Medtronic

# Micra™ VR2 MC2VR01

MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

Reference Manual

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

# Micra™ VR2 MC2VR01

Reference Manual

This manual describes the operation and intended use of the features of the Micra VR2 Model MC2VR01 MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

# Contents

# 1 Introduction

## 1.1 About this manual

This manual describes the operation and intended use of the Medtronic Micra VR2 Model MC2VR01 MR Conditional single chamber implantable transcatheter pacing system with SureScan technology.

Throughout this manual, the word “device” refers to the implanted Micra VR2 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 also contain information about the device:

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

**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.

**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 Patient follow-up guidelines

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 system

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 and in exported reports 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 Rate Histogram screen. Export a Rate Histogram Report. You can use the Rate Histogram screen and report to assess the patient's pacing and sensing history. For more information about Rate Histogram, see *Section 3.2*.

### 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 18*.

## 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 VR2 MC2VR01 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 4.4, Pacing with Capture Management , page 30*.

**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

**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 programming head 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 and Lower Rate parameters
- Percentage of time (% of Time) spent in sensing or pacing since the last patient session

### 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 VVI 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 histogram

Information about heart rates recorded between patient sessions can help you to monitor a patient's condition. Rate Histogram screen show the rate distribution of ventricular sensed and paced events recorded since the last follow-up session.

To access the rate histogram data from the Menu button, tap DATA > RATE HISTOGRAM.

### 3.2.1 Information provided by rate histogram

The Rate Histogram data is based on the ventricular event data stored by the device since the last patient follow-up session. The Rate Histogram data is presented in a histogram for ventricular rate on the Rate Histogram window. Data storage for the Rate Histogram data 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. The percentages are calculated from the daily counts of paced and sensed 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
- R-wave amplitude trend
- 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

### 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 > 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.

**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.

[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 VR2 MC2VR01 Device Manual.

### 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 sensed events. The device attempts to measure the amplitude of 5 normal intrinsic sensed events. After collecting these measurements, the device records their median value as the most recent R-wave amplitude measurement. 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 window, 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 the sensing amplitude may indicate a problem with the sensing electrode.

### 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 4.4*.

The results of the most recent daily pacing threshold measurements are displayed on the TRENDS - Capture Threshold Trend 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 Trend 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) screen 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.

To view the capture threshold trend on the programming screen, tap DATA > CAPTURE THRESHOLD TREND.

### 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.

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.

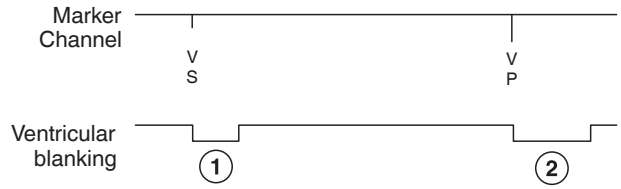
#### 4.1.1.1 Operation of sensing threshold

Ventricular sensing operates at a fixed, programmed ventricular sensitivity.

#### 4.1.1.2 Operation of 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

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.

### 4.1.2 Programming considerations for sensing

**Bradycardia pacing and sensing –** A combination of high pacing pulse width or high amplitude with a low sensing threshold may cause oversensing in the right ventricle. Programming a lower pulse width, lower amplitude, 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. This may result in asynchronous pacing.

**Low 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.

**Sensing threshold adjustment –** Setting the 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 threshold, evaluate for proper sensing.

### 4.1.3 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<br>Blank Post VS | From the menu select PARAMETERS > RV Blanking |

### 4.1.4 Evaluation of sensing

#### 4.1.4.1 Using the Sensing Test to evaluate 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.

#### 4.1.4.2 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.

#### 4.1.4.3 Viewing R-wave amplitude trends

To access R-wave amplitude trends, tap DATA > BATTERY AND DEVICE MEASUREMENTS > 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 sensed events. The device attempts to measure the amplitude of 5 normal intrinsic sensed events. After collecting these measurements, the device records their median value as the most recent R-wave amplitude measurement. 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.

