Medtronic

AMPLIA MRI™ CRT-D SURESCAN™ DTMB1D4

Digital implantable cardioverter defibrillator with cardiac resynchronization therapy and SureScan™ Technology (DDE-DDDR)

MR Conditional with PhysioCurve™ Design, AdaptivCRT™ Algorithm, CardioSync™ Optimization, SmartShock™ Technology, OptiVol™ 2.0 Fluid Status Monitoring, MVP™ Mode with Complete Capture Management™ Diagnostic (ACM, RVCM, LVCM)

Device Manual

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

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Contents

1 System overview

1.1 Introduction

This manual describes the Medtronic Model DTMB1D4 Amplia MRI dual chamber, implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT-D). It 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 includes information about device features and describes how to use a programmer to conduct a session. The reference manual applies to multiple models of CRT-D devices.

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 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 insert – This document provides Federal Communications Commission (FCC) regulations and compliance information for the transmitter in this active implantable medical device.

1.2 System description

The Medtronic Model DTMB1D4 Amplia MRI dual chamber, implantable cardioverter defibrillator with cardiac resynchronization therapy (CRT-D) 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; ventricular tachyarrhythmia therapies; and atrial tachyarrhythmia therapies.

The device can detect ventricular tachycardia and ventricular fibrillation (VT/VF) automatically and provide treatment with defibrillation, cardioversion, and antitachycardia pacing therapies. The device can also detect atrial tachycardia and atrial fibrillation (AT/AF) automatically and provide treatment with cardioversion and antitachycardia pacing therapies. Simultaneous or sequential biventricular pacing is used to provide patients with cardiac resynchronization therapy. The device responds to bradyarrhythmias by providing bradycardia pacing therapies.

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 bradycardia pacing. When programmed to On, MRI SureScan operation disables arrhythmia detection and all user-defined diagnostics. Before performing an MRI scan, refer to the MRI Technical Manual.

The device also provides diagnostic and monitoring information that assists with system evaluation and patient care.

Contents of sterile package – The package contains 1 implantable cardioverter defibrillator and 1 torque wrench.

Connectors – The device has the DF4 inline connector, which facilitates the connection of a DF4-LLHH or DF4-LLHO right ventricular (RV) lead during the implant. DF4-LLHH and DF4-LLHO refer to the international standard ISO 27186, which defines the lead connector contacts as low voltage (L), high voltage (H), and open (O).

Leads – The lead system used with this device must provide pacing to the left ventricle (LV); sensing, pacing, and cardioversion and defibrillation therapies 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 leads for this device, refer to Section 4.2, “Selecting and implanting the leads”, page 21.

Implantable device system – The Model DTMB1D4 Amplia MRI CRT-D device along with pacing leads and defibrillation leads constitute the implantable portion of the device system.

Programmers and software – The Medtronic programmer and software are used to program this device. Refer to the reference manual for information about using the programmer.

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 to gather information automatically 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 manual; for connection and usage information, refer to the patient monitor literature.

1.3 Indications and usage

The Amplia MRI system is indicated for patients who require ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias, for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk for developing atrial tachyarrhythmias and for providing cardiac resynchronization therapy in heart failure patients on stable, optimal heart failure medical therapy if indicated, and meet any of the following classifications:

- New York Heart Association (NYHA) Functional Class III or IV and who have a left ventricular ejection fraction ≤35% and a prolonged QRS duration
- Left bundle branch block (LBBB) with a QRS duration ≥130 ms, left ventricular ejection fraction ≤30%, and NYHA Functional Class II
- NYHA Functional Class I, II, or III and who have left ventricular ejection fraction ≤50% and 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.

1.4 MRI conditions for use

A complete SureScan CRT-D system is required for use in the MR environment. A complete SureScan CRT-D system includes the following components. Any other combination may result in a hazard to the patient during an MRI scan.

- the Amplia MRI device
- a SureScan right atrial pacing lead or a Model 6725 pin plug for the right atrial port
- a SureScan left ventricular pacing lead
- a SureScan defibrillation lead

To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

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

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

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

Cardiology 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 CRT-D system is implanted in the left or right pectoral region.
- The SureScan device is operating within the projected service life.
- For patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan 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.
  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: For pacemaker-dependent patients, 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. A higher pacing capture threshold may indicate an issue with the implanted lead.

Patient monitoring and rescue requirements:

- Continuous patient monitoring is required while MRI SureScan is programmed to On.
- 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.

Note: For radiology requirements for an MRI scan, refer to the MRI Technical Manual.

1.5 Contraindications

The Amplia MRI system is contraindicated for patients experiencing tachyarrhythmias with transient or reversible causes including, but not limited to, the following: acute myocardial infarction, drug intoxication, drowning, electric shock, electrolyte imbalance, hypoxia, or sepsis.

The device is contraindicated for patients who have a unipolar pacemaker implanted.

The device is contraindicated for patients with incessant VT or VF.

The device is contraindicated for patients whose primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF.

1.6 Pre-implant consideration

Patient evaluation for the implant of Amplia MRI Model DTMB1D4 should include the following consideration about a concomitant implant with a neurostimulator:

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

1.7 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 34.

1.7.1 Programmer software features

For more information about these features, see the reference manual.

Conexus wireless telemetry – This feature enables wireless transmission of data between an implanted device and the programmer in the hospital or clinic and between an implanted device and a home monitor in the patient's home.

Emergency therapies – During a patient session, defibrillation, cardioversion, fixed burst pacing, and emergency VVI can be initiated manually to treat ventricular tachyarrhythmia episodes quickly.

Live Rhythm Monitor – This window on the programmer displays ECG, Leadless ECG (LECG), Marker Channel with marker annotations, and telemetered EGM waveform traces. It also displays the patient heart rate and interval in the upper left-hand corner of the window.

Checklist – This feature presents an interactive list of common tasks that are performed during an implant session or a follow-up session. When a clinician selects a task, the associated programmer screen for that task appears. Clinicians can set up their own checklists or use a Medtronic standard checklist supplied with the programmer.

Leadless ECG – This device feature allows clinicians to view and record a signal equivalent to an ECG without attaching surface ECG leads.

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

Patient Information – This feature allows clinicians to store patient-related information on the programmer that they can view and print during a patient session.

Extend Wireless Telemetry Session – This feature enables the programmer inactivity timeout for the wireless telemetry session to be reset temporarily from 5 min to 2 hours during a patient in-office session. This extended inactivity timeout length facilitates device programming revisions, ablation monitoring, and other procedures. To reduce device battery depletion, the patient session reverts automatically to the 5 min programmer inactivity timeout when the patient in-office session is ended.

1.7.2 Diagnostic data features

Note: When MRI SureScan is programmed to On, diagnostic data is not collected. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

Quick Look II – This screen on the programmer presents overview data about device operation and patient rhythms collected since the last patient session. It includes links to more detailed status and diagnostic information stored in the device, such as arrhythmia episodes and therapies provided.

Medtronic CareAlert – If the device identifies any CareAlert programmed or automatic alert conditions, this feature sends a wireless alert signal to the patient monitor, transmits an alert notification to the clinic, and sounds a patient alert tone to notify the patient to seek medical attention.

RV Lead Integrity Alert – This feature sounds an alert tone to warn the patient that a potential RV lead problem is suspected, which could indicate a lead fracture. When the alert criteria are met, device settings are automatically adjusted to avoid the delivery of inappropriate therapy.

OptiVol 2.0 fluid status monitoring – This feature identifies a potential increase in thoracic fluid, which may indicate lung congestion, by monitoring changes in thoracic impedance. If the change exceeds the programmed threshold, an OptiVol clinical status observation appears on the programmer.

