

# Medtronic

## Azure™ S DR MRI SureScan™ W3DR01

MR Conditional dual chamber pacemaker with SureScan™ technology and Bluetooth® wireless telemetry (OOE-DDDR)

Device Manual

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

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# 1 System overview

## 1.1 Introduction

This manual describes the Medtronic Model W3DR01 Azure S DR MRI SureScan dual chamber, implantable pulse generator (IPG). It contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

The following manuals and documents also contain 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 IPG 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 Azure S DR MRI SureScan Model W3DR01 dual chamber implantable pulse generator (IPG) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single or dual chamber rate-responsive bradycardia pacing. This device features Bluetooth wireless technology.<sup>1</sup>

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.

**Rate response** – Rate response is controlled through an activity-based sensor.

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.
- 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.

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<sup>1</sup> The Bluetooth® word mark is a registered trademark of Bluetooth SIG, Inc. and any use of this mark by Medtronic is under license.

- 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 (IPG) and 1 torque wrench.

**Implantable device system** – The Azure S DR MRI SureScan Model W3DR01 device and the pacing leads constitute the implantable portions of the device system.

**Leads** – The lead system used with this device must provide sensing and pacing to the right ventricle (RV) and 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 15.

**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 Azure S DR MRI SureScan Model W3DR01 system is indicated for the following conditions:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity
- Accepted patient conditions warranting chronic cardiac pacing, which include:
  - Symptomatic paroxysmal or permanent second- or third-degree AV block
  - Symptomatic bilateral bundle branch block
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The Azure S DR MRI SureScan Model W3DR01 device is also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output
- VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm
- Vasovagal syndromes or hypersensitive carotid sinus syndromes

## 1.4 Contraindications

The Azure S DR MRI SureScan Model W3DR01 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.

## 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.** 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 when the paced leads have a pacing output of 5.0 V and a pulse width of 1.0 ms.

**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 the 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 25.

### 1.6.1 Pacing features

**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 Preference Pacing (APP)** – The system provides an overdrive pacing technique designed to counteract potential atrial tachyarrhythmia initiating mechanisms. APP maintains a consistent activation sequence by providing continuous pacing that is slightly higher than the intrinsic rate.

**Automatic polarity configuration** – This device uses lead impedance measurements to automatically configure 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.

**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)** – The MVP feature promotes 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.

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

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

## 1.6.2 Monitoring and follow-up features

**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.

**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).

**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.

## 1.7 Data security

Medtronic has designed safeguards to protect patient information and device data for the Azure S DR MRI SureScan Model W3DR01 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

**Before performing an MRI scan, refer to the Medtronic MRI technical manual for MRI-specific warnings and precautions.**

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** – Although Medtronic device connector modules conform to International Connector Standards, this device has not been tested for use with non-Medtronic leads. The known potential adverse consequences of using such a combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

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

## 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 product 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  $-18^{\circ}\text{C}$  and  $+55^{\circ}\text{C}$  ( $0^{\circ}\text{F}$  and  $131^{\circ}\text{F}$ ). Device reset may occur at temperatures below  $-18^{\circ}\text{C}$  ( $0^{\circ}\text{F}$ ). Device longevity may decrease and performance may be affected at temperatures above  $+55^{\circ}\text{C}$  ( $131^{\circ}\text{F}$ ).

## 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 Azure S DR MRI SureScan Model W3DR01 device, but if leads other than bipolar MRI SureScan leads 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.

**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.

**Device reset** – Temperatures below  $-18^{\circ}\text{C}$  ( $0^{\circ}\text{F}$ ) or strong electromagnetic fields can reset the device. 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.

**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.

**PMT (pacemaker-mediated tachycardia) 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.

**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.

### 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 the 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

The following are known potential adverse events associated with the use of pacing systems.

- Air embolism
- Allergic reaction
- Bleeding
- Body rejection phenomena including local tissue rejection
- Cardiac dissection
- Cardiac perforation
- Cardiac tamponade
- Chronic nerve damage
- Death
- Embolism
- Endocarditis
- Erosion of the device and lead through the skin
- Excessive fibrosis
- Extrusion
- Fibrillation or other arrhythmias
- Fluid accumulation
- Formation of cysts
- Heart block
- Heart wall rupture
- Hematoma/seroma
- Inappropriate acceleration of arrhythmias
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Muscle and nerve stimulation
- Myocardial damage
- Myocardial irritability
- Myopotential sensing
- Pericardial effusion
- Pericardial rub
- Pneumothorax
- Threshold elevation
- Thromboemboli
- Thrombosis
- Tissue damage due to heating of device or lead (during an MRI procedure)
- Transvenous lead-related thrombosis
- Valve damage
- Venous occlusion
- Venous perforation
- Vein wall rupture

## 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](http://www.medtronic.com/manuals).

The following clinical studies are related to this device:

**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 Azure S DR MRI SureScan Model W3DR01 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 in the Azure S DR MRI SureScan Model W3DR01 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 Azure S DR MRI SureScan Model W3DR01 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.

**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 Azure S DR MRI SureScan Model W3DR01 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.

**SureScan Pacing System Post-Approval Study** – This clinical study, which evaluated safety and performance of approved systems in a magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature.