## 4.2 Providing pacing therapies

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

### 4.2.1 Operation of 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 4.4*.

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*.

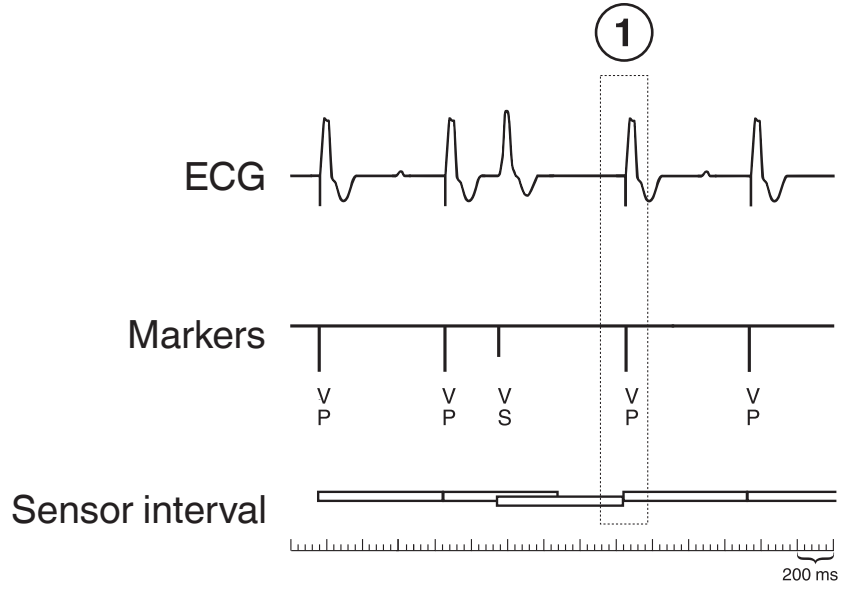
### 4.2.2 Operation of single chamber pacing

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

#### 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 2*).

**Figure 2.** 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 (bradycardia pacing off)

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.

### 4.2.2.4 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 sensing from the device.

### 4.2.3 Programming considerations for 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 pacing therapies

**Table 2.** How to navigate to ventricular pacing parameters

| Parameters | Path |
|---|---|
| Mode<br>Lower Rate<br>Upper Sensor<br>Amplitude<br>Pulse Width | From menu select PARAMETERS |

### 4.2.5 Evaluation of 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.

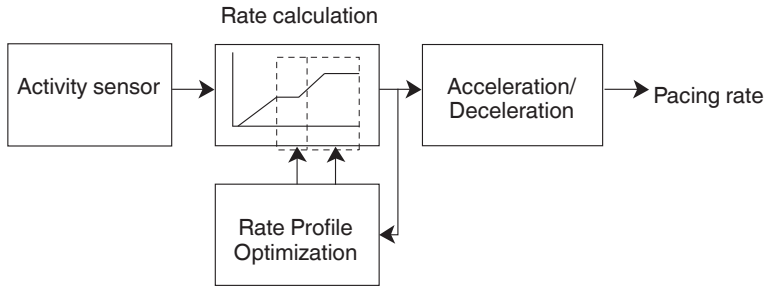
**Percentage of Time (% of Time) –** The % of Time section reports the patient's pacing and sensing as the percentage of the total time during the reporting period.

## 4.3 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.

### 4.3.1 Operation of Rate Response

**Figure 3.** Overview of Rate Response




The Rate Response feature functions when the device is operating in the VVIR 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.

