- programming a device
- performing a Save To Media operation
- performing a Read From Media operation
- saving a report or a frozen waveform strip as a PDF file

2.13.1 Saving device data

You can save interrogated device data from a patient session to a disk or to a USB flash drive.

To ensure the integrity and security of patient information, use a USB flash drive or a disk that is reserved for storing programmer data.

If you are saving to a USB flash drive, insert only one writable USB flash drive at a time. Inserting additional USB flash drives results in an error during data-saving operations and the USB indicator becomes unavailable. Insert a USB flash drive only if the programmer is powered on.

You can save to a disk if your programmer has a disk drive. If you are saving to a disk, the disk must be a formatted, IBM-compatible, 90 mm (3.5 inch) disk. If you save data to a disk that is corrupt or is not IBM-formatted, the programmer may become unresponsive. If this situation occurs, remove the disk, turn off the programmer, and then turn it on again. Normal operation should resume. Inform your Medtronic representative of this occurrence.

1. Tap **Interrogate** to interrogate the device.
2. Tap **Session** > **Save to Media…**.
3. Insert a USB flash drive into any available USB port on the programmer or insert a disk into the programmer disk drive.

4. Tap **Save**.

   If you are saving to a USB flash drive, a slight delay may occur while the USB flash drive is authorized. The USB indicator on the task bar turns green to indicate that the USB flash drive is available for use and the disk icon becomes unavailable.

While a Save To Media action is in progress, the progress indicator and the message “Save To Media - In Progress” are displayed. Before removing a USB flash drive, wait a few seconds after the progress indicator shows 100%.

2.13.2 Retrieving device data

Use the Read From Media application on the programmer to view saved data, print reports, and display all programmed parameter values.

You can use the Read From Media application only outside of a patient session. When you retrieve stored data, the programmer presents the 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 window is replaced with the device model and the words Read From Media.

Note: You cannot use the programmer to view reports that have been saved using the **Save to PDF File** option. Reports that have been saved using the **Save to PDF File** option can only be viewed on a computer equipped to display PDF files.

Warning: The Read From Media application is designed only for viewing saved data while no patient session is in progress. You cannot program a device or deliver emergency therapies from the Read From Media application.

Use the following steps to retrieve device data:

1. Insert a USB flash drive or a disk that contains information saved during a patient session.
2. From the **Select Model** screen, select the product category from the **View** list.
3. Select the Read From Media version of the device application.
4. Tap **Start**.

   A warning message is displayed informing you that programming a device and emergency operations are not possible while you are in the Read From Media application.
5. Tap **OK**.
6. Tap **Open File…**.

7. Select the data record that displays the desired device serial number, date, and time and tap **Open File**.

   The Read From Media application displays information from the saved session.

2.14 Ending a patient session

Use the **Session** icon to review changes made during a session, and use the **End Session…** button to save session data or end the patient session.

Note: Session data may be lost once a session has ended. Print session data or save the session data to a USB flash drive or disk prior to ending the session to avoid permanent loss of session data.

1. To review or print a list of changes made during this session, tap **Session** > **Changes This Session**.

   Note: Selecting **Print…** will allow you to print the list of changes made during this session.

2. Tap **End Session…**.

   The **End Session?** window is displayed.

3. Choose one of the following options:
   - To save the session data to a USB flash drive or a disk, tap **Save To Media…**.
   - To end the session and return to the **Select Model** screen, tap **End Now**.

3 Diagnostic data

3.1 Diagnostic data overview

The implanted device collects and stores a variety of data about the patient's condition and the performance of the implanted system. The programmer software allows you to access the stored data and use it to help manage patient care.

The following categories of data are available:

- CareAlert events, which include both clinical status events and system performance events
- Clinical diagnostic data
- Device and lead performance data

3.2 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.

3.2.1 Viewing CareAlert events

The implanted device stores alert events in the **Medtronic CareAlert Events** log. For each event, a log entry includes the date and time of the alert, a description of the event, and the measurement or information that caused the event. Up to 15 events are stored.

- To view the most recent Medtronic CareAlert Events, select **Data** > **CareAlert Events**.

3.3 Clinical diagnostic data

You can use a variety of diagnostic data that has been collected and stored by the device to help you assess the patient's clinical condition and the effectiveness of therapies.

3.3.1 Viewing Arrhythmia Episodes data

Use the **Arrhythmia Episodes** screen to view summary and detailed diagnostic data for arrhythmia episodes.

When viewing the most recent VT, Fast A&V, or AT/AF record details screen, you can tap the **Flashback** button to display a graph showing atrial and ventricular intervals that occurred immediately prior to the episode.

1. Tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data**.

   The **Arrhythmia Episodes** screen is displayed with events listed in the episode log, which appears in the upper portion of the **Arrhythmia Episodes** screen.

   Note: Data will not display for episodes that occur during a device session. These episodes are labeled as **Episode in progress** and are not available to view in the episode records until an interrogation is performed. To view the episode information for an **Episode in progress**, interrogate the device after episode termination.

2. Use the following filtering tools to specify which data to display:

Filtering tool	Steps
Specify the types of episodes (**VT/VF**, **AT/AF**, and **Fast A&V**) you want to display.	Select the applicable check boxes to display the episodes.
Display episodes with specific characteristics, choosing from **All Selected Types**, **Treated**, **Any Rx Failed**, **All Rx Failed**, **Monitored**, **Symptom**, or **EGM**.	Tap the box next to **View** to display a type of episode.
Display episodes that are longer than a specific amount of time.	Tap the box next to **>** and choose the maximum episode duration.

   Note: For each episode type, when the log capacity is reached, data from the most recent episodes overwrites the oldest episode data in the log.

3. To view detailed information about an episode, tap the episode in the episode log.

   Details about the episode are displayed in the episode record area, in the lower portion of the **Arrhythmia Episodes** screen.

4. Use the following options to control the data displayed in the episode record area:

Action	Steps
Move to a specific area of the EGM view.	Use the horizontal scroll bar to change the displayed area.
Select a specific portion of an episode for which to view EGM data.	Tap **Plot**. Use the arrow buttons to adjust the location of the yellow box to select a portion of the episode. Tap **EGM** to see the selected data in the EGM format.

Action	Steps
Change the format of the data for the selected episode.	Tap **Plot**, **EGM**, or **Text** to view the data in that format.
Maximize or minimize the plot, EGM, or text display.	Use the or buttons to change the size of the displayed episode in the window.
Switch the y-axis between interval and rate.	Tap the white **Interval/Rate** box (in Plot view) at the top of the y-axis.
Show or hide plot intervals as desired.	Tap the **Plot:** check boxes in the legend.
Display a selected atrial interval.	Tap **EGM** and maximize the display by tapping the button. Tap the white Atrial Interval box on the y-axis to change the atrial interval shown on the display.

3.3.2 Viewing Flashback Memory data

Use the **Flashback Memory** screen to view a graph showing atrial and ventricular intervals that occur immediately prior to tachyarrhythmia episodes or the most recent interrogation. This data may help to assess the patient's heart rhythm and the performance of other features such as Rate Response.

1. Tap **Data** > **Clinical Diagnostics** > **Flashback Memory** > **Open Data** or tap the **Flashback** button on the record detail view for the most recent VT, Fast A&V, or AT/AF episodes on the Arrhythmia Episodes screen.
2. Use the following options to control the data displayed:

Action	Steps
Select the interval to view.	Select an option under **View Intervals Prior to:**.
Show or hide plot intervals as desired.	Tap the **Plot:** check boxes.
Switch the y-axis between interval and rate.	Tap the white **Interval/Rate** box at the top of the y-axis.
Shrink or enlarge the region to display when the view is maximized.	Use the zoom region resize buttons to adjust the location of the yellow box to select a portion of the interval. Tap to shrink the region to display and tap to enlarge the region to display. Tap to maximize the view of the selected data in the yellow box.
Reposition the region to display when the view is maximized.	Use the arrow buttons to adjust the location of the yellow box to select a portion of the interval. Tap to maximize the view of the data in the yellow box.
Maximize or minimize the view of the selected region.	Use the or buttons to change the size of the displayed interval in the window.

3.3.3 Viewing Rate Drop Response Episodes data

Use the **Rate Drop Response Episodes** screen to help you analyze rate drop episodes and the events leading up to them.

1. Tap **Data** > **Clinical Diagnostics** > **Rate Drop Response Episodes** > **Open Data**.

   The **Rate Drop Response Episodes** screen is displayed with events listed in the episode log, which appears in the upper portion of the **Rate Drop Response Episodes** screen.

2. To view detailed information about an episode, tap the episode in the episode log.

   Details about the episode are displayed in the episode record area, in the lower portion of the **Rate Drop Response Episodes** screen.

