Medtronic

Micra™ MC1VR01

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

DRAFT

Clinician Manual

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

Micra™ MC1VR01

Clinician Manual

A guide to the operation and programming of the Micra Model MC1VR01 MR Conditional single chamber transcatheter pacing system with SureScan™ technology (VVIR)

Contents

1 System overview

1.1 Introduction

1.1.1 About this manual

This manual describes the operation and intended use of the Medtronic Micra Model MC1VR01 MR Conditional single chamber implantable transcatheter pacing system with SureScan technology.

1.1.1.1 Manual conventions

Throughout this manual, the word "device" refers to the Micra device.

The symbol ⬦ in parameter tables indicates the Medtronic nominal value for that parameter.

The programmer screen image examples in this manual were produced using a Medtronic CareLink Model 2090 Programmer. These screen images are provided for reference only and may not match the final software.

The names of on-screen buttons are shown within brackets: [Button Name].

Programming instructions in this manual are often represented by a programming block, which describes the path through the application software to specific screens or parameters. The following conventions are used in programming blocks:

- The "⇒" symbol precedes the screen text you can select to navigate to a new screen.

- The "▷" symbol precedes the name of a parameter you can program for a feature.

- When a navigation step refers to a field on the screen that is labeled with both a row title and a column title, the " | " character is used to divide the separate titles. Parameter values, however, do not use this convention.

- When a particular value for a parameter must be selected to make the remaining parameters or navigation possible, that value appears within <brackets>.

Here is an example of a programming block using these conventions:

```
Select Params icon
    ⇒  Screen text to select…
        ⇒  Screen field Row Title  |  Column Title…
            ▷  Parameter Name  <Required Value>
            ▷  Parameter Name
            ▷  Parameter Name
```

1.1.2 Product literature

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

- Read the product literature provided for information about prescribing, implanting, and using the device, and for conducting a patient follow-up session.

- Thoroughly read the technical manuals provided for the other system components.

- Discuss the device and implant procedure with the patient and any other interested parties, and provide them with any patient information materials packaged with the device.

1.1.3 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.

1.1.4 Customer education

For specific customer education, contact your local Medtronic representative.

1.1.5 Explanation of symbols

The following table contains symbols that apply to the Micra Model MC1VR01 device.

Table 1. Explanation of symbols on package labeling

Symbol	Explanation
	This symbol means that the device fully complies with the Australian Communications and Media Authority (ACMA) and the New Zealand Ministry of Economic Development Radio Spectrum Management standards for radio communications products.
MR	MR Conditional. The SureScan pacing system is safe for use in the MRI environment when used according to the instructions in the Medtronic MRI Technical Manual.
SureScan	Medtronic SureScan symbol

Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
CATHETER	Catheter
	Caution
	Open here
	Do not use if package is damaged
	Do not reuse
STERILE EO	Sterilized using ethylene oxide
	Consult instructions for use
	Date of manufacture
	Manufacturer
EC REP	Authorized representative in the European community
	Use by
REF	Reorder number
	Pace
	Pacemaker (single chamber RV)
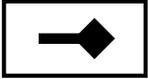
Table 1. Explanation of symbols on package labeling (continued)
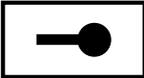
Symbol	Explanation
	Sense
SN	Serial number
+ XX °C / + XXX °F / − XX °C / − XX °F	Temperature limitation
	Adaptive
	Package contents
Medtronic	Transcatheter pacemaker
	Deployable tines
	Catheter delivered
	Transcatheter pacing system
	Implantable device, coated
	Introducer
	Product documentation
	Accessories
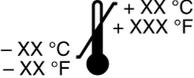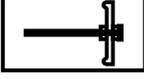
Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Amplitude/pulse width
	Inner diameter
	Outer diameter
	Lower rate
	Sensitivity
	Refractory period
	Pacing polarity (single chamber)
	Sensing polarity (single chamber)
	Steroid eluting
VVIR	VVIR pacing mode

1.1.6 Notice

The Patient Information screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the patient information that end users enter into the Patient Information screen. Medtronic SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

For more information about the Patient Information screen, see Section 4.8, "Viewing and entering patient information", page 57 .

1.2 System description

The Medtronic Micra Model MC1VR01 MR Conditional single chamber implantable transcatheter pacing system with SureScan technology is a programmable cardiac device that monitors and regulates the patient's heart rate by providing rate-responsive bradycardia pacing to the right ventricle.

The device senses the electrical activity of the patient's heart, using the sensing and pacing electrodes enclosed in the titanium capsule of the device. It monitors the heart rhythm for bradycardia and responds to bradycardia by providing pacing therapy based on the pacing parameters programmed. The device provides rate response, controlled through an activity-based sensor. It also provides diagnostic and monitoring information for guidance in the pacing system evaluation and in patient care.

Figure 1. Implanted Micra Model MC1VR01 transcatheter pacing system
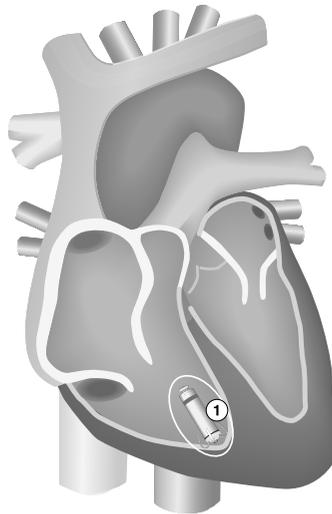
1 The device implant location in the right ventricle

The components of the Micra Model MC1VR01 transcatheter pacing system are shown in the following figure:

Figure 2. System components

Implantable device

Medtronic CareLink Programmer   Micra delivery catheter
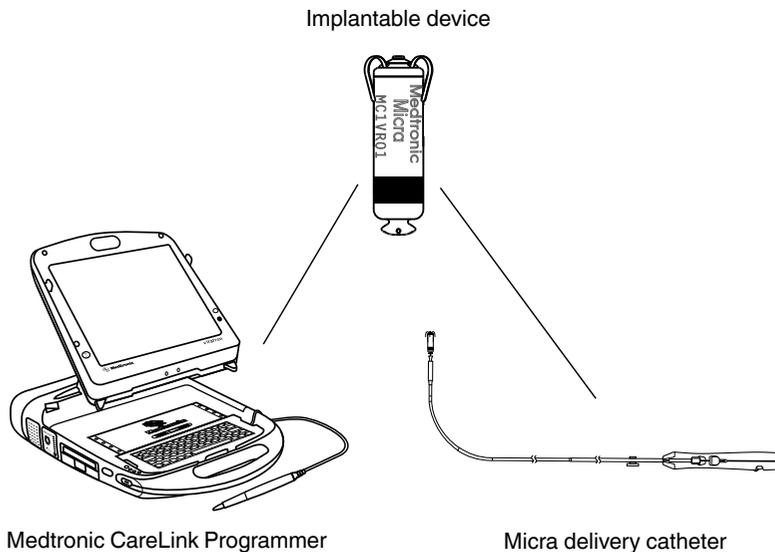
Implantable device – The Micra Model MC1VR01 is a miniaturized, single chamber transcatheter pacing system that provides bipolar sensing and pacing in the right ventricle. The device has an active fixation mechanism consisting of 4 electrically inactive tines designed to anchor it in the cardiac tissue at the implant location in the right ventricle.

MRI SureScan feature – Patients with an implanted Micra Model MC1VR01 pacing system can undergo an MRI scan if the system meets the requirements described in the Medtronic MRI Technical Manual. The MRI SureScan pacing feature allows the patient to be safely scanned while the device continues to provide appropriate pacing.

Labeling for the Micra pacing system includes the MRI SureScan symbol.

TM

SureScan

Before performing an MRI procedure, refer to the Medtronic MRI Technical Manual provided for this product for important information about procedures and MRI-specific contraindications, warnings, and precautions.

Device delivery catheter system – The Micra delivery catheter system consists of the following parts:

- A delivery catheter designed to carry, deliver, and position the device for implant in the right ventricle by accessing this chamber through the femoral vein. The delivery catheter has a steerable, flexible shaft with a rigid distal end that contains a device cup to hold the device and a recapture cone to retrieve it. It is compatible with a 7.8 mm (23 French) introducer sheath that is 56 cm (22 in) long or longer, such as the Medtronic Micra Introducer.

- A handle with controls to navigate the delivery catheter and deploy the device. The handle also provides a tether designed as an aid to test the device fixation and to retrieve and reposition the device for proper fixation during the implant procedure.

Programmer and software – The Medtronic CareLink Model 2090 Programmer and Model SW022 software are used to program the device for implant testing and patient follow-up sessions. The use of a programming head, Medtronic Model 2067 or Model 2067L, is required for communication between the device and the programmer. Programmers from other manufacturers are not compatible with Medtronic devices but will not damage Medtronic devices.

Contents of sterile package – The sterile package contains one implantable transcatheter pacing system, which includes the implantable device and delivery catheter system.

The Micra transcatheter pacing system is sterilized with ethylene oxide gas and packaged in a pouch that contains a sterile aseptic tray. The tray is designed to ease the placement of the pacing system in the sterile field. For the pacing system to be sterile, the pouch must not be damaged or opened. The outer surfaces of the pouch are **nonsterile** and must not be placed in the sterile field.

For instructions to open the sterile package, see Section 5.1.5, "How to open the sterile package", page 79.

1.3 Indications and usage

Micra Model MC1VR01 is indicated for use in patients who have experienced one or more of the following conditions:

- symptomatic paroxysmal or permanent high-grade AV block in the presence of AF

- symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

- symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy

Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.

1.4 Contraindications

Micra Model MC1VR01 is contraindicated for patients who have the following types of medical devices implanted:

- an implanted device that would interfere with the implant of the Micra device in the judgment of the implanting physician

- an implanted inferior vena cava filter

- a mechanical tricuspid valve

- an implanted cardiac device providing active cardiac therapy that may interfere with the sensing performance of the Micra device

The device is contraindicated for patients who have the following conditions:

- femoral venous anatomy unable to accommodate a 7.8 mm (23 French) introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity)

- morbid obesity that prevents the implanted device from obtaining telemetry communication within ≤12.5 cm (4.9 in)

- known intolerance to the materials listed in Section A.1, "Physical characteristics", page 168, or to heparin, or sensitivity to contrast media that cannot be adequately premedicated

Steroid use – Do not use in patients for whom a single dose of 1.0 mg dexamethasone acetate cannot be tolerated.

For the MRI contraindications for patients with a Micra MRI device, refer to the Medtronic MRI Technical Manual.

1.5 Pre-implant consideration

Patient evaluation for the implant of Micra Model MC1VR01 should include that the Micra device is not intended to be removed following the End of Service (EOS) condition.

Patient evaluation for the implant of Micra Model MC1VR01 should include the following consideration about a concomitant implant with a neurostimulator:

Concomitant neurostimulator and cardiac device implants – Some patients have medical conditions that require the implant of both a neurostimulator and a cardiac device (for example, pacemaker, defibrillator, or monitor). In this case, physicians (for example, neurologist, neurosurgeon, cardiologist, and cardiac surgeon) involved with either device should contact Medtronic Technical Services or their Medtronic representative before implanting the patient with the second device. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant procedure. For information about how to contact Medtronic, see the telephone numbers and addresses provided on the back cover of this manual.

Note: The Micra device has not been tested with active coexisting devices.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

MRI conditions for use – Before an MRI scan is performed on a patient implanted with the Micra MRI SureScan device, the cardiology and radiology professionals involved in this procedure must understand the requirements specific to their tasks. For information about MRI-specific warnings and precautions, refer to the Medtronic MRI Technical Manual provided for this device.

Anti-coagulation – Appropriate anticoagulation therapy should be administered to reduce potential thrombosis.

Anticoagulant agents, antiplatelet agents, and contrast media – Precautions should be taken before administering anticoagulant agents, antiplatelet agents, or contrast media in patients with known hypersensitivity to these agents.

Asynchronous VVIR pacing – Asynchronous VVIR pacing with sinus rhythm may not be appropriate when competitive pacing is considered undesirable or causes symptoms of pacemaker syndrome.

Electrical isolation during implant – Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use whenever tachyarrhythmias are possible.

Multiple devices – The use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant. Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices. Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without explantation of the Micra device, which should be turned off.

Patient's age and medical condition – The patient's age and medical condition should be considered by physicians and patients as they select the pacing system, mode of operation, and implant technique best suited to the individual.

Prosthetic tricuspid valve – Use caution when implanting a Micra device in a patient with a prosthetic tricuspid valve to avoid valve damage. During device implant, visualizing the prosthetic valve using the LAO fluoroscopic view can aid in limiting interaction with the valve leaflets.

Antibiotic prophylaxis with dental procedures – Due to the lack of long-term, chronic human experience, consider the use of prophylactic antibiotics prior to dental procedures to reduce the risk of endocarditis.

Temporary pacing – For patients with left bundle branch block: recognition of the inherent risk of complete heart block related to catheter and lead manipulation in the right ventricle is important. Consider insertion of temporary pacing capabilities before a Micra implant.

Steroid use – It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of this highly localized, controlled-release device. For a list of potential adverse effects, refer to the Physicians' Desk Reference.

Rate response – Data from the clinical trial supports rate response functionality. Further confirmation of rate response functionality will be completed through data collection obtained in the Micra Transcatheter Pacing System Post-Approval Study on the Micra device.

Rate-responsive mode – A rate-responsive mode may not be appropriate for patients who cannot tolerate pacing rates above the programmed Lower Rate.

Drug component description – The active ingredient in the device electrode is dexamethasone acetate [9-Fluoro-11β, 17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-acetate]. The structural formula for this steroid is as follows:

Dexamethasone acetate (DXAC) - $C_{24}H_{31}FO_6$

Figure 3. Structure of dexamethasone acetate (DXAC)
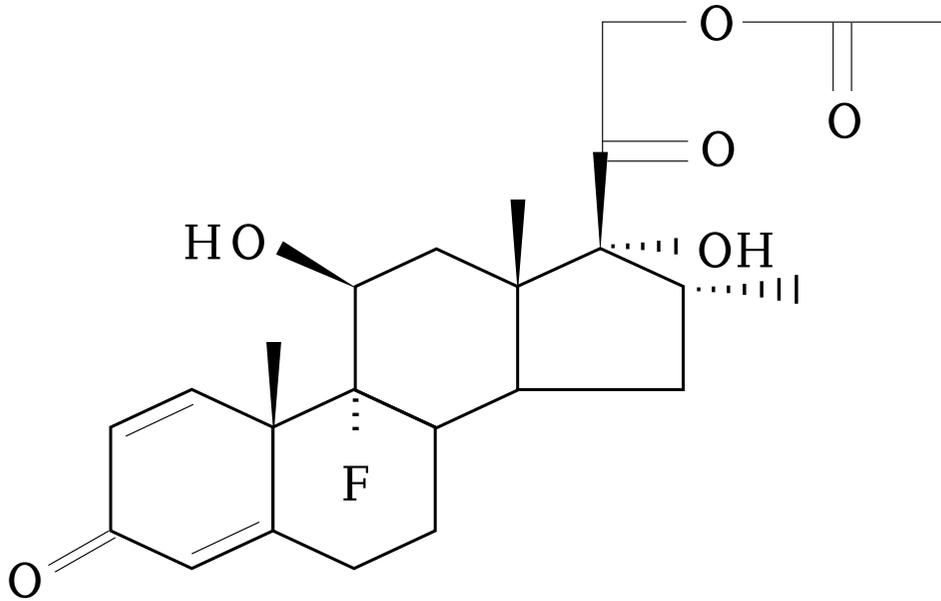
The target dosage of dexamethasone acetate in this device is 272 µg.

Cautions:

- Drug interactions of dexamethasone acetate with this device have not been studied.

- Before implanting this device, consider the total patient exposure to dexamethasone acetate.

2.2 Explant and disposal under care

Consider the following information about the explant and disposal of the device:

End of Service (EOS) – When the EOS condition is met, the clinician has the option of permanently programming the device to Off and leaving it in the heart, or retrieving the device as described in Section 5.4, "Retrieving and repositioning the device after the tether removal", page 99.

Note: Removal of the Micra device may be difficult because of the development of fibrotic tissue. If removal of the device is required, it is recommended that the removal be performed by a clinician who has expertise in the removal of implanted leads.

Please note that removal of the Micra device has not been fully evaluated clinically. As explained in the contraindications section, note the following:

- Currently recommended end of device life care for a Micra device may include the addition of a replacement device with or without the explantation of the Micra device, which should be turned off.

- Use of deactivated Micra devices in situ and an active Micra device, or an active transvenous pacemaker or defibrillator, has not been clinically tested to determine whether EMI or physical interaction is clinically significant.

- Bench testing supports that implantation of an active Micra device, or an active transvenous pacemaker or defibrillator, next to an inactivated Micra device is unlikely to cause EMI or physical interaction. Post-approval studies are planned to characterize risks of co-implanted, deactivated Micra devices.

Return mailer kits – Contact Medtronic for return mailer kits to return explanted devices for analysis and disposal. See the back cover for addresses.

2.3 Explant and disposal postmortem

Postmortem – The Micra device is not intended to be explanted postmortem. If the device is subjected to cremation, no technical difficulties or significant emissions are expected. In some countries, explanting battery-operated implantable devices postmortem is mandatory because of environmental concerns. Check the local regulations about battery-operated implantable devices and environmental disposal laws.

Device malfunction – If the Micra device is removed because of a malfunction, return it to Medtronic for analysis and disposal. See the back cover of this manual for Medtronic phone numbers and mailing addresses.

Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.

Return mailer kits – Contact Medtronic for return mailer kits to return explanted devices for analysis and disposal. See the back cover for addresses.

2.4 Handling and storage instructions

Carefully observe these guidelines when handling or storing the device.

2.4.1 Device handling

Checking and opening the package – Before opening the sterile pouch, which is the sterile barrier, visually check for any signs of damage that might invalidate the sterility of the package contents.

If the package is damaged – The device packaging consists of a sterile barrier pouch, aseptic tray, retainer cover, and protective clamshell. If the sterile barrier pouch is wet, punctured, opened, or damaged, do not use the device or delivery catheter system. Return the device and delivery catheter system to Medtronic because the integrity of the sterile packaging or the device functionality might be compromised. This device and delivery catheter system are not intended to be resterilized.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Handle with care – When handling the transcatheter pacing system, do not allow the delivery catheter to whip the implantable device against hard surfaces. If this action occurs inside or outside of the sterile field, do not implant the device.

Handling the steroid tip – Avoid reducing the amount of steroid available before implanting the device. Reducing the available amount of steroid may adversely affect low-threshold performance.
Do not allow the electrode surface to come into contact with surface contaminants.

Device fixation tines – Do not retract the device fixation tines all the way into the device cup until you are ready to insert the delivery catheter system into the introducer. Unlike the helix electrode of an active fixation lead, the device tines do not require pre-implant exercise. Excessively retracting the device tines into the device cup before implant could adversely affect their fixation performance.

"Use by" date – Do not implant the device after the "Use by" date because the battery longevity could be reduced.

For single use only – Do not resterilize and reimplant an explanted device.

2.4.2 Device storage

Avoid magnets – To avoid damaging the device, store the device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Temperature limits – Store the transcatheter pacing system package at 25 °C (77 °F). Excursions from this storage temperature are permitted in the range of 15 to 30 °C (59 to 86 °F). See USP (United States Pharmacopeia) Controlled Room Temperature. According to USP excursion conditions, transient spikes up to 40 °C (104 °F) are permitted, as long as they do not exceed 24 hours.

2.5 Device operation

Accessories – Use this device only with accessories, parts subject to wear, and disposable items that have been tested to technical standards and found safe by an approved testing agency.

Device status indicators – If any of the device status indicators (for example, Electrical Reset, RRT, and ERI) are displayed on the programmer after interrogating the device, inform a Medtronic representative immediately. If these device status indicators are displayed, pacing therapies may not be available to the patient.

Elective Replacement Indicator (ERI) – The programmer displays the ERI indicator when the device battery reaches the ERI condition. When the ERI indicator is displayed, implant a new device immediately.

Electrical reset – Electrical reset can be caused by exposure to temperatures below –18 °C (0 °F) or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a partial reset occurs, pacing resumes in the programmed mode with many of the programmed settings retained. If a full reset occurs, the device operates in VVI mode at 65 bpm. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed. Inform a Medtronic representative if your patient's device has reset.

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

Pacing and sensing safety margins – Provide an adequate safety margin when selecting values for pacing amplitude, pacing pulse width, and sensitivity parameters.

Programmers – Use only Medtronic programmers and application software to communicate with the device. Programmers and software from other manufacturers are not compatible with Medtronic devices.

Rate-responsive mode – Do not program the rate-responsive mode for patients who cannot tolerate rates above the programmed Lower Rate. The rate-responsive mode may cause discomfort for those patients.

Recommended Replacement Time (RRT) indicator – The programmer displays the RRT indicator when the device battery reaches the RRT condition. If the programmer displays the RRT indicator, schedule an appointment with the patient to implant a new device.

RV Capture Management – RV Capture Management does not adjust ventricular output to a value greater than 5.0 V.

Sensing Assurance – Sensing Assurance does not adjust sensitivities to values below 2.0 mV or above 5.6 mV. Manually program the RV Sensitivity threshold for patients who need a higher or lower Sensitivity threshold.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensitivity without verifying that the values provide adequate safety margins for the patient.

2.5.1 Pacemaker-dependent patients

Manual Sensing Test – Before starting the Sensing Test, select a temporary pacing rate that is likely to allow intrinsic sensed events and may be well tolerated by the patient. If the patient shows poor tolerance to the selected pacing rate when the test is in progress, stop the test by pressing the [STOP] button on the programmer screen. To complete this test, the device must detect 2 consecutive ventricular sensed events with an interval of at least 500 ms (a heart rate of 120 bpm or slower) between them. If such an interval is not identified after 30 s, the device stops the test. If a pacing rate suitable to the patient is not available to select, consider omitting the Sensing Test from the device measurement tests.

2.6 Warnings, precautions, and guidance for clinicians performing medical procedures on cardiac device patients

This section is intended for physicians and other health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems and who consult with the patients' cardiologists. This section provides warnings, precautions, and guidance related to medical therapies and diagnostic procedures that may cause serious injury to a patient, interfere with a Medtronic implanted cardiac device system, or permanently damage the system. This section also lists some common medical procedures that pose no risk.

For guidance on medical procedures that are not addressed in this section, contact your Medtronic representative.

Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction.

Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.

- Avoid direct contact between the ablation catheter and the implanted system.

- Position the return electrode patch so that the electrical current pathway does not pass through or near the device.

- Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO). After the ablation procedure, restore device parameters.

Capsule endoscopy, pH capsule procedures – Capsule endoscopy is a procedure in which a capsule containing a tiny camera is swallowed by the patient to take pictures of the patient's digestive tract. Capsule endoscopy and pH capsule procedures should pose no risk of electromagnetic interference.

Dental procedures – Dental equipment, such as ultrasonic scalers, drills, and pulp testers, poses no risk of electromagnetic interference. Keep a cardiac device at least 15 cm (6 in) away from magnets, such as magnets found in dental office pillow headrests.

Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays) – Diagnostic radiology refers to the following medical procedures:

- Computerized axial tomography (CT or CAT scan)

- Fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion by producing a video image)

- Mammograms

- X-rays (radiography, such as chest x-rays)

Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device. If the device is not directly exposed to the radiation beam, no risk of interference with device operation occurs. However, if the device is directly in a CT scan beam, see the following precautions in "CT scan". Similar interference may be observed for some forms of high-intensity fluoroscopy.

CT scan – A CT scan is a computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. If the device is not directly in the CT scan beam, the device is not affected. If the device is directly in the CT scan beam, oversensing may occur for the duration of time the device is in the beam. If the device will be in the beam for longer than 4 s, to avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO).

After completing the CT scan, restore device parameters.

Diagnostic ultrasound – Diagnostic ultrasound is an imaging technique that is used to visualize muscles and internal organs, their size, structures, and motion as well as any pathological lesions. It also is used for fetal monitoring and to detect and measure blood flow. Diagnostic ultrasound, such as echocardiogram, poses no risk of electromagnetic interference. For precautions about therapeutic ultrasound, see "Diathermy treatment (including therapeutic ultrasound)".

Diathermy treatment (including therapeutic ultrasound) – Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and therapeutic ultrasound. Except for therapeutic ultrasound, do not use diathermy treatments on cardiac device patients. Diathermy treatments may result in serious injury or damage to an implanted device. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound), is the use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound is acceptable if treatment is performed with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted device, as long as the ultrasonic beam is pointing away from the device.

Electrolysis – Electrolysis is the permanent removal of hair by using an electrified needle (AC or DC) that is inserted into the hair follicle. Electrolysis introduces electrical current into the body, which may cause oversensing. Evaluate any possible risks associated with oversensing with the patient's medical condition. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO).

After completing electrolysis, restore device parameters.

Electrosurgery – Electrosurgery (including electrocautery, electrosurgical cautery, Medtronic Advanced Energy surgical incision technology, and hyfrecator) is a process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted

tissue. Electrosurgery used on cardiac device patients may result in, but is not limited to, oversensing, unintended tissue damage, tachyarrhythmias, device damage, or device malfunction. If electrosurgery cannot be avoided, consider the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.

- Use a bipolar electrosurgery system or Medtronic Advanced Energy surgical incision technology, or hyfrecator, if possible. If a unipolar electrosurgery system is used, position the return electrode patch so that the electrical current pathway does not pass through or within 15 cm (6 in) of the device.

- Do not apply unipolar electrosurgery within 15 cm (6 in) of the device.

- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

- Always monitor the patient during electrosurgery. If the ECG tracing is not clear due to interference, manually monitor the patient's rhythm (take pulse); alternatively, monitor the patient by some other means such as ear or finger pulse oximetry, Doppler pulse detection, or arterial pressure display.

To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO).

After completing electrosurgery, restore the device parameters.

External defibrillation and cardioversion – External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal rhythm.

Medtronic cardiac devices are designed to withstand exposure to external defibrillation and cardioversion. While damage to an implanted device from an external shock is rare, the probability increases with increased energy levels. These procedures may also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium.

If external defibrillation or cardioversion is required, consider using the lowest clinically appropriate energy. After the therapy is delivered, use a Medtronic programmer to evaluate the device.

Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT) – Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapies with pressures exceeding 4.0 ATA, approximately 30 m (100 ft) of seawater, may affect device function or cause device damage. To avoid or mitigate risks, do not expose implanted devices to pressures exceeding 4.0 ATA.

Lithotripsy – Lithotripsy is a medical procedure that uses mechanical shock waves to break up kidney or gallbladder stones. If the device is at the focal point of the lithotripter beam,

lithotripsy may permanently damage the device. If lithotripsy is required, keep the focal point of the lithotripter beam a minimum of 2.5 cm (1 in) away from the device. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO).

After completing the lithotripsy treatment, restore device parameters.

Magnetic resonance imaging (MRI) – An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. If certain criteria are met and the warnings and precautions provided by Medtronic are followed, patients with an MR Conditional device are able to undergo an MRI scan. For details, refer to the MRI Technical Manual that Medtronic provided for this MR Conditional device.

Radiotherapy – Radiotherapy is a cancer treatment that uses radiation to control cell growth. When performing radiotherapy, take precautions to avoid oversensing, device damage, and device operational errors, as described in the following sections:

- Oversensing – If the patient undergoes radiotherapy treatment and the average dose rate at the device exceeds 1 cGy/min, the device may inappropriately sense direct or scattered radiation as cardiac activity for the duration of the procedure. To avoid or mitigate the effects of oversensing, if appropriate for the patient, initiate asynchronous pacing by programming the device to an asynchronous pacing mode (for example, VOO). After completing the radiotherapy treatment, restore the device parameters.

- Device damage – Exposing the device to high doses of direct or scattered radiation from any source that results in an accumulated dose greater than 500 cGy may damage the device. Damage may not be immediately apparent. If a patient requires radiation therapy from any source, do not expose the device to radiation that exceeds an accumulated dose of 500 cGy. To limit device exposure, use appropriate shielding or other measures. For patients who are undergoing multiple radiation treatments, consider the accumulated dose to the device from previous exposures.

- Device operational errors – Exposing the device to scattered neutrons may cause electrical reset of the device, errors in device functionality, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment by using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. An electrical reset requires reprogramming of device parameters. Electron beam treatments that do not produce neutrons do not cause electrical reset of the device.

Stereotaxis – Stereotaxis is a catheter navigation platform that allows clinicians to steer catheter-based diagnostic and therapeutic devices throughout the body by using magnetic

navigation. During a stereotaxis procedure, the magnetic field may cause interference to the device. The device resumes normal programmed operation after the procedure.

Transcutaneous electrical nerve stimulation (TENS) – TENS (including neuromuscular electrical stimulation or NMES) is a pain control technique that uses electrical impulses passed through the skin to stimulate nerves. A TENS device is not recommended for in-home use by cardiac device patients due to a potential for oversensing, inappropriate therapy, inhibition of pacing, or asynchronous pacing. If a TENS device is determined to be medically necessary, contact a Medtronic representative for more information.

Transurethral needle ablation (TUNA) and transurethral microwave therapy (TUMT) – TUNA and TUMT are surgical procedures used for benign prostatic hyperplasia (BPH) in which precisely focused energy is used to ablate prostate tissue. Patients with implanted cardiac devices may conditionally undergo procedures that use a TUNA or TUMT system. To avoid affecting the cardiac device function when performing a TUNA or TUMT procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the implanted device.

2.7 Warnings, precautions, and guidance related to electromagnetic interference (EMI) for cardiac device patients

Many cardiac device patients resume their normal daily activities after full recovery from surgery. However, there may be certain situations that patients need to avoid. Because a cardiac device is designed to sense the electrical activity of the heart, the device may sense a strong electromagnetic energy field outside of the body and deliver a therapy that is not needed or withhold a therapy that is needed. The following sections provide important information to share with patients about electrical equipment or environments that may cause interference with their implanted cardiac device. For additional guidance about EMI, contact your Medtronic representative.

General EMI guidelines for patients – Patients should observe the following general guidelines regarding EMI:

- Area restrictions – Before entering an area where signs are posted prohibiting persons with an implanted cardiac device, such as a pacemaker or ICD, consult with your doctor.

- Symptoms of EMI – If you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The cardiac device should immediately return to normal operation. If symptoms do not improve when you move away from the item, consult with your doctor.

- Proper grounding of electrical items – To avoid interference from electrical current that may leak from improperly grounded electrical items and pass through the body, observe the following precautions:
  - Make sure that all electrical items are properly wired and grounded.
  - Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Household and hobby items with motors or other items that cause EMI – Household and hobby items that have motors or items that generate electromagnetic energy fields could interfere with a cardiac device. Keep a cardiac device at least 15 cm (6 in) away from the following items:

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such as handheld hair dryers, electric shavers, electric or ultrasonic toothbrushes (base charger), or electric massagers

The following household and hobby items require special precautions:

- Boat motors – Keep a cardiac device at least 30 cm (12 in) away from electric trolling motors or gasoline-powered boat motors.
- Electronic body fat scale – Using this type of scale is not recommended for cardiac device patients because it passes electricity through the body and can interfere with the device.
- Electronic pet fences or invisible fences – Keep a cardiac device at least 30 cm (12 in) away from the buried wire and the indoor antenna of electronic pet fences or invisible fences.
- Home-use electric kilns – Keep a cardiac device at least 60 cm (24 in) away from home-use electric kilns.
- Induction cook tops – An induction cook top uses an alternating magnetic field to generate heat. Keep a cardiac device at least 60 cm (24 in) away from the heating zone when the induction cook top is turned on.
- Portable electric generators up to 20 kW – Keep a cardiac device at least 30 cm (12 in) away from portable electric generators.
- UPS (uninterruptible power source) up to 200 A – Keep a cardiac device at least 30 cm (12 in) away from a UPS. If the UPS is operating by battery source, keep a cardiac device at least 45 cm (18 in) away.

Home power tools – Most home power tools should not affect cardiac devices. Consider the following common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.

- Be certain that plug-in tools are properly grounded (or double insulated). Using a ground fault interrupter outlet is a good safety measure (this inexpensive device prevents a sustained electrical shock).

Some home power tools could affect cardiac device operation. Consider the following guidelines to reduce the possibility of interference:

- Electric yard and handheld power tools (plug-in and cordless) – Keep a cardiac device at least 15 cm (6 in) away from such tools.

- Soldering guns and demagnetizers – Keep a cardiac device at least 30 cm (12 in) away from these tools.

- Gasoline-powered tools and gasoline-powered yard equipment – Keep a cardiac device at least 30 cm (12 in) away from components of the ignition system. Turn off the motor before making adjustments.

- Car engine repair – Turn off car engines before making any adjustments. When the engine is running, keep a cardiac device at least 30 cm (12 in) away from components of the ignition system.

Industrial equipment – After recovering from implant surgery, you likely will be able to return to work, to school, or to your daily routine. However, if you will be using or working near high-voltage equipment, sources of high electrical current, magnetic fields, or other EMI sources that may affect device operation, consult with your doctor. You may need to avoid using, or working near, the following types of industrial equipment:

- Electric furnaces used in the manufacturing of steel

- Induction heating equipment and induction furnaces, such as kilns

- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing

- Industrial magnets or large magnets, such as those used in surface grinding and electromagnetic cranes

- Electric arc and resistance welding equipment

- Broadcasting antennas of AM, FM, shortwave radio, and TV stations

- Microwave transmitters. Note that microwave ovens are unlikely to affect cardiac devices.

- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect cardiac devices.

Radio transmitters – Determining a safe distance between the antenna of a radio transmitter and a cardiac device depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is high or if the antenna cannot be

directed away from a cardiac device, you may need to stay farther away from the antenna. Refer to the following guidelines for different types of radio transmitters:

- Two-way radio transmitter (less than 3 W) – These low-power devices present low risk to a cardiac device.

- Portable transmitter (3 to 15 W) – Keep a cardiac device at least 30 cm (12 in) away from the antenna.

- Commercial and government vehicle-mounted transmitters (15 to 30 W) – Keep a cardiac device at least 60 cm (24 in) away from the antenna.

- Other transmitters (125 to 250 W) – Keep a cardiac device at least 2.75 m (9 ft) away from the antenna.

  For transmission power levels higher than 250 W, contact a Medtronic representative for more information.

Security systems – When passing through security systems, follow these precautions:

- Electronic antitheft systems, such as in a store or library, and point-of-entry control systems, such as gates or readers that include radio frequency identification equipment – These systems should not affect a cardiac device, but as a precaution, do not linger near or lean against such systems. Simply walk through these systems at a normal pace. If you are near an electronic antitheft or entry control system and experience symptoms, promptly move away from the equipment. After you move away from the equipment, the cardiac device resumes its previous state of operation.

- Airport, courthouse, and jail security systems – Given the short duration of security screening, it is unlikely that metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and three-dimensional imaging scanners) in airports, courthouses, and jails will affect a cardiac device. When encountering these security systems, follow these guidelines:

  – Always carry your cardiac device ID card. If a cardiac device sets off a metal detector or security system, show your ID card to the security operator.

  – Minimize the risk of temporary interference with your cardiac device while going through the security screening process by not touching metal surfaces around any screening equipment.

  – Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace.

  – If a handheld wand is used, ask the security operator not to hold it over or wave it back and forth over your cardiac device.

  – If you have concerns about security screening methods, show your cardiac device ID card to the security operator, request alternative screening, and then follow the security operator's instructions.

2.8 Physician training

Implantation and system management – Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the system and must be in compliance with procedures described in the appropriate technical instructions. Inadequate training or failure to follow instructions may result in harm to the patients.

2.9 Potential adverse events

Potential adverse events associated with the use of the Micra Model MC1VR01 transcatheter pacing system include, but are not limited to, the following events:

- air embolism
- aneurysm or pseudoaneurysm
- bleeding or hematoma
- cardiac or vascular trauma, such as cardiac perforation, dissection, rupture, or tear, possibly resulting in tamponade or arterio-venous fistula
- device dislodgment or migration
- device embolization
- endocarditis
- fluid accumulation
- general surgery risks and complications from comorbidities, such as hypotension, dyspnea, syncope, pneumonia, hypertension, cardiac failure, renal failure, anemia, and death
- heart, vessel, or valve tissue damage, including coronary arterial constriction
- impaired cardiac function due to device
- incision site complication such as excessive fibrotic tissue growth
- incision site infection or other infection
- induction or acceleration of arrhythmias, including heart block
- ineffective rate response
- myocardial damage
- nerve damage
- nerve or extracardiac stimulation
- oversensing, undersensing, or loss of pacing therapy

- pacemaker syndrome

- pain at access site or chest

- pericarditis, pericardia effusion, or pericardial rub

- peripheral ischemia

- reduced device longevity — results in device replacement procedure earlier than expected and could result in complications from replacement procedure

- threshold elevation

- thrombus which may result in embolism (for example, deep vein thrombosis, pulmonary embolism or cerebrovascular accident)

- tissue necrosis such as myocardial infarction

- toxic/allergic reactions, including body rejection phenomena and local tissue reaction

- venous occlusion

- vessel spasm

2.10 Adverse events and clinical trial data

Information regarding clinical studies and adverse events related to this device is available at www.medtronic.com/manuals.

The following clinical studies are related to this device:

Micra Transcatheter Pacing Study – This clinical study, which evaluated the safety and efficacy of the Micra transcatheter pacing system, provides support for the system.

3   Drug information

3.1 Mechanism of action

Steroid suppresses the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes. Dexamethasone acetate is a synthetic steroid of the glucocorticoid family. Glucocorticoids have potent anti-inflammatory actions via direct and indirect effects on major inflammatory cells. Glucocorticosteroids bind to a cytoplasmic glucocorticoid receptor as well as a membrane-bound receptor. Binding to the cytoplasmic receptor leads to receptor activation and translocation to the nucleus. The receptor interacts with specific DNA sequences within the regulatory regions of affected genes. Thus, glucocorticoids inhibit the production of multiple cell factors that are critical in generating the inflammatory response.

3.2 Pharmacokinetics and metabolism

Pharmacokinetics – The pharmacokinetics (local drug levels and systemic levels) of dexamethasone acetate and its metabolites following implant were not evaluated in human clinical trials. When delivered intra-muscularly, the lipid-soluble dexamethasone acetate is slowly absorbed throughout the tissue.

Metabolism – The conversion of dexamethasone acetate to dexamethasone occurs within hours. The dexamethasone alcohol (dexamethasone) is the active glucocorticoid used in this Medtronic device. Steroid is applied via MCRD (Monolithic controlled release device) and eluted to the tissue interface where it will be used. The form of the steroid, whether it is a prodrug or the pharmacologically active dexamethasone, is irrelevant, as the steroid is directly present at the injury site to treat the inflammation. Dexamethasone acetate is hydrolyzed into dexamethasone, which is readily absorbed by the surrounding tissue and body fluids. Glucocorticoids, when given systemically, are eliminated primarily by renal excretion of inactive metabolites.

3.3 Mutagenesis, carcinogenicity, and reproductive toxicity

The mutagenesis, carcinogenicity, and reproductive toxicity of the Model MC1VR01 device have not been evaluated. However, the mutagenesis, carcinogenicity, and reproductive toxicity of dexamethasone acetate have previously been evaluated.

Mutagenesis – Genotoxicity evaluation of dexamethasone was undertaken using in vitro and in vivo assays. Analyses of chromosomal aberrations, sister-chromatid exchanges in human lymphocytes, and micronuclei and sister-chromatid exchanges in mouse bone

marrow showed dexamethasone to be capable of attacking the genetic material. However, the Ames/Salmonella assay, both with and without S9 mix, did not show any increase His+ revertants.

Carcinogenicity – Although adequate and well-controlled animal studies have not been performed on Dexamethasone acetate, use in humans has not shown an increase in malignant disease.

Reproductive Toxicity – Adrenocorticoids have been reported to increase or decrease the number and motility of spermatozoa. However, it is not known whether reproductive capacity in humans is adversely affected.

Pregnancy – Adrenocorticoids cross the placenta. Although adequate studies have not been performed in humans, there is some evidence that pharmacologic doses of adrenocorticoids may increase the risk of placental insufficiency, decreased birth weights or stillbirth. However, tetrogenic effects in humans have not been confirmed.

Infants born to mothers who have received substantial doses of adrenocorticoids during pregnancy should be carefully observed for signs of hypoadrenalism and replacement therapy administered as required.

Prenatal administration of dexamethasone to the mother to prevent respiratory distress syndrome in the premature neonate has not been shown to affect the child's growth or development adversely. Physiologic replacement doses of adrenocorticoids administered for treatment of adrenal insufficiency are also unlikely to adversely affect the fetus or neonate. Animal studies have shown that adrenocorticoids increase the instance of cleft palate, placental insufficiency, spontaneous abortions, and intrauterine growth retardation.

Lactation – Problems in humans have not been documented. Adrenocorticoids are excreted in breast milk and may cause unwanted defects such as growth suspension and inhibition of endogenous steroid production in the infant.

4   Using the programmer

4.1 Establishing telemetry between the device and the programmer

You can establish telemetry between the device and the programmer by using the Medtronic CareLink Model 2090 Programmer. If you are using the Medtronic CareLink Model 2090 Programmer with Conexus telemetry capability for wireless mode, you have to use the nonwireless mode to establish telemetry.

In addition to the Medtronic CareLink Model 2090 Programmer, you need to use a Medtronic Model 2067 or 2067L Programming Head. Refer to the programmer reference guide for instruction on how to set up the programmer for a patient session.

4.1.1 How to establish telemetry between the device and the programmer

Place the programming head over the device to establish telemetry between the programmer and the device. Successful interrogation or programming of the device verifies that reliable communication between the device and the programmer has occurred.

When the programming head is placed over the device and telemetry is established, the amber light on the programming head turns off, and 1 or more of the green indicator lights on the programming head illuminate. You can find the optimal position for the programming head by moving it around the implanted device until the greatest number of green lights illuminate. Position the programming head so that at least 1 or more of the green indicator lights illuminate to ensure that reliable telemetry has been established. If the programming head slides off the patient, the session does not terminate. Place the programming head back over the device to resume programming or interrogating the device.

Notes:

- A telemetry strength of 2 or more indicator lights is required to take initial electrical measurements during the device implant procedure.

- More information about the general use of the programming head is available in the programmer reference guide

4.1.2 How to select the new Micra device in a patient with an existing Micra device

If the patient is implanted with another Micra device before an existing Micra device reached the EOS condition, you have to select the new device to establish telemetry communication between this device and the programmer. On the Find Patient screen, each implanted Micra device is identified by its model name, implant year, and the serial number specific to it. You can select the appropriate Micra device based on the implant year and serial number associated with it, as shown in Figure 5. This information is available for the new device only after the device has been programmed to On, such as at a follow-up visit.

Note: The implant year of the newly implanted Micra device is appended to its model name on the Find Patient screen after this device is programmed from the Device Off mode to an operating mode for the first time.

To select the new Micra device on the Find Patient screen at the time of implant, follow these instructions:

1. Select the new Micra device by identifying the serial number specific to this device.

2. Select [Interrogate] from the Command bar. You may also interrogate the device by pressing the "I" button on the programming head.

3. Select [Start].

Figure 4. Find Patient screen: Identifying the new Micra device at the time of implant
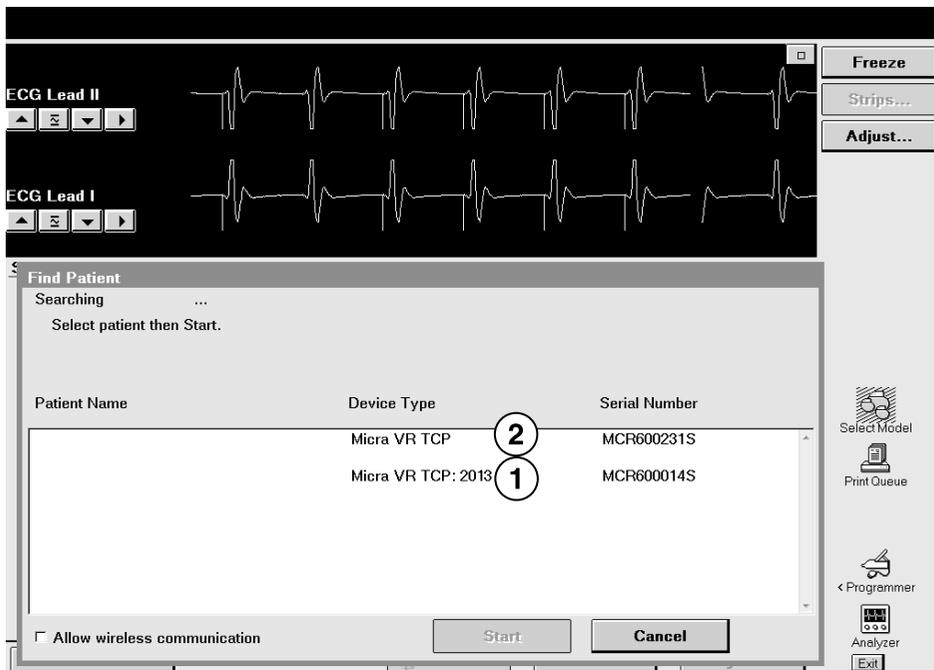
1 The implant year is appended to the model name of the existing Micra device.
2 The implant year of the newly implanted Micra device is appended to the model name after this device is programmed to an operating mode for the first time.

To select the current device for a patient follow-up session, follow these instructions:

1. Select the Micra device with the serial number and implant year specific to the new device (see Figure 5).

2. Select [Interrogate] from the Command bar. You may also interrogate the device by pressing the "I" button on the programming head.

3. Select [Start].

Figure 5. Find Patient screen: Selecting the current Micra device for a patient follow-up session
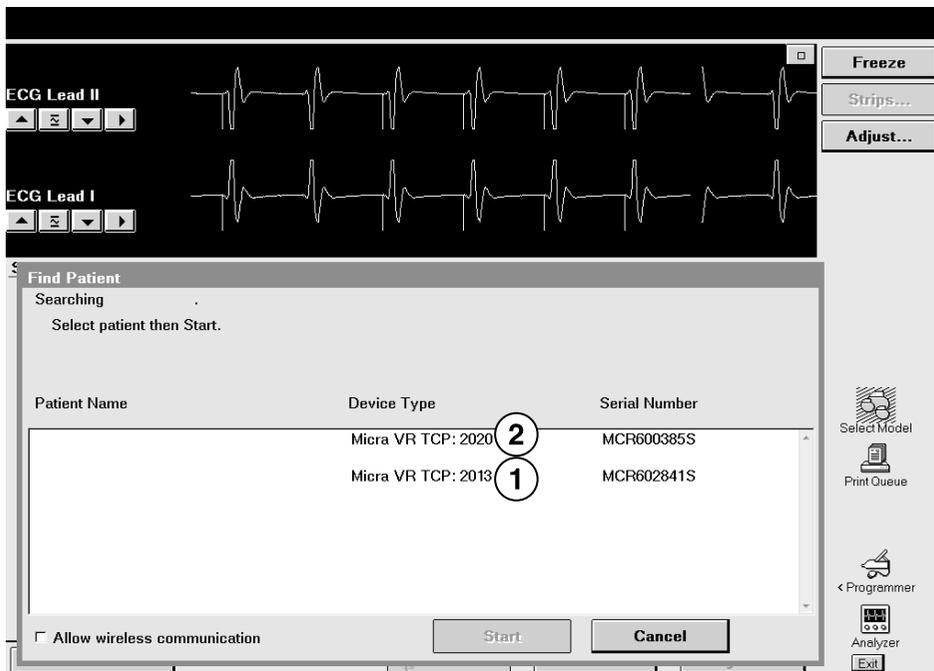
1 The implant year identifies the Micra device that was implanted earlier. If this device has not reached the EOS condition, it is programmed to the Device Off mode when the new device is implanted.
2 The implant year identifies the current Micra device as the appropriate device to select for a patient follow-up session.

4.1.3 How to maintain reliable telemetry

You can expect reliable telemetry between the implanted device and the programmer in a typical examination room or operating room. If you are having trouble maintaining consistent, reliable telemetry between a patient's implanted device and the programmer, remove any sources of electromagnetic interference (EMI) that may be affecting the telemetry signal, and position the programming head so that 1 or more of the green lights on the programming head are illuminated.

