Medtronic

Micra™ AV2 MC2AVR1

MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD)

Reference Manual

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

Micra™ AV2 MC2AVR1

Reference Manual

This manual describes the operation and intended use of the features of the Micra AV2 Model MC2AVR1 MR Conditional dual chamber transcatheter pacing system with SureScan™ technology (VDD).

Contents

1 Introduction

1.1 About this manual

This manual describes the operation and intended use of the features of the Micra AV2 Model MC2AVR1 MR Conditional dual chamber transcatheter pacing system with SureScan™ technology.

Throughout this manual, the word “device” refers to the implanted Micra AV2 device.

1.1.1 Product literature

Before implanting the device, it is recommended that you take the following actions:

- Read the product literature for information about prescribing, implanting, and using the device and for conducting a patient follow-up session.
- Thoroughly read the technical manuals for the other system components.
- Discuss the device and implant procedure with the patient and any other interested parties, and give them any patient information materials packaged with the device.

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

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.

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

Implantable device app help – The help explains how to use the implantable device app to program the device settings and view the stored device data.

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

1.1.2 Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users.

For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

2 Patient follow-up guidelines

2.1 Follow-up appointments

Schedule regular patient follow-up sessions during the service life of the device. The first follow-up session should occur within 72 hours of implant so that the patient can be checked for device dislodgment, wound healing, and postoperative complications.

During the first few months after implant, the patient may require close monitoring. Schedule follow-up sessions at least every 3 months to monitor the condition of the patient and the device and to verify that the device is configured appropriately for the patient.

2.1.1 Follow-up process

The process for conducting a follow-up evaluation includes the following steps:

1. Review the patient's presenting rhythm, including an ECG.
2. Verify the status of the implanted device.
3. Verify the clinical effectiveness of the implanted device.
4. During a follow-up appointment, adjust device parameters as necessary.

2.1.2 Reviewing the presenting rhythm

The presenting rhythm may indicate the presence of undersensing and oversensing or ventricular loss of capture. These are pacing issues that can affect the delivery of pacing therapy. These issues can often be resolved by making programming changes.

Review the presenting rhythm by viewing the Live Rhythm Monitor and recording the EGM, ECG, and marker annotations. If you identify issues with the patient's presenting rhythm, review the device settings and reprogram the device to values that are appropriate for the patient.

2.1.3 Verifying the status of the implanted device

Perform the following tasks to verify that the device is functioning correctly:

- Assess the battery status.
- Review the device status information on the Quick Look screen.
- Review any Observations on the Quick Look screen.

2.1.3.1 Assessing the battery status

To assess the status of the device battery, review the REMAINING LONGEVITY estimate on the Quick Look screen. If the device battery has reached a replacement threshold, the associated indicator is displayed.

To see more detail about the battery status, including battery voltage, tap REMAINING LONGEVITY on the Quick Look screen to see the device data provided by the BATTERY AND DEVICE MEASUREMENTS window.

Warning: When the battery voltage reaches the EOS condition, the device switches to the Device Off mode. The device permanently deactivates the pacing operation. The implantable device app indicates that the device is at EOS.

If the Recommended Replacement Time (RRT) indicator is displayed, or if the battery voltage is at or below the displayed RRT voltage, contact your Medtronic representative and schedule an appointment with the patient to implant a new device. For more information about the replacement indicators, see the implantable device app help.

2.1.3.2 Assessing the performance of the device

Follow-up appointment – During a follow-up appointment, you can check the performance of the device by reviewing the electrode impedance, capture threshold, and sensing trends on the Quick Look screen. To view this information, go to the Menu button (☰) and tap Quick Look.. For a more detailed history of each measurement, tap TRENDS. For more information about the automatic collection of these trends, see *Section 3.3, Battery and device performance data , page 14*.

If you also want to gather real-time information about the performance of the device, you can perform the following tests:

- Impedance test: Compare the results of the test to previous electrode impedance measurements to see if there have been significant changes since the last follow-up session.
- Threshold test: Perform this test to check the patient's Capture Management thresholds.
- Sensing test: Compare the test results to previous R-wave amplitude measurements.

For more information about performing these tests, refer to the implantable device app help.

2.1.4 Verifying the clinical effectiveness of the implanted device

You can use the information available from the Quick Look screen to assess whether the device is providing adequate clinical support for the patient.

2.1.4.1 How to assess effective pacing therapy

1. Interview the patient to confirm that the patient is receiving adequate cardiac support for daily living activities.
2. Review the pacing percentages on the Quick Look screen and the Data – Rate Histograms window. Export a Rate Histograms Report. You can use the data on the rate histogram window and in the report to assess the patient's pacing and sensing history. For more information about rate histograms, see *Section 3.2, Rate histograms , page 13*.
3. You can use the data on the A4 Amplitude Trend to assess changes in atrial sensing over time. Review the A4 Amplitude Trend data. Refer to the implantable device app help for more information about A4 Amplitude Trend.

2.1.5 Adjusting device parameters

Adjust the pacing and diagnostic data parameters as needed to address any issues identified during the follow-up appointment.

Note: Use caution when reprogramming the sensing parameters to ensure that appropriate sensing is maintained. For more information, see *Section 4.1, Sensing , page 19*.

2.2 Optimizing device longevity

Optimizing device longevity is a desirable goal because it may reduce the frequency of device replacement for patients. Optimizing device longevity requires balancing the benefit of device therapy and diagnostic features with the energy requirements placed on the battery for the operation of these features.

To view the Remaining Longevity estimate for the device, refer to the Quick Look screen. For information about the longevity of the device, see the Micra AV2 MC2AVR1 Device Manual.

The following sections describe strategies that can help to reduce the energy requirements placed on the battery.

2.2.1 Managing pacing outputs

Capture Management – The Capture Management feature provides the device with automatic monitoring and follow-up capabilities for managing pacing thresholds in the right ventricle. This feature is designed to monitor the pacing threshold and, optionally, to adjust the pacing outputs to maintain capture. Programming the Capture Management feature to the Adaptive mode allows the device to set the pacing amplitude just high enough to maintain

capture while preserving battery energy. For more information, see *Section 4.5, Pacing with Capture Management , page 51*.

Manual optimization of amplitude and pulse width – If you choose to program the Capture Management feature to Monitor or Off, you can optimize the patient's pacing output parameters manually. Perform a pacing threshold test to determine the patient's pacing threshold. Select amplitude and pulse width settings that provide an adequate safety margin above the patient's pacing threshold. An adequate safety margin decreases the pacing outputs and conserves battery energy. Refer to the implantable device app help for more information about performing a pacing threshold test.

Pacing rate – The more paced events that are delivered, the more battery longevity is reduced. Make sure that you have not programmed an unnecessarily high pacing rate for the patient. Carefully consider using features that increase the bradycardia pacing rate. Use features such as Rate Response only for patients who can receive therapeutic benefit from the feature.

2.2.2 Other longevity considerations

Atrial mechanical sensing – Atrial mechanical sensing (the VDD, VDI, or ODO pacing modes) decreases battery longevity. The AV Conduction Mode Switch feature disables atrial mechanical sensing during periods of intact AV conduction, reducing the longevity impact. Programming the sum of 3 vectors for atrial sensing (A. Sensing Vector) has a minor negative impact on battery longevity.

Holter telemetry – Extended use of the Holter telemetry feature substantially decreases the battery longevity. The Holter telemetry feature continues to transmit EGM and marker annotations for the programmed time duration, regardless of whether the patient connector is positioned over the device.

Note: Do not program the Holter telemetry feature to On unless instructed to do so by a Medtronic representative. Use of this feature requires that the patient is equipped with a customized Holter monitor provided by Medtronic for monitoring EGM.

3 Diagnostic data features

3.1 Quick Look summary data

At the start of a patient session, it is useful to quickly view summary information about device operation and the patient's condition. This overview can help you to determine whether you need to look more closely at diagnostic data or reprogram the device to optimize therapy for the patient.

The Quick Look data summarizes the most important indicators of system operation and the patient's condition. These indicators include battery and device status, pacing therapy information, and system-defined observations.

You can view Quick Look data on the Quick Look screen, which is displayed at the beginning of a patient session. To return to the Quick Look screen from another screen, tap Quick Look from the Menu button. For more information about using the Quick Look screen, refer to the implantable device app help.

3.1.1 Quick Look battery and device status information

The Quick Look data includes the following information about the battery and device status:

- Estimate of remaining battery longevity
- Trends of the weekly average impedance, capture threshold, and R-wave amplitude measurements
- Most recent measured values for impedance, capture threshold, and R-wave amplitude

3.1.2 Quick Look pacing therapy information

The Quick Look data includes the following information about pacing therapy:

- Programmed values for the Mode, Lower Rate, and Upper Tracking Rate parameters
- Percentage of time (% of Time) spent in sensing or pacing since the last patient session
- Percentage of time spent in AV Conduction Mode Switch, if applicable

3.1.3 Quick Look Observations

Observations are based on an analysis of programmed parameters and data collected since the last session. The following types of observations can occur:

- Device status observations inform you of conditions that affect device operation and require attention. Examples of such conditions include Recommended Replacement Time (RRT) or the occurrence of a device reset.
- Electrode status observations report any potential issues with the sensing integrity of the electrodes and abnormal Capture Management results. These observations can also warn you about possible inconsistencies in the performance of the device.
- Diagnostic data observations report noteworthy events, such as conditions that prevent diagnostic data from being collected effectively.
- Clinical status observations alert you to abnormal patient conditions, such as high pacing thresholds and a potential lack of effective VDD therapy.

When you select one of the displayed observations, the arrow next to the OBSERVATIONS section title becomes active if more information about the selected observation is available. To view the relevant details, tap OBSERVATIONS.

3.2 Rate histograms

Information about heart rates recorded between patient sessions can help you to monitor a patient's condition to assess the effectiveness of therapies. Rate histograms show the distribution of atrial mechanical sensed-ventricular paced (AM-VP) events, atrial mechanical sensed-ventricular sensed (AM-VS) events, ventricular sensed (VS) only events, and ventricular paced (VP) only events.

To access the rate histograms data from the Menu button, tap DATA > RATE HISTOGRAMS.

3.2.1 Information provided by rate histograms

Rate histograms report the atrial and ventricular event data stored by the device. There are histograms for 2 types of heart rate data: ventricular rate and atrial ventricular (AV) rate. The histograms include data from the current collection period. Data storage for rate histograms is automatic; no setup is required.

The rate histogram shows the percentage of time that the device was pacing and sensing within rate ranges. There are 20 rate ranges that are each 10 bpm in length. Rates slower than 40 bpm are included in the < to 40 range; rates faster than 220 bpm are included in the 220 to > range.

% of Time – This section shows the percentage of the total time that the device paced or sensed during the collection period. If atrial data was collected during this time, the device will also show the percent of events that were preceded by an atrial mechanical sense (AM-VP and AM-VS).

Atrial ventricular rate histogram – The atrial ventricular rate histogram shows the rate distribution of ventricular events, both ventricular sense (VS) and ventricular pace (VP), denoting which ventricular events were preceded by atrial mechanical sensing events (AM-VS and AM-VP).

Ventricular rate histogram – The ventricular rate histogram shows the rate distribution of ventricular sensed and paced events.

3.3 Battery and device performance data

The device automatically measures and records battery and device performance data every day. This information can help you assess the status of the device battery and identify issues with performance. The device records the following types of performance data:

- Remaining longevity estimate and replacement indicators
- Electrode impedance trend
- Sensing amplitude trends (R-wave amplitude and A4 amplitude)
- Capture threshold trend
- Sensing integrity counter

You can access battery and device performance data from several different screens on the implantable device app:

- Quick Look screen: from the menu select Quick Look
- Battery and device measurements window: from the menu select DATA > BATTERY AND DEVICE MEASUREMENTS
- Electrode impedance window: from the menu select DATA > ELECTRODE IMPEDANCE TREND
- Capture threshold window: from the menu select DATA > CAPTURE THRESHOLD TREND
- R-wave amplitude window: from the menu select DATA > R-WAVE AMPLITUDE TREND
- A4 amplitude window: from the menu select DATA > A4 AMPLITUDE TREND

3.3.1 Remaining Longevity estimate and replacement indicators

The device automatically measures the battery voltage once a day at 02:30. The automatic daily battery voltage measurement is displayed on the DATA > BATTERY AND DEVICE MEASUREMENTS window.

The device manager is able to estimate the remaining device longevity (the number of years until the battery reaches RRT) after 1 day of the device manufacture date. Longevity estimates are based on a history of battery voltage measurements made by the device since the manufacture date.

The Battery and Device Measurements screen provides the mean (Estimated at), minimum, and maximum values for remaining longevity. These values are based on a statistical analysis of accelerated battery discharge data. The maximum and minimum remaining longevity estimates are 95th percentile values calculated from the distribution of this data. That is, approximately 95% of devices are expected to reach RRT before the reported maximum value and approximately 95% of devices are expected to reach RRT after the reported minimum value.

If the device longevity estimator determines that there are less than 6 months (180 days) until the End of Service (EOS), the implantable device app displays the RRT symbol and the date when the battery reached the RRT condition. If the implantable device app displays the RRT symbol, contact your Medtronic representative and schedule a patient appointment to implant a new device.