## 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 19.

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 Azure S DR MRI SureScan Model W3DR01 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 Azure S DR MRI SureScan Model W3DR01 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:

**Before performing an MRI scan, refer to the Medtronic MRI Technical Manual for additional information.**

**Warning:** Bipolar or unipolar leads may be used with the Azure S DR MRI SureScan Model W3DR01 device, but if leads other than bipolar SureScan leads are used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic 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. 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, 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 could 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.  
**Note:** Do not enable a pacing feature that affects the pacing rate 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.** 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.

### 4.2.1 Selecting the leads

The device is typically implanted with the following leads:

- 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  $\leq 10$  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.

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

**Table 1.** Lead and connector compatibility

Connector port	Primary leads
A, V	IS-1 <sup>a</sup> bipolar and IS-1 unipolar

<sup>a</sup> 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.

## 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 that is 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.

**Table 2.** Acceptable sensing and pacing values

Measurements required	Acute transvenous leads	Chronic leads <sup>a</sup>
P-wave EGM amplitude (atrial)	≥ 2 mV	≥ 1 mV
R-wave EGM amplitude (RV)	≥ 5 mV	≥ 3 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)

<sup>a</sup> 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 the lead to the device, how to confirm that the lead connector is fully inserted in the connector block, and how to verify that the lead connection is secure.

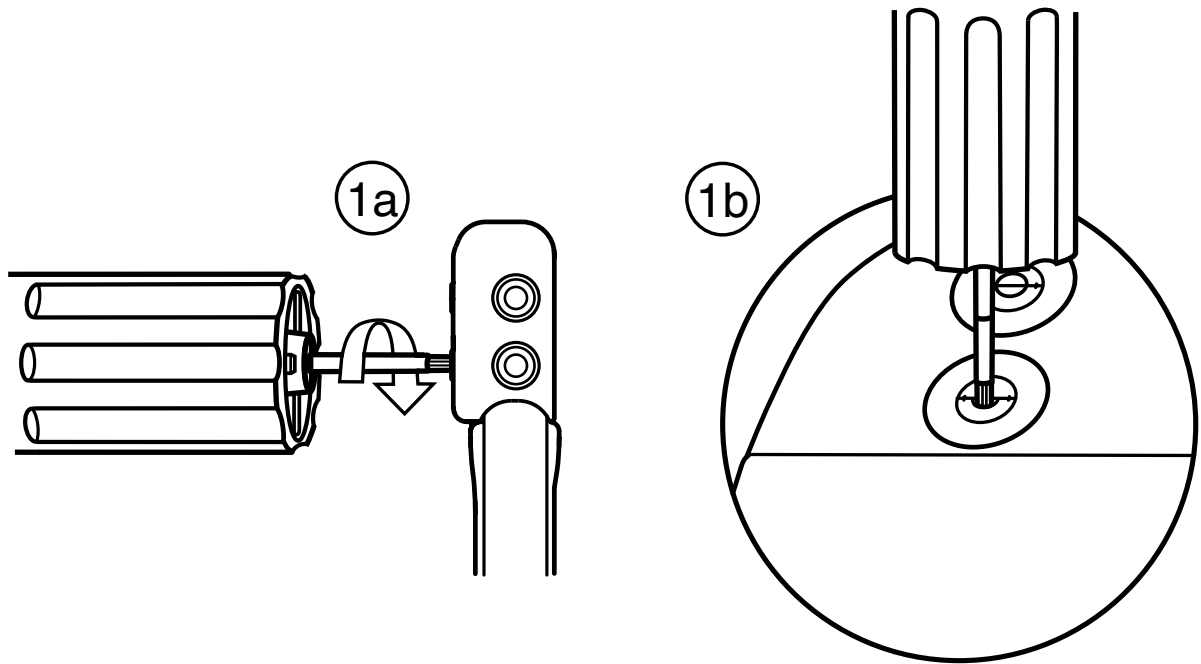
**Warning:** After connecting the leads, verify that the lead connections are secure by gently tugging on each lead. A loose lead connection may result in inappropriate sensing, which can cause false tracking and false inhibition of pacing.

**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

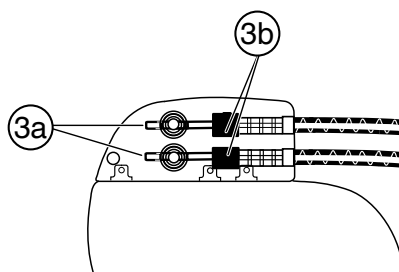
1. Insert the torque wrench into the appropriate setscrew.
  - a. If the setscrew obstructs the port, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see Figure 1).
  - b. Leave the torque wrench in the setscrew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

**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. 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 rotating 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.

