Medtronic

Micra™ AV SW044

Programmer software

Programming Guide

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

Micra™ AV SW044

Programming Guide

A guide to programming the Micra™ AV dual chamber transcatheter pacing system using the Medtronic SW044 application software on a Medtronic programmer

Contents

1 Software overview

1.1 Introduction

This manual describes the Medtronic Model SW044 programmer software and explains how to use a programmer to conduct a patient session.

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

If you have a printed copy of this manual and any part of it is illegible, contact a Medtronic representative to request a replacement manual.

The following manuals and documents contain additional information about the programmer and implanted device:

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

Reference manual – This manual provides detailed descriptions of device features.

Programmer reference manual – This manual provides a detailed description of the Medtronic programmer. There is a programmer reference manual for the Medtronic CareLink 2090 programmer and a programmer reference manual for the Medtronic CareLink Encore 29901 programmer.

Device manual – This manual provides summaries of device features, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, parameter tables, and an explanation of package symbols.

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

1.2 Software description

The Medtronic Model SW044 software runs on the Medtronic CareLink 2090 programmer and the Medtronic CareLink Encore 29901 programmer and communicates with an implanted device to program settings and view stored data. The software is compatible with an implanted Micra AV device.

The programmer and software are for use by healthcare professionals or by Medtronic personnel in a clinical or a hospital environment.

1.2.1 Notice

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.

For more information on the Patient Information screen, see Chapter 2.

1.3 Intended use

The Medtronic Model SW044 software is used to program device parameters and to evaluate the performance of the implanted pacing device. See the Micra AV Model MC1AVR1 device manual for device indications.

1.4 Contraindications

There are no known contraindications for the use of this software. However, contraindications for the use of the implantable device and the programmers that are compatible with this software are documented in their respective manuals.

1.5 Warnings and precautions

There are no general warnings or precautions related to the use of this software. See specific warnings and precautions in the functional sections to which they apply. For warnings and precautions related to the use of the implantable device or the programmers that are used with this software, refer to the device manual or the programmer manuals.

1.6 Potential adverse events

There are no known potential adverse events for the use of this software. However, potential adverse events for the use of the implantable device and the programmers that are compatible with this software are documented in their respective manuals.

1.7 Data security

Medtronic has designed safeguards to protect patient information and device data for the Micra AV Model MC1AVR1 device.

Inductive telemetry communication system – The Medtronic inductive telemetry communication system is used with the clinician programmer to interrogate and program the device. It can also be used to interrogate the device for remote monitoring, if available. This system uses short-range communication that protects patient information and device data.

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 the device and to program the device.

Use the programmer to perform the following tasks:

- Review the presenting rhythm.
- Verify the status and the 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 a Medtronic CareLink Programmer that features 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: Emergency programmer functions are available only after the initial interrogation.

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. Power on the programmer.
2. To establish telemetry between the device and the programmer, place the programming head over the device.

   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 1 of the green lights illuminates.

   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 moves 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 device manual.

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

2.3 Interrogating the device during a patient session

The programmer interrogates the device at the start of a patient session. You can also interrogate the device at any time during a patient session.

To interrogate the device during a patient session, tap **Interrogate** or press the **I** button on the programming head.

The **Interrogation In Progress** window displays during the device interrogation.

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 Electrical 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 ERROR	Contact a Medtronic representative. **Immediate replacement of the device is recommended.**

2.4.1 Responding to a device reset warning for an implanted device

If the programmer reports that an electrical reset occurred before the device is implanted, do not implant the device and contact a Medtronic representative.

If the programmer reports that an electrical reset occurred in an implanted device, contact a Medtronic representative and perform the following steps:

1. Remove any sources of electromagnetic interference (EMI).
2. Tap **Clear** in the pop-up window to clear the reset indicator. A confirmation window appears, indicating that all previously interrogated data in the programmer is cleared.
3. 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.

4. Interrogate the device.
   a. Note the time and date when counter data was last cleared. The time and date indicate when the electrical reset occurred.
   b. Determine, if possible, what the patient was doing at the time and date the electrical reset occurred.

c. Tap **End Session** > **Save to Media…**.

d. Follow the instructions in the **Save To Media - Insert Media** window to save the session data. Give a copy of this saved data file to your Medtronic representative. The data will help to determine the events that led to the reset.

5. If a full electrical reset occurred, the reprogrammed values are displayed in the error message. Verify the programmed device parameters and, if necessary, reprogram the device parameters for your patient.

