Medtronic

Percepta™ CRT-P MRI SureScan™ W1TR01

MR Conditional pacemaker with cardiac resynchronization therapy, SureScan™ technology, and Bluetooth® wireless telemetry (OAE-DDDR)

Device Manual

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

Contents

1 System overview

1.1 Introduction

This manual describes the Medtronic Model W1TR01 Percepta CRT-P MRI SureScan dual chamber, implantable pulse generator with cardiac resynchronization therapy (CRT-P). The manual contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

Additional manuals and documents with information about the device:

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

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

Programming guide – This manual explains how to use the programmer software to conduct a patient session.

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

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

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

1.2 System description

The Medtronic Percepta CRT-P MRI SureScan Model W1TR01 dual chamber implantable pulse generator with cardiac resynchronization therapy (CRT-P) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing, sequential biventricular pacing, and atrial tachyarrhythmia therapies. This device features Bluetooth wireless technology.[1]

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine while the device continues to provide appropriate pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection, magnet mode, and all user-defined diagnostics. Before performing an MRI scan, refer to the MRI technical manual.

The users of this device include medical professionals (physicians, nurses, technicians, and their supporting staff) trained in surgery, cardiology, radiology, and magnetic resonance (MR) technology and able to implement the procedures documented in the instructions for use for this device.

1.2.1 Usage environments

The device is intended to be used in the following environments and conditions:

- The device will be implanted in a properly equipped, staffed, and sterile surgical environment. Implant will take place under standard surgical protocols and in the patient population for which the device is indicated.
- Post-surgical patient and device follow-up care will take place in a properly equipped and staffed cardiology clinic or office.

[1] The Bluetooth® word mark is a registered trademark of Bluetooth SIG, Inc. and any use of this mark by Medtronic is under license.

- MRI procedures for patients with this device will take place in a properly equipped and staffed MR facility, and in consideration of the conditions and requirements described in Section 1.5, “MRI conditions for use”, page 6.
- After having an implant, patients may resume their lives at home, at work, and in other environments with consideration of the advice and restrictions documented in the Medical Procedure and EMI Warnings and Precautions Manual for Health Care Professionals and in the patient literature.

1.2.2 System components and accessories

Contents of sterile package – The package contains 1 implantable pulse generator with cardiac resynchronization therapy (CRT-P) and 1 torque wrench.

Implantable device system – The Percepta CRT-P MRI SureScan Model W1TR01 device and the pacing leads constitute the implantable portions of the device system.

Leads – The lead system used with this device must provide pacing to the left ventricle (LV), sensing and pacing to the right ventricle (RV), and sensing and pacing to the atrium (A). Do not use any lead with this device without first verifying lead and connector compatibility.

For information about selecting and implanting SureScan leads for this device, refer to Section 4.2, “Selecting and implanting the leads”, page 17.

Programmers and software – Medtronic programmers and software are used to program this device. Programmers from other manufacturers are not compatible with Medtronic devices, but they do not damage Medtronic devices.

Medtronic pacing system analyzer – A pacing system analyzer is used to measure the electrical characteristics of the implanted leads to assess their effectiveness for pacing and sensing.

Medtronic patient monitor – Patients use the Medtronic patient monitor, if available, to gather information from their implanted devices and communicate the information to their physicians through the Medtronic CareLink Network. For information on using the patient monitor, refer to the patient monitor literature.

1.3 Indications and usage

The Percepta CRT-P MRI SureScan system is indicated for:

- NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal medical therapy and have LVEF ≤ 35% and a prolonged QRS duration.
- NYHA Functional Class I, II, or III patients who have LVEF ≤ 50%, are on stable, optimal heart failure medical therapy if indicated and have atrioventricular block (AV block) that are expected to require a high percentage of ventricular pacing that cannot be managed with algorithms to minimize right ventricular pacing. Optimization of heart failure medical therapy that is limited due to AV block or the urgent need for pacing should be done post implant.

Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity.

Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony.

Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmia in patients with one or more of the above pacing indications.

1.4 Contraindications

The Percepta CRT-P MRI SureScan system is contraindicated for:

- Concomitant implant with another bradycardia device
- Concomitant implant with an implantable cardioverter defibrillator

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician.

- Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate.
- Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter.
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.
- Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance.
- ATP therapy is contraindicated in patients with an accessory antegrade pathway.

1.5 MRI conditions for use

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug for the right atrial port. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan pacing system.

Note: The MRI SureScan mode cannot be programmed to On if the device is recommended for replacement.

Cardiology requirements

Patients and their implanted systems must be screened to meet the following requirements:

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- The SureScan pacing system is implanted in the left or right pectoral region.
- The pace polarity parameters are set to Bipolar for programming the MRI SureScan mode to On.
- The SureScan device is operating within the projected service life.
- For patients whose device will be programmed to an asynchronous pacing mode when the MRI SureScan mode is programmed to On, no diaphragmatic stimulation is present at a pacing output of 5.0 V and at a pulse width of 1.0 ms.
  Note: The LV lead is not paced during SureScan operation, so the presence of diaphragmatic stimulation on the LV lead at a pacing output of 5.0 V and a pulse width of 1.0 ms does not need to be considered.

Caution: It is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms for pacemaker-dependent patients. A higher pacing capture threshold may indicate an issue with the implanted lead.

Notes:

- For radiology requirements, refer to the MRI technical manual.
- Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

Patient monitoring and rescue requirements

- Continuous patient monitoring is required during an MRI scan.
- In the event that patient rescue is required, an external defibrillator must be immediately available.

Training requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the MRI SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

1.6 Feature summary

The following features are available in this device. For a list of the features that are enabled at shipping, see the "Shipped" column of the tables in Chapter 6, "Device parameters", page 28.

1.6.1 Tachyarrhythmia detection and therapy features

Atrial antitachycardia pacing (ATP) – These therapies respond to an AT/AF episode or a Fast AT/AF episode with rapid sequences of pacing pulses to terminate detected atrial tachyarrhythmias.

Auto-adjusting sensitivity – This feature automatically adjusts the sensitivity thresholds after specific paced events and sensed events occur.

Reactive ATP – This feature allows the device to deliver atrial ATP therapies that had been unsuccessful earlier in an AT/AF episode. The device repeats the delivery of atrial ATP therapies after the programmed time interval or when the atrial rhythm changes.

1.6.2 Pacing and cardiac resynchronization features

AdaptivCRT – This feature adjusts CRT parameter values automatically while the patient is ambulatory. If the AdaptivCRT feature is programmed to Adaptive Bi-V and LV, the feature can switch automatically between biventricular pacing and LV-only pacing.

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

Atrial intervention pacing features – The system provides the following overdrive pacing techniques that are designed to counteract potential atrial tachyarrhythmia initiating mechanisms:

- **Atrial Preference Pacing (APP)** maintains a consistent activation sequence by providing continuous pacing that is slightly higher than the intrinsic rate.
- **Atrial Rate Stabilization (ARS)** adapts the atrial pacing rate in response to a PAC (premature atrial contraction) to avoid long sinus pauses following short atrial intervals.
- **Post Mode Switch Overdrive Pacing (PMOP)** works with the Mode Switch feature to deliver overdrive atrial pacing during the vulnerable phase following an AT/AF episode termination.

Automatic polarity configuration – This device uses lead impedance measurements to automatically configure atrial and RV pacing and sensing polarities during Implant Detection.

Automatic PVARP – This feature adjusts PVARP (Post-Ventricular Atrial Refractory Period) in response to changes in the patient's heart rate or pacing rate. PVARP is longer at lower tracking rates to prevent pacemaker-mediated tachycardia (PMT) and shorter at higher rates to maintain 1:1 tracking.

Cardiac resynchronization therapy (CRT) recovery options – There are 4 programmable features that help maintain CRT:

- **Ventricular Sense Response** triggers ventricular pacing in response to ventricular sensing to ensure that CRT pacing is delivered as programmed.
- **Conducted AF Response** dynamically adjusts and smooths the pacing rate to promote CRT delivery in the presence of sensed ventricular events in non-tracking modes.
- **Atrial Tracking Recovery** temporarily shortens PVARP to restore atrial tracking and CRT delivery if atrial tracking is lost due to PVCs or due to an atrial rhythm that is too fast to be tracked to the ventricle.
- **EffectivCRT during AF** dynamically adjusts the pacing rate in response to changes in the percentage of effective CRT pacing to promote CRT delivery in nontracking modes.

CardioSync Optimization Test – This feature measures the patient's intrinsic AV intervals and the waveform widths of the P-wave and QRS complex. Based on the measurements, the test provides optimized values for the following CRT parameters: V. Pacing configuration, V-V Pace Delay, Paced AV, and Sensed AV.

CRT ventricular pacing options – The ventricular pacing configuration in the CRT device provides the programming option for biventricular pacing or RV only pacing. The biventricular pacing sequence and V-V pace delay are programmable as an additional means to improve hemodynamics.

LV Capture Management – This feature monitors the left ventricular pacing threshold with daily pacing threshold searches and, if programmed to do so, adjusts the LV pacing amplitude toward a target amplitude.

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

MRI SureScan – This feature allows patients with an implanted MRI SureScan system, including the device and leads, to have a safe MRI procedure if the requirements provided in the MRI technical manual are followed.

MVP (Managed Ventricular Pacing) – When the device is not pacing for CRT, the MVP feature can promote intrinsic conduction by reducing unnecessary right ventricular pacing. This feature operates when the programmed mode is either AAIR<=>DDDR or AAI<=>DDD.

Non-Competitive Atrial Pacing (NCAP) – This feature prevents pacing the atrium too soon after a refractory atrial sense by delaying the scheduled atrial pace.

Pacemaker-mediated Tachycardia (PMT) Intervention – This feature provides automatic detection and interruption of device-defined PMTs.

PVC Response – This feature extends PVARP following a premature ventricular contraction (PVC) to avoid tracking a retrograde P-wave and to prevent retrograde conduction from inhibiting an atrial pace.

Rate Adaptive AV (RAAV) – This feature varies the Paced AV (PAV) and Sensed AV (SAV) intervals as the heart rate increases or decreases during dual chamber operation to maintain 1:1 tracking and AV synchrony.

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

Rate Profile Optimization – The goal of Rate Profile Optimization is to ensure that the rate response remains appropriate for the full range of patient activities. This feature monitors the patient's daily and monthly sensor rate profiles and adjusts the rate response curves over time to achieve a prescribed target rate profile.

Rate-responsive pacing – This feature varies the pacing rate in response to the patient's physical motion as detected by the activity sensor of the device.

RV Capture Management – This feature monitors the right ventricular pacing threshold with daily pacing threshold searches and, if programmed to do so, adjusts the RV pacing amplitude toward a target amplitude.

Sequential biventricular pacing – The ventricular pacing sequence and V-V pace delay are programmable as an additional means to improve hemodynamics during CRT therapy.

Sleep feature – This feature causes the device to pace at a slower rate during a programmed sleep period.