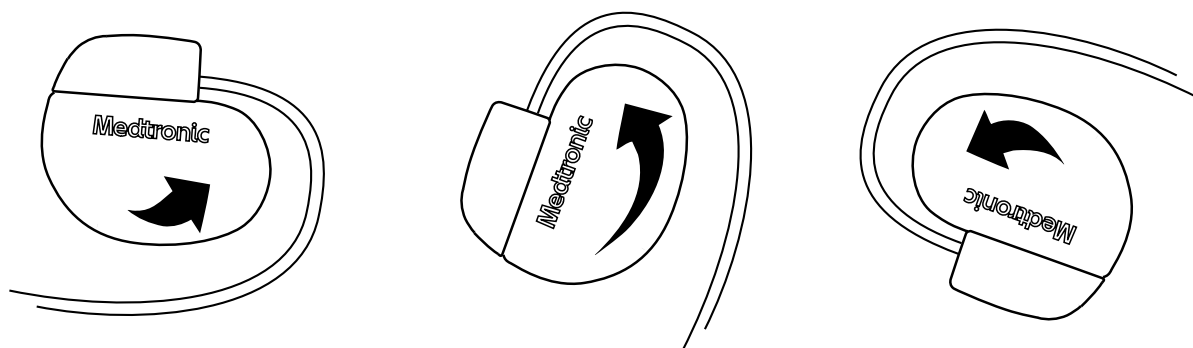
## 4.5 Positioning and securing the device

**Note:** Implant the device within 4 cm (1.6 in) of the surface of the skin to optimize post-implant ambulatory monitoring.

### 4.5.1 How to position and secure the device

1. Verify that each lead connector pin 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

### 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 and detection 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 the 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 Azure S DR MRI SureScan Model W3DR01 device, but if leads other than bipolar SureScan leads are used, the system is not approved for MRI scans. Before performing an MRI scan, refer to the Medtronic 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:** Unipolar atrial leads may be used with the device, but bipolar atrial leads are recommended. If unipolar atrial leads are used, 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 15.

**Note:** Any unused leads that remain implanted must be capped with a lead pin cap to avoid transmitting electrical signals. 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. Contact your Medtronic representative for information about lead pin caps.

#### 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 16). 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 17).
 


**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 18).
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 <sup>a</sup>	12.75 cm <sup>3</sup>
Mass	22.5 g
H x W x D <sup>b</sup>	46.6 mm x 50.8 mm x 7.4 mm
Radiopaque ID <sup>c</sup>	RNA
Medtronic identifier	
Surface area of titanium device can	33.48 cm <sup>2</sup>
Materials in contact with human tissue <sup>d</sup>	Titanium, polyurethane, silicone rubber
Battery	Lithium-hybrid CFx silver vanadium oxide

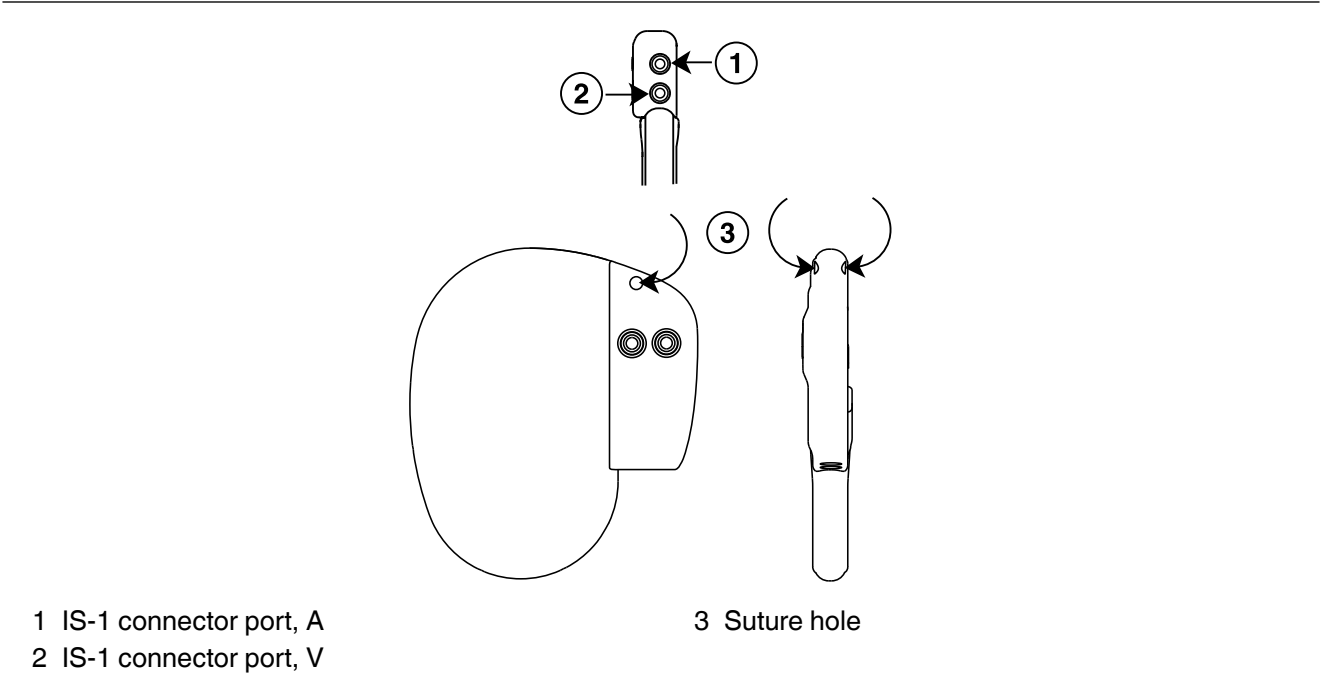
<sup>a</sup> Volume with connector holes unplugged.