The expected service life of the device after RRT, defined as the Prolonged Service Period (PSP), is 6 months (180 days). After the first 90 days of the PSP have passed, the device reaches the Elective Replacement Indicator (ERI) and the implantable device app displays the ERI indicator.[1] When the device reaches the ERI condition, it automatically changes the pacing mode to VVI and sets the pacing rate to 65 bpm, unless the device is programmed to a non-pacing mode. It also changes Rate Hysteresis to Off if this feature is programmed to On. When the ERI indicator is displayed on the implantable device app, implant a new device immediately. The device reaches End of Service (EOS) based on battery voltage and switches to the Device Off mode, permanently deactivating the pacing operation. The implantable device app displays the EOS symbol.[1]

For more information on the ERI indicator, see the implantable device app help.

Note: After ERI, all pacing parameters can be programmed, including mode and rate. Reprogramming the pacing parameters may reduce the duration of the ERI to EOS period.

[1] ERI may be indicated before the end of 90 days, and EOS may be indicated before the end of 180 days if the actual battery usage exceeds the expected conditions during the Prolonged Service Period. For an explanation of these conditions, see the Micra AV2 MC2AVR1 Device Manual.

Warning: When the battery voltage reaches the EOS condition, the device permanently deactivates pacing and sensing and switches to the Device Off mode. The EOS symbol appears on the implantable device app screen.

3.3.2 Electrode impedance trend

Every day at 02:30, the device delivers a ventricular pace and automatically measures the electrode impedance. 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.

The daily automatic electrode impedance measurements are displayed in ELECTRODE IMPEDANCE TREND, which plots the data as a graph. The graph shows up to 15 of the most recent measurements and up to 80 weekly summary measurements, providing minimum and maximum values for each week. Significant or sudden changes in electrode impedance may indicate a problem with the pacing electrode.

If the device is unable to perform automatic electrode impedance measurements, gaps are present in the trend graph.

3.3.3 Sensing amplitude trend

After completing the electrode impedance measurement, which starts at 02:30 every day, the device begins to measure the amplitude of intrinsic ventricular sensed events. The device attempts to measure the amplitude of 5 normal intrinsic ventricular sensed events. After collecting these measurements, the device records their median value as the most recent R-wave amplitude measurements. If the device has not collected 5 amplitude measurements for the day by midnight, no measurement is recorded. The sensing amplitude trend graph shows a gap for that day.

The daily automatic sensing amplitude measurements are displayed on the TRENDS - R-Wave Amplitude Trend and TRENDS - A4 Amplitude Trend windows, which plot the data as a graph. The graph shows up to 15 of the most recent measurements and up to 80 weekly summary measurements, providing minimum and maximum values for each week. Significant or sudden changes in the R-wave amplitude may indicate a problem with the sensing electrode. Significant or sudden changes in the A4 amplitude may indicate a problem with effective VDD pacing therapy.

When operating in the VDD mode, the device periodically collects A4 amplitude measurements over the course of the day. The A4 amplitude is measured as the maximum acceleration in the A4 window. This measurement is collected regardless of whether an atrial sense occurred in that cycle. At the end of the day at midnight (00:00), the device stores the most common measured A4 amplitude of the day in the A4 Amplitude Trend. If the device has not collected enough measurements for the day, no measurement is recorded. The A4 Amplitude Trend graph shows a gap for that day. This gap can happen if the device does not spend enough time per day operating in the VDD mode.

Note: The A4 Amplitude Trend measures the maximum acceleration in the A4 window, which may not be the true A4 amplitude if the A4 signal does not occur in the A4 window.

3.3.4 Capture threshold trend

If the Capture Management feature is programmed to Adaptive or Monitor, the device automatically performs daily pacing threshold searches and records the results in the Capture Threshold Trend data. In the adaptive mode, Capture Management also performs hourly pacing threshold confirmation checks. For more information about Capture Management, see *Section 4.5, Pacing with Capture Management , page 51*.

The results of the most recent daily pacing threshold measurements are displayed on the TRENDS window on the capture threshold trend graph. The graph shows up to 15 of the most recent measurements and up to 80 weekly summary measurements, including minimum and maximum values for each week. The Capture Threshold window also shows programmed values for pacing output and Capture Management parameters, the last measured threshold value, and a link to a detailed view of the last 15 days of the threshold measurement data.

The Capture Management (Last 15 days detail) window shows daily results from the last 15 days of threshold measurements. These results include the dates, times, threshold measurements, pacing amplitude values, and notes describing the results of each pacing threshold search.

The Capture Threshold trend data provides a means to evaluate the operation of Capture Management and the appropriateness of the current pacing output values. In addition, sudden or significant changes in the pacing threshold may indicate a problem with the pacing electrode.

Note: It is possible for a high threshold observation to occur without a corresponding value shown on the Capture Threshold Trend graph. The observation occurs when a single Capture Management test is aborted due to a high threshold value. When a single Capture Management test is aborted due to a high threshold value, the device attempts a new Capture Management test an hour later. If the new test does not result in a high threshold value, the device stores this result in the Capture Threshold Trend for the day. If 3 consecutive Capture Management tests are aborted due to a high threshold, a threshold value of > 5.0 V is stored in the Capture Threshold Trend. The device does not attempt any more Capture Management tests for that day.

3.3.5 Sensing Integrity Counter

The Sensing Integrity Counter records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate oversensing.

To view the Sensing Integrity Counter, from the menu select DATA > BATTERY AND DEVICE MEASURMENTS.

4 Configuring pacing therapies

4.1 Sensing

Effective sensing is essential for the safe and effective use of the device. The device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver therapies appropriately. Effective ventricular sensing can reduce the effects of long depolarizations after paced events, oversensing the same event, and sensing T-waves, noise, and interference. Effective atrial sensing can improve the efficacy of VDD pacing therapy.

Programmable blanking periods help to screen out extraneous sensing or to prevent the device from responding to it. Blanking periods follow pacing pulses and sensed events. Sensing is inhibited during blanking periods.

4.1.1 Ventricular sensing

The device senses electrically in the right ventricle. No sensing occurs in the left ventricle. Each sensitivity setting represents a threshold value that defines the minimum electrical amplitude recognized by the device as a sensed event in the right ventricle. Selecting a higher value for the sensing threshold reduces the sensitivity to lower amplitude signals.

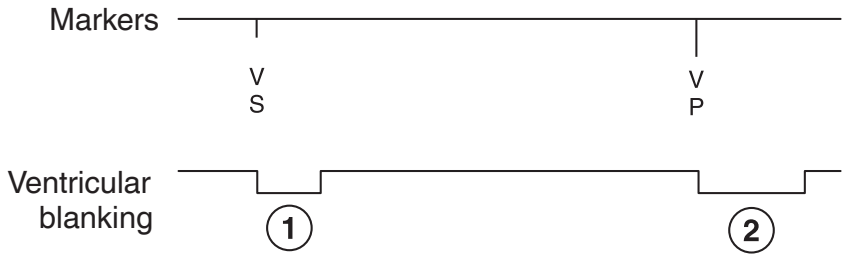
4.1.1.1 Operation of ventricular sensing threshold

Ventricular sensing operates at a fixed, programmed ventricular sensitivity.

4.1.1.2 Operation of ventricular blanking periods

Ventricular blanking periods follow paced and sensed ventricular events. Ventricular blanking periods help to prevent the device from sensing pacing pulses, post-pacing depolarization, T-waves, and oversensing of the same event.

Figure 1. Programmable blanking periods



1 For the duration of this ventricular blanking period, which is defined by the Blank Post VS parameter, ventricular sensing is disabled after a sensed ventricular event.

2 For the duration of this ventricular blanking period, which is defined by the Blank Post VP parameter, ventricular sensing is disabled after a paced ventricular event.

4.1.1.3 Noise reversion in the VVI and VVIR modes

The operation associated with continuous noise sensing is called noise reversion. Noise reversion identifies continuous noise detected above the programmed ventricular Sensitivity shortly after a ventricular event. During continuous noise reversion, ventricular sensing is disabled and ventricular pacing occurs at the sensor-indicated rate in the VVIR mode and at the programmed lower rate in the VVI mode.

4.1.1.4 Preventing noise sensing

Noise reversion may be caused by electromagnetic interference (EMI) or low sensitivity settings. You can reduce or eliminate noise reversion by one of the following actions:

- Identify the source of EMI and increase the distance between the patient and the EMI source.
- Reprogram Sensitivity to a less sensitive setting (higher numerical value).
- Reprogram Blank Post VP and Blank Post VS to blank the T-waves.

4.1.1.5 Ventricular sensing parameters

Table 1. How to navigate to ventricular-electrical sensing parameters

Parameters	Path
RV Sensitivity	From the menu select PARAMETERS > Sensitivity
Blank Post VP Blank Post VS	From the menu select PARAMETERS > RV Blanking

4.1.2 Atrial mechanical sensing

Although the device is located entirely in the right ventricle, mechanically sensing the atrium from the ventricle makes it possible to provide AV synchronous pacing for patients with AV block. The device senses and paces electrically in the right ventricle. The device also uses an accelerometer to detect the mechanical vibrations produced by the atrial contraction, called A4. The ventricular contraction and relaxation also produces mechanical vibrations, called A1, A2, and A3. The timing of A1, A2, A3, and A4 is similar to the heart sounds S1, S2, S3, and S4, respectively.

Warning: Patient activities and environments which present mechanical vibrations to the patient can interfere with the mechanical sensing of atrial contractions. This can result in loss of AV synchrony.

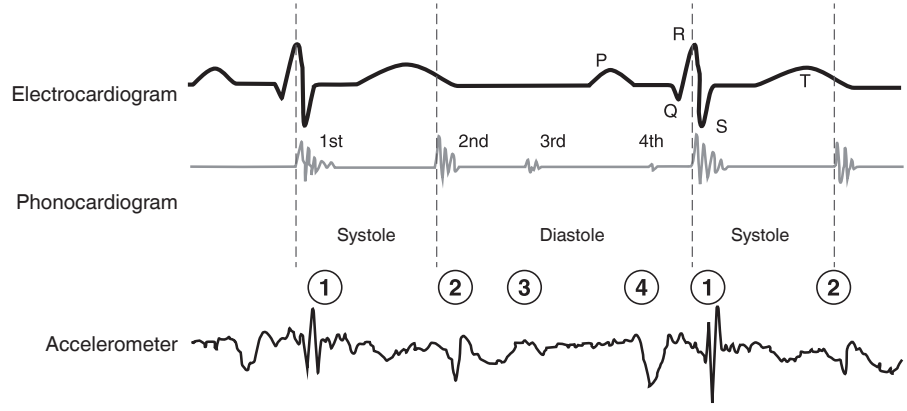
The signals are defined as follows:

- The A1 signal:
  - Occurs at the beginning of ventricular systole and represents the closing of the mitral valve and the tricuspid valve
  - Occurs after the beginning of the QRS complex on an ECG
- The A2 signal:
  - Occurs at the completion of ventricular systole and represents the closing of the aortic valve and the pulmonary valve
  - Occurs near the end of the T-wave on an ECG
- The A3 signal:
  - Occurs during ventricular diastole
  - Occurs after the T-wave on an ECG
  - Corresponds in timing to the E-wave on a Doppler echo
  - Represents the passive filling of blood from the atrium into the ventricle

- The A4 signal:
  - Occurs when the atrium contracts and pushes blood into the ventricle
  - Occurs after the P-wave on an ECG
  - Corresponds in timing to the A-wave on a Doppler echo
- The A7 signal:
  - Occurs when the A3 signal and the A4 signal fuse: the passive and active filling of the ventricles occurs simultaneously, resulting in a larger amplitude signal. This signal can be larger than the sum of the A3 + A4 signals.
  - Occurs during higher heart rates or when AV synchrony is missing
  - Corresponds to the summation of S3 and S4, known as the heart sounds summation gallop

The A1, A2, and A3 signals are associated with ventricular events and always follow ventricular activity, represented as the QRS complex on an ECG. The A4 signal is associated with an atrial contraction and always follows atrial activity, or the P-wave on an ECG (see *Figure 2*).

Figure 2. Mechanical waveform throughout the cardiac cycle



1 A1 signal
2 A2 signal
3 A3 signal
4 A4 signal

Note: Mechanical activity lags behind electrical activity by approximately 100 ms. Therefore, accelerometer activity will lag behind a corresponding electrical event (ECG) by approximately 100 ms, and the detected atrial mechanical sensed event should be after the P-Wave.

For more information, see *Section 4.3.2, Programming considerations for AV synchronous pacing , page 35*.

4.1.2.1 Operation of atrial sensing thresholds

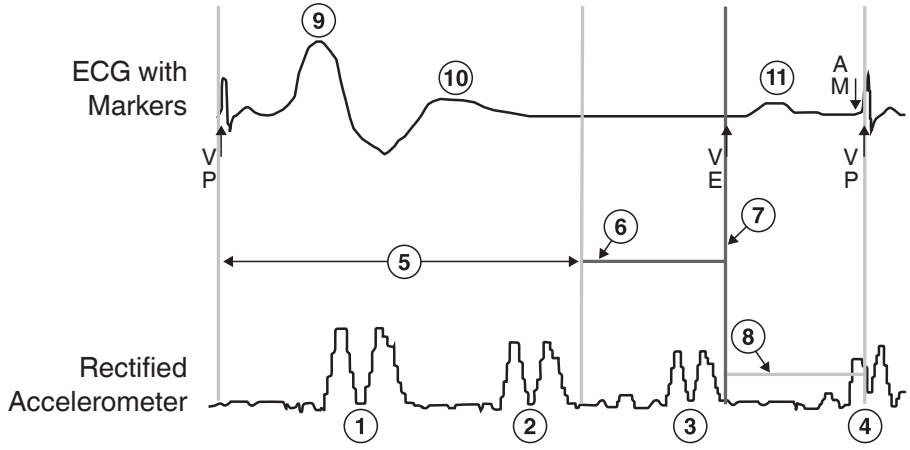
Atrial sensing operates in the following way: The accelerometer signal is filtered and rectified. The A1 and A2 signals are blanked with a programmable PVAB. Two sensing windows are defined: A3 and A4, each with separate sensing thresholds.