#### 4.3.1.1 Activity sensing

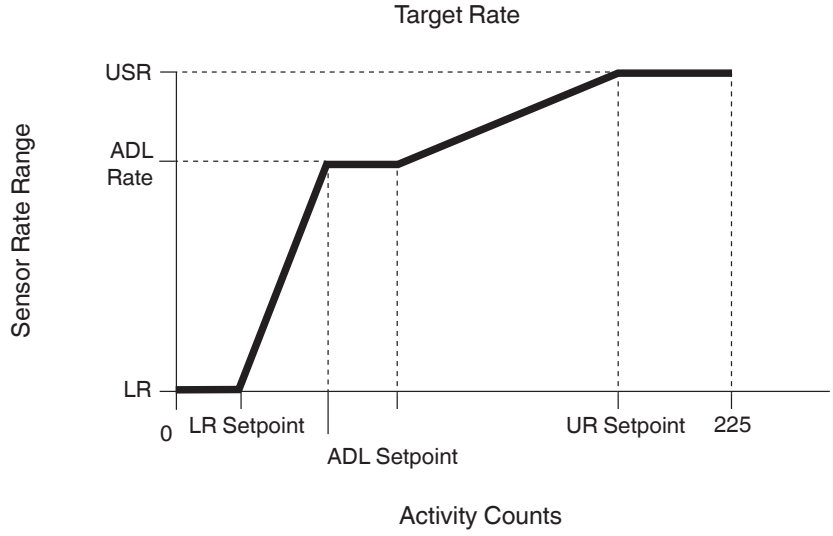
The activity sensor is an accelerometer in the device that detects the patient's body movements. The device provides appropriate rate response based on the detected level of patient's activity (activity counts) and the Activities of Daily Living Rate (ADL Rate) transfer function. The ADL Rate transfer 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 4*. 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.

### 4.3.1.2 Rate calculation

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

**Figure 4.** 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.

#### 4.3.1.3 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.

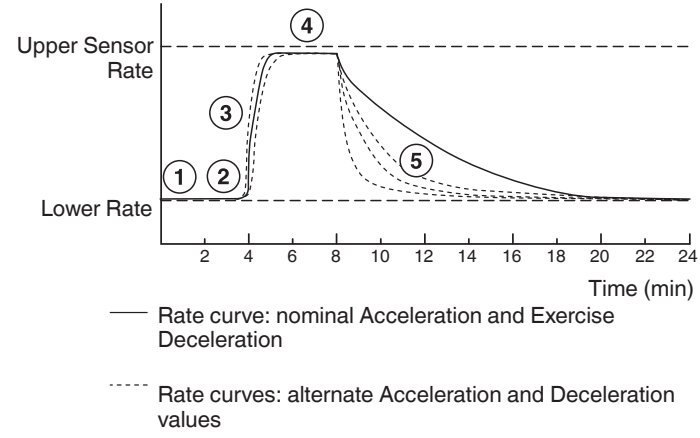
**Note:** If you manually program the setpoint values when Rate Profile Optimization is programmed to On, this feature is likely to change the setpoint values by the next patient follow-up session, as part of the automatic adjustment of these values.

### 4.3.1.4 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 5*, changing the values of the Activity Acceleration and the Activity Deceleration parameters affects the pacing rate during and after exertion.

**Figure 5.** 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.

### 4.3.1.5 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.

### 4.3.2 Programming considerations for Rate Response

**Programming the Activity Vector –** The implant location and orientation of the Micra VR2 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.

**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.

### 4.3.3 Programming Rate Response

**Table 3.** How to navigate to Rate Response parameters

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

#### 4.3.3.1 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.

### 4.3.4 Evaluation of Rate Response

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

#### 4.3.4.1 Rate histogram

To access the Rate Histogram, from the menu tap DATA > RATE HISTOGRAM.

## 4.4 Pacing with Capture Management

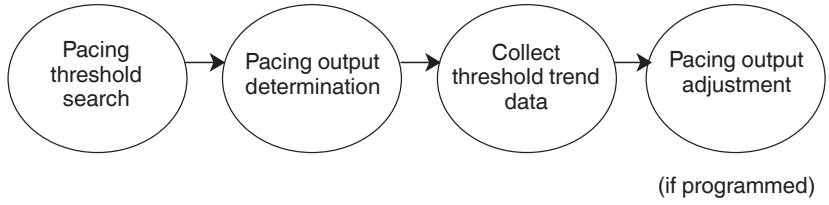
Maintaining adequate safety margins for pacing output energies and optimizing device longevity are critical to patient care. As the patient's condition changes, pacing thresholds may change, requiring pacing outputs to be monitored regularly and modified, if necessary, to capture the myocardium.