<sup>b</sup> Grommets may protrude slightly beyond the can surface.

<sup>c</sup> The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.

<sup>d</sup> 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.

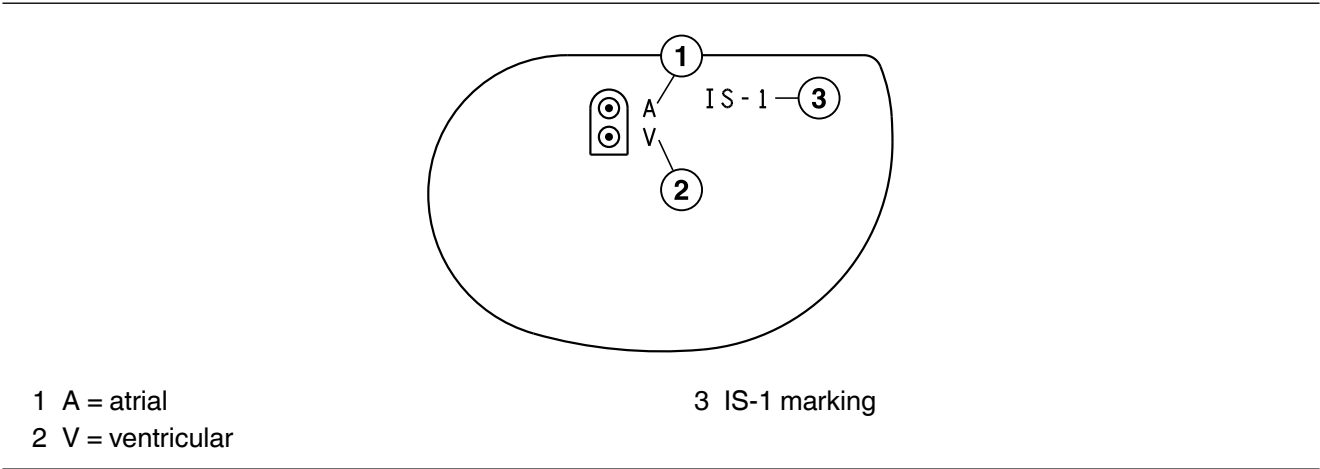
**Figure 4.** Connector and suture hole



The Model W3DR01 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 W3DR01



## 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)

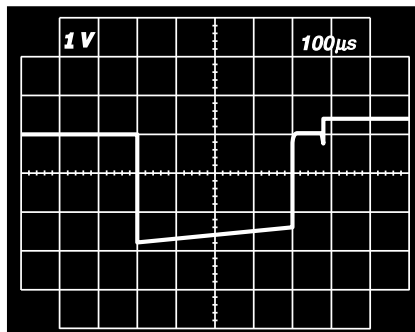
Nominal voltage	3.25 V
Mean usable capacity	1.2 Ah
Mean capacity to RRT	0.97 Ah
Residual usable capacity at RRT	0.23 Ah

**Table 5.** Current consumption

Current consumption (at 100% pacing) <sup>a</sup>	10.40 $\mu$ A
Current consumption (at 100% inhibition) <sup>b</sup>	6.71 $\mu$ A

<sup>a</sup> Current consumption when pacing into  $500\ \Omega \pm 1\%$  loads at the Beginning of Service in DDDR mode at 60 bpm, 2.5 V, 0.4 ms.

<sup>b</sup> Current consumption when at the Beginning of Service in DDDR mode at 60 bpm, 2.5 V, 0.4 ms,  $500\ \Omega \pm 1\%$ .

**Figure 6.** Output waveform at nominal conditions (resistive load: 500  $\Omega$ )

### 5.2.1 Variation with temperature

Basic rate, test pulse rate, pulse duration, and pulse amplitude remain within expected tolerances when the device temperature is between 22°C and 45°C (72°F to 113°F). Sensitivity at nominal conditions as measured at 37°C (98.6°F) can vary as much as  $\pm 1\%$  per °C from 22°C to 45°C (72°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)	$\leq 2.63$ V on 3 consecutive daily automatic measurements
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
RV Amplitude	as programmed
RV Pulse Width	as programmed
Rate Hysteresis	Off
Sleep	Off
Pre-arrhythmia EGM	Off <sup>a</sup>

<sup>a</sup> Pre-arrhythmia EGM cannot be reprogrammed after ERI.

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

**Note:** 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: 100% DDD pacing at 60 bpm, 2.5 V atrial and RV pacing amplitude; 0.4 ms pulse width; and 600  $\Omega$  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 in years for the device is shown in Table 8. The data is based on pacing outputs programmed to the specified amplitude and 0.4 ms pulse width and 60 bpm pacing rate.

The service life of the device is affected by the programmed settings for certain features, such as Pre-arrhythmia EGM storage.