   After a full electrical reset, the device operates in the VVI mode until it is reprogrammed. For a list of electrical reset parameter settings, see the Medtronic Micra AV Model MC1AVR1 device manual.

6. Verify that the device date and time are correct. If necessary, reprogram the date and time.
7. Tap **Interrogate** to re-interrogate the device.
8. Tap **Data** > **Diagnostics** > **Battery and Device Measurements** to navigate to the **Data - Battery and Device Measurements** screen. Check the **Data - Battery and Device Measurements** screen to verify that the battery voltage is >2.56 V.

   Note: A battery voltage of ≤2.56 V indicates that the Recommended Replacement Time (RRT) for the device has been reached.

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

9. If necessary, conduct an electrode impedance test, a sensing test, and a pacing threshold test.

2.5 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

2.5.1 Status bar

When the device has been interrogated, the status bar at the top of the display screen (located immediately below the task bar) shows the current pacing mode, the device model name, and any manual operation in progress.

2.5.2 Live Rhythm Monitor window

The Live Rhythm Monitor window displays ECG waveform traces, the A. Sensing waveform trace, 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 before 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, the heart rate and interval (in ms) display.
- 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. To expand the window to full-screen view, tap the small square button in the upper-right corner of the window, or tap **Adjust…**.

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.

2.5.2.1 About the Live Rhythm Monitor

The Live Rhythm Monitor can display up to 5 waveforms during a patient session:

- 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.

  Note: ECG signals are required to assess AV synchrony.

- The EGM signal is telemetered from the device to the programmer. The programmer cannot display or record an EGM waveform trace until the device has been interrogated.
- The A. Sensing or A. Sensing: Vector *[X]* labels show atrial activity in the form of mechanical signals sensed by the device accelerometer.
  - The waveform labelled A. Sensing simply shows sensed atrial activity. It is not used for any therapeutic purpose.
  - The waveform labelled A. Sensing: Vector 1, A. Sensing: Vector 2, or A. Sensing: Vector 3 indicates that the device is programmed to track the atrial mechanical signal (that is, atrial systole) to facilitate AV synchronous pacing. See the Medtronic Micra AV reference manual for a description of AV synchronous pacing.

2.5.2.2 Adjusting the Live Rhythm Monitor display

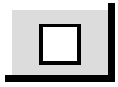
Use the Live Rhythm Monitor **Adjust…** window selections to change the waveform display.

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.
	Opens a list of which waveform trace, marker annotation, or marker intervals can be displayed on the selected line.
	Indicates which waveform traces have been selected for printing. Tap the button to clear the selection and choose a different trace.

Button	Description
	Select the waveform trace for printing. You can select 1 or 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.
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.

2.5.2.3 Marker Channel data

Markers on the waveform trace indicate events such as pacing and sensing.

The device continuously transmits marker channel data and supplementary marker data while telemetry is established and the programming head is positioned over the device. Markers 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 markers. The symbols sometimes appear compressed, depending on the printout speed of the programmer strip chart recorder. The symbols do not appear on screens.

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.
- If Holter Telemetry is programmed to On and telemetry has been established with a Holter monitor, the device transmits Marker Channel data and supplementary data to the Holter monitor regardless of the position of the programming head.

2.5.2.4 Live waveform trace recordings

At any time during a patient session, you can record a continuous, live trace of the patient's ECG, EGM, and A. Sensing waveforms 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 can include the following information:

- ECG, EGM, and A. Sensing 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)

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.

2.5.2.5 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, in ms, 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**.

2.5.2.6 Recalling saved waveform strips

Before terminating 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.

2.5.3 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 to display the **Quick Look II** screen and diagnostic data.
	Displays the **Parameters** screen to view and program device parameters.
	Displays options to perform system tests.
	Displays options to print reports.

Table 1. Navigation icons (continued)

	Displays the **Patient Information** screen.
	Displays options to adjust preferences, view parameter changes made during the session, save data, and end the session.

2.6 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 status information indicating whether the system is operating as expected.
- Information about 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**.

2.6.1 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.

To view relevant details about a section of the screen or a screen artifact, tap its associated » button, if active.

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

To access the **Battery and Device Measurements** screen, tap the ⏭ button next to the **Remaining Longevity** label.