Cardiac Compass Trends – This feature presents an overview of the patient's condition over the past 14 months with graphs that display long-term clinical trends in heart rhythm and device status, such as frequency of arrhythmias, heart rates, and device therapies.

Heart Failure Management Report – This printed report summarizes the patient's clinical status and observations since the last follow-up appointment. The report provides graphs that show trends in heart rates, arrhythmias, and fluid accumulation indicators over the past 14 months.

Arrhythmia episode data – The system compiles an arrhythmia episode log that the clinician can use to view summary and detailed diagnostic data quickly, including stored EGM, for the selected arrhythmia episode. Also available on the programmer are episode and therapy counters, stored data showing the number of times that arrhythmias and therapies have occurred.

Flashback Memory – This diagnostic feature records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

Ventricular sensing episodes data – This feature compiles diagnostic information to help the clinician identify the cause of ventricular sensing episodes and reprogram the device to avoid these episodes. Data collected includes date and time, duration, intervals and markers, maximum atrial and ventricular rates, and an indication of whether the episode was part of a tachyarrhythmia.

Rate Drop Response episodes data – This feature displays beat-to-beat data that is useful in analyzing Rate Drop Response episodes and the events leading up to these episodes. The feature records data about episodes that meet the programmed rate drop detection criteria.

Rate Histograms – This diagnostic feature shows range distributions for the patient's heart rate.

1.7.3 Pacing features

For more information about these features, see the reference manual.

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

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.

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

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.

LV Pacing Polarity – This feature provides 4 pacing polarities the clinician can use to select a pacing polarity that ensures capture, maximizes device longevity, and avoids phrenic nerve stimulation. It also enables the clinician to change pacing location, if necessary, by programming pacing polarity.

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

Rate Profile Optimization – 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. The goal is to ensure that the rate response remains appropriate for the full range of patient activities.

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

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

Auto PVARP – This feature adjusts the Post-Ventricular Atrial Refractory Period (PVARP) 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.

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.

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

Non-Competitive Atrial Pacing (NCAP) – This feature prohibits atrial pacing within a programmable interval after a refractory atrial event.

Pacemaker-mediated tachycardia (PMT) Intervention – This feature automatically detects and interrupts 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.

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

Mode Switch – This feature switches the device pacing mode from a dual-chamber atrial tracking mode to a nontracking mode during an atrial tachyarrhythmia. This feature prevents rapid ventricular pacing that can result from tracking a high atrial rate and restores the programmed pacing mode when the atrial tachyarrhythmia ends.

Atrial Tracking Recovery – If atrial tracking is lost because of PVCs or an atrial rhythm that is too fast to be tracked to the ventricle, this feature temporarily shortens PVARP to restore atrial tracking and CRT delivery.

Ventricular Sense Response – This feature triggers ventricular pacing in response to ventricular sensing to ensure that CRT pacing is delivered as programmed.

Conducted AF Response – This feature dynamically adjusts and smooths the pacing rate to promote CRT delivery in the presence of sensed ventricular events in nontracking modes.

Atrial Rate Stabilization (ARS) – This feature adapts the atrial pacing rate in response to a PAC (premature atrial contraction) to avoid long sinus pauses following short atrial intervals.

Atrial Preference Pacing (APP) – This feature maintains a consistent activation sequence by providing continuous pacing that is closely matched to the intrinsic rate.

Post Mode Switch Overdrive Pacing (PMOP) – This feature works with the Mode Switch feature to deliver overdrive atrial pacing during the vulnerable phase following an AT/AF episode termination.

Post VT/VF Shock Pacing – This feature provides temporary overdrive pacing for a programmed duration after a ventricular high-voltage therapy.

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

1.7.4 Tachyarrhythmia detection features

Note: When MRI SureScan is programmed to On, tachyarrhythmia detection and therapies are suspended. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

AT/AF detection – This feature analyzes the atrial rate and its effect on the ventricular rhythm to determine whether the patient is currently experiencing an atrial tachyarrhythmia. Evidence of an atrial tachyarrhythmia is based on the number and timing of atrial events during ventricular intervals. Depending on programming, the device delivers a programmed sequence of atrial therapies or continues monitoring without delivering therapy.

VT/VF detection – This feature uses programmable detection zones to classify ventricular events. If the number of tachyarrhythmia events in a zone exceeds a programmed threshold, the device detects a ventricular

tachyarrhythmia episode. Depending on programming, the device delivers a scheduled therapy, re-evaluates the patient's heart rhythm, and terminates or redetects the episode.

PR Logic – This set of features uses pattern and rate analysis to discriminate between supraventricular tachycardias (SVTs) and true ventricular tachyarrhythmias and to withhold inappropriate VT/VF detection and therapy during episodes of rapidly conducted SVT.

Wavelet – This feature is designed to prevent detection of rapidly conducted SVTs as ventricular tachyarrhythmias by comparing the shape of each QRS complex during a fast ventricular rate to a template. The feature offers the option to collect and maintain the stored template automatically.

Onset – This feature helps prevent detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate.

Stability – This feature helps to prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. If the device determines that the ventricular rate is not stable, it withholds VT detection.

High Rate Timeout – This feature allows the device to deliver therapy for any ventricular tachyarrhythmia that continues beyond the programmed length of time.

TWave Discrimination – This feature withholds VT/VF detection when a fast ventricular rate is detected because of oversensed T-waves, avoiding the delivery of an inappropriate therapy.

RV Lead Noise Discrimination – When the device identifies lead noise due to a suspected lead problem, this feature withholds VT/VF detection to prevent the delivery of inappropriate therapy. Also, if programmed, an alert tone sounds to notify the patient to seek medical attention.

1.7.5 Tachyarrhythmia therapy features

Note: When MRI SureScan is programmed to On, tachyarrhythmia detection and therapies are suspended. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

Atrial therapy scheduling – This feature enables the clinician to program the delivery of automatic atrial therapies. Each time that an AT/AF therapy is needed, the device schedules one of the available therapies based on clinician programming. The Reactive ATP option allows the device to repeat programmed atrial antitachycardia pacing (ATP) therapies during long AT/AF episodes. Therapies are repeated after a programmed interval or when the atrial rhythm changes in regularity or cycle length.

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. The device uses 3 programmable therapies, Burst+, Ramp, and 50 Hz Burst, to treat an episode.

Atrial cardioversion – This therapy delivers a high-voltage shock to treat an AT/AF episode or a Fast AT/AF episode. Atrial cardioversion delivery is synchronized to a sensed ventricular event and cannot exceed a programmable daily limit within programmable times. The patient also can request atrial cardioversion using an external Patient Assistant. Patient-activated atrial cardioversion is delivered only if an AT/AF episode is detected at the time of the request.

Programmable Active Can and SVC electrodes – The device provides the capability to disable either the Active Can or the SVC electrode as part of the high-voltage therapy delivery pathway.

Ventricular fibrillation (VF) therapies – Automatic defibrillation shocks are available to treat VF episodes. The first defibrillation therapy requires VF confirmation before delivery. After the first shock has been delivered, shocks are delivered asynchronously if synchronization fails. ATP During Charging allows the device to deliver a ventricular antitachycardia pacing therapy sequence while the device charges its capacitors for the first defibrillation therapy. The device can also be programmed to attempt an additional ATP therapy sequence before charging starts.

Ventricular antitachycardia pacing (ATP) – These therapies respond to a VT episode or an FVT episode with rapid sequences of pacing pulses to terminate detected ventricular tachyarrhythmias. Therapy options include Burst, Ramp, and Ramp+, each with a programmable number of sequences.

Ventricular cardioversion – This therapy delivers a high-voltage shock to treat a VT or FVT episode. Therapy is synchronized to a sensed ventricular event.