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

Pacing	Pre-arrhythmia EGM storage <sup>a</sup>	500 $\Omega$ pacing impedance		600 $\Omega$ pacing impedance		900 $\Omega$ pacing impedance	
		2.5 V	3.5 V	2.5 V	3.5 V	2.5 V	3.5 V
DDD, 0%	Off	15.8	15.8	15.8	15.8	15.8	15.8
	On	15.7	15.7	15.7	15.7	15.7	15.7
DDD, 15%	Off	14.6	13.6	14.8	13.9	15.1	14.4
	On	14.5	13.5	14.7	13.8	15.0	14.3

**Table 8.** Projected service life in years (continued)

Pacing	Pre-arrhythmia EGM storage <sup>a</sup>	500 $\Omega$ pacing impedance		600 $\Omega$ pacing impedance		900 $\Omega$ pacing impedance	
		2.5 V	3.5 V	2.5 V	3.5 V	2.5 V	3.5 V
DDD, 50%	Off	12.4	10.2	12.8	10.8	13.6	11.9
	On	12.3	10.1	12.7	10.7	13.5	11.9
AAI<=>DDD (MVP Mode) 50% Atrial, 5% Ventricular	Off	13.7	12.1	14.0	12.6	14.5	13.4
	On	13.6	12.1	13.9	12.5	14.4	13.3
DDD, 100%	Off	10.2	7.5	10.8	8.1	12.0	9.6
	On	10.1	7.4	10.7	8.1	11.9	9.5

<sup>a</sup> The data provided for programming Pre-arrhythmia EGM storage to On is based on a 6-month period (two 3-month follow-up intervals) over the life of the device. Additional use of Pre-arrhythmia EGM storage reduces projected service life by approximately 12.1% or 1.4 months per year.

**Note:** These projections are based on typical shelf storage time (5 months). Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 7%.

**Note:** The Capture Management feature can independently adapt each pacing amplitude value. An Atrial Pacing Amplitude of 1.5 V and an RV Pacing Amplitude of 2.0 V represent typical values when using the Capture Management feature. At these settings, and with 100% ventricular pacing (at 60 bpm, 0.4 ms, and 600  $\Omega$ ), the projected service life of the device is 12.6 years.

**Medtronic remote monitor transmissions** – Additional remote monitoring transmissions reduce the projected service life of the device. For example, from nominal pacing (at 2.5 V, 0.4 ms, 600  $\Omega$ , 60 bpm, 100% atrial and ventricular pacing), a patient can expect a projected service life of 10.7 years. More frequent remote monitoring transmissions will reduce this projected service life as follows:

- Monthly transmissions over the life of the device reduce projected service life by 16 days, or <1%.
- Weekly transmissions over the life of the device reduce projected service life by 87 days, or 2.2%.
- Daily transmissions over the life of the device reduce projected service life by 564 days, or 14.4%.

**Table 9.** Projected service life in years per conditions specified in EN 45502-2-1 and ISO 14708-2

	EN 45502-2-1	ISO 14708-2
	500 $\Omega$ $\pm$ 1% pacing impedance 70 bpm	600 $\Omega$ $\pm$ 1% pacing impedance 60 bpm
<b>Pacing</b>		
DDDR, 100%		
2.5 V, 0.5 ms	8.7 <sup>a</sup>	—
5.0 V, 0.5 ms	3.8 <sup>a</sup>	—
2.5 V, 0.4 ms	—	10.7 <sup>a</sup>
5.0 V, 0.4 ms	—	5.5 <sup>a</sup>

<sup>a</sup> Data storage and diagnostic functions applicable to the pacing mode are On.



## 6 Device parameters

### 6.1 Emergency settings

**Table 10.** Emergency VVI settings

Parameter	Selectable values
Pacing Mode	VVI
Lower Rate	70 bpm
RV Amplitude <sup>a</sup>	6 V
RV Pulse Width <sup>a</sup>	1.5 ms
RV Pace Polarity	Unipolar
V. Blank Post VP	240 ms
Rate Hysteresis	Off
MRI SureScan	Off

<sup>a</sup> 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 11.** Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
AT/AF Detection	Monitor◊	Monitor	Monitor
AT/AF Interval (Rate) <sup>a</sup>	150; 160 ... 350◊ ... 450 ms	350 ms	350 ms
VT Monitor	Monitor◊; Off	Monitor	Off
VT Monitor Interval (Rate) <sup>a</sup>	280; 290 ... 400◊ ... 500 ms	400 ms	400 ms

**Table 11.** Tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Reset
RV Sensitivity <sup>b,d</sup>	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 <sup>b,c</sup>	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

<sup>a</sup> 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.

<sup>b</sup> This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

<sup>c</sup> The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 1.8 mV or higher.

<sup>d</sup> The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 2.0 mV or higher.

## 6.4 Pacing parameters

**Table 12.** 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	AAI<=>DDD	VVI
Mode Switch	On; Off	On	Off
Lower Rate <sup>a</sup>	30; 35 ... 60; 70; 75 ... 150 bpm	60 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	30; 40 ... 180 ... 350 ms	180 ms	180 ms
Sensed AV	30; 40 ... 150 ... 350 ms	150 ms	150 ms
Maximum AV Interval limit	Off; 250; 260 ... 500	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

<sup>a</sup> The corresponding Lower Rate interval can be calculated as follows: Lower Rate interval (ms) = 60,000/Lower Rate.