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

4.2 Conducting a patient session

The programmer interrogates the patient's device at the start of a patient session. Because the programmer collects and stores data on a session-by-session basis, you need to start a new session for each patient. You must end the previous session before starting a session with another patient.

4.2.1 Starting a patient session

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

Note: Emergency programmer functions are available only after the initial interrogation.

4.2.1.1 How to start a patient session

1. Turn the programmer power on.
2. Place the programming head over the device and establish telemetry.
3. Press the "I" button on the programming head, or select [Find Patient…].

4.2.2 Device and telemetry effects during a patient session

Marker transmissions during a session – The device continuously transmits Marker Channel and supplementary marker data while telemetry is established and the programming head is positioned over the device. The device stops these transmissions when you lift the programming head. If Holter Telemetry is programmed to On, the device transmits Marker Channel and supplementary marker data regardless of the position of the programming head. Extended use of the Holter telemetry feature substantially decreases the device battery longevity.

4.2.3 How to interrogate the device during the session

At the start of the patient session, the programmer interrogates the device. You can manually interrogate the device at any time during the patient session.

Press [Interrogate] from the Command bar. You may also interrogate the device by pressing the "I" button on the programming head.

4.2.4 Ending a patient session

Before ending the patient session, you can review the programming changes made during the current session, print a record of these changes, save the session data to a disk or USB flash drive, and change the setting for clearing the session data.

4.2.4.1 How to end a patient session

Figure 6. Ending a patient session screens
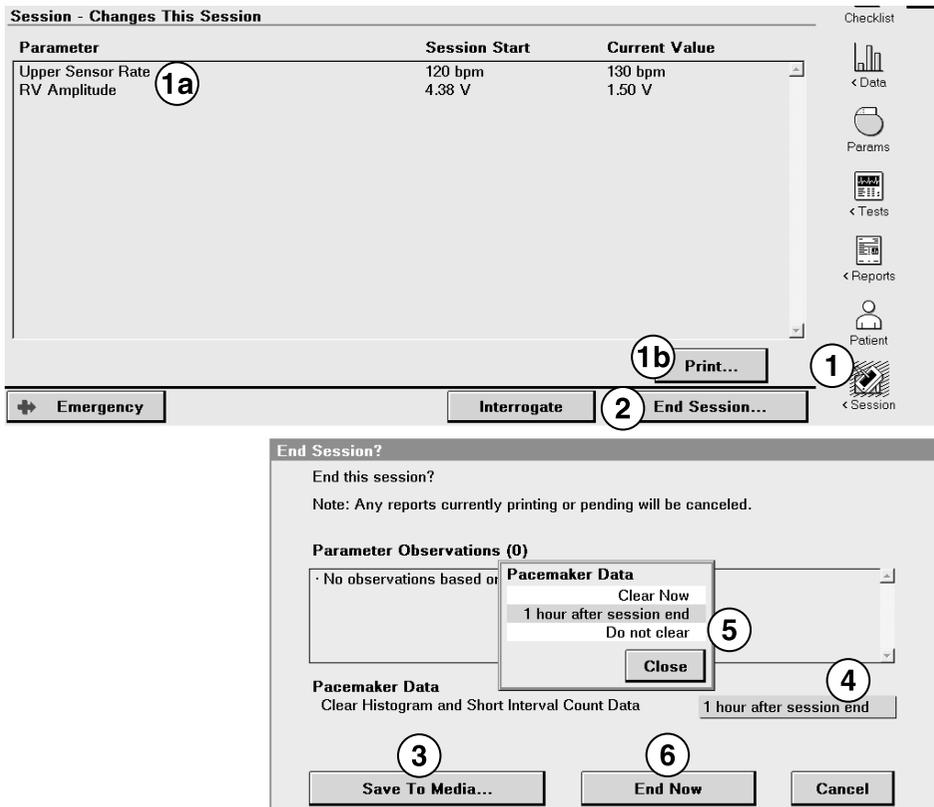
1. To review or print a list of changes made during this session, select Session > Changes This Session.

   a. Review the programming changes made during the patient session.

   b. To print a record of the changes, select [Print…].

2. Select [End Session…]. The End Session? window opens.

3. To save the session data to a disk, select [Save To Media…] from the End Session? window.

4. To change the setting for clearing the session data, select the Pacemaker Data field.

   When the device is interrogated at the start of the patient session, the programmer automatically clears the session-to-session data, such as the Rate Histogram and Short Interval Count Data 1 hour after the patient session ends. Only the data collected since the last session is available, but you can change the setting for data clearance before ending the session.

5. Select one of the following options:

   • Clear Now: The session data is cleared immediately.

   • 1 hour after session end: The session data is cleared 1 hour after the end of the session.

   • Do not clear: Data collection continues as though the device interrogation had not occurred. Data collection ends when the session data is cleared.

6. To end the session and return to the Select Model screen, select [End Now].

4.3 Display screen features

The programmer display screen is an interface that displays text and graphics. It is also a control panel that provides buttons and menu options that you can select by using the touch pen.

The main elements of a typical display screen during a patient session are shown in Figure 7.

Figure 7. Main elements of the display screen
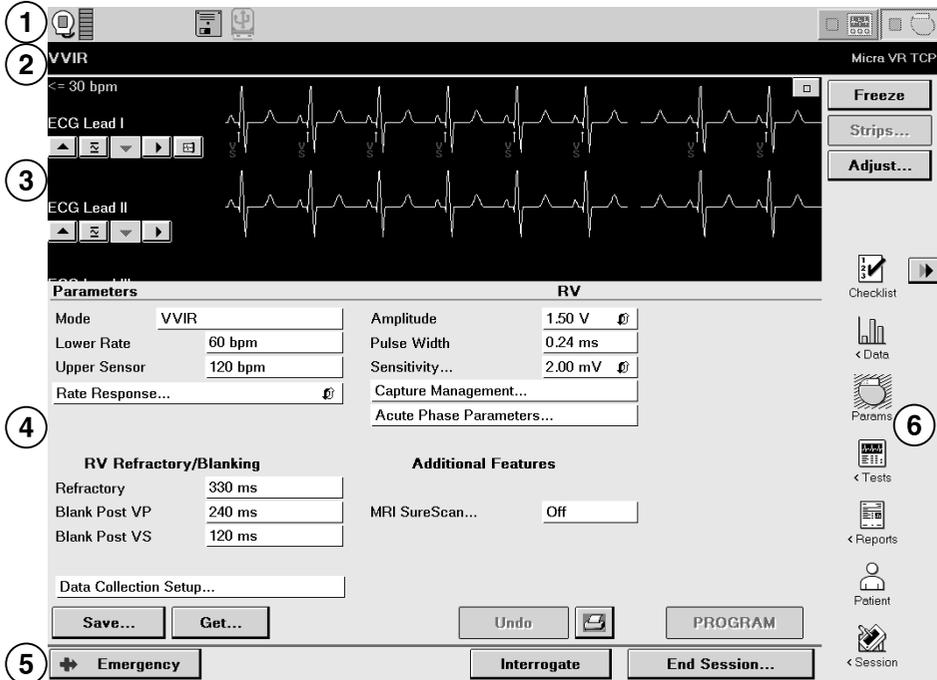
1 Task bar
2 Status bar
3 Live Rhythm Monitor window

4 Task area
5 Command bar
6 Tool palette

4.3.1 Task bar

The display screen features a task bar at the top of the screen. The task bar includes a telemetry icon and graphical representation of the telemetry strength light array on the programming head.

Figure 8. Task bar display

1 Telemetry icon and telemetry strength indicator
2 Disk icon

3 USB flash drive icon
4 Device icon

4.3.2 Status bar

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

Figure 9. Status bar display

1 Currently active pacing mode
2 The device model name

4.3.3 Live Rhythm Monitor window

The Live Rhythm Monitor window displays ECG, Marker Channel, Marker Intervals, and telemetered EGM waveform traces. In addition to waveform traces, the Live Rhythm Monitor shows the following information:

- Heart rate and rate interval are displayed if telemetry has been established with the device.
- The annotations above or below the waveform trace show the point at which parameters are programmed.

The Live Rhythm Monitor appears in the partial view by default, as shown in Figure 10. You can expand this window to its full size by selecting the small square button in the upper-right corner of the window or by selecting the [Adjust…] button. For more information about the Live Rhythm Monitor, see Section 4.9, "Working with the Live Rhythm Monitor", page 60.

Figure 10. Live Rhythm Monitor window
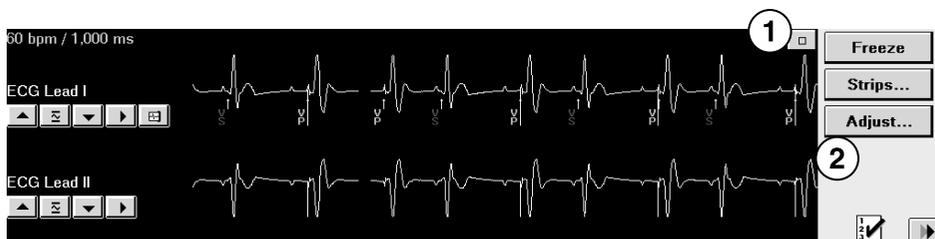
1 The square button expands the Live Rhythm Monitor window.
2 The [Adjust…] button opens the full screen of the Live Rhythm Monitor and the Adjust window to adjust the waveform traces.

4.3.4 Task area

The portion of the screen between the Live Rhythm Monitor window near the top of the screen and the command bar at the bottom of the screen changes according to the task or function you select.

One example of a task area is the Parameters screen, which is used to view and program device parameters as described in Section 4.6, "Viewing and programming device parameters", page 51.

Task areas display differently when you perform other functions such as diagnostics and system tests.

Figure 11. Task area of the screen
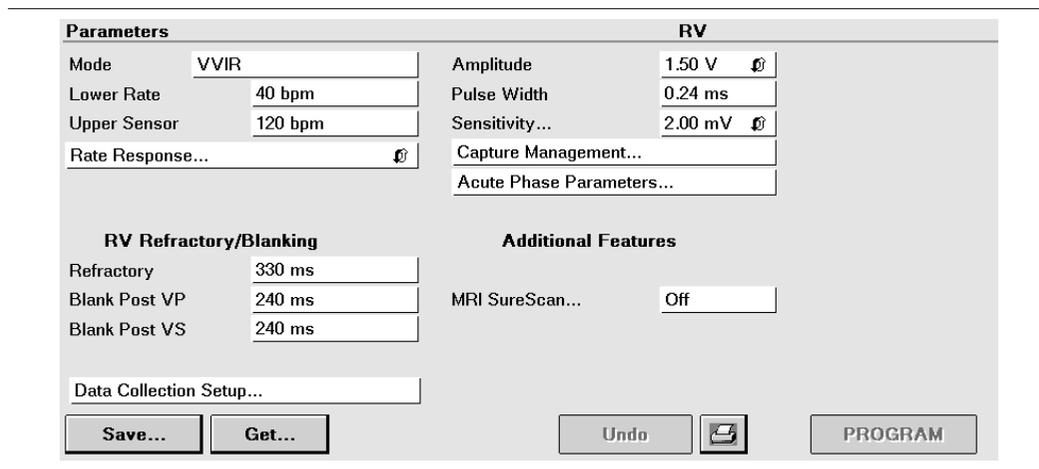
4.3.5 Command bar

The bar at the bottom of the screen always shows the buttons for programming Emergency parameters, interrogating the device, and ending the patient session.

Note: The [Interrogate] and [End Session…] buttons do not appear on the Emergency screen.

Figure 12. Command bar

4.3.6 Tool palette

The buttons and icons along the right edge of the programmer screen are referred to as the "tool palette". You can use these tools to display a task or function screen. After you start a patient session, the tool palette is displayed on all but the Emergency or Live Rhythm Monitor Adjust… screens, making it quick and easy to move to the task or function you want to perform.

Each of the icons acts like a button. To select an icon, touch the icon with the touch pen. Each option in the tool palette is described in Table 2.

Table 2. Tool palette options

Icon	Description
Freeze	The [Freeze] button captures a segment of the Live Rhythm Monitor display.
Strips…	The [Strips…] button accesses the waveform strips saved since the start of the session.
Adjust…	The [Adjust…] button opens a window of options for adjusting the Live Rhythm Monitor display.
Checklist	The Checklist icon opens the Checklist screen for simplified navigation through a set of follow-up tasks. The Checklist [>>] button navigates to the next task in the Checklist.
< Data	The Data icon displays options for viewing device information and diagnostic data.
Params	The Params icon displays the Parameters screen for viewing and programming device parameters.
< Tests	The Tests icon displays options for performing system tests.
< Reports	The Reports icon displays options for printing reports.
Patient	The Patient icon opens the Patient Information screen for viewing or editing patient information.
< Session	The Session icon displays options for adjusting preferences, viewing parameter changes made during the session, saving data, and ending the session.

4.3.7 Buttons

Buttons, such as those shown in Figure 13, respond when you "select" them by touching them with the tip of the touch pen.

Figure 13. Display screen buttons

Buttons with a less distinctly shaded label are inactive and do not respond if you select them.

Selecting a button with the touch pen causes one of the following responses:

- Buttons such as the [PROGRAM] button execute a command directly.
- Buttons such as the [Save…] and [Get…] buttons open a window that prompts another action. The labels on these buttons end with an ellipsis.

A procedure may instruct you to "press and hold" a button. In such cases, touch the tip of the touch pen to the button and continue to maintain pressure against the button. The button continues to respond to the touch pen until you remove the touch pen from the button.

4.4 Enabling emergency VVI pacing

You can use emergency VVI pacing to quickly enable 70 bpm, high-output ventricular bipolar pacing to restore ventricular support in an emergency situation.

4.4.1 Considerations for emergency VVI pacing

Parameter values – Emergency VVI pacing reprograms pacing parameters to emergency settings. See Section B.1, "Emergency settings", page 176, for a list of the emergency VVI parameter settings. To terminate emergency VVI pacing, you must reprogram pacing parameters from the Parameters screen.

4.4.2 How to enable emergency VVI pacing

1. During a patient session, establish telemetry with the device.

2. Press the emergency VVI button on the programmer to enable emergency VVI pacing.

   Depending on your model of Medtronic programmer, the emergency VVI button is:

   - a mechanical red button to the left of the programmer screen, on the programmer bezel.
   - a red button on the programmer button panel, above the programmer screen.

On all programmers, an [Emergency] button is implemented in the software and is available on the display screen. You can enable emergency VVI pacing by selecting the on-screen [Emergency] button. Emergency VVI pacing is enabled, and the programmer displays the Emergency screen.

4.5 Navigating a patient session with Checklist

Use the Checklist feature to cycle through common tasks that are performed during an implant session or a follow-up session. When you select a task, the associated programmer screen for that task appears. Once you complete a task, you can either go back to the Checklist or continue on to the screen associated with the next task. You can use the standard checklists created by Medtronic, or you can create customized checklists that reflect your personal workflow.

4.5.1 How to use a standard checklist

1. Select the Checklist icon on the tool palette of the programmer screen. Two standard checklists are available: the Medtronic Standard Followup checklist and the Medtronic Standard Implant checklist.

2. Select the checklist you want from the Checklist field.

3. Select either the [>>] button next to the Checklist icon or the [Go To Task] button to start using the checklist.

4. Use the [>>] button to continue from one task to the next. Any time you want to return to the Task list, select the Checklist icon.

5. To repeat a task or perform a task out of order, select the task and use the [Go To Task] button or the [>>] button.

When you have completed all the tasks on the Task list, the [>>] and [Go To Task] buttons become inactive. However, you can still select a task and use either button to complete the task. You can also use [>>] button to complete all the following tasks on the list.

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

4.5.2 How to create and use a custom checklist
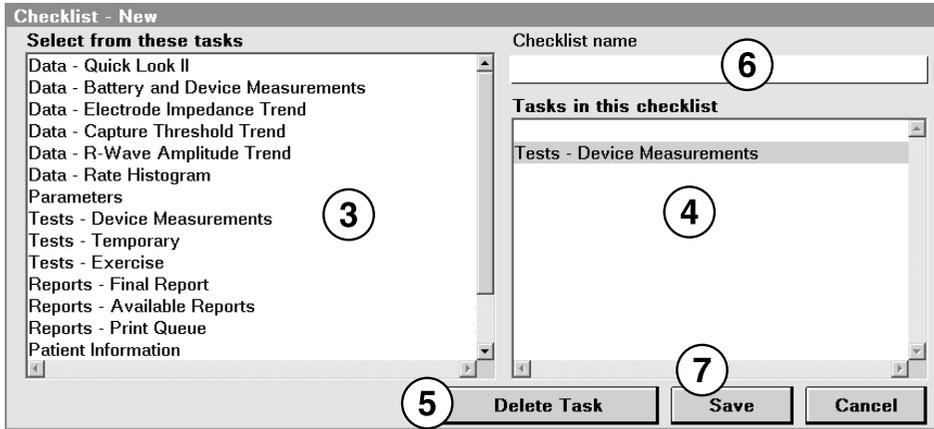
1. Select the Checklist icon.

2. Select [New…] from the Checklist screen.

3. Select the tasks you want to appear in your customized checklist from the box on the left.

   The tasks you select appear in the Tasks in this checklist box on the right. You can add the same task more than once. If you want a new task to follow a specific task on the list, rather than at the end, highlight the task that the new task should follow and select the new task. The new task appears below the highlighted task.

4. To delete a task, highlight the task in the Tasks in this checklist box.

5. Select [Delete Task].

6. To name your checklist, select the Checklist name field and enter a name.

7. Select [Save] to save the changes.

4.5.2.1 How to edit and delete a custom checklist

To edit a custom checklist, select the checklist in the Checklist field and select [Edit…]. Add or delete tasks as necessary. Then, select [Save].

To rename a custom checklist, select the checklist in the Checklist field and select [Edit…]. Change the name and select [Save].

To delete a custom checklist, select the checklist from the Checklist field and select [Delete]. A window appears, asking you to confirm that you want to delete the selected checklist. You cannot restore a deleted custom checklist.

The Medtronic Standard Followup checklist and the Medtronic Standard Implant checklist cannot be edited or deleted.

4.6 Viewing and programming device parameters

The Parameters screen is used for viewing and programming parameters that control device functions and data collection. All device parameters that you can view and program appear as "active fields" in the task area. Active fields, which appear as unshaded boxes next to parameter names, respond to the touch pen. Some active fields pertain to only 1 parameter, while other fields provide access to groups of parameters. If a parameter cannot be programmed, no active field appears next to its name. All permanent parameter changes can be programmed at the Parameters screen.

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

4.6.1 Understanding the symbols used on the Parameters screen

Certain combinations of parameter values are restricted because they are invalid or result in undesirable interactions. The programmer recognizes these combinations and may not allow programming until all parameter conflicts are resolved and all parameter selection requirements are met. A symbol that provides the status of a parameter value appears next to the value in the selection window. The following symbols can appear next to a parameter value.

Figure 14. Symbols that appear with parameter values

120 🚫
125 🚫   Parameter Interlock exists

180 ⚠
185 ⚠   Parameter warning exists

5.00 V ↻   Adaptive parameter

175 ⬥   Medtronic nominal parameter value

140 P   Programmed parameter value

Parameter interlock exists – When an interlock symbol appears next to a parameter value, it indicates that the parameter value conflicts with the setting of another present or pending value. Select another value or resolve the conflicting parameter value before programming the parameter.

Parameter warning exists – When an exclamation point enclosed in a triangle appears next to a parameter value, a warning message is available regarding that value. The message can be viewed either by selecting the message button or by reselecting that parameter. In the latter case, the warning is displayed as a warning note in the selection window. These parameter values can be programmed.

Adaptive parameter – When the adaptive symbol appears next to a parameter value on the Parameters screen, it indicates that the programmed value can be changed automatically by the device. The symbol does not necessarily indicate that the parameter value has been adapted from a previously programmed value, only that it is able to be adapted.

Medtronic nominal parameter value – When the "n" symbol appears next to a parameter value, it indicates that the value is the Medtronic nominal value.

Programmed parameter value – When the "P" symbol appears next to a parameter value, it indicates that the value is the programmed value.

The programmer may display a message button next to the [PROGRAM] button that, when selected, provides access to additional information about the pending parameters. The message button has one of the symbols described in Table 3. When the message button is selected, the programmer opens a second window displaying one or more messages.

Table 3. Symbols that appear on the message button

Symbol	Explanation
⊘ PROGRAM	Parameter interlock message
⚠ PROGRAM	Parameter warning message
ⓘ PROGRAM	Parameter informational message

Parameter interlock message – This button indicates that a parameter interlock exists. Programming is restricted until you resolve the conflict. Select this button for a message that describes the conflict.

Parameter warning message – This button indicates that there is a warning associated with programming one or more of the pending parameter values. Select this button to view the warning message and recommendations.

Parameter informational message – This button indicates that there is an informational message regarding one or more of the parameter values. Select this button to view the message.

If there are multiple messages regarding the pending parameter values, the most significant message determines the symbol that appears on the button.

4.6.2 How to access parameters
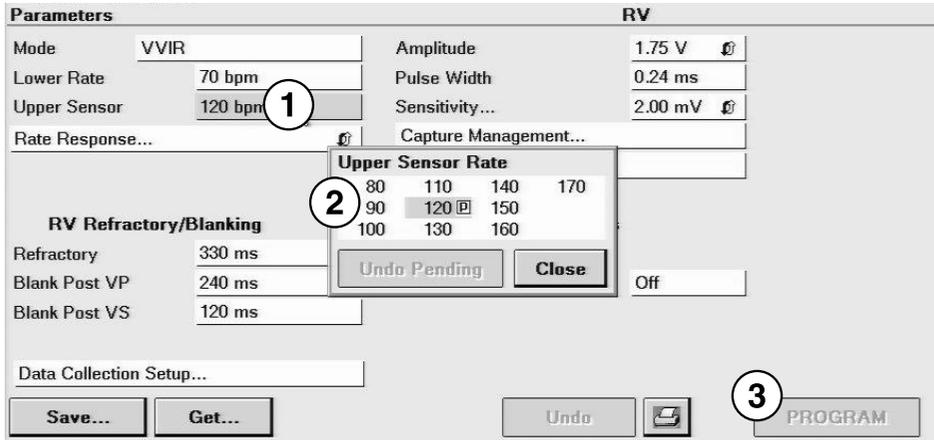
1. Select a parameter field. If there are only 2 values, such as Off and On, the parameter field typically switches to the alternate value. If there are more than 2 values, a window opens showing available values for that parameter.

2. Select a new value from this window. This new value displays as a pending value, and the window showing available values for that parameter closes. You can also select [Close] to close the window without changing the original value of the parameter.

3. Select [PROGRAM] to program the new value to the device memory or use the Program button (blue button) on the programming head.

4.6.2.1 How to access a group of related parameters
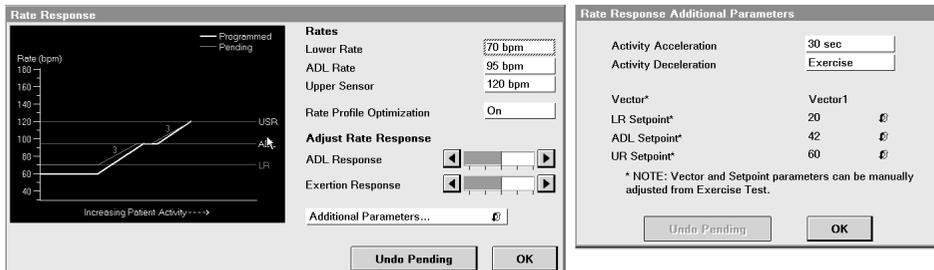
1. Select a parameter or a parameter field that ends with an ellipsis or a parameter field that contains a list of parameter names. A window opens for related secondary parameter fields, as shown in the example Rate Response… .

2. Select new values you want for the secondary parameters. New values are shown as pending values.

3. Select [OK] to close the secondary parameters window and return to the Parameters screen.

4. Select [PROGRAM] to program the new values to device memory.

4.7 Saving and retrieving a set of parameter values

Custom sets of parameter values can be saved on the programmer hard drive and retrieved either in the current patient session or in subsequent patient sessions. This flexibility allows you to save and quickly access a custom set of parameter values for a particular clinical situation. For example, you may want to save a set of parameter values for an initial implant setting, for a specific disease state, or for situations in which you need to repeatedly program a particular set of parameters.

The [Save…] button opens a window where you can assign a name to the set of parameter values presently displayed by the Parameters screen. A saved parameters set can include both programmed and pending values. The [Get…] button opens the Get Parameter Set window to retrieve a Medtronic Nominals parameter set, an Initial Interrogation parameter set, or a custom parameter set.

4.7.1 How to save a set of parameter values
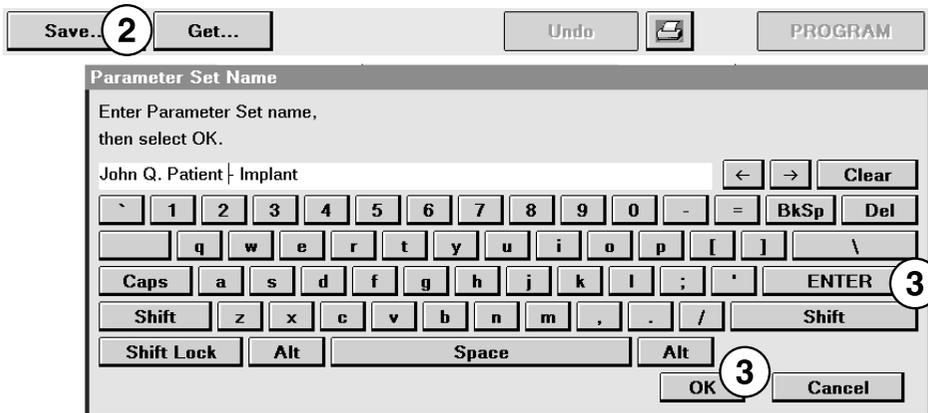
1. Select the Params icon. Then, select the parameters you want.

2. Select [Save…] to open the Parameter Set Name window.

3. Type a name for the parameter set and select either [OK] or [ENTER].

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

4.7.2 How to retrieve a set of parameter values
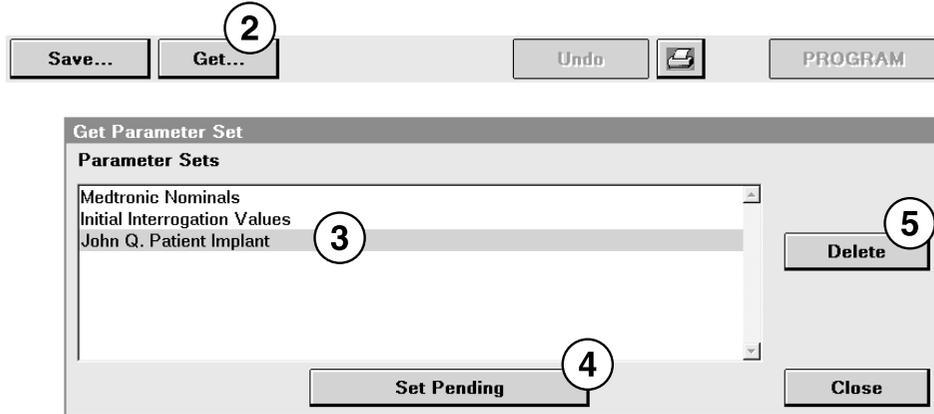
1. Select the Params icon.
2. Select [Get…] to open the Get Parameter Set window.
3. Select the parameter set you want to retrieve.
4. Select [Set Pending].
5. Optionally, to remove an unnecessary parameter set from the list, select the parameter set and select [Delete].

You can select the following options from the Get Parameter Set window:

*   Medtronic Nominals: Values set as nominal values for the device by Medtronic. The Medtronic Nominals cannot be customized or deleted.

*   Initial Interrogation Values: The permanently programmed parameter values as determined by the first interrogation of the device during the patient session.

*   Custom sets of values: All custom sets of values that were saved previously.

4.8 Viewing and entering patient information

The device can store patient-related information that you enter and program into the device memory. You can view and print this information during a patient session. Typically, the information about the patient's clinical conditions (Date of Birth and History) is programmed into the device memory at the time of implant, but it can be revised at any time.

The patient's name and ID and the device serial number are printed on all full-size and strip chart reports.

Note: The Patient Information screen should not be used in the place of the patient's medical chart (refer to Section 1.1.6, "Notice", page 12 in the Introduction).

If you enter text that does not fit in the parameter display area, the entry is shortened. The full entry is visible on the Patient Information Report. When displayed or printed from other screens, the text entry may be shortened.

Table 4. Description of the Patient Information screen

Information field	Description and required action
Patient	Enter the patient's name (up to 30 characters).
ID	Enter the patient ID (up to 15 characters).
Date of Birth	Select the patient's date of birth.
History…	Enter the patient's clinical conditions.
Serial Number (not selectable)	Displays the serial number of the implanted device. The serial number prefix "MCR" indicates that the interrogated device is a Medtronic Micra Model MC1VR01 transcatheter pacemaker.
Implant…	If the test values from the electrical measurements taken after implanting the device were not saved to the device memory, enter the test values for R-Wave Amplitude, Electrode Impedance, and Threshold. Also enter the Pulse Width value.
Notes	Enter notes about the patient or other information.
Physician Phone	Select the physician's name and phone number from a list. If they are not listed, add them to the list, and select them.
Hospital	Select the hospital name from a list. If it is not listed, add it to the list, and select it.
Last Update (not selectable)	Displays the date of the last Patient Information update.

4.8.1 How to view and enter patient information

1. Select the Patient icon on the tool palette. When the Patient Information screen is displayed, select each text field to enter content or change its content.

2. Select the Patient field and enter the patient's name. Then, select the ID field to enter the patient's ID number and the Date of Birth field to enter the date.

3. Select the Implant… field to view the test values from the initial electrical measurements. If the test values are saved to the device memory, the programmer exports these values to the Implant window. To enter the initial test values manually, select the Implant… field. Enter the test values and then select [OK].

Implant	
Implant Date	
Data from Implant	**RV**
R-Wave Amplitude (mV)	6.4 mV
Electrode Impedance (ohms)	410 ohms
Threshold (V)	0.88 V
Pulse Width (ms)	0.24 ms
Undo Pending	OK

4. To enter the information about the patient's clinical conditions, select the History… field. When the History window opens, enter the appropriate information about clinical conditions. Then, select [OK].

History

Atrial Status	Permanent AF
AV Conduction	Frequent 2° or 3° AV Block
Heart Failure	NYHA Class I
Activity Level	Average Activity

Undo Pending   OK

5. Select the Physician, Phone, and Hospital fields and select the appropriate information from the lists shown. To add new information to a list, select [Modify List…] and [Add…]. Select [OK].

6. When you have entered all the information you want, including any additional information in the Notes field, select [PROGRAM].

4.9 Working with the Live Rhythm Monitor

The Live Rhythm Monitor window displays ECG waveform traces, Marker Channel telemetry with marker annotations and marker intervals, and telemetered EGM waveform traces on the programmer screen. The Live Rhythm Monitor window also displays the patient's heart rate and interval in the upper left corner of the window. You can view live waveform traces, freeze waveform traces, record live waveform traces from the programmer's strip chart recorder, and recall any saved waveform strips before ending a patient session.

By default, the Live Rhythm Monitor appears in partial view. You can expand this window to its full size by selecting the small square button in the upper-right corner of the window or by selecting [Adjust…]. The display of waveform traces in the Live Rhythm Monitor window depends on which waveform source is selected and how waveform traces are arranged in the full-screen view.

4.9.1 Viewing live waveform traces

The Live Rhythm Monitor can display up to 4 different waveforms during a patient session:

- The ECG Lead I, ECG Lead II, and ECG Lead III waveforms display ECG signals that are detected using skin electrodes attached to the patient. The ECG cable attached to these electrodes must be connected to the programmer.

- The EGM signal is telemetered from the device to the programmer. The programmer cannot display or record an EGM waveform trace until the device has been interrogated.

4.9.1.1 How to select and adjust the waveforms

You can use the waveform adjustment button bar to change the appearance of the waveforms in view.

Figure 15. Waveform adjustment button bar
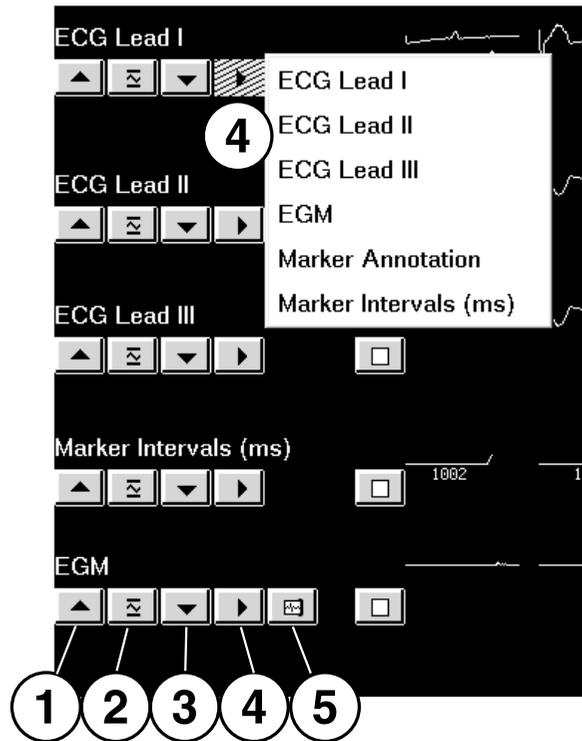
1 The up arrow button increases the size of the waveform trace.
2 The Normalize button restores the waveform trace to its default size.
3 The down arrow button decreases the size of the waveform trace.
4 The forward arrow button is used to select the waveform trace to display.
5 The waveform print selection button is used to select up to 2 waveform traces for printing.

4.9.1.2 How to change the appearance of the waveform

You can use the Adjust… window to make additional changes to the waveform display. Select [Adjust…] on the tool palette to view the full screen of the Live Rhythm Monitor and the Adjust window. To adjust the source and print selection option for each waveform trace, use the waveform adjustment button bar.

Figure 16. Waveform appearance change window
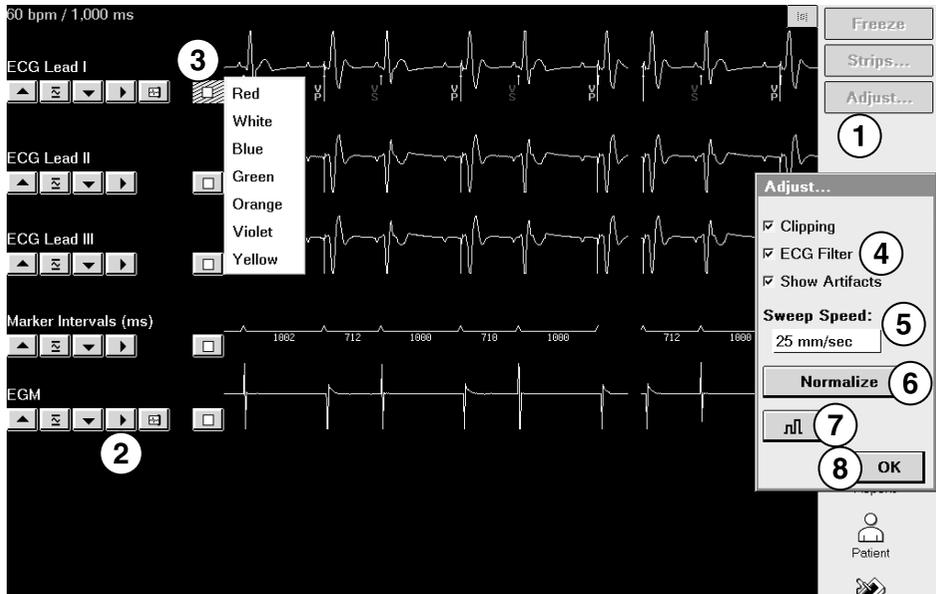
1. Select [Adjust…] to display the full screen Live Rhythm Monitor and the Adjust window.

2. Adjust the size, source, and print selection options for each waveform trace using the waveform adjustment button bar.

3. Select the color button to change the color of a waveform.

4. Select or clear the Clipping, ECG Filter, and Show Artifacts check boxes, as preferred.

    • Clipping truncates the tops and bottoms of waveform traces at a 22 mm boundary.

    • ECG Filter changes the bandwidth of waveforms to improve the clarity of the displayed ECG in the presence of interference. (Select the check box to set the bandwidth to 0.5 to 40 Hz, or clear the check box to set the bandwidth to 0.05 to 100 Hz.)

    • Show Artifacts displays pacing artifacts superimposed over waveform traces.

5. Select a Sweep Speed if preferred. Sweep Speed controls how quickly the waveform is drawn across the display. Selecting a fast Sweep Speed produces a wide waveform. Selecting a slow Sweep Speed produces a narrow waveform. Sweep Speed can be set to 12.5; 25; 50; or 100 mm/s.

6. Select [Normalize] to equalize the spacing between the waveform traces and to resize each trace to its default setting.

7. Select the calibrate button to add a reference signal to the analog output, the screen, and the real-time strip recorder.

8. When you finish making the adjustments, select [OK].

4.9.1.3 How to interpret Marker Channel annotations and symbols

Marker Channel annotations appear as 2 characters above or below the Marker Channel waveform trace. These annotations indicate pacing and sensing events. See Figure 17 for an example of Marker Channel annotations and symbols.

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

Note: Any interruption in telemetry with the device may result in missing marker annotations and symbols on the waveform trace display.

Figure 17. Pacing Marker Channel annotations and symbols

V P	V S	V R	V L	V C
Ventricular pace	Ventricular sense	Ventricular refractory sense	Ventricular capture loss	Ventricular capture
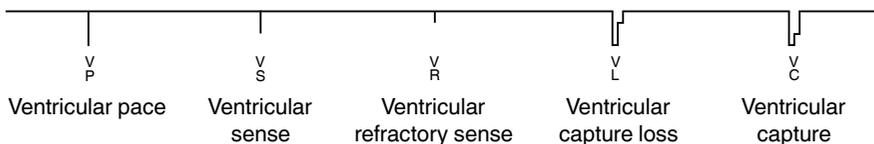
4.9.2 Recording live waveform traces

At any time during a patient session, you can record a continuous, live waveform trace of the patient's ECG and EGM[1] on the programmer strip chart recorder. Since the printed waveform strip is of a higher resolution than the programmer display, the printed waveform strip may show artifacts and events that do not appear on the programmer display.

A printout of the live waveform trace includes the following information:

*   ECG and EGM traces

*   an indication of an executed command when confirmation of the command is received

*   test values during system tests

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[1] The programmer cannot display or record an EGM trace until the device has been interrogated.

- telemetry markers that show telemetry from the programmer to the device (programming the device) and telemetry from the device to the programmer (confirming the programming)

Printing a report while recording a live waveform trace – If you select an option from the Print menu while recording a live waveform trace, the report goes to the print queue. Alternatively, if you start recording a live waveform trace while the programmer is printing a report, the report stops printing and returns to the print queue.

Note: This interruption to printing applies only to reports printed on the programmer strip chart recorder. Printing to a separate printer is not affected.

4.9.3 Freezing live waveform traces

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

You can use controls in the frozen strip viewing window to perform the following functions:

- View earlier or later portions of the strip by using the horizontal scroll bar.
- See frozen waveform strips that are not visible in the window by using the vertical scroll bar.
- Measure a time interval with on-screen calipers.

Figure 18. Frozen strip viewing window
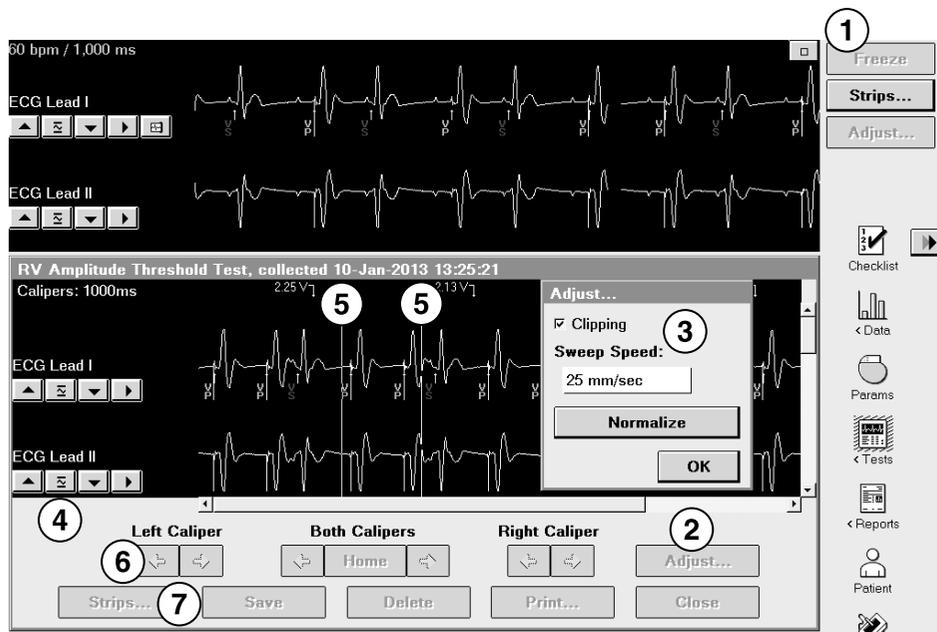
1 The [Freeze] button freezes a live waveform trace and displays it in the frozen strip viewing window on the programmer screen.

2 The [Adjust…] button opens the Adjust window for the strip viewer.

3 The Adjust window, which is similar to the Adjust window for the Live Rhythm Monitor, provides display options for the frozen strip viewer.

4 The Waveform adjustment button bar allows you to normalize the trace, resize the trace, and change the waveform source.

5 The on-screen calipers define time intervals. The Calipers measurement in the upper left corner of the strip viewer is the time interval between the on-screen calipers.

6 The Arrow buttons move the on-screen calipers to show the beginning and end of a time interval.

7 The button bar provides the [Strips…] button to open a list of other frozen strips and buttons to save the on-screen frozen strip, delete the strip if it was saved, print the strip, and close the frozen strip viewer.

4.9.4 Recalling waveform strips

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

4.9.4.1 How to recall a waveform strip
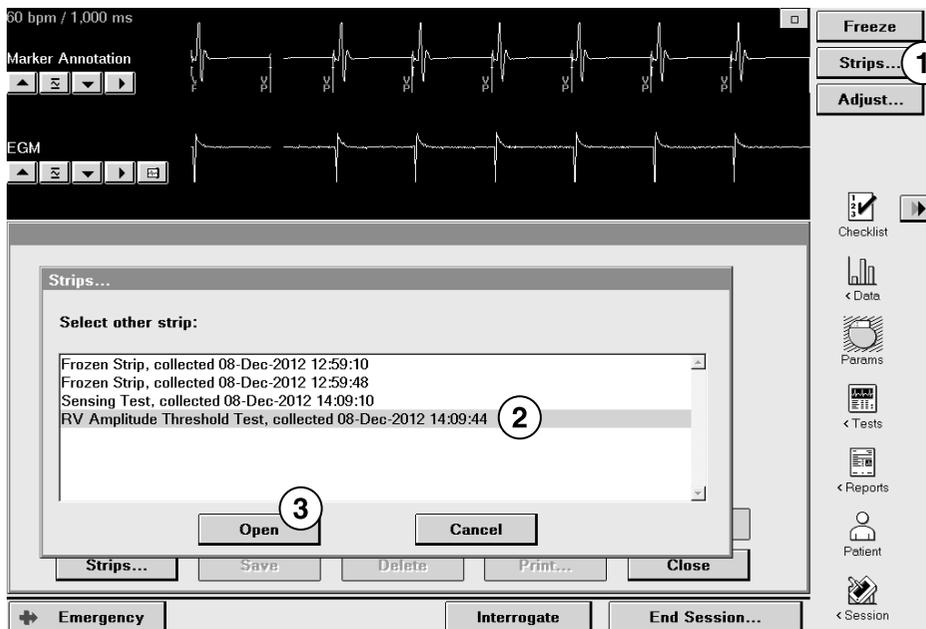
1. Select [Strips…] in the tool palette or in the strip viewer.

2. Select a strip to view.

3. Select [Open]. The strip viewer displays the selected strip.

4.10 Saving and retrieving device data

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

Note: Medtronic programmers are equipped either of two ways: with a disk drive for 3.5 inch disks plus a USB port for USB flash drives, or with a USB port only. If your programmer has a USB port only, please disregard content in this section that documents the use of disk drives.

4.10.1 Saving device data

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

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

Interrogate first – Interrogate the device before saving data to a USB flash drive or a disk because the programmer saves only the data it has interrogated.

Emergency functions while saving – During the save operation, the [Emergency] button remains displayed, and all Emergency functions are available. If an error occurs during a save, there may be a delay in initiating the Emergency screens. If an Emergency function is used during a save operation, the device aborts the save operation.

4.10.1.1 Considerations for saving device data on a USB flash drive

Insert only one USB flash drive – Insert only one writable USB flash drive at a time. Inserting additional USB flash drives results in an error during data-saving operations and the USB indicator becomes unavailable.

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

Programmer powered on – Insert a USB flash drive only if the programmer is powered on. Insert a writable USB flash drive in the programmer using any available USB port. A slight delay may occur while the USB flash drive is authorized. The USB indicator on the task bar turns green to indicate that the USB flash drive is available for use and the disk icon becomes unavailable.

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

- programming a device
- performing a save-to-disk
- performing a reload session data operation
- saving a report as a PDF file

4.10.1.2 How to save device data to a USB flash drive

1. Select [Interrogate] to interrogate the device.

2. Insert a USB flash drive into the USB port on the programmer.

3. Select Session > Save To Media….

4. Select [Save].

You can also Save To Media when you select [End Session…].

4.10.1.3 Preparing to save data to a disk

The disk must be a formatted, IBM-compatible, 90 mm (3.5 inch) disk.

If you save data to a disk that is corrupt or is not IBM-formatted, the programmer may become unresponsive. If this situation occurs, remove the disk, turn off the programmer, and then turn it on again. Normal operation should resume. Inform your Medtronic representative of this occurrence.

4.10.1.4 How to save device data to a disk

1. Select [Interrogate] to interrogate the device.

2. Select Session > Save To Media….

3. Insert a disk into the programmer disk drive.

4. Select [Save].

You also have the option to Save To Media when you select [End Session…].

4.10.2 Retrieving device data

When the programmer has read the data that was saved during a patient session, it presents the information in a read-only view. In the read-only view, the data is presented in a slightly different way than what is seen in a live session. No Live Rhythm Monitor window is displayed because this is not a live session. Instead, the Live Rhythm Monitor window is replaced with the device model and the words Read From Media. While in the Read From Media application, the programmer allows you to view the saved data, print reports, and display all programmed parameter values.

Reports that have been saved as PDF files to storage media (USB flash drive or disk) can only be viewed on a computer. They cannot be viewed on the programmer itself. After saving the reports, remove the USB flash drive or disk and insert it into a computer equipped to display files that are in PDF format.

All reports from one patient session are contained in one PDF file.

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

Device testing – You cannot perform tests on the device when reading data from media.

4.10.2.1 How to read device data from a USB flash drive or a disk

1. Insert a USB flash drive or a disk that contains information saved during a patient session.

2. From the Select Model screen, select the product category from the View list.

3. Select the Read From Media version of the device.

4. Select [Start].

5. Select [OK] after reading the warning message that informs you that programming a device and emergency operations are not possible while you are in the Read From Media application.

6. Select [Open File…].

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

8. Select [Open File]. The Read From Media screen displays information from the saved session.

4.11 Printing reports

The programmer provides flexibility in printing reports that are available from the system. You can print informative standard reports, and you can access print functions in a variety of ways. You can also specify when to print a particular report and which printer to use.

4.11.1 Setting preferences for printing, reports, and tests

The Preferences screen provides print options, such as number of copies, printer type, and whether you want to print now or later. You can choose to print reports anytime during a patient session. Your printing preferences are then applied automatically whenever you select the [Print…] button or the Print icon.

If you prefer to set print preferences each time you print a report, select the check box next to "Pop up these options when any Print button is selected".

For more information about setting up an external full-size printer, see the user guide for your Medtronic programmer.