Progressive Episodes Therapies – This feature causes the device to skip therapies or modify high-voltage energy levels to ensure that each therapy delivered during an episode is at least as aggressive as the previous therapy.

1.7.6 Testing features

For more information about these features, see the reference manual.

Underlying Rhythm Test – This feature temporarily inhibits the pacing output of the device to enable the clinician to evaluate the patient's intrinsic heart rhythm. During the test, the device is temporarily programmed to a nonpacing mode.

Pacing Threshold Test – This feature allows the clinician to determine the patient's pacing thresholds and, in the LV, to determine phrenic nerve stimulation thresholds. For LV threshold testing, each test result is recorded in the LV Test Results window as the clinician performs it. The clinician then can view all threshold test results at the same time, making it easier to decide on the appropriate pacing amplitude and pulse width settings for the patient.

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.

Wavelet Test – This feature evaluates the accuracy of the current Wavelet template and allows the clinician to collect a new template, if necessary.

Lead Impedance Test – This feature tests the integrity of the implanted lead system by measuring the impedance of the pacing and high-voltage electrodes. The test uses low-voltage, subthreshold pulses to make these measurements.

Sensing Test – This feature measures P-wave and R-wave amplitudes to help the clinician assess lead integrity and sensing performance. Mode, AV Delay, and Lower Rate can be programmed temporarily so that the device is not pacing the patient's heart, increasing the likelihood that sensed events will occur.

Charge/Dump Test – This feature tests the charge time of the capacitors and dumps any charge remaining on the capacitors.

EP Studies – This set of protocols allows clinicians to induce arrhythmias during electrophysiology studies. The available induction protocols are T-Shock, 50 Hz Burst, Fixed Burst, and Programmed Electrical Stimulation. Manual therapies are also available.

1.7.7 Additional operations

MRI SureScan feature – This feature allows patients to be safely scanned by an MRI machine when used according to the specified MRI conditions for use. Refer to the MRI Technical Manual for additional information.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

A complete SureScan CRT-D 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 CRT-D system includes the following components:

- the Amplia MRI CRT-D device
- a SureScan right atrial pacing lead or a Model 6725 pin plug for the right atrial port

- a SureScan left ventricular pacing lead
- a SureScan defibrillation lead

To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

Refer to the Medical Procedure and EMI 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.

Avoiding shock during handling – Disable tachyarrhythmia detection during implant, explant, or postmortem procedures. The device can deliver a high-voltage shock if the defibrillation terminals are touched.

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.

Note: An external defibrillator must be immediately available while MRI SureScan is programmed to On.

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.

Occurrence of stroke – Following an ischemic or cerebrovascular accident, disable atrial cardioversion therapies until the patient has stabilized.

2.2 Explant and disposal

Consider the following information related to device explant and disposal:

- To prevent the device from delivering unwanted shocks, interrogate the device and disable tachyarrhythmia detection before explanting, cleaning, or shipping the device.
- Explant the implanted device postmortem. In some countries, explanting battery-operated implantable devices is mandatory because of environmental concerns; check the local regulations. In addition, the device may explode if subjected to incineration or cremation temperatures.
- 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.

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

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

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

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 device 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). Electrical 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.

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.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

Lead Impedance – Consider the following information about lead impedance when evaluating the lead system:

- Ensure that the defibrillation lead impedance is greater than 20 Ω. An impedance of less than 20 Ω may damage the device or prevent delivery of high-voltage therapy.
- Before taking electrical or defibrillation efficacy measurements, move objects made from conductive materials, such as guide wires, away from all electrodes. Metal objects, such as guide wires, can short circuit a device and lead, causing electrical current to bypass the heart and possibly damage the device and lead.
- If the LV pacing impedance for pacing LVtip to RVcoil is greater than 3000 Ω and the V. Defib (RVcoil) impedance is greater than 200 Ω, then use LV EGM (Can to LVtip) to assess the integrity of the LV lead.

2.5 Device operation

Warning: Leads other than SureScan leads may be used with the DTMB1D4 device, but if leads other than 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.

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.

Atrial Capture Management – 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.

Battery depletion – Carefully monitor device longevity by checking battery voltage and replacement indicators. Battery depletion eventually causes the device to stop functioning. Cardioversion and defibrillation are high-energy therapies that shorten device longevity. An excessive number of charging cycles also shortens device longevity.

Charge Circuit Timeout or Charge Circuit Inactive message – Contact a Medtronic representative and replace the device immediately if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message. If this message is displayed, high-voltage therapies are not available for the patient.

Concurrent pacemaker use – If a separate pacemaker is used concurrently with the ICD, verify that the ICD does not sense the pacemaker output pulses because this can affect the detection of tachyarrhythmias by the ICD. Program the pacemaker to deliver pacing pulses at intervals longer than the ICD tachyarrhythmia detection intervals.

Device status indicators – If any of the device status indicators (for example, Electrical 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.

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

End of Service (EOS) indicator – 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.

Follow-up testing – Consider the following information when performing follow-up testing of the device:

- Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing.
- Changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), preventing the device from terminating the patient's tachyarrhythmias postoperatively. Successful termination of ventricular fibrillation or ventricular tachycardia during the implant procedure is no assurance that tachyarrhythmias can be terminated postoperatively.

Higher than programmed energy – The device may deliver a therapy of higher than programmed energy if it was previously charged to a higher energy and that charge remains on the capacitors.

Magnets – Positioning a magnet over the device suspends tachyarrhythmia detection but does not alter bradycardia therapy. If you place a programming head over the device during a wireless telemetry session, the magnet in the programming head always suspends tachyarrhythmia detection. If you place a programming head over the device and establish a nonwireless telemetry session, tachyarrhythmia detection is not suspended.

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.

Patient safety during a wireless telemetry session – Make sure that you have selected the appropriate patient before proceeding with a wireless patient session. Maintain visual contact with the patient for the duration of the session. If you select the wrong patient and continue with the session, you may inadvertently program the patient's device to the wrong settings.

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. 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.

RV Capture Management – 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.

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.

Twiddler's syndrome – Twiddler's syndrome, the tendency of some patients to manipulate their device after implant, may cause the pacing rate to increase temporarily if the device is programmed to a rate-responsive mode.

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.

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 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
- constrictive pericarditis
- death
- device migration
- endocarditis
- erosion
- excessive fibrotic tissue growth
- extrusion
- fibrillation or other arrhythmias
- fluid accumulation
- formation of hematomas/seromas or cysts
- heart block
- heart wall or vein wall rupture
- hemothorax
- infection
- keloid formation
- lead abrasion and discontinuity
- lead migration/dislodgment
- complications and mortality due to inability to deliver appropriate and intended therapy
- muscle and/or nerve stimulation
- myocardial damage
- myocardial irritability
- myopotential sensing
- pericardial effusion
- pericardial rub
- pneumothorax
- poor connection of the lead to the device, which may lead to oversensing, undersensing, or a loss of therapy
- stroke
- threshold elevation
- thrombotic embolism
- thrombosis
- tissue necrosis
- valve damage (particularly in fragile hearts)
- venous occlusion
- venous perforation

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

Additional potential adverse events associated with the use of ICD systems include, but are not limited to, the following events:

- inappropriate shocks
- potential mortality due to inability to defibrillate
- shunting current or insulating myocardium during defibrillation

Patients susceptible to frequent shocks despite medical management could develop psychological intolerance to an ICD system that might include the following conditions:

- dependency
- depression
- fear of premature battery depletion
- fear of shocking while conscious
- fear that shocking capability may be lost
- imagined shocking (phantom shock)

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 Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 devices. Note that the Ventricular Response Pacing (VRP) feature mentioned in the study is called Conducted AF Response in the Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 devices.