3. Use the following options to control the data displayed in the episode record area:

Action	Steps
Move to a specific area of the Markers view.	Use the horizontal scroll bar to change the displayed area.
Select a portion of the plot that will be expanded when entering the Markers view.	Tap **Plot** and use the arrow buttons to adjust the location of the yellow Marker Channel box to select a portion of the plot. Tap **Markers** to see the selected data in the Markers view.
Change the format of the data for the selected episode.	Tap **Plot**, **Markers**, or **Text** to view the data in that format.
Maximize or minimize the plot, markers, or text display.	Use the  or  buttons to change the size of the displayed episode in the window.
Switch the y-axis between interval and rate.	Tap the white **Interval/Rate** box (in Plot view) at the top of the y-axis.
Show or hide plot intervals as desired.	Tap the **Plot:** check boxes (in Plot view) in the legend.
Display a selected atrial interval.	Tap **Markers** and maximize the display by tapping the  button. Tap the white Atrial Interval box on the y-axis to change the atrial interval shown on the display.

3.3.4 Viewing MVP Mode Switches

Use the **MVP Mode Switches** screen to view a list of the 10 most recent MVP mode switches to DDD(R). This information can help you assess the mode switches.

- Tap **Data** > **Clinical Diagnostics** > **MVP Mode Switches** > **Open Data**.

  The **MVP Mode Switches** data is displayed.

3.3.5 Viewing Cardiac Compass Trends data

Use the **Cardiac Compass Trends** screen to view data about the patient's condition during the last 14 months. The trend information can help you to assess whether device therapies or antiarrhythmic drugs are effective.

- Tap **Data** > **Clinical Diagnostics** > **Cardiac Compass Trends** > **Open Data**.

  The Cardiac Compass Trends data is displayed.

3.3.6 Viewing Rate Histograms data

Use the **Rate Histograms** screen to view information about heart rates recorded between patient sessions. This data can help you to monitor a patient's condition and assesses the effectiveness of therapies.

- Tap **Data** > **Clinical Diagnostics** > **Rate Histograms** > **Open Data**.

  The Rate Histograms data is displayed.

3.3.7 Viewing Counters data

Use Counters data for information about the number of times VT/VF episodes and AT/AF episodes and therapies have occurred.

1. Tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data**.

   The **Counters** screen is displayed.
2. Use the options near the top of the screen to specify which counters to display (**VT/VF Episodes**, **AT/AF Episodes**, or **AT/AF Rx**).

3.4 Device and lead performance data

The device automatically measures and records device and lead performance data every day. Detailed views of this data are available from the Battery and Lead Measurements screen and the Lead Trends screen.

3.4.1 Viewing battery and lead measurements

Use the **Battery and Lead Measurements** screen to view the most recent values for key measures of device and lead performance.

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

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

1. Tap **Data** > **Device/Lead Diagnostics** > **Battery and Lead Measurements** > **Open Data**.

   The **Battery and Lead Measurements** window is displayed.

   - For lead impedance measurements, the screen displays the most recent manually performed measurements or the most recent daily automatic measurements.
   - For sensing amplitude measurements, the screen displays the most recent daily automatic measurements. Measurements performed with the manual Sensing Test are not displayed on the **Battery and Lead Measurements** screen.

2. Optionally, tap the ⏭ button near the Lead Impedance or the Sensing data to compare the most recent measurements to the trends of daily automatic measurements.

   The **Lead Trends** window is displayed.

3.4.2 Viewing lead impedance trends

Use the **Lead Trends** screen to view a graph displaying the automatic daily lead impedance measurements. Significant or sudden changes in lead impedance may indicate a problem with the lead.

The graph displays up to 15 of the most recent automatic daily measurements and up to 60 weekly summary measurements. Gaps in the trend graph occur if the device was unable to perform automatic lead impedance measurements.

1. Tap **Data** > **Device/Lead Diagnostics** > **Lead Impedance Trends** > **Open Data**.

   The **Lead Trends** screen is displayed.

2. Select the measurement trend to display.
3. Select the polarity to display.

3.4.3 Viewing capture threshold trends

Use the **Lead Trends** screen to view a graph of capture threshold trend data. You can use this data to evaluate Capture Management operation and the appropriateness of the current

pacing output values. In addition, sudden or significant changes in pacing threshold may indicate a problem with a lead.

The graph displays up to 15 of the most recent automatic daily measurements and up to 60 weekly summary measurements. Gaps in the trend graph occur if the device was unable to perform a daily capture threshold measurement.

The capture threshold data is collected only when the Capture Management parameter is programmed to Adaptive or Monitor.

1. Tap **Data** > **Device/Lead Diagnostics** > **Capture Threshold Trends** > **Open Data**.

   The **Lead Trends** screen is displayed.
2. Select the chamber to display.
3. Optionally, tap the ⏭ button to view details of the last 15 days of threshold measurement data.