**Table 13.** Atrial parameters

Parameter	Programmable values	Shipped	Reset
Atrial Amplitude	0.5; 0.75 ... 3.5 ... 5; 5.5; 6; 8 V <sup>a</sup>	3.5 V	—
Atrial Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ... 1.5 ms	0.4 ms	—

**Table 13.** Atrial parameters (continued)

Parameter	Programmable values	Shipped	Reset
Atrial Sensitivity <sup>b</sup>	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 $\diamond$ mV Bipolar: 0.3 $\diamond$ mV	0.3 mV	0.45 mV
Atrial Pace Polarity	Bipolar; Unipolar	Configure <sup>c</sup>	—
Atrial Sense Polarity	Bipolar; Unipolar	Configure <sup>c</sup>	Unipolar
Atrial Lead Monitor	Monitor Only; Adaptive	Monitor Only	Monitor Only
Min Limit	200 $\diamond$ ; 300; 400; 500 $\Omega$	200 $\Omega$	200 $\Omega$
Max Limit	1000; 1500; 2000; 3000 $\diamond$ $\Omega$	3000 $\Omega$	3000 $\Omega$

<sup>a</sup> When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.

<sup>b</sup> This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

<sup>c</sup> “Configure” is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.

**Table 14.** RV parameters

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

<sup>a</sup> When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

<sup>b</sup> This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

<sup>c</sup> “Configure” is displayed when the device is automatically configuring the lead polarity at implant. It is not a selectable value.

**Table 15.** Atrial Capture Management parameters

Parameter	Programmable values	Shipped	Reset
Atrial Capture Management	Adaptive $\diamond$ ; Monitor; Off	Adaptive	Off
Atrial Amplitude Safety Margin	1.5x; 2.0x $\diamond$ ; 2.5x; 3.0x	2.0x	2.0x

**Table 15.** Atrial Capture Management parameters (continued)

Parameter	Programmable values	Shipped	Reset
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 16.** 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 17.** Blanking periods

Parameter	Programmable values	Shipped	Reset
PVAB Interval	10 <sup>a</sup> ; 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 ... 200◊ ... 320 ms	200 ms	240 ms
V. Blank Post VS	120◊; 130 ... 170; 200; 220; 250; 280; 300; 320 ms	120 ms	120 ms

<sup>a</sup> If the PVAB Method is set to Partial, the minimum selectable value for the PVAB Interval is 100 ms

**Table 18.** Rate Response Pacing parameters

Parameter	Programmable values	Shipped	Reset
Upper Sensor Rate	80; 85 ... 130◊ ... 175 bpm	130 bpm	120 bpm
ADL Rate	60; 65 ... 95◊ ... 170 bpm	95 bpm	95 bpm
Rate Profile Optimization	On◊; Off	On	Off
ADL Response	1; 2; 3◊; 4; 5	3	3
Exertion Response	1; 2; 3◊; 4; 5	3	3
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 19.** Rate Adaptive AV parameters

Parameter	Programmable values	Shipped	Reset
Rate Adaptive AV	Off $\diamond$ ; On	Off	On
Start Rate	50; 55 ... 90 $\diamond$ ... 145 bpm	90 bpm	60 bpm
Stop Rate	55; 60 ... 130 $\diamond$ ... 175 bpm	130 bpm	120 bpm
Minimum Paced AV	30; 40 ... 140 $\diamond$ ... 200 ms	140 ms	140 ms
Minimum Sensed AV	30; 40 ... 110 $\diamond$ ... 200 ms	110 ms	110 ms

**Table 20.** Atrial Preference Pacing parameters

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

**Table 21.** Rate Drop Response parameters

Parameter	Programmable values	Shipped	Reset
Rate Drop Response <sup>a</sup>	On; Off $\diamond$	Off	Off
Detection Type	Drop $\diamond$ ; Low Rate; Both	Drop	Drop
<b>Drop Detection</b>			
Drop Size	10; 15 ... 25 $\diamond$ ... 50 bpm	25 bpm	25 bpm
Drop Rate	30; 40 ... 60 $\diamond$ ... 100 bpm	60 bpm	60 bpm
Detection Window	10; 15; 20; 25; 30 s 1 $\diamond$ ; 1.5; 2; 2.5 min	1 min	1 min
<b>Low Rate Detection</b>			
Detection Beats	1; 2; 3 $\diamond$ beats	3 beats	3 beats
<b>Intervention</b>			
Intervention Rate	70; 75 ... 100 $\diamond$ ... 150 bpm	100 bpm	100 bpm
Intervention Duration	1; 2 $\diamond$ ... 15 min	2 min	2 min

<sup>a</sup> When Rate Drop Response is set to On, the lower rate is automatically set to 45 bpm.