Concerto AT clinical study – This clinical study evaluated the safety of the Concerto system and the efficacy of atrial shock therapy in patients with a current indication for Cardiac Resynchronization Therapy (CRT) and an Implantable Cardioverter Defibrillator (ICD). It provides support for atrial cardioversion therapy in the Amplia MRI Model DTMB1D4 devices.

The Enhanced Surveillance of Right Ventricle Lead Integrity Alert (RV LIA) – This study, which prospectively assessed the performance of the Right Ventricle Lead Integrity Alert, provided an estimate of the probability of receiving a three-day warning for patients with a lead fracture. The study provides support for the RV Lead Integrity Alert feature in Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 devices.

EnTrust clinical study – This clinical study, which evaluated the safety and clinical performance of the EnTrust ICD system, provides support for the Amplia MRI Model DTMB1D4 devices.

EnTrust tachyarrhythmia detection performance vs. GEM DR tachyarrhythmia detection performance – This retrospective evaluation of the EnTrust detection algorithm was performed on spontaneous rhythms recorded in patients implanted with the GEM DR ICD. It provided support for the modifications made to the PR Logic Sinus

Tachycardia criterion in the EnTrust devices. These modifications also apply to the Amplia MRI Model DTMB1D4 devices.

Evera MRI SureScan defibrillation system clinical study – This clinical study, which evaluated the safety and efficacy of the Evera MRI SureScan defibrillation system in the clinical magnetic resonance imaging (MRI) environment, provides support for the MRI SureScan feature.

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 Amplia MRI Model DTMB1D4 devices.

GEM DR clinical study – This clinical study, which evaluated the appropriateness of dual chamber sensing and tachyarrhythmia detection during induced and simulated cardiac arrhythmias in GEM DR devices, provides support for the Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 devices.

InSync ICD clinical study – This clinical study, which evaluated the safety and efficacy of cardiac resynchronization therapy (CRT) in patients who are indicated for an ICD, provides support for CRT pacing in Amplia MRI Model DTMB1D4 devices.

InSync Marquis clinical study – This clinical study assessed the safety of the InSync Marquis dual chamber, rate responsive ICD with CRT Therapy, and confirmed appropriate VT/VF detection and biventricular capture over the range of heart rates achieved during exercise. It provides support for the Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 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 of the Amplia MRI device.

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 Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 devices.

Marquis VR Single Chamber ICD study – This clinical study, which evaluated the operation of the Wavelet Auto-Template Algorithm in the Model 7230 Marquis VR devices, provides support for the Wavelet detection feature in Amplia MRI Model DTMB1D4 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 Amplia MRI Model DTMB1D4 devices.

PR Logic with Wavelet performance – This retrospective evaluation was conducted to demonstrate the safety and performance of the combined PR Logic and Wavelet SVT discrimination features by assessing the impact to VT/VF detection sensitivity and specificity of turning Wavelet on in dual chamber ICD and CRT-D devices. This evaluation provides support for the PR Logic and Wavelet features in Amplia MRI Model DTMB1D4 devices.

Protecta detection performance – This retrospective evaluation was performed using human rhythms collected from various clinical trials and provides support that the addition of multiple therapy discriminators in the Protecta products do not affect the overall detection performance of the Amplia MRI Model DTMB1D4 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).

Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) and Resynchronization/Defibrillation for Ambulatory Heart Failure Trial (RAFT) – These clinical studies, which evaluated cardiac resynchronization therapy in mildly (REVERSE and RAFT) symptomatic and moderately symptomatic (RAFT) heart failure patients, provide support for Amplia MRI Model DTMB1D4 devices in these patients.

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 in the Amplia MRI device.

RV Lead Integrity Alert performance retrospective evaluation – This retrospective evaluation assessed the ability of the RV Lead Integrity Alert feature to provide advance notice of a Sprint Fidelis lead fracture. The evaluation provides support for the RV Lead Integrity Alert feature in Amplia MRI Model DTMB1D4 devices.

RV Lead Integrity Alert Performance retrospective evaluation for non-Medtronic leads – This retrospective evaluation assessed the performance of the RV Lead Integrity Alert feature when used with a St. Jude Riata/Durata lead or Boston Scientific Endotak lead. This evaluation provides information regarding the performance of the RV Lead Integrity Alert feature in these non-Medtronic lead families.

RV Lead Noise Discrimination VF detection performance – This retrospective evaluation was conducted using spontaneous rhythms and provides support that the RV Lead Noise Discrimination algorithm does not impact time to detection in Amplia MRI Model DTMB1D4 devices.

Template Matching Morphology (TEMM) study – This clinical study, which evaluated the functionality of the Template Matching Morphology (TEMM) algorithm, provides support for the Wavelet detection feature in Amplia MRI Model DTMB1D4 devices.

TWave Discrimination VF detection performance – This retrospective evaluation was conducted using induced rhythms and provides support that the TWave Discrimination algorithm does not impact time to detection in Amplia MRI Model DTMB1D4 devices.

4 Implant procedure

4.1 Preparing for an implant

To retain the ability to safely scan the SureScan CRT-D system during MRI scans, the MRI conditions for use in Section 1.4 must be followed. Refer to the MRI Technical Manual for additional information.

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 4.8, "Replacing a device", page 29.

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

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 (for example, the Medtronic CareLink Model 2090 Programmer)
- programmer software application for the Amplia MRI Model DTMB1D4 device[1]
- 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 (if a programming head is used)
  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 Medtronic CareLink Programmer Reference Manual for instructions about how to set up the programmer. The Model SW034 software should be installed on the programmer. 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: Leads other than SureScan leads may be used with the DTMB1D4 device, but if leads other than 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 defibrillation leads. Implanting the device outside of the pectoral region may adversely affect the results of the OptiVol fluid measurements. No claims of safety and performance can be made with regard to other acutely or chronically implanted lead systems that are not manufactured by Medtronic.

Caution: Lead coils and Active Can electrodes that are in contact during a high-voltage therapy may cause electrical current to bypass the heart, possibly damaging the device and leads. While the device is connected to the leads, verify that therapeutic electrodes, stylets, or guide wires are not touching or connected by any material that may conduct electricity. Move objects made from conductive materials (for example, an implanted guide wire) well away from all electrodes before delivering a high-voltage shock.

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

Caution: 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.

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[1] Your Medtronic representative can install the Model SW034 software application.

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 an electrical reset occurred, do not implant the device. Contact a Medtronic representative.
2. Check the status of the Remaining Longevity estimate on the Quick Look II screen to confirm that the device is acceptable for implant. The Remaining Longevity estimate graphic is gray if the battery status is not acceptable for implant and it is green if the battery status is acceptable for implant.
   If the device has been exposed to low temperatures, the battery voltage may be temporarily lower and the charge time may increase. If the battery status is unacceptable, store the device at room temperature for 48 hours and check the battery status again to determine if the device is acceptable for implant. If an acceptable battery status cannot be obtained after 48 hours, contact a Medtronic representative.
   Note: If the Remaining Longevity estimate graphic on the Quick Look II screen is gray, indicating that the battery status is unacceptable, do not charge the capacitors.
3. Select Params > Data Collection Setup > Device Date/Time… to set the internal clock of the device to the correct date and time.
4. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that tachyarrhythmia detection is not programmed to On.
   Notes:
   - 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.
   - Patient information typically is entered at the time of initial implant, and it can be revised at any time.

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 CRT-D 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 CRT-D system includes the following components:

- the Amplia MRI CRT-D device
- a SureScan right atrial pacing lead or a Model 6725 pin plug for the right atrial port
- a SureScan left ventricular pacing lead
- a SureScan defibrillation lead

To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

4.2.1 Selecting the leads

The device typically is implanted with the following leads:

- 1 transvenous lead with an IS-1 connector in the left ventricle (LV) for pacing
- 1 quadripolar/tripolar transvenous lead with a DF4-LLHH or DF4-LLHO connector in the right ventricle (RV) for sensing and pacing, and for cardioversion and defibrillation therapies
- 1 bipolar transvenous lead with an IS-1 connector 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 port.