3.4.4 Viewing sensing amplitude trends

Use the **Lead Trends** screen to view a graph displaying the automatic daily sensing amplitude measurements. Significant or sudden changes in sensing amplitude may indicate a problem with the lead.

The sensing amplitude graph displays up to 15 of the most recent automatic 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 trend graph occur if the device was unable to collect 9 amplitude measurements on a given day.

1. Tap **Data** > **Device/Lead Diagnostics** > **P/R Wave Amplitude Trends** > **Open Data**.

   The **Lead Trends** screen is displayed.
2. Select the amplitude measurement type to display.

4 System test and EP study features

4.1 Overview of system test and EP study features

System test features include manual tests of the patient's condition and the device's functionality. Electrophysiology (EP) study features include arrhythmia induction protocols and manual therapy delivery.

System test features

- Underlying Rhythm Test: evaluate the patient's intrinsic heart rhythm.
- Pacing Threshold Test: Determine the patient's pacing stimulation thresholds.
- Lead Impedance Test: Test the integrity of the implanted lead system.
- Sensing Test: Measure P-wave and R-wave amplitudes.
- Magnet test: Observe and document magnet mode operation.

Electrophysiology (EP) study features

- Arrhythmia induction protocols: 50 Hz Burst, Fixed Burst, and Programmed Electrical Stimulation (PES).
- Manual therapies: Ramp, Burst, Ramp+, and Burst+.

4.1.1 Setting test preferences for the Live Rhythm Monitor

You can choose to make the live rhythm display arrange the waveforms to show the EGM of the heart chamber being tested, or to keep the waveform arrangement unchanged.

1. Tap **Reports** > **Preferences** > **Tests**

   Waveform display options become available on the **Preferences** screen.

2. Select one of the following options:

Option	Steps
Automatically display the EGM for the heart chamber being tested.	Select **Auto-arrange waveforms**.
Leave the waveform display unchanged during a test.	Select **Do not auto-arrange waveforms**.

3. Tap **OK**.

   Test preferences are saved and the **Preferences** screen closes.

4.2 Performing an Underlying Rhythm Test

The Underlying Rhythm Test enables you to evaluate the patient's intrinsic heart rhythm by temporarily inhibiting the pacing output of the device.

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

Considerations for performing an underlying rhythm test:

- For all patients, consider lowering the programmed Lower Rate and ensuring that the patient is at this rate before inhibiting pacing. These actions may help avoid sudden changes in the ventricular rate support.
- Tachyarrhythmia detection is suspended during the Underlying Rhythm Test

Use the following steps to perform an underlying rhythm test:

1. Tap **Tests** > **Underlying Rhythm**.
2. Verify the **Permanent Values** for **Mode** and **Lower Rate**.
    - Consider lowering the programmed lower rate to help avoid sudden changes in ventricular rate support.
    - Tap **Params** > **Lower Rate** and select an appropriate rate. Tap **PROGRAM** to program any pending changes. The device will pace at the lower rate shown on the **Parameters** screen.
    - Tap **Tests** > **Underlying Rhythm** to return to the **Tests - Underlying Rhythm** screen.
3. Press and hold **INHIBIT Press and Hold**.
4. Observe the display of the heart's intrinsic rhythm.

    Note: Pacing is inhibited until this button is released.

5. Release the button.
6. If **Lower Rate** was changed prior to conducting the underlying rhythm test, return to the **Parameters** screen to return the rate to its original value.

4.3 Measuring pacing thresholds

The Pacing Threshold Test enables you to determine the patient's pacing stimulation thresholds. Pacing threshold information may be used to determine appropriate amplitude

and pulse width settings to ensure capture while minimizing output to maximize battery longevity.

Considerations for measuring pacing thresholds:

- The selectable and default values provided by the Pacing Threshold Test depend on the programmed values for bradycardia pacing therapy.
- After performing a Pacing Threshold Test, make sure that the permanently programmed pulse width and amplitude parameters provide an adequate safety margin above the pacing threshold.
- Tachyarrhythmia detection is suspended during the Pacing Threshold Test.

1. Tap **Tests** > **Pacing Threshold**.
2. Review the displayed values and consider the following options:

Optional task	Steps
Change the values for **Test Type**, **Chamber**, or **Decrement after**.	Tap the field next to the parameter you wish to change and select the desired value for that parameter.
Change the Test Value for **Pace Polarity**, **Mode**, **Lower Rate**, **AV Delay**, **Amplitude**, or **Pulse Width**.	Tap the field next to the parameter you wish to change and select the desired value for that parameter.
Change the values for **V. Pace Blanking**, **A. Pace Blanking**, or **PVARP**.	Tap **Additional Settings…** and then tap the field next to the parameter you wish to change. Select the desired value for that parameter.