The A3 window has a higher threshold to detect the fused, larger A7 signal. The A3 Threshold must be programmed higher than the A3 signal so that the A3 signal is not sensed as the atrial contraction. An appropriately programmed A3 Threshold is higher than the patient's A3 signal. An optimally programmed A3 Threshold is also low enough to sense an A7 signal.

The A3 window begins at PVAB and ends at the programmed A3 Window End. The timing of the A3 Window End parameter is in relation to the previous ventricular event. An appropriately programmed A3 Window will end after the A1 – A3 ventricular-event signals have occurred. To aid in the troubleshooting of the A3 Window End, the VE marker appears at the end of the A3 window. The VE marker stands for "ventricular end," or the end of the A1 – A3 ventricular-event signals. The VE marker is unique because it represents a pacemaker timing window instead of a physiological event. If the A3 Window End is inappropriately programmed before the end of the A3 signal, the A3 signal may be oversensed as if it were the atrial contraction, or the A4 signal. If the A3 Window End is inappropriately programmed longer than the intrinsic atrial rate, the A4 signal may be undersensed.

The A4 window has a lower threshold to detect the A4 signal in isolation. An appropriately programmed A4 Threshold is lower than the A4 signal but higher than the noise floor. The A4 window begins as soon as the A3 window ends. See *Figure 3*.

Figure 3. ECG and rectified accelerometer markers



1 A1 signal
2 A2 signal
3 A3 signal
4 A4 signal
5 PVAB
6 A3 threshold
7 A3 window end
8 A4 threshold
9 QRS complex
10 T-wave
11 P-wave

4.1.2.2 Automatic atrial sensing features

Auto A3 Threshold – This feature automatically adjusts the height of the A3 threshold, and it is programmed on through the A3 Threshold Auto Adjustment parameter. If A3 Threshold Auto Adjustment is programmed to Auto, the device automatically adjusts the A3 threshold based on the height of the A3 signal and the height of the A4 threshold. The feature aims to set the A3 threshold higher than the signal in the A3 window. If the signal in the A3 window increases, the feature slowly increases the A3 threshold. This allows short periods of A7 tracking. If Auto A3 Threshold is programmed to Off, the A3 Threshold operates at the fixed programmable value. To access these parameters, go to the menu then tapPARAMETERS > A3 Threshold… > Auto Adjustment.

Note: If consistent tracking of the A7 signal in the A3 window is desired, consider programming Auto A3 Threshold to Off. Auto A3 Threshold prevents prolonged periods of atrial sensing in the A3 window.

Auto+ A3 Threshold – This feature collects measurements of the A3 amplitude, looking for true A3 signals, throughout the day in a histogram. Once per day, it adjusts the A3 threshold using the histogram data and user programmed A3 amplitude margin.

Auto A3 Window End – This feature automatically adjusts the A3 Window End, and it is programmable to Off or On. If Auto A3 Window End is programmed to On, the device will adjust the A3 Window End within the lower and upper limits that you program using Min Auto A3 Window End and Max Auto A3 Window End. Auto A3 Window End adjusts the A3 Window End based on the signal end detected in the A3 window and the signal detected in the A4 window. Auto A3 Window End adjusts the A3 Window End to keep it between the A3 signal and the A4 signal. If Auto A3 Window End is programmed to Off, the A3 Window End operates at the fixed programmable value. To access these parameters, go to menu and then tap PARAMETERS > A3 Window End….

Auto A4 Threshold – This feature automatically adjusts the height of the A4 threshold, and it is programmable to Off or On. If Auto A4 Threshold is programmed to On, the device will change the A4 threshold based on the signal in the A4 window and the number of A4 detections in recent history. Auto A4 Threshold aims to detect the A4 signal with an adequate safety margin. Auto A4 Threshold will not lower the A4 threshold below the programmable Min Auto A4 Threshold value and it will not raise the A4 threshold above the programmable Max Auto A4 Threshold value. If Auto A4 Threshold is programmed to Off, the A4 Threshold operates at the fixed programmable value. To access these parameters, go to menu and then tap PARAMETERS > A4 Threshold….

4.1.2.3 Operation of atrial blanking periods

Post-Ventricular Atrial Blanking (PVAB) – The device uses a programmable Post-Ventricular Atrial Blanking (PVAB) after a sensed or paced ventricular event to block ventricular-event based accelerometer activity that may have occurred during the blanking period, namely, the A1 and A2 signals. PVAB can be programmed to a fixed value or Auto. Auto PVAB adjusts PVAB to the user programmable Min PVAB value when the ventricular rate is faster than the user programmable PVAB Switch Rate. Auto PVAB adjusts PVAB to the user programmable Max PVAB value when the ventricular rate is equal to or slower than the PVAB Switch Rate. Having a dynamic PVAB value allows for a higher effective Upper Tracking Rate in patients who have a later A2 signal end at slower sinus rates and an earlier A2 signal end at faster sinus rates. Min PVAB should be programmed to blank the A2 signal above the PVAB Switch rate and Max PVAB should be programmed to blank the A2 signal at and below the PVAB Switch Rate. The PVAB period is long enough to prevent mechanical tracking of retrograde conduction. Accelerometer activity that occurs during this period is not sensed by the device.

4.1.2.4 Operation of atrial refractory periods

During a refractory period, the device senses normally but classifies sensed events as refractory (AR) and limits its response to these events. One AR event can be produced per pacing cycle.

Post-Ventricular Atrial Refractory Period (PVARP) – PVARP begins after a ventricular sensed or paced event and is only available in the VDD mode. PVARP can be programmed to a fixed value or to Auto. Automatic PVARP lengthens PVARP at lower ventricular rates and provides a higher 2:1 block rate by shortening PVARP at higher rates.

4.1.2.5 Noise reversion in the VDD mode or the VDI mode

The operation of continuous electrical noise sensing is called noise reversion. Noise reversion identifies continuous noise detected above the programmed ventricular Sensitivity shortly after a ventricular event. When the device is in the VDD mode, the device continues to track the atrium and to provide ventricular pacing at the Sensed AV Interval while ventricular sensing is disabled due to noise reversion. If no atrial event is sensed and Rate Smoothing is enabled, the device paces at the Rate Smoothing rate. If Rate Smoothing is not enabled, the device paces at the programmed Lower Rate.

If the device is in the VDI mode, the device will continue to sense the atrium but ventricular sensing is disabled. The device will provide ventricular pacing at the Lower Rate.

4.1.2.6 Atrial sensing vector

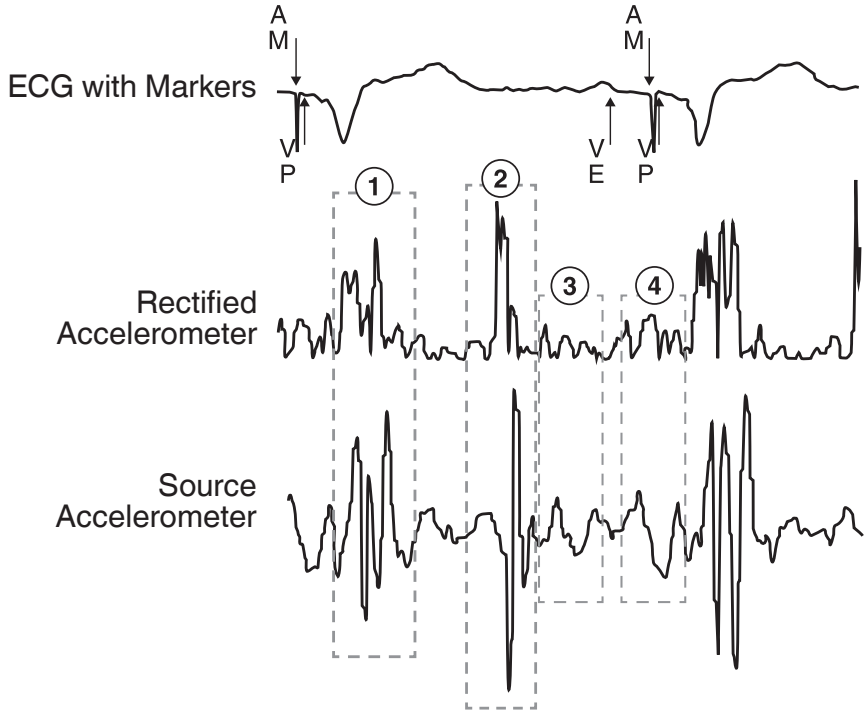
The Micra AV2 device contains an accelerometer with 3 perpendicular vectors. Atrial sensing can operate from any combination of these 3 accelerometer vectors.

A. Sensing Vector – This parameter allows you to choose the accelerometer vector or combinations of vectors that provide the strongest signal and lowest noise atrial mechanical signal. The A. Sensing Vector is independent from the Activity Vector used for rate-responsive pacing. To access this parameter, go to menu and select PARAMETERS > A. Sensing Vector….

Live Waveform Display – This parameter determines which atrial mechanical signal to display on the Live Rhythm Monitor. If you choose Vector 1 Source, Vector 2 Source, or Vector 3 Source, the source accelerometer signal for a single vector will display, which includes the positive and negative components of the signal. If you choose Rectified, the rectified accelerometer signal for the programmed A. Sensing Vector will display on the live waveform. This signal only includes positive components, and it is the signal the device uses to sense the atrial contraction. To access this parameter, go to menu and select PARAMETERS > A. Sensing Vector… > Live Waveform Display.

See *Figure 4* for an example of the source and rectified waveforms.

Figure 4. Source and rectified waveforms



1 A1 signal
2 A2 signal
3 A3 signal
4 A4 signal

4.1.2.7 Atrial mechanical sensing parameters

Table 2. How to navigate to atrial-mechanical sensing parameters

Parameters	Path
A. Sensing Vector... A3 Threshold… A3 Window End… A4 Threshold…	From the menu select PARAMETERS
Sensed AV PVAB PVARP	From the menu select PARAMETERS > Atrial Parameters…

4.1.3 Programming considerations for ventricular sensing

Bradycardia pacing and sensing – A combination of high pacing pulse width or high amplitude with a low sensing threshold may cause ventricular oversensing. Programming a lower pulse width, a lower amplitude, a longer pace blanking, or a higher sensing threshold may eliminate this inappropriate sensing.

High ventricular sensing threshold – If the Sensitivity value is set too high, the device may undersense ventricular events. This action may result in asynchronous pacing.

Low ventricular sensing threshold – If you set the Sensitivity parameter to its most sensitive value, the device is more susceptible to electromagnetic interference (EMI) and oversensing. Oversensing may result in the inhibition of ventricular pacing.

Recommended sensing threshold – Setting the ventricular Sensitivity parameter to 2.0 mV, the nominal value, may limit the possibility of oversensing.

Testing sensitivity after reprogramming – If you change the ventricular sensing parameters, evaluate for proper sensing.

4.1.4 Programming considerations for atrial mechanical sensing

Lower Rate – If the sinus rate is lower than the Lower Rate, the device cannot sense the atrial contraction. This action can result in pacing faster than the atrial rate and a loss of AV synchrony.

High atrial sensing threshold – If the A4 Threshold value is set too high, the device may undersense the atrial contraction. If the A3 Threshold value is set too high, the device may undersense the atrial contraction when the A3 signal and the A4 signal fuse (A7 signal), which occurs at higher rates. This action can result in ventricular pacing slower than the atrial rate and a loss of AV synchrony.

A3 Window End – An appropriate A3 Window End is between the A3 signal and the A4 signal. A good starting point for manual A3 Window End optimization is slightly faster than the sinus rate.

Early A3 Window End – An earlier A3 Window End allows for tracking of A4 signals at higher sinus rates. An earlier Min Auto A3 Window End allows Auto A3 Window End to move the A3 Window End value earlier. If the A3 Window End or the Min Auto A3 Window End value is set too early, the device may oversense the A3 signal in the A4 window, resulting in ventricular pacing faster than the atrial rate and a loss of AV synchrony.

Note: Min A3 Window End or A3 Window End < 650 ms may cause mechanical oversensing of the A3 signal.

Late A3 Window End – A later A3 Window End prevents oversensing of the A3 signal in the A4 window. A later Max Auto A3 Window End allows Auto A3 Window to move the A3

Window End value later. If the A3 Window End or the Max Auto A3 Window End value is set too late, the device may undersense the A4 signal because it is in the A3 window. These actions can result in ventricular pacing slower than the atrial rate and a loss of AV synchrony.

Low atrial sensing threshold – If the A4 Threshold or the Min Auto A4 Threshold value is set too low, the device may oversense mechanical noise. If the A3 Threshold value is set too low, the device may oversense the A3 signal or mechanical noise. These actions can result in ventricular pacing faster than the atrial rate and a loss of AV synchrony.