You can set the Report preferences to be specific to the report being produced, as described in the procedures included in the following sections.

4.11.1.1 How to set printing preferences
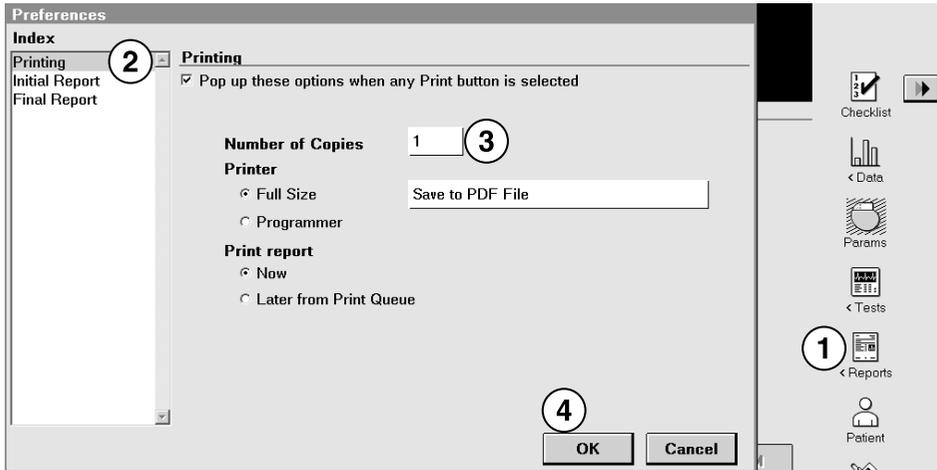
1. After starting a patient session, select Reports > Preferences…

2. From the Index selection box, select the Printing option.

3. Select your printing preferences.

4. Select [OK].

Basic printing preferences take effect immediately.

4.11.2 Printing an Initial Interrogation Report

The programmer automatically prints certain reports after the first interrogation in a patient session if you set Initial Report preferences to do so. The reports that print automatically after the first interrogation in a patient session are collectively called the Initial Interrogation Report. The Quick Look II Report is always a part of the Initial Interrogation Report. You can also select other reports to print as part of the Initial Interrogation Report.

4.11.2.1 How to set Initial Report preferences
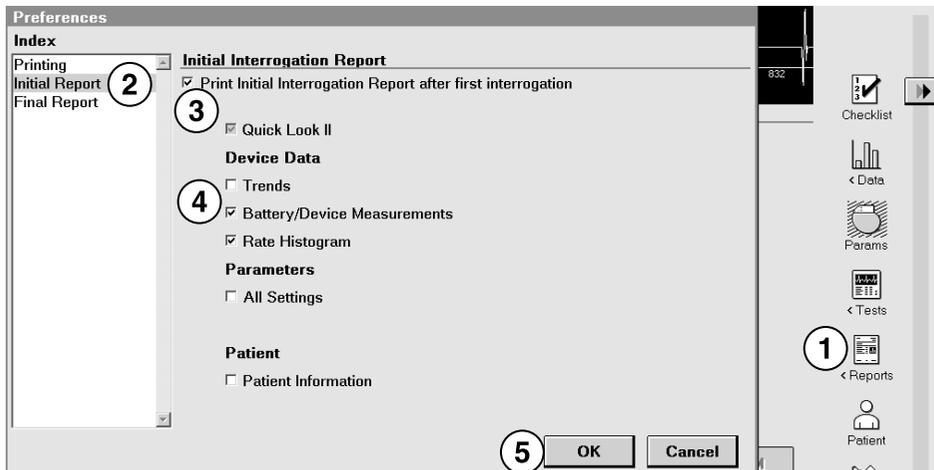
1. After starting a patient session, select Reports > Preferences…

2. From the Index selection box, select the Initial Report option.

3. Select the check box next to "Print Initial Interrogation Report after first interrogation", if desired. The report prints automatically at the beginning of a patient session after the device is interrogated.

4. Select the additional reports to include in the Initial Interrogation Report.

5. Select [OK].

6. To print an Initial Interrogation Report for a patient session that is in progress, end and restart the patient session.

The Initial Interrogation Report prints automatically after interrogation. Initial Report preferences take effect at the start of a new session and remain in effect until you change them and start a new session.

4.11.3 Printing reports during a patient session

The programmer allows you to specify a particular set of reports for printing and to print a report based on the screen you are viewing.

4.11.3.1 How to print a customized set of reports
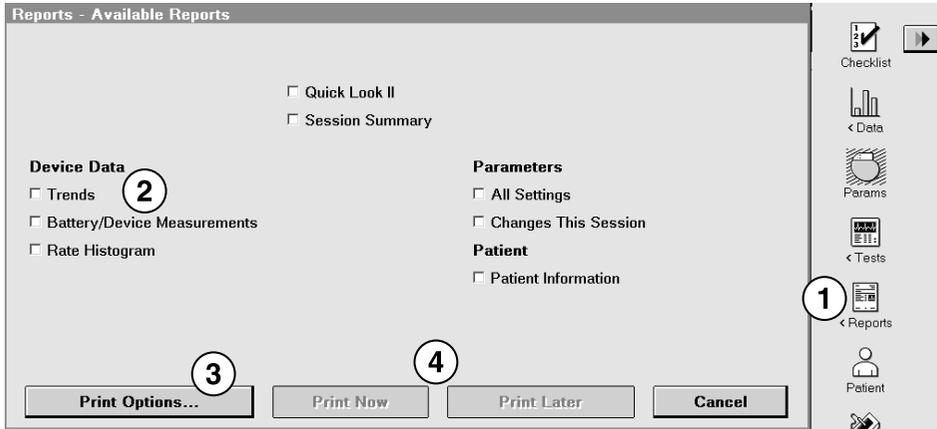
1. To print a customized set of reports, select Reports > Available Reports…

2. Select the reports you want to print. A report can be printed only if its data has been collected. If no data has been collected, the name of the report appears gray.

3. Select [Print Options…] to set printing preferences. If [Print Options…] is not available, continue with Step 4.

4. Select [Print Now] for immediate printing, or select [Print Later] to add the print request to the print queue.

4.11.3.2 How to print a report on a specific programming screen

1. Select [Print…] or select the Print icon on the programmer screen.

2. If the printing preferences window appears, select printing preferences as desired. If the printing preferences window does not appear, the report prints according to the previously set printing preferences.

4.11.4 Printing a summary report for the patient session

The system allows you to print a summary report at the end of a patient session.

4.11.4.1 How to print a summary report for the patient session

1. Select Reports > Final Report….

2. If the printing preferences window appears, select printing preferences as desired. If the printing preferences window does not appear, the Session Summary Report and other reports you have selected print according to the previously set printing preferences. For more information, see Section 4.11.4.2.

4.11.4.2 How to set Final Report preferences

You can select the reports you want printed as a part of the Final Report. The Session Summary Report always prints when a Final Report print request is made. The Session Summary check box is selected and cannot be unselected to ensure that at least one report is printed when a Final Report print request is made.
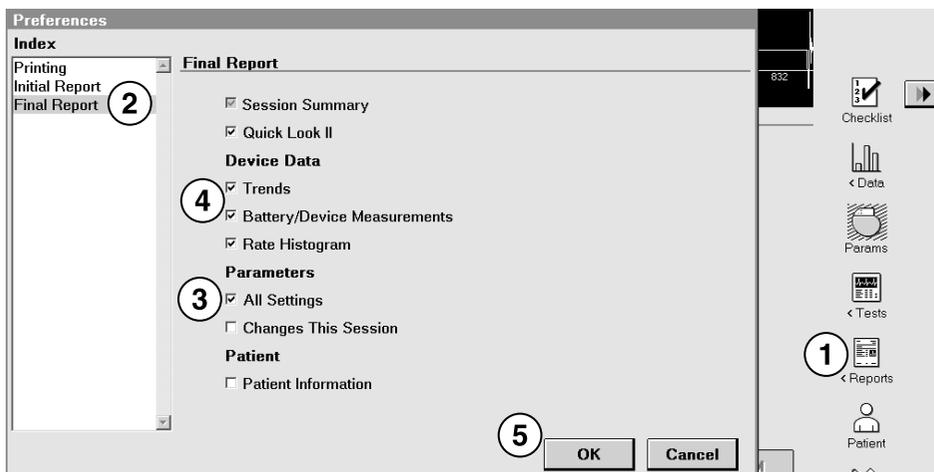
1. Before ending a patient session, select Reports > Preferences…

2. From the Index selection box, select the Final Report option.

3. If this is the first time you are establishing Final Report preferences, select the All Settings check box.

4. Select the additional reports to include in the Final Report.

5. Select [OK].

Note: The selections you make using the Final Report Preferences feature remain between sessions and across all applications.

To print the selections you made using the Final Report Preferences feature, follow the steps in Section 4.11.4.1.

4.11.5 Managing the Print Queue

The Print Queue window indicates the printing status of reports that you select to print as you progress through a patient session.

When you end the patient session, the Print Queue window is still available. It lists any reports held from that session and other previous sessions.

4.11.5.1 How to use the Print Queue window during a patient session

At the start of a patient session, the Print Queue window is empty because it lists reports selected to print in the current session only. If you select [Print Later] for a report, the report is held in the print queue.

To display the Print Queue window during a patient session, select Reports > Print Queue. From this window, you can check the status of print jobs from the current patient session only. You can print or delete a print job from the queue. A report cannot be deleted if its status is "printing" or "waiting".

4.11.5.2 How to use the Print Queue window outside of a patient session

The Print Queue window is available outside of a patient session. To display the Print Queue window when you are not in a patient session, select the Print Queue icon from the Select Model screen. The Print Queue window lists any reports held from that session and other previous sessions. You can print or delete a print job from the queue. A report cannot be deleted if its status is "printing" or "waiting".

4.11.5.3 Interpreting the Print Queue Status column

The Print Queue Status column lists the print status for each report to be printed by the programmer:
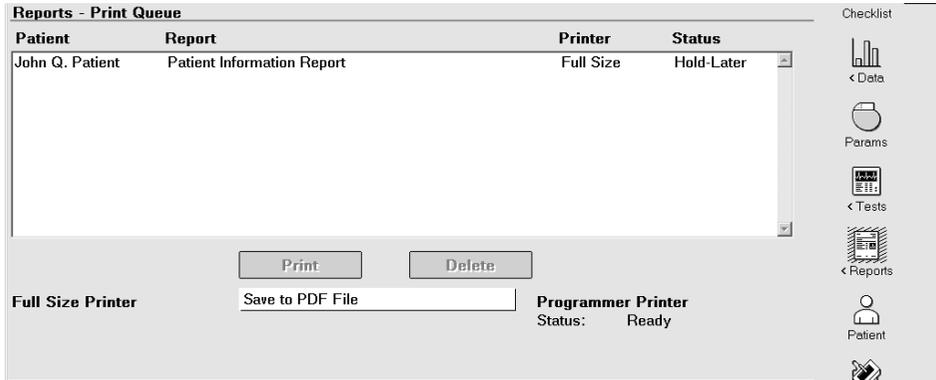
- Printing: Indicates that a report is currently being printed.

- Deleting: Indicates that a report is currently being deleted (after the [Delete] button is selected).

- Waiting: Indicates that a report is waiting to be printed while another report is printing.

- Hold-Later: Indicates that a report is on hold until you request that it be printed (using the [Print] button). A Hold-Later status can also mean that the printing of a report was interrupted by the start of a recording or that the printer is not operational (because it is out of paper, for example).

- Done: Indicates that a report has been printed.

5   Implanting the device

5.1 Preparing for an implant

The following implant procedures are provided for reference only. Proper surgical procedures and sterile techniques are the responsibility of the physician. Each physician must apply the information in these procedures according to professional medical training and experience.

In general, Medtronic recommends that implanting physicians choose the level of anesthesia that minimizes patient risk and is commonly used in their implanting centers. In the clinical trial, sedation has ranged from local anesthesia in the groin to fully intubated, deep central anesthesia.

Ensure that you have all of the necessary instruments, system components, and sterile accessories to perform the implant.

5.1.1 Instruments, components, and accessories required for an implant

The following non-implanted instruments and equipment are used to support the implant procedure:

- Medtronic CareLink Model 2090 Programmer with a Model 2067 or 2067L programming head

- Model SW022 software application

- external defibrillator

    Note: For patients deemed at a more significant risk of VT or VF, place adhesive defibrillation electrode patches on the patient prior to device implant.

The following sterile system components and accessories are used to perform the device implant:

- Micra Model MC1VR01 transcatheter pacing system, which consists of the implantable device and delivery system

- sterile programming head sleeve (not required if a sterilized programming head is used for the implant or if the programming head is not used in a sterile field)

- 7.8 mm (23 French) introducer sheath that is 56 cm (22 in) long or longer, such as the Medtronic Micra Introducer

- 0.89 mm (0.035 in) stiff guidewire that is 180 cm (70.866 in) long

5.1.2 Setting up the programmer and starting the application

For instructions about how to set up the programmer, see the programmer reference guide. After setting up the programmer, follow these steps to start the application:

- Install the SW022 application software in the programmer.

- Establish telemetry with the device and start a patient session.

5.1.3 Warnings and precautions when preparing for the device implant

Before implanting the MRI SureScan device in a patient, refer to the Medtronic MRI Technical Manual provided for MRI-specific requirements and instructions.

Review the following information before implanting the device:

Warning: Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

Warning: Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing, implant procedures, and post-implant testing.

Caution: Do not implant the device after the "Use by" date on the package label. Battery longevity may be reduced.

5.1.4 How to prepare the device for implant

Before opening the sterile package, perform the following steps to prepare the device for implant:

1. Interrogate the device and print an Initial Interrogation Report.

   Caution: If the programmer reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.

2. Check the Initial Interrogation Report to confirm that the battery voltage is at least 3.0 V at room temperature.

   If the device has been exposed to low temperatures, the battery voltage will be temporarily lower. Allow the device to warm to room temperature for at least 48 hours and check the battery voltage again. If an acceptable battery voltage cannot be obtained, contact a Medtronic representative.

   Note: The device automatically measures the battery voltage once a day at 02:30. The automatic daily battery voltage measurement is displayed on the Battery and Device Measurements screen.

3. Program the device from the Device Off mode to VVI mode.

4. Select Params > Data Collection Setup > Device Date/Time… to set the internal clock of the device to the correct date and time.

5. Program the pacing parameters to values appropriate for the patient.

   Notes:

   - Do not enable a pacing feature that affects the pacing rate before implanting the device. Doing so may result in an elevated pacing rate that is faster than expected.

   - Patient information is typically entered at the time of initial implant, and it can be revised at any time.

6. Program the device to the Device Off mode to prepare it for the implant.

5.1.5 How to open the sterile package

Open the sterile package containing the Micra transcatheter pacing system by following these instructions:

1. Open the pouch on the end with the angle-shaped seal, the end at which the device is located, and fold back the flaps.

Figure 19. Opening the pouch
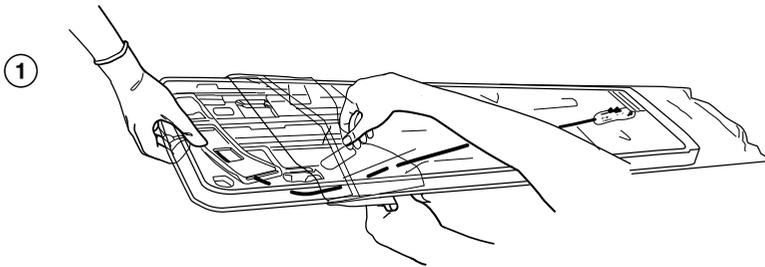
2. Remove the tray containing the transcatheter pacing system from the pouch and place the tray in the sterile field. Then, remove the tray cover.

Figure 20. Removing the tray and placing it in a sterile field
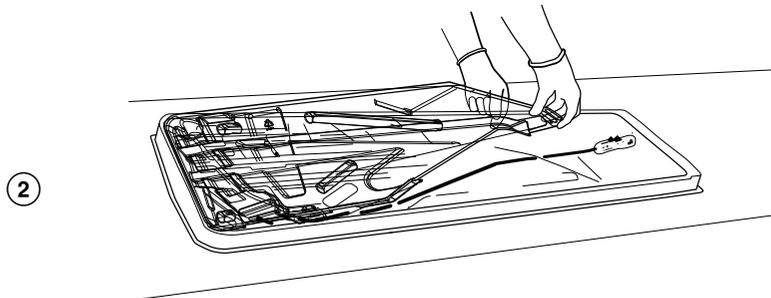
3. Hold the handle of the delivery catheter system with one hand and remove it from the tray, while holding the clamshell with the other hand.

Figure 21. Removing the delivery catheter system from the tray
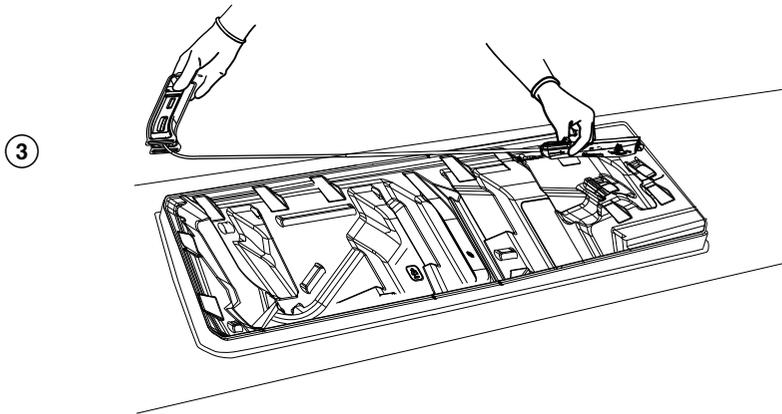
4. Open the clamshell and hold down the cover with one hand. With the other hand, hold the distal end of the delivery catheter system in mid position, as indicated by the arrows on the clamshell, and remove the system.

Figure 22. Removing the delivery catheter system from the clamshell
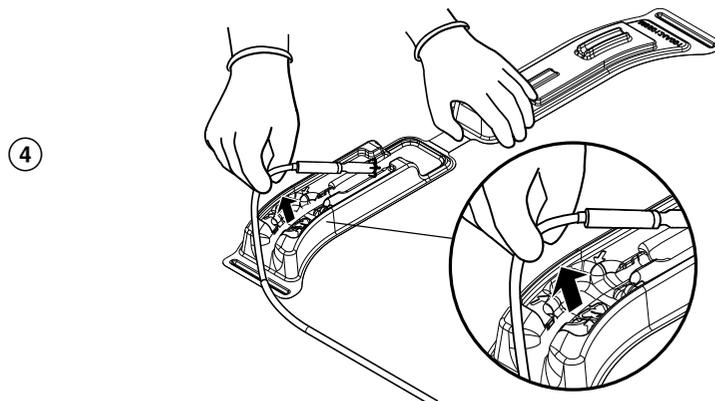
Cautions:

- After removing the delivery catheter system from the clamshell, check the system shaft for any damage or kinking. If there is any damage or kinking in the system shaft, do not use the transcatheter pacing system.

- Do not place the delivery catheter system back in the sterile tray after removing the system because doing so may expose the device to static buildup in the tray.

5.2 Implanting the device

The device implant consists of the following tasks:

- performing the implant procedure
  - preparing the delivery system and device for implant
  - inserting a percutaneous introducer into the patient's femoral vein
  - navigating the delivery system and deploying the device in the right ventricle
- assessing the device fixation
  - performing the pull and hold test
  - taking the initial electrical measurements
  - repositioning the device if necessary for proper fixation
- completing the implant procedure
  - completing the device programming
- assessing the device performance

5.2.1 How to implant the device

This section describes how to prepare the delivery system and device for implant, insert the introducer into the patient's femoral vein, navigate the delivery system to the right ventricle, and deploy the device at the implant location.

Figure 23. Overview of the Micra transcatheter pacing system
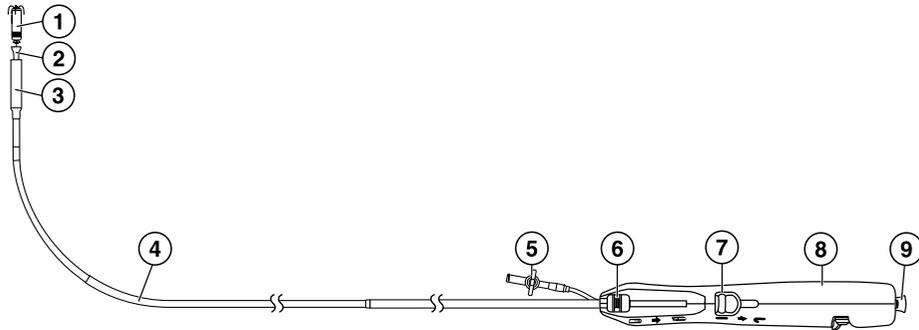
1 Micra device	6 Device deployment button
2 Device recapture cone	7 Catheter curve deflection button
3 Device cup	8 Delivery system handle
4 Delivery catheter	9 Tether port
5 Flush port	

Figure 24. The Micra device

1 Micra device capsule	3 Pacing cathode
2 Fixation tines	4 Pacing anode

5.2.1.1 How to prepare the Micra transcatheter pacing system for implant

Observe the following warnings and instructions to prepare the delivery system and device for navigation through the femoral vein:

Warnings:

- The delivery system lumens contain air when the system is shipped. Use proper de-airing techniques before and during use to reduce the risk of air embolization.

- Do not retract the device fixation tines all the way into the device cup until you are ready to insert the delivery catheter system into the introducer. Unlike the helix electrode of an active fixation lead, the device tines do not require pre-implant exercise. Excessively retracting the device tines into the device cup before implant could adversely affect their fixation performance.

1. Connect a syringe of saline to the flush port and flush the delivery system.

2. Press down the deployment button on the delivery system handle to unlock the button. See Figure 25. Then, slide forward the deployment button to retract the device into the device cup.

3. While keeping the device retracted into the device cup, flush the delivery system, again.

Figure 25. Micra delivery catheter system: deployment handle
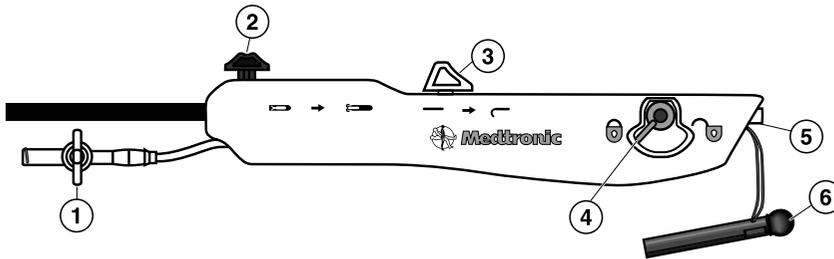
1 Flush port	4 Tether lock button
2 Device deployment button	5 Tether port
3 Catheter curve deflection button	6 Tether retainer pin

5.2.1.2 How to insert a percutaneous introducer into the patient's femoral vein

Note: The procedure for inserting the Micra transcatheter pacing system into the femoral vein requires the use of a 7.8 mm (23 French) introducer sheath that is 56 cm (22 in) long or longer, such as the Medtronic Micra Introducer. For instructions on how to insert the percutaneous introducer, refer to the technical manual provided with this product.

Note: Consider ultrasonic or echo-guided access to reduce risk of arterial puncture.

Warnings:

- To minimize the risk of air embolization, ensure proper de-airing of the introducer before inserting the delivery system into it.

- Before inserting the delivery system into the patient's femoral vein, aspirate and then flush the introducer through the introducer sideport. Use of a syringe that is 30 cm^3 or larger is recommended.

Before navigating the delivery system through the femoral vein, perform the following steps:

1. Advance the introducer with the dilator over the guidewire to the mid atrium.

2. Remove the dilator and guidewire.

3. Attach a continuous heparinized saline drip to the sideport on the introducer to prevent clot formation.

5.2.1.3 How to navigate the delivery system and deploy the device

Notes:

- While positioning and deploying the device, closely observe the fluoroscopic image for guidance.

- Some patients may have unique anatomy that may make it more challenging to navigate to the target location; contrast injection may be useful to assist in visualizing anatomical details.

To navigate the delivery system and deploy the device at the implant location in the right ventricle, follow these instructions:

1. Continue to flush while you are inserting the delivery system into the introducer.

   Note: Make sure that the tether lock button on the handle of the delivery system is in the lock position. See Figure 25, page 84.

   Caution: To ensure that no damage is caused to the delivery system, hold the shaft of the system directly behind the device cup while inserting it into the introducer.

2. Advance the delivery system through the introducer into the right atrium.

3. Retract the introducer out of the atrium and down into the inferior vena cava (IVC).

   Note: Make sure that the introducer is retracted far enough into the IVC so that you can deflect the curve of the delivery system.

4. Form a curve in the delivery system by sliding back the curve deflection button on the handle. See Figure 25, page 84.

   Warning: When steering the delivery system, do not apply excessive pressure on the heart. Doing so may cause injury to the cardiac tissue or damage to the delivery system, or both problems. If you feel resistance, use the fluoroscopic image to assess the tissue and the delivery system before proceeding.

5. Deflect the delivery system to cross the tricuspid valve. Release the deflection and navigate the delivery system to the implant location in the right ventricle.

6. Confirm the location of the delivery system from different fluoroscopic views (AP, LAO, and RAO).

7. Remove the tether retainer pin from the delivery system handle. See Figure 25, page 84.

8. Unlock the tether lock button.

   Warning: If you do not unlock the tether lock button, the device may be dislodged when you attempt to retract the delivery system after deploying the device.

9. Applying adequate pressure at the tip of the delivery system, press down the deployment button on the handle. Then, slide back the button half way. Release the tip pressure and continue to slide back the button all the way to deploy the device at the implant location.

   Caution: Do not to apply excessive pressure on the delivery system. Excessive pressure may cause damage to the delivery system, bending or kinking the shaft.

10. Retract the delivery system as far back as necessary to ensure that it has no interaction with the deployed device.

    Warning: Before performing the pull and hold test to assess the adequacy of the device fixation, be sure to retract the delivery system far enough from the device to avoid an interaction with it. If any interaction with the device occurs during the pull and hold test, the test result may be incorrect.

For instructions on how to assess the device fixation, see Section 5.2.2, "How to assess the device fixation", page 86.

5.2.2 How to assess the device fixation

After positioning the device in the right ventricle, it is important that you assess the adequacy of the device fixation in the patient's cardiac tissue. You can perform this assessment based on the pull and hold test result, EGM waveform, and initial electrical measurements.

5.2.2.1 How to perform the pull and hold test

The pull and hold test is designed to be an aid to determine whether the device is deployed properly and fixed adequately at the implant location.

Note: To help you assess the adequacy of the device fixation during the pull and hold test, magnify the fluoroscopic image of the device and record a cine loop of ≥15 FPS to view the device tines.

1. While gently putting tension on the tether of the delivery system, view the fluoroscopic image closely to examine the fixation of the device tines in the cardiac tissue. For an example of the tine fixation, see Figure 26.

    If 2 or more of the 4 device tines are engaged firmly in the cardiac tissue, you can determine that the device fixation is adequate. If only one of the device tines, or none of them, is engaged, repositioning of the device is required. If 2 tines cannot be seen to be engaged, then another view, such as LAO, may be required to confirm. This action should be performed before repositioning the device. For instructions on how to reposition the device, see Section 5.2.2.3, "How to reposition the device during the implant procedure", page 92.

Figure 26. Assessment of the device tine fixation
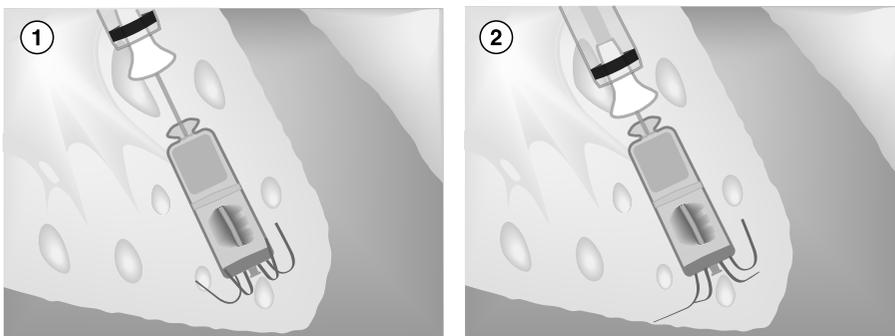
1 The device tines are curved toward the device when it is deployed at the implant location.
2 The device tines that are turned outward, as viewed on the fluoroscopic image while tension is applied to the device during the pull and hold test, indicate that they are engaged in the cardiac tissue. As shown in the illustration, the 3 tines that are in an outward position are engaged in the cardiac tissue, while the tine that remains curved toward the device is not engaged.

2. If the pull and hold test reveals that the device is fixed adequately, take the initial electrical measurements to check the sensing and pacing values. For information about how to take the initial electrical measurements from the programmer, see Section 5.2.2.2.

5.2.2.2 How to take the initial electrical measurements

The electrical measurement tests, performed after the pull and hold test, help you determine whether the sensing, electrode impedance, and pacing threshold values are acceptable for the device implant. To prepare for the electrical measurement tests, follow these instructions:

1. Place the programming head over the patient's heart to establish telemetry communication between the device and the programmer. To establish acceptable telemetry, it may be necessary to adjust the position of the programming head over the patient's heart. Position the programming head in such a way that 2 or more of the indicator lights for telemetry strength are illuminated, as required to ensure adequate telemetry strength when taking electrical measurements during the device implant.

2. Activate the implanted device by programming it from the Device Off mode to VVI, VVIR, or VOO mode on the Parameters screen.

3. View the patient's EGM waveform displayed in the Live Rhythm Monitor window to assess the stability of the heart rhythm.

    Caution: Before taking the electrical measurements, be sure to pull back the delivery system from the device. If the delivery system is not pulled back far enough, the electrical measurements may be incorrect.

From the Device Measurements screen, you can perform the electrical measurement tests for sensing, electrode impedance, and pacing threshold automatically by pressing a single button. The programmer executes the selected tests in sequence. The test results shown on the Device Measurements screen provide a basis to assess the adequacy of the device fixation, in addition to the pull and hold test result and EGM waveform.

The Device Measurements screen also allows you to perform only the selected electrical measurement tests. For more information about these tests, see Section 8.1, "Performing the device measurement tests", page 153.

Figure 27. Device Measurements screen and Recommended Values window

1. Select the Tests icon from the tool palette to access the tests menu. Then, select Device Measurements to open this screen.

2. Select Sensing Test. If you want to change the default test values for the Sensing Test parameters Mode and Lower Rate, select the corresponding parameter field to set a new value.

   Warning: Before starting the Sensing Test, select a temporary pacing rate that is likely to allow intrinsic sensed events and may be well tolerated by the patient. If the patient shows poor tolerance to the selected pacing rate when the test is in progress, stop the test by pressing the [STOP] button on the programmer screen. To complete this test, the device must detect 2 consecutive ventricular sensed events with an interval of at least 500 ms (a heart rate of 120 bpm or slower) between them. If such an interval is not identified after 30 s, the device stops the test. If a pacing rate suitable to the patient is not available to select, consider omitting the Sensing Test from the device measurement tests.

3. Select Impedance Test.

4. Select Threshold Test. In the test value field for the Threshold Test, you can select the type of test to be performed: Capture Management or Amplitude – Auto Decrement. If you accept the default test value, Capture Management, the threshold test is performed automatically. If you want to perform the manual threshold test, select Amplitude – Auto Decrement.

   Note: If you selected Amplitude – Auto Decrement for the threshold test type, the Pacing Threshold window opens when this test is ready to be performed. This window allows you to change the values for the test parameters and execute the manual threshold test by pressing the [TEST Press and Hold] button. For more information about how to perform the manual threshold test, see Section 8.1, "Performing the device measurement tests", page 153.

5. Press [START Tests]. The programmer conducts the selected tests in sequence, starting with the Sensing Test. After starting each test, the programmer displays a message as to which test is in progress. Wait for the programmer to complete each test.

6. Assess whether the test values shown on the screen for R-wave, Impedance, and Threshold are acceptable. For guidance, see the Recommended Values window by pressing the information icon on the screen. If a test value is within the recommended range, a check mark appears next to this value. If a test value is not within the recommended range, a warning symbol appears next to this value. The Recommended Values window shows the following test values for device implant:

- R-Wave: >=5 mV
- Impedance: 400 – 1500 Ω
- Threshold: <=1.00 V

7. Select [Save…] to save the test values to the device memory.
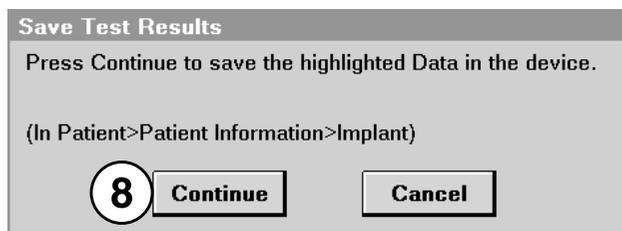
8. Press [Continue] on the Save Test Results window. You can view the test values stored by the device in the Implant window by accessing it from the Patient Information screen. See Section 4.8, "Viewing and entering patient information", page 57.

9. Select [Print…] to print the test values.

Notes:

- If the electrical measurements are not acceptable, prepare the device for repositioning it in the right ventricle. See instructions in Section 5.2.2.3, "How to reposition the device during the implant procedure", page 92 and repeat the pull and hold test and electrical measurement tests to assess the device fixation.

- If the electrical measurements continue to be unacceptable, it may be an indication that there are blood clots on the device electrodes. Remove the device from the patient's body and flush the delivery catheter system and the device with heparinized saline to make sure that there are no blood clots on the device electrodes. Repeat the procedures in Section 5.2.1.3, "How to navigate the delivery system and deploy the device", page 85 , Section 5.2.2.1, "How to perform the pull and hold test", page 87, and Section 5.2.2.2, "How to take the initial electrical measurements", page 88.

5.2.2.3 How to reposition the device during the implant procedure

If the device repositioning is required to achieve adequate fixation or acceptable electrical measurements, or both outcomes, it is necessary to deploy it at a different implant location in the right ventricle and assess the adequacy of the device fixation at the new location.

1. Program the device to the Device Off mode.

2. Extend the recapture cone completely out of the device cup. Apply tension to the tether while advancing the delivery system back to the device until the recapture cone is in contact with the device.

3. View the fluoroscopic image from 2 views, such as LAO and RAO, to make sure that the recapture cone and device are aligned axially, as shown in Figure 28.

Figure 28. Retracting the device into the device cup
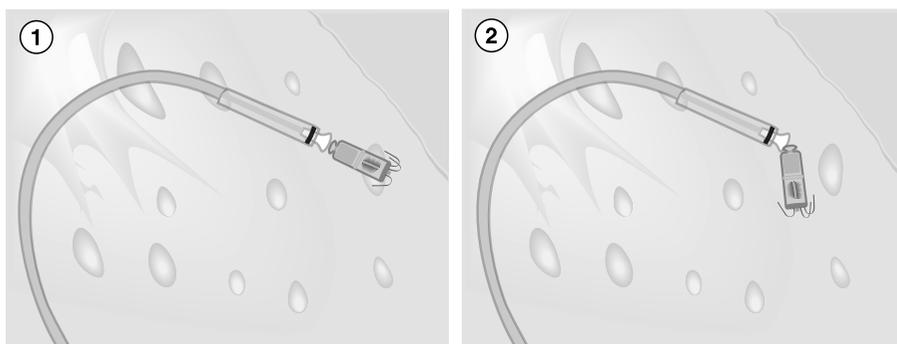
1 Correct alignment of the recapture cone with the device
2 Incorrect alignment of the recapture cone with device

4. Lock the tether lock button.

5. Retract the device into the device cup by pressing down the deployment button and then sliding it forward. To make sure that the device is retracted completely, view the fluoroscopic image and verify that the device tines are fully inside the device cup.

   If you recaptured the device into the device cup successfully, proceed to Step 6.

   Caution: If you feel any resistance when advancing or retracting the deployment button, stop sliding this button. Cardiac tissue may be caught between the device cup and the device, or the device cup and the device may not be aligned axially. To avoid damage to the cardiac tissue or the device cup, or both, while attempting to recapture the device, follow these instructions:

a. Unlock the tether lock button and release the device from the recapture cone.

b. Flush the delivery system.

c. Apply tension on the tether and attempt to advance the delivery system back to the device from a different angle than in the initial attempt.

d. View the fluoroscopic image from 2 views, such as LAO and RAO, to make sure that the recapture cone and the device are aligned axially and that there is no gap between them. If a gap exists, pull harder on the tether while bringing the recapture cone toward the device.

e. Attempt to recapture the device into the device cup while maintaining tension on the tether and gently sliding the deployment button forward.

f. If you are unable to recapture the device, position the delivery system as close to the device as possible.

g. Lock the tether lock button and pull the delivery system and device out of the cardiac tissue.

h. If a gap exists between the device and the recapture cone, as viewed on the fluoroscopic image, unlock the tether lock button and retract the device by pulling on the tether.

i. Lock the tether lock button and retract the device into the device cup by sliding the deployment button forward.

j. Proceed to Step 6.

6. Advance the delivery system to the new implant location.

7. Unlock the tether lock button.

8. Applying adequate pressure at the tip of the delivery system, press down the deployment button on the handle. Then, slide back the button half way. Release the tip pressure and continue to slide back the button all the way to deploy the device at the implant location.

    Caution: Do not to apply excessive pressure on the delivery system. Excessive pressure may cause damage to the delivery system, bending or kinking the shaft.

9. Retract the delivery system as far back as necessary to ensure that it has no interaction with the device.

10. Perform the pull and hold test to assess the device fixation, as explained in Section 5.2.2.1, "How to perform the pull and hold test", page 87.

11. Take electrical measurements for sensing, electrode impedance, and pacing threshold and determine whether the test values are acceptable. For instructions, see Section 5.2.2.2.

5.2.3 How to complete the implant procedure

If you determine that the device fixation is adequate, based on the pull and hold test result, EGM waveform, and electrical measurements, complete the implant procedure and program the device parameters.

1. Before removing the tether, flush the lumens of the delivery system with heparinized saline.

   Warning: If the delivery system lumens are not flushed with heparinized saline to remove any blood clots on the tether, the device may be dislodged when the tether is pulled out.

2. Make sure that the delivery system is positioned close to the device. Then, cut one end of the tether and gently pull the tether out of the delivery system while viewing the fluoroscopic image to ensure that excessive force is not being applied to the implanted device.

   Caution: If you feel resistance when pulling out the tether, advance the recapture cone closer to the device to avoid dislodgment of the device.

3. Remove the delivery system from the introducer.
4. Remove the introducer from the femoral vein.
5. Apply adequate pressure at the venous access site to obtain hemostasis.
6. Program the sensing and pacing parameters as appropriate for the patient.

Warning: Device dislodgment after the implant is possible due to interaction with other therapeutic devices or instruments. For warnings, precautions, and guidance for medical procedures on cardiac device patients, see Section 2.6.

5.2.3.1 How to complete the device programming

Complete the device programming as follows:

1. Verify that the pacing parameters are programmed to values that are appropriate for the patient.

   Note: Make sure that the permanently programmed pulse width and amplitude parameters provide an adequate safety margin above the pacing threshold for the patient.

2. Enter the patient's information on the Patient Information screen.

3. Program the Data Collection Setup parameters.

5.2.4 How to assess the device performance

Before the patient is discharged from the hospital, follow these steps to assess the performance of the implanted device:

1. Monitor the patient's electrocardiogram until the patient is discharged. If the device is dislodged, it usually occurs during the immediate postoperative period.

2. Check the pacing and sensing values, and adjust the programmed values if necessary.

3. Interrogate the device and print a Final Report to document the postoperative status of the programmed device.

5.3 Implanting a new Micra device in a patient with an existing Micra device

When the Micra device implanted in a patient has reached the Recommended Replacement Time (RRT) condition, the patient may require the implant of a new Micra device. The new Micra device should be implanted at a different location in the right ventricle. The existing device must be inactivated before completing the implant procedure for the new device.

For instructions about how to prepare for the implant of the Micra device, see Section 5.1, "Preparing for an implant", page 77.

The major tasks required for the implant of the new Micra device are the same as those performed for the implant of the previous Micra device. However, the new device implant requires some additional steps in the implant procedures covered in the following sections:

- Navigating the delivery catheter system and deploying the device. See Section 5.3.2, "How to navigate the delivery catheter system and deploy the new Micra device", page 97

- Assessing the device fixation. See Section 5.3.3, "How to assess the device fixation", page 98

- Completing the implant procedure. See Section 5.3.4, "How to complete the implant procedure", page 98

For instructions about implant procedures that are the same as those performed when the previous Micra device was implanted, see the following sections:

- Preparing the delivery catheter system and device for implant. See Section 5.2.1, "How to implant the device", page 82

- Inserting a percutaneous introducer into the patient's femoral vein Section 5.2.1.2, "How to insert a percutaneous introducer into the patient's femoral vein", page 84

- Repositioning the device to achieve adequate device fixation or electrical measurements. See Section 5.2.2.3, "How to reposition the device during the implant procedure", page 92

- Assessing the device performance Section 5.2.4, "How to assess the device performance", page 95

5.3.1 Considerations for implanting the new Micra device

Since the existing Micra device continues to provide pacing until it reaches the EOS condition, it is necessary to avoid the possibility of competitive pacing with the newly implanted Micra device. Before starting the procedure for the new device implant, take one of the following actions:

- If the patient needs pacing support during the implant of the new Micra device, consider programming the existing device to a pacing rate that is low enough to sense the patient's intrinsic R-wave.

- If the patient is pacemaker-dependent, consider using a temporary pacemaker to provide pacing support during the implant of the new device.

- If the patient is not pacemaker dependent, consider programming the existing device to the "Device Off" mode.

5.3.2 How to navigate the delivery catheter system and deploy the new Micra device

Note: While positioning and deploying the device, closely observe the fluoroscopic image for guidance.

To navigate the delivery system and deploy the new Micra device at the implant location in the right ventricle, follow the instructions in this section.

1. Insert the delivery system into the introducer.

   Note: Make sure that the tether lock button on the handle of the delivery system is in the lock position. See Figure 25, page 84.

   Caution: To ensure that no damage is caused to the delivery system, hold the shaft of the system directly behind the device cup while inserting it into the introducer.

2. Advance the delivery system through the introducer into the right atrium.

3. Retract the introducer out of the atrium and down into the inferior vena cava (IVC).

   Note: Make sure that the introducer is retracted far enough into the IVC so that you can deflect the curve of the delivery system.

4. Form a curve in the delivery system by sliding back the curve deflection button on the handle. See Figure 25, page 84.

   Warning: When steering the delivery system, do not apply excessive pressure on the heart. Doing so may cause injury to the cardiac tissue or damage to the delivery system, or both problems. If you feel resistance, use the fluoroscopic image to assess the tissue and the delivery system before proceeding.

5. Deflect the delivery system to cross the tricuspid valve. Release the deflection and navigate the delivery system to the new implant location in the right ventricle.

6. Confirm the location of the delivery system from different fluoroscopic views (AP, LAO, and RAO).

   Note: When positioning and deploying the new Micra device, be sure to select an implant location where the new device and its tines do not have contact with the existing device and its tines so that no mechanical interaction occurs.

7. Remove the tether retainer pin from the delivery system handle. See Figure 25, page 84.

8. Unlock the tether lock button.

   Warning: If you do not unlock the tether lock button, the device may be dislodged when you attempt to retract the delivery system after deploying the device.

9. Applying adequate pressure at the tip of the delivery system, press down the deployment button on the handle. Then, slide back the button half way. Release the tip pressure and continue to slide back the button all the way to deploy the device at the implant location.

   Caution: Do not to apply excessive pressure on the delivery system. Excessive pressure may cause damage to the delivery system, bending or kinking the shaft.

10. Retract the delivery system as far back as necessary to ensure that it has no interaction with the deployed device.

    Warning: Before performing the pull and hold test to assess the adequacy of the device fixation, be sure to retract the delivery system far enough from the device to avoid any interaction with it. If any interaction with the device occurs during the pull and hold test, the test result may be incorrect.

5.3.3 How to assess the device fixation

After deploying the new Micra device at the implant location, assess the device fixation by performing the pull and hold test and initial electrical measurement tests for sensing, electrode impedance, and pacing threshold, as described in the following sections:

- To perform the pull and hold test, see Section 5.2.2.1, "How to perform the pull and hold test", page 87.

- To perform the initial electrical measurement tests, see Section 5.2.2.2, "How to take the initial electrical measurements", page 88 . For instructions about how to select the new Micra device for the initial electrical measurement tests, see Section 4.1.2, "How to select the new Micra device in a patient with an existing Micra device", page 38.

In addition to these tests, assess the EGM waveform on the programmer screen to determine the adequacy of the device fixation. If it is necessary to reposition the device to achieve adequate fixation or obtain acceptable electrical measurements, follow the instructions in Section 5.2.2.3, "How to reposition the device during the implant procedure", page 92.

5.3.4 How to complete the implant procedure

If you determine that the device fixation is adequate, based on the pull and hold test result, EGM waveform, and electrical measurements, complete the implant procedure according to the instructions in Section 5.3.4, "How to complete the implant procedure", page 98.

5.3.4.1 How to complete the device programming

Note: If the previously implanted Micra has not been inactivated, program this device to the "Device Off" mode before completing the parameter programming for the new device.

To program permanent values for the new Micra device parameters, follow these instructions:

1. Verify that the pacing parameters are programmed to values that are appropriate for the patient.

   Notes:

   - Make sure that the permanently programmed values for pulse width and amplitude parameters provide an adequate safety margin above the pacing threshold for the patient.

   - 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.

2. Enter the patient's information on the Patient Information screen.

3. Program the Data Collection Setup parameters.

5.4 Retrieving and repositioning the device after the tether removal

The Micra device is designed to provide options at EOS or for situations where the physician determines that Micra therapy is no longer required. As there is currently no imaging modality that allows for determining level of encapsulation, the Micra device can be programmed to Device OFF mode, permanently disabling therapy, and remain in the body. However, the Micra design allows for retrieval of the device with commercially available, off-the-shelf tools.

This section provides instructions on how to retrieve and reposition the implanted Micra device after removing the tether on the delivery system.

Warnings:

- Retrieval of the device after it is fully encapsulated may result in injury to the patient's cardiac tissue. If device retrieval is required after it is encapsulated, refer the patient to a medical center that has expertise in the removal of implanted leads or call a Medtronic representative for more information.

  For related information, see Section 2.2, "Explant and disposal under care", page 20

- Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the implanted device when it is being retrieved and repositioned.

5.4.1 Instruments, components, and accessories required for device retrieval

Make sure that you have all the instruments, system components, and sterile accessories required to perform the procedures for device retrieval and repositioning.

The following non-implanted instruments and equipment are required to retrieve and reposition the implanted device:

- Medtronic CareLink Model 2090 Programmer with a Model 2067 or 2067L programming head
- Model SW022 software application
- external defibrillator

The following sterile system components and accessories are required to retrieve and reposition the implanted device:

- Micra Introducer
- Micra Model MC1VR01 transcatheter pacing system

  Note: If you need to reposition the device after removing the tether during the initial implant procedure, you can use the original introducer and delivery system. To reposition the device at a later date, a new introducer and new Micra Model MC1VR01 system are required.

- device retrieval snare that is 175 cm long or longer with a 3 French or smaller outer diameter

Note: For information about how to use the Micra Introducer and retrieval snare, refer to the technical manuals provided with these products.

5.4.2 How to retrieve the device after the tether removal

This section provides instructions to retrieve the implanted device, using a retrieval snare:

1. Program the device to Device Off or OVO mode to prepare it for retrieval.

2. Insert the Introducer into the patient's femoral vein. For instructions on how to insert the introducer, see Section 5.2, "Implanting the device", page 82. Also, refer to the technical manual provided with the introducer.

3. Obtain the Micra system. If you are using a new Micra system, remove the device from the delivery system by cutting the tether and pulling the device out of the distal end of system.

4. Insert the proximal (non-looped) end of the snare wire into the distal end of the delivery system until this wire exits from the handle of the delivery system.

5. Front load the snare sheath over the snare wire through the lumen of the delivery system.

6. Insert the delivery system containing the snare into the introducer.

    Caution: Do not lock the tether lock button on the delivery system. Locking the tether may cause damage to the snare.