**Table 22.** Sleep parameters

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

**Table 23.** Non-Competitive Atrial Pacing (NCAP) parameters

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

**Table 24.** 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 25.** Additional pacing features

Parameter	Programmable values	Shipped	Reset
PMT Intervention	On; Off $\diamond$	Off	Off
PVC Response	On $\diamond$ ; Off	On	On
V. Safety Pacing	On $\diamond$ ; Off	On	On
Rate Hysteresis	Off $\diamond$ ; 30; 40 ... 80 bpm	Off	Off

## 6.5 Data collection parameters

**Table 26.** Data collection parameters

Parameter	Programmable values	Shipped	Reset
EGM 1 Source	Can to Aring; Can to RVring; Atip to Aring $\diamond$ ; Atip to RVring; Atip to Can; Aring to RVring; RVtip to RVring; RVtip to Can	Atip to Aring	Atip to Aring
EGM 1 Range	$\pm 1$ ; $\pm 2$ ; $\pm 4$ ; $\pm 8$ $\diamond$ ; $\pm 12$ ; $\pm 16$ ; $\pm 32$ mV	$\pm 8$ mV	$\pm 8$ mV
EGM 2 Source	Can to RVring; RVtip to RVring $\diamond$ ; RVtip to Can	RVtip to RVring	RVtip to RVring
EGM 2 Range	$\pm 1$ ; $\pm 2$ ; $\pm 4$ ; $\pm 8$ $\diamond$ ; $\pm 12$ ; $\pm 16$ ; $\pm 32$ mV	$\pm 8$ mV	$\pm 8$ mV
EGM 3 Source	RVtip to RVring; Can to RVring $\diamond$ ; Atip to RVring; Atip to Aring; Can to Aring	Can to RVring	Can to RVring
EGM 3 Range	$\pm 1$ ; $\pm 2$ ; $\pm 4$ ; $\pm 8$ $\diamond$ ; $\pm 12$ ; $\pm 16$ ; $\pm 32$ mV	$\pm 8$ mV	$\pm 8$ mV
Monitored	EGM1 and EGM2 $\diamond$ ; EGM1 and EGM3; EGM2 and EGM3	EGM1 and EGM2	EGM1 and EGM2
Pre-arrhythmia EGM	Off $\diamond$ ; On – 1 month; On – 3 months; On Continuous	Off	Off
Device Date/Time <sup>a</sup>	(select Time Zone)	—	—

**Table 26.** Data collection parameters (continued)

Parameter	Programmable values	Shipped	Reset
Holter Telemetry	Off $\diamond$ ; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off
Wireless Teleme-try with Monitor	On; Off	On	On <sup>b</sup>

<sup>a</sup> The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

<sup>b</sup> The reset value may be set to Off if there is an issue with wireless communication that requires it to be disabled.

## 6.6 Medtronic CareAlert parameters

**Table 27.** Clinical Management Alerts

Parameter	Programmable values	Shipped	Reset
<b>AT/AF Burden and Rate Settings...</b>			
AT/AF Alerts			
AT/AF Daily Burden Enable	Off $\diamond$ ; On	Off	Off
Daily AT/AF Burden (hr/24hr)	0.5; 1; 2; 6 $\diamond$ ; 12; 24 hr/24 hr	6 hr	6 hr
Avg. V. Rate During AT/AF Enable	Off $\diamond$ ; On	Off	Off
Daily Burden for Avg. V. Rate (hr/24hr)	0.5; 1; 2; 6 $\diamond$ ; 12; 24 hr/24 hr	6 hr	6 hr
Avg. V. Rate During AT/AF (bpm)	90; 100 $\diamond$ ... 150 bpm	100 bpm	100 bpm
<b>Monitored VT Episode Detected</b>	Off $\diamond$ ; On	Off	Off
<b>Cumulative Right Ventricular Pacing &gt; 40%<sup>a</sup></b>	Off $\diamond$ ; On <sup>b</sup>	Off	Off

<sup>a</sup> There is no observation for Cumulative Right Ventricular Pacing > 40%.

<sup>b</sup> Alert triggered if cumulative percent of right ventricular pacing exceeds 40% for 7 consecutive days.

**Table 28.** Lead/Device Integrity Alerts

Parameter	Programmable values	Shipped	Reset
<b>Low Battery Voltage RRT</b>	On $\diamond$ ; Off	On	Off
<b>Lead Impedance Out of Range...</b>			
Lead Impedance			
A. Pacing Enable	On $\diamond$ ; Off	On	Off
A. Pacing Less than	200 $\diamond$ ; 300; 400; 500 $\Omega$	200 $\Omega$	200 $\Omega$
A. Pacing Greater than	1000; 1500; 2000; 3000 $\diamond$ $\Omega$	3000 $\Omega$	3000 $\Omega$
RV Pacing Enable	On $\diamond$ ; Off	On	Off
RV Pacing Less than	200 $\diamond$ ; 300; 400; 500 $\Omega$	200 $\Omega$	200 $\Omega$
RV Pacing Greater than	1000; 1500; 2000; 3000 $\diamond$ $\Omega$	3000 $\Omega$	3000 $\Omega$

**Table 28.** Lead/Device Integrity Alerts (continued)

Parameter	Programmable values	Shipped	Reset
<b>Capture Management High Threshold</b>			
High Threshold			
A. Capture Enable <sup>a</sup>	Off $\diamond$ ; On	Off	Off
RV Capture Enable <sup>b</sup>	Off $\diamond$ ; On	Off	Off

<sup>a</sup> If programmed to On, alert notification is sent if A. capture management has measured high thresholds for 3 consecutive days.

<sup>b</sup> If programmed to On, alert notification is sent if RV capture management has measured high thresholds for 3 consecutive days.