Note: Lead adaptors compromise the ability to safely scan the SureScan CRT-D system during an MRI scan. Patients with lead adaptors are contraindicated for an MRI scan. Refer to the MRI Technical Manual for additional information.

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

Note: If you are using a lead that requires an adaptor for this device, contact your Medtronic representative for information about compatible lead adaptors.

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

Table 1. Lead and connector compatibility

Connector port (electrodes)	Primary lead
RV (RVtip, RVring, RVcoil, SVC coil)	DF4-LLHH or DF4-LLHO[a] quadripolar/tripolar
LV (LVtip, LVring)	IS-1[b] bipolar
A (Atip, Aring)	IS-1[b] bipolar

[a] DF4-LLHH and DF4-LLHO refer to the international standard ISO 27186, where the lead connector contacts are defined as low voltage (L), high voltage (H), or open (O).
[b] 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 cause unwanted high-voltage therapies or 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.

4.3.1 Considerations for testing the lead system

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

Lead positioning – Final lead positioning should attempt to optimize pacing threshold, sensing, defibrillation threshold, and resynchronization, if appropriate.

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 changing the pacing polarity or repositioning the lead.

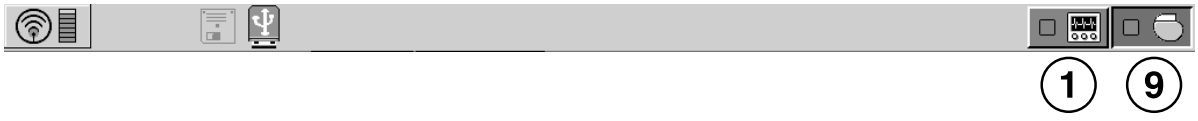
4.3.2 How to verify and save the sensing and pacing values

Medtronic recommends that you use a Model 2290 Analyzer to perform sensing and pacing measurements. When the analyzer and the device sessions are running concurrently, you can export the saved lead measurements from the analyzer session into the patient information parameters in the device session. Refer to the analyzer technical manual for detailed procedures about performing the lead measurements.

Note: If you perform the lead measurements using an implant support instrument other than a Model 2290 Analyzer, enter the measurements in the device session manually.

Note: The intracardiac EGM telemetered from the device cannot be used to directly assess sensing.

1. From the device session, launch a new analyzer session by selecting the Analyzer icon, which is located on the task bar.



2. Measure the EGM amplitude, slew rate, and capture threshold using a Model 2290 Analyzer.
3. Use the information in Table 2 to verify that the measured values are acceptable.
   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 and for additional information about sensing and pacing values.
4. Select [Save…] at the bottom of the column that corresponds to the lead you are testing.
5. In the Lead field, select the type of lead you are testing and then select [Save].
6. Select [View Saved…].
7. Select the saved measurements that you want to export. You can select a single measurement for each lead type.
8. Select [Export] and [Close]. The selected measurements are exported to the Implant… field on the Patient Information screen in the device session.
9. Select the Device icon on the task bar to return to the device session.
10. Select Patient > Patient Information and then select [Program] to program the imported values into the device memory.

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 (LV to RVring or LV to RVcoil)	≥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.

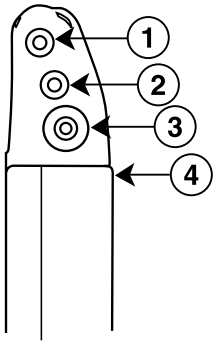
Warning: After connecting the leads, verify that the lead connections are secure by gently tugging on each lead. A loose lead connection may result in inappropriate sensing, which can cause inappropriate arrhythmia therapy or a failure to deliver arrhythmia therapy.

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.

Caution: If you are not implanting an atrial lead, insert a Model 6725 pin plug into the atrial port to prevent electrical leakage.

See Figure 1 for information about the lead connector ports on the device.

Figure 1. Lead connector ports

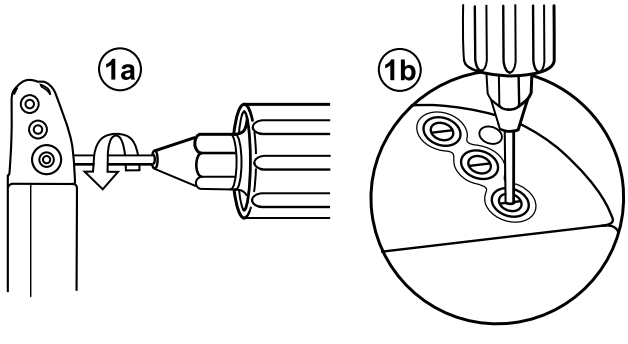


1 IS-1 connector port, A
2 IS-1 connector port, LV
3 DF4-LLHH connector port, RV
4 Device Active Can electrode

4.4.1 How to connect a lead to the device

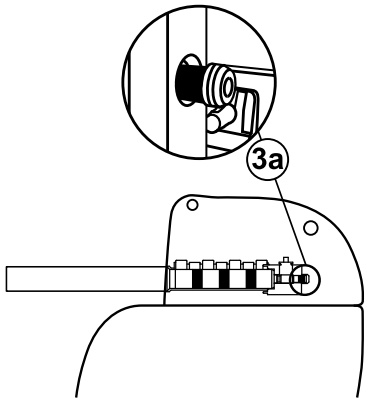
1. Insert the torque wrench into the appropriate setscrew.
   a. If the setscrew obstructs the port, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see Figure 2).
   b. Leave the torque wrench in the setscrew until the lead connection is secure to allow a pathway for venting trapped air when the lead connector is inserted into the connector port (see Figure 2).

Figure 2. Inserting the torque wrench into the setscrew



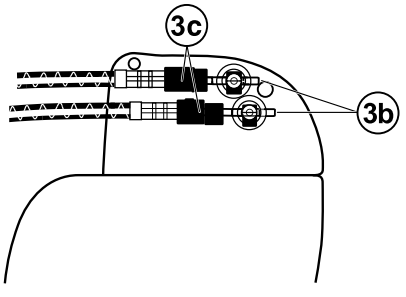
2. Insert the lead connector into the connector port, keeping twisting to a minimum. Insert the lead connector until the lead connector pin is visible in the pin viewing area. If necessary, sterile water may be used as a lubricant. No sealant is required.
3. Confirm that the lead is fully inserted into the connector pin cavity by viewing the device connector block from the side.
   a. For the DF4-LLHH connector port (RV), the color band on the tip of the lead connector pin is visible in the pin viewing area when the pin is fully inserted (see Figure 3).

Figure 3. Confirming the DF4-LLHH or DF4-LLHO lead connection



   b. For the IS-1 connector port, the lead connector pin should be clearly visible beyond the setscrew block (see Figure 4).
   c. For the IS-1 connector port, the lead connector ring should be completely inside the spring contact block. There is no setscrew in this location (see Figure 4).

Figure 4. Confirming the IS-1 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 Performing ventricular defibrillation threshold tests

Ventricular defibrillation operation and effectiveness of the implanted lead system may be tested by inducing VF using either the T-Shock or the 50 Hz Burst method and then allowing the device to detect and treat the VF using the programmed automatic therapies. Follow your preferred method to establish that an adequate sensing safety margin and an adequate defibrillation safety margin exist.

The decision to induce VF for testing the ventricular defibrillation operation and implanted lead system effectiveness should be carefully considered for each patient. Physicians should use their discretion in deciding whether to test or how to test for an adequate safety margin.

4.5.1 High-voltage implant values

See Table 3 for information about the measured high-voltage therapy values that are recommended at implant.