Figure 29. Device retrieval snare inserted into the delivery system
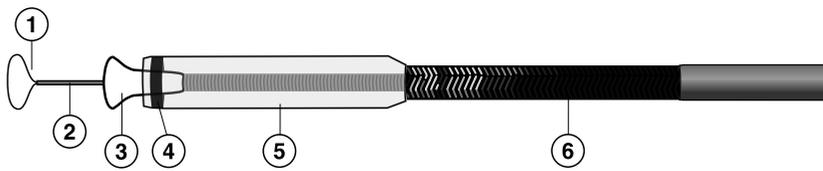
1 Snare loop	4 Marker for device retrieval
2 Tether	5 Device cup
3 Recapture cone	6 Delivery catheter

7. Advance the delivery system through the introducer to the right atrium.

8. Retract the introducer out of the right atrium down to the IVC.

9. Steer the delivery system and snare loop close to the implanted device.

10. Under fluoroscopic guidance, advance the snare loop and place it around the proximal end of the device.

Figure 30. Using the snare to retrieve the device
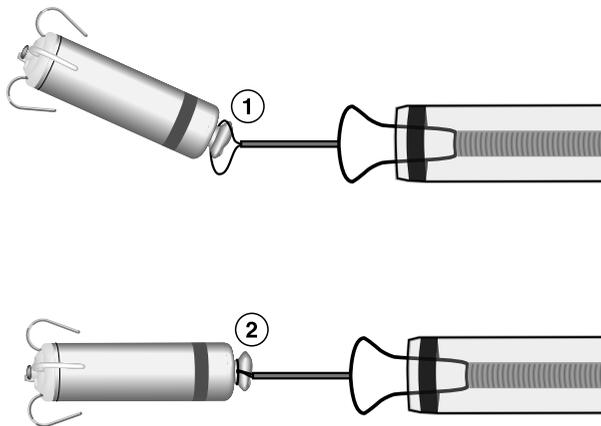
1 The snare loop is placed around the device.
2 The snare loop is tightened to hold the device firmly.

11. Tighten the snare loop around the device and maintain tension on it to ensure that it is holding the device firmly.

12. Retract the device into the delivery system by pushing down the deployment button and then sliding it up.

    Caution: Do not lock the tether lock button on the delivery system. Locking the tether may cause damage to the snare.

5.4.3 How to reposition the device after retrieval

After retrieving the implanted device into the delivery system, deploy it at a different implant location in the right ventricle and assess the adequacy of the device fixation at this location.

Note: The procedure for repositioning the device after retrieval is similar to repositioning the device during the initial implant procedure. However, use of the retrieval snare, instead of the tether, is required when performing the pull and hold test to assess the device fixation.

1. Advance the delivery system to the new implant location in the right ventricle.

2. Applying adequate pressure at the tip of the delivery system, push down the deployment button on the handle. Then, slide back the button to deploy the device at the implant location.

3. Retract the delivery system as far back as necessary to ensure that it has no interaction with the device.

4. Perform the pull and hold test by gently pulling on the snare, while viewing the fluoroscopic image closely to examine the fixation of the device tines. For further instructions on how to perform the pull and hold test, see Section 5.2, "Implanting the device", page 82.

5. Perform the programmer tests to take the initial electrical measurements. For instructions on how to take the electrical measurements, see Section 5.2, "Implanting the device", page 82.

   Note: If the electrical measurements are not acceptable, retrieve the device into the delivery system and reposition it according to instructions in this section. Repeat all the tests required to assess the device fixation.

6. If the result of the pull and hold test and electrical measurements are acceptable, release the snare from the device. For instructions on how to release the snare, see the technical manual provided for this product.

7. Retract the delivery system and snare out of the introducer.

8. Remove the introducer from the femoral vein.

9. Obtain hemostasis at the venous access site.

10. Program the sensing and pacing parameters as appropriate for the patient.

11. Assess the device performance after repositioning it. For instructions on how to assess the device performance, see Section 5.2, "Implanting the device", page 82.

5.5 Considerations for redeployment of the Micra device

If you have deployed the Micra device 3 to 5 times, consider the following:

- Ensure that there is adequate tip pressure.
- Consider a contrast injection to visualize the device cup against the endocardial wall.
- Remove the delivery system tool and check for clots.
- Consider an R-wave as low as 2 mV.
- Consider accepting a higher pacing threshold, depending on the pacing and longevity needs of the patient. (Consult the estimated longevity table.)

If you have deployed the Micra device 10 times or more, consider abandoning the system and reverting back to the traditional transvenous approach.

6 Conducting a patient follow-up session

6.1 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.

6.1.1 Follow-up tools

The system provides several tools that are designed to increase the efficiency of follow-up sessions.

Quick Look II screen – The Quick Look II screen appears when you start the programmer application. It provides a summary of the most important indicators of the system operation and the patient's condition since the last follow-up session.

You can perform the following tasks from the Quick Look II screen:

- Assess that the device is functioning correctly.
- Review information about pacing and sensing events.
- Review any observations in the Observations window.

You can compare the information on the Quick Look II screen with historical information about the patient contained in printed reports. For information about printing reports, see Section 4.11, "Printing reports", page 70. The printed reports should be retained in the patient's file for future reference.

Checklist – The Checklist feature provides a standard list of tasks to perform at a follow-up session. You can also customize your own checklists. For more information, see Section 4.5, "Navigating a patient session with Checklist", page 49.

6.1.2 Reviewing the presenting rhythm

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

Review the presenting rhythm by viewing the Live Rhythm Monitor and by printing the EGM and Marker Channel traces. 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.

6.1.3 Verifying the status of the implanted system

To verify that the device is functioning correctly, review the device status information and Observations available from the Quick Look II screen.

For detailed information about viewing and interpreting the information available from the Quick Look II screen, see Section 6.2, "Viewing a summary of recently stored data", page 106.

6.1.3.1 How to review the battery voltage and device status indicators

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 programmer screen.

On the Quick Look II screen, review the Remaining Longevity. On the Battery and Device Measurements screen (accessed by selecting the [>>] button next to the Remaining Longevity field on the Quick Look II screen), review the battery voltage. If the RRT indicator is displayed on the screen, schedule a patient appointment to implant a new device. For information about the minimum and expected longevity of the device, see Section A.3, "Replacement indicators", page 173.

6.1.3.2 How to assess the performance of the device

1. To review trends in electrode impedance, pacing threshold, and R-wave amplitude, select the [>>] button next to the corresponding trend graph on the Quick Look II screen. The programmer displays a detailed history of automatic impedance, pacing threshold, and sensing measurements. For more information about viewing the trends data, see Section 6.4, "Viewing detailed battery and device performance data", page 111 .

2. If you want to gather real-time information about the performance of the device during the patient follow-up session, you can perform the following device measurement tests:

   • Sensing Test: Compare the test results to previous R-wave amplitude measurements.

   • Electrode Impedance Test: Compare the results of the test to previous electrode impedance measurements to determine whether there have been significant changes since the last follow-up session.

- Pacing Threshold Test: Perform this test to check the patient's capture thresholds. Determine the appropriate amplitude and pulse width settings to ensure capture and maximize battery longevity.

For more information about the sensing, electrode impedance, and pacing threshold tests, see Section 8.1, "Performing the device measurement tests", page 153.

6.1.4 Verifying the clinical effectiveness of the implanted device

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

6.1.4.1 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 II screen and the Rate Histogram Data screen. Print 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 6.3, "Using the rate histogram to assess heart rates", page 109.

6.2 Viewing a summary of recently stored data

At the start of a patient session, it is useful to quickly view summary information about device operation and the patient's condition over the period since the last follow-up appointment. 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 II screen provides a summary of the most important indicators of the system operation and patient's condition. It includes links to more detailed status and diagnostic information stored in the device. Device status information indicates whether the system is operating as expected. Information about pacing and sensing provided gives a picture of the patient's clinical status since the last follow-up appointment. System-defined observations alert you to unexpected conditions and suggest how to optimize the device settings.

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

6.2.1 How to view the Quick Look II screen

The Quick Look II screen is automatically displayed after the patient session is started. You can also access the Quick Look II screen through the Data icon.

Select Data icon
  ⇒ Quick Look II

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

6.2.2 Information provided by the Quick Look II screen

The Quick Look II screen shows information in 5 sections.

Figure 31. Quick Look II screen
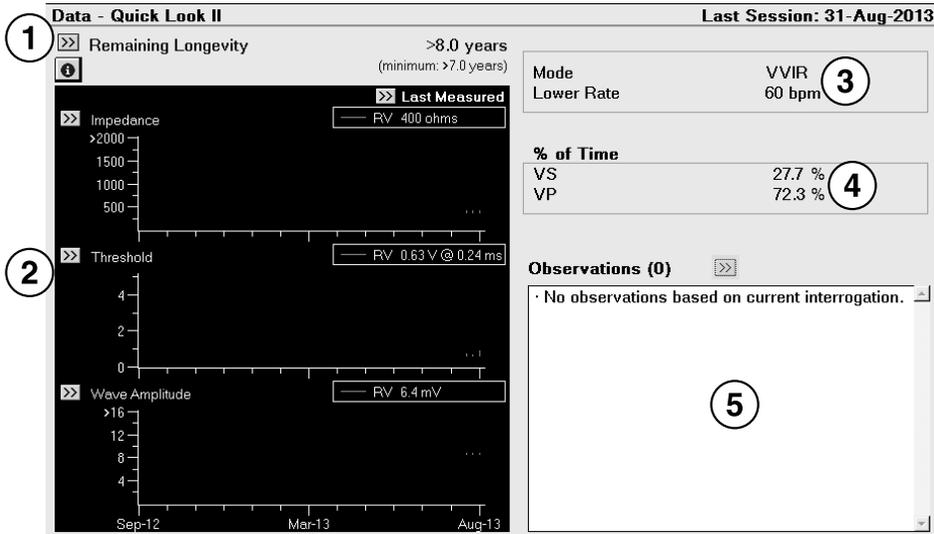
1 Battery information	4 Pacing and sensing percentages
2 Device performance trend graphs	5 Observations
3 Permanently programmed values for Mode and Lower Rate	

The [>>] button for Observations becomes active if you select an observation that has more information available. You can use the [>>] button to see the details relevant to this observation.

6.2.2.1 Assessing the device status

Battery information – The Remaining Longevity section on the Quick Look II screen provides the estimated battery longevity. Battery voltage is measured daily and displayed on the Battery and Device Measurements screen. You can access this screen by selecting the [>>] button next to Remaining Longevity. The Battery and Device Measurements screen and its associated printed report provide the most recent battery voltage measurement and the Recommended Replacement time (RRT) indicator with date and time, if applicable. For more information about viewing the battery measurement data, see Section 6.4, "Viewing detailed battery and device performance data", page 111.

If the device longevity estimator determines that there may be less than 6 months (180 days) until EOS, the date that the battery reached the RRT condition is shown on the Quick Look II screen and in the Initial Interrogation Report. For information about the RRT condition, see Section A.3, "Replacement indicators", page 173.

Device performance trend graphs – The trend graphs on the Quick Look II screen show the electrode impedance, pacing threshold, and sensing amplitude measurements recorded over the last 12 months. Information in the trend graphs helps you to assess the performance of the sensing and pacing electrodes and identify any unusual conditions.

The Last Measured column in the Impedance graph shows the most recent measurement for pacing impedance. Select the [>>] button in this column to see the details about impedance measurements and relevant programmed settings.

The Threshold graph shows the most recent pacing threshold measurement and the Wave Amplitude graph shows the most recent sensing amplitude measurement.

Select the [>>] button next to a trend graph to see detailed information about the specific trend. The detailed trend graphs show up to 15 of the most recent daily measurements and up to 80 weekly summary measurements, including minimum and maximum values for each week.

For more information about the device performance trend graphs, see Section 6.4, "Viewing detailed battery and device performance data", page 111.

6.2.2.2 Assessing the patient's condition

Pacing and sensing information – This information can help to assess the patient's clinical condition and evaluate the effectiveness of programmed device settings.

Information about ventricular pacing and sensing is shown as percentages of the total time during the reporting period.

6.2.2.3 Quick Look II observations

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

- Device status observations inform you when the device reached RRT or EOS condition. An observation is also reported if a device reset has occurred.

- Electrode status observations report any potential issues with the sensing integrity of the electrodes and abnormal capture management results. In addition, these observations may warn you about possible inconsistencies in the device performance.

- 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.

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

6.3 Using the rate histogram to assess heart rates

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

6.3.1 How to view the rate histogram screen and print the report

You can view the Rate Histogram screen by accessing it from the Data icon.

Select Data icon
   ⇒ Diagnostics
      ⇒ Rate Histogram
         ⇒ Open Data

Figure 32. Rate Histogram screen
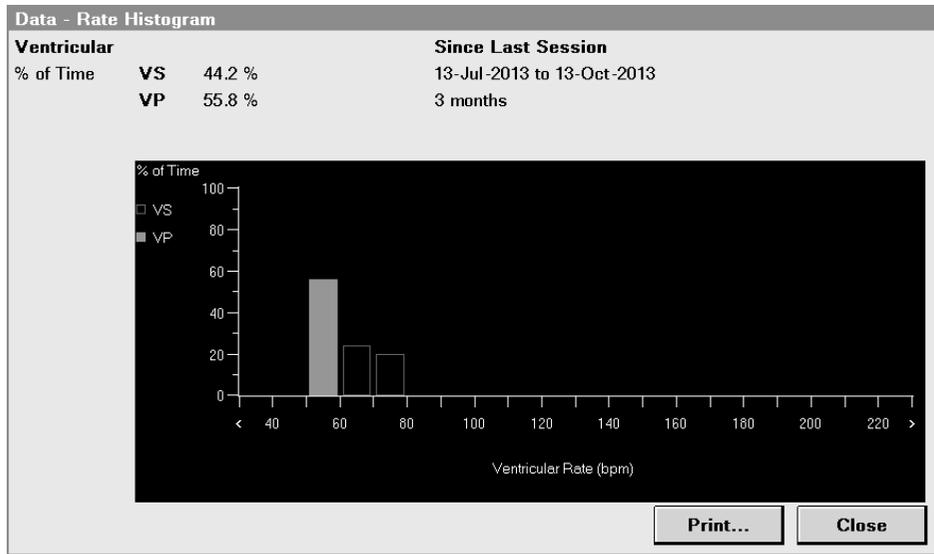
The Rate Histogram Report is available only as a printed report. You can print this report by accessing it from the Reports icon.

Select Reports icon
⇒ Available Reports…
⇒ Rate Histogram

Figure 33. Rate Histogram Report
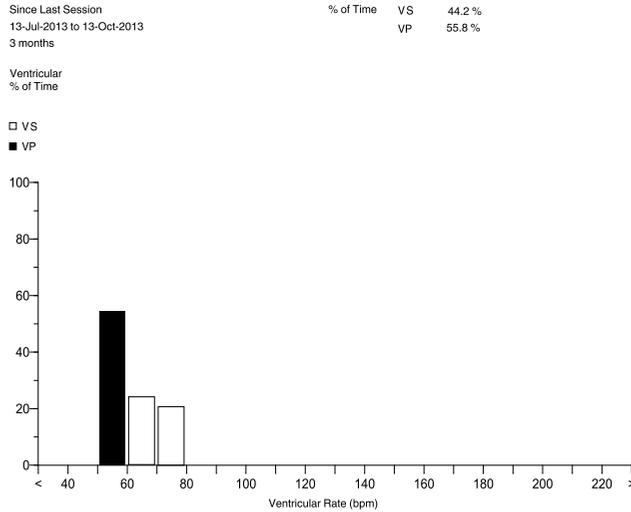
6.3.2 Information provided by the rate histogram screen and report

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 histograms for ventricular rate on the Rate Histogram screen and in the Rate Histogram Report. Data storage for the Rate Histogram data is automatic; no setup is required.

Rate histograms show 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 "<40" range; rates faster than 220 bpm are included in the ">220" 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.

6.4 Viewing detailed battery and device performance data

The device automatically measures the battery and device performance every day and records the daily measurements. Details of this data are available from the Battery and Device Measurements screen and the Electrode Impedance Trend, R-Wave Amplitude Trend, and Capture Threshold Trend screens.

6.4.1 Viewing battery and device measurement data

The Battery and Device Measurements screen displays the most recent values for key measures of battery and device performance. These may include automatically measured values or those measured during manual system tests.

6.4.1.1 How to view the battery and device measurement data

Select Data icon
  ⇒ Diagnostics
      ⇒ Battery and Device Measurements
          ⇒ Open Data

Figure 34. Battery and Device Measurements screen
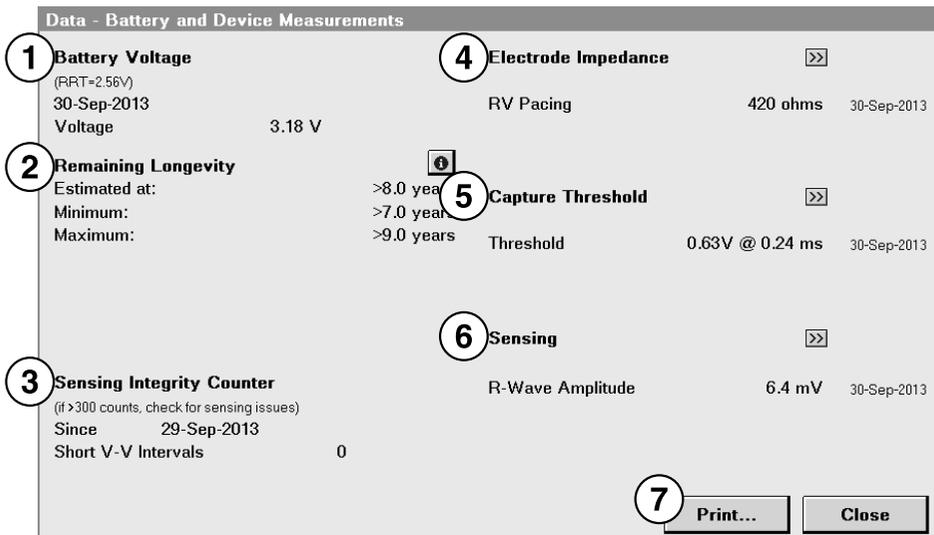
1 Battery voltage and replacement indicator information
2 Longevity estimates
3 Sensing Integrity Counter
4 Most recent electrode impedance measurement
5 Most recent capture threshold measurement
6 Most recent daily automatic sensing amplitude measurement
7 Button to print the Battery and Device Measurements Report

6.4.1.2 Battery voltage 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 Battery and Device Measurements screen.

If the device longevity estimator determines that there are less than 6 months (180 days) until the End of Service (EOS), the programmer displays the RRT symbol and the date when the battery reached the RRT condition. If the programmer 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 programmer displays the ERI indicator.[2] 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 the Device Off mode. It also changes Rate Hysteresis to Off if this feature is programmed to On. When the ERI indicator is displayed on the programmer, implant a new device immediately. For more information, see Section A.3, "Replacement indicators", page 173. After the 180-day PSP has expired, the device reaches End of Service (EOS) and switches to the Device Off mode, permanently deactivating the pacing operation. The programmer displays the EOS symbol.[2]

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 programmer screen.

6.4.1.3 Remaining longevity estimates

The programmer is able to estimate the remaining device longevity (the number of years until the battery reaches RRT) after 11 days of the device manufacture date. Longevity estimates are based on a history of battery voltage measurements made by the device since the manufacture date.

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[2] 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 Section A.3, "Replacement indicators", page 173.

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.

When the device reaches the RRT condition, the Battery and Device Measurements screen displays the RRT symbol, instead of an estimate of remaining longevity. To schedule the patient for the implant of a new device, do not use the estimate of remaining longevity. Instead, schedule a new device implant after the RRT condition is reached. See Section A.3, "Replacement indicators", page 173 for more information.

6.4.1.4 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.

6.4.1.5 Electrode impedance, capture threshold, and sensing amplitude measurements

The Battery and Device Measurements screen shows recent measurements for electrode impedance, sensing amplitude, and capture threshold. You can compare the most recent measurements on the Battery and Device Measurements screen to daily automatic measurements on the trends screens by selecting the navigation button [>>] for Electrode Impedance, Capture Threshold, or Sensing.

For information about performing manual tests to measure electrode impedance, sensing amplitude, and pacing threshold, see Section 8.1, "Performing the device measurement tests", page 153.

6.4.2 Viewing the 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 on the Electrode Impedance Trend screen, 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.

6.4.2.1 How to view the electrode impedance trend

Select Data icon
   ⇒ Diagnostics
      ⇒ Electrode Impedance Trend
         ⇒ Open Data

Figure 35. Electrode Impedance Trend screen
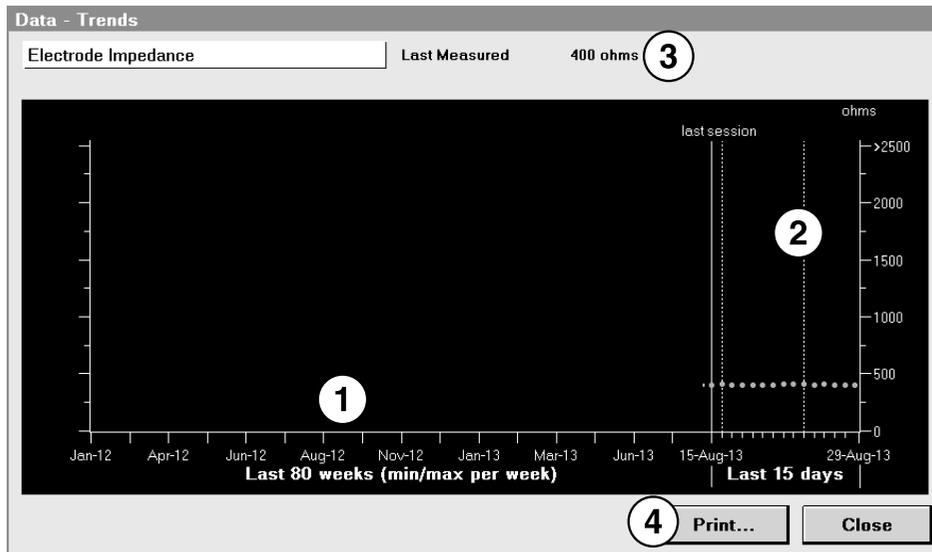
1 Weekly minimum and maximum values	3 Last measured impedance value
2 Most recently measured values	4 Button to print the trend reports

6.4.3 Viewing the sensing amplitude trend

After completing the electrode impedance measurement, which starts at 02:30 everyday, 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 R-Wave Amplitude Trend screen, 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.

6.4.3.1 How to view the sensing amplitude trend

Select Data icon
> ⇒ Diagnostics
> > ⇒ R-Wave Amplitude Trend
> > > ⇒ Open Data

Figure 36. R-Wave Amplitude Trend screen
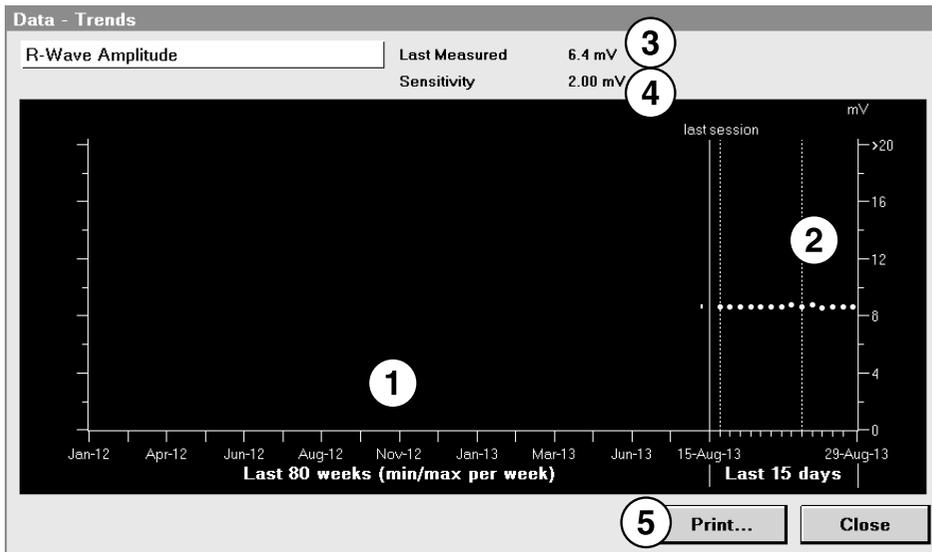
1	Weekly minimum and maximum values	4	Currently programmed Sensitivity value
2	Most recently measured values	5	Button to print trend reports
3	Last automatic daily measurement		

6.4.4 Viewing the 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 7.4, "Managing pacing output energies with Capture Management", page 140.

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

6.4.4.1 How to view the capture threshold trend

Select Data icon
  ⇒ Diagnostics
    ⇒ Capture Threshold Trend
      ⇒ Open Data

Figure 37. Capture Threshold Trend screen
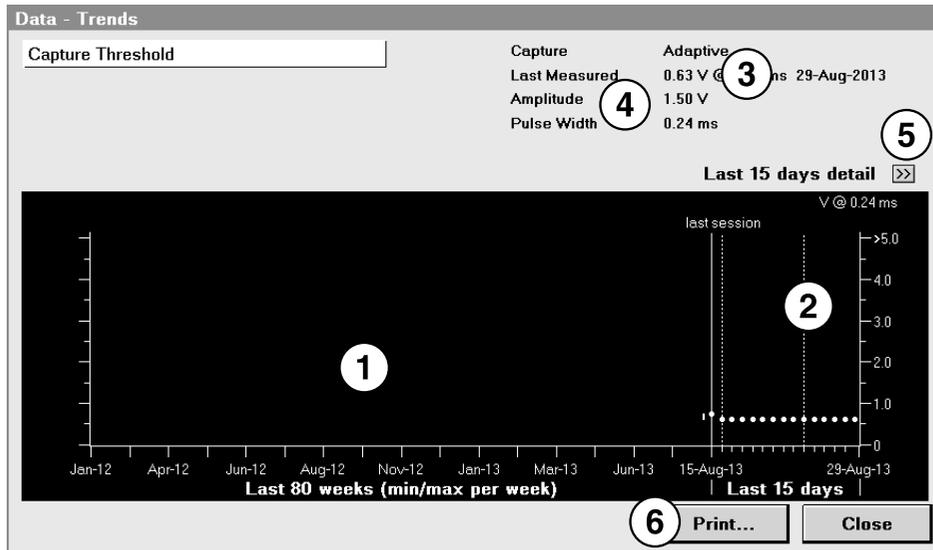
1 Weekly minimum and maximum values
2 Most recently measured values
3 Last measured threshold value
4 Capture Management and pacing output parameter values
5 Navigation button to view threshold measurement details from the last 15 days
6 Button to print the Capture Threshold Trend Report

Figure 38. Capture Management detail screen

Capture Management (Last 15 days detail)			
Capture		Adaptive	
Amplitude		1.50 V	
Pulse Width		0.24 ms	
Programmed Safety Margin		+ 0.50 V	
Date	Time hh:mm	Threshold V @ 0.24 ms	Notes
29-Aug-2013	00:00	0.63	Measurement OK
28-Aug-2013	00:00	0.63	Measurement OK
27-Aug-2013	00:00	0.63	Measurement OK
26-Aug-2013	00:00	0.63	Measurement OK
25-Aug-2013	00:00	0.63	Measurement OK
24-Aug-2013	00:00	0.63	Measurement OK
23-Aug-2013	00:00	0.63	Measurement OK
22-Aug-2013	00:00	0.63	Measurement OK
21-Aug-2013	00:00	0.63	Measurement OK
20-Aug-2013	00:00	0.63	Measurement OK
19-Aug-2013	00:00	0.63	Measurement OK
18-Aug-2013	00:00	0.63	Measurement OK
17-Aug-2013	00:17	0.63	Measurement OK
17-Sep-2013	00:00	0.63	Measurement OK
16-Sep-2013	03:00	0.75	Measurement OK

Print...   Close

6.5 Automatic device status monitoring

The device automatically and continuously monitors for electrical reset conditions. During each interrogation, the device reports detected conditions that require attention as device status indicator warnings and then displays these warnings on the programmer screen. Device status indicator warnings are displayed both as a pop-up window on the programmer screen and in the Observations box on the Quick Look II screen. A specific procedure about how to respond to the device status indicator warning for electrical reset is provided in Section 6.5.2, "How to respond to the device status indicator warning for electrical reset", page 120.

Caution: The device status indicators are important. Please inform your Medtronic representative if any of the indicators are displayed on the programmer screen after interrogating a device.

To clear the displayed status indicator, select [Clear] in the pop-up window that displays the device status indicator warning.

6.5.1 Definitions of device status indicator warnings

Warning - Device Electrical Reset – Indicates that an electrical reset has occurred. An electrical reset can be either a full reset or a partial one. When a full reset occurs, the programmed parameters are reset to the default electrical reset values. When a partial reset occurs, the reset does not affect any programmed parameters. For information about reset settings, see Appendix B, "Device parameters", page 176. Read the message accompanying the indicator and follow the screen instructions carefully. See the following section for instructions about what to do in the event of an electrical reset. If the error message does not indicate that parameters have been reprogrammed, then the reset was a partial reset and did not affect any programmed parameters.

An electrical reset is a device-activated safety feature that can reset device parameters to values that provide basic device functionality. These basic parameters are considered safe for most of the patients. Pacing in VVI mode remains active during a reset condition. An electrical reset may occur when the device is exposed to extreme conditions, such as cold temperatures (before implant); intense, direct x-ray exposure; electrocautery; or external defibrillation. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen.

After an electrical reset, the programmer may not be able to communicate with the device. If this communication problem occurs, inform a Medtronic representative. **Immediate implant of a new device is recommended.**

SERIOUS DEVICE ERROR – Indicates an error has occurred from which the device cannot recover. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen. **Immediate implant of a new device is recommended.**

6.5.2 How to respond to the device status indicator warning for electrical reset

If the programmer reports that an electrical reset occurred and the device is not yet implanted, do not implant the device. Contact a Medtronic representative. If the device is implanted, perform the following steps:

1. Remove any sources of electromagnetic interference (EMI).

2. Notify a Medtronic representative.

3. Select [Clear] in the pop-up window to clear the reset indicator. A confirmation window appears indicating that all previously interrogated data in the programmer will be cleared.

4. Select [Continue].

5. Interrogate the device.

    a. Note the time and date when counter data was last cleared because this indicates when the electrical reset occurred.

    b. Determine, if possible, what the patient was doing at the time and date the electrical reset occurred.

    c. Save your session data to USB flash drive or disk. You should give a copy of this saved data file to your Medtronic representative. The data would be helpful in determining the events leading up to the reset.

6. Verify the programmed device parameters. If a full reset occurred, the reprogrammed values are displayed in the error message. If a full electrical reset occurred, reprogram the device parameters.

    After this type of reset, the device operates in VVI mode until it is reprogrammed. For a list of electrical reset parameter settings, see Appendix B, "Device parameters", page 176.

7. Verify that the device date and time are correct. If necessary, reprogram the date and time.

8. Interrogate the device again. Check the Battery and Device Measurements screen to verify that the battery voltage is acceptable.

9. Conduct electrode impedance, sensing, and pacing threshold tests if necessary.

6.6 Optimizing device longevity

Optimizing device longevity is a desirable goal helped by conserving the battery energy. 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 estimated Remaining Longevity of a device, refer to the Quick Look II screen . For information about the longevity of the device, see Section A.4, "Projected service life", page 174.

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

6.6.1 Managing pacing outputs

Capture Management – Capture Management 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 Capture Management 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 about Capture Management, see Section 7.4, "Managing pacing output energies with Capture Management", page 140.

Manually optimizing amplitude and pulse width – If you choose to program Capture Management 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. For more information about the pacing threshold, see Section 8.1, "Performing the device measurement tests", page 153 .

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 bradycardia pacing rate. Use features such as Rate Response only for patients who can receive therapeutic benefit from the feature.

6.6.2 Considering how diagnostic features with data storage affect device 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 Channel data 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.

7   Configuring pacing therapies

7.1   Sensing intrinsic cardiac activity

The device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver the pacing therapy appropriately. Effective sensing can reduce the effects of long depolarizations after paced events, oversensing the same event, sensing T-waves, noise, and interference. As the patient's condition changes, the sensing threshold may change, requiring the threshold to be monitored regularly and adjusted to intracardiac signals, if necessary.

7.1.1   System solution: sensing

The device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver the pacing therapy appropriately. Effective sensing is essential for the safe and effective use of the device. The device senses in the right ventricle using the sensing electrodes in the implanted device. You can adjust the sensitivity to intracardiac signals manually or use the Sensing Assurance feature of the device to adjust the sensitivity automatically. 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.

Note: Selecting a higher value for the sensing threshold reduces the sensitivity to lower amplitude signals.

Programmable blanking periods and refractory periods help to screen out extraneous sensing or to prevent the device from responding to it. Both blanking periods and refractory periods follow pacing pulses and sensed events. Sensing is inhibited during blanking periods. The device is able to sense events that occur during refractory periods, but it marks them as refractory events. Refractory events generally have no effect on the timing of subsequent pacing events.

7.1.2   Operation of sensing threshold

When the Sensing Assurance feature is programmed to On and the device is operating in the VVI or VVIR mode, the RV Sensitivity parameter is adjusted automatically based on the amplitude of sensed R-waves. Sensing Assurance is designed to minimize oversensing and undersensing of R-waves by monitoring the peak amplitude of sensed signals and increasing or decreasing sensitivity to maintain an adequate sensing margin with respect to the sensed R-waves. This feature also adjusts the RV Sensitivity threshold based on the number of paced events and whether the paced events resulted from noise reversion.

The device monitors each nonrefractory sensed event by measuring the ratio of the peak amplitude of the R-wave to the Sensitivity setting. The device then compares the measured sensing margin to a target sensing margin. Sensing Assurance provides a sensing margin of 2.8:1 ratio to 4:1 ratio, as shown in Figure 39.

Figure 39. Maintaining a sensing margin of 3:1
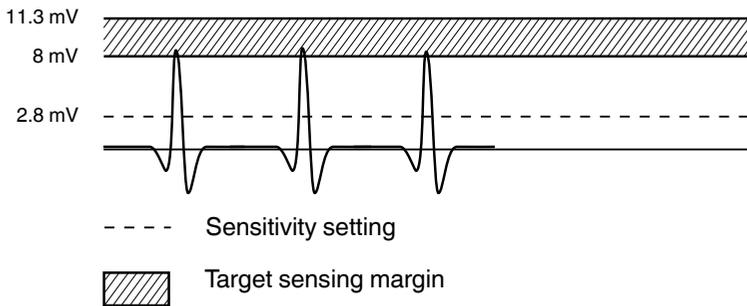
Note: When high-amplitude sensed events occur, the decrease in sensitivity is limited to prevent undersensing of subsequent intrinsic events.

7.1.2.1 Qualifying sensed events

When monitoring nonrefractory sensed events, the device checks each event to consider whether it qualifies for use in determining Sensitivity threshold adjustments. The device disqualifies sensed events that occur under these conditions:

- The device is monitoring a high level of continuous interference.

- Multiple ventricular refractory senses occur before a sensed event.

7.1.2.2 Adjusting sensing thresholds

To adjust sensing thresholds, the device keeps a record of many sensed events. Non-PVC, nonrefractory senses that fall below the target sensing margin (low events) are assigned a negative value, and those that are above the target sensing margin (high events) are assigned a positive value. When the accumulated value of the events exceeds the upper limits or lower limits of a counter, the device adjusts the sensitivity by 1 setting. Many low events indicate an adjustment of 1 setting to a more sensitive (smaller numerical) setting. Many high events indicate an adjustment of 1 setting to a less sensitive (larger numerical) setting.

At least 17 low events are required to cause an adjustment to the next more sensitive setting and 36 high events are required to cause an adjustment to the next less sensitive setting. Adjustments occur more gradually if a combination of low and high events is occurring or if paced events are mixed with sensed events. If fewer than 60% of events are high (or low), or if the pace to sense ratio is greater than 5:1, no sensitivity adjustment is made. Pacemaker-defined PVCs cause ventricular sensitivity adjustments that are slower than those for non-PVC, non-refractory senses.

7.1.2.3 Adjustments during periods of infrequent sensing

The device maintains a long-term running average of the sensitivity adjustments. During periods when the pacing percentage is near 100%, the device may adjust the thresholds toward the long-term average. If persistent undersensing or persistent noise reversion pacing (due to continuous interference) is occurring, the device adjusts the threshold toward the long-term average. Automatic Sensitivity adjustments are restricted to the 2.0 – 5.6 mV range.

7.1.3 Operation of blanking periods

Blanking periods follow paced and sensed events. Blanking periods help to prevent the device from sensing pacing pulses, post-pacing depolarization, T-waves, and oversensing of the same event. The blanking periods after paced events are longer than or equal to those after sensed events to avoid sensing ventricular depolarizations.

The blanking periods that follow sensed events and paced events cannot be programmed to be longer than the refractory periods.

Figure 40. Programmable blanking periods
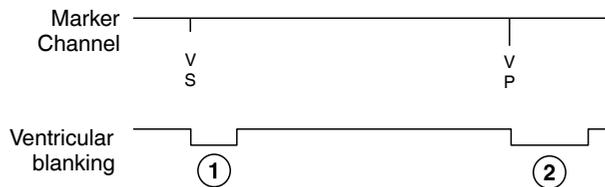
1 For the duration of this ventricular blanking period, which is defined by the Blank Post VS parameter, ventricular sensing is disabled after a sensed ventricular event.
2 For the duration of this ventricular blanking period, which is defined by the Blank Post VP parameter, ventricular sensing is disabled after a paced ventricular event.

7.1.4 Operation of refractory periods

During a refractory period, the device senses normally but classifies sensed events as refractory and limits its response to these events. The pacing refractory periods prevent inappropriately sensed signals, such as T-waves or electrical noise, from triggering certain pacing timing intervals.

7.1.4.1 Noise reversion

When sensing occurs during the refractory period, the device restarts the refractory period and its blanking period. The operation associated with continuous refractory sensing is called noise reversion. Multiple restarts of the refractory period (continuous noise reversion) do not inhibit scheduled pacing. During continuous noise reversion, pacing occurs at the sensor-indicated rate in the VVIR mode and at the programmed lower rate in the other pacing modes.

On the ECG, noise reversion may be difficult to distinguish from loss of sensing, but Marker Channel recordings show refractory sense markers when noise reversion occurs.

Figure 41. Noise reversion in VVIR mode at sensor rate
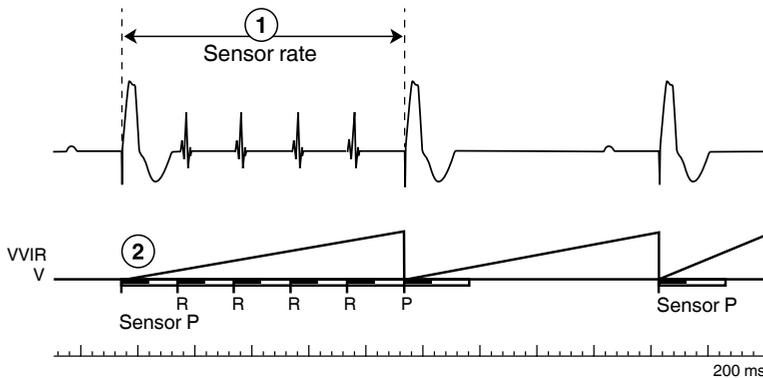
1 Sensor Rate = 60 bpm
2 Refractory = 240 ms

7.1.5 Preventing noise sensing

Noise reversion may be caused by electromagnetic interference (EMI), low sensitivity settings, or T-Wave oversensing. When noise reversion is identified, you can reduce it or eliminate it 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) or program Sensing Assurance to On to monitor the Sensitivity value and, if necessary, adjust it. For more information about Sensing Assurance, see Section 7.1.2.

- Reprogram Refractory to Off and reprogram Blank Post VP and Blank Post VS to blank the T-waves.

7.1.6 Programming considerations for sensing

Sensing threshold – The sensing threshold, set by programming the Sensitivity parameter, applies to all features related to sensing, including bradycardia pacing and the Sensing Test.

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. The Sensing Assurance feature automatically adjusts the Sensitivity value to be between 2.0 mV and 5.6 mV.

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

7.1.7 Programming sensing parameters

7.1.7.1 Programming sensitivity, refractory, and blanking parameters

Select Params icon
⇒ RV Sensitivity…
▷ Sensitivity
▷ Sensing Assurance
⇒ RV Refractory/Blanking
▷ Refractory
▷ Blank Post VP
▷ Blank Post VS

7.1.8 Evaluation of sensing

7.1.8.1 Using the Sensing Test to evaluate sensing

The Sensing Test allows you to measure R-wave amplitudes by performing this test from the Device Measurements screen. 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 print the results. For more information, refer to Section 8.1, "Performing the device measurement tests", page 153.

7.1.8.2 Viewing the 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 programmer displays a Quick Look II observation.

Select Data icon
> ⇒ Diagnostics
>> ⇒ Battery and Device Measurements
>>> ⇒ Open Data

Figure 42. Battery and Device Measurements screen
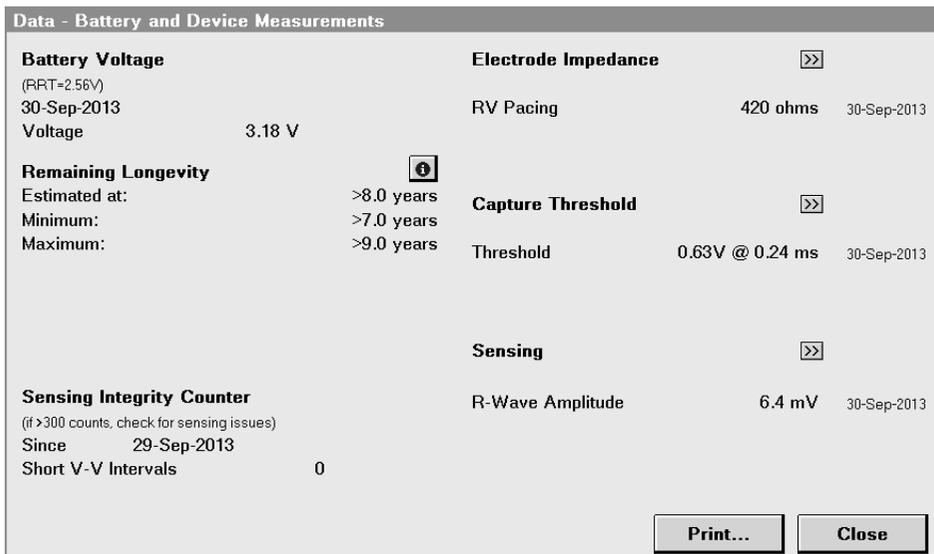
7.1.8.3 Viewing R-wave amplitude trends

Select Data icon
   ⇒   Diagnostics
        ⇒   R-Wave Amplitude Trend
             ⇒   Open Data
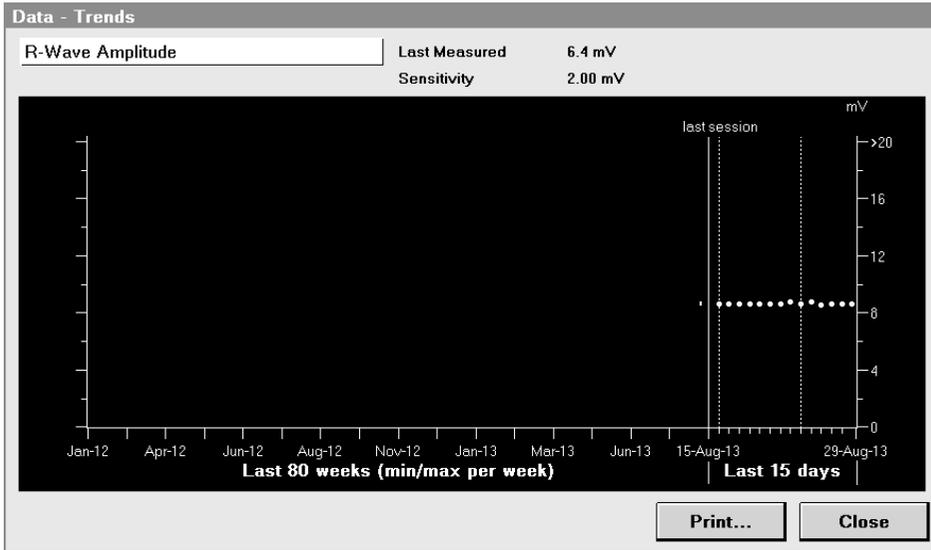
After completing the electrode impedance measurement, which starts at 02:30 every day, the device begins to measure the amplitude of intrinsic sensed events. The device attempts to measure the amplitude of 5 normal intrinsic sensed events. After collecting these measurements, the device records their 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.

7.2 Providing pacing therapies

Patients have a variety of conditions for which pacing therapy may be indicated. These conditions include cardiac asystole or poor ventricular function due to heart failure.

7.2.1 System solution: pacing therapies

The system provides single chamber ventricular pacing modes to address different cardiac conditions. Single chamber ventricular pacing supports patients with infrequent or no occurrences of asystole, patients with conduction disorders, or for whom dual chamber pacing is not justified.

7.2.2 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 these parameters manually, the Capture Management feature is available to manage the pacing output energy in the right ventricle. For more information about Capture Management, refer to Section 7.4, "Managing pacing output energies with Capture Management", page 140.

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. The Sensing Assurance feature is available to adjust the sensitivity threshold automatically, although you can adjust the setting for sensitivity to intracardiac signals manually. For information about the sensing threshold and refractory and blanking periods, refer to Section 7.1, "Sensing intrinsic cardiac activity", page 123.

7.2.3 Operation of single chamber pacing

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

7.2.3.1 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 43).

Figure 43. Single chamber ventricular pacing in VVIR mode
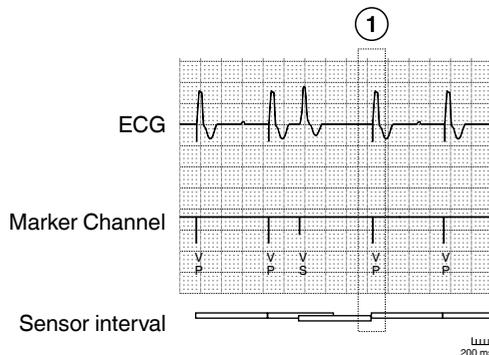
1 A ventricular paced event occurs when no intrinsic ventricular event is sensed.

7.2.3.2 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 R-wave amplitude measurement test, where bradycardia pacing is not necessary or is detrimental to the patient.

7.2.3.3 VOO mode

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

7.2.3.4 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.

7.2.4 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.

7.2.5 Programming pacing therapies

Select Params icon
- ▷ Mode
- ▷ Lower Rate
- ▷ Upper Sensor
- ▷ RV Amplitude
- ▷ RV Pulse Width

7.2.6 Evaluation of pacing therapies

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

Select Data icon
- ⇒ Quick Look II

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.

7.3 Providing rate-responsive pacing

Some patients exhibit heart rates that do not adapt to changes in their physical activity. Patients include those with chronotropic incompetence. Their symptoms might be shortness of breath, fatigue, or dizziness.

7.3.1 System solution: Rate Response

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.

7.3.2 Operation of Rate Response

Figure 44. Overview of Rate Response
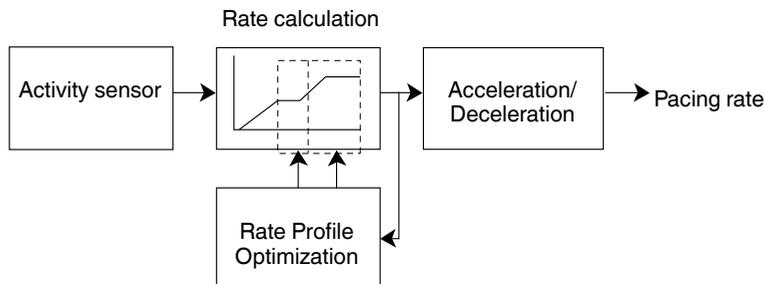
The Rate Response feature functions when the device is operating in the VVIR mode. The Rate Response system includes an activity sensor to measure patient movement, rate calculation to convert the patient's level of physical activity to a pacing rate, Rate Profile Optimization to automatically adjust rate response settings over time, and acceleration and deceleration to smooth the pacing rate. This pacing rate is also described as the sensor rate.