Ventricular Rate Stabilization (VRS) – This feature adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature ventricular contraction (PVC).

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

1.6.3 Monitoring and follow-up features

Cardiac Compass Trends – This feature provides a Cardiac Compass Trends report that shows an overview of the patient's condition, with graphs that display long-term trends in heart rhythm over the last 14 months. The report also includes the OptiVol 2.0 fluid trend data.

EffectivCRT episodes data – This feature compiles diagnostic information to help the clinician identify the cause of ineffective CRT pacing and reprogram the device to avoid it. Data collected includes date and time, average atrial and ventricular beats per minute, event markers, an indication of whether ATAF was present, and an indication of which ventricular paces were effective.

Medtronic CareAlert Monitoring – If the device identifies any programmed or automatic CareAlert conditions, this feature sends a wireless alert signal to the patient monitor (if available). The patient monitor then transmits the CareAlert Event data to the Medtronic CareLink Network. If configured to do so, the Medtronic CareLink Network then sends an alert notification to the clinic.

Episode data and EGM storage – The system provides an arrhythmia episode log that enables you to view the summary and detailed diagnostic data quickly, including stored EGM, for the selected arrhythmia episode.

Flashback memory – This diagnostic feature records intervals that occur immediately prior to tachyarrhythmia episodes or the most recent interrogation and plots the interval data over time.

Heart Failure Management Report – This report provides an overview of the patient's condition over the short and long term, with a focus on heart failure management. The report includes graphs that show OptiVol 2.0 fluid trends and trends related to heart failure over the last 14 months.

Holter telemetry – This function allows the implanted device to transmit an EGM with marker telemetry continuously for up to 46 hours, regardless of the use of the programming head.

Implant Detection – Implant Detection is a 30 min period, beginning when the device is placed in the surgical pocket. During this period, the device verifies lead connection by measuring lead impedance. When the Implant Detection period is completed, various automatic features and diagnostics are activated.

Lead Monitor – This feature measures lead impedances during the life of the implanted device and controls automatic configuration of lead polarities at implant. If Lead Monitor is programmed to Adaptive, the device automatically switches bipolar pacing and sensing to unipolar pacing and sensing if the integrity of a bipolar lead is compromised.

MVP Mode Switches – This feature lists the 10 most recent MVP Mode Switches to DDD(R).

OptiVol 2.0 fluid trends – This feature provides the capability to monitor the following trends:

- The Thoracic Impedance trend plots thoracic impedance for up to 14 months.
- The OptiVol 2.0 Fluid Index trend plots the accumulated differences between the Daily Impedance and Reference Impedance values. Possible fluid accumulation in the patient's thoracic cavity exists when the OptiVol 2.0 Fluid Index exceeds the OptiVol Threshold.

Rate Histograms report – This report shows heart rate range distributions for the patient.

TherapyGuide – This feature provides a set of suggested parameters based on the programmed information about the patient's clinical conditions. The TherapyGuide feature does not replace a physician's expert judgment. The physician is free to accept, reject, or modify any of the suggested parameter values.

Ventricular Sensing Episodes – This diagnostic records extended periods of ventricular sensing to help the clinician assess the continuity of CRT delivery.

1.7 Data security

Medtronic has designed safeguards to protect patient information and device data for the Percepta CRT-P MRI SureScan Model W1TR01 device.

Bluetooth communication system – The device shows its availability through Bluetooth communication. Critical data accepted or sent through the Bluetooth communication from the device is encrypted by the device before it is sent over the Bluetooth channel. The device responds only to authorized commands.

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

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

A complete SureScan pacing system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug for the right atrial port. Any other combination may result in a hazard to the patient during an MRI scan.

Refer to the Medical Procedure and EMI Warnings and Precautions Manual for information about hazards related to medical therapies and diagnostic procedures on patients with cardiac devices. This manual also includes information about sources of EMI in the patient's environment.

Anti-coagulation – Use of the device should not change the application of established anti-coagulation protocols.

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 or intentionally induced during device testing, implant procedures, or post-implant testing.

Lead compatibility – Do not use another manufacturer's leads without demonstrated compatibility with Medtronic devices. If a lead is not compatible with a Medtronic device, the result may be undersensing of cardiac activity, failure to deliver necessary therapy, or a leaking or intermittent electrical connection.

2.2 Explant and disposal

Consider the following information related to device explant and disposal:

- Explant the implantable device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; please check the local regulations. In addition, if subjected to incineration or cremation temperatures, the device may explode.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses. **Note:** Disposal of explanted devices or leads is subject to local, state, and federal regulations.

2.3 Handling and storage instructions

Carefully observe these guidelines when handling or storing the device.

2.3.1 Device handling

Checking and opening the package – Before opening the sterile package tray, 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 an outer tray and an inner tray. Do not use the device or accessories if the outer or inner packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

If the package information is damaged – If any information on the outer package or the sterile package is defaced or damaged so that you cannot read it, notify Medtronic so that the device can be replaced.

If the printed manual is illegible – If this manual is supplied in its printed form and any part of it is illegible, contact Medtronic to request a replacement manual.

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.

Dropped device – Do not implant the device if it is dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

Fluid immersion – Do not immerse the device in fluid or flush the connector ports at the time of implant. Doing so could adversely affect the performance of the device and lead system.

"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.

2.3.2 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 and transport the package between –18°C and +55°C (0°F and 131°F). Device reset may occur at temperatures below –18°C (0°F). Device longevity may decrease and performance may be affected at temperatures above +55°C (131°F).

2.4 Lead evaluation and lead connection

Refer to the lead technical manuals for specific instructions and precautions about lead handling.

A Medtronic MRI SureScan system includes a Medtronic MRI SureScan device connected to Medtronic MRI SureScan leads. **Before performing an MRI procedure, refer to the Medtronic MRI technical manual for additional information.**

Torque wrench – Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew. Other torque wrenches (for example, a blue-handled or right-angled hex wrench) have torque capabilities greater than the lead connector can tolerate.

Lead connection – Consider the following information when connecting the lead and the device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Plug any unused lead ports to protect the device.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

2.5 Device operation

Leads – Bipolar or unipolar leads may be used with the Percepta CRT-P MRI SureScan Model W1TR01 device, but if leads other than bipolar MRI SureScan leads or a Model 6725 pin plug are used, the system is contraindicated for MRI scans.

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.

Maximum output for the Atrial Capture Management feature – The Atrial Capture Management feature does not adjust atrial outputs to values greater than 5.0 V or 1.0 ms. If the patient needs atrial pacing output greater than 5.0 V or 1.0 ms, manually program the atrial amplitude and pulse width. If a lead dislodges partially or completely, the Atrial Capture Management feature may not prevent loss of capture.

Atrial lead maturation – Do not program AT/AF detection to On or enable automatic atrial ATP therapies until the atrial lead has matured (approximately 1 month after implant). If the atrial lead dislodges and migrates to the ventricle, the device could inappropriately detect AT/AF, deliver atrial ATP to the ventricle, and possibly induce a life-threatening ventricular tachyarrhythmia.

Device reset – Device 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. Device 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.

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

Effects of myopotential sensing in unipolar sensing configurations – In unipolar sensing configurations, the device may not distinguish myopotentials from cardiac signals. This may result in a loss of pacing due to inhibition. Also, unipolar atrial sensing in atrial tracking modes can result in elevated ventricular pacing rates. To address these situations, the device may be programmed to be less sensitive (using higher sensitivity values). However, the sensitivity level must be balanced against the potential to undersense true cardiac signals. Typically, this balance is easily attained for ventricular sensing using sensitivity values around 2.8 mV, but it may be difficult to attain for atrial sensing because of the smaller P-wave amplitudes.

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

Extended Upper Tracking Rate – When programming Upper Tracking Rates of 190, 200, or 210 bpm, be careful to ensure that these rates are appropriate for the patient.

False bipolar pathway with unipolar lead – When implanting a unipolar lead, ensure that the tip setscrew is properly engaged and that all electrical contacts are sealed to prevent electrical leakage. Electrical leakage may cause the device to inappropriately identify a unipolar lead as bipolar, resulting in loss of output.

Magnets – Placing a magnet over the device suspends tachyarrhythmia detection and initiates asynchronous, fixed-rate bradycardia pacing. The programming head contains a magnet that can cause magnet operation to occur. However, magnet operation does not occur if telemetry between the device and the programmer is established or if the MRI SureScan mode is programmed to On.

Pace polarity – Pace polarity must be bipolar to program the MRI SureScan mode to On.

Pacemaker-mediated tachycardia (PMT) intervention – Even with the PMT Intervention feature programmed to On, PMTs may still require clinical intervention, such as device reprogramming, drug therapy, or lead evaluation.

Pacing and sensing safety margins – Lead maturation (at least one month after implant) may cause sensing amplitudes to decrease and pacing thresholds to increase, which can cause undersensing or a loss of capture. Provide an adequate safety margin when selecting values for pacing amplitude, pacing pulse width, and sensitivity parameters.

Phrenic nerve stimulation – Phrenic nerve stimulation may occur as a result of left ventricular pacing at higher amplitudes. Although this condition is not life threatening, it is recommended that you test for phrenic nerve stimulation at various pacing amplitude settings with the patient in various positions. If phrenic nerve stimulation occurs with the patient, determine the minimum pacing threshold for phrenic nerve stimulation and program the pacing amplitude to a value that minimizes stimulation but provides an adequate pacing safety margin. Also, consider the use of alternate left ventricular pacing vectors to alleviate phrenic nerve stimulation. If the LV Capture Management feature is used, set the LV Maximum Adapted Amplitude to a value that minimizes phrenic nerve stimulation but provides an adequate pacing safety margin. Carefully consider the relative risks of phrenic nerve stimulation versus loss of capture before programming lower pacing amplitudes for the patient.

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 control – Decisions regarding rate control should not be based on the ability of the device to prevent atrial arrhythmias.

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

Right ventricular apical pacing – Right ventricular apical pacing may be associated with an increased risk of atrial fibrillation, left ventricular dysfunction, and congestive heart failure.

Maximum output for the RV Capture Management feature – The RV Capture Management feature does not program right ventricular outputs to values greater than 5.0 V or 1.0 ms. If the patient needs right ventricular pacing output greater than 5.0 V or 1.0 ms, manually program right ventricular amplitude and pulse width. If a lead dislodges partially or completely, the RV Capture Management feature may not prevent loss of capture.

Sensitivity setting – Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to a more sensitive setting.

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.

Single chamber atrial modes – Do not program single chamber atrial modes for patients with impaired AV nodal conduction. Ventricular pacing does not occur in these modes.

Slow retrograde conduction and PMT – Slow retrograde conduction may induce pacemaker-mediated tachycardia (PMT) when the VA conduction time is greater than 400 ms. Programming PMT Intervention can help prevent PMT only when the VA conduction time is less than 400 ms.

Testing for cross-stimulation – At implant, and regularly when atrial ATP therapy is enabled, conduct testing at the programmed atrial ATP output settings to ensure that ventricular capture does not occur. This is particularly important when the lead is placed in the inferior atrium.