Note: A4 Threshold ≤ 0.8 m/s^2 may cause mechanical oversensing.

Long PVARP – If PVARP or Max PVARP is programmed too long, the atrial contraction may be sensed as a refractory event. This action can result in pacing slower than the atrial rate and a loss of AV synchrony.

Long PVAB – If PVAB or Max PVAB is programmed too long, the atrial contraction at higher rates (A7) may be blanked. This action can result in pacing slower than the atrial rate and a loss of AV synchrony.

Short PVAB – If PVAB or Min PVAB is programmed too short, the ventricular contraction (A2) may be oversensed in the A3 window as the atrial contraction. This action can result in pacing faster than the atrial rate and a loss of AV synchrony.

Testing sensitivity after reprogramming – If you change the atrial sensing parameters, evaluate for proper sensing.

4.1.4.1 Programming considerations for high atrial rates

When programming for high atrial rates, consider taking the following actions:

- Ensuring A3 Threshold Auto Adjustment is programmed to Auto+. A3 Threshold Auto Adjustment can also be programmed Off.
  - If A3 Threshold Auto Adjustment is programmed Off, select an A3 Threshold value that is lower than the A7 signal but higher than the A3 signal. A good starting point for manual adjustment of A3 Threshold is 1.0-1.5 m/s^2 above the A3 signal.
- Ensuring Tracking Check is Off or raise the Tracking Check Rate above the intrinsic sinus rate.
- Shortening the Rate Smoothing delta or programming Rate Smoothing to Off
- Shortening the Sensed AV interval
- Shortening PVARP or Max PVARP

- Raising the Upper Tracking Rate
  - Note that if the Upper Tracking Rate is raised, PVAB may need to be shortened, but should still be programmed long enough to blank the A2 signal. The shortest offered PVAB value of 425 ms is only available as a Min PVAB value when using Auto PVAB.
- Auto PVAB can be used if the patient requires a longer PVAB value at slower sinus rates and a shorter PVAB value at higher sinus rates to blank the A2 signal.

Atrial arrhythmia – An atrial arrhythmia results in partial or complete undersensing of the atrial signal. The device will sense any atrial signal that exceeds the atrial sensing threshold within the A3 window or the A4 window. Program the VVI mode or the VVIR mode if the pacing behavior in the VDD mode is not acceptable.

4.1.5 Evaluation of sensing

4.1.5.1 Using the Sensing Test to evaluate ventricular sensing

The Sensing Test allows you to measure R-wave amplitudes. To access the Sensing Test, tap TESTS > DEVICE MEASUREMENTS > Sensing Test. These measurements may be useful for assessing electrode integrity and sensing performance. After the Sensing Test is complete, the test results are displayed on the test screen. You can view and export the results. For more information about the sensing test, refer to the implantable device app help.

4.1.5.2 Viewing the Sensing Integrity Counter

To access the Sensing Integrity Counter, go to the menu and tap DATA > BATTERY AND DEVICE MEASUREMENTS > Sensing Integrity Counter.

The Sensing Integrity Counter records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate oversensing.

Note: If the number of short intervals that are displayed exceeds 300, the implantable device app displays an observation in the Observations box on the Quick Look screen.

4.1.5.3 Using the Manual Atrial Mechanical Test to evaluate atrial sensing

The Manual Atrial Mechanical Test is a press and hold test that allows you to observe and assess atrial sensing parameters and the atrial sensing waveform. To access the Manual Atrial Mechanical Test, from the menu select TESTS > MANUAL ATRIAL MECHANICAL. For more information, refer to *Section 4.3.3.2, Manual Atrial Mechanical Test , page 39*.

4.1.5.4 Viewing the R-wave amplitude trend

To access R-wave amplitude trends, tap DATA > R Wave Amplitude Trend.

After completing the electrode impedance measurement, which starts at 02:30 every day, the device begins to measure the amplitude of intrinsic ventricular sensed events. The device attempts to measure the amplitude of 5 normal intrinsic ventricular sensed events. After collecting these measurements, the device records their median value as the most recent R-wave amplitude measurements. If the device has not collected 5 amplitude measurements for the day by midnight, no measurement is recorded. The sensing amplitude trend graph shows a gap for that day.

4.1.5.5 Viewing the A4 amplitude trend

To access A4 amplitude trends, tap DATA > A4 Amplitude Trend.

When operating in the VDD mode, the device periodically collects A4 Amplitude measurements over the course of the day. The A4 Amplitude is measured as the maximum acceleration in the A4 window. This measurement is collected regardless of whether an atrial sense occurred in that cycle. At the end of the day at midnight (00:00), the device stores the most common measured A4 amplitude of the day in the A4 Amplitude Trend. If the device has not collected enough measurements for the day, no measurement is recorded. The A4 Amplitude Trend graph shows a gap for that day. This gap may happen if the device does not spend enough time per day operating in the VDD mode.

Note: The A4 Amplitude Trend measures the maximum acceleration in the A4 window, which may not be the true A4 amplitude if the A4 signal does not occur in the A4 window.

4.2 Single chamber pacing therapies

The system provides single chamber ventricular pacing modes to address different cardiac conditions.

4.2.1 Operation of ventricular pacing and sensing

The output energy for pacing pulses is determined by individually programmed amplitude and pulse width parameters. Although you can program the amplitude manually, the Capture Management feature is available to manage the pacing amplitude in the right ventricle. For more information about Capture Management, refer to *Section 3.3.4, Capture threshold trend , page 17*.

The minimum amplitude of the intracardiac signal that the device recognizes as a sensed event depends on the programmed value for the RV Sensitivity parameter. For information about the sensing threshold and blanking periods, refer to *Section 4.1.1, Ventricular sensing , page 19*.

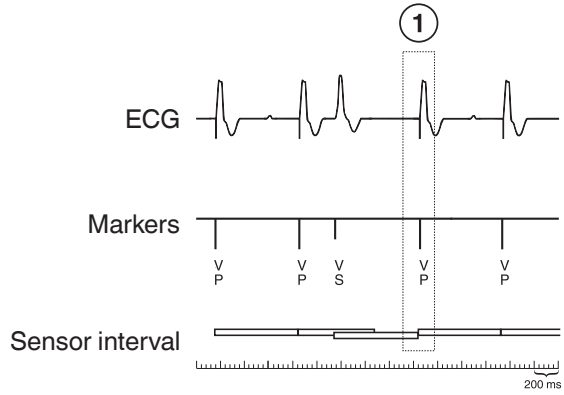
4.2.2 Operation of single chamber pacing

Single-chamber pacing modes are used to pace and sense the right ventricle only.

4.2.2.1 VVIR and VVI modes

In the VVIR and VVI modes, the ventricle is paced if no intrinsic events are sensed. Pacing occurs at the programmed Lower Rate in the VVI mode and at the sensor rate in the VVIR mode (see *Figure 5*).

Figure 5. Single chamber ventricular pacing in VVIR mode



1 A ventricular paced event occurs when no intrinsic ventricular event is sensed.

4.2.2.2 OVO mode

The OVO mode does not deliver ventricular pacing regardless of the intrinsic rate. The OVO mode is intended only for those situations in which bradycardia pacing is not necessary. Ventricular sensing continues to operate as programmed when pacing is programmed to the OVO mode.

Caution: Use the OVO mode only in clinical situations, such as the manual sensing test, where bradycardia pacing is not necessary or is detrimental to the patient.

4.2.2.3 VOO mode

The VOO mode provides ventricular pacing at the programmed Lower Rate with no inhibition by intrinsic ventricular events.

4.2.3 Programming considerations for ventricular pacing therapies

Pacing safety margins – Pacing pulses must be delivered at an adequate safety margin above the stimulation thresholds.

High pacing output levels – The pulse width and amplitude settings affect the longevity of the device, particularly if the patient requires bradycardia pacing therapy most of the time.

4.2.4 Programming ventricular pacing therapies

Table 3. How to navigate to ventricular pacing parameters

Parameters	Path
Mode Lower Rate Upper Sensor Amplitude Pulse Width	From menu select PARAMETERS

4.2.5 Evaluation of ventricular pacing therapies

To verify that the device is pacing appropriately, review the Percentage of Time (% of Time) data on the Quick Look screen. From the menu tap Quick Look.

Percentage of Time (% of Time) – The % of Time section reports the patient's pacing and sensing as the percentage of the total time during the reporting period.

4.3 Dual chamber modes

The Micra AV2 device offers atrial sensing when in the VDD mode, the VDI mode, and the ODO mode.

4.3.1 Operation of dual chamber modes

Dual chamber modes are used to pace the right ventricle, while sensing the atrium.

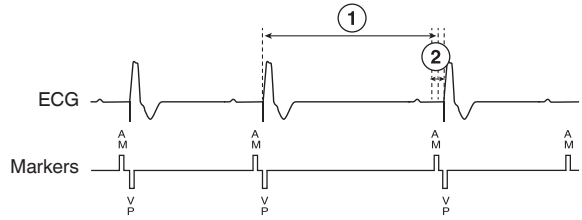
4.3.1.1 VDD mode

In the VDD mode, the device paces and electrically senses the right ventricle, while mechanically sensing the atrium. The device responds to an atrial sensed event by pacing the ventricle after the programmed Sensed AV interval, providing AV synchronous pacing. If no atrial event is sensed and Rate Smoothing is enabled, the device paces at the Rate Smoothing rate. If Rate Smoothing is not enabled, the device paces at the programmed Lower Rate (see *Figure 6*).

If a ventricular sensed event occurs during the Sensed AV interval, ventricular pacing is inhibited. A sensed atrial event that occurs during the Post Ventricular Atrial Refractory Period (PVARP) is classified as refractory.

Only one atrial refractory (AR) event and one atrial mechanical sensed (AM) event can occur per pacing cycle.

Figure 6. VDD mode



1 Lower Rate interval (50 bpm, 1200 ms)

2 SAV Interval (20 ms)

4.3.1.2 VDI mode

In the VDI mode, the device paces and electrically senses in the right ventricle, while mechanically sensing the atrium. The device does not respond to an atrial sensed event. The device provides ventricular pacing at the programmed Lower Rate.

4.3.1.3 ODO mode

In the ODO mode, the device mechanically senses in the atrium and electrically senses in the ventricle, but no pacing occurs. The ODO mode is intended only for those situations when bradycardia pacing is not necessary. Ventricular and atrial sensing continue to operate as programmed when pacing is programmed to the ODO mode.

Caution: Use the ODO mode only in clinical situations where bradycardia pacing is not necessary or is detrimental to the patient.

4.3.1.4 Device Off mode

In the Device Off mode, the device does not pace or sense the heart. The Device Off mode is intended only for those situations where the clinician wants to turn off bradycardia pacing and all sensing from the device.

4.3.2 Programming considerations for AV synchronous pacing

Note: ECG signals are required to assess AV synchrony.

Inadequate AV synchrony – Program the device to the VVI mode or the VVIR mode in a patient who cannot achieve adequate AV synchrony.

4.3.2.1 Parameters to optimize AV synchrony

Consider the following parameters when programming for AV synchrony for the Medtronic Micra AV2 device.

Sensed AV – This parameter sets the interval between an atrial mechanical sense and when the device delivers a ventricular pace. Due to the approximately 100 ms physiologic electro-mechanical delay, the mechanically sensed atrial event occurs later than in devices that electrically sense. Thus, the offered programmable Sensed AV intervals are shorter than in electrically based sensing devices.

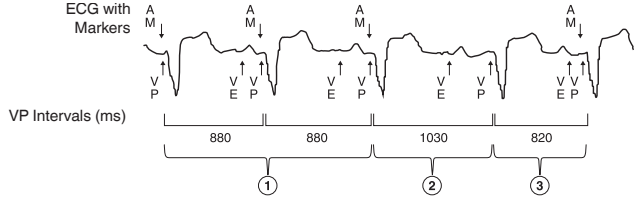
Note: A long sensed AV can reduce the ability to track the atrial contraction at higher rates.

Upper tracking rate – The device cannot pace faster than the upper tracking rate. If an atrial event is sensed and the Sensed AV interval expires before the upper tracking rate interval expires, the device will not pace until the upper tracking rate interval expires. Due to the approximately 100 ms physiologic electro-mechanical delay, atrial blanking (PVAB) must be longer than in electrically based sensing devices. Thus, the offered programmable Upper Tracking Rate values are lower than in electrically based sensing devices.

4.3.2.2 Features for optimizing AV synchrony

Rate Smoothing – This feature is designed to improve AV synchrony during intermittent A4 undersensing. When Rate Smoothing is programmed to On, after ventricular paced events, the device sets the Rate Smoothing pacing interval based on the recent pacing history plus an offset. This Rate Smoothing interval is bounded by the programmed Lower Rate. If no atrial contraction is sensed and the Rate Smoothing interval times out, the device will pace at this Rate Smoothing rate. Setting the Rate Smoothing interval based on the pacing history allows the device to predict and pace close to where the next atrial event is likely to occur, even if the atrial event is undersensed. Adding the Rate Smoothing offset to the Rate Smoothing pacing interval allows tracking of the atrial rate in the presence of some sinus rate variation. The Rate Smoothing offset can be programmed via the Smoothing Delta. After ventricular sensed events, the Rate Smoothing interval is based off of the previous ventricular to ventricular event interval plus an offset and is bounded to be no faster than 800 ms and no slower than the programmed Lower Rate. This assists in keeping a stable ventricular rate post PVCs. See *Figure 7* for an example of Rate Smoothing.