Electrode impedance, capture threshold and sensing amplitude measurements – The **Battery and Device Measurements** screen shows the most recent measurements for electrode impedance, capture threshold, or sensing amplitude. To compare these measurements to daily measurement trends, tap the ⏭ button next to the **Electrode Impedance** label, the **Capture Threshold** label, or the **Sensing** label. To perform manual tests to measure these device performance variables, see the Medtronic Micra AV reference manual.

Rate histograms data – Rate histograms provide 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 **% of Time** label.

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 status, parameter settings, and clinical status.

If you select one of the displayed observations, the ⏭ button becomes active if observation details are available. Tap the ⏭ button to see observation details.

2.7 Enabling emergency VVI pacing

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

Note: Operation of the MRI SureScan feature 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 **Emergency**.

   Emergency VVI pacing is enabled, and the programmer displays the **Emergency Program - VVI Pacing** window.

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 included 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.

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 and the device into the **Patient Information** screen.

1. Tap **Patient**.

   The **Patient Information** screen displays.

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. **Note:** This field cannot be changed.

Field	Description
Implant…	Enter the test values for **R-Wave Amplitude**, **Electrode Impedance**, and **Threshold**. Also enter the **Pulse Width** value.
Notes	Enter notes about the patient or other information (up to 80 characters).
History…	Enter the patient's clinical conditions.
Physician/Phone/Hospital	Select the physician's name, telephone 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**.

2.9 Parameters

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

All programmable parameters appear as active fields that you can tap. Some active fields pertain to only 1 parameter, while other active fields provide a pathway to a group or groups of parameters. If a parameter cannot be programmed, no active field appears next to its name.

After you select new values for parameters, the new values display as pending values. A field containing a pending value displays a dashed rectangle around its border. Values remain pending until you tap **PROGRAM** to program them to device memory.

2.9.1 Accessing and programming parameters

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

1. Tap the **Params** icon.

   The **Parameters** screen displays.

2. Make the desired parameter selections.

   The new values display 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 Parameter sets

Parameter sets are collections of parameter values that have been stored for quick retrieval. Tap the **Get…** button to see the list of parameter sets in the **Get Parameter Set** window. Available parameters sets include:

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 customized set of parameters for your patients. The set of parameter values that you save can include both programmed and pending values.

2.9.4 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.

2.9.5 Retrieving a parameter set

Use the **Get…** button to retrieve a Medtronic Nominals parameter set, an Initial Interrogation Values 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.	1. 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. 2. Tap **PROGRAM** to program the pending values to device memory.
Remove an unneeded parameter set from the list.	1. Tap **Get…** to display the **Get Parameter Set** window. 2. Tap the name of the custom set of parameters. 3. Tap **Delete**. The **Delete - Are you sure?** window displays. 4. Tap **Delete** > **Close**.

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 you can create and use your own checklists.

When you select a task from a checklist, the associated programmer screen for that task displays. 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 displays.

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 a selected checklist appear in the Task list.

   Check marks appear next to the names of any programmer screens that were visited during a session.
3. Follow these actions to advance through the checklist tasks:

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 reactivate 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 work flow.

To create a new checklist, use the following steps:

1. Tap the **Checklist** icon.

   The **Checklist** screen displays.
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 displays 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 displays 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 displays 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 Task**.

4. Tap **Checklist name** 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** list and tap **Edit…**. Change the name and tap **Save**.
Delete a custom checklist.	Tap the checklist in the **Checklist** list 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 tapping the **Print…** button or the printer 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 preferences to print an initial interrogation report following device interrogation. You can also specify which data to include in the report.

Preferences for the initial interrogation report take effect at the start of a new session and remain in effect until you change them.

1. During a patient session, tap **Reports** > **Preferences…** > **Initial Report** to display the preferences for the Initial Interrogation Report.
2. Select the check box for **Print Initial Interrogation Report after first interrogation**. If you select this check box, the report prints at the beginning of a patient session following device interrogation.

3. Select the reports to include in the initial interrogation report and tap **OK**.

   The selected preferences are stored and the **Preferences** window closes. The initial interrogation report prints following device interrogation.

   Note: The Quick Look II Report is always included in the initial interrogation report and cannot be deselected.

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 at the end of a patient session. A session summary report is included in the final report.

Note: Your final report preferences remain in effect between sessions and across all applications.