7.3.2.1 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 45. 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.

7.3.2.2 Rate calculation

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

Figure 45. Rate curve
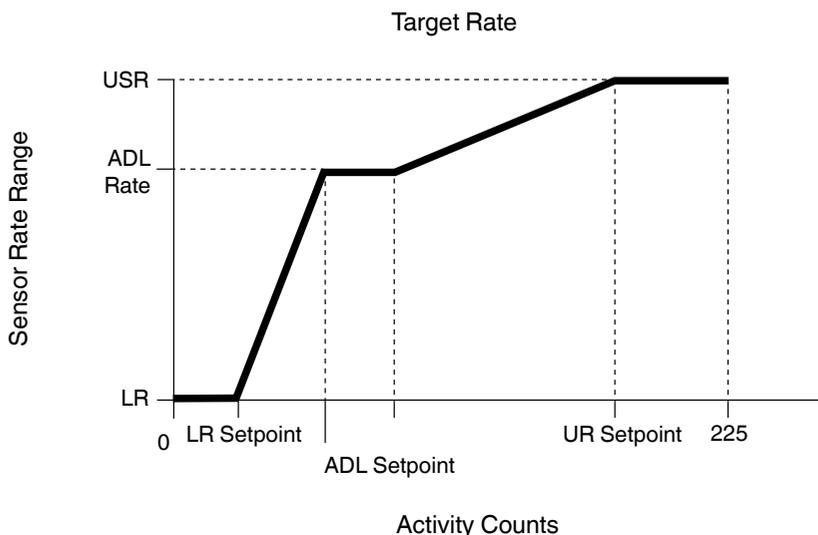
Programmable rates – The Lower Rate is the slowest rate at which pacing occurs in the absence of a sinus rate or physical activity. The ADL Rate is the approximate pacing rate that the patient's heart is expected to reach during moderate activity and provides a plateau which helps maintain a stable pacing 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.

7.3.2.3 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.

7.3.2.4 Activity Acceleration and Activity Deceleration

The Activity Acceleration and Activity Deceleration parameters 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 46, changing the values of the Activity Acceleration and Activity Deceleration parameters affects the pacing rate during and after exertion.

Figure 46. Activity Acceleration and Deceleration curves for rate response

Rate curve: nominal Acceleration and Exercise Deceleration

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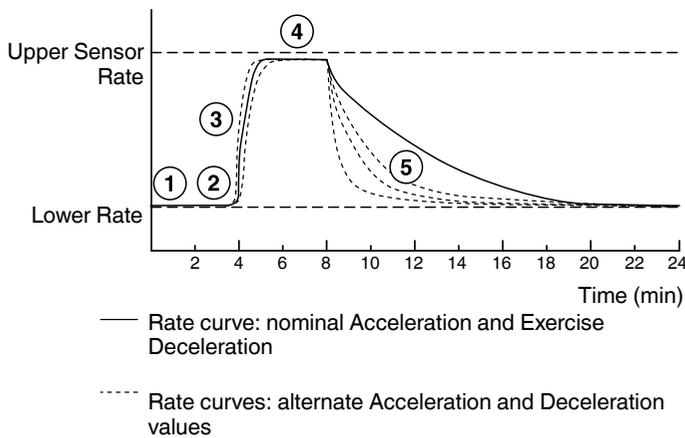
1 Pacing occurs with the patient at rest.
2 Activity increases and Activity Acceleration begins.
3 Activity Acceleration continues toward a higher pacing rate.
4 Pacing occurs at a higher rate during exertion.
5 Exertion ends and the pacing rate decelerates.

7.3.2.5 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 Exercise test, see Section 8.2, "Conducting an Exercise test", page 159.

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.

Figure 47. Rate Response parameters screen
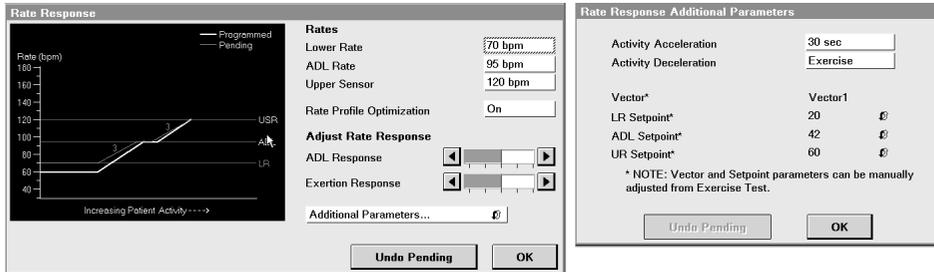
7.3.3 Programming considerations for Rate Response

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

7.3.4 Programming Rate Response

Select Params icon
 ⇒ Rate Response…
  ▷ Lower Rate
  ▷ ADL Rate
  ▷ Upper Sensor
  ▷ Rate Profile Optimization
  ▷ ADL Response
  ▷ Exertion Response
  ⇒ Additional Parameters…
   ▷ Activity Acceleration
   ▷ Activity Deceleration

7.3.5 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 6.3, "Using the rate histogram to assess heart rates", page 109

7.3.5.1 Rate Histogram screen

You can view the Rate Histogram screen by accessing it from the Data icon.

Select Data icon
 ⇒ Diagnostics
  ⇒ Rate Histogram
   ⇒ Open Data

Figure 48. Rate Histogram screen
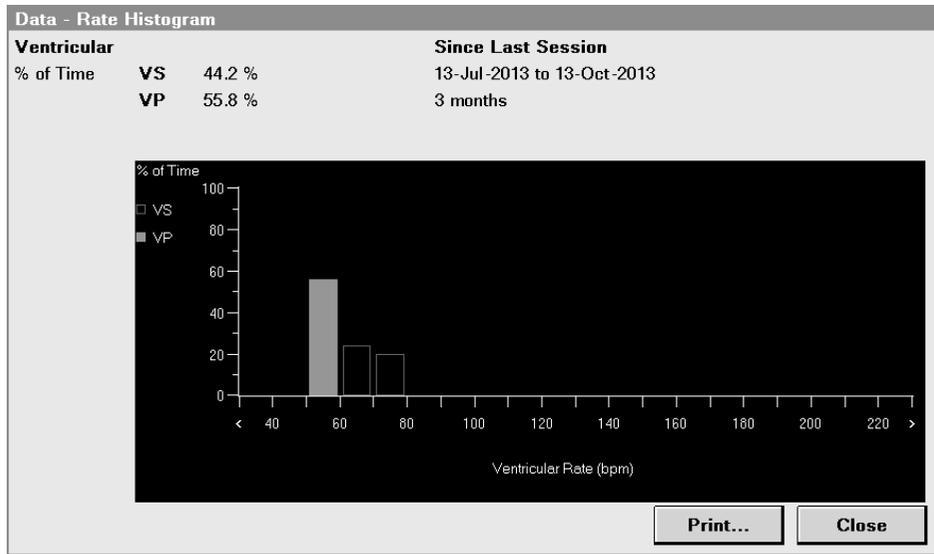
7.3.5.2 Rate Histogram Report

The Rate Histogram Report is available only as a printed report. You can print this report by accessing it from the Reports icon.

Select Reports icon
- ⇒ Available Reports…
    - ⇒ Rate Histogram

Figure 49. Rate Histogram Report
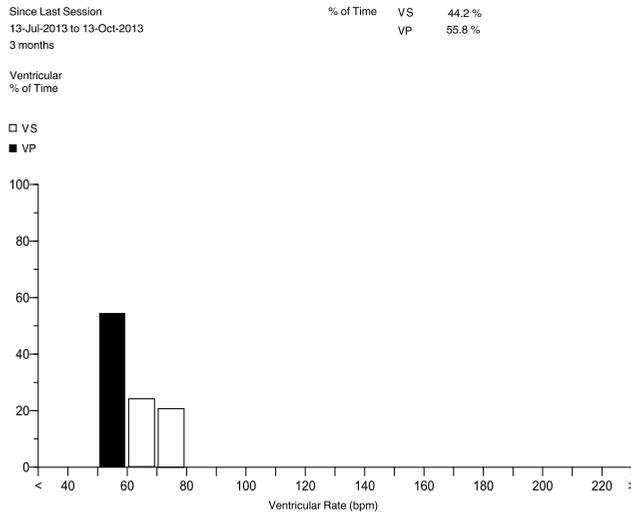
7.4 Managing pacing output energies with Capture Management

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.

7.4.1 System solution: Capture Management

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.

7.4.2 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 50. Overview of Capture Management
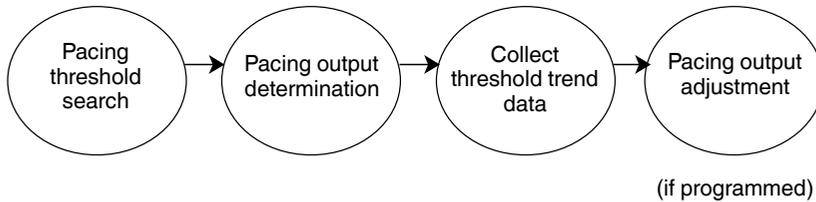
(if programmed)

7.4.2.1 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 pacing output parameters. For more information about manual programming, refer to Section 7.2, "Providing pacing therapies", page 129.

7.4.2.2 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 51. 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 51. Pacing threshold and safety margin curve
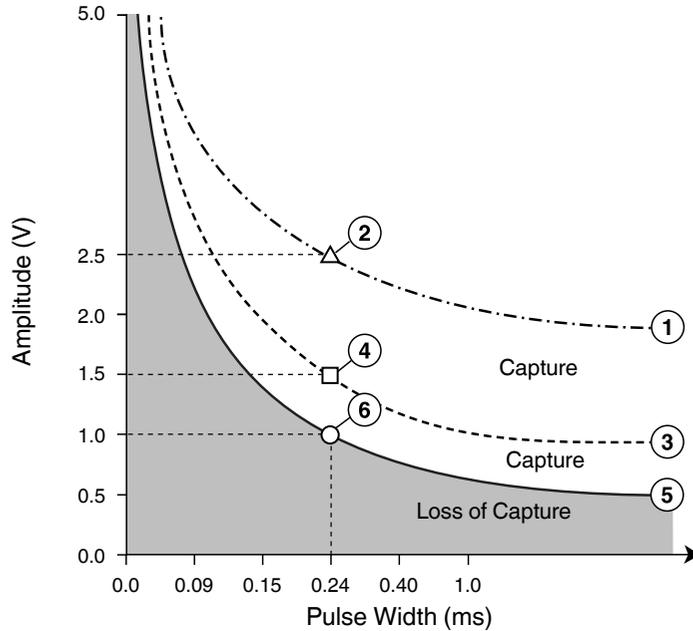
1 Safety margin curve for acute phase   4 Target amplitude for chronic phase
2 Target amplitude for acute phase   5 Pacing threshold curve
3 Safety margin curve for chronic phase   6 Threshold measurement

7.4.3 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.

7.4.3.1 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.

7.4.3.2 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 and 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 7.4.3.4.

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 52.) 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 52. Capture Management test sequence

S = Support cycle

T = Test pace

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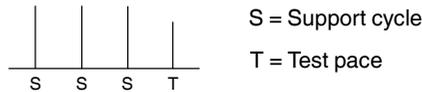
During a pacing threshold search, the device promotes ventricular pacing, which may affect the normal pacing operation.

7.4.3.3 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 7.4.2.2

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.

7.4.3.4 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 7.4.6.

7.4.4 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.

7.4.5 Programming Capture Management

For information about programming amplitude and pulse width parameters manually, refer to Section 7.2, "Providing pacing therapies", page 129.

Figure 53. Pacing and Capture Management parameters

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.

Select Params icon
> ⇒   Capture Management…
>> ▷   Capture Management
>> ▷   Amplitude Safety Margin

Select Params icon
> ⇒   Acute Phase Parameters…
>> ▷   Acute Phase Remaining

7.4.6   Evaluation of Capture Management

7.4.6.1   Quick Look II

Select Data icon
> ⇒   Quick Look II

Figure 54. Quick Look II screen
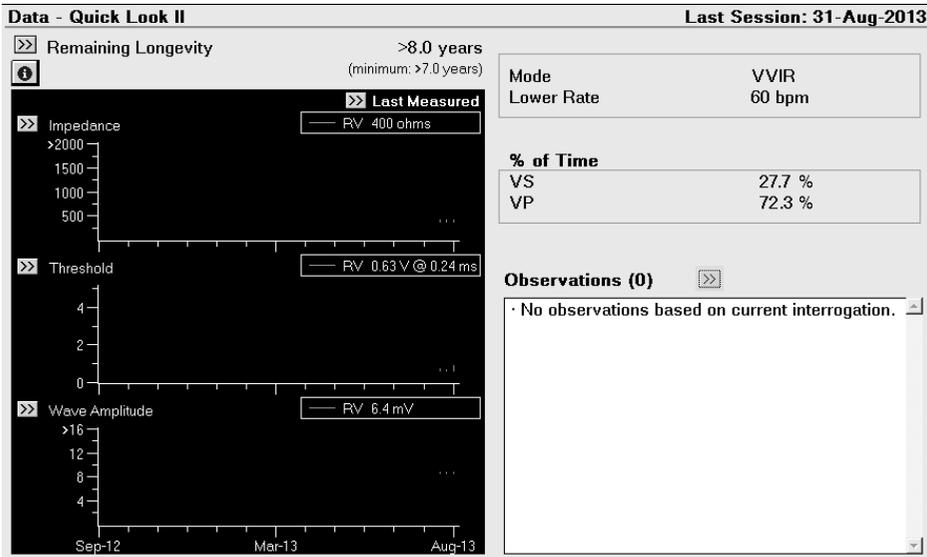
Threshold trends – The Quick Look II screen shows trends of minimum and maximum capture thresholds. The threshold data is collected by the automatic daily threshold tests performed by Capture Management. Select the Threshold [>>] button to view the Capture Threshold diagnostic screens.

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

7.4.6.2 Capture Threshold trends

Select Data icon
  ⇒ Diagnostics
    ⇒ Capture Threshold Trend
      ⇒ Open Data

Figure 55. Capture Threshold Trend screen
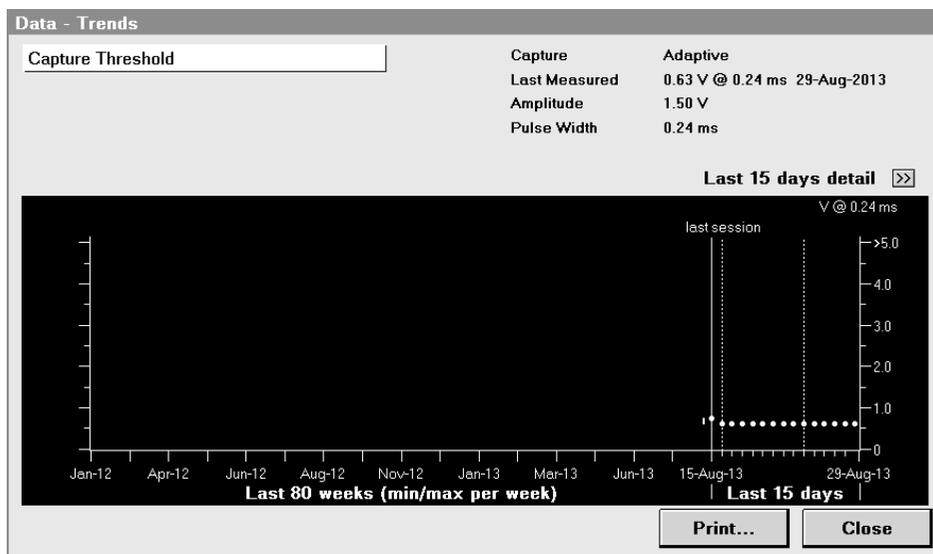
The results of the daily pacing threshold measurements are displayed on the Capture Threshold Trend screen in the Capture Threshold trend graph. The graph displays up to 15 days of the most recent measurements and up to 80 weekly summary measurements (showing minimum and maximum values for each week).

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 Capture Threshold Trend screen, you can select the Last 15 days detail [>>] button 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.

Figure 56. Capture Management detail screen

7.5 Promoting the intrinsic rate during periods of inactivity

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

7.5.1 System solution: Rate Hysteresis

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

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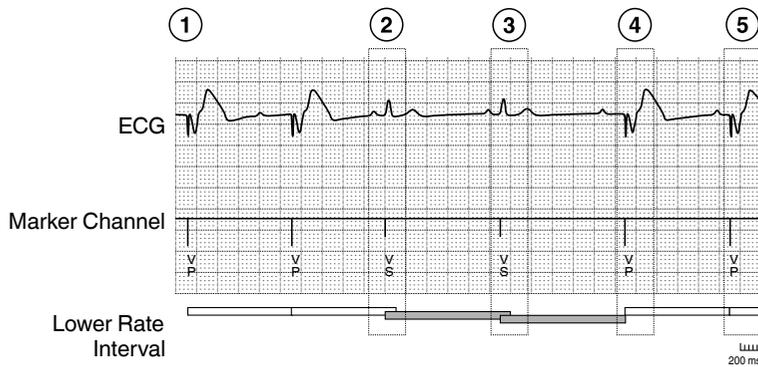
1 The device paces in VVI mode at the programmed Lower Rate.
2 After a ventricular sensed event, the device applies the hysteresis interval (shaded bar).
3 A sensed event occurs before the hysteresis interval expires, so hysteresis operation continues.
4 The hysteresis interval expires, and the device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

7.5.3 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.

7.5.4 Programming Rate Hysteresis

Select Params icon
  ⇒ Rate Hysteresis

7.5.5 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.

7.5.5.1 Viewing the Rate Histogram screen

You can view the Rate Histogram screen by accessing it from the Data icon.

Select Data icon
  ⇒ Diagnostics
    ⇒ Rate Histogram
      ⇒ Open Data

Figure 58. Rate Histogram screen
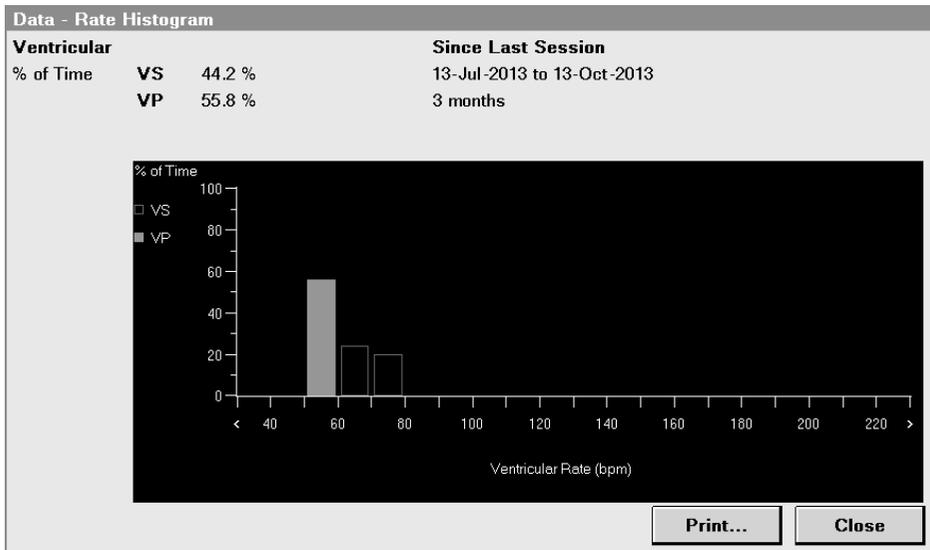
The Rate Histogram Report is available only as a printed report. You can print this report by accessing it from the Reports icon.

Select Reports icon
⇒ Available Reports…
⇒ Rate Histogram

Figure 59. Rate Histogram Report
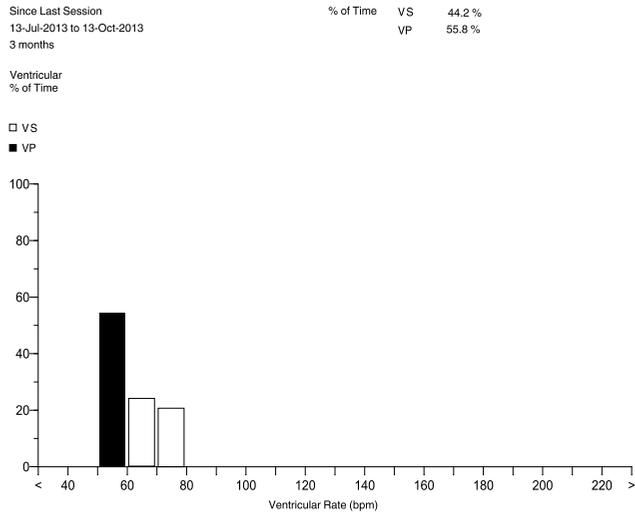
For more information about the rate histogram, see Section 6.3, "Using the rate histogram to assess heart rates", page 109.

8   Testing the system

8.1 Performing the device measurement tests

During a patient follow-up session, you can assess whether the sensing, electrode impedance, and pacing threshold measurements for the patient are acceptable by performing the device measurement tests on the programmer.

From the Device Measurements screen, you can select the Sensing Test, Impedance Test, and Threshold Test and perform these tests automatically by pressing a single button, [START Tests]. The programmer executes the selected tests in sequence. The Device Measurements screen also allows you to perform each test separately by selecting only a specific test.

Figure 60. The Device Measurements screen
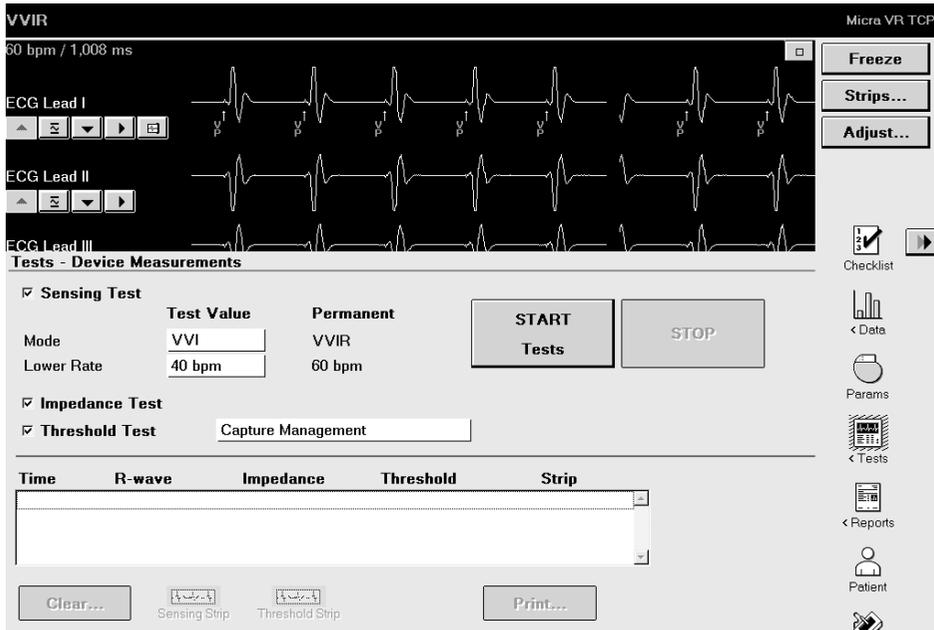
8.1.1 Preparing for the device measurement tests

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

1. Place the programming head over the implanted device to establish telemetry communication between the device and the programmer. If necessary to find the optimum position for the programming head, move it over the patient's heart until 1 or more of the indicator lights are illuminated, signalling reliable telemetry.

2. Interrogate the device by selecting [Interrogate].

3. Select the Tests icon on the programmer tool palette. When the tests menu opens, select Device Measurements to open this screen.

8.1.2 Performing the Sensing Test

The Sensing Test allows you to obtain the R-wave amplitude measurement, which may be useful in assessing electrode and sensing performance. Before performing the Sensing Test, you can set temporary values for the test parameters Mode and Lower Rate so that the device is not pacing the patient during the test and increases the likelihood that sensed events occur.

8.1.2.1 Considerations for performing the Sensing Test

Warning: Before starting the Sensing Test, select a temporary pacing rate that is likely to allow intrinsic sensed events and may be well tolerated by the patient. If the patient shows poor tolerance to the selected pacing rate when the test is in progress, stop the test by pressing the [STOP] button on the programmer screen. To complete this test, the device must detect 2 consecutive ventricular sensed events with an interval of at least 500 ms (a heart rate of 120 bpm or slower) between them. If such an interval is not identified after 30 s, the device stops the test. If a pacing rate suitable to the patient is not available to select, consider omitting the Sensing Test from the device measurement tests.

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

Pacing modes for the Sensing Test – The Sensing Test parameter Mode provides the option to set the device to the VVI or OVO test mode in the Test Value field. The device returns to the permanently programmed mode after the Sensing Test is completed. If the device is programmed to the Device Off mode, you cannot perform the Sensing Test.

Patient comfort – Before performing the Sensing Test, select a Lower Rate test value that is not much below the patient's expected intrinsic rate to minimize patient symptoms associated with abrupt changes in the heart rate.

Automatic timeout – The Sensing Test ends automatically after 30 s. The device restores the programmed settings if no intrinsic events occur and no changes are made to the permanently programmed pacing rate.

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

Selecting sensitivity values – Do not adjust the values for RV Sensitivity based on the results of the Sensing Test. For more information, see Section 7.1, "Sensing intrinsic cardiac activity", page 123.

8.1.2.2 How to perform the Sensing Test

1. Select Sensing Test on the Device Measurements screen.

2. To change the Sensing Test default values for Mode and Lower Rate, select the corresponding Test Value field for each parameter and set a new value.

3. Select [START Tests].

4. Observe the Live Rhythm Monitor for an intrinsic rhythm.

5. If the patient shows poor tolerance to the test pacing rate when the test is in progress, stop the test by pressing the [STOP] button on the Device Measurements screen. The test values set for Mode and Lower Rate return to the programmed values.

   For information about selecting a sensing test value that is appropriate for the patient, see Section 8.1.2.1, "Considerations for performing the Sensing Test", page 154 .

After the Sensing Test is completed, the measurement value is shown in the R-wave column in the test results area of the Device Measurements screen. You can compare the Sensing Test measurement value with the automatic daily sensing amplitude measurement values on the R-Wave Amplitude Trend screen.

8.1.3 Performing the Impedance Test

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

8.1.3.1 Considerations for the Impedance Test

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

8.1.3.2 How to perform the Impedance Test

1. Select Impedance Test on the Device Measurements screen.
2. Select [START Tests]. Wait for the message on the screen that the test is in progress.
3. If necessary, end the test by selecting [STOP].

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

8.1.4 Performing the Threshold Test

The Threshold Test allows you to measure the patient's pacing stimulation thresholds. The Threshold Test provides the option to select the automatic test or manual test for checking the pacing stimulation thresholds. If you select Capture Management, the automatic test, the programmer checks the pacing stimulation thresholds at different pacing amplitude settings. If you select Amplitude – Auto Decrement, the manual test, you can check the pacing stimulation thresholds at different pacing amplitude and pulse width settings. The pacing threshold information may be used to determine the appropriate amplitude setting to ensure capture while minimizing the output to maximize battery longevity.

8.1.4.1 Considerations for performing the Threshold Test

Selectable and default values – The selectable and default values provided by the pacing Threshold Test depend on the programmed values for bradycardia pacing therapy.

Pacing threshold and safety margin – After performing a Pacing Threshold Test, make sure that the permanently programmed amplitude parameter value provides an adequate safety margin above the patient's pacing threshold.

8.1.4.2 How to perform the automatic Threshold Test

1. Select Threshold Test on the Device Measurements screen.

2. Accept the default test value, Capture Management, in the Threshold Test parameter field.

3. Select [START Tests]. When the threshold test is in progress, the Marker Channel waveform trace in the Live Rhythm Monitor window shows the annotations VC or VL to indicate ventricular capture or loss of capture for the test paces delivered.

4. If necessary, end the test by selecting [STOP].

When the test is completed, the test measurement value is shown in the Threshold column in the test results area of the Device Measurements screen. You can determine whether the pacing threshold measurement has changed by comparing the test measurement value to the automatic daily threshold measurement values on the Capture Threshold Trend screen.

8.1.4.3 How to perform the manual Threshold Test

The manual Threshold Test allows you to check the pacing stimulation thresholds at different pacing amplitude and pulse width settings.

1. Select Threshold Test on the Device Measurements screen.
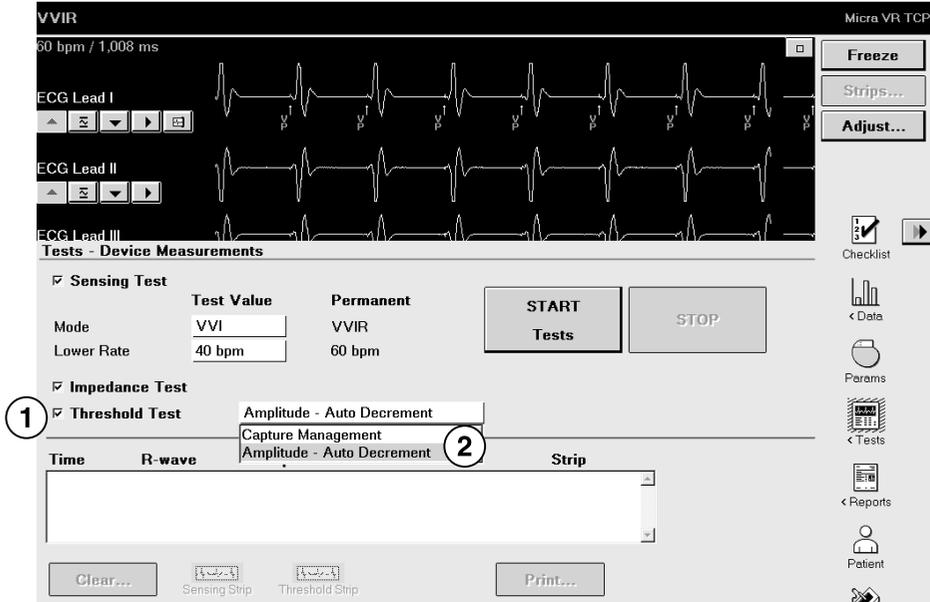
2. Select Amplitude – Auto Decrement in the Threshold Test parameter field. Then, press [START Tests]. The Pacing Threshold window opens, allowing you to set new values for the Test parameters.

3. Select the Decrement after field on the Pacing Threshold window and set the number of pulses.

4. Select the starting test values in the Test Value fields for Mode, Lower Rate, RV Amplitude, RV Pulse Width, and V. Pace Blanking on the Pacing Threshold window or accept the default test values shown.
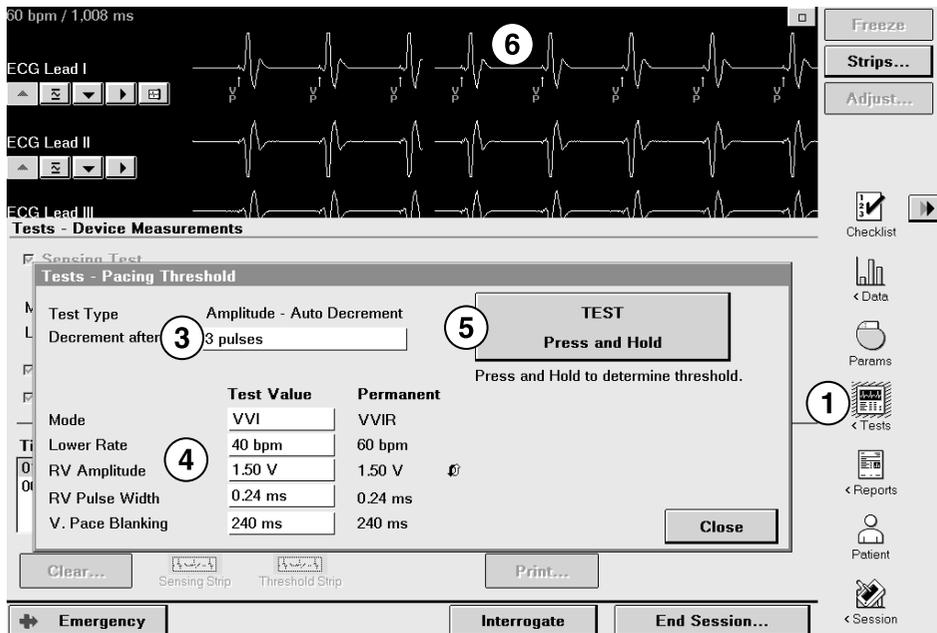
5. Press and hold the [TEST Press and Hold] button. The programmer begins to decrement the amplitude value.

6. Observe the Live Rhythm Monitor for loss of capture. When capture is lost, immediately release the [TEST Press and Hold] button. The device resumes its original pacing values and displays the RV Amplitude Threshold Test – Results window.
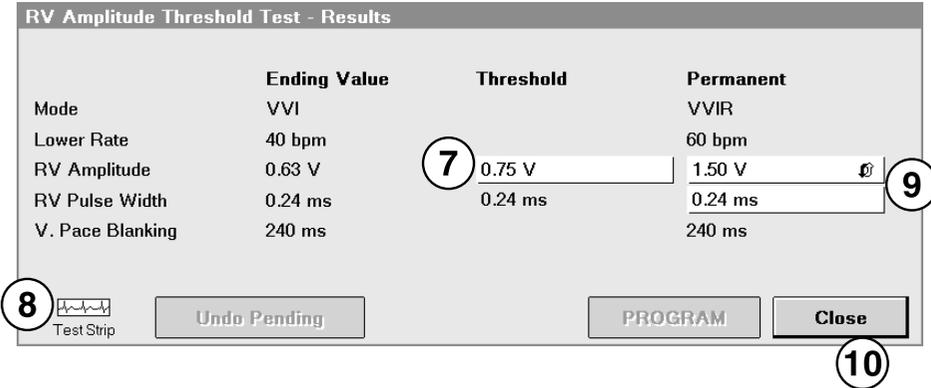
7. If you want to change the RV Amplitude test measurement value, select the new value from the Threshold field.

8. To view a test strip from the Pacing Threshold Test, select the Test Strip icon. For more information, see Section 4.9, "Working with the Live Rhythm Monitor", page 60.

9. To program a new value for RV Amplitude or RV Pulse Width, select the value from the corresponding field in the Permanent column. Then, press [PROGRAM].

10. Press [Close] to close the threshold test results window.

When the test is completed, the threshold test measurement value is shown in the Threshold column in the test results area of the Device Measurements screen. You can determine whether the pacing threshold measurement has changed by comparing the test measurement value to the automatic daily threshold measurement values on the Capture Threshold Trend screen.

8.2 Conducting an Exercise test

The Exercise test is used when the device is operating in the VVIR mode to set the patient's rate-response settings to appropriate levels immediately. As an alternative to automatic Rate Profile Optimization, you can conduct an Exercise test from the programmer to set the rate response for the Lower Rate, ADL Rate, and Upper Sensor Rate ranges. If Rate Profile Optimization is programmed to Off, the rate-response parameters remain set to their programmed values. When Rate Profile Optimization is programmed to On, this feature adjusts the rate-response parameters once each day. For more information about rate-responsive pacing, see Section 7.3, "Providing rate-responsive pacing", page 132.

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

- LR Setpoint (Lower Rate Setpoint) determines the activity counts required to pace at a rate higher than the lower rate

- ADL Setpoint (Activities of Daily Living Setpoint) determines the minimum sensor response to pace at the ADL Rate, which falls within the ADL rate range.

- UR Setpoint (Upper Rate Setpoint) determines the minimum sensor response to pace at the Upper Sensor Rate, which is at the upper limit of the exertion rate range.

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

8.2.1 How to start the Exercise test

1. While positioning the programming head over the patient's device, select the Tests icon to access the Tests menu.

2. Select Exercise from the Tests menu to open the Exercise test screen. If the exercise test data from a previous test is available in the device, this data is shown on the Exercise test screen.

3. Select the Duration field on the Exercise test screen and set the value for the test duration (5 or 20 min).

4. Select the Vector field and set the value from the list shown. Press [PROGRAM] to program the Vector value selected for the test.

   Note: Do not change the currently programmed values for LR Setpoint, ADL Setpoint, and UR Setpoint before conducting the exercise test. These values may serve as the baseline to determine whether it is necessary to adjust the rate-response setpoints for the patient, depending on the test results.

5. Press [START] to start the test. A message window with a warning appears on the screen that starting another exercise test will overwrite the current test results.

6. Select [Continue] to initiate the test in the device or [Cancel] to return to the Exercise test screen without starting the test.

7. If you selected [Continue] on the message window, instruct the patient on the type of activity, such as hall walk or treadmill walk, to perform. If you want the patient to perform activities that require progressively higher levels of exertion, such as sitting, walking, or vigorous exercise, during the test, instruct the patient accordingly.

8. Remove the programming head from the device.

9. While the exercise test is in progress, observe the patient's activity. If the patient is instructed to perform different activities, observe the duration of each.

Figure 61. Exercise test Start screen
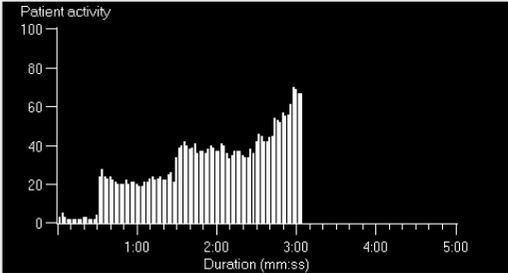
8.2.2 How to retrieve the Exercise test data and adjust the rate-response setpoints

For each exercise test, the device collects and stores the following information, which is displayed on the Exercise test screen:

- start time for the test

- programmed activity Vector

- exercise test duration

- activity count data

- heart rate data

- sensor rate data

1. When the Test Complete message appears on the Exercise test screen, reposition the programming head over the patient's device.

2. Press [Stop and Retrieve] to collect the test data. The test data is displayed as the Activity Counts graph on the Exercise test screen. See Figure 62 .

   Note: You can stop an exercise test that is in progress by repositioning the programming head over the device and pressing [Stop and Retrieve] to see the data collected up to that point.

3. Examine the exercise test results shown on the Activity Counts graph and compare the patient activity count data to the programmed values for LR Setpoint, ADL Setpoint, and UR Setpoint.

   Note: To determine whether it is necessary to adjust the rate-response setpoint values, consider the type of activity or types of activities that the patient was engaged in during the exercise test. For example, if the patient was sitting still during the first minute of the test, set the LR Setpoint to a value slightly higher than the highest patient activity count value for the first minute. If the patient was walking during the second minute of the test, set the ADL Setpoint to the average patient activity count value for the second minute. If the patient was vigorously exercising during the third minute of the test, set the UR Setpoint to a value slightly lower than the average patient activity count value for the third minute.

4. To adjust a setpoint value, select the corresponding field and set a new value from the list shown. Then, press [PROGRAM].

5. To view the patient's heart rate, sensor rate, and the device activity during the exercise test, press the Activity Counts field and select Rate Graph. See Figure 63.

6. To print the Exercise test results, select [Print…].

Figure 62. Exercise test: Stop and Retrieve screen
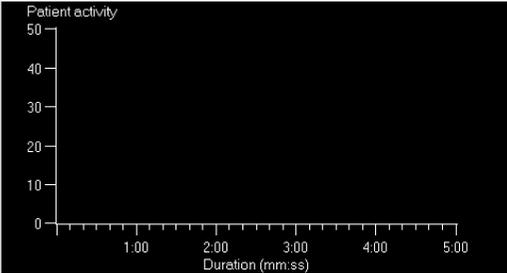
Figure 63. Exercise test: Rate Graph screen for sensor rate and heart rate

8.3 Conducting the Temporary test

The Temporary test is used to evaluate the device parameter settings, while having the option to return to the permanently programmed settings quickly and easily. The test settings are in effect only while this test is in progress.

The Temporary test allows you to change the values for the following parameters to evaluate how these changes affect the pacing and sensing operations of the device:

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

8.3.1 How to conduct the Temporary test

Before starting the Temporary test, position the programming head over the patient's device and establish telemetry with the programmer. To maintain telemetry, hold the programming head over the device for the duration of the test.

Figure 64. The Temporary test screen
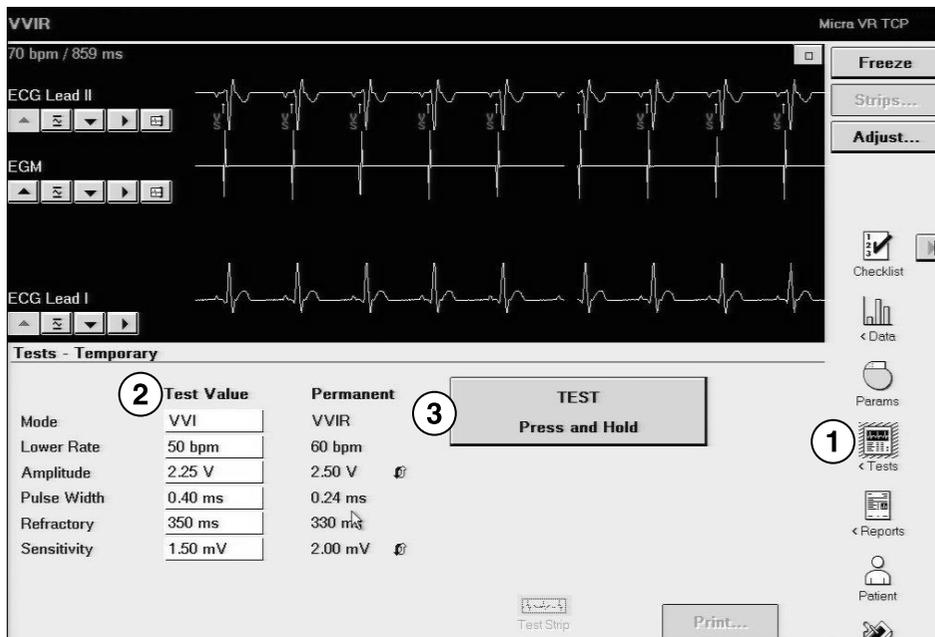
1. Select the Tests icon to access the Tests menu. Then, select Temporary from the Tests menu to open the Temporary test screen.

2. To change the default test values for the parameters shown on the screen, select the Test Value field that corresponds to the parameter and set the new value from the values available.

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

3. To start the test, press and hold down the [TEST Press and Hold] button on the screen. When the test starts, the message Test Started appears on the Live Rhythm Monitor window.

    While continuing to hold down the [TEST Press and Hold] button, observe the changes in the waveform. When you are ready to end the test, release this button. The message Test Ended appears on the Live Rhythm Monitor window. Remove the programming head placed over the device.

    You can view a 10-second ECG test strip and print it by selecting the appropriate button on the screen.
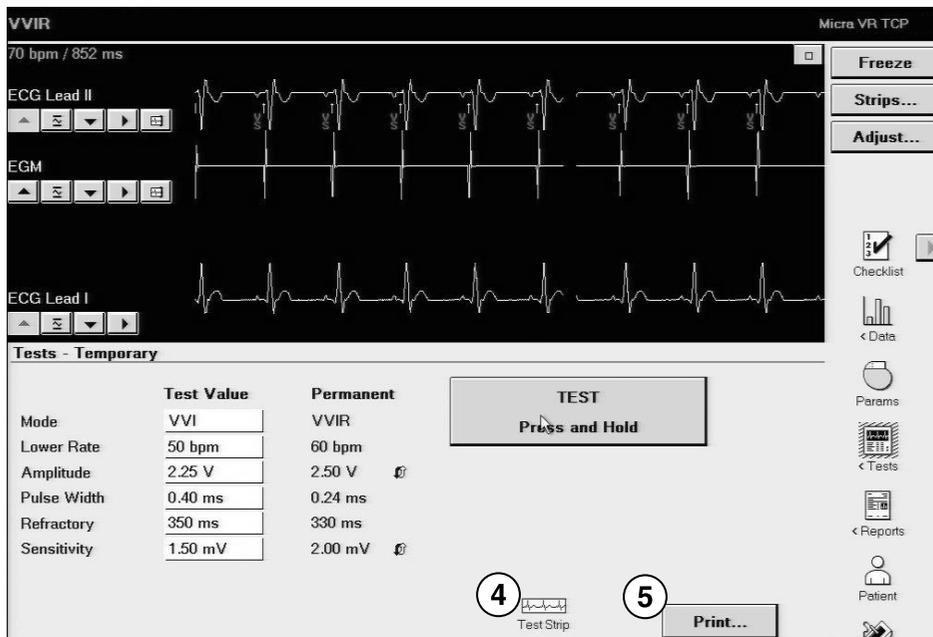
4. Select the [Test Strip] button to view the ECG strip in the Temporary test strip window.
5. Select the [Print…] button to print the ECG strip.

8.4 Conducting an Activity Vector 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 Section 8.2, "Conducting an Exercise test", page 159 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 Section 8.2.1, "How to start the Exercise test", page 160, 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 allternate 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.

A   Quick reference

A.1 Physical characteristics

Table 5. Physical characteristics of the device

Volume	1 cm^3
Length	25.9 mm
Outer diameter	6.7 mm (20.1 French)
Mass	1.75 g
Materials in chronic contact with human tissue[a]	Titanium, titanium nitride, parylene C, primer for parylene C, PEEK, siloxane, nitinol, platinum, iridium, liquid silicone rubber, and silicone medical adhesive
Steroid	Dexamethasone acetate, <1.0 mg, MCRD release mechanism
Fixation mechanism	Nitinol tines
Battery	Lithium-hybrid CFx silver vanadium oxide
Nominal pacing cathode	2.5 mm^2, Pt sintered, TiN coated
Minimum pacing anode	22 mm^2, TiN coated
Cathode to anode spacing	18 mm

[a] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Figure 65. Radiopaque ID as viewed on the fluoroscopic image
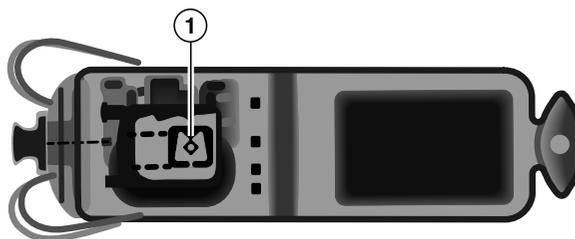
1 Radiopaque ID

Table 6. Physical characteristics of the delivery catheter

Outer diameter	7.8 mm (23 French)
Effective length	105 cm (41.3 in)

A.2 Electrical specifications

Table 7. Battery characteristics

Manufacturer	Medtronic Energy and Component Center
Model	M957651A001
Chemistry	Lithium-hybrid CFx silver vanadium oxide
Initial voltage	3.2 V
Mean usable capacity	120 mAh
Estimated time from RRT to EOS	6 months (180 days)

Table 8. Estimated current consumption

Current consumption (at 100% pacing)[a]	1.3 µA
Current consumption (at 100% inhibition)[b]	0.8 µA

[a] Current consumption when pacing into 500 Ω ± 1% loads at the Beginning of Service in VVIR mode at 60 bpm, 1.5 V, and 0.24 ms.
[b] Current consumption when at the Beginning of Service in VVIR mode at 60 bpm, 1.5 V, and 0.24 ms.

A.2.1 Output waveforms

Figure 66. Output waveform at nominal conditions (resistive load: 500 Ω)
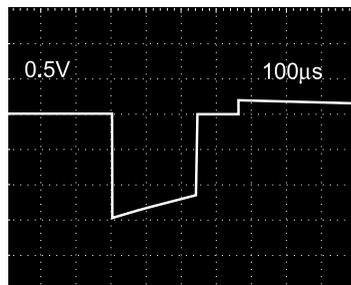
A.2.2 Measuring methods

Important parameters, such as pulse duration, pulse amplitude, and sensitivity (sensing threshold), are measured according to the standard ISO 14708-2:2012.

Pulse duration – Pulse duration is measured at 10% of the programmed amplitude and 90% of the trailing edge amplitude according to the standard ISO 14708-2:2012. See Figure 68 for definitions of amplitude measurements.