3. Initiate the Pacing Threshold Test. Press and hold **TEST Press and Hold**.
4. Observe the Live Rhythm Monitor for loss of capture.
5. When capture is lost, immediately release **TEST Press and Hold**.

   The device resumes its original pacing values and displays the **Test Results** window.
6. Verify the detected pacing threshold at which loss of capture occurred.

   Note: If necessary, change the value for the detected pacing threshold by tapping that value in the **Threshold** column on the **Test Results** window.
7. If desired, use the following options to view or change data in the **Test Results** window:

Optional task	Steps
Change the programmed value for **Pace Polarity**.	Tap the **Pace Polarity** value in the **Permanent** column. Select the desired value. Tap **PROGRAM** to program a pending value.
Change the programmed values for **Amplitude** or **Pulse Width**.	Tap the value in the **Permanent** column to display the **Capture** window. Select the desired values and tap **OK**. Tap **PROGRAM** to program the pending values.
View the ending value and permanent value for **V. Pace Blanking**, **A. Pace Blanking**, and **PVARP** parameters.	Tap **Additional Settings…** to view the values. Tap **OK** to return to the **Test Results** window.
View a test strip from the most recent pacing threshold test.	Tap the **Test Strip** icon to view the test strip. Tap **Close** to return to the **Test Results** window.
Print a Pacing Threshold Test Report.	Tap **Print…**.

8. When you have finished viewing or changing data on the **Test Results** window, tap **Close** to return to the Pacing Threshold Test screen.

4.4 Measuring lead impedance

The Lead Impedance Test enables you to test the integrity of the implanted lead system by measuring the impedance of the atrial and ventricular pacing electrodes.

Considerations for measuring lead impedance:

- Impedance measurements are made with low-voltage subthreshold pulses that do not capture the heart.
- During a sequence of lead impedance measurements, the device may sense the subthreshold test pulses as atrial refractory events or atrial sensed events. The test pulses may also cause small variations on 1 or more of the EGM channels.
- Tachyarrhythmia detection is suspended during the Lead Impedance Test.

After performing the Lead Impedance Test, you can determine if the lead impedance has changed by comparing the measured values to the values reported on the **Lead Trends** Pacing Impedance screen and to the impedance values measured during previous follow-up appointments, if they were recorded in the patient's chart.

1. Tap **Tests** > **Lead Impedance**.
2. Tap **START Measurement**.
   a. Wait for confirmation of programming and a message indicating that measurements are in progress.
   b. If necessary, end the test by tapping **STOP**. Lead impedance measurements are not updated from a test that is stopped.

   When the test is complete, the new measured impedance values for the tested polarities are displayed.
3. To view the measurements for all available lead polarities, tap the All Measured Polarities ⏭ button.

4.5 Performing a Sensing Test

The Sensing Test enables you to measure P-wave and R-wave amplitudes, which may be useful for assessing lead integrity and sensing performance.

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

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 the device collects and reports in the sensing amplitude trends. Because of this difference in measurement operations, Sensing Test results may differ from those reported in the sensing amplitude trend data.

Considerations for performing a Sensing Test

- During a Sensing Test, reduce the pacing rate gradually to minimize patient symptoms associated with abrupt changes in heart rate.
- The Sensing Test ends automatically after a few seconds and restores the programmed settings if no intrinsic events occur and no changes are made to the pacing rate.
- Do not adjust the values for A. Sensitivity and RV Sensitivity based on the results of the Sensing Test.
- Tachyarrhythmia detection is suspended during the Sensing Test.

Use the following steps to perform a sensing test:

1. Tap **Tests** > **Sensing**.

   Note: You must 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 the device is programmed to an asynchronous pacing mode (VOO, for example), or when polarities are programmed to **Configure**.

2. Verify the programmed Test Value parameters for **Mode** and **AV Delay** or accept the values displayed.

   Note: The pacing modes available under Test Value depend on the programmed pacing mode.

3. Tap **START Measurement**.
4. Observe the Live Rhythm Monitor for an intrinsic rhythm. If consistent pacing is still occurring, decrease the **Lower Rate** using the down arrow button next to the value for **Lower Rate**.

   Notes:

   - If necessary, abort the test by tapping **STOP and Restore**.
   - After the test has started, you may continue to decrease the pacing rate until the intrinsic heart rhythm prevails. The device measures amplitudes only on intrinsic events. The maximum amplitude value that the Sensing Test can measure is 20 mV. If the amplitude is over 20 mV, the results are displayed as >20 mV.