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.

### 4.4.1 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 6.** Overview of Capture Management




#### 4.4.1.1 Manual adjustment of pacing outputs

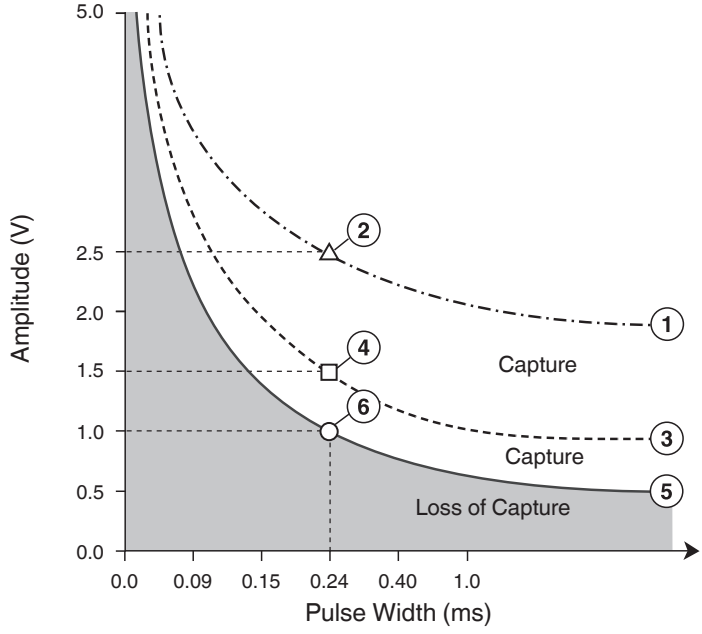
You have the option to program pacing outputs manually instead of using automatic Capture Management. The pacing safety margins should be checked if the programmed setting for Capture Management is Off or Monitor. Threshold data that is collected during pacing threshold searches can make it easier for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

#### 4.4.1.2 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 7*. 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 7.** 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

### 4.4.2 Operation of Capture Management

Capture Management is available when the device is operating in the VVIR or 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 should be programmed to 0.24 or 0.40 ms.

#### 4.4.2.1 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 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.

#### 4.4.2.2 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 0.40 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, 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 4.4.2.4*.

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 8*.) 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 8.** 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.

### 4.4.2.3 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 4.4.1.2*.

**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.

#### 4.4.2.4 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 4.4.5*.

### 4.4.3 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 should 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.

### 4.4.4 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 4.** How to navigate to Capture Management parameters

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

### 4.4.5 Evaluation of the Capture Management feature

#### 4.4.5.1 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.

#### 4.4.5.2 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.

## 4.5 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.

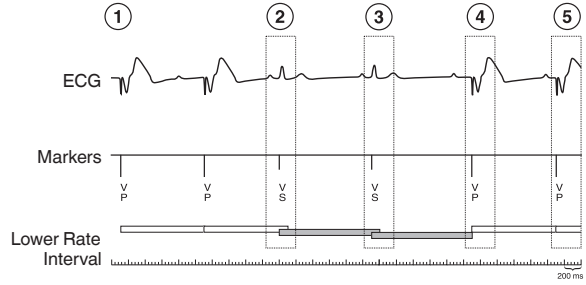
Rate Hysteresis allows intrinsic rhythms to occur below the programmed Lower Rate.

### 4.5.1 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 9.** 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.

### 4.5.2 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.

### 4.5.3 Programming Rate Hysteresis

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

### 4.5.4 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.

#### 4.5.4.1 Viewing Rate Histogram

To access Rate Histogram, from the menu tap DATA > RATE HISTOGRAM.

For more information about the rate histogram, see *Section 3.2*.

# Glossary

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

**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.

**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 programmer.

**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.

**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.

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

**Remaining Longevity estimate** – an estimate of remaining device longevity that is displayed on the Quick Look 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.

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

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

**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.

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

# Index

## T



## U



## V

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