Figure 67. Measurement of pulse duration
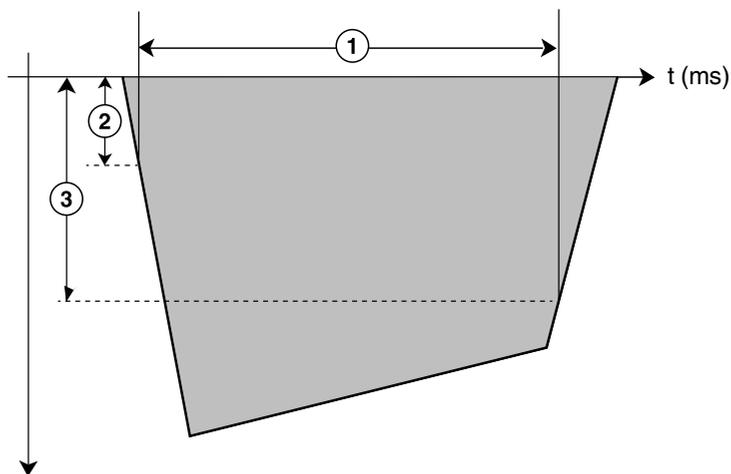
1 Pulse duration	3 90% of the trailing edge amplitude (90% A $_s$)
2 10% of the programmed amplitude	

Pulse amplitude – The peak pulse amplitude is measured according to the standard ISO 14708-2:2012.

Figure 68. Measurement of pulse amplitude
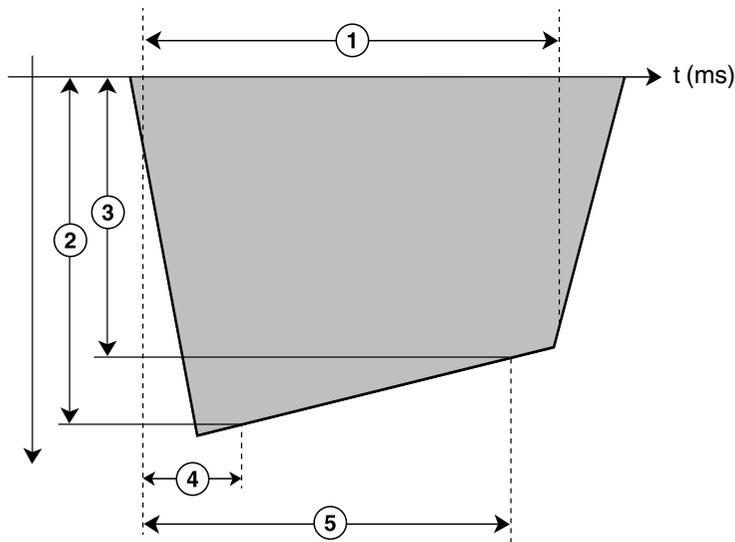
1 Pulse duration
2 Pulse amplitude (A_{max})
3 Trailing edge amplitude (A_s)
4 Voltage sample A_{max} is taken at time $t_1 = 10$ µs.
5 Voltage sample A_s is taken at time t_2, which is the programmed pulse duration value –30 µs.

Note: Effective capacitance is calculated as follows: $C = -(t_2-t_1)/R_L*[1/LN(A_s/A_{max})]$, where $R_L = 500$ Ω, $t_1 = 10$ µs, and $t_2 = 370$ µs

Sensitivity (sensing threshold) – Ventricular sensitivity is defined as the voltage amplitude of a standard ISO 14708-2:2012 test signal that is just sufficient to be sensed by the device. The signal from a test signal generator used for the exact determination of sensitivity (sensing threshold) is illustrated in Figure 69.

Figure 69. Measurement of sensitivity
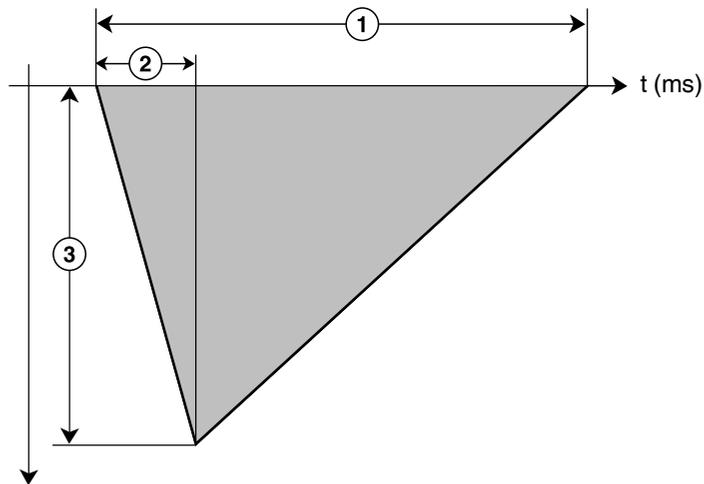
1 $T = 15$ ms ± 1 ms   3 Signal amplitude A_T
2 $t = 2$ ms ± 0.2 ms

Note: The signal may be either positive or negative.

A.2.3 Variation with temperature

When the device temperature is within the 17 to 45 °C (63 to 113 °F) range, variations from the measured values obtained at the Beginning of Service (BOS) and at 37 °C apply to the pacing rates, pacing intervals, sensing intervals, pulse width, pulse amplitude, and Sensitivity (sensing threshold) listed in Table 9.

Table 9. Variation with temperature between 17 and 45 °C (63 and 113 °F)

Parameter	Tolerance value
• Lower Rate • Upper Sensor Rate • Pulse Width • Refractory • Blank Post VP • Blank Post VS • Rate Hysteresis	±2%
Pulse amplitude	±0.13 V (±50 mV for amplitude values 0.13 V and 0.25 V)
Sensitivity (sensing threshold)	±15%

A.3 Replacement indicators

The battery voltage and messages about replacement status appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT), Elective Replacement Indicator (ERI), and the End of Service (EOS) conditions are listed in Table 10.

Table 10. Replacement indicators

Recommended Replacement Time (RRT)	6 months (180 days) before EOS
Elective Replacement Indicator (ERI)	3 months (90 days) after RRT
End of Service (EOS)	≤2.5 V on 3 consecutive daily automatic measurements

RRT date – The programmer displays the date when the battery reached RRT on the Quick Look II and Battery and Device Measurements screens.

RRT operation – When the device reaches RRT, it continues to operate with its programmed parameters.

ERI operation – When the battery voltage reaches the ERI condition, the device sets the pacing mode to VVI and the Lower Rate to 65 bpm. The device also sets Rate Hysteresis to Off. The RV Amplitude and RV Pulse Width parameter values remain as programmed. If the device is programmed to the Device Off mode when it reaches ERI, it does not change the pacing mode or the lower rate.

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.

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

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS conditions. The PSP duration is at least 6 months (180 days), assuming the following conditions: 100% VVI pacing at 60 bpm, with 2.5 V pacing amplitude, 0.4 ms pulse width, and a 600 Ω pacing load. If the device is programmed to settings that consume more current than these conditions, EOS may be indicated on the programmer screen before the end of 6 months (180 days). The average PSP under nominal conditions (100% VVIR pacing at 60 bpm with 1.5 V pacing amplitude and 0.24 ms pulse width at a 500 Ω pacing load) is expected to be at least 6 months (180 days).

A.4 Projected service life

The projected service life in years for the device is shown in Table 11. The service life of the device is affected by the programmed settings for certain features, such as Rate Response.

Projected service life and estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Table 11. Projected service life in years

VVIR or VVI pacing %	Amplitude	Pacing rate	Impedance	Longevity in years	
				Pulse width 0.24 ms	Pulse width 0.4 ms
0%	1.5 V	60 bpm	500 Ω	14.6	14.5
50%	1.0 V	60 bpm	500 Ω	13.3	12.5
	1.5 V	60 bpm	500 Ω	11.7	10.4
	2.0 V	60 bpm	500 Ω	9.6	8.1
100%	1.0 V	60 bpm	500 Ω	11.8	10.5
	1.5 V	60 bpm	500 Ω	9.6	8.0
	2.0 V	60 bpm	500 Ω	7.1	5.5
	2.5 V	60 bpm	500 Ω	5.8	4.3
100%	1.5 V	60 bpm	400 Ω	9.0	7.4
	1.5 V	60 bpm	600 Ω	10.0	8.4
100%	1.5 V	70 bpm	500 Ω	9.1	7.5
	1.5 V	100 bpm	500 Ω	8.0	6.4
100%	2.5 V	60 bpm	600 Ω	6.3	4.7
	3.5 V	60 bpm	500 Ω	3.6	2.4
	5.0 V	60 bpm	500 Ω	1.8	1.2

Note: The longevity projections are based on typical shelf storage time. Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 5.4%.

A.5 Stored data and diagnostics

Table 12. Battery and device measurements data

The device automatically and continuously monitors its battery, pacing, and sensing performance throughout the life of the device. You can view the following data on the programmer screen and print reports:

- Battery and Device Measurements
  - Battery Voltage
  - Remaining Longevity
  - Sensing Integrity Counter
  - Electrode Impedance
  - Capture Threshold
  - Sensing
- Electrode Impedance Trend
- Capture Threshold Trend
- R-Wave Amplitude Trend
- Rate Histogram

Table 13. Device performance trend data

The device stores the daily measurements for 15 days. After 15 days, the device stores the weekly high and low measurements up to 80 weeks. Beyond 80 weeks, the data is maintained on a first-collected, first-deleted basis.

- Electrode Impedance Trend
- Capture Threshold Trend
- R-Wave Amplitude Trend

Table 14. Rate Histogram data

Rate Histogram data is available to view on the programmer screen and print as a report.

The Rate Histogram data shows the percent of total time for ventricular pacing and sensing. This data also shows the distribution of ventricular rate for paced and sensed events recorded since the last patient session.

B   Device parameters

B.1   Emergency settings

Table 15. Emergency VVI settings

Parameter	Selectable values
Mode	VVI
Lower Rate	70 bpm
Sensitivity	2.0 mV
Amplitude	5 V
Pulse Width	1 ms
Refractory	Off
Blank Post VP	240 ms
Blank Post VS	120 ms
Rate Hysteresis	Off

B.2   Pacing parameters

Table 16. Modes, rate, and intervals

Parameter	Programmable values	Shipped	Reset
Mode	VVIR◈; VVI; VOO; OVO; Device Off	Device Off	VVI
Lower Rate[a,b,c]	30; 35; 40 … 60◈ … 80; 90 … 170 bpm	60 bpm	65 bpm
Refractory[d]	Off◈; 160; 170 … 330 … 500 ms	Off	330 ms

[a] The corresponding Lower Rate interval can be calculated as follows: Lower Rate interval (ms) = 60,000/Lower Rate.

[b] Programmable values for Lower Rate do not include 65 bpm.

[c] If an EMI source interferes with the R-wave detection, the device starts pacing at the programmed lower rate in the VVI mode and at the programmed lower rate or sensor rate in the VVIR mode. When measured according to the standard ISO 14708-2:2012, clause 6.1.5, the escape interval is within −10 and 25 ms of the programmed lower rate interval.

[d] Blank Post VP and Blank Post VS parameters must be programmed to values lower than the programmed value for Refractory. If Refractory is programmed to Off, the refractory period is determined by the programmed value for Blank Post VP or Blank Post VS.

Table 17. RV sensing and pacing parameters

Parameter	Programmable values	Shipped	Reset
Amplitude	0.13; 0.25 ; 0.38; 0.50; 0.63; 0.75; 0.88; 1.00;1.13 … 1.50◈ … 5.00 V	2.5 V	3.5 V
Pulse Width	0.09; 0.15; 0.24◈; 0.40 ; 1.00 ms	0.24 ms	0.24 ms
Sensitivity[a],[b]	0.45; 0.60; 0.90; 1.50; 2.00◈; 2.80; 4.00; 5.60; 8.00; 11.30 mV	2.00 mV	2.80 mV
Sensing Assurance	Off◈; On	Off	On

[a] This setting applies to all sensing for bradycardia pacing operations.
[b] With a 40 ms sine^2 waveform. When using the waveform according to the standard ISO 14708-2:2012, clause 6.1.3, the sensing threshold value is 1.5 times the sine^2 sensing threshold.

Table 18. RV Capture Management parameters

Parameter	Programmable values	Shipped	Reset
Capture Management	Adaptive◈; Monitor; Off	Adaptive	Adaptive
Amplitude Safety Margin	0.25; 0.50◈; 0.75; 1.00; 1.25; 1.50 V	+0.5 V	+0.5 V
Acute Phase Remaining	Off; Device Repositioned (112 days)◈	112 days	—

Table 19. Blanking periods

Parameter	Programmable values	Shipped	Reset
Blank Post VP[a]	150; 160 … 240◈ … 450 ms	240 ms	240 ms
Blank Post VS[a]	120◈; 130 …350 ms	120 ms	120 ms

[a] Blank Post VP and Blank Post VS must be programmed to values lower than the programmed value for the Refractory parameter. If Refractory is programmed to Off, the refractory period is determined by the programmed value for Blank Post VP or Blank Post VS.

Table 20. Rate Response pacing parameters

Parameter	Programmable values	Shipped	Reset
Upper Sensor Rate[a]	80; 90; 100 …120◈ …170 bpm	120 bpm	120 bpm
ADL Rate	60; 65 … 95◈ … 160 bpm	95 bpm	95 bpm
Rate Profile Optimization	On◈; Off	On	On
ADL Response	1; 2; 3◈; 4; 5	3	3
Exertion Response	1; 2; 3◈; 4; 5	3	3
Activity Acceleration	15; 30◈; 60 s	30 s	30 s
Activity Deceleration	Exercise◈; 2.5; 5; 10 min	Exercise	Exercise
Exercise test parameters[b]			
Activity Vector	Vector 1; Vector 2; Vector 3	Vector 1	Vector 1

Table 20. Rate Response pacing parameters (continued)

Parameter	Programmable values	Shipped	Reset
LR Setpoint	0; 1; 2 … 40; 42 … 50	30	20
ADL Setpoint	5; 6 … 40; 42 … 80; 85 …100	42	30
UR Setpoint	15; 16 … 40; 42 … 80; 85 … 200	60	50

[a] If Rate Response is enabled, the Upper Sensor Rate must be greater than the ADL Rate, which must be greater than the Lower Rate.
[b] Exercise test parameters, Activity Vector and rate-response setpoints, can be programmed only from the Exercise test screen.

Table 21. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
MRI Pacing Mode	VOO; OVO	—	—
MRI Pacing Rate	60; 70; 75; 80; 90 … 120 bpm	—	—

Table 22. Additional pacing features

Parameter	Programmable values	Shipped	Reset
Rate Hysteresis[a]	Off◈; 30; 40 … 80 bpm	Off	Off

[a] The programmed value for Rate Hysteresis must be lower than the Lower Rate value unless Rate Hysteresis is programmed to Off.

B.3 Data collection parameters

Table 23. Data collection parameters

Parameter	Programmable values	Shipped	Reset
Device Date/Time[a]	(enter current date and time)	—	—
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24 hr	Off	Off

[a] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

B.4 System test parameters

Table 24. System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Threshold Test	Capture Management[a] Amplitude — Auto Decrement
Decrement after	2; 3 … 15 pulses

Table 24. System test parameters (continued)

Parameter	Selectable values
Mode[b] (RV test)	VVI; VOO
Lower Rate	30; 35 … 60; 70; 75; 80; 90 … 170 bpm
Amplitude	0.13; 0.25; 0.38; 0.50; 0.63 … 5.00 V
Pulse Width	0.09; 0.15; 0.24; 0.40; 1.00 ms
V. Pace Blanking[c]	150; 160 … 450 ms
Sensing Test parameters	
Mode	VVI; OVO
Lower Rate	30; 35 … 60; 70; 75; 80; 90 … 170 bpm
Exercise test parameters	
Duration	5 min; 20 min
Activity Vector	Vector 1; Vector 2; Vector 3
LR Setpoint	0; 1; 2 … 40; 42 … 50
ADL Setpoint	5; 6 … 40; 42 … 80; 85 …100
UR Setpoint	15; 16 … 40; 42 … 80; 85 … 200

[a] If the permanently programmed pacing mode is VOO, Capture Management is not available for selection.
[b] The selectable test values for this parameter depend on the permanently programmed pacing mode.
[c] The selectable values for V. Pace Blanking depend on the programmed value for the Refractory parameter.

B.5 Temporary test parameters

Table 25. Temporary test parameters

Parameter	Selectable values
Mode	VVI; VOO; OVO
Lower Rate	30; 35; 40 … 60; 70; 75; 80; 90 … 170 bpm
Amplitude	0.13; 0.25; 0.38; 0.50; 0.63 … 5.00 V
Pulse Width	0.09; 0.15; 0.24; 0.40; 1.00 ms
Refractory	Off; 250; 260; 270 … 500 ms
Sensitivity	0.45; 0.60; 0.90; 1.50; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV

B.6 Nonprogrammable parameters

Table 26. Nonprogrammable parameters

Parameter	Value
Pacing rate limit (runaway pacing rate protection)	195 bpm
Minimum input impedance	150 kΩ
Pacing output capacitance	2.2 µF

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.

AP (anteroposterior) view – fluoroscopic x-ray of the chest taken from front to back, as opposed to from back to front.

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.

Checklist – interactive list of programmer screens that helps users operate the programmer more efficiently. Clinicians can set up their own checklists or use a Medtronic standard checklist supplied with the programmer.

device status indicators – programmer warnings, such as "Warning - Device Electrical Reset," that describe problems with device memory or operation.

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

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

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

ERI (Elective Replacement Indicator) – battery status indicator displayed on the programmer to indicate when the implant of a new device is required. Key device parameters are automatically switched. For example, pacing mode switches to VVI and Lower Rate goes to 65 bpm.

event – a sensed or paced beat.

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.

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.

Interrogate – command to transmit the device parameter settings and stored data to the programmer.

LAO (left anterior oblique) view – fluoroscopic x-ray of the chest taken especially to assess the size of the left atrium and ventricle.

Live Rhythm Monitor – configurable programmer window that displays ECG, Marker Channel with marker annotations, and telemetered EGM waveform trace. It also displays the patient heart rate and interval in the upper left corner of the window.

longevity – number of years before the device battery reaches the recommended replacement time (RRT) voltage. This is also referred to as "projected service life".

manual operations – device functions that can only be initiated using the programmer in a patient session (for example, manual system tests).

Marker Channel telemetry – telemetered symbols that annotate the device sensing and pacing operations.

nominal – parameter value that is suggested by Medtronic and may be acceptable for the majority of patients.

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.

projected service life – estimated number of years before the device battery reaches the Recommended Replacement Time (RRT) voltage.

Prolonged Service Period (PSP) – estimated number of days the device operates when the RRT condition is reached.

radiopaque ID – a small metallic plate (inside the device) featuring the Medtronic identifier symbol for identifying the device under fluoroscopy.

RAO (right anterior oblique) view – fluoroscopic x-ray taken to view the front portion of the heart.

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.

Recommended Replacement Time – see "RRT".

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

RRT (Recommended Replacement Time) – battery status indicator displayed by the programmer 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 Assurance – The Sensing Assurance feature is designed to minimize oversensing and undersensing of R-waves by monitoring the peak amplitude of sensed signals and increasing or decreasing sensitivity to maintain an adequate sensing margin with respect to the sensed R-waves.

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 double-counted R-waves or problem with an electrode.

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.

telemetry – transmission of data between the device and the programmer by radio waves.

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

waveform – graphic plot of electrical activity, for example, intracardiac EGM or surface ECG trace.

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Micra™ Transcatheter Pacing Study
Summary of clinical results

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1   Summary of Clinical Results

The Micra™ Transcatheter Pacing System (TPS) is a miniaturized single chamber pacemaker system that is delivered via catheter through the femoral vein and is implanted directly inside the right ventricle of the heart. The clinical study investigated the safety and efficacy of the Micra TPS at 6 months. Long-term device performance will be evaluated once all subjects have the opportunity to complete the 12-month follow-up visit.

2   Study Purpose

The purpose of the Micra™ TPS clinical study was to demonstrate safety and effectiveness of the Micra TPS and to assess long-term device performance.

3   Study Scope, Design, and Methods

The Micra TPS clinical study was a prospective, multi-site, single-arm worldwide Investigational Device Exemption (IDE) clinical study. The study was designed to have a continuously growing body of evidence, and data analyses were planned at various time points to evaluate the primary safety and efficacy objectives. The study utilized a group sequential analysis plan where the study's primary objectives could be evaluated at up to three time points shown in **Figure 1**.

The primary safety objective of the study was to evaluate major complications related to the Micra system or procedure. The primary safety endpoint was evaluated at 6-months post-implant. The primary efficacy objective, Micra pacing capture thresholds, was also evaluated at 6-months post-implant. Both primary objectives were met at Analysis #1 after 300 subjects completed the 6-month visit, the results of which are presented in Section 6.

Figure 1: Study Analysis Time Points
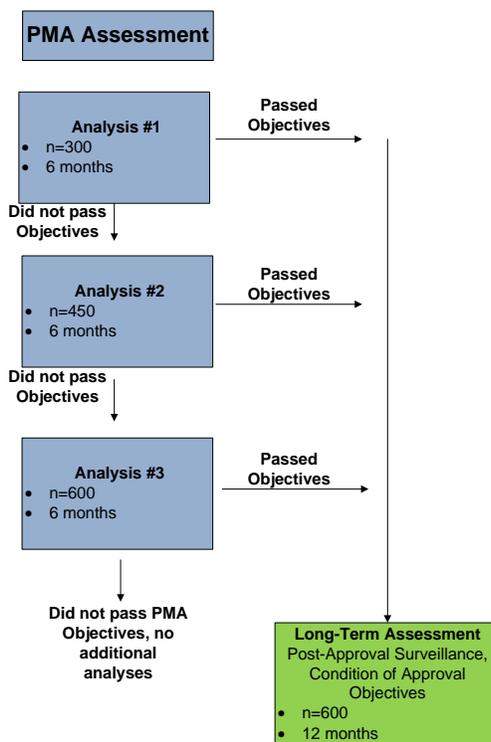
Clinical data were collected at baseline, implant/pre-hospital discharge, 1-month, 3-month, 6-month post-implant visits, and every 6-months thereafter until study closure. Data were collected using electronic case report forms (eCRFs) using an electronic data management system for clinical studies. In addition to eCRF data, non-CRF data was collected which included: digital medium for fluoroscopy cine recordings, x-rays, programmer strips, Holters, device interrogation files, and source documents (when requested).

There were some changes which occurred during the course of the study in the investigation plan, patient population inclusion, and software programming. The Table 1 below summarizes these changes and their potential impact on the study.

Table 1: Changes during Study and Assessment on Potential Impact

Change Made During Study	Timing of Change	Impact of Change	Corresponding Reference Material
CIP changes from Version 1 to Version 2	Began to implement CIP Version 2 (dated January 6, 2014) in all geographies in February 2014 post-FDA approval.	U.S. patients began enrolling under CIP v.2 (never enrolled under CIP v.1). Some sites outside the U.S. began enrolling under CIP v. 1 but CIP changes caused little impact on overall study since changes were largely statistical in nature and data collection measures remained essentially the same.	Micra Clinical Investigation Plan, Appendix N outlines specific details of changes from CIP Version 1.0 to Version 2.0.
Allowed expansion into pacemaker dependent patients	Medtronic notified all sites on July 23, 2014 that the restriction against pacemaker dependent subjects was lifted, following review of the Early Performance Assessment, as both early safety assessment objectives were met. The Early Performance Holter Report was reviewed by the FDA, the study steering committee, and the study Data Monitoring Committee. Subjects entirely pacemaker dependent (escape rhythm <30 bpm) could be included in the study after July 23, 2014.	There was no clinical impact on the scientific validity of the clinical study due to this change, since the study always planned to evaluate device performance in pacemaker dependent patients after it was confirmed that the device was performing as intended. Additionally in a pre-specified subgroup analysis there were no significant differences in the primary safety and efficacy objectives and pacemaker dependence status. See 6. Results Of the 719 subjects implanted with Micra, 2.8% (20/719) were considered pacemaker dependent (escape rhythm <30 bpm). In addition, 62 patients	Micra Final Holter Report (MDT2162679) FDA approved this change per IDE/S005

Change Made During Study	Timing of Change	Impact of Change	Corresponding Reference Material
		(8.5%) indicated an AV nodal ablation was pending at the time of enrollment, so it is expected these patients also became pacemaker dependent following the AV nodal ablation procedure.	
Allowed RPO to be turned on after software updated to Version 1.1	• U.S.: Communication dated February 26, 2015 was sent to U.S. sites as notification that they could turn RPO on after software was updated following IRB approval of updated software (via CIP Appendix K) • Europe: Countries began implementing in May 2015, after country approvals obtained • Other geographies: Some geographies still do not have approval; timing varied according to regulatory approval	This change had no impact on clinical results as rate response setpoints were manually programmed until RPO could be turned on (to enable setpoints to be automatically determined by the device).	FDA approved this change per IDE/S019

4   Subject Inclusion and Exclusion Criteria

Subjects who satisfied all inclusion and no exclusion criteria were eligible to participate in the study.

Inclusion criteria

INCLUSION Criteria	
Criteria	**Rationale**
Subjects who have a Class I or II indication for implantation of a single chamber ventricular pacemaker according to ACC/AHA/HRS 2008 guidelines and any national guidelines[1,2]	Study will be evaluated in the standard patient population that is actually indicated for the device under evaluation.
Subjects who are able and willing to undergo the study requirements and are expected to be geographically stable for the duration of the follow-up.	Ensure ascertainment of data required for clinical evaluation.
Subjects who are at least 18 years of age (or older, if required by local law).	Ensure age is appropriate to provide informed consent.

Exclusion criteria

There were two phases for enrollment criteria regarding pacemaker dependent subjects:

Epstein AE, DiMarco JP, Ellenbogen KA, Estes NA, Freedman RA, Gettes LS, Gillinov AM, Gregoratos G, Hammill SC, Hayes DL, Hlatky MA, Newby LK, Page RL, Schoenfeld MH, Silka MJ, Stevenson LW, Sweeney MO. ACC/AHA/HRS 2008 Guidelines for Device-based Therapy of Cardiac Rhythm Abnormalities: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices). 2008.
Europace 2006 8. 746-837 doi:10.1093/europace/eul108

- Phase 1: Initial enrollment was restricted to non-pacemaker dependent subjects (defined as escape rhythm <30 bpm).

- Phase 2: Restrictions against pacemaker dependent subjects were lifted after a steering committee safety review of the Holter and device diagnostic data from the 1st 25 usable Holters collected at the 1 month visit to ensure the device was performing as intended. Medtronic informed study sites on 24 JUL 2014 when this exclusion restriction was lifted following steering committee and data monitoring committee approval. FDA also reviewed the Holter analysis and provided permission to lift this exclusion criterion prior to informing study sites.

EXCLUSION Criteria	
Criteria	**Rationale**
Subjects who are entirely pacemaker dependent (escape rhythm <30 bpm). **NOTE: Restrictions against pacemaker dependent patients were lifted on 23 JUL 2014 after a steering committee and data monitoring committee safety review of the Holter and device diagnostic data from the 1st 25 usable Holters at 1 month. FDA also reviewed the Holter analysis and provided permission to lift this exclusion criterion prior to informing study sites.	Subjects who are entirely pacemaker dependent will be excluded in the initial cohort until device reliability is verified in a conservative effort to maximize patient protection and minimize risk for potential patient harm.
Subject has an existing or prior pacemaker, ICD or CRT device implant.	Avoid possible confounding factors (i.e. complications due to device change-outs).
Subject has unstable angina pectoris or has had an acute myocardial infarction (AMI) in the 30 days prior to eligibility assessment.	Avoid possible confounding factors (i.e. environment more susceptible to complications due to pre-existing conditions).
Subjects with current implantation of neurostimulator or any other chronically implanted device which uses current in the body. Note that a temporary pacing wire is allowed.	Necessary to avoid any possible electrical interference with Micra device.
Subjects with a mechanical tricuspid valve, implanted vena cava filter, or left ventricular assist device (LVAD).	Necessary to avoid electrical or mechanical interference when placing Micra device.
Subjects who are morbidly obese and physician believes telemetry communication of ≤5 inches (12.7 cm) could not be obtained with programmer head.	Necessary to ensure ability to communicate with programmer.
Subjects whose femoral venous anatomy is unable to accommodate a 23 French introducer sheath or implant on the right side of the heart (for example, due to obstructions or severe tortuosity) in the opinion of the implanter.	Necessary to place Micra introducer sheath.
Subjects who are considered as unable to tolerate an urgent sternotomy	Necessary in case of emergency where urgent vascular surgery would be required
Subjects with a known intolerance to Nickel-Titanium (Nitinol) Alloy.	Necessary since Micra tines are comprised of Nitinol material.

EXCLUSION Criteria	
Criteria	**Rationale**
Subjects for whom a single dose of 1.0mg dexamethasone acetate may be contraindicated.	Necessary due to steroid material on Micra electrode (standard exclusion for all pacing studies with steroid on the electrode).
Subjects with a life expectancy of less than 12-months.	Standard exclusion criteria to ensure study cohort is expected to survive to the time of endpoint evaluation.
Subjects who are currently enrolled or planning to participate in a potentially confounding drug or device trial during the course of this study. Co-enrollment in concurrent trials is only allowed when document pre-approval is obtained from the Medtronic study manager.	Standard exclusion criteria to avoid confounding procedural requirements due to multiple experimental studies.
Pregnant women, or women of child bearing potential and who are not on a reliable form of birth control.	Standard exclusion criteria to avoid harm to the fetus caused by fluoroscopy requirements.
Subjects with exclusion criteria required by local law (e.g. age, breast feeding, etc.).	Standard exclusion criteria to comply with any additional local requirements which may apply.

5   Primary Objectives

There is one primary safety objective and one primary efficacy objective. In order for the study to be considered successful, the study needed to meet both primary objectives.

<u>Primary Safety Objective</u>

The primary safety objective was to demonstrate that the freedom from major complications related to the Micra system and/or procedure at 6-months post-implant is greater than 83%.

For an adverse event to meet the endpoint the event must have occurred within 183 days (inclusive) of the Micra system implant and be adjudicated by the Clinical Events Committee(CEC) as being a major complication related to the Micra system and/or procedure. Major complications are those complications resulting in:

- Death
- Permanent loss of device function due to mechanical or electrical dysfunction of the device (e.g. pacing function disabled, leaving device abandoned electrically)
- Hospitalization
- Prolonged Hospitalization by at least 48 hours
- System revision (reposition, replacement, explant)

<u>Primary Efficacy Objective</u>

The primary efficacy objective was to demonstrate the percentage of subjects with an adequate pacing capture threshold at 6-months post-implant exceeds 80%.

An adequate pacing capture threshold (PCT) is defined as:

- A 6-month PCT ≤ 2V at a pulse duration of 0.24 ms AND
- An increase in PCT from implant to 6-months ≤ 1.5 months (0.24 ms pulse width)

6   Secondary Objectives

The following secondary objectives were prospectively defined:

Secondary Objective #1: Capture Management

The first secondary objective was to demonstrate the accuracy of Micra Ventricular Capture Management (VCM) pacing thresholds compared to manual pacing capture thresholds.

This objective was evaluated by demonstrating the percentage of subjects successfully implanted with the Micra system who have a VCM pacing threshold within 0.5V of the PCT measured manually (at a pulse duration of 0.24 ms) exceeds 85%.

Secondary Objective #2: Rate Response

The second secondary objective was to demonstrate the rate response operation of the Micra system

This objective was assessed by determining if the Micra sensor-indicated rate derived from the input of the accelerometer during the Minnesota Pacemaker Response Exercise Protocol (M-PREP) was proportional to the workload using the Kay-Wilkoff model. This objective was evaluated in a subset of study sites at the 3-month and 6-month visits.

7   Results

The first worldwide subject was enrolled in the Micra Transcatheter Pacing System Study on December 4, 2013 and implanted with a Micra system on December 5, 2013. The 300th implanted subject completed the 6-month follow-up visit on May 19, 2015, triggering the visit cutoff date for the first analysis where the primary and secondary objectives were evaluated. The study database was frozen for analysis on June 24, 2015. As of the May 19, 2015 visit cutoff date, 744 subjects have been enrolled in the study. There were 725 subjects who underwent an implant attempt with the Micra system with 719 (99.2%) subjects successfully implanted by 94 physicians at 56 centers in 19 countries.   Of the 744 enrolled subjects, there were 26 total exits, with 25 occurring prior to successful Micra implant. There was one subject in India that was enrolled and implanted after the May 19, 2015 visit cutoff date, after which enrollment in the study was completed.

Patient Accountability

A total of 744 subjects were enrolled at 56 centers in 19 countries worldwide. There were 725 subjects who had a Micra implant attempt with 719 subjects successfully implanted with the Micra system. There were 6 subjects with a Micra implant attempt that were not successfully implanted with a Micra system; 5 of the 6 received an alternate system. Figure 2 displays the disposition of all 744 enrolled subjects.

Figure 2: **Disposition of Enrolled Subjects**

```
                              ┌─────────────────┐
                              │    Enrolled     │
                              │     n=744       │
                              └─────────────────┘
┌───────────────────────┐              │
│ Exit: 19              │              │
│ Death: 0              │──────────────┤
│ Awaiting Implant: 0   │              │
└───────────────────────┘    ┌─────────────────┐      ┌─────────────────────┐
                              │ Implant Attempt │      │ Unsuccessful Implant│
                              │     n=725       │──────│      n=6            │
                              └─────────────────┘      │    Exited: 6        │
                                       │               └─────────────────────┘
                              ┌─────────────────┐
                              │ Successful Implant│
                              │     n=719       │
                              └─────────────────┘
┌───────────────────────┐              │
│ Exit: 0               │              │
│ Death: 9              │──────────────┤
│ Awaiting Visit: 23    │              │
└───────────────────────┘    ┌─────────────────┐
                              │ 1-Month Follow-up│
                              │  Completed: 678 │
                              │   Missed: 9     │
                              └─────────────────┘
┌───────────────────────┐              │
│ Exit: 1               │              │
│ Death: 9              │──────────────┤
│ Awaiting Visit: 168   │              │
└───────────────────────┘    ┌─────────────────┐
                              │ 3-Month Follow-up│
                              │  Completed: 504 │
                              │   Missed: 5     │
                              └─────────────────┘
┌───────────────────────┐              │
│ Exit: 0               │              │
│ Death: 5              │──────────────┤
│ Awaiting Visit: 199   │              │
└───────────────────────┘    ┌─────────────────┐
                              │ 6-Month Follow-up│
                              │  Completed: 301 │
                              │   Missed: 4     │
                              └─────────────────┘
┌───────────────────────┐              │
│ Exit: 0               │              │
│ Death: 5              │──────────────┤
│ Awaiting Visit: 237   │              │
└───────────────────────┘    ┌─────────────────┐
                              │ 12-Month Follow-up│
                              │  Completed: 62  │
                              │   Missed: 1     │
                              └─────────────────┘
┌───────────────────────┐              │
│ Exit: 0               │              │
│ Death: 1              │──────────────┤
│ Awaiting Visit: 63    │              │
└───────────────────────┘    ┌─────────────────┐
                              │ 18-Month Follow-up│
                              │  Completed: 0   │
                              │   Missed: 0     │
                              └─────────────────┘
```

Subject Demographics

Subject demographics were collected at the time of enrollment into the Micra Transcatheter Pacing study. Tables for baseline demographic, implant indication, medical history characteristics for the 744 subjects enrolled into the study are presented below. Of the 744 enrolled subjects, 309 (42%) were female and the average age was 76 years. The Micra study cohort reflects a very broad exposure across numerous countries and ethnicities, with a wide variety of implanted subjects:

- average weight 79 kg/174 lbs. (ranging from 37-155 kg/82-342 lbs.)
- average height 169 cm/66.5 in (ranging from 134-203 cm/52.8-79.9 in)
- average BMI 27.6 (ranging from 14-57)
- average age 76 years (ranging from 19-94 years)

Table 2: Baseline Demographics

Subject Characteristics	Enrolled (N = 744)	Implanted (N = 719)
Gender (N,%)		
Male	434 (58.3%)	424 (59.0%)
Female	309 (41.5%)	295 (41.0%)
No response	1 (0.1%)	0 (0.0%)
Age (years)		
Mean ± Standard Deviation	75.7 ± 11.0	75.8 ± 11.0
Median	78.0	78.0
25th Percentile - 75th Percentile	71 - 83	72 – 83
Minimum – Maximum	19 - 94	19 – 94
Subjects With Measure Available (N,%)	743 (99.9%)	719 (100.0%)
Race (N,%)*		
Not reportable per local laws or regulations	181 (24.3%)	179 (24.9%)
Subject/physician chose not to provide information	2 (0.3%)	2 (0.3%)
White or Caucasian	447 (60.1%)	431 (59.9%)
Black	21 (2.8%)	20 (2.8%)
American Indian or Alaska Native	0 (0.0%)	0 (0.0%)
Native Hawaiian	0 (0.0%)	0 (0.0%)
Guamanian or Chamorro	0 (0.0%)	0 (0.0%)
Samoan	0 (0.0%)	0 (0.0%)
Other Pacific Islander	0 (0.0%)	0 (0.0%)
Asian Indian	23 (3.1%)	23 (3.2%)
Chinese	15 (2.0%)	13 (1.8%)
Filipino	0 (0.0%)	0 (0.0%)
Japanese	38 (5.1%)	36 (5.0%)
Korean	0 (0.0%)	0 (0.0%)
Vietnamese	0 (0.0%)	0 (0.0%)
Other Asian	12 (1.6%)	12 (1.7%)
Two or more races	4 (0.5%)	3 (0.4%)
No response	1 (0.1%)	0 (0.0%)
Ethnicity (N,%)*		
Not reportable per local laws or regulations	185 (24.9%)	182 (25.3%)
Subject/physician chose not to provide information	8 (1.1%)	6 (0.8%)
Not Hispanic or Latino	464 (62.4%)	446 (62.0%)
Hispanic or Latino	14 (1.9%)	13 (1.8%)
No response	73 (9.8%)	72 (10.0%)

* Regulations in many European Union countries preclude the collection of race, and therefore this could not be collected, so it is not possible to accurately determine the percentage of non-white/non-Caucasian subjects.

Table 3: Baseline Physical Exam and Testing Results

Subject Characteristics	Enrolled (N = 744)	Implanted (N = 719)
Height (cm)		
Mean ± Standard Deviation	168.6 ± 10.8	168.8 ± 10.7
Median	170.0	170.0
25th Percentile - 75th Percentile	160 - 176	161 - 176
Minimum – Maximum	134 - 203	138 - 203
Subjects With Measure Available (N,%)	741 (99.6%)	717 (99.7%)
Weight (kg)		
Mean ± Standard Deviation	78.9 ± 18.6	79.1 ± 18.4
Median	77.0	77.0
25th Percentile - 75th Percentile	66 - 90	67 - 90
Minimum – Maximum	37 - 155	37 - 155
Subjects With Measure Available (N,%)	741 (99.6%)	717 (99.7%)
Body Mass Index		
Mean ± Standard Deviation	27.6 ± 5.3	27.6 ± 5.3
Median	26.7	26.7
25th Percentile - 75th Percentile	24 - 31	24 - 31
Minimum – Maximum	14 - 57	14 - 57
Subjects With Measure Available (N,%)	741 (99.6%)	717 (99.7%)
LVEF (%)		
Mean ± Standard Deviation	58.8 ± 8.8	58.8 ± 8.8
Median	60.0	60.0
25th Percentile - 75th Percentile	55 - 65	55 - 65
Minimum – Maximum	25 - 91	25 - 91
Subjects With Measure Available (N,%)	629 (84.5%)	608 (84.6%)

Table 4 summarizes the primary pacing indication for the 744 enrolled subjects and indicates that 64% of the 719 successfully implanted subjects had a pacing indication associated with persistent or permanent atrial arrhythmias. Additionally, 2.8% (20/719) subjects successfully implanted with the Micra system were considered pacemaker dependent (escape rhythm ≤30 bpm) at the time of their Micra implant.

Table 4: Primary Pacing Indication

Subject Characteristics	Enrolled (N = 744)	Implanted (N = 719)
Symptomatic Sinus Node Dysfunction	**323 (43.4%)**	**310 (43.1%)**
Without AV Block and without persistent/permanent atrial arrhythmias	118 (15.9%)	114 (15.9%)
With AV Block and with persistent/permanent atrial arrhythmias	41 (5.5%)	40 (5.6%)
With AV Block but without persistent/permanent atrial arrhythmias	12 (1.6%)	12 (1.7%)

Subject Characteristics	Enrolled (N = 744)	Implanted (N = 719)
Without AV Block but with persistent/permanent atrial arrhthmias	152 (20.4%)	144 (20.0%)
AV Blocks	**361 (48.5%)**	**351 (48.8%)**
2nd degree without atrial arrhythmias	45 (6.0%)	44 (6.1%)
3rd degree without atrial arrhythmias	67 (9.0%)	62 (8.6%)
AV block with atrial arrhythmias	186 (25.0%)	184 (25.6%)
Pending AV nodal ablation with atrial arrhythmias	62 (8.3%)	61 (8.5%)
Pending AV nodal ablation without atrial arrhythmias	1 (0.1%)	0 (0.0%)
Other Indications	**59 (7.9%)**	**58 (8.1%)**
Syncope	17 (2.3%)	16 (2.2%)
Other with atrial arrhythmias	31 (4.2%)	31 (4.3%)[1]
Other without atrial arrhythmias	11 (1.5%)	11 (1.5%)[2]
No Response	1 (0.1%)	0 (0.0%)
Pacing Indications Associated with pers/perm atrial arrhythmias (N, %)		
Yes	472 (63.4%)	460 (64.0%)
No	271 (36.4%)	259 (36.0%)
Escape Rhythm ≤30 bpm (N, %)		
Yes	20 (2.7%)	20 (2.8%)
No	721 (96.9%)	699 (97.2%)
No response	3 (0.4%)	0 (0.0%)

[1]Includes drug induced bradycardia (6), carotid sinus syndrome (11), atrial fibrillation with bradycardia (6), atrial fibrillation with long R-R intervals (3), atrial flutter with long R-R interval (1), intrinsic conduction system disease (1), permanent atrial fibrillation with intermittent pauses (1), persistent junctional rhythm after TAVI (1), and underlying bifasicular block (1).

[2]Includes carotid sinus syndrome (2), left bundle branch block (3), trifasicular block (3), swallow syncope (1), bifasicular block (1), and conduction disorder infrahisian (HV=80) (1).

Table 5 indicates that the most frequent reason for implanting a single chamber pacemaker among the 744 enrolled subjects were indication(s) associated with persistent/permanent/chronic atrial tachycardia/fibrillation flutter (65%) followed by frequent pacing not expected (30%).

Table 5: Reason for Selecting a Single Chamber Ventricular Pacemaker

	Enrolled (N = 744)	Implanted (N = 719)
Reason for Selecting a Single Chamber Ventricular Pacemaker (N, %)		
Frequent pacing not expected	224 (30.1%)	214 (29.8%)
Significant co-morbidities likely to influence patient's survival and clinical outcome	29 (3.9%)	26 (3.6%)
Indication(s) associated with persistent/permanent/chronic atrial tachycardia/fibrillation/flutter	480 (64.5%)	467 (65.0%)
Previous or planned AV nodal ablation	70 (9.4%)	67 (9.3%)
Patient's advanced age	135 (18.1%)	128 (17.8%)
Patient expected to be sedentary	27 (3.6%)	25 (3.5%)
Patient's anatomy precludes placement of atrial lead	10 (1.3%)	8 (1.1%)
Complication risk associated with dual chamber pacing system deemed too high	10 (1.3%)	9 (1.3%)
Value of new technology (e.g. patient preference)	91 (12.2%)	87 (12.1%)
Patient condition precludes traditional pacemaker implant	15 (2.0%)	13 (1.8%)
Other	5 (0.7%)	5 (0.7%)[1]
No response	1 (0.1%)	0 (0.0%)
Traditional Pacemaker Implant Issue (N, %)		
No response	1 (0.1%)	0 (0.0%)
No	696 (93.5%)	674 (93.7%)
Yes	47 (6.3%)	45 (6.3%)
Subject has compromised venous access	36 (4.8%)	34 (4.7%)
Need to preserve veins for hemodialysis	19 (2.6%)	18 (2.5%)
Thrombosis	12 (1.6%)	12 (1.7%)
History of infection	4 (0.5%)	4 (0.6%)
Cancer with need for indwelling catheter	6 (0.8%)	6 (0.8%)
Other	5 (0.7%)	5 (0.7%)[2]

[1] Other includes complete BAV (1), high risk to be complete AV block (1), syncope related to conduction abnormality (2), and failed traditional pacemaker implant attempt (1).
[2] Other incudes fibrosing mediastinitis (1), failed traditional pacemaker implant attempt (1), presence of bilateral pleural drainage with high risk for infection (1), psoriasis + interious lesions prone to infection (1), and skin allergis (1).

Table 6 through Table 14 display the relevant medical history for the 744 enrolled subjects. The most commonly reported medical history was hypertension followed by supraventricular tachyarrhythmias with 78% and 75% of enrolled subjects reporting respectively. Of note, 13% of enrolled subjects reported a history of COPD and 11% of enrolled subjects reported a history of pulmonary hypertension.