The sensing test automatically stops when it is complete. When the test is complete, the measurement results are displayed on the test screen and the pacing settings return to the programmed values.

To compare the Sensing Test measurements with the automatic daily sensing amplitude measurements, tap the P/R Wave Amplitude Trends ⊠ button.

4.6 Performing a Magnet Test

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

During magnet mode operation, the device provides asynchronous pacing at a fixed rate. While the 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.

Note: At any time during a Magnet test, lifting the programming head from over the patient's pacemaker for at least 2 s restores operation of the pacemaker to its permanent status. This action should be taken in the event of programmer malfunction, loss of power, or the absence of an appropriate command confirmation.

1. Tap **Tests** > **Magnet**.
2. The **Magnet Strip** check box is selected by default. If you want the test to also automatically record a strip showing non-magnet operation, select the **Non-Magnet Strip** check box.
3. Select **Strip Durations** values for the automatically collected strips.
4. Tap **START Test**.

   Note: If necessary, you can stop the Magnet test by tapping **STOP Test**.

5. Tap the **Magnet Strip** icon or the **Non-Magnet Strip** icon to view the collected strip in the frozen strip viewer.

4.7 Arrhythmia inductions with EP Study Tests

The system provides several electrophysiology study (EP Study) test functions that may be used 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.

Considerations for inducing an arrhythmia

Telemetry – Ensure that there is a telemetry link between the device and the programmer before performing an EP study function. Successful interrogation or programming confirms proper communication between the device and the programmer.

Resuming detection – Tachyarrhythmia detection is automatically suspended during all EP Study tests. If detection is manually suspended before the induction, it 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.

Select the check box for **Resume at BURST** or **Resume at DELIVER** to enable automatic resume for an induction. To resume detection after a manual therapy or after an induction

delivered with automatic resume disabled, tap **Resume** or remove the programming head from the implanted device.

Aborting an induction or therapy – As a safety measure, the programmer displays an **ABORT** button that may be selected to immediately abort any induction or tachyarrhythmia therapy in progress. A burst induction may also be aborted by releasing the **Press and Hold** button. When a manual therapy is delivered, the device automatically aborts any induction or automatic therapy in progress.

Temporary parameter values – 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.

Programming head buttons – The programming head buttons are disabled during the following situations:

- The Program button on the programming head is disabled during EP study inductions and manual therapies. Use the appropriate button on the programmer screen to deliver an induction or manual therapy.
- The Interrogate button on the programming head is disabled during EP study inductions only. Use the **Interrogate** button on the programmer screen to interrogate the device while the EP study induction screen is active.

4.7.1 Inducing AT/AF with an atrial 50 Hz Burst

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

You can specify the amplitude and pulse width of these pulses, but the pacing interval is fixed at 20 ms.

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

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.

Use the following steps to induce AT/AF with a 50 Hz burst:

1. Tap **Tests** > **EP Study**.
2. Tap **50 Hz Burst** in the list of inductions and therapies.
3. Set up the test using the following options:

Optional task	Steps
Maintain automatic detection and therapy during the test.	Select the **Resume at BURST** check box.
Treat the induced episode with a manual therapy.	Clear the **Resume at BURST** check box, then tap the **Suspend** button at the top of the screen to prevent automatic detection.

4. Verify the displayed test values. If needed, select new test values by tapping the value you wish to change.

   Note: If you want to provide VOO Backup pacing during the pacing burst, select values for VOO Backup.

5. Press and hold **50 Hz BURST Press and Hold**. As long as you press and hold the **50 Hz BURST Press and Hold** button on the programmer screen, the device continues delivering the induction (up to a maximum of 10 s). Release the button to end the induction.

   Note: If necessary, tap **ABORT** to abort a therapy in progress.

4.7.2 Inducing AT or VT with Fixed Burst induction

You can use a Fixed Burst induction 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.

The pacing pulses are delivered at a uniform, selectable interval to the designated chamber. You can also specify the amplitude and pulse width of the pulses.

If you perform an atrial Fixed Burst induction, you may choose to have the device deliver VVI Backup pacing. However, VVI Backup pacing during an atrial Fixed Burst induction may be inhibited by crosstalk if the test value for atrial Amplitude is greater than 6 V.

Use the following steps to induce AT or VT with a Fixed Burst induction:

1. Tap **Tests** > **EP Study**.
2. Tap **Fixed Burst** in the list of inductions and therapies.
3. If the **Chamber Selection** window appears, tap **Atrium** or **RV** to select a chamber in which to perform the test.
4. Set up the test using the following options:

Optional task	Steps
Maintain automatic detection and therapy during the test.	Select the **Resume at BURST** check box.
Treat the induced episode with a manual therapy.	Clear the **Resume at BURST** check box, then tap the **Suspend** button at the top of the screen to prevent automatic detection.