Your first final report

Follow these steps the first time you create a final report:

1. Tap **Reports** > **Preferences…** > **Final Report**.
2. Select the reports you want to print in addition to the Session Summary report.
3. Tap **OK**.
4. Tap **Reports** > **Final Report…**.
5. Select the **Number of Copies** and the **Printer**.
6. Tap **Print Now** or **Print Later**.

Subsequent final reports

Follow these steps if you have created a final report in the past and you know your report preferences:

1. Tap **Reports** > **Final Report…**.
2. Select the **Number of Copies** and the **Printer**.
3. Tap **Print Now** or **Print Later**.

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 Adobe 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. 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.

Before saving data to a USB flash drive or a disk, interrogate the device. The programmer saves only the data it has interrogated.

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 - VVI Pacing** screen. Do not save to media 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:

- performing a Save To Media operation
- performing a Read From Media operation
- saving a report or a frozen waveform strip as an Adobe 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. Insert a USB flash drive into any available USB port on the programmer or insert a disk into the programmer disk drive.

   If you are saving to a USB flash drive, a short 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.
2. Tap **Interrogate** to interrogate the device.
3. Tap **Session** > **Save to Media…**.
4. Tap **Save**.

While a save-to-media action is in progress, the **Save To Media - In Progress** window and progress indicator display.

Note: Before you remove a USB flash drive, wait a few seconds after the progress indicator reaches 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 cannot use the Read From Media application during 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 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. 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 a disk before you end the session to avoid permanent loss of the session data.

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

   Note: Tap **Print…** to print the list of changes made during this session.
2. Tap **End Session…**.

   The **End Session?** window displays.
3. If you want to change the setting for clearing the session data, select one of the following options from the **Pacemaker Data** drop-down list, or proceed to Step 4:
   - Select **Clear Now** to immediately clear the session data.
   - Select **1 hour after session end** to clear session data 1 hour after the end of the session.

- Select **Do not clear** if you want data collection to continue as if there were no device interrogation. Data collection will end when the session data is cleared.

4. 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 System tests

3.1 Performing the Device Measurements tests

The Micra AV Model SW044 software provides 3 assessment tools to measure device electrical performance for your patient. These tests, the sensing test, the impedance test, and the threshold test, can be performed individually or in an automated sequence from the **Tests - Device Measurements** screen.

Tap **Tests** > **Device Measurements** to access the **Tests - Device Measurements** screen.

3.1.1 Performing the device measurement tests in automated sequence

You can perform 2 or 3 of the device measurement tests in an automated sequence.

To prepare for the device measurement tests, follow these steps:

1. Tap **Tests** > **Device Measurements** to open the **Tests - Device Measurements** screen.
2. Select the 2 or 3 tests that you wish to perform. If you wish to perform only 1 test, see the procedure for that test in the following sections.

   Make your pre-test parameter changes for the sensing test or the threshold test (the impedance test has no parameters):

   - For more information on the sensing test parameters, see Section 3.1.2.
   - For more information on the threshold test parameters, see Section 3.1.4.
3. Place the programming head over the implanted device to establish the telemetry between the device and the programmer. Move the programming head over the patient's heart until 1 or more of the green indicator lights illuminate on the programming head.
4. Tap **Interrogate**.

   Wait for the device interrogation to complete.
5. Following the device interrogation, tap **START Tests** to perform the selected device measurements tests.

3.1.2 Performing a Sensing Test

The sensing test allows you to measure R-wave amplitudes. This test can help you assess sensing performance.

Before you perform the sensing test, you can set temporary values for the test parameters. These temporary values help ensure that the device does not pace the patient during the test. The temporary values increase the likelihood that sensed events will occur.

Warning: Before you start the sensing test, select a temporary pacing rate that allows intrinsic sensed events that can be well tolerated by the patient. If the patient shows poor tolerance to the selected pacing rate during the test, tap **Stop**. To complete the sensing test, the device must detect 2 consecutive ventricular sensed events, and the interval between them must be at least 500 ms (120 bpm). If after 10 s this interval is not detected between 2 consecutive ventricular sensed events, the device aborts the sensing test. If you cannot select a pacing rate that is well tolerated by the patient, consider withholding the sensing test.

3.1.2.1 Considerations for performing the Sensing Test

- If you need to conduct consecutive sensing tests to collect data, reduce the pacing rate gradually to avoid or minimize patient symptoms associated with abrupt changes in heart rate.
- A successful sensing test ends after a few seconds and restores the programmed settings. No changes are made to the permanent Lower Rate.
- Do not adjust the value for RV Sensitivity based on the results of the sensing test. For more information, refer to the Medtronic Micra AV reference manual.