Table 6: General Cardiovascular History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
General CV history, NONE	35 (4.7%)	34 (4.7%)
Cardiac arrest	15 (2.0%)	14 (1.9%)
Cardiac arrest, due to ventricular arrhythmia	2 (0.3%)	2 (0.3%)
Cardiac arrest - due to transient or reversible cause	8 (1.1%)	7 (1.0%)
Cardiac arrest - unknown cause	6 (0.8%)	6 (0.8%)
Cardiomyopathy	78 (10.5%)	75 (10.4%)
Cardiomyopathy, dilated / congestive	8 (1.1%)	8 (1.1%)
Cardiomyopathy, hypertrophic	13 (1.7%)	13 (1.8%)
Cardiomyopathy, ischemic	36 (4.8%)	34 (4.7%)
Cardiomyopathy, restrictive	1 (0.1%)	1 (0.1%)
Cardiomyopathy, other	23 (3.1%)	21 (2.9%)
Congenital heart disease	9 (1.2%)	9 (1.3%)
Congestive heart failure	126 (16.9%)	121 (16.8%)
Coronary artery disease	206 (27.7%)	199 (27.7%)
Familial or inherited conditions with high risk for VT	0 (0.0%)	0 (0.0%)
Hypertension	583 (78.4%)	564 (78.4%)
Hypotension	18 (2.4%)	17 (2.4%)
Idiopathic structural heart disease	0 (0.0%)	0 (0.0%)
Left ventricular hypertrophy	119 (16.0%)	116 (16.1%)
Myocardial infarction	78 (10.5%)	75 (10.4%)
Pulmonary hypertension (PH)	81 (10.9%)	77 (10.7%)
Syncope	265 (35.6%)	258 (35.9%)
Syncope, due to known or suspected VT	4 (0.5%)	4 (0.6%)
Syncope, due to carotid sinus hypersensitivity	18 (2.4%)	18 (2.5%)
Syncope, vasovagal	15 (2.0%)	14 (1.9%)
Syncope, due to bradycardia	155 (20.8%)	152 (21.1%)
Syncope, due to SVT	5 (0.7%)	4 (0.6%)
Syncope, idiopathic / unknown	77 (10.3%)	75 (10.4%)
Valve dysfunction	308 (41.4%)	303 (42.1%)
Valve dysfunction, aortic	149 (20.0%)	148 (20.6%)
Valve dysfunction, mitral	215 (28.9%)	211 (29.3%)
Valve dysfunction, tricuspid	184 (24.7%)	179 (24.9%)
Valve dysfunction, pulmonary	19 (2.6%)	19 (2.6%)
Other cardiovascular history	69 (9.3%)	66 (9.2%)
No response	3 (0.4%)	0 (0.0%)

Table 7: Cardiovascular Surgical and Intervention History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
CV surgical/intervention history, NONE	438 (58.9%)	423 (58.8%)
Abdominal aortic aneurysm repair	5 (0.7%)	5 (0.7%)
Ablation	65 (8.7%)	62 (8.6%)
Ablation, atrial isthmus	24 (3.2%)	24 (3.3%)
Ablation, accessory pathway	5 (0.7%)	5 (0.7%)
Ablation, AV node	3 (0.4%)	2 (0.3%)
Ablation, epicardial	0 (0.0%)	0 (0.0%)
Ablation, HIS bundle	1 (0.1%)	1 (0.1%)
Ablation, MAZE	14 (1.9%)	13 (1.8%)
Ablation, pulmonary vein	27 (3.6%)	25 (3.5%)
Ablation, sinus node	0 (0.0%)	0 (0.0%)
Ablation, unknown	5 (0.7%)	4 (0.6%)
Cardiac transplant	0 (0.0%)	0 (0.0%)
Carotid endarterectomy	14 (1.9%)	14 (1.9%)
Carotid stent	4 (0.5%)	4 (0.6%)
Coronary artery bypass graft (CABG)	76 (10.2%)	74 (10.3%)
Coronary artery intervention	113 (15.2%)	110 (15.3%)
Coronary artery intervention, balloon angioplasty	34 (4.6%)	33 (4.6%)
Coronary artery intervention, bare metal stent	39 (5.2%)	39 (5.4%)
Coronary artery intervention, drug eluting stent	51 (6.9%)	50 (7.0%)
Coronary artery intervention, other	15 (2.0%)	14 (1.9%)
Venous stent	4 (0.5%)	4 (0.6%)
Renal stent	4 (0.5%)	4 (0.6%)
Valve surgery	94 (12.6%)	94 (13.1%)
Valve surgery, aortic	60 (8.1%)	60 (8.3%)
Valve surgery, mitral	43 (5.8%)	43 (6.0%)
Valve surgery, tricuspid	18 (2.4%)	18 (2.5%)
Valve surgery, pulmonary	0 (0.0%)	0 (0.0%)
Other cardiovascular surgery	38 (5.1%)	38 (5.3%)
No response	3 (0.4%)	0 (0.0%)

Table 8: Atrial Arrhythmia History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
Atrial arrhythmias, NONE	171 (23.0%)	165 (22.9%)
AV nodal re-entrant tachycardia	4 (0.5%)	3 (0.4%)
Premature atrial complexes	49 (6.6%)	47 (6.5%)
Premature atrial complexes, non-conducted	2 (0.3%)	2 (0.3%)
SA nodal re-entry	0 (0.0%)	0 (0.0%)
Supraventricular tachycardia	559 (75.1%)	543 (75.5%)
Atrial fibrillation, paroxysmal	133 (17.9%)	126 (17.5%)
Atrial fibrillation, persistent	145 (19.5%)	138 (19.2%)
Atrial fibrillation, permanent	277 (37.2%)	274 (38.1%)
Atrial flutter	111 (14.9%)	107 (14.9%)
Atrial tachycardia	33 (4.4%)	30 (4.2%)
Wandering atrial pacemaker	0 (0.0%)	0 (0.0%)
Other atrial arrhythmias	6 (0.8%)	4 (0.6%)
No response	3 (0.4%)	0 (0.0%)

Table 9: Sinus Node Dysfunction History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
Sinus Node Dysfunction, NONE	367 (49.3%)	360 (50.1%)
Bradycardia - tachycardia syndrome	175 (23.5%)	167 (23.2%)
Chronotropic incompetence	23 (3.1%)	23 (3.2%)
Sinus arrest / pause / exit block	133 (17.9%)	127 (17.7%)
Sinus bradycardia	139 (18.7%)	135 (18.8%)
Sinus tachycardia	12 (1.6%)	11 (1.5%)
Other sinus node dysfunction	7 (0.9%)	6 (0.8%)
No response	3 (0.4%)	0 (0.0%)

Table 10: Ventricular Arrhythmia History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
Ventricular arrhythmias, NONE	588 (79.0%)	569 (79.1%)
Premature ventricular complexes	130 (17.5%)	127 (17.7%)
Torsades de pointes	3 (0.4%)	3 (0.4%)
Ventricular fibrillation	2 (0.3%)	2 (0.3%)
Ventricular flutter	1 (0.1%)	1 (0.1%)
Ventricular tachycardia, non-sustained	38 (5.1%)	38 (5.3%)
Ventricular tachycardia, sustained monomorphic	0 (0.0%)	0 (0.0%)
Ventricular tachycardia, sustained polymorphic	1 (0.1%)	1 (0.1%)
Ventricular tachycardia, sustained, unknown morphology	0 (0.0%)	0 (0.0%)
Other ventricular arrhythmias	7 (0.9%)	7 (1.0%)
No response	3 (0.4%)	0 (0.0%)

Table 11: AV Junctional Arrhythmia and Block History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
AV junctional arrhythmias and blocks, NONE	326 (43.8%)	317 (44.1%)
1st degree AV block	89 (12.0%)	85 (11.8%)
2nd degree AV block	83 (11.2%)	82 (11.4%)
3rd degree AV block	144 (19.4%)	140 (19.5%)
AV junctional rhythm	31 (4.2%)	31 (4.3%)
Left bundle branch block	98 (13.2%)	98 (13.6%)
Intraventricular conduction delay	8 (1.1%)	7 (1.0%)
Right bundle branch block	131 (17.6%)	129 (17.9%)
Pre-excitation syndromes (e.g. Wolf Parkinson White)	0 (0.0%)	0 (0.0%)
Premature junctional contractions	1 (0.1%)	1 (0.1%)
Other AV junctional arrhythmias and blocks	63 (8.5%)	59 (8.2%)
No response	3 (0.4%)	0 (0.0%)

Table 12: Endocrine History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
Endocrine, NONE	225 (30.2%)	220 (30.6%)
Diabetes	212 (28.5%)	205 (28.5%)
Diabetes, type 1	9 (1.2%)	8 (1.1%)
Diabetes, type 2	203 (27.3%)	197 (27.4%)
Diabetes, gestational	0 (0.0%)	0 (0.0%)
Dyslipidemia	332 (44.6%)	320 (44.5%)
Hormone replacement therapy	8 (1.1%)	7 (1.0%)
Hyperthyroidism	17 (2.3%)	16 (2.2%)
Hypothyroidism	98 (13.2%)	96 (13.4%)
Renal dysfunction	148 (19.9%)	143 (19.9%)
Renal dysfunction, requiring dialysis	28 (3.8%)	26 (3.6%)
Renal dysfunction, not requiring dialysis	120 (16.1%)	117 (16.3%)
Other endocrine	57 (7.7%)	56 (7.8%)
No response	4 (0.5%)	1 (0.1%)

Table 13: Vascular History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
Vascular disease history, NONE	440 (59.1%)	422 (58.7%)
Carotid artery disease	60 (8.1%)	60 (8.3%)
Cerebral artery disease	48 (6.5%)	46 (6.4%)
Cerebral arterial stenosis	6 (0.8%)	6 (0.8%)
Cerebral artery revascularization/percutaneous intervention	1 (0.1%)	1 (0.1%)
Transient ischemic attack	41 (5.5%)	39 (5.4%)
Deep vein thrombosis	22 (3.0%)	22 (3.1%)
Intermittent claudication	11 (1.5%)	11 (1.5%)
Peripheral edema	62 (8.3%)	61 (8.5%)
Peripheral vascular disease	54 (7.3%)	53 (7.4%)
Poor peripheral perfusion	9 (1.2%)	9 (1.3%)
Pulmonary edema	8 (1.1%)	8 (1.1%)
Pulmonary embolism	12 (1.6%)	11 (1.5%)
Raynaud's phenomenon	4 (0.5%)	4 (0.6%)
Renal artery disease	7 (0.9%)	7 (1.0%)
Stroke	88 (11.8%)	87 (12.1%)
Stroke, ischemic stroke	56 (7.5%)	56 (7.8%)
Stroke, intracerebral hemorrhage	7 (0.9%)	6 (0.8%)
Stroke, subarachnoid hemorrhage	4 (0.5%)	4 (0.6%)
Stroke, unknown type	25 (3.4%)	25 (3.5%)
Vascular aneurysm	14 (1.9%)	14 (1.9%)
Other vascular	61 (8.2%)	59 (8.2%)
No response	4 (0.5%)	1 (0.1%)

Table 14: Respiratory/Pulmonary History

Subject Characteristics (N, %)	Enrolled (N = 744)	Implanted (N = 719)
Respiratory/pulmonary, NONE	356 (47.8%)	343 (47.7%)
Asthma	34 (4.6%)	33 (4.6%)
Chronic obstructive pulmonary disease (COPD)	93 (12.5%)	89 (12.4%)
Emphysema	12 (1.6%)	11 (1.5%)
Hemoptysis	2 (0.3%)	2 (0.3%)
Lung cancer	5 (0.7%)	5 (0.7%)
Pleural effusion	26 (3.5%)	25 (3.5%)
Pneumonia	36 (4.8%)	35 (4.9%)
Pulmonary fibrosis	9 (1.2%)	9 (1.3%)
Respiratory failure	11 (1.5%)	10 (1.4%)
Sleep apnea	73 (9.8%)	71 (9.9%)
Smoking	243 (32.7%)	236 (32.8%)
Smoking, current	33 (4.4%)	31 (4.3%)
Smoking, former	212 (28.5%)	207 (28.8%)
Tuberculosis	8 (1.1%)	8 (1.1%)
Other respiratory	57 (7.7%)	56 (7.8%)
No response	4 (0.5%)	1 (0.1%)

Table 15 displays the cardiovascular medications in descending order of frequency reported at baseline among the 744 enrolled subjects. The most common cardiovascular medications used at baseline were ACE inhibitors (49%), followed by anticoagulants (45%) and diuretics (32%).

Table 15: Baseline Cardiovascular Medications

Medication Class (N, %)	Enrolled (N=744)	Implanted (N=719)
At least one CV medication at baseline	**658 (88.4%)**	**643 (89.4%)**
ACE INHIBITORS	364 (48.9%)	354 (49.2%)
ANTICOAGULANT	335 (45.0%)	328 (45.6%)
DIURETICS	239 (32.1%)	237 (33.0%)
ANTIPLATELET	220 (29.6%)	212 (29.5%)
BETA-BLOCKER	209 (28.1%)	205 (28.5%)
CALCIUM CHANNEL BLOCKERS	204 (27.4%)	201 (28.0%)
ANGIOTENSIN RECEPTOR BLOCKERS	142 (19.1%)	139 (19.3%)
ALDOSTERONE ANTAGONISTS	90 (12.1%)	89 (12.4%)
VASODILATORS AND NITRATES	82 (11.0%)	81 (11.3%)
CARDIAC GLYCOSIDES	53 (7.1%)	51 (7.1%)
ALPHA-ADRENERGIC BLOCKING	46 (6.2%)	46 (6.4%)
ANTIARRHYTHMIC - CLASS III	33 (4.4%)	30 (4.2%)
OTHER ANTIHYPERTENSIVES	33 (4.4%)	32 (4.5%)
ANTI-HYPERLIPIDEMIA	26 (3.5%)	26 (3.6%)
OTHER CARDIOVASCULAR	18 (2.4%)	18 (2.5%)
ANTIARRHYTHMIC - CLASS 1C	15 (2.0%)	15 (2.1%)
BETA - AGONIST	8 (1.1%)	8 (1.1%)
POSITIVE INOTROPES	8 (1.1%)	8 (1.1%)
ALPHA-ADRENERGIC AGONIST	5 (0.7%)	5 (0.7%)
ANTIARRHYTHMICS	3 (0.4%)	3 (0.4%)
ANTICOAGULANT ANTAGONIST	3 (0.4%)	3 (0.4%)
PHOSPHODIESTERASE INHIBITORS	3 (0.4%)	3 (0.4%)
ANTIARRHYTHMIC - CLASS 1B	1 (0.1%)	1 (0.1%)
NARCOTIC	1 (0.1%)	1 (0.1%)
NONSTEROIDAL ANTI-INFLAMMATORY	1 (0.1%)	1 (0.1%)
RENIN INHIBITOR	1 (0.1%)	1 (0.1%)

Subjects Included in Analysis of Primary Objectives

Primary Safety Objective was met.

The 300th 6-month follow-up visit was completed on 19 May 2015 triggering the visit cutoff for the data reported in this summary (Note that there were 301 6-month visits accrued by this date). At the time of the visit cutoff 725 subjects had an attempted implant of the Micra system and were included in the analysis. There were 28 major complications related to the Micra system or procedure in 25 subjects. Of the 28 major complications, the majority (54%) occurred within 1 day of a Micra implant attempt, with 71% within 7 days of an implant attempt. All major complications occurred within 6-months of the implant attempt shown in Table 16.

Table 16: System or Procedure Related Major Complications

Adverse Event Keyterm	Major Complications
TOTAL EVENTS	**28 (25, 3.45%)**
EMBOLISM AND THROMBOSIS	**2 (2, 0.28%)**
DEEP VEIN THROMBOSIS	1 (1, 0.14%)
PULMONARY EMBOLISM	1 (1, 0.14%)
EVENTS AT GROIN PUNCTURE SITE	**5 (5, 0.69%)**
ARTERIOVENOUS FISTULA	4 (4, 0.55%)
VASCULAR PSEUDOANEURYSM	1 (1, 0.14%)
TRAUMATIC CARDIAC INJURY	**11 (11, 1.52%)**
CARDIAC PERFORATION	3 (3, 0.41%)
PERICARDIAL EFFUSION	8 (8, 1.10%)
PACING ISSUES	**2 (2, 0.28%)**
DEVICE DISLOCATION	1 (1, 0.14%)
DEVICE PACING ISSUE	1 (1, 0.14%)
OTHER	**8 (8, 1.10%)**
ACUTE MYOCARDIAL INFARCTION	1 (1, 0.14%)
CARDIAC FAILURE	3 (3, 0.41%)
METABOLIC ACIDOSIS	1 (1, 0.14%)
PACEMAKER SYNDROME	1 (1, 0.14%)
PRESYNCOPE	1 (1, 0.14%)
SYNCOPE	1 (1, 0.14%)

The most common reason an event met the major complication endpoint was prolonged hospitalization (18 of 28 or 64% of major complications) as displayed in Table 17. Of the 725 subjects with an implant attempt, 3 (0.4%) required a system revision.

Table 17: Major Complication Criteria Met

Major Complication Criterion (not Mutually Exclusive)	Major Complications (N = 28)
Led to death	1 (3.6%)
Led to permanent loss of device function due to mechanical or electrical dysfunction of the device	1 (3.6%)
Led to hospitalization	13 (46.4%)
Led to prolonged Hospitalization by 48 hours or more	18 (64.3%)
Led to system revision (explant, reposition, replacement)	3 (10.7%)

Figure 3 displays the Kaplan-Meier estimates for the freedom from major complications related to the Micra system or procedure using Greenwood's formula for variance estimates and confidence intervals. The Kaplan-Meier estimate for the freedom from major complications related to Micra system or procedure at 6-months (183 days) post-implant was 96.0% (98.66% CI: 93.3% - 97.6%). This was significantly higher than the pre-specified performance criterion of 83% (P<0.0001). Since the p-value associated with this test was lower than the p-value required to reject the null hypothesis at the first interim analysis (0.0067), the null hypothesis was rejected and the primary safety objective was considered met.

Of note, there was 1 successfully implanted subject that was considered lost-to-follow-up (this subject was later found and is in the process of re-consent) and 21 successfully implanted subjects who died prior to completing their 6-month study visit and without meeting the primary safety endpoint. Data from these subjects was included in the Kaplan-Meier analysis, but they were considered censored at the time of study exit or death.

There are 387 implanted subjects who have not had a major complication and have not yet completed at least 183 days of follow-up. These 387 subjects along with all other subjects active in the Micra study continue to be followed and will be included in future study reports once all subjects have the opportunity to complete the 12-month follow-up visit.

Figure 3: Freedom from Major Complications Related to the Micra System or Procedure through 6 Months Post-Implant
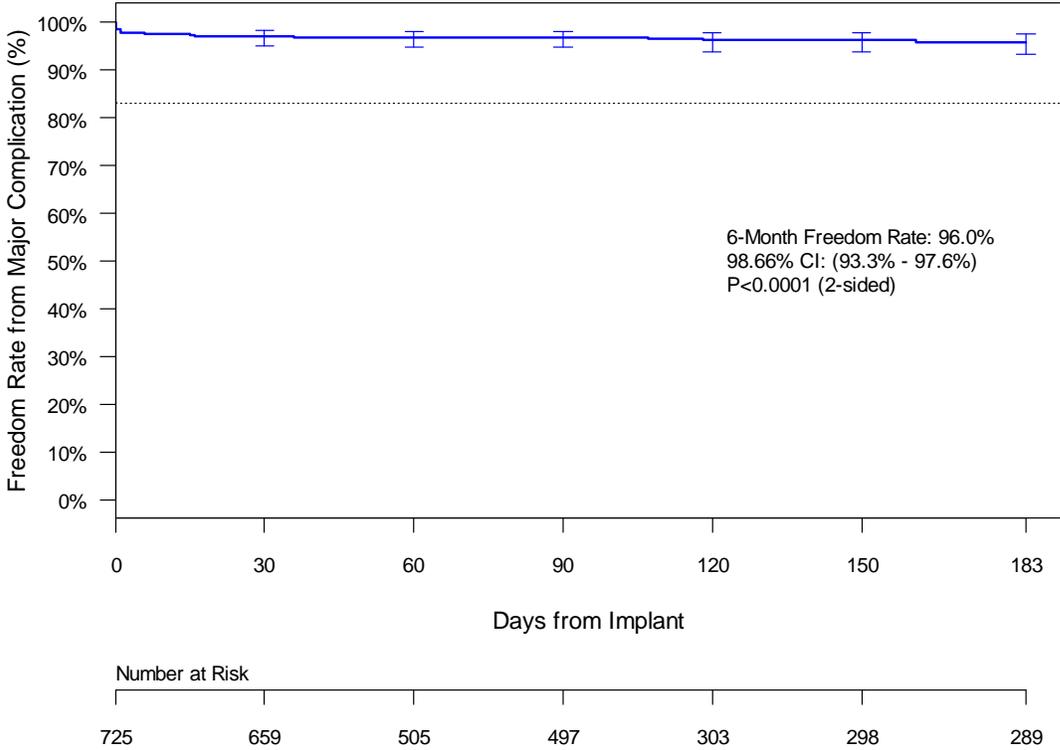
Figure 4 displays the freedom from major complications related to the Micra system or procedure through 12-months post-implant and indicates that there has been no change in the estimated major complication rate between six and twelve months. Since the latest (relative to Micra implant) major complication occurred on day 161, there has been no change to either the Kaplan-Meier estimate or its associated confidence interval following six months (day 183).

Figure 4: Freedom from Major Complications Related to the Micra System or Procedure through 12 Months Post-Implant
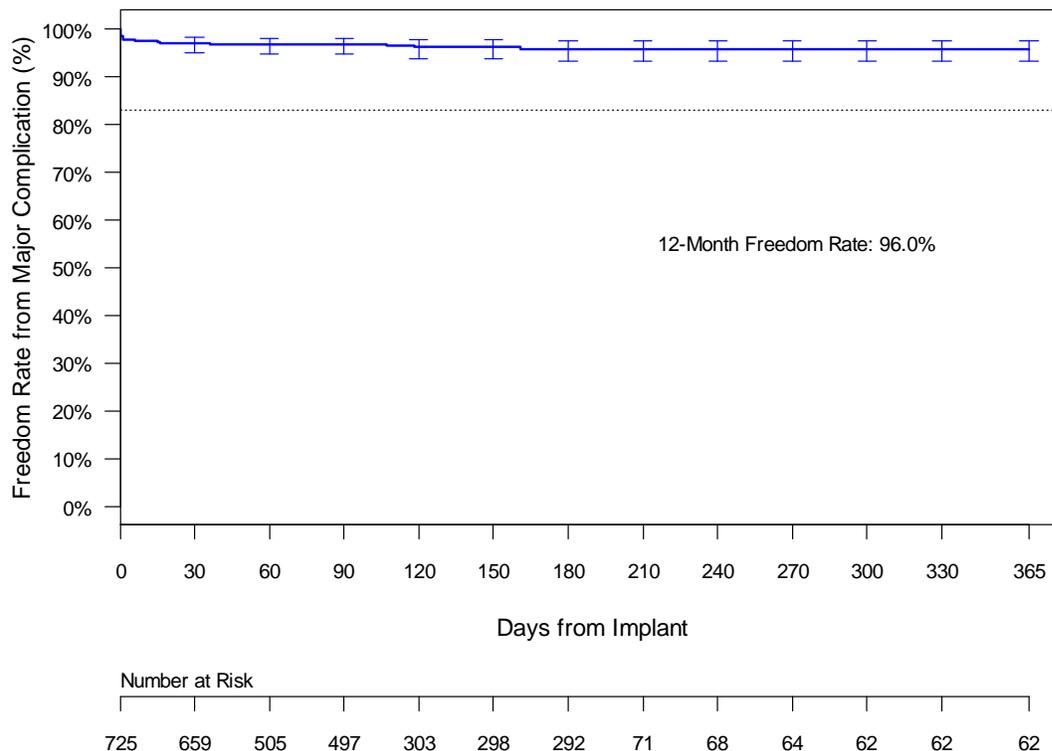
Figure 5 displays the freedom rate from major complications related to the pacing system or procedure at 6-months (183-days) post implant for the six recent Medtronic pacemaker studies used to derive the performance goal and the Micra system in relation to the performance requirement (red dashed line). The 977 subjects from the six previous Medtronic studies with a history of AF were used to derive the performance goal of 83%. The 6-month freedom from major complications for the 6 predicate studies (n=977 implant attempts with n=718 subjects at risk at 6-months post-implant) was 91.6% with a 95% confidence interval of 89.7% - 93.2%. In comparison, the 6-month freedom from major complication rate for Micra was 96.0% with a 98.66% confidence interval of 93.3% to 97.6%. Figure 5 suggests that the Micra safety profile is comparable to that of the predicate pacing systems and performed better than was expected at the study design stage.

Figure 5: 6-Month Freedom from Major Procedure or System Related Complications (Micra vs Reference Dataset – 977 AF Reference Subjects Only)
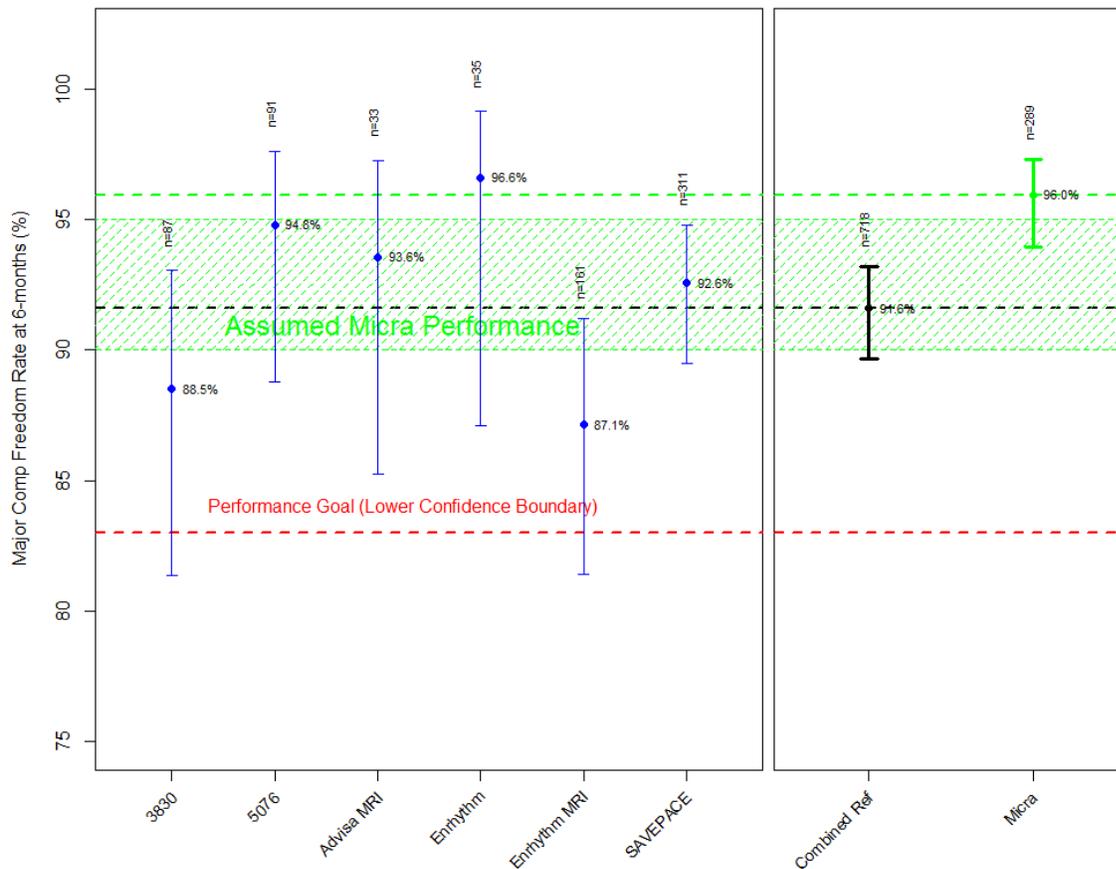
Notes: n is the number of subjects remaining at risk 183 days post-implant.

The figure above compares Micra performance to a reference dataset comprised of 6 recent Medtronic dual chamber pacing studies. The Micra study established the 83% criteria for the lower confidence bound based on this dual chamber dataset. Given that no single chamber studies have been conducted in recent years, a single chamber reference dataset was simulated by excluding any complications related only to the right atrial lead. The population from these 6 previous studies was very large, including 2667 subjects. Originally, Medtronic assumed the reference dataset should only include subjects with atrial fibrillation in order to mimic a typical single chamber patient population, and therefore used the 977 subjects with AF to establish the lower confidence bound criteria, rather than the full population of 2667 patients. However, not all of the Micra subjects have AF and it is most conservative to compare Micra performance to the full population of 2667 patients (i.e. major complication rate in 977 subjects is 8.4% compared to 7.4% in full population of 2667). Therefore, to be conservative, the figure below and the upcoming post-hoc safety analyses in this summary provide comparisons for the full population of all 2667 subjects from the 6 reference studies.

This post-hoc analysis comparing the freedom from major complication rates at 6-months post-implant between the 725 subjects with a Micra implant attempt and all 2667 subjects with an implant attempt in the 6 reference studies demonstrates that the 6-month major complication rate was lower for Micra than the leaded pacemaker systems (4.0% Micra vs 7.4% leaded systems, post-hoc P=0.006).

Figure 6: 6-Month Freedom from Major Procedure or System Related Complications (Micra vs Reference Dataset – All 2667 Reference Subjects)
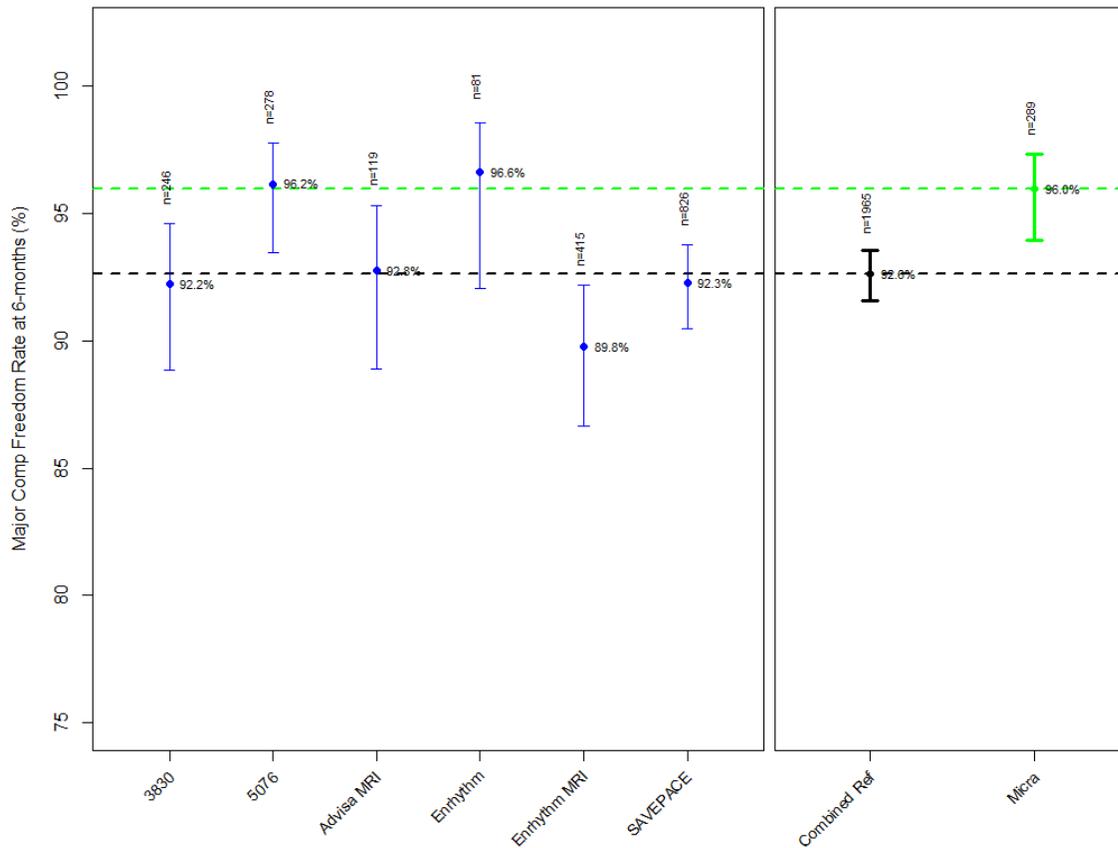
Notes: n is the number of subjects remaining at risk 183 days post-implant.

As a post-hoc analysis to compare the Micra safety profile to that of the reference dataset, the rate of different categories of major complications at 6-months post-implant (183 days post-implant) were compared between the Micra system and the pooled reference dataset. A two-sided statistical test of the 6-month freedom rates based on the Kaplan-Meier estimates was constructed using log-log transformation of each Kaplan-Meier estimate. If no events were observed in one of the datasets, Fisher's Exact test was used to compare the groups. For the Fisher's exact test the numerator was the number of observed events on or prior to day 183 and the denominator was the number of subjects remaining at risk for an event on day 183 plus the number of subjects with an event on or prior to day 183.

Figure 7 displays the 6-month major complication rates as estimated using the Kaplan-Meier method for Micra and the reference pacemaker study subjects by major complication category. The lower rate of major complications observed with the Micra system relative to the six reference Medtronic pacemaker studies appeared to have been largely driven by reductions in access site events (primarily implant site haematoma and implant site infections), pacing issues (primarily device capture and device pacing issues), and fixation events (there were no device/lead dislodgements in the Micra study). Of note the rate of major complications related to cardiac injury (i.e. pericardial effusion or perforation) were higher in the Micra study than in the six reference Medtronic pacemaker studies (P=0.288).

**Figure 7: 6-Month Major Complication Rates by Category (Micra vs Reference Dataset –
All 2667 Reference Subjects)**
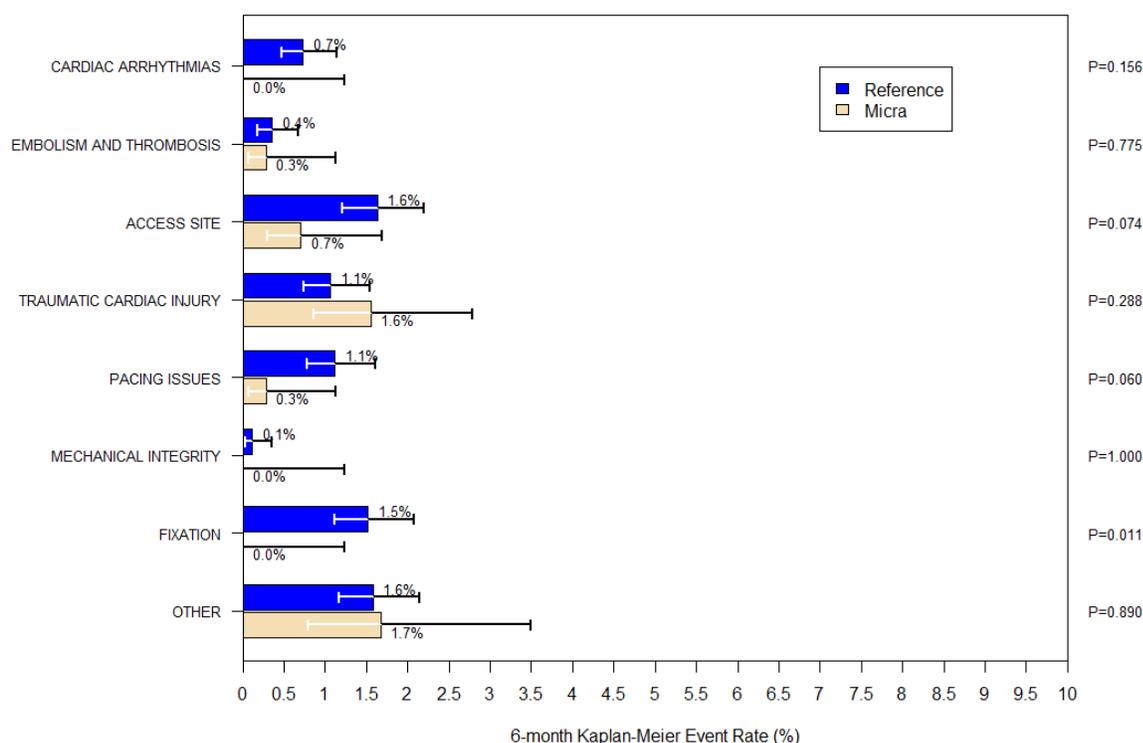
Notes: Confidence intervals are based on log-log transformation of the survival estimate except in cases where zero events were observed (mechanical integrity and fixation) where they are based on the exact binomial distribution.

P-value based on comparison of Kaplan-Meier estimates at 183 days post-implant except in cases where zero events were observed in one group. In this case the P-value is based on Fisher's exact test.

Conclusion
There were 28 major complications in 25 subjects related to the Micra system or procedure as determined by the CEC occurring in the 725 subjects with a Micra implant attempt during a total of 3124.1 months of follow-up. The Kaplan-Meier estimate for the freedom from major complications related to Micra system or procedure at 6-months (183 days) post-implant was 96.0% (98.66% CI: 93.3% - 97.6%). This was significantly higher than the pre-specified performance criterion of 83% (P<0.0001). Since the p-value associated with this test was lower than the p-value required to reject the null hypothesis at the first interim analysis (0.0067), the null hypothesis was rejected and the primary safety objective was considered met.

Primary Efficacy Objective was met.
At the time of the visit cutoff, there were 301 6-month visits among the 719 successfully implanted subjects. Figure 8 summarizes the data available for the main analysis of the primary efficacy objective. Of the 301 subjects with 6-month visits, 295 (98.7%) had their PCT measured at 0.24 ms using the pre-specified auto decrement test at both the implant and 6-month visit and were included in the main analysis of this objective. Additionally, one subject had a system modification with the original Micra device extracted and a second Micra implanted, at 16 days post initial implant, due to elevated threshold; another subject had an alternate device implant with Micra programmed to OOO (off), at 32 days post implant, due to elevated threshold. These two subjects were also included in the primary efficacy analysis as failures.

Figure 8: Data Available for Primary Efficacy Objective
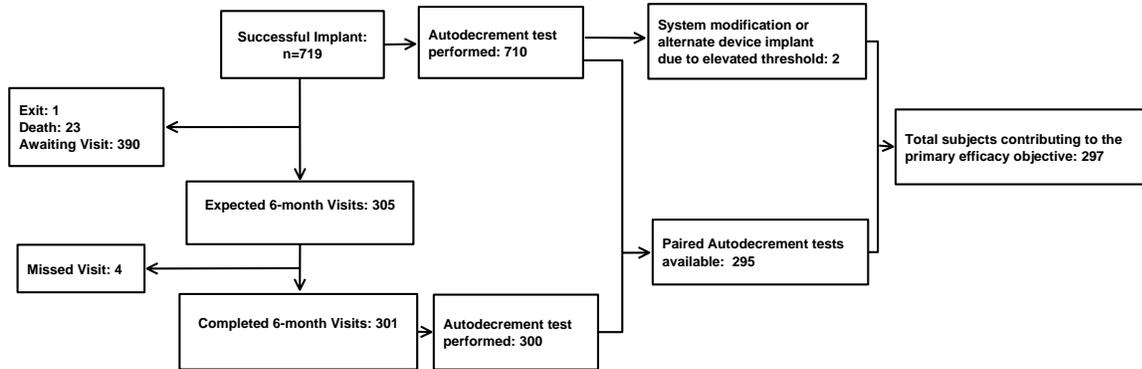
Figure 9 displays a scatter plot of the auto decrement PCT values (at 0.24 ms) for the 295 subjects with paired implant and 6-month follow-up data available. Points plotted in the green region indicate subjects that had an adequate safety margin (≤ 2 Volts, and ≤ 1.5 Volts increase from implant) and met the primary efficacy endpoint.

Figure 9: Scatter Plot of Auto Decrement PCTs at Implant and 6-Months
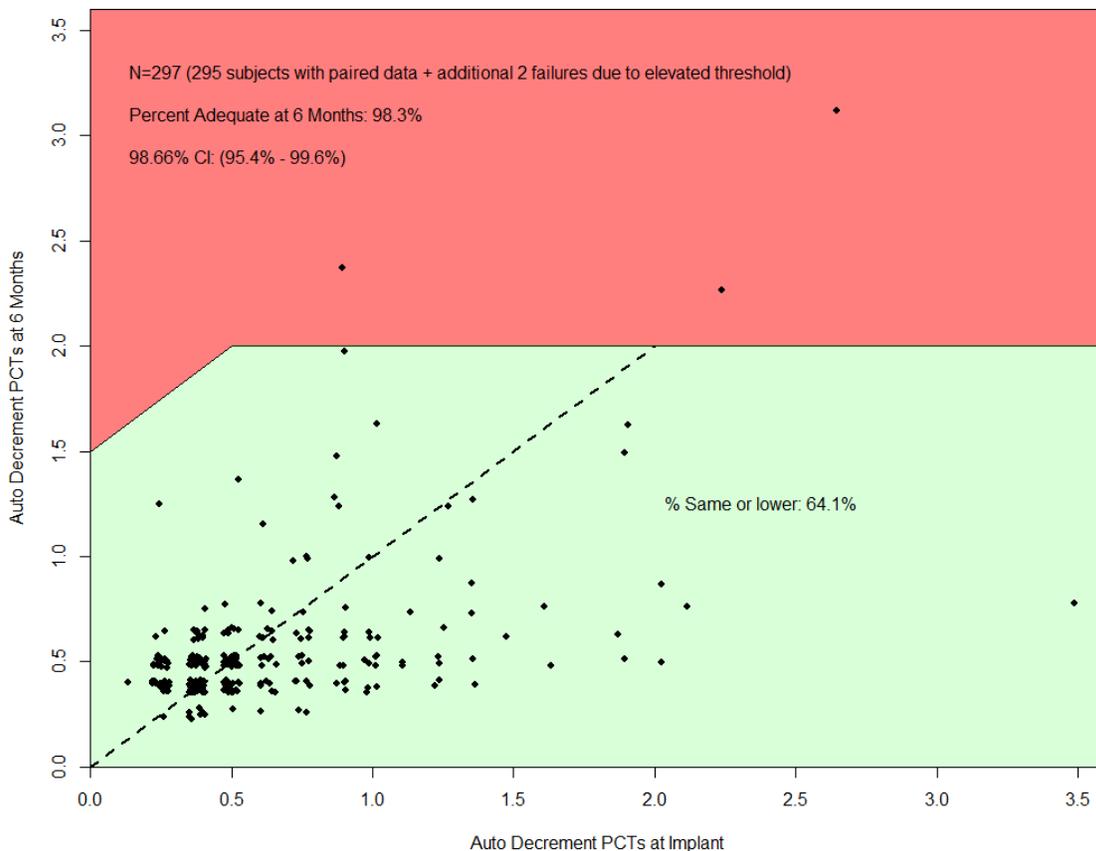
Notes: The dashed 45 degree line represents the line of equality. Data points below and to the right of the solid lines meet the primary efficacy endpoint. The data points were jittered to show distribution density.

Table 18 displays the main result of the primary efficacy analysis. Of the 297 subjects who contributed to the primary efficacy analysis, 292 (98.3%) had an adequate 6-month PCT, meaning they had a 6-month PCT no greater than 2.0V and had a rise in PCT from implant to 6-months of no more than 1.5V. This observed percentage of subjects with an adequate safety margin was significantly greater than the pre-specified goal of 80% since the nominal one-sided P-value was lower than the nominal alpha level of 0.0067 dictated by the Hwang-Shih-DeCani alpha spending rule. Therefore the null hypothesis associated with the primary efficacy objective was rejected and the primary efficacy objective was considered met.

Table 18: Percent Subjects with Adequate 6-month PCT

Subjects[1]	Subjects with Adequate 6-Month PCT	% Subjects with Adequate 6-Month PCT	98.66% CI[2]	Performance Goal	Nominal One-sided P-value[3]
297	292	98.3%	(95.4%, 99.6%)	80%	<0.0001

[1]Subjects with paired implant and 6-month auto decrement PCT values (0.24 ms), or who had a system modification or alternative device implant prior to 6 months due to elevated threshold.
[2]Confidence interval coverage probability dictated by the Hwang-Shih-DeCani alpha spending function..
[3]P-value from Exact Binomial test.

There were 10 subjects who could have completed the primary efficacy endpoint but did not due to missing data or missed visit, and 24 subjects who exited or died prior to completing their 6-month visit. These 34 additional subjects were further evaluated below to assess the robustness of the primary efficacy objective results. Following the pre-specified missing data imputation rules (values for 7 subjects imputed) and assuming that subjects whose data could not be imputed were failures (remaining 27 subjects) the percentage of subjects meeting the primary efficacy endpoint was 90.3% with a 98.66% CI of 85.6% - 93.9%. Since the lower confidence boundary was above the performance goal of 80%, the inference regarding the primary efficacy objective was robust to the missing data.

Conclusion
Of the 297 subjects with primary efficacy endpoint data available, 292 (98.3%) had an adequate 6-month PCT, meaning they had a 6-month PCT no greater than 2.0V and had a rise in PCT from implant to 6-months of no more than 1.5V. This observed percentage of subjects with an adequate safety margin was significantly greater than the pre-specified goal of 80% since the nominal one-sided P-value was lower than the nominal alpha level of 0.0067 dictated by the Hwang-Shih-DeCani alpha spending rule. Therefore the null hypothesis associated with the primary efficacy objective was rejected and the primary efficacy objective was considered met.

Secondary Objective #1 was met.
At the time of the visit cutoff, there were 301 6-month visits among the 719 successfully implanted subjects. Figure 10 summarizes the data available for the main analysis of secondary objective #1. Of the 301 subjects with 6-month visits, 280 (93.0%) had their PCT measured using both the manual (auto decrement) test and the VCM test measured at 0.24 ms, therefore were included in the main analysis of this objective. There were 25 subjects who were successfully implanted with the Micra system, but were not included in the main analysis of this objective due to missing data (missed 6 month visit – 4, capture management threshold test did not complete successfully due to high heart rate – 20, auto decrement test was not performed – 1).