2.5.1 Pacemaker-dependent patients

Ventricular Safety Pacing – Always program Ventricular Safety Pacing (VSP) to On for pacemaker-dependent patients. Ventricular Safety Pacing prevents ventricular asystole due to inappropriate inhibition of ventricular pacing caused by oversensing in the ventricle.

ODO pacing mode – Pacing is disabled under ODO pacing mode. Do not program the ODO mode for pacemaker-dependent patients. Instead, use the Underlying Rhythm Test to provide a brief period without pacing support.

Polarity override – Do not override the polarity verification prompt with bipolar polarity when a unipolar lead is connected. Overriding the polarity verification prompt results in no pacing output.

Underlying Rhythm Test – Use caution when using the Underlying Rhythm Test to inhibit pacing. The patient is without pacing support when pacing is inhibited.

2.6 Potential adverse events

Potential adverse events associated with the use of transvenous leads and pacing systems include, but are not limited to, the following events:

- acceleration of tachyarrhythmias (caused by device)
- air embolism
- bleeding
- body rejection phenomena including local tissue reaction
- cardiac dissection
- cardiac perforation
- cardiac tamponade
- chronic nerve damage
- death
- endocarditis
- erosion
- erosion through the skin
- excessive fibrotic tissue growth
- extrusion

- fibrillation or other arrhythmias
- formation of hematomas or cysts
- heart wall or vein wall rupture
- infection
- lead abrasion and discontinuity
- muscle stimulation, nerve stimulation, or both
- myocardial irritability
- pericardial effusion
- pneumothorax
- threshold elevation
- thrombolytic and air embolism
- transvenous lead-related thrombosis
- venous occlusion
- fluid accumulation
- heart block
- hematoma/seroma
- keloid formation
- lead migration/dislodgment
- myocardial damage
- myopotential sensing
- pericardial rub
- rejection phenomena (local tissue reaction, fibrotic tissue formation, device migration)
- thromboemboli
- thrombosis
- valve damage (particularly in fragile hearts)
- venous or cardiac perforation

An additional potential adverse event associated with the use of transvenous left ventricular pacing leads is coronary sinus dissection.

3 Clinical data

3.1 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:

AdaptivCRT (Adaptive Cardiac Resynchronization Therapy) clinical study – This clinical study evaluated the safety and efficacy of the AdaptivCRT algorithm to provide patient-specific selection of LV or BiV CRT pacing as well as dynamic adjustment of AV and VV delays based on periodic automatic evaluation of intrinsic electrical conduction.

Advisa DR MRI system study – This clinical study, which evaluated the safety and efficacy of the Advisa DR MRI SureScan pacing system in the clinical magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature. This study supports removal of the C1-T12 positioning restriction, so that any region of the body can be scanned when the MR Conditions for Use are followed.

Atrial Capture Management (ACM) study – This clinical study, which evaluated the Atrial Capture Management feature in EnPulse pacemakers, provides support for the Atrial Capture Management feature in Percepta CRT-P MRI SureScan Model W1TR01 devices.

Atrial Fibrillation Symptoms Mediated by Pacing to Mean Rates (AF SYMPTOMS) – This study evaluated the long-term effects of Conducted AF Response in patients with atrial fibrillation and intact atrioventricular (AV) conduction. It provides support for the Conducted AF Response feature in Percepta CRT-P MRI SureScan Model W1TR01 devices. Note that the Ventricular Response Pacing (VRP) feature mentioned in the study is called Conducted AF Response in Percepta CRT-P MRI SureScan Model W1TR01 devices

Atrial Septal Pacing Efficacy Trial (ASPECT) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDRP Pacing System devices, provides support for the atrial intervention pacing therapies.

Atrial Therapy Efficacy and Safety Trial (ATTEST) – This clinical study, which evaluated the safety and efficacy of the Medtronic AT500 DDDRP Pacing System devices, provides support for the Percepta CRT-P MRI SureScan Model W1TR01 devices.

BLOCK HF clinical study – The Biventricular versus Right Ventricular Pacing in Heart Failure Patients with Atrioventricular Block Clinical Study investigated the safety and efficacy of biventricular pacing compared to right ventricular pacing. This study provides support for biventricular pacing in Percepta CRT-P MRI SureScan Model W1TR01 devices.

Care-HF clinical study – This clinical study, which evaluated the effects of cardiac resynchronization therapy (CRT) in InSync and InSync III devices on the mortality and morbidity of patients with moderate or severe heart failure due to left ventricular systolic dysfunction and cardiac dyssynchrony, provides support for CRT pacing in Percepta CRT-P MRI SureScan Model W1TR01 devices.

EnRhythm clinical study – This clinical study, which evaluated the safety and efficacy of the EnRhythm Model P1501DR devices, provides support for MVP mode pacing and the Reactive ATP feature in the Percepta CRT-P MRI SureScan Model W1TR01 devices.

FAST study – This clinical study, which evaluated the OptiVol Fluid Monitoring feature in InSync Marquis devices to corroborate the MIDHeFT clinical data, provides support for the OptiVol Fluid Monitoring feature in Percepta CRT-P MRI SureScan Model W1TR01 devices.

GEM III DR Model 7275 MVP study – This clinical study, which evaluated the performance of MVP mode pacing in the GEM III DR Model 7275 devices, provides support for MVP mode in the Percepta CRT-P MRI SureScan Model W1TR01 devices.

InSync clinical study – This clinical study, which was used as the historical control for the cardiac resynchronization therapy evaluation of the InSync III clinical study, provides support for CRT pacing in Percepta CRT-P MRI SureScan Model W1TR01 devices.

InSync III clinical study – This clinical study, which evaluated the safety and efficacy of sequential biventricular CRT pacing and the general safety and efficacy of CRT in InSync III devices, provides support for CRT pacing in Percepta CRT-P MRI SureScan Model W1TR01 devices.

InSync III Marquis clinical study – This clinical study, which evaluated the safety and efficacy of sequential biventricular CRT pacing and the Conducted AF Response feature in the InSync III Marquis devices, provides support for CRT pacing and Conducted AF Response in Percepta CRT-P MRI SureScan Model W1TR01 devices.

Kappa 700 clinical study – This study, which evaluated the safety and clinical performance of the Kappa 700 pacemakers, provides support for the Right Ventricular Capture Management feature and other bradycardia pacing features.

Left Ventricular Capture Management Software Download Clinical Trial (LVCM) – This clinical study, which evaluated the accuracy of the Left Ventricular Capture Management feature in modified InSync II Marquis devices, provides support for the Left Ventricular Capture Management feature in Percepta CRT-P MRI SureScan Model W1TR01 devices.

Marquis MVP download study – This clinical study, which evaluated the performance of MVP mode pacing in the Marquis DR Model 7274 devices, provides support for MVP mode in the Percepta CRT-P MRI SureScan Model W1TR01 devices.

Medtronic Impedance Diagnostics in Heart Failure Trial (MIDHeFT) – This clinical study, which demonstrated the use of intrathoracic impedance as a surrogate measure of fluid status in patients with heart failure, provides support for the OptiVol Fluid Status Monitoring feature in Percepta CRT-P MRI SureScan Model W1TR01 devices.

Reducing Episodes by Septal Pacing Efficacy Confirmation Trial (RESPECT) – This clinical study evaluated the efficacy of the intervention pacing therapies on symptomatic AT/AF episodes in subjects where the lead was placed in the Bachmann's Bundle region. The results of the study failed to demonstrate effectiveness of the intervention pacing therapies. Evaluation of the RESPECT study data indicated that the intervention pacing features did not significantly reduce the rate of symptomatic AT/AF episodes and these results did not confirm the

findings from previous trials. The pre-specified subgroups were tested for therapeutic effect, but none had results suggesting benefit. When intervention pacing algorithms were programmed ON, atrial pacing percentage increased by 18.1% (P<0.001) with a modest, yet statistically significant, increase in mean heart rate of 2.4 beats per minute (P<0.001).

Revo MRI SureScan pacing system clinical study – This clinical study, which evaluated the safety and efficacy of the EnRhythm MRI SureScan pacing system in the clinical magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature. This study was conducted with the C1 – T12 MRI scan exclusion zone in place.

4 Implant procedure

4.1 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.

For information about replacing a previously implanted device, see Section 4.7, “Replacing a device”, page 22.

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

Connect the skin electrodes to the patient if you would like to display surface ECG signals on the programmer. See the programmer reference manual for more information.

4.1.1 Instruments, components, and accessories required for an implant

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

- Medtronic programmer with a programming head
- programmer software application for the Percepta CRT-P MRI SureScan Model W1TR01 device
- Model 2290 Analyzer or equivalent pacing system analyzer
- external defibrillator

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

- implantable device and lead system components
- programming head sleeve
  Note: If a sterilized programming head is used during an implant, a sterile programming head sleeve is not necessary.
- pacing system analyzer cables
- lead introducers appropriate for the lead system
- extra stylets of appropriate length and shape

4.1.2 Setting up the programmer and starting the application

See the programmer reference manual for instructions about how to set up the programmer. The software application for the Percepta CRT-P MRI SureScan Model W1TR01 device should be installed on the programmer. Your Medtronic representative can install this software, if necessary. Establish telemetry with the device and start a patient session.

4.1.3 Considerations for preparing for an implant

Review the following information before implanting the leads or device:

Warning: Bipolar or unipolar leads may be used with the Percepta CRT-P MRI SureScan Model W1TR01 device, but if leads other than bipolar SureScan leads are used, the system is contraindicated for MRI scans. Before performing an MRI scan, refer to the MRI technical manual for additional information.

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: The device is intended for implant in the pectoral region with Medtronic transvenous leads. Implanting the device outside of the pectoral region may adversely affect the results of the OptiVol 2.0 fluid measurements. Implanting a unipolar RV lead instead of a bipolar lead will result in no OptiVol 2.0 fluid measurements. No claims of safety and efficacy can be made with regard to other acutely or chronically implanted lead systems that are not manufactured by Medtronic.

Caution: Unipolar atrial leads may be used with the device, but bipolar atrial leads are recommended. If unipolar atrial leads are used, AT/AF Detection must be programmed to Monitor and the Capture Management feature must be programmed to Off.

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

To retain the ability to safely scan the SureScan pacing system during MRI scans, the MRI conditions for use in Section 1.5, "MRI conditions for use", page 6 must be followed. Refer to the MRI technical manual for additional information.

4.1.4 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 a device 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 2.85 V at room temperature. If the device has been exposed to low temperatures, then 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 several times a day. The battery voltage reported on the Battery and Lead Measurements screen is an average of recent automatic measurement values.
3. Select Params > Data Collection Setup > Device Date/Time… to select the Time Zone for the internal clock of the device.
4. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that tachyarrhythmia detection is not programmed to On.
   Note: Do not enable a pacing feature that affects the pacing rate (for example, Ventricular Rate Stabilization) before implanting the device. Doing so may result in a pacing rate that is faster than expected.