5. Verify the displayed test values. If needed, select new test values by tapping the value you wish to change.
6. Press and hold **Fixed BURST Press and Hold**. Release the button to end the induction.

   Note: If necessary, tap **ABORT** to abort a therapy in progress.

4.7.3 Inducing AT or VT with a Programmed Electrical Stimulation (PES)

You can use Programmed Electrical Stimulation (PES) to induce AT or VT by delivering a selectable number of pacing pulses and individually-selectable 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.

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. You can specify the chamber, amplitude, pulse width, and pacing intervals for the induction.

If you perform an atrial PES induction, you may choose to have the device deliver VVI Backup pacing. However, VVI Backup pacing during an atrial PES induction may be inhibited by crosstalk if the test value for atrial Amplitude is greater than 6 V.

Use the following steps to induce AT or VT with a PES:

1. Tap **Tests** > **EP Study**.
2. Tap **PES** in the list of inductions and therapies.
3. If the **Chamber Selection** window appears, tap **Atrium** or **RV** to select a chamber in which to perform the test.
4. Set up the test using the following options:

Optional task	Steps
Maintain automatic detection and therapy during the test.	Select the **Resume at DELIVER** check box.
Treat the induced episode with a manual therapy.	Clear the **Resume at DELIVER** check box, then tap the **Suspend** button at the top of the screen to prevent automatic detection.

5. Verify the displayed test values. If needed, select new test values by tapping the value you wish to change.
6. Tap **DELIVER PES**. Release the button to end the induction.

   Note: If necessary, tap **ABORT** to abort a therapy in progress.

4.8 Manual therapy

During EP testing, you can initiate tachyarrhythmia therapies manually from the programmer.

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.

During follow-up appointments, manual therapies may be helpful in assessing therapy effectiveness and making any necessary adjustments as part of chronic care. The available manual therapies include Atrial Burst+, Atrial Ramp, Ventricular Ramp, Ventricular Burst, and Ventricular Ramp+ pacing therapies.

Considerations for manual therapy

VVI Backup pacing inhibition by crosstalk – 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.

Aborting an induction or therapy – As a safety precaution, you can select the **ABORT** button displayed on the programmer to terminate any induction, manual therapy, or automatic therapy in progress. When a manual therapy is delivered, the device automatically aborts any induction or automatic therapy already in progress.

Detection suspended during manual therapy – Tachyarrhythmia detection is automatically suspended when delivering a manual therapy. Detection stays suspended until you tap **Resume** or the telemetry session between the programmer and device ends.

Temporary parameter values – 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.

Programming head buttons – The Program button on the programming head is disabled during manual therapies. Tap the appropriate **DELIVER** button to deliver a manual therapy.

Telemetry – Ensure that there is a telemetry link between the device and the programmer before performing a manual therapy. Successful interrogation or programming confirms proper communication between the device and the programmer.

Operation of manual therapies

Manual ATP therapies deliver one sequence of the selected therapy. Each therapy provides a set of adjustable parameters to apply during therapy delivery.

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 of 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.

4.8.1 Delivering a manual therapy

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

1. Tap **Tests** > **EP Study**.
2. Tap the desired manual therapy from the list of inductions and therapies.
3. If the **Select Chamber** window appears, tap **Atrium** or **RV** as appropriate.
4. If you want to treat the induced episode with a manual therapy, tap **Suspend** to prevent automatic detection.
5. Accept the displayed test values or select new test values.
6. Tap **DELIVER**.

   Note: If necessary, tap **ABORT** to terminate the manual therapy.

Glossary

antitachycardia pacing (ATP) – therapies that deliver rapid sequences of pacing pulses to terminate tachyarrhythmias.

AT/AF detection – feature that analyzes the atrial rate and its effect on the ventricular rhythm to determine whether the patient is currently experiencing an atrial tachyarrhythmia. Depending on programming, the device delivers a programmed sequence of atrial therapies or continues monitoring without delivering therapy.

Burst pacing – manual antitachycardia pacing (ATP) therapy that delivers ventricular pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length.

Burst+ pacing – antitachycardia pacing (ATP) therapy that delivers sequences of atrial pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length, followed by up to 2 premature stimuli delivered at programmable intervals. With each sequence of Burst+ pacing delivered, the device shortens the pacing interval by a programmable interval.

Capture Management – feature that monitors pacing thresholds with daily pacing threshold searches and, if programmed to do so, adjusts the pacing amplitudes toward a target amplitude.