Table 3. High-voltage (HV) therapy values recommended at implant

Measurement	Acute or chronic leads
HV delivery pathway impedance	20–200 Ω
Defibrillation threshold	≤25 J

4.5.2 How to prepare for defibrillation threshold testing

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.

1. Establish telemetry between the device and programmer, and start a patient session. If you are using wireless telemetry, verify that at least 3 of the green lights on the wireless telemetry icon are illuminated. Interrogate the device if it has not been interrogated.
2. Select the Params icon, select the VF Therapies field, and then select [Shared Settings…]. Program the Active Can/SVC Coil parameter to On or Off, as is appropriate for the patient.
3. Observe the Marker Channel annotations to verify that the device is sensing properly.
4. Perform a manual Lead Impedance Test to verify defibrillation lead connections. For information about acceptable impedance values, refer to the lead technical manual and see Table 3. Perform this test with the device in the surgical pocket. Keep the surgical pocket very moist. If the lead impedance is out of range, perform one or more of the following tasks:
   - Recheck the lead connections and lead electrode placement.
   - Inspect the EGM for abnormalities.
   - Repeat the manual Lead Impedance Test.

4.5.3 How to perform defibrillation threshold testing using T-Shock

1. Select Tests > EP Study.
2. Select T-Shock from the list of EP Study functions.
3. Confirm that the Resume at DELIVER check box is selected to resume arrhythmia detection after the induction is delivered.
   Note: During a wireless telemetry session, you cannot deliver a T-Shock induction when there is a magnet or programming head over the device and the Resume at DELIVER check box is selected. If an error message appears, remove the magnet or programming head or clear the Resume at DELIVER check box.
4. Select [Adjust Permanent…].
5. Set the Energy parameter for VF Therapy Rx1 to 10 J less than the desired final programmed value. Set VF Therapies Rx2 through Rx6 to the maximum value.
6. Set the RV Sensitivity parameter to a value that results in an adequate safety margin for detecting VF. For a final programmed RV Sensitivity of 0.3 mV, an adequate safety margin typically is attained by setting the value to 1.2 mV during testing.
7. Set VF Enable to On. This also automatically sets the AF/AfI, Sinus Tach, and Wavelet features to On.
8. Select [PROGRAM].
9. Select [Close].
10. Select the Enable check box.
11. Select [DELIVER T-Shock]. If necessary, select [ABORT] to abort the induction or any therapy in progress.
12. Observe the Live Rhythm Monitor for proper detection, therapy, and post-shock sensing.

13. To review the stored data for the induced episode, select [Retrieve Data…]. To view more details, print a Last VT/VF with EGM report or select Data > Clinical Diagnostics > Arrhythmia Episodes to view the data on the programmer.
14. Select [Adjust Permanent…] to program a new VF Therapy Rx1 energy level or to change the Pathway, if desired.
15. Wait until the on-screen timer reaches 5 min; then repeat Step 10 through Step 15 as needed.
16. Before closing the pocket, select the Params icon and program VF Detection, FVT Detection, and VT Detection to Off.

4.5.4 How to perform defibrillation threshold testing using 50 Hz Burst

1. Select Tests > EP Study.
2. Select 50 Hz Burst from the list of EP Study functions.
3. Select [RV] if the Select Chamber box appears. Otherwise, set the Chamber parameter to the desired ventricular setting.
4. Confirm that the Resume at BURST check box is selected to resume arrhythmia detection after the induction is delivered.
   Note: During a wireless telemetry session, you cannot deliver a 50 Hz Burst induction when there is a magnet or programming head over the device and the Resume at BURST check box is selected. If an error message appears, remove the magnet or programming head, or clear the Resume at BURST check box.
5. Select [Adjust Permanent…].
6. Set the Energy parameter for VF Therapy Rx1 to 10 J less than the desired final programmed value. Set VF Therapies Rx2 through Rx6 to the maximum value.
7. Set the RV Sensitivity parameter to a value that results in an adequate safety margin for detecting VF. For a final programmed RV Sensitivity of 0.3 mV, an adequate safety margin typically is attained by setting the value to 1.2 mV during testing.
8. Set VF Enable to On. This also automatically sets the AF/Afl, Sinus Tach, and Wavelet features to On.
9. Select [PROGRAM].
10. Select [Close].
11. Press and hold the [50 Hz BURST Press and Hold] button. Remove the touch pen from the [50 Hz BURST Press and Hold] button to automatically abort the induction or therapy.
12. Observe the Live Rhythm Monitor for proper detection, therapy, and post-shock sensing.
13. To review the stored data for the induced episode, select [Retrieve Data…]. To view more details, print a Last VT/VF with EGM report, or select Data > Clinical Diagnostics > Arrhythmia Episodes to view the data on the programmer.
14. Select [Adjust Permanent…] to program a new VF Therapy Rx1 energy level or to change the Pathway, if desired.
15. Wait until the on-screen timer reaches 5 min, then repeat Step 11 through Step 15 as needed.
16. Before closing the pocket, select the Params icon and program VF Detection, FVT Detection, and VT Detection to Off.

4.6 Positioning and securing the device

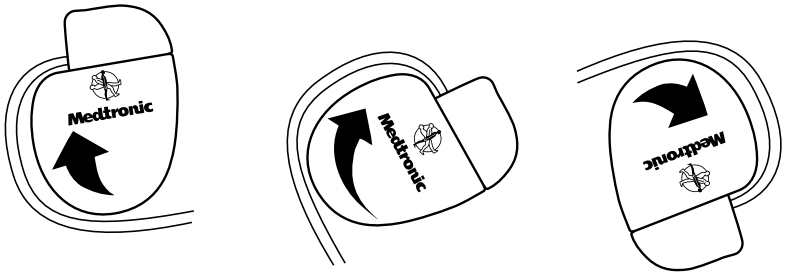
Caution: Program tachyarrhythmia detection to Off or Monitor to avoid inappropriate detection or therapy delivery while closing the surgical pocket.

Note: Implant the device within 5 cm (2 in) of the surface of the skin to optimize post-implant ambulatory monitoring. The side of the device engraved with the Medtronic logo should face toward the skin so it is easier for the patient to hear the alert tones. In addition, this orientation is most compatible with the device PhysioCurve Design.

4.6.1 How to position and secure the device

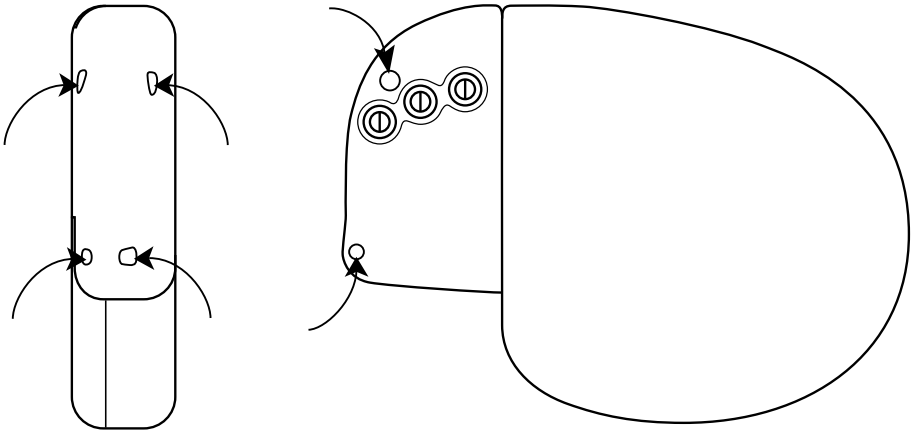
1. Verify that each lead connector pin is fully inserted into the connector port and that all setscrews are tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see Figure 5). Do not kink the lead body.