4.2 Selecting and implanting the leads

Use the guidelines in this section to select leads that are compatible with the device. The appropriate techniques for implanting the leads may vary according to physician preference and the patient's anatomy or physical condition. Consult the technical manuals supplied with the leads for specific implant instructions.

A complete SureScan pacing system is required for use in the MR environment. A complete SureScan pacing system includes a SureScan device with Medtronic SureScan leads or a Model 6725 pin plug. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Caution: Unipolar atrial leads may be used with the device, but bipolar atrial leads are recommended. If unipolar atrial leads are used, the AT/AF detection feature can only be programmed to Monitor.

4.2.1 Selecting the leads

Do not use any lead with this device without first verifying lead and connector compatibility.

The device is typically implanted with the following leads:

- 1 transvenous lead in the left ventricle (LV) for pacing
- 1 bipolar transvenous lead in the right ventricle (RV) for sensing and pacing
- 1 bipolar transvenous lead in the atrium (A) for sensing and pacing. Use of a bipolar atrial lead with ring and tip electrodes spaced ≤ 10 mm apart to reduce far-field R-wave sensing is recommended.

4.2.2 How to verify lead and connector compatibility

Warning: Verify lead and connector compatibility before using a lead with this device. Using an incompatible lead may damage the connector, resulting in electrical current leakage or resulting in an intermittent electrical connection.

Note: Medtronic 3.2 mm low-profile leads are not directly compatible with the device IS-1 connector block.

Note: Lead adaptors compromise the ability to safely scan the SureScan pacing system during an MRI scan. Patients with lead adaptors are contraindicated for an MRI scan.

Note: Using a lead adaptor may affect the accuracy of OptiVol 2.0 fluid measurements.

Use the information in Table 1 to select a compatible lead.

Table 1. Lead and connector compatibility

Connector port	Primary leads
A, RV, LV	IS-1[a] bipolar, IS-1 unipolar

[a] IS-1 refers to the international standard ISO 5841-3.

4.2.3 Implanting the leads

Implant the leads according to the instructions in the technical manuals supplied with the leads unless suitable chronic leads are already in place.

Warning: Pinching the lead can damage the lead conductor or insulation, which may result in the loss of sensing or pacing therapy.

Transvenous leads – If you use a subclavian approach to implant a transvenous lead, position the lead laterally to avoid pinching the lead body between the clavicle and the first rib.

Do not implant the LV, atrial, and RV leads in the same venous access site. Medtronic recommends using the subclavian vein and the cephalic vein to separate the entry site of the leads.

LV leads – Due to the variability of cardiac venous systems, assess the venous anatomy before implanting the LV lead to determine an optimal LV lead position. Before placing a lead in the coronary sinus, obtain a venogram.

4.3 Testing the lead system

After the leads are implanted, test the lead system to verify that the sensing and pacing values are acceptable. Refer to the literature provided with the pacing system analyzer for instructions.

Note: Do not measure the intracardiac EGM telemetered from the device to assess sensing.

Note: The measured pacing lead impedance is a reflection of measuring equipment and lead technology. Refer to the lead technical manual for acceptable impedance values.

Bipolar leads – When measuring sensing and pacing values, measure between the tip (cathode) and ring (anode) of each bipolar pacing/sensing lead.

Unipolar leads – When measuring sensing and pacing values, measure between the tip (cathode) of each unipolar pacing/sensing lead and an indifferent electrode (anode) used in place of the device can.

Lead positioning – Final lead positioning should attempt to optimize cardiac resynchronization.

Extracardiac stimulation – When pacing at 10 V using an external pacing device, test for extracardiac stimulation from the LV lead. If extracardiac stimulation is present, consider repositioning the lead.

Table 2. Acceptable sensing and pacing values

Measurements required	Acute transvenous leads	Chronic leads[a]
P-wave EGM amplitude (atrial)	≥ 2 mV	≥ 1 mV
R-wave EGM amplitude (RV)	≥ 5 mV	≥ 3 mV
LV EGM amplitude	≥ 4 mV	≥ 1 mV
Slew rate		
	≥ 0.5 V/s (atrial)	≥ 0.3 V/s (atrial)
	≥ 0.75 V/s (RV)	≥ 0.5 V/s (RV)
Capture threshold (0.5 ms pulse width)		
	≤ 1.5 V (atrial)	≤ 3.0 V (atrial)
	≤ 1.0 V (RV)	≤ 3.0 V (RV)
	≤ 3.0 V (LV)	≤ 4.0 V (LV)

[a] Chronic leads are leads implanted for 30 days or more.

4.4 Connecting the leads to the device

The following procedure describes how to connect a lead to the device, confirm that the lead connector is fully inserted in the connector block, and verify that the lead connection is secure.

Warning: After connecting the leads, verify that the lead connections are secure by gently tugging on each lead. A loose lead connection may result in inappropriate sensing, which can cause false tracking and false inhibition of pacing, or inappropriate atrial tachyarrhythmia therapy.

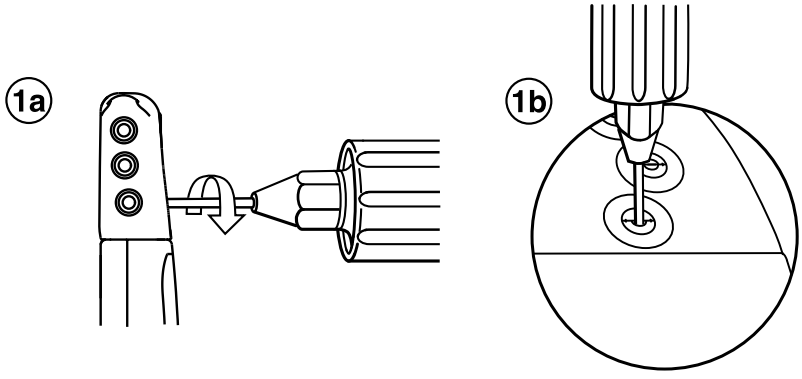
Caution: Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew.

4.4.1 How to connect a lead to the device

1. Insert the torque wrench into the appropriate setscrew.
   a. If the setscrew obstructs the port, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see Figure 1).

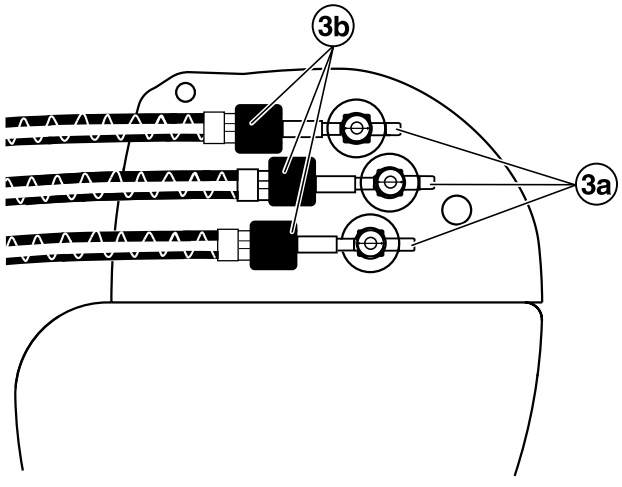
b. Leave the torque wrench in the setscrew until the lead connection is secure. This action allows a pathway for venting trapped air when the lead connector is inserted into the connector port (see Figure 1).

Figure 1. Inserting the torque wrench into the setscrew



2. Push the lead connector into the connector port until the lead connector pin is clearly visible in the pin viewing area. If necessary, sterile water may be used as a lubricant. No sealant is required.
3. Confirm that the lead is fully inserted into the connector pin cavity by viewing the device connector block from the side or end.
   a. The lead connector pin should be clearly visible beyond the setscrew block (see Figure 2).
   b. The lead connector ring should be completely inside the spring contact block. There is no setscrew in this location (see Figure 2).

Figure 2. Confirming the lead connection



4. Tighten the setscrew by turning it clockwise until the torque wrench clicks. Remove the torque wrench.
5. Gently tug on the lead to confirm a secure fit. Do not pull on the lead until the setscrew has been tightened.
6. Repeat these steps for each lead.

4.5 Positioning and securing the device

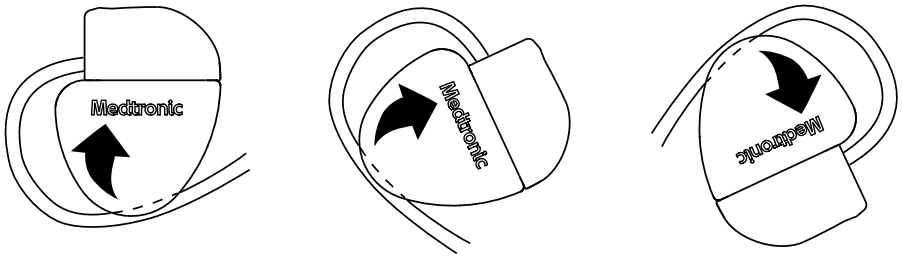
Caution: Program AT/AF detection to Monitor to avoid inappropriate therapy delivery while closing the pocket.

Note: To optimize the ability of the device to connect to a wireless monitor, implant the device within 4 cm (1.6 in) of the surface of the skin.

4.5.1 How to position and secure the device

1. Verify that each lead connector pin or pin plug is fully inserted into the connector port and that all setscrews are tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see Figure 3). Do not kink the lead body.

Figure 3. Rotating the device to wrap the leads



3. Place the device and the leads into the surgical pocket.
4. Use nonabsorbable sutures to secure the device within the pocket and minimize post-implant rotation and migration. Use a surgical needle to penetrate the suture hole on the device.
5. Suture the pocket incision closed.

4.6 Completing the implant procedure

Warning: Do not program AT/AF Detection to On or enable automatic atrial ATP therapies until the atrial lead has matured (approximately 1 month after implant). If the atrial lead dislodges and migrates to the ventricle, the device could inappropriately detect AT/AF, deliver atrial ATP to the ventricle, and possibly induce a life-threatening ventricular tachyarrhythmia.

4.6.1 How to complete programming the device

1. If unipolar leads are implanted, you may want to manually complete the Implant Detection process.
   a. Select the Params icon.
   b. Program the Pace Polarity and Sense Polarity parameters to Unipolar.
   c. Select Additional Features… and program the Implant Detection parameter to Off/Complete.
2. Verify that the pacing, detection, and atrial ATP therapies parameters are programmed to values that are appropriate for the patient.
3. Enter the patient's information.
   Note: Be sure to use the Patient Information screen to enter complete information about the implanted leads. Be sure to use the MRI SureScan System/Other Hardware screen to enter complete information about other hardware implanted in the patient, including abandoned devices or leads, and lead extenders or adaptors. This information will be used in the future if the patient needs to be evaluated for an MRI scan. For more information, see the programming guide.
4. Program the Medtronic CareAlert parameters, if applicable.
5. Program the Data Collection Setup parameters.

4.6.2 How to assess the performance of the device and leads

After implanting the device, x-ray the patient as soon as possible to verify device and lead placement. Before the patient is discharged from the hospital, assess the performance of the implanted device and leads.

1. Monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.
2. Check the pacing and sensing values, and adjust the values if necessary. Verify the safety margin for the pacing threshold.
3. Interrogate the device, and print a Final Report to document the postoperative programmed device status.

4.7 Replacing a device

To retain the ability to safely scan the SureScan pacing system during MRI scans, the MRI conditions for use in Section 1.5, "MRI conditions for use", page 6 must be followed. Refer to the Medtronic MRI technical manual for additional information.

Warning: Bipolar or unipolar leads may be used with the Percepta CRT-P MRI SureScan Model W1TR01 device, but if leads other than bipolar SureScan leads are used, the system is contraindicated for MRI scans. Before performing an MRI scan, refer to the MRI technical manual for additional information.

Warning: Abandoned leads or previously implanted non-MRI labeled leads compromise the ability to safely scan the SureScan pacing system during future MRI scans. When implanting a SureScan pacing system, consider the risks associated with removing previously implanted leads before removing the leads to maintain the ability to safely scan the SureScan pacing system. Refer to the Medtronic MRI technical manual for additional information.

Warning: Keep external pacing equipment nearby for immediate use. The patient does not receive pacing therapy from the device when the lead is disconnected, or when the device is removed from the pocket while the device is operating in unipolar pacing mode.

Caution: Disable tachyarrhythmia detection to avoid inappropriate therapy delivery while explanting the device.

Caution: Unipolar atrial leads may be used with the device, but bipolar atrial leads are recommended. If unipolar atrial leads are used, AT/AF Detection must be programmed to Monitor and the Capture Management feature must be programmed to Off.

Note: To meet the implant requirements, you may need to reposition or replace the chronic leads. For more information, see Section 4.2, "Selecting and implanting the leads", page 17.

Note: Any unused leads that remain implanted must be capped with a lead pin cap to avoid transmitting electrical signals. Contact your Medtronic representative for information about lead pin caps. Any capped or unused leads are considered abandoned leads in the MRI conditions for use, and their presence will contraindicate the system for MRI scanning.

4.7.1 How to explant and replace a device

1. Program the device to a mode that is not rate-responsive to avoid potential rate increases while explanting the device.
2. Dissect the leads and the device free from the surgical pocket. Do not nick or breach the lead insulation.
3. Use a torque wrench to loosen the setscrews in the connector block.
4. Gently pull the leads out of the connector ports.
5. Evaluate the condition of each lead (see Section 4.3, "Testing the lead system", page 19). Replace a lead if the electrical integrity is not acceptable or if the lead connector pin is pitted or corroded. If you explant the lead, return the lead to Medtronic for analysis and disposal.
6. Connect the leads to the replacement device (see Section 4.4, "Connecting the leads to the device", page 19).
   Note: Lead adaptors may be needed to connect the leads to the replacement device. Contact a Medtronic representative for information about compatible lead adaptors.
   Note: Lead adaptors compromise the ability to safely perform an MRI scan on the SureScan pacing system in the future. Patients with lead adaptors are contraindicated for an MRI scan.

7. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see Section 4.5, “Positioning and securing the device”, page 20).
8. Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses. **Note:** Disposal of explanted devices or leads is subject to local, state, and federal regulations.

5 Product specifications

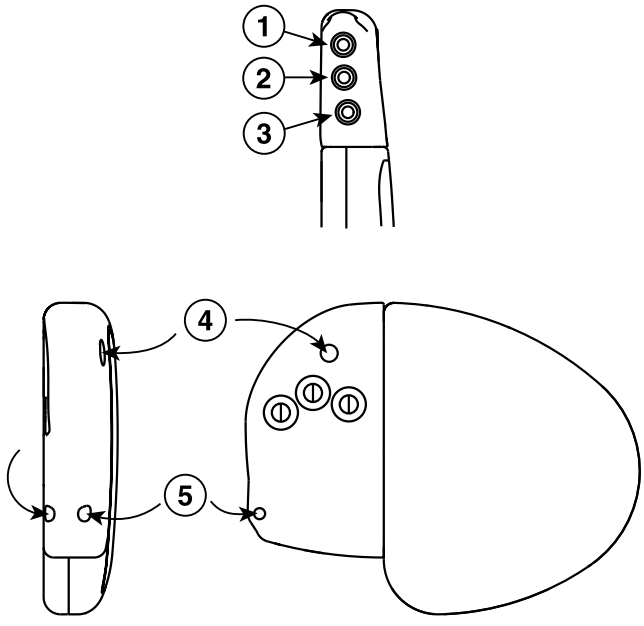
5.1 Physical characteristics

Table 3. Physical characteristics

Volume[a]	20 cm^3
Mass	30 g
H x W x D[b]	59 mm x 46.5 mm x 11 mm
Radiopaque ID[c]	RNP
Medtronic identifier	
Surface area of titanium device can	40.5 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium-hybrid CFx silver vanadium oxide

[a] Volume with connector holes unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[d] 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 4. Connector and suture holes

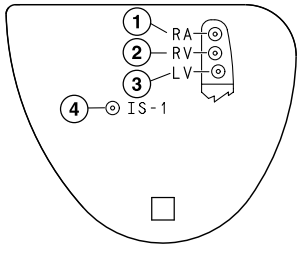


1 IS-1 connector port, A
2 IS-1 connector port, RV
3 IS-1 connector port, LV
4 Suture hole
5 Suture hole

The Model W1TR01 shield graphics are shown in Figure 5.

The IS-1 marking in Figure 5 indicates that the lead connectors conform to ISO 5841-3.

Figure 5. Shield graphics: Model W1TR01



1 RA = right atrial
2 RV = right ventricular
3 LV = left ventricular
4 IS-1 marking

5.2 Electrical specifications

Table 4. Battery characteristics

Manufacturer	Medtronic Energy and Component Center
Model	Delta 26H3
Number of battery cells	1
Chemistry	Lithium-hybrid CFx silver vanadium oxide

Table 4. Battery characteristics (continued)

Nominal voltage	3.25 V
Mean usable capacity	1.19 Ah
Mean capacity to RRT	1.03 Ah
Residual usable capacity at RRT	0.16 Ah

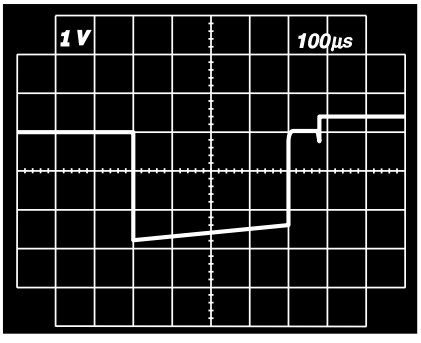
Table 5. Current consumption

Current consumption (at 100% pacing)[a]	12.77 µA
Current consumption (at 100% inhibition)[b]	7.14 µA

[a] Current consumption when pacing into 500 Ω ±1% loads at the Beginning of Service in DDDR mode at 60 bpm, 2.5 V, 0.4 ms.
[b] Current consumption when at the Beginning of Service in DDDR mode at 60 bpm, 2.5 V, 0.4 ms, 500 Ω ±1%.

5.2.1 Output waveforms

Figure 6. Output waveform at nominal conditions (resistive load: 500 Ω)



5.2.2 Variation with temperature

Basic rate, test pulse rate, pulse duration, and pulse amplitude remain within expected tolerances when the device temperature is between 17°C and 45°C (63°F to 113°F). Sensitivity at nominal conditions as measured at 37°C (98.6°F) can vary as much as ±1% per °C from 17°C to 45°C (63°F to 113°F).

5.3 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 6.

Table 6. Replacement indicators

Recommended Replacement Time (RRT)	180 days after 3 consecutive daily automatic measurements of ≤ 2.63 V or immediately after 3 consecutive daily automatic measurements of ≤ 2.60 V, whichever comes first
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

RRT date – The programmer displays the date when the battery reached RRT on the Quick Look II and Battery and Lead Measurements screens.

Replace at EOS – If the programmer indicates that the device is at EOS, replace the device immediately.

RRT operation – When the device reaches RRT, it continues to operate with its programmed parameters. However, placing a magnet over the device initiates asynchronous pacing at 65 bpm rather than at 85 bpm.

ERI operation – When the device reaches ERI, it automatically changes the value of several parameters as shown in Table 7.

Table 7. Parameter settings after ERI

Pacing Mode	VVI
Lower Rate	65 bpm
V. Pacing	as programmed
RV Amplitude, LV Amplitude	as programmed
RV Pulse Width, LV Pulse Width	as programmed
Sleep	Off
V. Rate Stabilization	Off
AT/AF Detection	Monitor[a]
Pre-arrhythmia EGM	Off[b]

[a] When AT/AF Detection is set to Monitor, AT/AF therapies are not available.
[b] Pre-arrhythmia EGM cannot be reprogrammed after ERI.

Notes:
- 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.
- When the MRI SureScan mode is programmed to On, battery measurements are taken, but the device does not report RRT, EOS, or ERI until the MRI SureScan mode has been programmed to Off.

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS. The PSP is defined as 6 months assuming the following conditions, in conformance with ISO 14708: 100% DDD pacing at 60 bpm, 2.5 V atrial, RV, and LV pacing amplitudes; 0.4 ms pulse width; and 600 Ω pacing load. The EOS may be indicated before the end of 6 months if the device exceeds these conditions.

5.4 Projected service life

The projected service life estimates in Table 8 and Table 9 are based on DDD mode pacing, with pacing amplitudes programmed to the specified values, pulse width values of 0.4 ms, and a 60 bpm pacing rate.

The projected service life estimates in Table 10 are based on the pacing characteristics stated in the table.

All of the projected service life estimates are based on the following assumptions:
- Pre-arrhythmia EGM storage programmed to On for the lifetime of the device
- EGM Source parameters set to nominal values
- A quarterly schedule of Medtronic patient monitor transmissions
- Typical shelf storage time before implant

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. These values should not be interpreted as precise numbers.

Table 8. Projected service life in years, with the AdaptivCRT feature programmed to Adaptive Bi-V or Nonadaptive CRT

Percent pacing			500 Ω pacing impedance		600 Ω pacing impedance	
Atrial %	**RV %**	**LV %**	**2.5 V**	**3.5 V**	**2.5 V**	**3.5 V**
0%	100%	100%	10.1	7.7	10.6	8.2
15%	100%	100%	9.9	7.4	10.4	8.0
50%	100%	100%	9.4	6.8	9.9	7.4
100%	100%	100%	8.7	6.1	9.3	6.8

Table 9. Projected service life in years, with the AdaptivCRT feature programmed to Adaptive Bi-V and LV

Percent pacing			500 Ω pacing impedance		600 Ω pacing impedance	
Atrial %	**RV %**	**LV %**	**2.5 V**	**3.5 V**	**2.5 V**	**3.5 V**
0%	50%	100%	10.8	8.6	11.2	9.1
15%	50%	100%	10.5	8.2	11.0	8.8
50%	50%	100%	9.9	7.5	10.4	8.1
100%	50%	100%	9.2	6.7	9.7	7.3

Table 10. Projected service life in years per conditions specified in EN 45502-2-1 and ISO 14708-2

Standard conditions[a]	2.5 V	5.0 V
EN 45502-2-1 • 100% DDDR pacing • 500 Ω ±1% pacing impedance • 70 bpm • 0.4 ms	7.4	2.8
ISO 14708-2 • 100% DDDR pacing • 600 Ω ±1% pacing impedance • 60 bpm • 0.4 ms	9.3	4.2

[a] Data storage and diagnostic functions applicable to the pacing mode are On.