Comparison to sensing trends – Sensing amplitude measurements taken during a sensing test may include events that are atypical or a result of oversensing (for example, noise interference). These events are excluded from the daily measurements of automatic sensing amplitude that the device collects and reports in the R-wave amplitude trend. Due to this difference in measurement operations, sensing test results may differ from R-wave amplitude trend data.

3.1.2.2 How to perform the Sensing Test

Follow this procedure if you are performing a sensing test only. If you are performing the device measurement tests in an automated sequence, see Section 3.1.1.

Follow these steps to perform a sensing test:

1. Tap **Tests** > **Device Measurements** > **Sensing Test**.

   Note: Make sure that Impedance Test and Threshold Test are not selected.

2. If necessary, change the values for Mode and Lower Rate by tapping the corresponding Test Value field for each parameter. Select new values.

   Note: The pacing modes available under Test Value depend on the programmed pacing mode, displayed below the Permanent label.

3. Tap **START Tests**.
4. Observe the Live Rhythm Monitor for an intrinsic rhythm.
5. If you see an intrinsic rhythm at a rate that is within the normal rate range for the patient, the test is successful. The R-wave measurement value displays in the test results at the bottom of the **Device Measurements** screen.
   a. If the patient shows poor tolerance to the test pacing rate, tap **STOP**.
   b. Reset the Mode and Lower Rate values as appropriate for the patient.
   c. Resume the test beginning with Step 3.

      Note: If you are unable to program a test pacing rate that the patient can tolerate, consider withholding the sensing test.

After the sensing test is completed, the measurement value is shown in the R-wave column in the test results area at the bottom of the **Device Measurements** screen. Compare the sensing test R-wave measurement value with the measurement values in the **R-Wave Amplitude** window. To see the **R-Wave Amplitude** window, tap **Data** > **Diagnostics** > **R-Wave Amplitude Trend** > **Open Data**.

3.1.3 Performing an Impedance Test

An electrode impedance test tests the integrity of the implanted device by measuring the impedance of the pacing electrode. Impedance measurements are made by delivering a pacing pulse. If the intrinsic heart rate is faster than the programmed pacing rate, the device increases the pacing rate to be slightly faster than the intrinsic rate for 1 interval.

Note: The upper limit for the pacing rate can vary depending on the programmed pacing mode.

3.1.3.1 Considerations for the Impedance Test

Sensing measurement pulses – During a sequence of electrode impedance measurements, the device may pace at a rate faster than the programmed value for the lower rate for 1 or more pacing cycles.

3.1.3.2 How to perform the Impedance Test

Follow this procedure if you are performing the impedance test only. If you are performing the device measurement tests in an automated sequence, see Section 3.1.1.

Follow these steps to perform an impedance test:

1. Tap **Tests** > **Device Measurements** > **Impedance Test**.

   Note: Make sure that Sensing Test and Threshold Test are not selected.

2. Tap **START Tests**. The message Impedance Test In Progress… displays.
3. If necessary, tap **STOP** to end the test.

When the test is complete, the new value for impedance measurement is shown in the Impedance column in the test results area of the **Tests - Device Measurements** screen. You can determine whether the electrode impedance has changed by comparing the impedance measurement value to the daily impedance measurement values on the **Electrode Impedance Trend** window and to the values measured during the previous follow-up appointments (see the patient's chart). To see the **Electrode Impedance Trend** window, tap **Data** > **Diagnostics** > **Electrode Impedance Trend** > **Open Data**.

3.1.4 Performing the Threshold Test

The threshold test allows you to measure the pacing stimulation thresholds. The threshold test provides the option to select an automatic test (Capture Management) or a manual pacing threshold test (Amplitude – Auto Decrement) to check the pacing stimulation thresholds.

If you select **Capture Management**, the programmer checks the pacing stimulation thresholds at different pacing amplitude settings. If you select **Amplitude – Auto Decrement**, you can program your own mode and pacing settings to identify the pacing stimulation thresholds.

You can use the results of the pacing threshold test to program pacing amplitude and pulse width to capture the heart and optimize battery longevity.

3.1.4.1 Considerations for performing the Threshold Test

Selectable and default values – The parameter values available for the pacing threshold test depend on the permanent (programmed) values for pacing therapy.