Cardiac Compass Trends – overview of the patient's condition over the last 14 months with graphs that display long-term clinical trends in heart rhythm, such as frequency of arrhythmias, heart rates, and device therapies.

crosstalk – condition when pacing in one chamber is sensed as intrinsic activity in another chamber.

Decision Channel annotations – annotations to stored and telemetered EGM that document details about tachyarrhythmia detection operations.

device reset – automatic device operation to recover from a disruption in device memory and control circuitry. Programmed parameters may be set to default reset values. This operation triggers a device status indicator.

device status indicator – value recorded in device memory to signify a condition or problem that may affect device operation and that requires attention.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that may interfere with device operations, such as sensing, or may potentially damage device circuitry.

EOS (End of Service) – battery status indicator displayed by the programmer to indicate that the device should be replaced immediately and that it may not operate per specifications.

ERI (Elective Replacement Indicator) – battery status indicator for when replacement of the device is recommended. Key device parameters are automatically switched. For example, pacing mode switches to VVI and Lower Rate goes to 65 bpm.

event – a sensed or paced beat.

Flashback Memory – diagnostic feature that records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

Holter telemetry – telemetry feature that transmits EGM and Marker Channel data continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and programmer.

last session – refers to the last time the device was successfully interrogated before the current interrogation. A session ends 8 hours after the last interrogation.

Marker Channel recording – a pacing system feature used to simplify ECG interpretation by identifying pacing and/or sensing operations.

Mode Switch – feature that switches the device pacing mode from a dual chamber atrial tracking mode to a nontracking mode during an atrial tachyarrhythmia. This feature prevents rapid ventricular pacing that may result from tracking a high atrial rate and restores the programmed pacing mode when the atrial tachyarrhythmia ends.

MR Conditional – an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

MRI SureScan – a feature that permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine while the device continues to provide appropriate pacing.

MVP (Managed Ventricular Pacing) – atrial-based pacing mode that is designed to switch to a dual chamber pacing mode in the presence of AV block. The MVP feature is intended to reduce unnecessary right ventricular pacing by promoting intrinsic conduction. The MVP modes are AAIR<=>DDDR and AAI<=>DDD.

oversensing – inappropriate sensing of cardiac events or noncardiac signals. Examples include far-field R-waves, T-waves, myopotentials, and electromagnetic interference.

pacing threshold – minimum pacing output that consistently captures the heart.

PVC (premature ventricular contraction) – a sensed ventricular event that directly follows any other ventricular event with no atrial event between them.

Quick Look II data – overview data summarizing the most important indicators of system operation and the patient's condition, including information about device and lead status, pacing therapy, arrhythmia episodes, and system-defined observations.

Ramp pacing – antitachycardia pacing (ATP) therapy that delivers pacing pulses with progressively shorter pacing intervals per pulse. Each sequence of Ramp pacing that is delivered during a therapy includes an additional pacing pulse.

Ramp+ pacing – manual antitachycardia pacing (ATP) therapy that delivers ventricular pacing pulses at programmable intervals that are based on percentages of the tachycardia cycle length.

Rate Drop Response – feature that monitors the heart for a significant drop in rate and responds by pacing the heart at an elevated rate for a programmed duration.

Rate Drop Response episodes data – feature that displays beat-to-beat data that is useful in analyzing Rate Drop Response episodes and the events leading up to those episodes.

Rate Histograms – diagnostic feature that shows range distributions for a patient's heart rate.

Rate Response – feature that adjusts the cardiac pacing rate in response to changes in sensed patient activity.

Remaining Longevity estimate – an estimate of remaining device longevity that is displayed on the Quick Look II and Battery and Lead Measurements screens. On both screens, this information includes a graphical display for easy reference and the estimated number of years or months of remaining longevity. On the Battery and Lead Measurements screen, the Minimum and Maximum number of years or months of remaining device longevity are also provided.

Resume – programming command that reinstates automatic tachyarrhythmia detection.

RRT (Recommended Replacement Time) – battery status indicator displayed by the programmer to indicate when replacement of the device is recommended.

sensed event – electrical activity across the sensing electrodes that exceeds the programmed sensitivity threshold and is identified by the device as a cardiac event.

sensor rate – the pacing rate determined by the level of patient activity and the programmed rate response parameters; this rate is adjusted between the Upper Sensor Rate and the operating Lower Rate.

Suspend – programming command that temporarily deactivates the tachyarrhythmia detection functions.

Ventricular Safety Pacing (VSP) – pacing therapy feature that prevents inappropriate inhibition of ventricular pacing caused by crosstalk or ventricular oversensing.

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