5.4.1 Projected service life considerations

Shelf storage time – These projections are based on typical shelf storage time (5 months). Assuming worst-case shelf storage time (18 months), longevity is reduced by an additional 6.4%.

Pre-arrhythmia EGM storage – These projections assume that Pre-arrhythmia EGM storage is programmed to On for the lifetime of the device. Programming Pre-arrhythmia EGM storage to Off increases the projected service life of the device by approximately 3.2% or 12 days per year.

Capture Management – The Capture Management feature can independently adapt each pacing amplitude value. An Atrial Amplitude of 1.5 V, an RV Amplitude of 2.0 V, and an LV Amplitude of 2.5 V represent typical values when using the Capture Management feature. At these settings, and with 100% atrial and biventricular pacing (at 60 bpm, 0.4 ms, and 600 Ω), the projected service life of the device is 10.6 years.

Medtronic patient monitor remote transmissions – Additional Medtronic patient monitor remote transmissions reduce projected service life. For example, with 4 remote transmissions per year, and with 100% atrial and biventricular pacing (at 60 bpm, 2.5 V, 0.4 ms, and 600 Ω), the projected service life of the device is 9.3 years. Projected service life reductions for more frequent remote transmission rates are as follows:

- Monthly transmissions over the life of the device reduce projected service life by 10 days, or 0.3%.
- Weekly transmissions over the life of the device reduce projected service life by 59 days, or 1.7%.
- Daily transmissions over the life of the device reduce projected service life by 394 days, or 11.5%

6 Device parameters

6.1 Emergency settings

Table 11. Emergency VVI settings

Parameter	Selectable values
Pacing Mode	VVI
Lower Rate	70 bpm
RV Amplitude[a]	6 V
RV Pulse Width[a]	1.5 ms
RV Pace Polarity	Unipolar
V. Pacing	RV
V. Blank Post VP	240 ms
V. Rate Stabilization	Off
V. Sense Response	Off

[a] If the programmed RV Amplitude is 8 V, VVI pacing is delivered at 8 V with a pulse width of 1.2 ms.

6.2 Magnet application

When a magnet is placed near the device, the pacing mode changes from the programmed mode to DOO, VOO, or AOO, and the pacing rate changes to 100 bpm for 5 beats and then changes to 85 bpm or 65 bpm, as described at the end of this section. Placing a magnet near the device suspends tachyarrhythmia detection. When the magnet is removed, the device returns to its programmed operation.

Note: Magnet operation does not occur if telemetry between the device and programmer is established or if the MRI SureScan mode is programmed to On.

The pacing mode will be DOO when the programmed pacing mode is a dual chamber mode or an MVP mode (AAIR<=>DDDR, AAI<=>DDD), VOO when the programmed pacing mode is a single chamber ventricular mode, and AOO when the programmed pacing mode is a single chamber atrial mode.

The pacing rate will be 85 bpm if the device conditions are normal and it will be 65 bpm if a Recommended Replacement Time (RRT) indicator or a device reset has occurred.

6.3 Tachyarrhythmia detection parameters

Table 12. Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
AT/AF Detection	On; Monitor◈	Monitor	Monitor
Zones	1◈; 2	—	—
AT/AF Interval (Rate)[a]	150; 160 … 350◈ … 450 ms	350 ms	350 ms
Fast AT/AF Interval (Rate)[a]	150; 160 … 200◈ … 250 ms	200 ms	200 ms
VT Monitor	Monitor◈; Off	Monitor	Off
VT Monitor Interval (Rate)[a]	280; 290 … 400◈ … 500 ms	400 ms	400 ms
RV Sensitivity[b]	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Bipolar: 0.9◈ mV Unipolar: 2.80◈ mV	0.9 mV	2.8 mV
Atrial Sensitivity[c]	0.15; 0.30; 0.45; 0.60; 0.90; 1.20; 1.50; 1.80; 2.10; 4.0 mV; Off Bipolar: 0.3◈ mV Unipolar: 0.45◈ mV	0.3 mV	0.45 mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 2.0 mV or higher.
[c] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 1.8 mV or higher.

6.4 Atrial tachyarrhythmia therapy parameters

Table 13. Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
Anti-Tachy Pacing (ATP)			
Fast AT/AF Rx Status	On; Off◈	Off	Off
Therapy Type	Ramp; Burst+ Rx1: Ramp◈ Rx2: Burst+◈ Rx3: Ramp◈	—	—
AT/AF Rx Status	On; Off◈	Off	Off
Therapy Type	Ramp; Burst+ Rx1: Ramp◈ Rx2: Burst+◈ Rx3: Ramp◈	—	—
Burst+ parameters			
Initial # S1 Pulses	1; 2; 3 … 11◈ … 15; 20; 25	—	—
A-S1 Interval (%AA)	28; 31; 34; 38; 41 … 59; 63; 66; 69 … 84◈; 88; 91; 94; 97%		

Table 13. Atrial tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
S1-S2 (%AA)	28; 31; 34; 38; 41 … 59; 63; 66; 69 … 81◈; 84; 88; 91; 94; 97%; Off	—	—
S2-S3 Decrement	0; 10; 20◈ … 80 ms; Off	—	—
Interval Decrement	0; 10◈; 20; 30; 40 ms	—	—
# Sequences	1; 2; 3 … 10◈	—	—
Ramp parameters			
Initial # S1 Pulses	1; 2; 3 … 13◈; 14; 15; 20; 25	—	—
A-S1 Interval (%AA)			
Rx1	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
Rx2	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
Rx3	28; 31; 34; 38; 41 … 59; 63; 66 … 81◈; 84; 88; 91; 94; 97%	—	—
Interval Decrement	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 8; 9; 10◈	—	—
Stop Atrial Rx After (shared)			
Rx/Lead Suspect…			
Disable Atrial ATP if it accelerates V. rate?	Yes◈; No	Yes	Yes
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes◈; No	Yes	No
Duration to Stop	12; 24; 48◈; 72 hr; None	48 hr	48 hr
Episode Duration Before Rx Delivery			
Episode Duration Before ATP	0; 1◈; 2 … 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr	1 min	1 min
Reactive ATP			
Rhythm Change	On◈; Off	On	On
Time Interval	Off◈; 2; 4; 7; 12; 24; 36; 48 hr	Off	Off
Shared A. ATP			
A-A Minimum ATP Interval[a]	100; 110; … 150◈ … 400 ms	150 ms	150 ms
A. Pacing Amplitude	1; 2; 3 …6◈; 8 V	6 V	6 V
A. Pacing Pulse Width	0.1; 0.2 … 1.5◈ ms	1.5 ms	1.5 ms

Table 13. Atrial tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
VVI Backup Pacing	Off; On (Always); On (Auto-Enable)◈	On (Auto-Enable)	On (Auto-Enable)
VVI Backup Pacing Rate	60; 70◈ … 120 bpm	70 bpm	70 bpm

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

6.5 Pacing parameters

Table 14. Modes, rates, and intervals

Parameter	Programmable values	Shipped	Reset
Mode	DDDR; DDD◈; AAIR<=>DDDR; AAI<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO	DDD	VVI
Mode Switch	On◈; Off	On	Off
Lower Rate[a]	30; 35 … 50◈; 70; 75 … 150 bpm	50 bpm (1000 ms)	65 bpm (920 ms)
Upper Tracking Rate	80; 85 … 130◈ …175 bpm; 180; 190 … 210 bpm	130 bpm	120 bpm
Paced AV[b]	30; 40 … 130◈ … 350 ms	130 ms	180 ms
Sensed AV[b]	30; 40 … 100◈ … 350 ms	100 ms	150 ms
Maximum AV Interval limit	Off◈; 250; 260 … 500 ms	Off	Off
PVARP	Auto◈; 150; 160 … 500 ms	Auto	Auto
Minimum PVARP	150; 160 … 250◈ … 500 ms	250 ms	250 ms
A. Refractory Period	150; 160 … 310◈ … 500 ms	310 ms	310 ms

[a] The corresponding Lower Rate interval can be calculated as follows: Lower Rate interval (ms) = 60,000/Lower Rate.
[b] If CRT is adaptive, Paced AV and Sensed AV cannot be selected or programmed.

Table 15. Atrial parameters

Parameter	Programmable values	Shipped	Reset
Atrial Amplitude	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V[a]	3.5 V	—
Atrial Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	—
Atrial Sensitivity	Off; 0.15; 0.3; 0.45; 0.6; 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV Unipolar: 0.45◈ mV Bipolar: 0.3◈ mV	0.3 mV	0.45 mV
Atrial Pace Polarity	Bipolar; Unipolar	Configure[b]	—
Atrial Sense Polarity	Bipolar; Unipolar	Configure[b]	Unipolar

Table 15. Atrial parameters (continued)

Parameter	Programmable values	Shipped	Reset
Atrial Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
Max Limit	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

[a] When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.
[b] "Configure" is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.

Table 16. RV parameters

Parameter	Programmable values	Shipped	Reset
RV Amplitude	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V[a]	3.5 V	6 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	1.5 ms
RV Sensitivity	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Unipolar: 2.80◈ mV Bipolar: 0.90◈ mV	0.90 mV	2.80 mV
RV Pace Polarity	Bipolar; Unipolar	Configure[b]	Unipolar
RV Sense Polarity	Bipolar; Unipolar	Configure[b]	Unipolar
RV Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
Max Limit	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

[a] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.
[b] "Configure" is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.

Table 17. LV parameters

Parameter	Programmable values	Shipped	Reset
LV Amplitude	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V[a]	3.5 V	—
LV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	1.5 ms
LV Pace Polarity	LVtip to RVring; LVtip to Can; LVring to RVring; LVring to Can; LVtip to LVring	LVtip to Can	LVtip to Can
LV Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
Max Limit	800; 1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

[a] When LV Amplitude is 8 V, LV Pulse Width must be less than 1.3 ms.

Table 18. CRT pacing parameters

Parameter	Programmable values	Shipped	Reset
AdaptivCRT	Adaptive Bi-V and LV◈; Adaptive Bi-V; Nonadaptive CRT	Adaptive Bi-V and LV	Nonadaptive CRT
V. Pacing[a]	RV; RV→LV; LV→RV◈	LV→RV	RV
V-V Pace Delay	Auto◈; 0; 10 … 80 ms	Auto	0 ms
EffectivCRT During AF	On◈; Off	On	Off
Maximum Rate	80; 85 …110◈ … 130 bpm	110 bpm	—
V. Sense Response	On◈; Off	On	Off
Maximum Rate	95; 100 …130◈ … 150 bpm	130 bpm	—
Atrial Tracking Recovery	On◈; Off	On	—

[a] If CRT is adaptive, V. Pacing cannot be selected or programmed.