Figure 10: Data Available for Secondary Objective #1

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              ┌─────────────────────┐
              │  Successful Implant  │
              │       n=719         │
              └──────────┬──────────┘
                         │         ┌──────────────────────────────┐
                         │         │ Exit: 1                      │
                         │         │ Death: 23                    │
                         │         │ Awaiting 6-month Visit: 390  │
                         │         └──────────────────────────────┘
              ┌──────────┴──────────┐
              │ Expected 6-Month    │
              │ Visits: 305         │
              └──────────┬──────────┘
                         │         ┌──────────────────┐
                         │         │ Missed Visit: 4  │
                         │         └──────────────────┘
              ┌──────────┴──────────┐
              │ Completed 6-Month   │
              │ Visits: 301         │
              └──────────┬──────────┘
            ┌────────────┴────────────┐
   ┌────────┴────────┐       ┌────────┴──────────┐
   │ Autodecrement   │       │ Capture Management│
   │ Test Performed: │       │ Test Performed:   │
   │ 300             │       │ 301               │
   └────────┬────────┘       └────────┬──────────┘
   ┌────────┴────────┐       ┌────────┴──────────┐
   │ Autodecrement   │       │ Capture Management│
   │ Test Completed: │       │ Test Completed:   │
   │ 300             │       │ 281               │
   └────────┬────────┘       └────────┬──────────┘
            └────────────┬────────────┘
              ┌──────────┴──────────────────┐
              │ Paired Data Available for    │
              │ Analysis: 280                │
              └──────────────────────────────┘
```
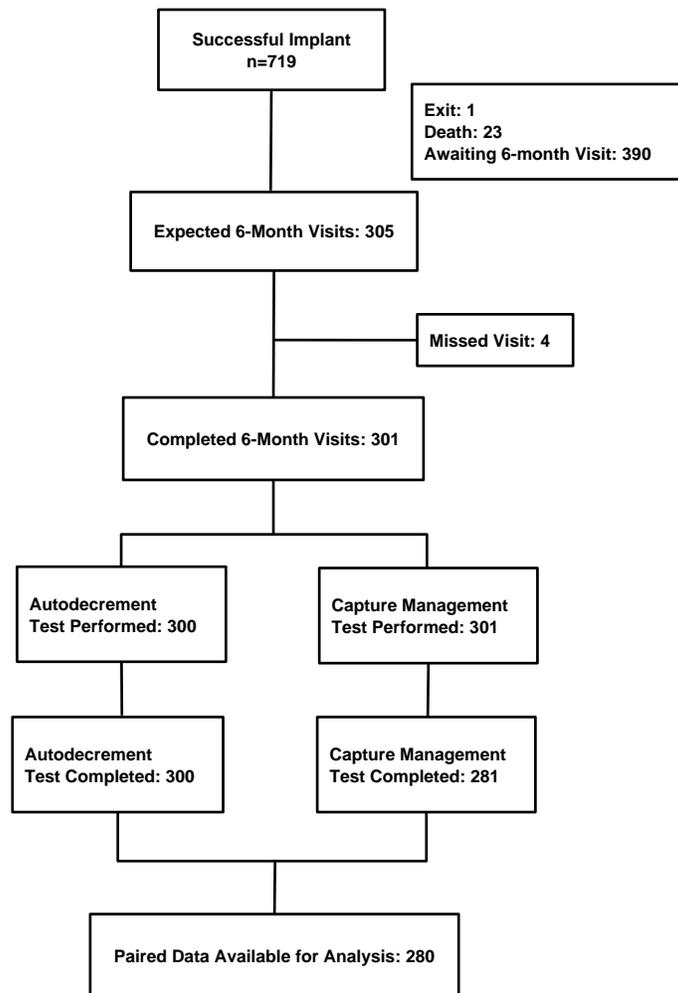
Figure 11 displays a Bland-Altman plot for the 280 subjects with paired auto decrement and ventricular capture management values (both measured at 0.24 ms) measured at the 6-month visit. Of the 280 subjects with paired 6-month auto decrement and VCM PCT values, 279 (99.6%) had VCM values within ± 0.5V of the auto decrement PCT value. Visual inspection of the Bland-Altman plot also suggested that there was no systematic deviation between the PCT measurements across the range of PCT values.

Figure 11: Bland-Altman Plot of PCT Values at 6-months
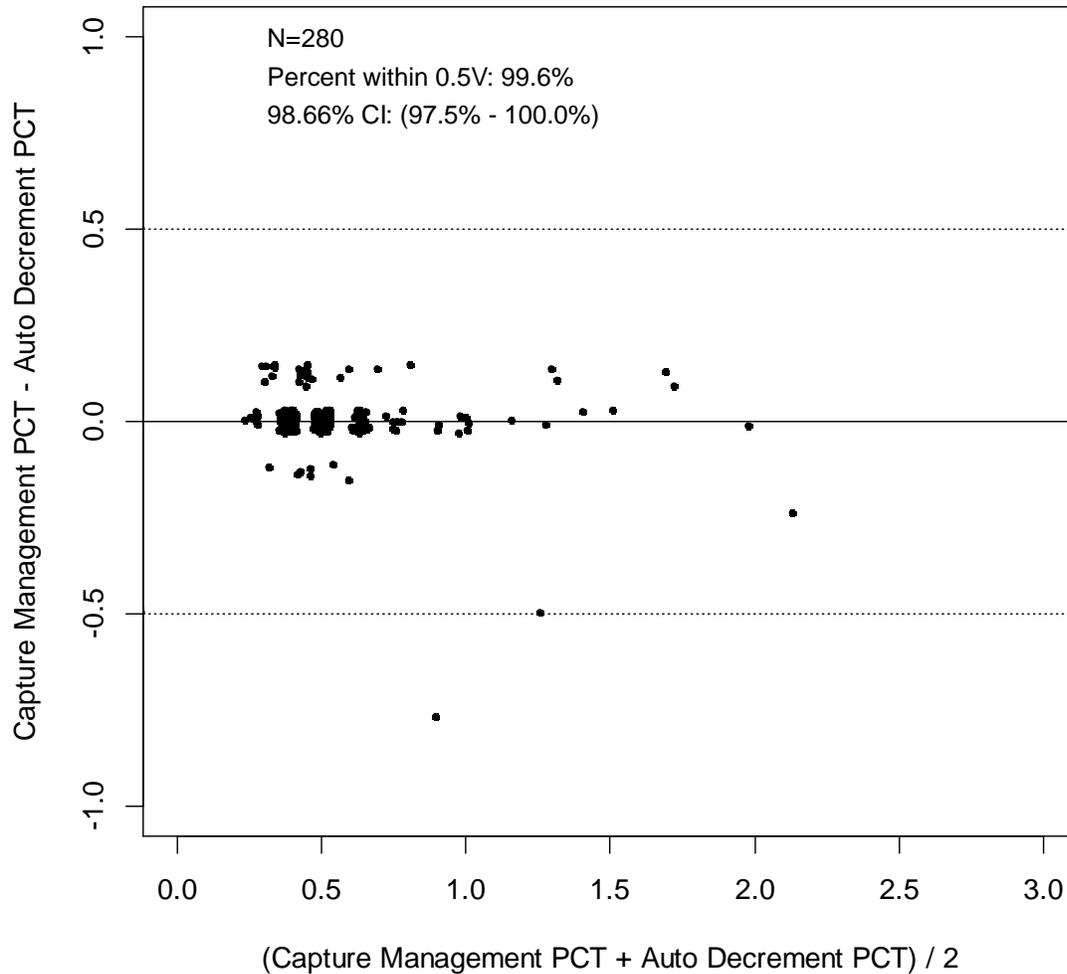
Notes: The data points were jittered to show distribution density.

Table 19 displays the percent of subjects with an accurate VCM PCT value at the 6-month visit. Of the 280 subjects with paired PCT values available at 6-months, 279 (99.6%) had a VCM PCT value within ±0.5V (inclusive) of the auto decrement value measured at 0.24 ms. This percentage was significantly greater than the pre-specified goal of 85% since the Holm adjusted P-value (i.e. twice the nominal one-sided P-value) was lower than the nominal alpha level of 0.0067 dictated by the Hwang-Shih-DeCani alpha spending rule. Therefore, secondary objective #1 was considered met.

Table 19: Percent of Subjects with Accurate 6-month Ventricular Capture Management Values

Subjects[1]	Subjects with Accurate VCM Value[2]	% Subjects with Accurate VCM Value	98.66% CI[3]	Performance Goal	Nominal One-sided P-value[4]
280	279	99.6%	(97.5%, 100.0%)	85%	<0.0001

[1]Number of subjects with paired VCM and auto decrement PCT data available at the 6-month visit.
[2]Number of subjects with a VCM PCT within ±0.5V (inclusive) of the auto decrement PCT measured at 0.24 ms.
[3]Confidence interval coverage probability dictated by the Hwang-Shih-DeCani alpha spending function.
[4]P-value from Exact Binomial test.

The Micra investigation plan required that both the VCM PCT and auto decrement PCT be measured at a pulse duration of 0.24ms at the implant, 3-month, and 6-month visits. Figure 12 displays Bland-Altman plots of the VCM and auto decrement PCT value for each of these study visits. These plots show the accuracy of the VCM PCT measurement as compared to the auto decrement PCT test was at least 98.3% across all these visits.

Figure 12: Bland-Altman Plots of PCT Values by Study Visit

Implant

(VCM PCT + Auto Decrement PCT)/2

3-Month Visit

(VCM PCT + Auto Decrement PCT)/2

6-Month Visit

(VCM PCT + Auto Decrement PCT)/2
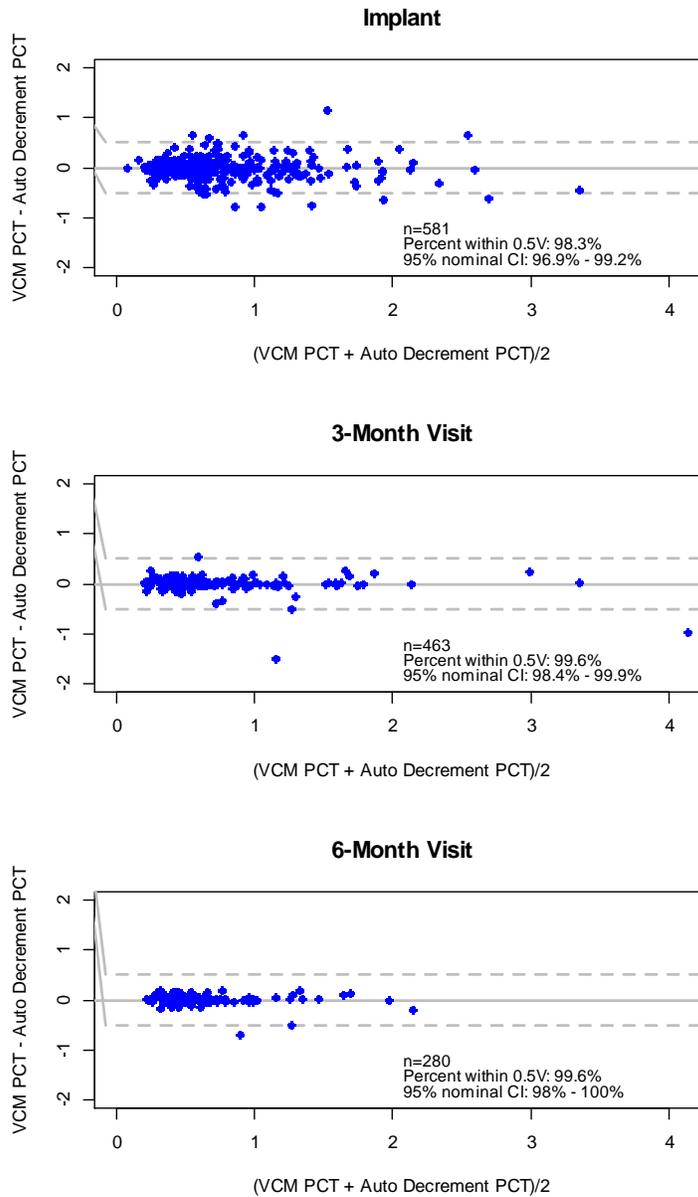
Notes: The data points were jittered to show distribution density.

Secondary Objective #2 was met.

M-PREP exercise tests were attempted by 40 subjects at the 3-month visit and 29 subjects at the 6-month visit with 27 subjects attempting M-PREP tests at both the 3-month and 6-mont visit. For an M-PREP test to be included in the analysis of this objective, subjects needed to reach at least stage 4 of the M-PREP test protocol without continually using the treadmill handle bars to ensure that the rate response feature could be adequately tested. Table 20 provides the accountability of all 69 M-PREP test attempts and indicates that the most common reason for not using a M-PREP test in the analysis was for not reaching stage 4 of the test protocol. There were 30 usable M-PREP tests (15 at the 3-month visit and 15 at the 6-month visit) from 20 unique subjects that were included in the analysis of the objective.

Table 20: Summary of Attempted M-PREP Tests

M-MPREP Test Status	3-Month Test (N = 40)	6-Month Test (N = 29)	Total (N = 69)
Continuous handle bar use	7 (17.5%)	9 (31.0%)	16 (23.2%)
Stage 4 not reached	18 (45.0%)	5 (17.2%)	23 (33.3%)
Incorrectly performed M-PREP	0 (0.0%)	0 (0.0%)	0 (0.0%)
Missing device interrogation file	0 (0.0%)	0 (0.0%)	0 (0.0%)
Usable M-PREP test	**15 (37.5%)**	**15 (51.7%)**	**30 (43.5%)**

Notes: Of the 27 subjects that attempted M-PREP tests at both the 3-month and 6-month visit 10 had usable M-PREP tests at both visits.

Figure 13 displays the normalized rate response for each of the 30 usable M-PREP treadmill tests by plotting the normalized sensor rate (scaled so the sensor rate is 0 at rest and 1 at the maximum M-PREP state reached) versus normalized workload (scaled so that a value of 0 is rest and a value of 1 is maximum workload). Examination of Figure 13 shows that in general the sensor rate increased proportionally to workload for all treadmill tests.

Figure 13: Normalized Sensor Rate versus Normalized Workload for 30 Useable M-PREP Treadmill Tests
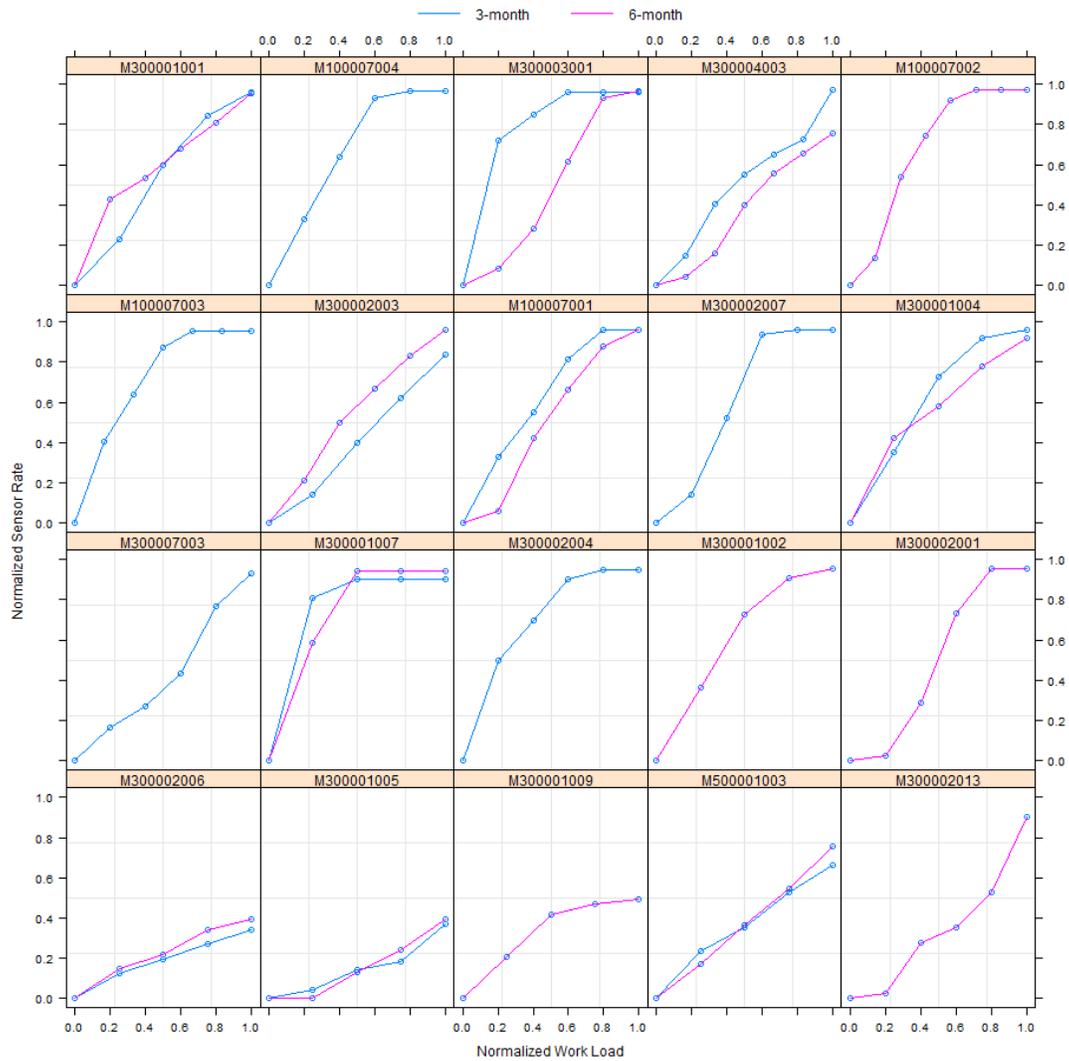
The random effects linear regression model that allowed for subject specific slopes and intercepts and fixed effects for study visit (3-months or 6-months), normalized workload from the Kay-Wilkoff model, and normalized workload by study visit interaction indicated that there was not a significant workload by visit interaction (P=0.508) therefore the study visit by workload term was dropped from the model. Since the Holm adjusted P-value for Secondary Objective #1 was less than the critical value, Secondary Objective #2 (rate response) could be tested at the nominal 0.05 level using the TOST procedure. Table 21 shows that the slope parameter for the Kay-Wilkoff model for the combined 3-month and 6-month visits was 0.864 with a nominal two sided 90% CI ranging from 0.768 to 0.961. Since this confidence interval lays completely within the equivalence margin of 0.65 to 1.35 the null hypothesis was rejected and it was concluded that the Micra system provided adequate rate response (TOST P-value: <0.001). Table 21 also indicates that the Kay-Wilkoff slope parameter was consistent between the 3-month and 6-month visits.

Table 21: Metabolic-Chronotropic Response based on Kay-Wilkoff Slope Parameter

Visit	Attempted Treadmill Tests	Usable M-PREP Tests	Kay-Wilkoff Slope Parameter	90% Confidence Interval	Nominal TOST[1] P-value
Combined[2]	63	30	0.864	0.768-0.961	<0.001
3-month	37	15	0.839	0.716-0.962	0.008
6-month	26	15	0.850	0.731-0.969	0.005

[1]TOST = Two one-sided test procedure.
[2]P=0.508 for test of visit by normalized work load interaction.

Figure 14 displays the normalized sensor rate versus the normalized workload for the 3-month (panel A) and 6-month (panel B) M-PREP tests. Figure 14 panels A and B also display the fitted regression lines from the random effects linear regression model allowing for subject specific intercepts and slopes and fixed effects for normalized workload and visit. Figure 14 panel C displays the distribution of 20 subject specific slopes obtained from the random effects regression model.

Figure 14: Normalized Sensor Rate versus Normalized Workload
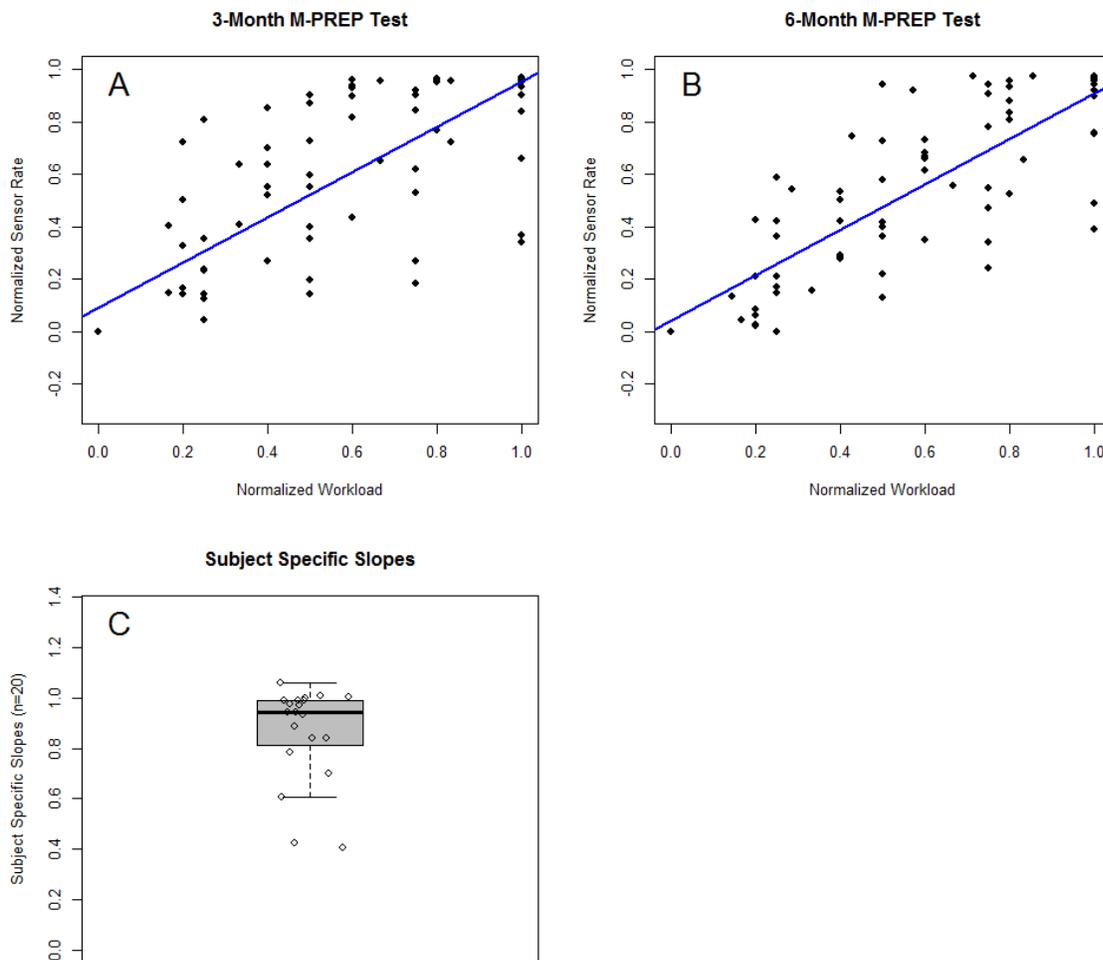
Figure 15 and Figure 16 display the subject specific relationship between normalized workload and normalized sensor rate for the 3-month and 6-month visits respectively as computed by random effect linear regression models for each visit that include subject specific intercepts and slopes and fixed effects for normalized workload (i.e. fixed effect for slope).

Figure 15: Subject Specific Relationship between Normalized Sensor Rate and Normalized Workload (3-month M-PREP test)
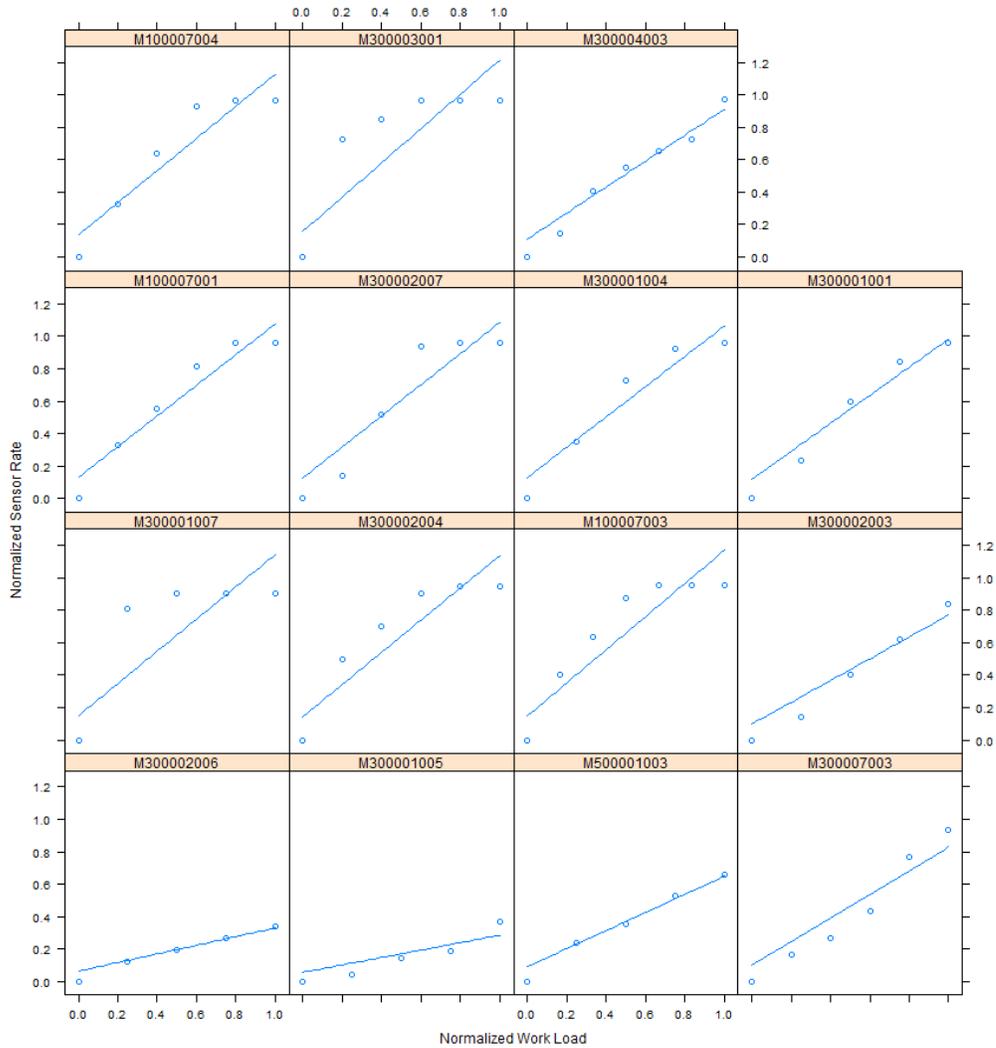
Figure 16: Subject Specific Relationship between Normalized Sensor Rate and Normalized Workload (6-month M-PREP test)
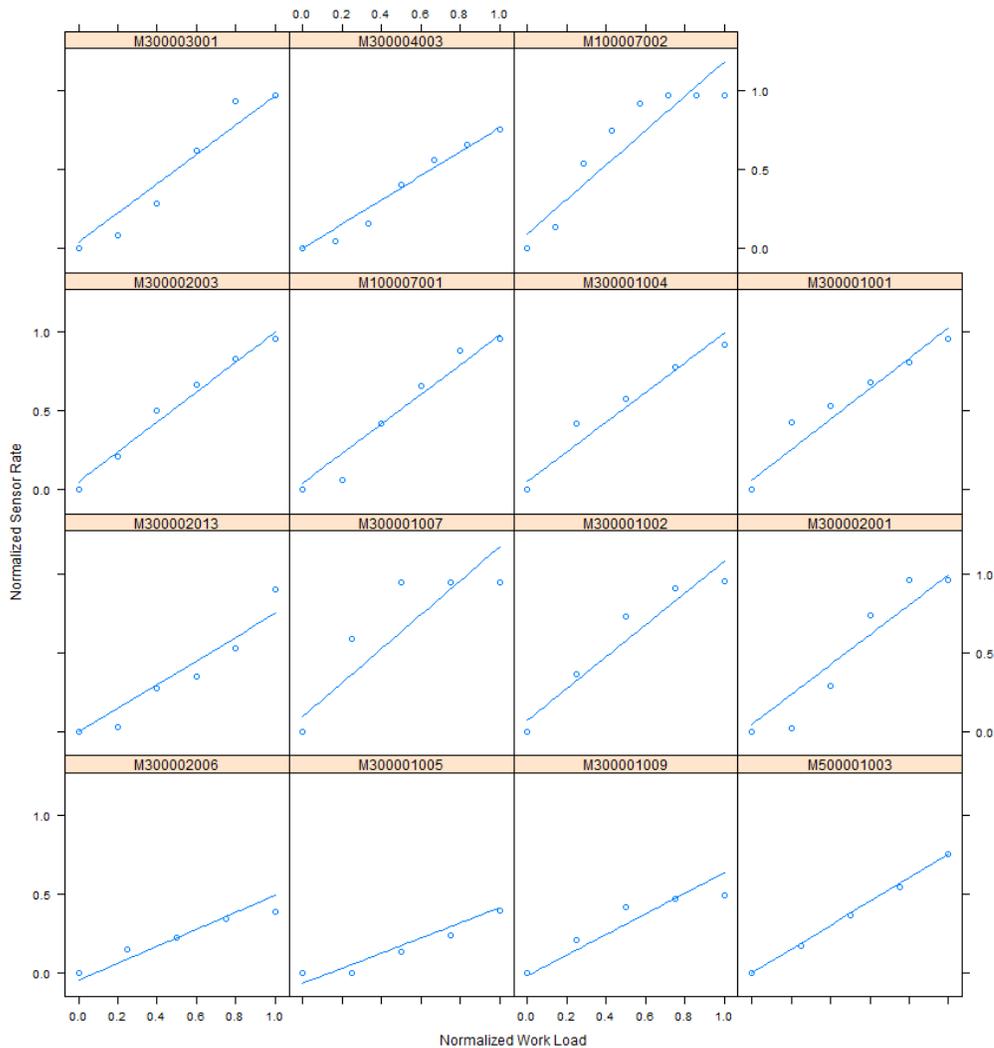
Conclusion

The rate response operation of the Micra system was confirmed by demonstrating that the slope parameter from the Kay-Wilkoff model fell within an equivalence margin of 0.65 to 1.35. Since Holm adjusted P-value for Secondary Objective #1 was less than the critical value, Secondary Objective #2 (rate response) could be tested at the nominal 0.05 level using the TOST procedure. Specifically, the estimated slope parameter across all subjects and M-PREP tests was 0.864 (90% CI: 0.768 – 0.961; TOST P-value <0.001).

8   Adverse Events Summary

To summarize all adverse events collected during the study. Reportable adverse events included all procedure-related, system-related, accessory-related, cardiovascular-related, and serious adverse events. At the time of the database freeze 100% of the AEs were adjudicated. Of the 744 enrolled subjects, there have been 612 adverse events experienced by 341 subjects. Of the 612 adverse events, 11 occurred prior to an implant attempt and 601 occurred during or after an implant attempt. Table 22 provides a summary of all 612 adverse events regardless of relationship to the study system or procedure.

Table 22: Summary of Adverse Events

Number of Events (Number, % Subjects)	Enrolled (N = 744)	Implant Attempt (N = 725)
Total Adverse Events	**612 (341, 45.8%)**	**609 (338, 46.6%)**
Serious Adverse Event		
Yes	390 (232, 31.2%)	387 (229, 31.6%)
No	222 (169, 22.7%)	222 (169, 23.3%)
Unanticipated Adverse Device Effect		
Yes	0 (0, 0.0%)	0 (0, 0.0%)
No	612 (341, 45.8%)	609 (338, 46.6%)
Unanticipated Serious Adverse Device Effect		
Yes	0 (0, 0.0%)	0 (0, 0.0%)
No	612 (341, 45.8%)	609 (338, 46.6%)
Procedure Relatedness		
Related[1]	116 (100, 13.4%)	116 (100, 13.8%)
Implant	116 (100, 13.4%)	116 (100, 13.8%)
System modification	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	495 (278, 37.4%)	492 (275, 37.9%)
Unknown	1 (1, 0.1%)	1 (1, 0.1%)
Implant	1 (1, 0.1%)	1 (1, 0.1%)
System modification	0 (0, 0.0%)	0 (0, 0.0%)
System Relatedness		
Related[2]	53 (49, 6.6%)	53 (49, 6.8%)
Micra device	36 (34, 4.6%)	36 (34, 4.7%)
Delivery catheter	24 (23, 3.1%)	24 (23, 3.2%)
Software	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	554 (313, 42.1%)	551 (310, 42.8%)
Unknown	5 (5, 0.7%)	5 (5, 0.7%)
Accessory Relatedness		
Related[3]	53 (49, 6.6%)	53 (49, 6.8%)
Programmer	0 (0, 0.0%)	0 (0, 0.0%)
Introducer	51 (48, 6.5%)	51 (48, 6.6%)
Other implant tool(s)[4]	2 (2, 0.3%)	2 (2, 0.3%)
Extraction tool	0 (0, 0.0%)	0 (0, 0.0%)
Holter	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	558 (316, 42.5%)	555 (313, 43.2%)
Unknown	1 (1, 0.1%)	1 (1, 0.1%)
Cardiovascular Relatedness		
Related	361 (242, 32.5%)	360 (241, 33.2%)
Not Related	220 (145, 19.5%)	219 (144, 19.9%)
Unknown	31 (29, 3.9%)	30 (28, 3.9%)

Notes: 100% of AEs have been adjudicated by the CEC.

[1]An AE may be both procedure-related and system-related.

[2] System-related AEs may be related to more than one system component.

[3]Accessory related AEs may be related to more than one accessory component.

[4]The other implant tool was specified by the site as a Xemex Introducer.

There were 40 AEs that were considered related to both the procedure and the system. Additionally, the 5 events with an unknown relationship to the system were also considered procedure-related.

Table 23 displays the 11 adverse events that occurred prior to a Micra implant attempt.

Table 23: Adverse Events Occurring Prior to a Micra Implant Attempt

Number of Events (Number, % Subjects) (Denominator = 744 Enrolled Subjects)		
Adverse Event Keyterm	**Event**	**Serious Event**
Total Adverse Events	**11 (11, 1.5%)**	**7 (7, 0.9%)**
Acute myocardial infarction	1 (1, 0.1%)	1 (1, 0.1%)
Brain stem infarction	1 (1, 0.1%)	1 (1, 0.1%)
Cardiac failure	1 (1, 0.1%)	1 (1, 0.1%)
Cholelithiasis	1 (1, 0.1%)	1 (1, 0.1%)
Dehydration	1 (1, 0.1%)	1 (1, 0.1%)
Hypertension	1 (1, 0.1%)	1 (1, 0.1%)
Hypoxia	1 (1, 0.1%)	1 (1, 0.1%)
Aortic aneurysm	1 (1, 0.1%)	0 (0, 0.0%)
Haematoma[1]	1 (1, 0.1%)	0 (0, 0.0%)
Phlebitis	1 (1, 0.1%)	0 (0, 0.0%)
Soft tissue mass	1 (1, 0.1%)	0 (0, 0.0%)

[1] An event for femoral hematoma was reported for subject M300006001 from a coronarography puncture that occurred 13 days prior the Micra implant procedure

Of the 601 events occurring during or following a Micra implant attempt, 383 events in 226 subjects were considered serious (regardless of relationship to the Micra system, procedure, or accessory component). The most commonly reported adverse events (classified by MedDRA preferred term) during or following a Micra implant attempt were cardiac failure (77 events in 62 subjects; 8.6%) followed by atrial fibrillation (26 events in 24 subjects; 3.3%).

Table 24 displays a summary of all Micra procedure or Micra system related adverse events among the 725 subjects with a Micra implant attempt. There were 130 events (in 111 of the subjects) that were considered procedure or system related events (Table 24). The overall system or procedure related complication rate was 6.6%; most of the events were observations and did not require invasive intervention for resolution. Forty (in 38 subjects) of the 130 events were considered both system and procedure related, 76 (in 68 subjects) were considered only procedure related, 13 (in 13 subjects were considered only system related, and 1 (in 1 subject) was considered to have an unknown relationship to the procedure but not related to the system.   Additionally, of the 76 procedure related events, 5 had an unknown relationship to the Micra system.

Of note, 91% (118/130) of the Micra system or Micra procedure related adverse events occurred within 30 days of the Micra implant attempt.

Table 24: Procedure or System Related Adverse Events

Number of Events (Number, % Subjects) (Denominator = 725 Subjects with Implant Attempt)

Adverse Event Keyterm	Event	Serious Event	Complication
Total Adverse Events	**130 (111, 15.3%)**	**54 (50, 6.9%)**	**54 (48, 6.6%)**
Cardiac arrhythmias	**18 (17, 2.3%)**	**8 (8, 1.1%)**	**7 (7, 1.0%)**
Atrioventricular block complete	8 (8, 1.1%)	5 (5, 0.7%)	5 (5, 0.7%)
Bundle branch block right	4 (4, 0.6%)	1 (1, 0.1%)	0 (0, 0.0%)
Sick sinus syndrome	1 (1, 0.1%)	0 (0, 0.0%)	0 (0, 0.0%)
Ventricular fibrillation	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)
Ventricular tachycardia	4 (4, 0.6%)	1 (1, 0.1%)	1 (1, 0.1%)
Embolism and thrombosis	**5 (5, 0.7%)**	**3 (3, 0.4%)**	**3 (3, 0.4%)**
Deep vein thrombosis	4 (4, 0.6%)	2 (2, 0.3%)	2 (2, 0.3%)
Pulmonary embolism	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)
Events at Groin Puncture Site	**51 (49, 6.8%)**	**11 (11, 1.5%)**	**11 (11, 1.5%)**
Arterial injury	5 (5, 0.7%)	0 (0, 0.0%)	1 (1, 0.1%)
Arteriovenous fistula	5 (5, 0.7%)	4 (4, 0.6%)	4 (4, 0.6%)
Impaired healing	1 (1, 0.1%)	0 (0, 0.0%)	0 (0, 0.0%)
Incision site complication	1 (1, 0.1%)	0 (0, 0.0%)	0 (0, 0.0%)
Incision site haematoma	8 (8, 1.1%)	0 (0, 0.0%)	1 (1, 0.1%)
Incision site haemorrhage	18 (17, 2.3%)	3 (3, 0.4%)	2 (2, 0.3%)
Incision site infection	2 (2, 0.3%)	0 (0, 0.0%)	0 (0, 0.0%)
Incision site pain	3 (3, 0.4%)	0 (0, 0.0%)	0 (0, 0.0%)
Incisional drainage	6 (6, 0.8%)	2 (2, 0.3%)	2 (2, 0.3%)
Vascular pseudoaneurysm	2 (2, 0.3%)	2 (2, 0.3%)	1 (1, 0.1%)
Traumatic Cardiac Injury	**13 (13, 1.8%)**	**12 (12, 1.7%)**	**12 (12, 1.7%)**
Cardiac perforation	3 (3, 0.4%)	3 (3, 0.4%)	3 (3, 0.4%)
Pericardial effusion	10 (10, 1.4%)	9 (9, 1.2%)	9 (9, 1.2%)
Pacing Issues	**6 (6, 0.8%)**	**2 (2, 0.3%)**	**2 (2, 0.3%)**
Device dislocation	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)
Device pacing issue	5 (5, 0.7%)	1 (1, 0.1%)	1 (1, 0.1%)
Other	**37 (36, 5.0%)**	**18 (18, 2.5%)**	**19 (19, 2.6%)**
Acute myocardial infarction	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)
Angina pectoris	3 (3, 0.4%)	0 (0, 0.0%)	0 (0, 0.0%)
Back pain	1 (1, 0.1%)	0 (0, 0.0%)	0 (0, 0.0%)
Cardiac failure	4 (4, 0.6%)	4 (4, 0.6%)	3 (3, 0.4%)
Chest pain	1 (1, 0.1%)	0 (0, 0.0%)	0 (0, 0.0%)
Dysuria	1 (1, 0.1%)	0 (0, 0.0%)	0 (0, 0.0%)
Hypotension	3 (3, 0.4%)	1 (1, 0.1%)	3 (3, 0.4%)
Medication error	2 (2, 0.3%)	1 (1, 0.1%)	2 (2, 0.3%)
Metabolic acidosis	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)

Number of Events (Number, % Subjects) (Denominator = 725 Subjects with Implant Attempt)			
Adverse Event Keyterm	**Event**	**Serious Event**	**Complication**
Non-cardiac chest pain	6 (6, 0.8%)	1 (1, 0.1%)	1 (1, 0.1%)
Osteoarthritis	1 (1, 0.1%)	0 (0, 0.0%)	1 (1, 0.1%)
Pacemaker syndrome	4 (4, 0.6%)	2 (2, 0.3%)	1 (1, 0.1%)
Pericarditis	2 (2, 0.3%)	1 (1, 0.1%)	1 (1, 0.1%)
Presyncope	5 (5, 0.7%)	5 (5, 0.7%)	3 (3, 0.4%)
Syncope	1 (1, 0.1%)	1 (1, 0.1%)	1 (1, 0.1%)
Urinary retention	1 (1, 0.1%)	0 (0, 0.0%)	1 (1, 0.1%)

Figure 17 displays the freedom from Micra system or procedure related complications. This figure suggests that the majority of Micra related complications occur shortly following an implant attempt.

Figure 17: Freedom from Micra System or Procedure Related Complications

12-Month Freedom Rate: 92.9%
95% CI: (90.7% - 94.7%)

Number at Risk

| 725 | 638 | 485 | 477 | 286 | 281 | 276 | 66 | 63 | 59 | 57 | 57 | 57 |
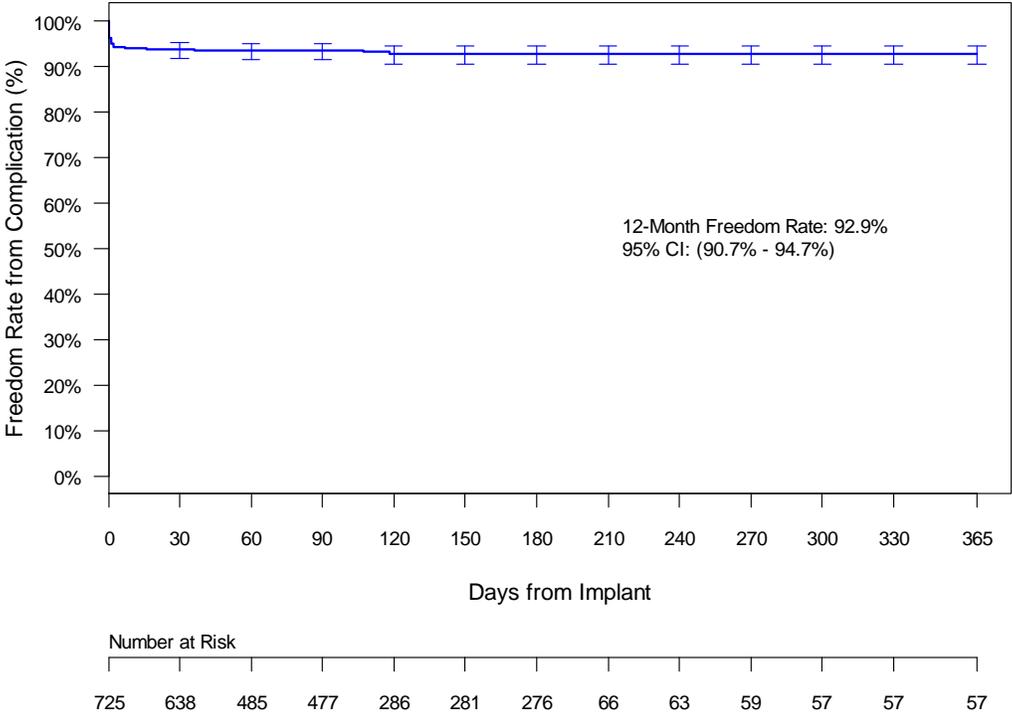
For context and comparison, the below tables compare specific types of Micra implant adverse events to Advisa MRI and the full historical control (6 previous pacing studies) as of December 2015. The below tables outcomes from cardiac injury events (i.e. perforation or cardiac effusion) and vascular injury events (e.g. AV fistula, arterial injury, pseudoaneurysm).

Table 25: Comparison of Perforation / Effusion Outcomes: Micra vs Traditional Pacemakers

	Micra IDE (n=725) (n=13 total events, 12 complications, 11 major	Micra Continued Access (n=56) (n=2 total events, 2 major	Advisa MRI (n=266) (n=9 total events, 8 complications, 7	Full Historical Control (n=2667) (n=50 total events, 32 major complications, 7 minor

	complications)	complications)	major complications)	complications)
Hypotension	54% (7 of 13)	50% (1 of 2)	11% (1 of 9)	24% (12 of 50)
Shock/Tamponade	31% (4 of 13)	50% (1 of 2)	0% (0 of 9)	16% (8 of 50)
CPR	15% (2 of 13)	0% (0 of 2)	0% (0 of 9)	0% (0 of 50)
Intubation	8% (1 of 13)	50% (1 of 2)	0% (0 of 9)	0% (0 of 50)
Prolonged or New Hospitalization	85% (11 of 13)	100% (2 of 2)	100% (9 of 9)	54% (27 of 50)
Pericardiocentesis	70% (9 of 13)	50% (1 of 2)	11% (1 of 9)	22% (11 of 50)
Surgical Repair	15% (2 of 13)	50% (1 of 2)	0% (0 of 9)	4% (2 of 50)
Lead Revision	Not applicable	Not applicable	44% (4 of 9)	24% (12 of 50)
Resulted in death	0% (0 of 13)	0% (0 of 2)	0% (0 of 9)	0% (0 of 50)

*Not mutually exclusive; a single event may apply to multiple symptoms or interventions

Table 26: Comparison of Vascular injury Outcomes: Micra vs Traditional Pacemakers

	Micra IDE (n=725) =AV fistula, arterial injury, pseudoaneurysm (n=12 total, 6 complications, 5 major complications)	Micra Continued Access (n=56) =AV fistula, arterial injury, pseudoaneurysm (n=1, 1 major complication)	Advisa MRI (n=266) Vascular Injury (n=0)	Full Historical Control (n=2667) (n=1 total event)
Hypotension	0 of 12	0 of 1	0	0 of 1
Shock/Tamponade	0 of 12	0 of 1	0	0 of 1
CPR	0 of 12	0 of 1	0	0 of 1
Intubation	0 of 12	0 of 1	0	0 of 1
Prolonged or New Hospitalization	5 of 12	1 of 1	0	1 of 1
Pericardiocentesis	0 of 12	0 of 1	0	0 of 1
Surgical Intervention/Repair	4 of 12	0 of 1	0	0 of 1
Resulted in death	0 of 12	0 of 1	0	0 of 1

*Not mutually exclusive; a single event may apply to multiple symptoms or interventions

9   Death Summary

There have been 29 deaths among the 744 enrolled subjects. All 29 deaths occurred following a successful Micra implant and all 29 deaths have been adjudicated by the study's Clinical Events Committee (CEC). Of the 29 study deaths, all 29 were considered not related to the Micra system, while 1 of the 29 was considered related to the Micra implant procedure. Specifically, one subject experienced metabolic acidosis following a successful Micra implant and expired 6 hours following the Micra procedure. The cause of death diagnosis was thought to be progressive acidosis, either as a result of the subject's underlying end stage renal disease and prolonged procedure time, or hypoventilation during or after the procedure. Table 27 provides a summary of the 29 deaths.

Table 27: Summary of Deaths

Number of Deaths (Number, % Subjects)	Enrolled (N = 744)	Implanted (N = 719)
Total Deaths	**29 (29, 3.9%)**	**29 (29, 4.0%)**
Death classification		
Sudden cardiac death	4 (4, 0.5%)	4 (4, 0.6%)
Non-sudden cardiac death	9 (9, 1.2%)	9 (9, 1.3%)
Non-cardiac death	15 (15, 2.0%)	15 (15, 2.1%)
Unknown classification	1 (1, 0.1%)	1 (1, 0.1%)
Procedure Relatedness		
Related	1 (1, 0.1%)	1 (1, 0.1%)
Implant	1 (1, 0.1%)	1 (1, 0.1%)
System modification	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	28 (28, 3.8%)	28 (28, 3.9%)
Unknown	0 (0, 0.0%)	0 (0, 0.0%)
Implant	0 (0, 0.0%)	0 (0, 0.0%)
System modification	0 (0, 0.0%)	0 (0, 0.0%)
System Relatedness		
Related	0 (0, 0.0%)	0 (0, 0.0%)
Micra device	0 (0, 0.0%)	0 (0, 0.0%)
Delivery catheter	0 (0, 0.0%)	0 (0, 0.0%)
Software	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	29 (29, 3.9%)	29 (29, 4.0%)
Unknown	0 (0, 0.0%)	0 (0, 0.0%)
Accessory Relatedness		
Related	0 (0, 0.0%)	0 (0, 0.0%)
Programmer	0 (0, 0.0%)	0 (0, 0.0%)
Introducer	0 (0, 0.0%)	0 (0, 0.0%)
Other implant tool(s)	0 (0, 0.0%)	0 (0, 0.0%)
Extraction tool	0 (0, 0.0%)	0 (0, 0.0%)
Holter	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	29 (29, 3.9%)	29 (29, 4.0%)
Unknown	0 (0, 0.0%)	0 (0, 0.0%)
Cardiovascular Relatedness		
Related	9 (9, 1.2%)	9 (9, 1.3%)
Not Related	18 (18, 2.4%)	18 (18, 2.5%)
Unknown	2 (2, 0.3%)	2 (2, 0.3%)

10   Clinical Study Conclusion

The Micra Transcatheter Pacing system demonstrated safety and efficacy by passing its pre-specified primary safety and efficacy objectives after 725 subjects underwent implant attempt (719 successful, 99.2%) and 301 subjects completed the 6-month post-implant visit. The freedom from major complications at 6-months post-implant among the 725 subjects with a Micra implant attempt was 96% (98.66% CI: 93.3% - 97.6%), exceeding the pre-specified performance criterion of 83% derived from 977 subjects with atrial fibrillation (AF) from 6 previous pacemaker studies (P<0.0001).

In a post-hoc analysis, Micra was compared to traditional leaded pacing technology using all 2667 subjects in the 6 previous Medtronic pacemaker studies, including those subjects without AF. Originally, when deriving the Micra study's performance criterion, Medtronic assumed that the reference dataset should include only subjects with atrial fibrillation in order to mimic a typical single chamber patient population, and therefore used the 977 subjects with AF to establish the lower confidence bound criteria, rather than the full population of 2667 subjects from these studies. However, not all of the Micra subjects have AF and it is most conservative to compare Micra performance to the full population of 2667 subjects (i.e. major complication rate in 977 subjects is 8.4% compared to 7.4% in full population of 2667). Thus, when Micra was compared to this reference pacemaker datasets, Micra demonstrated a significant

reduction in total major complications at 6 months (4.0% for Micra vs 7.4% for traditional technology, P=0.006).

Micra appeared to reduce the rate of major complications associated with cardiac arrhythmias, the access site, and device fixation compared to the reference dataset used to derive the performance criterion. There were no areas where Micra significantly increased the risk of major complication relative to the reference pacemaker studies. Additionally, there have been no reports of gross device dislodgement during the follow-up period and no observations of device orientation change based on X-ray analysis at the 3-month and 12-month visits suggesting robust device fixation.

In summary, the safety experience showed:
- Low 6 month major complication rate compared to Medtronic reference dataset (4% Micra versus 7.4% in 2667 patients from 6 previous Medtronic studies)
- Low rate of system revision (explant, reposition, replacement) (3 in 725 = 0.4%). The occurrences included 1 Micra retrieval with a new Micra implanted and 2 patients where the Micra remained in the body and a traditional pacing device was implanted.
- No unforeseen events (0%)
- No device telemetry issues (0%)
- No gross dislodgements (0%)
- No systemic infections (0%)

The percentage of subjects with a low (≤2V) and stable (≤1.5V rise from implant) pacing capture threshold measured at 0.24ms at 6-months post-implant was 98.3% (98.66% CI: 95.4% - 98.3%)exceeding the pre-specified performance goal for the primary efficacy objective of 80% (P<0.0001). The low and stable thresholds observed with Micra result in an estimated average battery longevity of 12.5 years based on actual device use conditions through 6-months of follow-up.

The accuracy of Micra's ventricular capture management feature was confirmed as 99.6% of subjects (98.66% CI: 97.5% - 100%) had a ventricular capture management threshold within 0.5V of the manually performed auto decrement threshold at 6-months post implant exceeding the pre-specified performance goal of 85%. Rate responsiveness of the Micra system was also confirmed based on 30 treadmill tests.

The implant procedure and device handling have been favorably accepted by implanting physicians and subjects in multiple geographies. The implant procedure has been successfully performed by 94 physicians in 56 study centers with the majority of physicians describing the procedure as "easy" or "extremely easy."

Long term monitoring of all successfully implant subjects continues and the study's pre-specified long-term safety objective will be evaluated once all successfully implanted subjects have the opportunity to complete their 12-month post-implant visit. The device and implant procedure has met or exceeded all of its planned objectives. Thus, this study provides reasonable assurance of the safety and efficacy of the Micra system.