Figure 7. Rate Smoothing



1 Appropriate atrial sensing with AV synchronous pacing

2 Atrial undersense. Ventricular pace occurs at the Rate Smoothing interval, instead of Lower Rate (1200 ms)

3 Recovery of appropriate atrial sensing with AV synchronous pacing

To access this parameter, from the menu select PARAMETERS > Atrial Parameters… > Rate Smoothing….

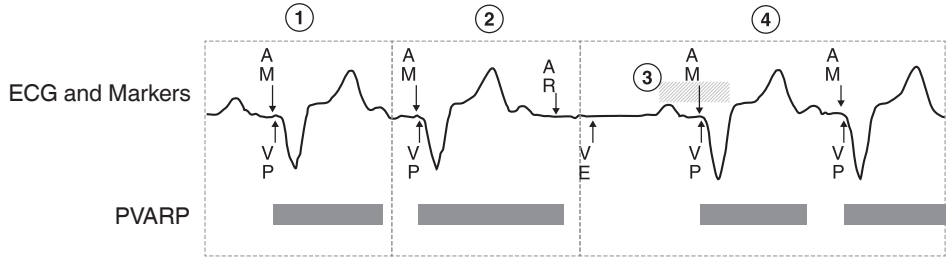
Note: For patients with more sinus rate variation, the Smoothing Delta may need to be programmed longer. For patients with higher sinus rates, the Smoothing Delta may need to be programmed shorter. If the sinus rate variation is more than the longest programmable Smoothing Delta, Rate Smoothing may need to be programmed to Off.

Operation of Tracking Check – The Tracking Check feature is available in the programmed VDD mode and functions when the device is operating in the VDD mode. Atrial oversensing of the A3 signal or mechanical noise can cause pacing above the patient's sinus rate. Tracking Check identifies a potential oversensing-induced tachycardia when the median ventricular rate is at or above the Tracking Check rate and at least half of the most recent

cycles contained AM-VP events. Tracking Check then extends PVARP, which causes the next atrial mechanical sense to fall within the refractory period. Tracking Check estimates the expected location of the next AM event if the device had been tracking the patient's sinus rate. If the next AM event falls within that window, the appropriate sinus tracking is confirmed, and the device returns to normal VDD operation for approximately 1.5 min. If the next AM event falls outside of that window, then oversensing-induced tachycardia is confirmed, and Tracking Check maintains the extended PVARP for approximately 40 s.

To access this parameter, from the menu select PARAMETERS > Atrial Parameters… > Tracking Check.

Figure 8. Tracking Check rhythm



1 AM-VP rhythm at or above Tracking Check Rate. PVARP operating at programmed PVARP value.

2 After the median ventricular rate reaches Tracking Check Rate, Tracking Check extends PVARP so that the next atrial mechanical sense falls in the refractory period.

3 Tracking Check estimates the location of the next AM event if the device had been tracking the patient's sinus rate.

4 The next AM falls in the expected range, appropriate tracking is confirmed, and PVARP is returned to its programmed PVARP value.

Note: If the Tracking Check Rate is programmed at or below the patient's sinus rate, the Tracking Check feature may impact AV synchrony. If the patient's sinus rate is higher than or equal to the Tracking Check Rate, increase the Tracking Check Rate or program Tracking Check to Off.

4.3.3 Setting up or adjusting AV synchrony parameters

Atrial Sensing Setup and the Manual Atrial Mechanical Test can be used to set up atrial sensing parameters. The Manual Atrial Mechanical Test can also be used to observe and adjust atrial sensing parameters after setup.

4.3.3.1 Atrial sensing setup

Atrial sensing setup can be used after implant is complete to set up the atrial sensing parameters, or it can be run at a later follow-up session to reset the atrial sensing parameters. When programmed to On/Restart, Atrial Sensing Setup enters the Scheduled state: VDI mode with pacing at the programmed Lower Rate. After telemetry has been removed, Atrial Sensing Setup enters the In Progress state, and the Lower Rate becomes 50 bpm. During the In Progress state, the device collects atrial sensing data and then makes final adjustments to the atrial sensing parameters in both the VDI and the VDD operating pacing modes. The data collection and adjustment of parameters takes about 30 min from the removal of telemetry. If you program permanent or temporary parameters, the patient becomes active, or the patient has a high or variable ventricular rhythm during atrial sensing setup, the device discontinues the attempt and returns to the Scheduled state. Atrial sensing setup will later attempt to return to the In Progress state. Atrial sensing setup will try for approximately 4 hours to successfully complete. After approximately 4 hours, atrial sensing setup completes with a status of unsuccessful.

Atrial sensing setup can be stopped at any time by programming it to “Off/Complete”. This will return the device to its permanently programmed parameters.

When atrial sensing setup completes successfully, it automatically programs the A. Sensing Vector, the A3 Window End parameters, A3 Threshold, and A4 Threshold to patient-specific settings. If atrial sensing setup does not complete successfully, the atrial sensing parameters are returned to their permanent values.

Histogram data collection will restart after completion of the atrial sensing setup, unless telemetry is already established when the atrial sensing setup completes.

Regardless of how the atrial sensing setup completes, assess AV synchrony by reviewing current patient rhythm, atrial sensing parameters, and diagnostic data. Resolve any interlocks. Additional parameter changes may be required to establish AV synchronous pacing.

For additional information on the steps required to run atrial sensing setup, see the implantable device app help.

Note: Because the device operates in the VDI mode and changes atrial sensing parameters during the setup process, loss of atrial sensing and loss of AV synchrony are expected during atrial sensing setup.

Note: If telemetry is already established when the atrial sensing setup completes, you will need to re-interrogate the device to view the new parameters and any generated Observations.

Note: Atrial mechanical sensing can be affected by the presence of the delivery system tether; for this reason, begin atrial sensing setup after implant is complete.

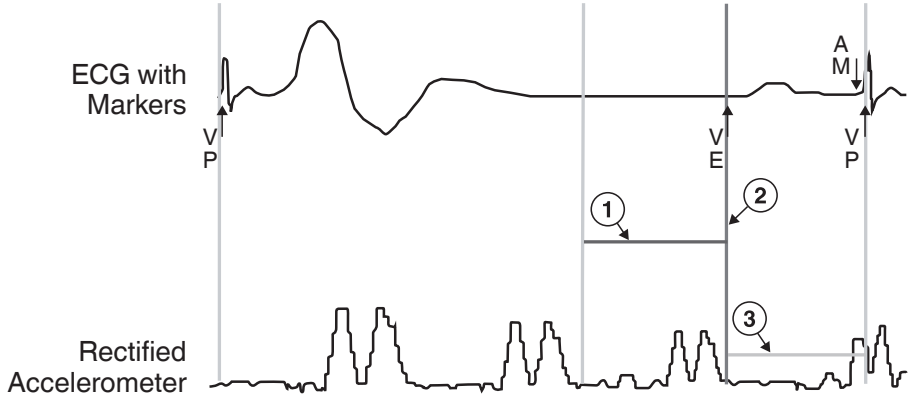
4.3.3.2 Manual Atrial Mechanical Test

The Manual Atrial Mechanical Test (MAMT) is a press and hold test that helps you adjust the atrial sensing parameters. To access this test, from the menu tap TESTS > MANUAL ATRIAL MECHANICAL. The MAMT collects ECG, accelerometer waveform, and markers from the live waveform. The signals collected from the live waveform are then displayed as separate cardiac cycle images. You can arrow through the images to select the cardiac cycle image that is ideal for observing and adjusting atrial sensing parameters. An ideal cardiac cycle image has the P-wave in diastole, where the A3 signal and the A4 signal are clearly identifiable. The A3 Window End, the A4 Threshold, and the A3 Threshold values are superimposed on top of the rectified accelerometer signal displayed on the cardiac cycle image. The MAMT allows you to adjust these values, which adjusts the superimposed values. The new values can be superimposed on other cardiac cycle images by arrowing through the images to confirm that the values are appropriate. Once you have adjusted the parameters, you can repeat the press and hold test to temporarily test the new values. If the new values are effective, you can program them from the MANUAL ATRIAL MECHANICAL TEST > ADJUST PERMANENT window. If the values are not effective, you can make further adjustments.

The MAMT feature disables all advanced sensing and pacing features during the test operation, including Auto A4 Threshold, AV Conduction Mode Switch, and Rate Smoothing.

If the automatic atrial sensing algorithms are On, the device will continue to adjust the permanent A3 Threshold, A4 Threshold, and A3 Window End programmed from the MAMT screen. The Min Auto A4 Threshold, the Max Auto A4 Threshold, the Min Auto A3 Window End, and the Max Auto A3 Window End may need adjustment based on the MAMT results and can be programmed from the MANUAL ATRIAL MECHANICAL TEST > ADJUST PERMANENT window.(see *Figure 9*).

Figure 9. Manual Atrial Mechanical Test



1 The MAMT displays the A3 Threshold value in relation to the rectified accelerometer waveform. When the A3 Threshold value is changed in the MAMT, the A3 Threshold line on the display moves to the new value.

2 The MAMT displays the A3 Window End value in relation to the rectified accelerometer waveform. When the A3 Window End value is changed in the MAMT, the A3 Window End line on the display moves to the new value.

3 The MAMT displays the A4 Threshold value in relation to the rectified accelerometer waveform. When the A4 Threshold value is changed in the MAMT, the A4 Threshold line on the display moves to the new value.

Note: Consider running the test in the VDI mode if you are unable to distinguish A3 and A4 signals. For chronic AV block patients, this action disassociates the P and R waves.

Note: When programming from the MANUAL ATRIAL MECHANICAL TEST > ADJUST PERMANENT window is enabled, interlocks are applied. Resolving these interlocks may require programming from the PARAMETERS screen.

Note: The MANUAL ATRIAL MECHANICAL TEST > ADJUST PERMANENT window displays key atrial sensing parameters. Programming of additional atrial sensing or AV synchronous pacing parameters may be required from the Parameters screen to optimize AV synchrony.

4.3.4 Mode-switching features

The Micra AV2 device includes 2 mode-switching features to further optimize pacing therapy.

4.3.4.1 AV Conduction Mode Switch

The AV Conduction Mode Switch feature is offered in the programmed VDD mode and is designed to facilitate intrinsic AV conduction and to maximize device longevity. This feature aims to detect intact AV Conduction by periodically dropping into VVI mode at the programmed AV Conduction Mode Switch Lower Rate (the VVI+ mode). If the intrinsic rate is above the programmable AV Conduction Mode Switch Lower Rate (ventricular sensing), the device stays in the VVI+ mode. When the intrinsic rate drops below the AV Conduction Mode Switch Lower Rate (2 of 4 beats are ventricular pacing), the device switches back to the VDD mode. During the VVI+ mode, atrial sensing is turned off, improving device longevity.

After switching to the VDD mode, the device periodically checks for AV conduction by switching to the VVI+ mode. The first conduction check is up to 1 min after switching to the VDD mode. If the device detects AV block shortly after switching to the VVI+ mode, the time between conduction checks doubles (2, 4, 8 … min up to a maximum of 8 hours). If AV block occurs after a prolonged period of AV conduction, the first conduction check is reset to the initial value. To minimize interruption of ventricular rate support, the device only attempts to switch to the VVI+ mode when the Sensor Rate is near the programmed Lower Rate (the patient is at rest).

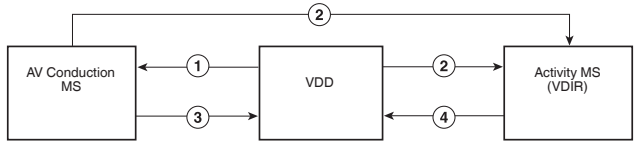
AV Conduction Mode Switch can be programmed to On or Off. To access this parameter, from the menu tap PARAMETERS > Mode Swtich… > AV Conduction Mode Switch.

Note: The AV Conduction Mode Switch changes the operating Lower Rate to the programmable AV Conduction Mode Switch Lower Rate. When AV Conduction Mode Switch is programmed to On, ensure that the programmable AV Conduction Mode Switch Lower Rate is tolerated by the patient.

Note: If the patient has AV block and a ventricular intrinsic rate above the AV Conduction Mode Switch Lower Rate, program AV Conduction Mode Switch Lower Rate to value higher than the patient's ventricular intrinsic rate.

See *Figure 10* for a flow chart of mode-switching states.

Figure 10. Mode Switching



1 Conduction Check + Low Sensor Rate (patient at rest)
2 Low Ventricular Rate + High Activity (needs rate support)
3 Ventricular Pacing (AV Block)
4 Sensor Rate < ADL Rate (activity ceased)

Note: When the device is in the VVI+ mode, atrial mechanical sense (AM) markers and ventricular end (VE) markers do not appear because they are not applicable to VVI therapy.

Note: Transition to the VVI+ mode is affected by the programmed Rate Response settings.

To understand how AV Conduction Mode Switch interacts with Activity Mode Switch, refer to *Section 4.3.4.2*.

4.3.4.2 Activity Mode Switch

The Activity Mode Switch feature is offered in programmed VDD mode and is designed to provide appropriate rate support during patient activity. Patient activity can result in atrial oversensing, which can cause the ventricular pacing rate to be lower than the optimal rate for the activity. An example of an activity that can cause atrial oversensing is vigorous walking. During vigorous walking, atrial oversensing of footsteps can occur, causing the VDD pacing rate to be lower than the sinus rate and below the optimal rate support needed for this activity. The Activity Mode Switch feature monitors for scenarios like this one by monitoring the device's target pacing rate for the given activity input, as determined by Rate Response.