Table 19. Atrial Capture Management parameters

Parameter	Programmable values	Shipped	Reset
Atrial Capture Management	Adaptive◈; Monitor; Off	Adaptive	Off
Atrial Amplitude Safety Margin	1.5x; 2.0x◈; 2.5x; 3.0x	2.0x	2.0x
Atrial Minimum Adapted Amplitude	1.0; 1.5◈; 2.0; 2.5; 3.0; 3.5 V	1.5 V	1.5 V
Atrial Acute Phase Remaining	Off; 30; 60; 90; 120◈; 150 days	120 days	120 days

Table 20. RV Capture Management parameters

Parameter	Programmable values	Shipped	Reset
RV Capture Management	Adaptive◈; Monitor; Off	Adaptive	Off
RV Amplitude Safety Margin	1.5x; 2.0x◈; 2.5x; 3.0x	2.0x	2.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0◈; 2.5; 3.0; 3.5 V	2 V	2 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120◈; 150 days	120 days	120 days

Table 21. LV Capture Management parameters

Parameter	Programmable values	Shipped	Reset
LV Capture Management	Adaptive◈; Monitor; Off	Adaptive	Off
LV Amplitude Safety Margin	+Auto◈; +0.5; +1.0; +1.5; +2.0; +2.5 V	+Auto	—
LV Maximum Adapted Amplitude	0.5; 0.75 … 5.0; 5.5; 6◈ V	6.0 V	6.0 V

Table 22. Blanking periods

Parameter	Programmable values	Shipped	Reset
PVAB Interval	10[a]; 20 … 100; 110; 120 …150◈ … 300 ms	150 ms	150 ms
PVAB Method	Partial◈; Partial+; Absolute	Partial	Partial
A. Blank Post AP	150; 160 … 200◈ … 250 ms	200 ms	240 ms
A. Blank Post AS	100◈; 110 … 170 ms	100 ms	100 ms
V. Blank Post VP	150; 160 … 230◈ … 320 ms	230 ms	240 ms
V. Blank Post VS	120◈; 130 … 170; 200; 220; 250; 280; 300; 320 ms	120 ms	120 ms

[a] If the PVAB Method is set to Partial, the minimum selectable value for the PVAB Interval is 100 ms

Table 23. Rate Response Pacing parameters

Parameter	Programmable values	Shipped	Reset
Rates			
ADL Rate	60; 65 … 95◈ … 170 bpm	95 bpm	95 bpm
Upper Sensor	80; 85 … 120◈ … 175 bpm	120 bpm	120 bpm
Rate Profile Optimization	On◈; Off	On	Off
Adjust Rate Response			
ADL Response	1; 2; 3◈; 4; 5	3	3
Exertion Response	1; 2; 3◈; 4; 5	3	3
Additional Parameters…			
Activity Threshold	Low◈; Medium Low; Medium High; High	Low	Medium Low
Activity Acceleration	15; 30◈; 60 s	30 s	30 s
Activity Deceleration	Exercise◈; 2.5; 5; 10 min	Exercise	5 min
ADL Setpoint	5; 6 … 40; 42 … 80	18	18
UR Setpoint	15; 16 … 40; 42 … 80; 85 … 180	40	40

Table 24. Rate Adaptive AV parameters

Parameter	Programmable values	Shipped	Reset
Rate Adaptive AV[a]	On◈; Off	On	On
Start Rate	50; 55 … 90◈ … 145 bpm	90 bpm	60 bpm
Stop Rate	55; 60 … 130◈ … 175 bpm	130 bpm	120 bpm
Minimum Paced AV	30; 40 … 100◈ … 200 ms	100 ms	140 ms
Minimum Sensed AV	30; 40 … 70◈ … 200 ms	70 ms	110 ms

[a] If CRT is adaptive, Rate Adaptive AV cannot be selected or programmed.

Table 25. Atrial Rate Stabilization parameters

Parameter	Programmable values	Shipped	Reset
A. Rate Stabilization	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ … 150 bpm	100 bpm	100 bpm
Interval Percentage Increment	12.5; 25◈; 50%	25%	25%

Table 26. Atrial Preference Pacing parameters

Parameter	Programmable values	Shipped	Reset
A. Preference Pacing	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ … 150 bpm	100 bpm	100 bpm
Interval Decrement	30◈; 40; 50 … 100; 150 ms	30 ms	50 ms
Search Beats	5; 10; 15; 20◈ … 25; 50	20	5

Table 27. Post Mode Switch Overdrive Pacing (PMOP) parameters

Parameter	Programmable values	Shipped	Reset
Post Mode Switch	On; Off◈	Off	Off
Overdrive Rate	70; 75; 80◈ … 120 bpm	80 bpm	65 bpm
Overdrive Duration	0.5; 1; 2; 3; 5◈; 10; 20; 30; 60; 90; 120 min	5 min	5 min

Table 28. Conducted AF Response parameters

Parameter	Programmable values	Shipped	Reset
Conducted AF Response	On◈; Off	On	Off
Response Level	Low; Medium◈; High	Medium	Medium
Maximum Rate	80; 85 … 110◈ … 130 bpm	110 bpm	110 bpm

Table 29. Ventricular Rate Stabilization parameters

Parameter	Programmable values	Shipped	Reset
V. Rate Stabilization	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ …120 bpm	100 bpm	120 bpm
Interval Increment	100; 110 … 150◈ … 400 ms	150 ms	150 ms

Table 30. Rate Drop Response parameters

Parameter	Programmable values	Shipped	Reset
Rate Drop Response[a]	On; Off◈	Off	Off
Detection Type	Drop◈; Low Rate; Both	Drop	Drop
Drop Detection			
Drop Size	10; 15 … 25◈ … 50 bpm	25 bpm	25 bpm

Table 30. Rate Drop Response parameters (continued)

Parameter	Programmable values	Shipped	Reset
Drop Rate	30; 40 … 60◈ … 100 bpm	60 bpm	60 bpm
Detection Window	10; 15; 20; 25; 30 s 1◈; 1.5; 2; 2.5 min	1 min	1 min
Low Rate Detection			
Detection Beats	1; 2; 3◈ beats	3 beats	3 beats
Intervention			
Intervention Rate	70; 75 … 100◈ … 150 bpm	100 bpm	100 bpm
Intervention Duration	1; 2◈ … 15 min	2 min	2 min

[a] When Rate Drop Response is set to On, the lower rate is automatically set to 45 bpm.

Table 31. Sleep parameters

Parameter	Programmable values	Shipped	Reset
Sleep	On; Off◈	Off	Off
Sleep Rate	30; 35 … 50◈; 55; 60; 70; 75 … 100 bpm	50 bpm	50 bpm
Bed Time	00:00; 00:10 … 22:00◈ … 23:50	22:00	22:00
Wake Time	00:00; 00:10 … 07:00◈ … 23:50	07:00	07:00

Table 32. Non-Competitive Atrial Pacing (NCAP) parameters

Parameter	Programmable values	Shipped	Reset
Non-Comp Atrial Pacing	On◈; Off	On	On
NCAP Interval	200; 250; 300◈; 350; 400 ms	300 ms	300 ms

Table 33. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
MRI Pacing Mode	DOO; AOO; VOO; ODO	—	—
MRI Pacing Rate	60; 70; 75; 80 … 120 bpm	—	—

Table 34. Additional pacing features

Parameter	Programmable values	Shipped	Reset
PMT Intervention	On◈; Off	On	Off
PVC Response	On◈; Off	On	On
V. Safety Pacing[a]	On◈; Off	On	On

[a] Delivered as LV pacing when the AdaptivCRT operating value is LV. Delivered as RV pacing when RV only pacing is permanently programmed. Otherwise, delivered as BiV pacing.

6.6 Data collection parameters

Table 35. Data collection parameters

Parameter	Programmable values	Shipped	Reset
EGM 1 Source	Can to Aring (LECG); Can to RVring; Atip to Aring◈; Atip to RVring; Atip to Can; Aring to RVring; RVtip to RVring; RVtip to Can	Atip to Aring	Atip to Aring
EGM 1 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 2 Source	Can to RVring; RVtip to RVring◈; RVtip to Can; LVtip to Can; LVtip to LVring[a]; LVring to Can	RVtip to RVring	RVtip to RVring
EGM 2 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 3 Source	RVtip to RVring; Can to RVring; Atip to RVring; Atip to Aring; Can to Aring (LECG)◈; LVtip to Can; LVtip to LVring[a]; LVring to Can	Can to Aring (LECG)	Can to Aring (LECG)
EGM 3 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
Monitored	EGM1 and EGM2◈; EGM1 and EGM3; EGM2 and EGM3	EGM1 and EGM2	EGM1 and EGM2
Pre-arrhythmia EGM	Off; On Continuous◈	On Continuous	Off
AT/AF Daily Burden	0.5; 1; 2; 6◈; 12; 24 hr/24hr	6 hr	6 hr
Avg. V. Rate During AT/AF Burden	0.5; 1; 2; 6◈; 12; 24 hr/24hr	6 hr	6 hr
Avg. V. Rate During AT/AF V. Rate	90; 100◈…130; 140; 150 bpm	100 bpm	100 bpm
OptiVol Threshold[b]	30; 40; 50; 60◈…160; 170; 180	60	60
V. Sensing Episodes…			
Consecutive VS to detect >=	5; 8; 10◈; 15; 20; 30; 40; 50; 100; 150; 200	10 senses	10 senses
Consecutive VP to terminate >=	2; 3◈; 5; 10	3 paces	3 paces
Device Date/Time[c]	(select Time Zone)	—	—
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off
Wireless Telemetry with Monitor	On; Off	On	On[d]

[a] A bipolar LV lead must be present for this configuration.

[b] Decreasing the OptiVol Threshold will make the device more sensitive to changes in the patient's thoracic fluid status. Increasing the OptiVol Threshold could delay or prevent device observation of significant changes in the patient's thoracic fluid status.

[c] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

[d] The reset value may be set to Off if there is an issue with wireless communication that requires it to be disabled.

6.7 Medtronic CareAlert parameters

Table 36. Clinical Management Alerts

Parameter	Programmable values	Shipped	Reset
AT/AF Burden and Rate Settings…			
AT/AF Alerts			
AT/AF Daily Burden Enable	Off◈; On	Off	Off
Daily AT/AF Burden	0.5; 1; 2; 6◈; 12; 24 hr/24hr	6 hr	6 hr
Avg. V. Rate During AT/AF Enable	Off◈; On	Off	Off
Daily Burden for Avg. V. Rate	0.5; 1; 2; 6◈; 12; 24 hr/24hr	6 hr	6 hr
Avg. V. Rate During AT/AF	90; 100◈ … 150 bpm	100 bpm	100 bpm
Monitored VT Episode Detected	Off◈; On	Off	Off
Total VP < 90%	Off◈; On[a]	Off	Off
OptiVol 2.0 Fluid Settings…	Off◈	Off	Off
Observation Conditions			
OptiVol Threshold[b]	30; 40; 50; 60◈ … 100; 120 … 180	60	60

[a] Alert triggered if percent of cumulative ventricular pacing is less than 90% for 7 consecutive days.
[b] Decreasing the OptiVol Threshold makes the device more sensitive to changes in the patient's thoracic fluid status. Increasing the OptiVol Threshold could delay or prevent device observation of significant changes in the patient's thoracic fluid status.