Pacing threshold and safety margin – Following a pacing threshold test, make sure that the programmed value for the RV Amplitude parameter provides an adequate safety margin above the patient's pacing threshold.

3.1.4.2 How to perform the automatic Threshold Test

Follow this procedure if you are performing a single automatic (Capture Management) threshold test. If you are performing the device measurement tests in an automated sequence, see Section 3.1.1.

1. Tap **Tests** > **Device Measurements** > **Threshold Test**.
2. Select **Capture Management** from the Threshold Test parameter list.
3. Tap **START Tests**. The Capture Management test begins. When the test is in progress, the Marker Channel waveform trace in the Live Rhythm Monitor window shows the annotations VC (ventricular capture) or VL (ventricular loss) for the delivered test paces.

   If you need to end the test, tap **STOP**.

When the test has finished, the test measurement value displays in the Threshold column in the test results area of the **Tests - Device Measurements** screen. To determine if the pacing threshold measurement has changed, compare the Threshold value to the automatic daily threshold measurement values on the **Capture Threshold Trend** screen. To see the **Capture Threshold Trend** screen, tap **Data** > **Diagnostics** > **Capture Threshold Trend** > **Open Data**.

3.1.4.3 How to perform the manual Pacing Threshold Test

The manual 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 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.

1. Tap **Tests** > **Device Measurements**.

   Make sure that Sensing Test and Impedance Test are not checked in the **Tests - Device Measurements** window.
2. Select **Amplitude - Auto Decrement** from the Threshold Test drop-down list.
3. Tap **START Tests** to display the **Tests - Pacing Threshold** window.
4. Review the displayed values and consider the following options:

Optional task	Steps
Change the value for **Decrement after**.	Tap the field next to the parameter if you wish to change the test value.
Change the Test Value for **Mode**, **Lower Rate**, **RV Amplitude**, or **RV Pulse Width**.	Tap the fields next to these parameters you wish to change the test values.
Change the Test Value for **V. Pace Blanking**.	Tap the field next to the parameter if you wish to change the test value.

5. Initiate the pacing threshold test. Press and hold the **TEST Press and Hold** button.
6. Observe the Live Rhythm Monitor for loss of capture.
7. When capture is lost, immediately release the **TEST Press and Hold** button.

   The device resumes its original pacing values and displays the **RV Amplitude Threshold Test - Results** window.
8. In the Ending Value column, verify the detected RV Amplitude at which loss of capture occurred.
9. If you want to retest the pacing threshold, use the following options to view or change data in the **RV Amplitude Threshold Test - Results** window:

Optional task	Steps
Change the programmed values for **RV Amplitude** or **RV Pulse Width**.	Tap the value in the Permanent column to display the **RV Amplitude** parameters pop-up window or the **RV Pulse Width** parameters pop-up window. Select the desired values and tap **PROGRAM** to program the pending values.
View the ending value and the permanent value for **V. Pace Blanking** parameter.	—
View a test strip from the most recent pacing threshold test.	If the **RV Amplitude Threshold Test - Results** window is displayed, tap the Test Strip icon in the lower left corner of the test results window to see the test results. Tap **Close** in the test strip window to return to the **Tests - Device Measurements** window, or tap **Print…** to print the report.

10. When you have finished viewing or changing data on the **Pacing Threshold** window, tap **Close** to return to the **Device Measurements** screen.

3.2 Conducting the Temporary test

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

The temporary test allows you to evaluate changes to these parameters:

- Mode
- Lower Rate
- Amplitude
- Pulse Width
- Sensitivity

3.2.1 How to conduct the Temporary test

Place the programming head over the device to establish telemetry. Move the programming head until you see 1 or more of the green indicator lights on the programming head, then hold it in place.

Follow these steps to perform a temporary test:

1. Tap **Tests** > **Temporary** to display the **Tests - Temporary** screen.
2. To change the parameters for the test, tap the parameters under the Test Value label and select from the range of temporary values for that parameter.

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

   Warning: High-rate stimulation of the ventricle could result in ventricular tachycardia or fibrillation. Apply temporary high-rate pacing under careful patient monitoring and control.

3. To start the test, press and hold **TEST Press and Hold**.

   When the test starts, the annotation Test Started appears above the waveform trace in the Live Rhythm Monitor.