When both of the following conditions occur, the device switches to the VDIR mode and begins providing therapy at the Sensor Rate indicated by Rate Response:

1. The target pacing rate is greater than or equal to the programmed ADL Rate, signifying that patient activity is occurring.
2. The target pacing rate is significantly higher than the current ventricular rate, signifying a loss of appropriate rate support.

This mode switch can also occur when the operating mode is VVI+ due to AV Conduction Mode Switch. Patients who have exercise-induced 2:1 block or chronotropic incompetence may remain in VVI+ during exercise due to having a ventricular rate greater than the AV Conduction Mode Switch Lower Rate. However, their ventricular rate may not be appropriate for their activity. The Activity Mode Switch feature provides appropriate pacing support for these patients.

When the Sensor Rate returns to a rate below the programmed ADL Rate (indicating that patient activity has ceased), the device switches to the VDD mode. The device does not immediately return to the VVI+ mode due to patients potentially having idioventricular rates greater than the AV Conduction Mode Switch Lower Rate immediately after exercise. The next VVI+ mode transition will occur based on the VVI+ feature outlined in this section.

Activity Mode Switch can be programmed to On or Off. To access this parameter, from the menu tap PARAMETERS > Mode Switch… > Activity Mode Switch.

See *Figure 10* for a flow chart of mode switching states.

Note: Transitions into and out of VDIR mode, as well as therapy delivered in the VDIR mode, are affected by the programmed Rate Response settings.

4.3.5 Programming AV synchronous pacing

Table 4. How to navigate to AV synchronous pacing parameters

Parameters	Path
Rate Smoothing	From the menu tap PARAMETERS > Atrial Parameters…
Tracking Check	From the menu tap PARAMETERS > Atrial Parameters…
Activity Mode Switch AV Conduction Mode Switch	From the menu tap PARAMETERS > Mode Switch…

4.3.6 Evaluation of AV synchronous pacing therapies

The following can help to assess the performance of AV synchronous pacing:

- Live Rhythm Monitor
- Percentage of Time (% of Time)
- Mode Switch Percentage (Mode Switch %)
- Rate histograms

- A4 Amplitude Trend
- Manual Atrial Mechanical Test (MAMT)

Live Rhythm Monitor – This requires a surface ECG. The Live Rhythm Monitor can be used to determine if the patient's current rhythm is AV synchronous.

% of Time – % of Time values for AM-VS (atrial mechanical sense followed by ventricular sense), VS only (ventricular sensing), AM-VP (atrial mechanical sense followed by ventricular pace), and VP only (ventricular pacing) are available on the Quick Look screen or the Rate Histogram screen. This data indicates the percentage of total time spent in each event sequence over the last collection period.

Note: VS only or VP only indicates the absence of atrial mechanical sensing. This could be due to atrial undersensing or the device operating in a non-atrial sensing mode (for example, VVI+).

Note: AM-VS or AM-VP indicates the presence of atrial sensing. This could be due to appropriate atrial sensing or atrial oversensing.

Mode Switch % – The Mode Switch Percentage of Time (Mode Switch %) gives the % of Time spent in the AV Conduction Mode Switch (VVI+) mode and the Activity Mode Switch (VDIR) mode during the last reporting period. During the AV Conduction Mode Switch, atrial sensing is disabled, so only VS only and VP only events will occur. During Activity Mode Switch, ventricular pacing may occur, with or without atrial sensing (VP only or AM-VP), up to the programmed Sensor Rate, which may be above the Upper Tracking Rate.

Rate histograms – The atrial ventricular rate histogram shows the rate distribution of ventricular events, both ventricular sense (VS) and ventricular pace (VP), denoting which ventricular events were preceded by atrial mechanical sensing events (AM-VS and AM-VP).

A4 Amplitude Trend – When operating in the VDD mode, the device periodically collects A4 amplitude measurements over the course of the day. The A4 Amplitude is measured as the maximum acceleration in the A4 window. This measurement is collected regardless of whether an atrial sense occurred in that cycle. At the end of the day at midnight (00:00), the device stores the most common measured A4 amplitude of the day in the A4 Amplitude Trend. If the device has not collected enough measurements for the day, no measurement is recorded. The A4 Amplitude Trend graph shows a gap for that day. This gap may happen if the device does not spend enough time per day operating in the VDD mode.

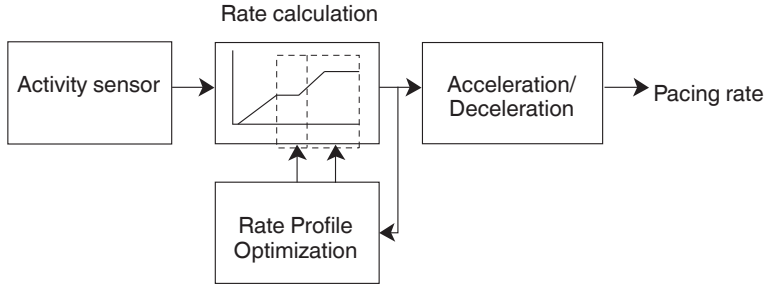
Manual Atrial Mechanical Test (MAMT) – The MAMT is a press and hold test that helps you observe and adjust the atrial sensing parameters. See *Section 4.3.3.2, Manual Atrial Mechanical Test , page 39* for more details.

4.4 Rate-responsive pacing

Rate-responsive pacing adapts the pacing rate to changes in patients' physical activity. This device uses an activity sensor to measure the patient's movement and to determine the appropriate pacing rate. It provides dual-slope rate response that may be either automatic or manual.

4.4.1 Operation of Rate Response

Figure 11. Overview of Rate Response



The Rate Response feature functions when the device is permanently programmed to the VVIR mode or the VDD mode. The Rate Response system includes an activity sensor to measure patient movement, rate calculation to convert the patient's level of physical activity to a pacing rate, Rate Profile Optimization to automatically adjust rate response settings over time, and acceleration and deceleration to smooth the pacing rate. This pacing rate is also described as the sensor rate. The sensor rate is only applied as the pacing rate when the device is operating in the VVIR pacing mode or the VDIR pacing mode.

4.4.1.1 Activity sensing

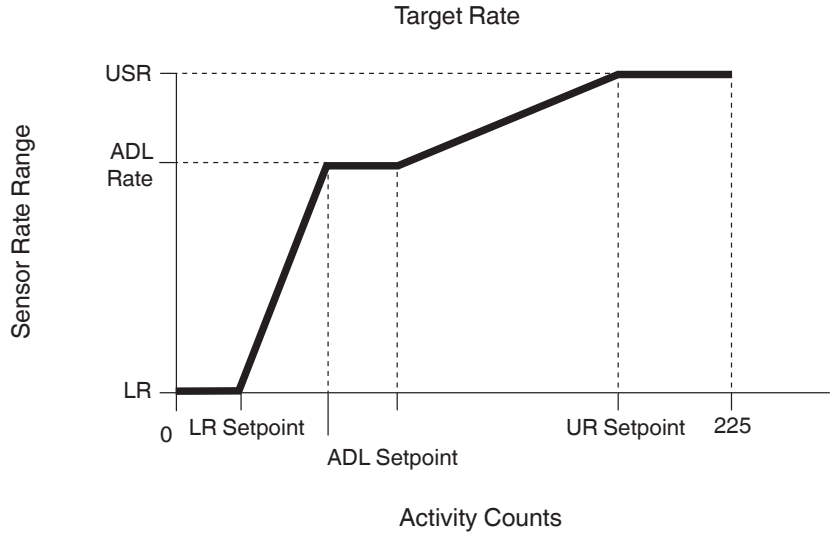
The activity sensor is an accelerometer in the device that detects the patient's body movements. The device provides appropriate rate response based on the detected level of the patient's activity (activity counts) and the Activities of Daily Living Rate (ADL Rate) transfer function. The ADL Rate transfer function uses the activity counts to obtain a target pacing rate during typical daily activities, such as walking or daily chores, and also during exertion, such as exercise and other vigorous activities, as illustrated in *Figure 12*. The activity counts used to calculate the sensor rate are based on the frequency and amplitude of the accelerometer signal.

The programmable parameters Lower Rate, ADL Rate, and Upper Sensor Rate control the appropriate rate response in both the ADL Response range and the Exertion Response range. The device provides for independent control of rate response in both the ADL rate range and exertion rate range.

4.4.1.2 Rate calculation

The rate curve shows how the device calculates the pacing rate as the patient's activity level changes.

Figure 12. Rate curve



Programmable rates – The Lower Rate is the slowest rate at which pacing occurs in the absence of a sinus rate or physical activity. The ADL Rate is the approximate pacing rate that the patient's heart is expected to reach during moderate activity and provides a plateau which helps maintain a stable pacing rate during changes in moderate activity. The Upper Sensor Rate is the upper limit for the pacing rate during vigorous exercise.

Rate Response setpoints – The setpoints define the 2 slopes characteristic of dual-slope Rate Response. The LR Setpoint determines the activity counts required to pace at a rate higher than the lower rate. The ADL Setpoint determines the activity counts that cause the pacing rate to reach the ADL Rate. The UR Setpoint determines the activity counts that cause the pacing rate to reach the Upper Sensor Rate. A lower setpoint means fewer activity counts are required to reach upper rates.

Automatic Rate Response – With automatic Rate Response, Rate Profile Optimization continues to adjust the rate curve by varying the setpoints. The slopes in the rate curve are calculated based on the programmed values for the Rate Response parameters and the highest ADL activity count value that the device obtains for the ADL Rate range.

The rate curve adjustment is based on how the ADL Response and Exertion Response parameters are programmed. The LR Setpoint is determined based on the number of activity counts caused by cardiac motion. The transition from the Lower Rate to the ADL Rate sets the first slope. The ADL Response controls the first slope, determining how aggressively the pacing rate increases from the Lower Rate to the ADL Rate. The transition from the ADL Rate to the Upper Sensor Rate sets the second slope. The Exertion Response controls the second slope, determining how aggressively the pacing rate approaches the Upper Sensor Rate.

Whenever the programmed values for parameters that control the rate curve are changed, Rate Profile Optimization recalculates the slopes that are controlled by the changed parameter values.

Manual Rate Response – With manual Rate Response, the rate curve is established during a patient session when the rates and setpoints are programmed. If Rate Profile Optimization is programmed to Off, the rate curve remains constant until this feature is programmed to On.

4.4.1.3 Rate Profile Optimization

Rate Profile Optimization automatically adjusts the patient's rate response between office follow-up visits. The goal of Rate Profile Optimization is to ensure that the rate response remains appropriate for the full range of patient activities. Each day, the device collects and stores daily and long-term averages of the percentage of time that the patient sensor indicated rate is at different pacing rates. The device then uses the ADL Response and Exertion Response parameters to define the percentage of time that the pacing rate stays in the ADL rate range and exertion rate range respectively. Based on daily comparisons, the device adjusts the LR Setpoint, ADL Setpoint, and the UR Setpoint, as necessary.

By programming new settings for rates or Rate Profile Optimization, you are affecting the comparisons. Immediate changes occur. These changes project how rate response should change in the future based on stored sensor rate information and the selected Rate Profile Optimization settings. The device continues to adjust the rate response over time.

The device adapts Rate Response more rapidly for the first 10 days after Rate Profile Optimization is first activated post-implant or after certain Rate Response parameters are manually reprogrammed (Lower Rate, ADL Rate, Upper Sensor Rate, ADL Response, or Exertion Response). The intent is to quickly match Rate Response to the operation prescribed by the parameter changes.

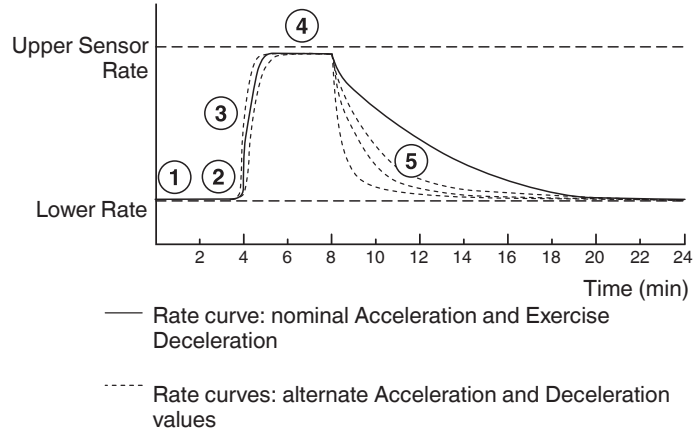
Note: If you manually program the setpoint values when Rate Profile Optimization is programmed to On, this feature is likely to change the setpoint values by the next patient follow-up session, as part of the automatic adjustment of these values.

4.4.1.4 Activity Acceleration and Activity Deceleration

The Activity Acceleration parameter and the Activity Deceleration parameter are used to smooth the pacing rate. Activity Acceleration controls how rapidly the pacing rate increases. Activity Deceleration controls how rapidly the pacing rate decreases and has both fixed values and the Exercise option. The Exercise setting adjusts the deceleration dynamically based on the intensity and duration of exercise, and it can extend the deceleration up to 20 min.