Figure 5. 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 holes on the device (see Figure 6).

Figure 6. Locating the suture holes



5. Suture the pocket incision closed.

4.7 Completing the implant procedure

Warning: Do not program the Other 1:1 SVTs feature to On until the atrial lead has matured (approximately 1 month after implant). If the atrial lead dislodges and migrates to the ventricle, the Other 1:1 SVTs feature could inappropriately withhold detection and therapy.

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.

4.7.1 How to complete programming the device

1. Enable tachyarrhythmia detection and the desired tachyarrhythmia therapies.
2. Perform a final VF induction, and allow the implanted system to detect and treat the tachyarrhythmia.
3. Verify that the pacing, detection, and therapy parameters are programmed to values that are appropriate for the patient.

4. 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 reference manual.
5. Configure the Medtronic CareAlert feature.
6. Program the Data Collection Setup parameters.

4.7.2 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. If any tachyarrhythmia therapies are enabled while the patient is in the hospital, interrogate the device after any spontaneous episodes to evaluate the detection and therapy parameter settings.
3. If the patient has not experienced spontaneous episodes, you may induce tachyarrhythmias using the non-invasive EP study features to further assess the performance of the system.
4. Check the pacing and sensing values, and adjust the values if necessary.
5. Demonstrate the alert tones.
6. Interrogate the device, and print a Final Report to document the postoperative programmed device status.

4.8 Replacing a device

To retain the ability to safely scan the SureScan CRT-D system during future MRI scans, refer to the MRI Technical Manual for additional information.

Warning: Leads other than SureScan leads may be used with the DTMB1D4 device, but if leads other than 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 CRT-D system during future MRI scans. When implanting a SureScan CRT-D system, consider the risks associated with removing previously implanted leads before removing the leads to maintain the ability to safely scan the SureScan CRT-D system.

Warning: Keep external defibrillation and pacing equipment nearby for immediate use. The patient does not receive defibrillation or pacing therapy from the device when the lead is disconnected.

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

Note: To meet the implant requirements, you may need to reposition or replace the chronic leads, or add an additional high-voltage electrode.

Note: If you use a high-voltage lead in the RV that is not compatible with the DF4-LLHH connector port, an adaptor must be used. Contact your Medtronic representative for information about compatible lead adaptors.

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.

4.8.1 How to explant and replace a device

1. Disable tachyarrhythmia detection to avoid potential inappropriate shocks to the patient or implanter while explanting the device.
2. Program the device to a mode that is not rate responsive to avoid potential rate increases while explanting the device.
3. Dissect the leads and the device free from the surgical pocket. Do not nick or breach the lead insulation.
4. Use a torque wrench to loosen the setscrews in the connector block.
5. Gently pull the leads out of the connector ports.
6. Evaluate the condition of each lead (see Section 4.3, “Testing the lead system”, page 22). 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 it to Medtronic for analysis and disposal.
7. Connect the leads to the replacement device (see Section 4.4, “Connecting the leads to the device”, page 24).
   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 CRT-D system in the future. Patients with lead adaptors are contraindicated for an MRI scan. Refer to the MRI Technical Manual for additional information.
8. Evaluate defibrillation effectiveness using the replacement device (see Section 4.5, “Performing ventricular defibrillation threshold tests”, page 25).
9. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see Section 4.6, “Positioning and securing the device”, page 27).
10. 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

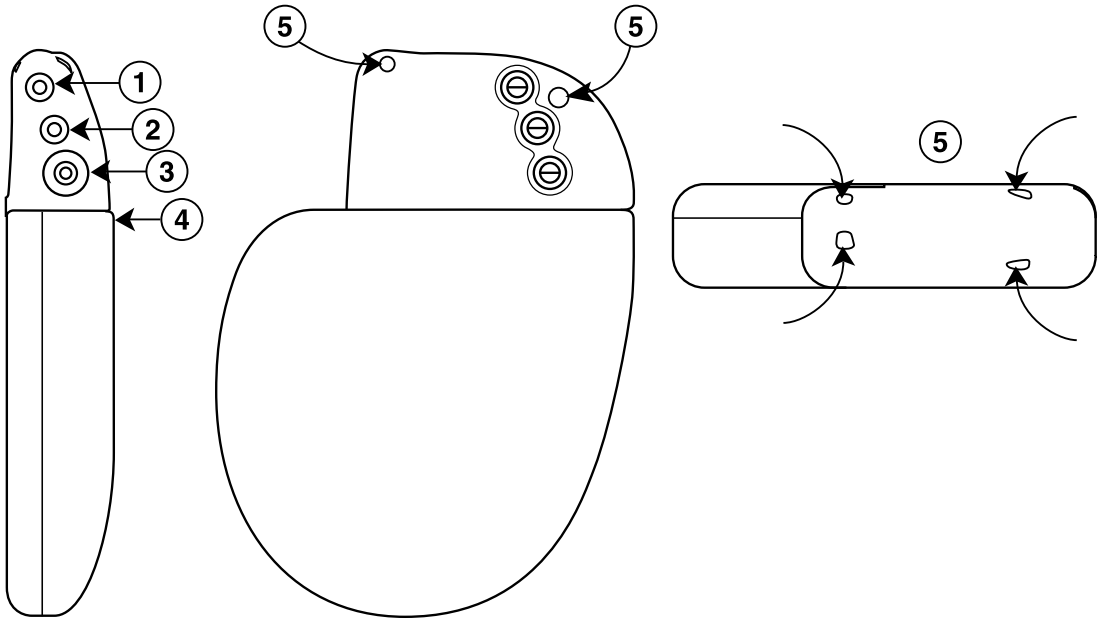
5.1 Physical characteristics

Table 4. Physical characteristics

Volume[a]	35 cm^3
Mass	80 g
H x W x D	73 mm x 51 mm x 13 mm
Surface area of device can	57 cm^2
Radiopaque ID[b]	PFZ
Medtronic radiopaque identifier[b]	
Materials in contact with human tissue[c]	Titanium, polyurethane, silicone rubber, titanium dioxide
Battery	Hybrid CFx lithium/silver vanadium oxide

[a] Volume with connector ports unplugged.
[b] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[c] 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 7. Connector ports and suture holes



1 IS-1 connector port, A
2 IS-1 connector port, LV
3 DF4-LLHH connector port, RV
4 Device Active Can electrode
5 Suture holes

5.2 Replacement indicators

The Remaining Longevity estimate, replacement status, and battery voltage appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT) and the End of Service (EOS) conditions are listed in Table 5.

Table 5. Replacement indicators

Recommended Replacement Time (RRT)	<2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Remaining Longevity – The Remaining Longevity estimate displays the estimated time remaining until device RRT.

RRT (Recommended Replacement Time) – The programmer displays the RRT battery status to indicate that replacement of the device is recommended.

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

EOS (End of Service) – The programmer displays the EOS battery status to indicate that the device should be replaced immediately and may not operate per specifications.

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

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS. The PSP is defined as 3 months assuming the following conditions: 100% DDD pacing at 60 bpm, 2.5 V atrial and RV

pacing amplitude, 3.0 V LV pacing amplitude, 0.4 ms pulse width; 600 Ω pacing load; and 6 full-energy charges. If the device exceeds these conditions, the EOS may be indicated before the end of 3 months.

5.3 Projected service life

The projected service life in years for the device is shown in Table 6. The data is based on pacing outputs programmed to the DDD mode, specified amplitude and 0.4 ms pulse width, 15% atrial pacing with 100% biventricular pacing at 60 bpm lower rate and 70 bpm atrial tracking.

The projected service life in years for the device with AdaptivCRT programmed to Adaptive Bi-V and LV is shown in Table 7. The data is based on pacing outputs programmed to the DDD mode, specified amplitude and 0.4 ms pulse width, 15% atrial pacing with 50% right ventricular pacing and 100% left ventricular pacing.