   Continue to hold **TEST Press and Hold** to observe changes in the waveform.
4. To end the test, release **TEST Press and Hold**. The annotation Test Ended appears above the waveform trace in the Live Rhythm Monitor.
5. Remove the programming head.
6. To view the last 10 s of the temporary test ECG test strip, tap the **Test Strip** icon to see the **Temporary Test, collected [date and time stamp]** window.
7. If you want to keep a copy of the ECG test strip, tap **Print…** to display the **Print - Options** window.

   Make your print selections.

3.3 Conducting tests to optimize atrial mechanical sensing for AV synchrony

There are 2 ways that the Model MC1AVR1 can be set up for AV synchrony, where the atrial mechanical signal is properly sensed in order to know when to pace the ventricle:

- The Atrial Sensing Setup process is automated. It takes place following implant. It collects atrial sensing data and then sets the atrial sensing parameters to patient-specific values based on the collected data.
- The Manual Atrial Mechanical test allows you view the A3 signal and the A4 signal on the programmer and program the atrial sensing parameters as you choose.

Note: Connect a surface ECG between the patient and the programmer to confirm atrial sensing.

3.3.1 Atrial sensing setup

Atrial sensing setup is performed shortly following device implant without clinician intervention. Following atrial sensing setup, you should interrogate the device to verify AV synchrony performance.

For more information on atrial sensing setup, see the Medtronic Micra AV reference manual.

3.3.1.1 Starting the atrial sensing setup process

The Atrial Sensing Setup parameter is shipped at On/Restart, so the atrial sensing setup process will initiate without clinician intervention following device implant if the programmed mode is VDD.

If you choose to initiate the atrial sensing setup process and the device is programmed, perform the following steps:

1. Place the programming head over the implanted device to establish telemetry.
2. Program the pacing mode to VDD.
3. Program the Atrial Sensing Setup parameter to On/Restart.

   The following events take place:

   a. The pacing mode switches to VDI.

   b. The message Atrial Sensing Setup Scheduled displays in the upper right corner of the programmer.
4. Remove the programming head from the patient for at least 3 min.

3.3.1.2 The atrial sensing setup process

During the atrial sensing setup process, if telemetry is re-established, the message Atrial Sensing Setup in Progress displays in the upper right corner of the programmer.

Process suspension and reversion to scheduled status

If the atrial sensing setup suspends and reverts to the scheduled status, the message Atrial Sensing Setup Scheduled displays in the upper right corner of the programmer. If the atrial sensing setup attempts to restart, the message Atrial Sensing Setup In Progress displays in the upper right corner of the programmer.

Note: Programming parameters or running tests during the atrial sensing setup process will cause it to suspend. For other suspension causes, see the Medtronic Micra AV reference manual.

To stop the atrial sensing setup process at any time, program the Atrial Sensing Setup parameter to Off/Complete.

3.3.1.3 Completing the atrial sensing setup process

When the atrial sensing setup process completes, the device programs the Atrial Sensing Setup parameter to Off/Complete, and no message displays in the upper right corner of the programmer.

Note: The device can reprogram some parameters or record relevant Observations in the Quick Look II screen in response to its analysis of the cardiac cycle collected during the atrial sensing setup process.

3.3.2 The Manual Atrial Mechanical test

You can observe and program the atrial sensing parameters with the assistance of the manual atrial mechanical test.

The manual atrial mechanical test displays the patient's ECG signal and the device accelerometer signal. Your settings for the A3 Threshold, the A3 Window End, and the A4 Threshold parameters are represented as lines superimposed on the accelerometer signals. The accelerometer blanking and threshold windows are labeled PVAB, A3, and A4.

The manual atrial mechanical test can be used to adjust the A3 and A4 parameter thresholds and the A3 Window End relative to the A3 and A4 signals so that the atrial and ventricular event markers in the test window indicate effective AV synchrony. See the Medtronic Micra AV reference manual for more details.

Note: The initial parameter settings shown in the **Tests - Manual Atrial Mechanical** screen are the current programmed settings.

3.3.2.1 Manual Atrial Mechanical test procedure

Follow these steps to conduct a manual atrial mechanical test:

1. Attach a surface ECG to the patient to monitor and confirm atrial sensing and AV synchrony.

   Note: ECG signals are required to assess AV synchrony.

2. Place the programming head over the device to establish telemetry. Move the programming head until you see 1 or more of the green indicator lights on the programming head, then hold it in place.