As shown in *Figure 13*, changing the values of the Activity Acceleration and the Activity Deceleration parameters affects the pacing rate during and after exertion.

Figure 13. Activity Acceleration and Deceleration curves for rate response



1 Pacing occurs with the patient at rest.
2 Activity increases and Activity Acceleration begins.
3 Activity Acceleration continues toward a higher pacing rate.
4 Pacing occurs at a higher rate during exertion.
5 Exertion ends and the pacing rate decelerates.

4.4.1.5 Rate Response parameters screen

The parameters screen for Rate Response shows the rate curve corresponding to the interrogated parameter values. You can program the Rate Response setpoints manually from the Exercise test screen. For more information about the Exercise Test, see the implantable device app help.

Warning: Do not program the device to the VVIR mode until the device implant procedure is completed, as Rate Response starts operating when the device is programmed to this mode.

4.4.2 Programming considerations for Rate Response

Programming the Activity Vector – The implant location and orientation of the Micra AV2 device can sometimes result in the sensing of cardiac motion as casual patient activity. Before the patient is discharged after implant, it is recommended to compare the recorded level of activity at rest versus during a casual hall walk to make sure the nominal Activity Vector is appropriate. If there is insufficient difference in activity counts between resting and walking, programming to one of the other two orthogonal Activity Vectors may perform better for the patient. The A. Sensing Vector is independent of the Activity Vector used for rate-responsive pacing. For more information about choosing the Activity Vector (Exercise test), see *Section 4.4.3.1*.

Adjusting Rate Profile Optimization – Before programming other Rate Response parameters, first verify that the settings for Lower Rate, ADL Rate, and Upper Sensor Rate are appropriate for the patient.

It may be necessary to reprogram the ADL Response and Exertion Response parameters if reprogramming the rates does not have the desired effect on Rate Profile Optimization. By reprogramming the ADL Response and Exertion Response parameters, you can prescribe a rate profile that matches the patient's lifestyle or activity levels in each rate range.

Adjust the ADL Response to prescribe how quickly the patient reaches the ADL Rate and the Exertion Response to prescribe how quickly the patient reaches the Upper Sensor Rate. In both cases, a lower value decreases the rate responsiveness and a higher value increases the rate responsiveness.

Note: If increasing the Exertion Response setting does not make Rate Response aggressive enough, increase the ADL Response setting.

Adjusting the Rate Response setpoints manually – To set the Rate Response setpoints manually, you can conduct an Exercise test to examine the activity count. If Rate Profile Optimization is programmed to On, this operation may change the manually programmed values for LR Setpoint, ADL Setpoint, and UR Setpoint to adjust the rate response as appropriate for the patient's range of activities over time.

Note: The Exercise Test can only be performed when the device is programmed to the VVIR mode.

4.4.3 Programming Rate Response

Table 5. How to navigate to Rate Response parameters

Parameters	Path
Lower Rate ADL Rate Upper Sensor Rate Profile Optimization ADL Response Exertion Response	From the menu select PARAMETERS > Rate Response…
Activity Acceleration Activity Deceleration	From the menu select PARAMETERS > Rate Response… > Additional Parameters…
Activity Vector LR Setpoint ADL Setpoint UR Setpoint	From the menu select TESTS > EXERCISE

4.4.3.1 Conducting an Activity Vector test (Exercise test)

The Activity Vector test is performed before the patient is discharged to make sure that the vector by which activity is sensed is not overly sensitive to cardiac motion. Conduct the Exercise test described in the implantable device app help using Vector 1 for 5 min, and have the patient perform the following activities, as the patient is able, once the test has started (programming rate response setpoint values is not a required part of this test):

1. Have the patient lie on the left side for 30 s, then roll onto the back for 30 s, and then onto the right side for 30 s.
2. Have the patient sit upright for 30 s.
3. Have the patient walk at the patient's normal pace in an open area, such as a hallway, for 30 to 60 s.
4. Complete the test by having the patient rest for 30 to 60 s.

After retrieving the exercise test data as described in the implantable device app help, compare the highest activity counts observed while the patient was stationary in each posture to the average counts while the patient was walking. If the difference is less than 8 counts and Rate Profile Optimization is programmed to On (On is the nominal), rate response may perform better for this patient using an alternate activity vector. Compare the counts of the resting period at the end of the test with the counts while the patient was walking. If the counts have not decreased relative to the average counts while walking, rate response may perform better for this patient using an alternate activity vector. It is recommended that you run this test again on Vectors 2 and 3, and permanently program whichever of the 3 activity vectors has the largest differential between resting and walking counts and also shows a decrease in counts after activity has completed.

4.4.4 Evaluation of Rate Response

The Rate Histograms screen and Rate Histograms Report provide information about how Rate Response has performed since the previous patient session. For more information about rate histograms, see *Section 3.2, Rate histograms , page 13*.

4.4.4.1 Rate histograms

To access Rate Histograms, from the menu tap DATA > RATE HISTOGRAMS.

4.5 Pacing with Capture Management

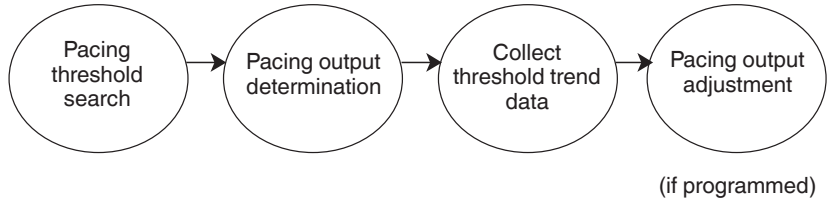
Maintaining adequate safety margins for pacing output energies and optimizing device longevity are critical to patient care. As the patient's condition changes, pacing thresholds may change, requiring pacing outputs to be monitored regularly and modified, if necessary, to capture the myocardium.

The Capture Management feature automatically manages the pacing threshold in the right ventricle. It monitors whether pacing pulses capture the myocardium and, optionally, adjusts their amplitude to changing patient conditions.

4.5.1 Overview of Capture Management

Capture Management is a programmable feature designed to monitor the pacing threshold and, optionally, adjust the pacing output settings to maintain capture. In Capture Management operation, the device prepares for a pacing threshold search, conducts the pacing threshold search, and determines the pacing threshold. Over time, the threshold measurements are collected to create threshold trends. If Capture Management is programmed to Adaptive, the device may automatically adjust the pacing outputs. If Capture Management is programmed to Monitor, no adjustments occur.

Figure 14. Overview of Capture Management



4.5.1.1 Manual adjustment of pacing outputs

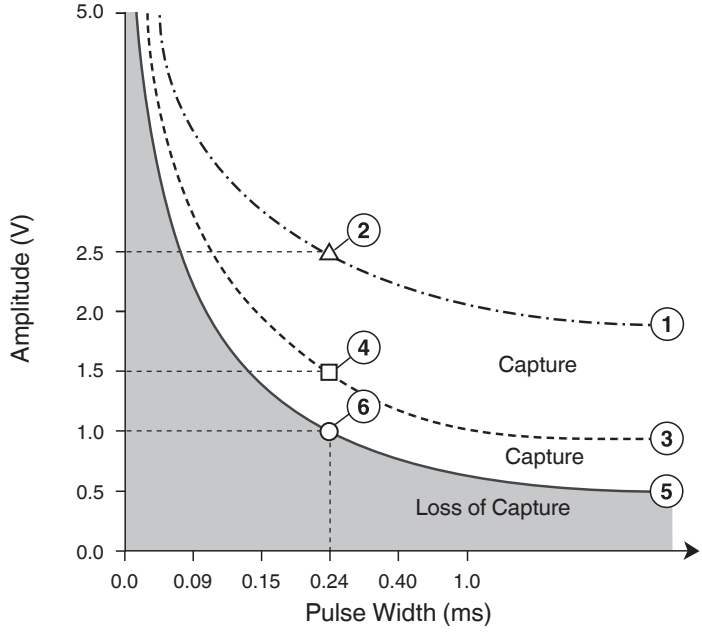
You have the option to program pacing outputs manually instead of using automatic Capture Management. The pacing safety margins should be checked if the programmed setting for Capture Management is Off or Monitor. Threshold data that is collected during pacing threshold searches can make it easier for you to select values for the pacing output parameters. For more information about manual programming, refer to the implantable device app help.

4.5.1.2 Pacing threshold and safety margin

The amplitude and pulse width parameters control the output energy of pacing pulses in the ventricular chamber. The pacing output energy determines whether pacing pulses capture the myocardium. It is necessary for pacing output settings to exceed the pacing threshold by a safety margin. Pacing threshold variations may be caused by exercise, eating, sleeping, drug therapy, or changes in other cardiac conditions.

Both a threshold curve and a safety margin curve are shown in *Figure 15*. The threshold curve consists of combinations of amplitude and pulse width settings. Pacing output settings on or above the curve result in capture, whereas settings below the curve result in loss of capture. The safety margin curve consists of pacing output settings, each of which has a target amplitude that is equal to a threshold amplitude with a safety margin applied.

Figure 15. Pacing threshold and safety margin curve



1 Safety margin curve for acute phase
2 Target amplitude for acute phase
3 Safety margin curve for chronic phase
4 Target amplitude for chronic phase
5 Pacing threshold curve
6 Threshold measurement

4.5.2 Operation of Capture Management

Capture Management is available when the device is programmed to the VDD mode, the VDI mode, the VVIR mode, or the VVI mode. If Capture Management is programmed to the Monitor or Adaptive setting, the device conducts a pacing threshold search to determine the pacing threshold. If Capture Management is programmed to the Adaptive setting, the device uses the pacing threshold to define a target amplitude and adjusts the pacing amplitude toward the target amplitude. The target amplitude is based on the programmed setting for the Amplitude Safety Margin parameter. For the pacing amplitude adjustment, Pulse Width must be programmed to 0.24 or 0.40 ms.

4.5.2.1 Preparing for a pacing threshold search

The device prepares to schedule Capture Management operations every day at midnight or on the first hour after device implant. Capture Management starts with a device check to determine whether any parameter settings would prevent a search. For example, the permanent value programmed for the RV Pulse Width parameter must be 0.24 or 0.40 ms. A pacing threshold search begins at a test amplitude that is 0.13 V lower than the last measured threshold. If the device detects loss of capture during the pacing threshold search or during confirmation surveillance, that beat is dropped and the subsequent support pace occurs sooner.

The device also evaluates whether the patient's current rhythm is stable enough to support a pacing threshold search. If the stability check is successful, the pacing threshold search is initiated. If stability checks are unsuccessful, the device automatically continues to schedule searches once every hour until the end of the day. If the device is unable to complete a stability check successfully during one day, the process is repeated on the following day.

When operating in the VDIR mode, the device performs the pacing threshold search or the confirmation surveillance in the VVIR mode. When operating in the VDI mode, the VVI+ mode, or the VDD mode, the device performs the pacing threshold search or the confirmation surveillance in the VVI mode. After the pacing threshold search or confirmation surveillance is complete, the device returns to the programmed pacing mode.

4.5.2.2 Searching for and determining the pacing threshold

The device conducts a pacing threshold search every day, in the Adaptive or Monitor mode, to determine the patient's pacing amplitude threshold, using the programmed pulse width of 0.24 ms or 0.4 ms. If the pacing threshold search is aborted, the device schedules an hourly search. If the pacing threshold search is successful, the device schedules the next pacing threshold search for the next day. Additionally, if the programmed mode is Adaptive, the device schedules an hourly Threshold Confirmation Test for the rest of the day. Capture Management varies the amplitude of test paces to find the lowest amplitude that consistently captures the ventricular myocardium. The device evaluates capture by detecting the evoked response signal following each test pace.

If the myocardium responds to the test pace, the result is "Capture". If no response is detected, the result is "Loss of capture". The result of a test pace is ignored if the device cannot determine whether the test pace captures the myocardium. In this case, testing may continue with additional test paces at the same test amplitude. If there are too many inconclusive results, the device stops the pacing threshold search and retries it at the next scheduled period. For more information about an incomplete pacing threshold search, see *Section 4.5.2.4*.

A pacing threshold search begins at a test amplitude that is 0.13 V lower than the last measured threshold. If there was no previous search, a new search begins at 1.0 V. The device decreases the test amplitude in steps of 0.13 V until a test amplitude is classified as being below the pacing threshold. The device then increases the test amplitude in steps of 0.13 V until the same test amplitude is classified as being above the pacing threshold 3 times in succession. This test amplitude is the pacing threshold.

In each threshold measurement, the test pace is part of a test sequence (see *Figure 16*.) In each test sequence, 3 support cycles precede the test pace. The support cycles provide pacing at the programmed amplitude and pulse width. The support cycles may include ventricular sensed events or paced events.

Figure 16. Capture Management test sequence

S = Support cycle

T = Test pace

During a pacing threshold search, the device promotes ventricular pacing, which may affect the normal pacing operation.

4.5.2.3 Adjusting the pacing output

If Capture Management is programmed to the Adaptive setting, the device automatically adjusts the RV Amplitude based on the pacing threshold search results. After a successful pacing threshold search, the device calculates the amplitude of the reference pacing threshold by using the highest pacing threshold value from the last 14 days. Then, the device adds the programmed value for Amplitude Safety Margin to the reference pacing threshold to determine the target amplitude. The device calculation for the target amplitude is rounded up to the next programmable amplitude setting. If the target amplitude is higher than 5 V, the device sets it to 5 V. For information about target amplitudes and safety margins, refer to *Section 4.5.1.2*.