Table 37. Lead/Device Integrity Alerts

Parameter	Programmable values	Shipped	Reset
Low Battery Voltage RRT	On◈; Off	On	Off
Lead Impedance Out of Range…			
Lead Impedance			
A. Pacing Enable	On◈; Off	On	Off
A. Pacing Less than	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
A. Pacing Greater than	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω
RV Pacing Enable	On◈; Off	On	Off
RV Pacing Less than	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
RV Pacing Greater than	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω
LV Pacing Enable	On◈; Off	On	Off
LV Pacing Less than	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
LV Pacing Greater than	800; 1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω

Table 37. Lead/Device Integrity Alerts (continued)

Parameter	Programmable values	Shipped	Reset
Capture Management High Threshold			
High Threshold			
A. Capture Enable[a]	Off◈; On	Off	Off
RV Capture Enable[b]	Off◈; On	Off	Off
LV Capture Enable[c]	Off◈; On	Off	Off

[a] If programmed to On, alert notification is sent if A. capture management has measured high thresholds for 3 consecutive days.
[b] If programmed to On, alert notification is sent if RV capture management has measured high thresholds for 3 consecutive days.
[c] If programmed to On, alert notification is sent if LV capture management has measured high thresholds for one day.

6.8 System test parameters

Table 38. System test parameters

Parameter	Selectable values
Sensing Test parameters	
Mode[a]	AAI; DDD; DDI; VVI; ODO
AV Delay	30; 40 … 350 ms
Lower Rate[b]	30; 35 … 60; 70; 75 … 120 bpm
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Chamber	Atrium; RV; LV
Decrement after	2; 3 … 15 pulses
Pace Polarity (Atrium, RV)	Unipolar; Bipolar
Pace Polarity (LV)	LVtip to RVring; LVtip to Can; LVring to RVring; LVring to Can; LVtip to LVring
Mode[a] (RV or LV test)	VVI; VOO; DDI; DDD; DOO
Mode[a] (Atrium test)	AAI; AOO; DDI; DDD; DOO
Lower Rate[b]	30; 35 … 60; 70; 75 … 150 bpm
AV Delay	30; 40 … 350 ms
RV Amplitude	0.25; 0.5 … 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 … 1.5 ms
LV Amplitude	0.25; 0.5 … 5; 5.5; 6; 8 V
LV Pulse Width	0.03; 0.06; 0.1; 0.2 … 1.5 ms
A. Amplitude	0.25; 0.5 … 5; 5.5; 6; 8 V
A. Pulse Width	0.03; 0.06; 0.1; 0.2 … 1.5 ms
V. Pace Blanking	150; 160 … 320 ms

Table 38. System test parameters (continued)

Parameter	Selectable values
A. Pace Blanking	150; 160 … 250 ms
PVARP	150; 160 … 500 ms
CardioSync Optimization Test parameters	
Sensing Lower Rate	30; 35 … 60; 70; 75 … 90 bpm
Pacing Lower Rate	35; 40 … 60; 70; 75 … 95 bpm

[a] The selectable values for this parameter depend on the programmed pacing mode.
[b] When performing the test in DDD mode, the Lower Rate must be less than the programmed Upper Tracking Rate.

6.9 EP study parameters

Table 39. 50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled◈; Disabled
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V[a]
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms[b]
VOO Backup (for atrial 50 Hz Burst)[c]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm
V. Amplitude[d,e]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[d]	0.10; 0.20 … 1.50 ms

[a] Amplitude accuracy: ≤ 2.5 V (+0.50 V/-33%), > 2.5 V to ≤ 6.0 V (+20%/-33%), ≥ 6.0 V (+20%/-55%) to ERI.
[b] Pulse width accuracy: +3/-3 ms at 37°C.
[c] V. Backup Pacing is delivered to the RV chamber.
[d] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[e] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Table 40. Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled◈; Disabled
Chamber[a]	Atrium; RV; RV+LV; LV
Interval	100; 110 … 600◈ ms
Amplitude[b]	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width[b]	0.10; 0.20 … 0.50◈ … 1.50 ms
VVI Backup (for atrial Fixed Burst)[c]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm

Table 40. Fixed Burst induction parameters (continued)

Parameter	Selectable values
V. Amplitude[d,e]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[d]	0.10; 0.20 … 1.50 ms

[a] If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.
[b] Applies to all ventricular chambers paced.
[c] V. Backup Pacing is delivered to the RV chamber.
[d] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[e] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Table 41. PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled◈; Disabled
Chamber[a]	Atrium; RV; RV+LV; LV
#S1	1; 2 … 8◈ … 15
S1S1	100; 110 … 600◈ … 2000 ms
S1S2	Off; 100; 110 … 400◈ … 600 ms
S2S3	Off◈; 100; 110 … 600 ms
S3S4	Off◈; 100; 110 … 600 ms
Amplitude[b]	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width[b]	0.10; 0.20 … 0.50◈ … 1.50 ms
VVI Backup (for atrial PES)[c]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm
V. Amplitude[d,e]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[d]	0.10; 0.20 … 1.50 ms

[a] If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.
[b] Applies to all ventricular chambers paced.
[c] V. Backup Pacing is delivered to the RV chamber.
[d] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[e] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Table 42. Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (atrial ATP)	100; 110; 120; 130◈ … 400 ms
Minimum Interval (ventricular ATP)	150; 160 … 200◈ … 400 ms
Amplitude[a]	1; 2 … 6◈; 8 V
Pulse Width[a]	0.10; 0.20 … 1.50◈ ms
VVI Backup (for atrial ATP therapy)[b]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm

Table 42. Shared manual ATP therapy parameters (continued)

Parameter	Selectable values
V. Amplitude[c,d]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[c]	0.10; 0.20 … 1.50 ms

[a] Applies to all ventricular chambers paced.
[b] V. Backup Pacing is delivered to the RV chamber.
[c] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[d] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Table 43. Manual Ramp therapy parameters

Parameter	Selectable values
Chamber[a]	Atrium; RV; RV+LV; LV
Ventricular Ramp therapy parameters	
#Pulses	1; 2 … 6◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88; 91; 94; 97◈%
Dec/Pulse	0; 10◈; 20; 30; 40 ms
Atrial Ramp therapy parameters	
#Pulses	1; 2 … 6◈ … 15; 20; 30 … 100
%AA Interval	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91; 94; 97◈%
Dec/Pulse	0; 10◈; 20; 30; 40 ms

[a] If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

Table 44. Manual Burst therapy parameters

Parameter	Selectable values
Chamber[a]	RV◈; RV+LV; LV
#Pulses	1; 2 … 8◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%

[a] If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

Table 45. Manual Ramp+ therapy parameters

Parameter	Selectable values
Chamber[a]	RV◈; RV+LV; LV
#Pulses	1; 2; 3◈ … 15
R-S1(%RR)	50; 53; 56; 59; 63; 66 … 75◈ … 84; 88; 91; 94; 97%
S1S2(%RR)	50; 53; 56; 59; 63; 66; 69◈ … 84; 88; 91; 94; 97%
S2SN(%RR)	50; 53; 56; 59; 63; 66◈ … 84; 88; 91; 94; 97%

[a] If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.

Table 46. Manual Burst+ therapy parameters

Parameter	Selectable values
#S1 Pulses	1; 2 … 6◈ … 15; 20; 30 … 100
%AA Interval	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%
S1S2	Off; 28; 31; 34; 38; 41 … 59; 63; 66 … 84◈; 88; 91; 94; 97%
S2S3 Dec	Off; 0; 10; 20◈ … 80 ms

6.10 Nonprogrammable parameters

Table 47. Nonprogrammable parameters

Parameter	Value
Premature event threshold for counting PVCs and Runs of PVCs	69%
Fixed blanking periods	
Atrial blanking after a paced ventricular event[a] (bipolar atrial sensing)	30 ms
Atrial blanking after a paced ventricular event (unipolar atrial sensing)	40 ms
Ventricular blanking after a paced atrial event (bipolar ventricular sensing)	30 ms[b]
Ventricular blanking after a paced atrial event (unipolar ventricular sensing)	40 ms
Fixed bradycardia pacing parameters	
Ventricular Safety Pacing intervals[c]	110 ms
PVARP value applied by PVC Response and PMT Intervention[d]	400 ms
NCAP value applied by PVC Response and PMT Intervention[e]	400 ms
Fixed automatic atrial ATP therapy parameters	
VVI Backup Pacing amplitude	6 V
VVI Backup Pacing pulse width	1.5 ms
Fixed EP study parameters	
50 Hz burst pacing interval	20 ms
Hardware parameters	
Pacing rate limit[f] (protective feature)	200 bpm[g]
Input impedance	150 kΩ minimum
Effective pacing capacitance	4 µF

Table 47. Nonprogrammable parameters (continued)

Parameter	Value
Recommended Replacement Time (RRT)	
Battery Voltage Threshold	180 days after 3 consecutive daily automatic measurements of ≤ 2.63 V or immediately after 3 consecutive daily automatic measurements of ≤ 2.60 V, whichever comes first

[a] The time between biventricular pacing pulses may affect the duration of the atrial blanking period.
[b] 35 ms when the ventricular pacing amplitude is programmed to 8 V.
[c] The VSP interval may be shortened from 110 ms to 70 ms automatically by the device at higher pacing rates when necessary to help support ventricular tachycardia detection.
[d] PVARP is extended to 400 ms only if the current PVARP is less than 400 ms.
[e] The NCAP extension applies only if NCAP is enabled.
[f] Does not apply during ATP therapies or ventricular safety pacing.
[g] If the Upper Tracking Rate is programmed to a value greater than 180 bpm, the pacing rate limit is 230 bpm.

Table 48. Nonprogrammable parameters for the MRI SureScan mode

Parameter	Value
Pacing amplitude	Programmed pacing amplitude value when >5 V; 5 V when programmed pacing amplitude value is ≤5 V
Pulse width	Programmed pulse width value when >1 ms; 1 ms when programmed pulse width value is ≤1 ms
Sensitivity	Programmed value
Input impedance	150 kΩ
AV interval	Programmed PAV value when PAV is ≥50 ms and ≤100 ms; 50 ms when PAV is <50 ms; 110 ms when PAV is >110 ms
Pacing rate limit	200 bpm
Effective pacing capacitance	4 µF
Refractory period	—
Blanking period	
ODO mode	Programmed blanking period value
DOO, VOO, and AOO modes	—

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