## 6.7 System test parameters

**Table 29.** System test parameters

Parameter	Selectable values
<b>Pacing Threshold Test parameters</b>	
Test Type	Amplitude; Pulse Width
Chamber	Atrium; RV
Decrement after	2; 3 ... 15 pulses
Mode <sup>a</sup> (RV test)	VVI; VOO; DDI; DDD; DOO
Mode <sup>a</sup> (Atrium test)	AAI; AOO; DDI; DDD; DOO
Lower Rate	30; 35 ... 60; 70; 75 ... 150 <sup>c</sup> bpm
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
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
AV Delay <sup>b</sup>	30; 40 ... 350 ms
V. Pace Blanking	150; 160 ... 320 ms
A. Pace Blanking	150; 160 ... 250 ms
PVARP	150; 160 ... 500 ms
Pace Polarity	Unipolar; Bipolar
<b>Sensing Test parameters</b>	
Mode <sup>a</sup>	AAI; DDD; DDI; VVI; ODO
AV Delay <sup>b</sup>	30; 40 ... 350 ms
Lower Rate <sup>c</sup>	30; 35 ... 60; 70; 75 ... 120 bpm

<sup>a</sup> The selectable values for this parameter depend on the programmed pacing mode.

<sup>b</sup> The selectable values for this parameter depend on the programmed Lower Rate.

<sup>c</sup> When performing the test in DDD mode, the Lower Rate must be less than the programmed Upper Tracking Rate.



## 6.8 EP Study parameters

**Table 30.** Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled☐; Disabled
Chamber	RV; Atrium
Interval	100; 110 ... 600☐ ms
Amplitude	1; 2; 3; 4☐; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50☐ ... 1.50 ms
VVI Backup (for atrial Fixed Burst) <sup>a</sup>	On; Off☐
Pacing Rate	60; 70☐ ... 120 bpm
V. Amplitude <sup>b</sup>	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width <sup>b</sup>	0.10; 0.20 ... 1.50 ms

<sup>a</sup> Crosstalk may occur when atrial pacing amplitude is greater than 6 V.

<sup>b</sup> The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

**Table 31.** PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled☐; Disabled
Chamber	RV; Atrium
#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	1; 2; 3; 4☐; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50☐ ... 1.50 ms
VVI Backup (for atrial PES) <sup>a</sup>	On; Off☐
Pacing Rate	60; 70☐ ... 120 bpm
V. Amplitude <sup>b</sup>	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width <sup>b</sup>	0.10; 0.20 ... 1.50 ms

<sup>a</sup> Crosstalk may occur when atrial pacing amplitude is greater than 6 V.

<sup>b</sup> The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

**Table 32.** 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

**Table 32.** Shared manual ATP therapy parameters (continued)

Parameter	Selectable values
Amplitude	1; 2 ... 6⬢; 8 V
Pulse Width	0.10; 0.20 ... 1.50⬢ ms
VVI Backup (for atrial ATP therapy) <sup>a</sup>	On; Off⬢
Pacing Rate	60; 70⬢ ... 120 bpm
V Amplitude <sup>b</sup>	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V Pulse Width <sup>b</sup>	0.10; 0.20 ... 1.50 ms

<sup>a</sup> Crosstalk may occur when atrial pacing amplitude is greater than 6 V.

<sup>b</sup> The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

**Table 33.** Manual Ramp therapy parameters

Parameter	Selectable values
Chamber	Atrium; RV
RV 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

**Table 34.** Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 8⬢ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88⬢; 91; 94; 97%

**Table 35.** Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3⬢ ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75⬢ ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69⬢ ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66⬢ ... 84; 88; 91; 94; 97%

**Table 36.** 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

## 6.9 Nonprogrammable parameters

**Table 37.** Nonprogrammable parameters

Parameter	Value
Premature event threshold for counting PVCs and Runs of PVCs	69%
<b>Fixed blanking periods</b>	
Atrial blanking after a paced ventricular event (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 <sup>a</sup>
Ventricular blanking after a paced atrial event (unipolar ventricular sensing)	40 ms
<b>Fixed bradycardia pacing parameters</b>	
Ventricular Safety Pacing intervals <sup>b</sup>	110 ms
PVARP value applied by PVC Response and PMT Intervention <sup>c</sup>	400 ms
NCAP value applied by PVC Response and PMT Intervention <sup>d</sup>	400 ms
<b>Hardware parameters</b>	
Pacing rate limit (protective feature) <sup>e</sup>	200 bpm <sup>f</sup>
Input impedance	150 kΩ minimum
Effective pacing capacitance	4 μF
<b>Recommended Replacement Time (RRT)</b>	
Battery Voltage Threshold	≤ 2.63

<sup>a</sup> 35 ms when the ventricular pacing amplitude is programmed to 8 V.

<sup>b</sup> 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.

<sup>c</sup> PVARP is extended to 400 ms only if the current PVARP is less than 400 ms.

<sup>d</sup> The NCAP extension applies only if NCAP is enabled.

<sup>e</sup> Does not apply during ventricular safety pacing.

<sup>f</sup> If the Upper Tracking Rate is programmed to a value greater than 180 bpm, the pacing rate limit is 230 bpm.

**Table 38.** 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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