3. Tap **Tests** > **Manual Atrial Mechanical**.

   The **Tests - Manual Atrial Mechanical** screen displays. The current parameter values listed in the Permanent column are the same as the values in the Test Value column.

4. Change the Test Value parameter values as you choose.
5. Tap and hold the **TEST Press and Hold** button for multiple cardiac cycles shown on the ECG. Collect cycles where the P-wave and R-wave appear to be synchronous and the A3 and A4 signals can be distinguished from each other.

   Note: Up to 10 s of cardiac cycles are recorded.

6. Release the **TEST Press and Hold** button. The recorded test cardiac cycles display in the test results window. The cardiac cycles are displayed in the reverse order that they were recorded. For example, if you record 9 cycles, the first cycle you will see in the test results window is labeled 9/9.
7. Tap on the left and right arrow icons on the right and left edges on the test results window to see the collected cardiac cycles.
8. Tap **Enable Program** > **PROGRAM** to program your updated parameter settings.

   If you are **not** satisfied with the test results, repeat Step 4 through Step 7 until you are satisfied with the test results.

If you wish to print the test results, tap **Test Strip** > **Print**.

3.4 Conducting an Exercise test

The exercise test helps you to assess the patient's settings for rate-response. The rate-response settings are applied when the device is operating in either VVIR or VDIR mode.

Note: VDIR mode is used when the device is programmed to VDD mode and operating under the Activity Mode Switch.

As an alternative to automatic Rate Profile Optimization, you can conduct an exercise test from the programmer to set the rate response ranges for the Lower Rate, ADL Rate, and Upper Sensor Rate. If Rate Profile Optimization is programmed to Off, the rate-response parameters remain at their programmed values. When Rate Profile Optimization is programmed to On, this feature adjusts the 3 rate-response parameters once each day. For more information about rate-responsive pacing, see the Medtronic Micra AV reference manual.

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

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

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

3.4.1 Performing an Exercise test

1. Program the pacing mode to VVIR.
2. Position the programming head over the patient's device to establish telemetry. Move it until you see at least 1 green light on the programming head.
3. Tap **Tests** > **Exercise**. If test data from a previous exercise test is in the device memory, this data is shown on the **Exercise** test screen.
4. Tap the **Duration** field and select the test duration (5 or 20 min).
5. Tap the **Activity Vector** field, select from the vector list, and tap **PROGRAM**.

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

6. Tap **Start**. The message "Warning - Data will be lost" warns that you that the current test results will be overwritten if you start the exercise test.

   Note: Print or otherwise record the current values if you want to compare them to the test values.

7. Tap **Continue** to start the test or tap **Cancel** to return to the **Exercise** test screen.
8. Continue the test until you see the message Test Complete, or stop the test at any time. The data recorded up to that point will be saved.
9. Re-establish telemetry with the device as explained in Step 2.

10. Tap **Stop and Retrieve** to display the test results.
11. See Section 3.4.2 to interpret the test results.

3.4.2 Interpreting Exercise test data and adjusting rate-response setpoints

The device collects and displays the following information on the **Tests - Exercise** screen:

- A time stamp when the test data was most recently collected
- Programmed Activity Vector
- Exercise test duration
- Activity count data

  Note: In the test printout, activity count data is labelled as “Patient activity”.

- Heart rate data
- Sensor rate data

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

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

   - The LR Setpoint (that is, the lower rate set point) corresponds to when the patient is at rest at the beginning of the test. Following the test, tap **LR Setpoint** and select a value slightly higher than the highest activity count for when the patient is at rest.
   - The ADL Setpoint (that is, the activities of daily living set point) corresponds to when the patient is engaged in moderate activity. Following the test, tap **ADL Setpoint** and select the average activity count for when the patient is engaged in moderate activity.
   - The UR Setpoint (that is, the upper rate setpoint) corresponds to when the patient is engaged in vigorous activity. Following the test, tap **UR Setpoint** and select a value slightly lower than the average activity count for when the patient is engaged in vigorous activity.

4. Tap **PROGRAM** to program the updated rate-response values.

   Note: The rate-response setpoint values can also be programmed when the device is programmed to VDD mode.

5. To print the results of the exercise test, tap **Print…**.

Glossary

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 can interfere with device operations, such as sensing, or can potentially damage device circuitry.

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.

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

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

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

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

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

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

Medtronic

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

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

Technical manuals
www.medtronic.com/manuals

M991357A001 B
2020-01-22

M991357A001