Acute phase – The Acute Phase duration corresponds to the period for maturation of the cardiac tissue around the implanted device. The acute phase begins when the device is programmed from the Device Off mode to a pacing mode for the first time after the implant. The nominal duration of the acute phase is 112 days. The RV Acute Phase Remaining parameter keeps track of the number of days left for the acute phase completion. However, you can program RV Acute Phase Remaining to Off. If the device is removed and repositioned, you can program RV Acute Phase Remaining to the Device Repositioned setting to reset the Acute Phase Remaining duration.

Capture Management maintains RV Pulse Width at the value (0.24 or 0.40 ms) programmed by the user. The Amplitude Safety Margin during the acute phase is 1.5 V.

Amplitude adjustments – The device adds the applicable safety margin (1.5 V during the acute phase and the programmed Amplitude Safety Margin after the acute phase) to the reference pacing amplitude measured at the programmed pulse width to determine the new amplitude setting. The device then adjusts the current RV Amplitude toward this target. If the operating amplitude is above the target, the device reduces the amplitude by 0.13 V every day until it reaches the target amplitude. If the operating amplitude is below the target, the device adjusts it to the target immediately.

Upper limit for adjustments – The device adjusts the RV Amplitude to the maximum amplitude value of 5.0 V.

4.5.2.4 Stopping the pacing threshold search in progress

The device stops a pacing threshold search immediately if there are sudden changes in the patient's heart rate or if other device features take precedence over the search.

When a pacing threshold search cannot be completed, the device automatically reschedules the search for every hour. Whenever the pacing threshold search is rescheduled, a device check occurs again, and the process is repeated. The reasons for stopping a pacing threshold search are noted in the Capture Management (Last 15 days detail) diagnostic information. See *Section 4.5.5*.

4.5.3 Programming considerations for Capture Management

Warning: Capture Management does not adjust the pacing amplitude output to be above 5.0 V. For pacing amplitude adjustment, RV Pulse Width must be programmed to 0.24 or 0.40 ms. Capture Management does not adjust the RV Pulse Width value.

Conditions that may influence threshold measurements – In a small percentage of patients, the following condition may influence thresholds measured by Capture Management:

In rare instances, combinations of morphology and rhythm may result in a low threshold measurement. This may occur if the pacing threshold search is unable to differentiate between myocardial contractions caused by the pacing pulse and those caused by physiologic means.

High threshold measurements by Capture Management – In rare instances, the device may not detect the waveform created by the contracting myocardium immediately following a pacing pulse. In such instances, a high threshold measurement may result.

4.5.4 Programming the Capture Management feature

For information about programming the amplitude and pulse width parameters manually, refer to the implantable device app help.

Note: An Adaptive symbol next to the value of the RV Amplitude parameter indicates that the programmed value can be adapted by the device. The symbol does not necessarily indicate that the parameter value has been adapted.

Table 6. How to navigate to Capture Management parameters

Parameters	Path
Capture Management Amplitude Safety Margin	From the menu select PARAMETERS > Capture Management
Acute Phase Remaining	From the menu select PARAMETERS > Acute Phase Parameters… > Acute Phase Remaining

4.5.5 Evaluation of the Capture Management feature

4.5.5.1 Quick Look

To access Quick Look Observations, from the menu select Quick Look. To access capture threshold trends, from menu tap DATA > CAPTURE THRESHOLD TREND.

Threshold trends – The Capture Threshold screen shows trends of minimum and maximum capture thresholds. The threshold data is collected by the automatic daily threshold tests performed by Capture Management.

Quick Look Observations – If there are significant observations about Capture Management, they are shown in the Quick Look Observations window.

4.5.5.2 Capture Threshold trends

The results of the daily pacing threshold measurements are displayed on the Capture Threshold Trend window in the Capture Threshold trend graph. The graph displays up to 15 days of the most recent measurements and up to 80 weekly summary measurements (showing minimum and maximum values for each week).

Note: It is possible for a high threshold observation to occur without a corresponding value shown on the Capture Threshold Trend graph. The observation occurs when a single Capture Management test is aborted due to a high threshold value. When a single Capture Management test is aborted due to a high threshold value, the device attempts a new Capture Management test an hour later. If the new test does not result in a high threshold value, the device stores this result in the Capture Threshold Trend for the day. If 3 consecutive Capture Management tests are aborted due to a high threshold, a threshold value of > 5.0 V is stored in the Capture Threshold Trend. The device does not attempt any more Capture Management tests for that day.

From the TRENDS - Capture Threshold screen, you can select the LAST 15 DAYS DETAIL to view details about the daily capture threshold searches. The details screen shows daily results from the last 15 days of threshold measurements, including dates, times, and threshold measurements. The Notes column describes the results of each pacing threshold search.

4.6 Rate Hysteresis

The patient's intrinsic heart rate is preferable to pacing during extended periods of patient inactivity, such as when the patient is sleeping.

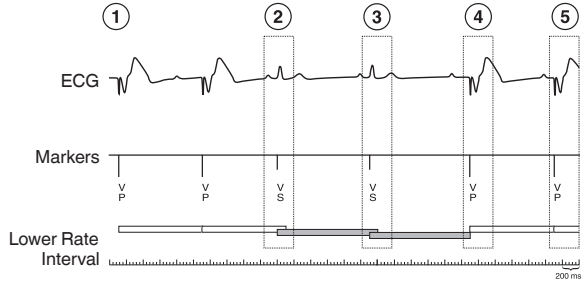
Rate Hysteresis allows intrinsic rhythms to occur below the programmed Lower Rate.

4.6.1 Operation of Rate Hysteresis

Rate Hysteresis is available when the device is operating in the VVI mode.

Rate Hysteresis allows a slower lower rate when the intrinsic rate is below the programmed Lower Rate. After each sensed event, the programmed hysteresis rate is applied. After each paced event, the programmed Lower Rate is applied.

Figure 17. Operation of Rate Hysteresis in VVI mode



1 The device paces in VVI mode at the programmed Lower Rate.
2 After a ventricular sensed event, the device applies the hysteresis interval (shaded bar).
3 A sensed event occurs before the hysteresis interval expires, so hysteresis operation continues.
4 The hysteresis interval expires, and the device paces the ventricle and reapplies the Lower Rate interval.
5 The ventricle is paced at the Lower Rate.

4.6.2 Programming considerations for Rate Hysteresis

Verifying adequate cardiac support – The programmed hysteresis rate determines the slowest heart rate that can occur before pacing starts. Ensure that the selected hysteresis rate is adequate to support the patient's cardiac condition.

Programming the hysteresis rate – To avoid large, sudden changes in heart rate, you would normally select a hysteresis rate that is no more than 30 bpm below the programmed Lower Rate.

Lower Rate – You cannot program the hysteresis rate to a value equal to or above the Lower Rate.

4.6.3 Programming Rate Hysteresis

To access Rate Hysteresis parameters, program the device in the VVI mode. Rate Hysteresis appears on the PARAMETERS screen.

4.6.4 Evaluation of Rate Hysteresis

The Rate Histogram feature indicates when the device has allowed the patient's intrinsic heart rhythm to prevail at rates lower than the Lower Rate. You can view the recorded information about the patient's heart rates on the Rate Histogram screen.

4.6.4.1 Viewing Rate Histograms

To access Rate Histograms, from the menu tap DATA > RATE HISTOGRAMS.

For more information about the rate histogram, see *Section 3.2, Rate histograms , page 13*.

Glossary

2:1 block rate – a conduction ratio in which every second atrial event is refractory. This results in a ventricular pacing rate that is one half as fast as the atrial rate. Also known as second-degree Mobitz Type II AV block.

A1, A2, A3 signals – mechanical vibrations caused by ventricular contraction and relaxation. These signals should not be detected as atrial mechanical sensing.

A4 signal – mechanical vibrations caused by atrial contraction. This signal should be detected as atrial mechanical sensing. The A4 signal follows the P-wave on an ECG.

A7 signal – mechanical vibrations caused when the A3 signal and the A4 signal fuse due to the passive and active filling of the ventricles occurring simultaneously, resulting in a larger amplitude signal.

activities of daily living (ADL) – level of patient movement during basic life tasks such as dressing, eating, or housekeeping.

activities of daily living rate (ADL Rate) – the approximate target rate that the patient's heart rate is expected to reach during activities of daily living.

activities of daily living response (ADL Response) – a programmable parameter that alters the slope of the rate response curve to adjust the targeted rate distribution in the submaximal rate range to match the patient's activity level.

Activity Mode Switch – feature that provides appropriate rate support (operating in the VDIR mode) during patient activity in programmed VDD mode.

activity sensor – accelerometer in the device that detects the patient's body movement.

Atrial mechanical sensing – ability of the device to sense cardiac activity (vibrations) in the atrium, using an accelerometer in the right ventricle, which makes it possible to provide AV synchronous pacing.

Atrial Sensing Setup – feature that collects atrial sensing data and then sets atrial sensing parameters to patient-specific rates based on the collected data.

atrial tracking – dual-chamber pacing operation that paces the ventricle in response to atrial events.

Auto PVAB – Adjusts PVAB (Post Ventricular Atrial Blanking) to the user programmable Min PVAB value when the ventricular rate is faster than the user programmable PVAB Switch Rate. Auto PVAB adjusts PVAB to the user programmable Max PVAB value when the ventricular rate is equal to or slower than the PVAB Switch Rate.

Auto PVARP – Adjusts PVARP (Post-Ventricular Atrial Refractory Period) in response to changes in the patient's heart rate or pacing rate. PVARP is longer at lower tracking rates and shorter at higher rates to maintain 1:1 tracking.

AV Conduction Mode Switch – feature that facilitates intrinsic AV conduction and maximizes device longevity by switching to the VVI mode at the AV Conduction Mode Switch Lower Rate (called VVI+) during periods of intact AV conduction, in programmed VDD mode

AV synchronous pacing – restores the AV (atria to ventricles) contraction pattern by sensing the atrial contraction and then pacing the ventricles appropriately afterward.

AV synchrony – coordinated contraction of the atria and ventricles for most effective cardiac output.

blanking period – time interval during which sensing in a chamber is disabled to avoid oversensing.

capture – depolarization of cardiac tissue by an electrical stimulus delivered by a cardiac device.

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.

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.

EOS (End of Service) – battery status indicator displayed by the implantable device app to indicate that the device deactivated pacing and sensing operations and switched to the Device Off mode.

event – a sensed or paced beat.

evoked response detection – the act of detecting the electrical signal generated by the contracting myocardium immediately following a pacing pulse.

exertion rate range – rates at or near the Upper Sensor Rate that are achieved during vigorous exercise.

Holter telemetry – telemetry feature that transmits EGM and marker annotations continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and device manager.

hysteresis – a pacing operation and programmable parameter that allows a longer escape interval after a sensed event, giving the heart a greater opportunity to beat on its own.

impedance – total opposition that a circuit presents to electrical current flow; the device electrode impedance can be measured to assess the implanted system integrity.

Live Rhythm Monitor – configurable implantable device app window that displays ECG, marker annotations, and telemetered EGM and accelerometer waveform traces. It also displays the patient's heart rate and interval.

Manual Atrial Mechanical Test (MAMT) – press and hold test that helps the clinician observe and adjust atrial sensing parameters.

mode switch – 2 features that switch the device pacing mode from VDD mode to a nontracking mode. AV Conduction Mode Switch operates during periods of intact AV conduction. Activity Mode Switch operates during patient activity.

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.

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

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

PVAB (Post-Ventricular Atrial Blanking) – interval after ventricular events during which atrial events are ignored by bradycardia pacing features or are not sensed by the device.

PVARP (Post Ventricular Atrial Refractory Period) – atrial refractory period following a ventricular event used to prevent inhibition in dual chamber pacing modes.

Quick Look 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.

rate profile – rate histogram of the sensor rates used by Rate Profile optimization to automatically adjust Rate Response settings.

Rate Profile Optimization – feature that monitors the patient's daily sensor rate profile and adjusts the rate response curves over time to achieve a prescribed target.

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

Rate Smoothing – feature designed to improve AV synchrony during intermittent A4 undersensing.

rectified waveform – accelerometer signal with only positive components. It is the signal that the device uses to sense the atrial contraction.

refractory period – time interval during which the device senses events normally but classifies them as refractory and responds to them in a limited way.

Remaining Longevity estimate – an estimate of remaining device longevity that is displayed on the Quick Look screen and Battery and Device Measurements window. This information includes a graphical display for easy reference and the estimated number of months of remaining longevity. In the BATTERY AND DEVICE MEASUREMENTS window, the minimum and maximum number of months of remaining device longevity is also provided.

retrograde conduction – electrical conduction from the ventricles to the atria.

RRT (Recommended Replacement Time) – battery status indicator displayed by the implantable device app to indicate that a new device implant is recommended.

Sensed AV (SAV) interval – programmable delay following an atrial sensed event that schedules a corresponding ventricular pace.

sensed event – atrial mechanical or ventricular electrical activity that exceeds the programmed sensitivity threshold and is identified by the device as a cardiac event.

Sensing Integrity Counter – diagnostic counter that records the number of short ventricular intervals that occur between patient sessions. A large number of short ventricular intervals may indicate a sensing problem.

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.

Tracking Check – feature that identifies a potential oversensing-induced tachycardia.

undersensing – failure of the device to sense intrinsic cardiac activity.

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