The service life projections are based on the following assumptions:

- Semi-annual maximum energy charging frequency
- Pre-arrhythmia EGM storage programmed to On for a 6-month period (two 3-month follow-up intervals), over the entire life of the device
- A quarterly schedule of Medtronic patient monitor telemetry remote transmissions
- Typical shelf storage time before implant
- 3 hours of wireless telemetry during implant
- 1 hour of in-office wireless telemetry annually

Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Table 6. Projected service life in years

Pacing Amplitude		Projected service life in years	
RA/RV 15%/100%	**LV 100%**	**500 Ω pacing impedance**	**600 Ω pacing impedance**
2.0 V	2.5 V	7.0	7.3
2.0 V	4.0 V	5.4	5.8
2.5 V	2.5 V	6.8	7.1
2.5 V	3.0 V	6.1	6.4
2.5 V	4.0 V	5.3	5.6
3.5 V	2.5 V	5.8	6.1
3.5 V	4.0 V	4.7	5.0

Table 7. Projected service life in years, with AdaptivCRT programmed to Adaptive Bi-V and LV

Pacing Amplitude		Projected service life in years (with AdaptivCRT)	
RA/RV 15%/50%	**LV 100%**	**500 Ω pacing impedance**	**600 Ω pacing impedance**
2.0 V	2.5 V	7.4	7.6
2.0 V	4.0 V	5.6	6.0
2.5 V	2.5 V	7.3	7.5
2.5 V	3.0 V	6.5	6.8
2.5 V	4.0 V	5.6	5.9

Table 7. Projected service life in years, with AdaptivCRT programmed to Adaptive Bi-V and LV (continued)

Pacing Amplitude		Projected service life in years (with AdaptivCRT)	
RA/RV 15%/50%	**LV 100%**	**500 Ω pacing impedance**	**600 Ω pacing impedance**
3.5 V	2.5 V	6.6	6.9
3.5 V	4.0 V	5.2	5.5

Table 8. Projected service life in years, with the Pacing Mode programmed to AAI<=>DDD

		Projected service life in years	
Pacing mode, percent pacing	**Pacing amplitude**	**500 Ω Pacing impedance**	**600 Ω Pacing impedance**
AAI<=>DDD (MVP mode) 50% atrial/5% ventricular	2.5 V	8.9	9.0
	3.5 V	8.2	8.3

Projected service life per conditions specified in EN 45502-2-2 – The service life projections per EN 45502-2-2 specifications assume 100% ventricular pacing, 500 Ω pacing impedance, 2.5 V RA and RV amplitude, 3.0 V LV amplitude, and EGM Pre-arrhythmia storage programmed to Off.

- Projected service life with 0% atrial pacing is 6.3 years.
- Projected service life with 100% atrial pacing is 6.0 years.

5.3.1 Projected service life considerations

Additional full-energy charges – Each additional full-energy charge due to therapy shock or device testing reduces projected service life by approximately 24 days.

Pre-arrhythmia EGM storage – Full-time use of Pre-arrhythmia EGM storage reduces projected service life by approximately 2 additional months per year, or 16%.

Medtronic patient monitor remote transmissions – Additional Medtronic patient monitor remote transmissions reduce projected service life. For example, a CRT patient who receives 15% atrial pacing, 100% biventricular pacing at 70 bpm atrial tracking, 2.0 V amplitude (2.5 V LV amplitude), DDD mode, with 600 Ω impedance, would expect 7.3 years projected service life. 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 46 days, or 2%.
- Weekly transmissions over the life of the device reduce projected service life by 223 days, or 8%.
- Daily transmissions over the life of the device reduce projected service life by 992 days, or 37%
- A single additional transmission reduces projected service life by approximately 0.6 days, or 0.02%.

Shelf storage time – Maximum shelf storage time of 18 months reduces projected service life by approximately 6.5%.

Wireless telemetry – Each additional hour of wireless telemetry use (in-office or implant) reduces the projected service life by approximately 5.7 days or 0.25%.

5.4 Energy levels and typical charge times

Energy levels – Stored energy is always greater than the delivered energy. Stored energy is derived from the peak capacitor charge.

Typical charge times – The most recent capacitor charge time appears on the programmer display and on printed reports. You can evaluate charge time using the Charge/Dump Test.

Table 9. Maximum energy levels and typical full energy charge times

Maximum programmed energy	35 J
Maximum delivered energy[a,b]	36 J
Maximum stored energy[c]	42 J
Typical charge time at Beginning of Service (BOS)[d]	8.3 s
Typical charge time at Recommended Replacement Time (RRT)[d]	12.0 s

[a] Energy delivered at connector block into a 50 Ω load.
[b] For 35 J programmed energy, delivered energy exceeds 35 J.
[c] Energy stored at charge end on capacitor.
[d] Charge time during a nonwireless telemetry session may be slightly higher.

5.5 Magnet application

When a magnet is placed near the device, tachyarrhythmia detection is suspended and no tachyarrhythmia therapies are delivered. Alert tones sound if programmed. The device ignores the magnet in the programmer head when telemetry communication is established through the programmer head. Before implant and for the first 6 hours after implant, the device does not sound audible tones when a magnet is placed over the device.

Note: If MRI SureScan is programmed to On, tachyarrhythmia detection and Medtronic CareAlerts (including audible alerts) are suspended.

6 Device parameters

6.1 Emergency settings

Table 10. Emergency settings and default values

Parameter	Selectable values
Defibrillation	
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J
Pathway[a]	B>AX
MRI SureScan	Off
Cardioversion	
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J
Pathway[a]	B>AX
MRI SureScan	Off
Fixed Burst	
Interval	100; 110 … 350◈ … 600 ms
RV Amplitude	8 V
RV Pulse Width	1.5 ms
V. Pacing	RV
MRI SureScan	Off

Table 10. Emergency settings and default values (continued)

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

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.
[b] 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 Tachyarrhythmia detection parameters

Warning: Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.15 mV.

Table 11. 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	—	—
VF Detection[b]	On◈; OFF	OFF	On
VF Interval (Rate)[a]	240; 250 … 320◈ … 400 ms	320 ms	320 ms
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40◈; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160	30/40	30/40
VF Beats to Redetect	6/8; 9/12; 12/16◈; 18/24; 21/28; 24/32; 27/36; 30/40	12/16	12/16
FVT Detection	OFF◈; via VF; via VT	OFF	OFF
FVT Interval (Rate)[a]	200; 210 … 240◈ … 600 ms	—	—
VT Detection	On; OFF◈	OFF	OFF
VT Interval (Rate)[a]	280; 290 … 360◈ … 650 ms	360 ms	400 ms
VT Initial Beats to Detect	12; 16◈ … 52; 76; 100	16	16
VT Beats to Redetect	8; 12◈ … 52	12	12

Table 11. Tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Reset
VT Monitor	Monitor◈; Off	Off	Off
VT Monitor Interval (Rate)[a]	280; 290 … 450◈ … 650 ms	450 ms	450 ms
Monitored VT Beats to Detect	16; 20; 24; 28; 32◈ … 56; 80; 110; 130	32	32
PR Logic/Wavelet			
AF/Afl[b]	On◈; Off	Off	Off
Sinus Tach[b]	On◈; Off	Off	Off
Other 1:1 SVTs	On; Off◈	Off	Off
Wavelet…			
Wavelet[b]	On◈; Off; Monitor	Off	Off
Template	[date]	None	None
Match Threshold	40; 43; 46 …70◈ … 97%	—	—
Auto Collection	On; Off◈	—	—
SVT V. Limit[a]	240; 250; 260◈ … 650 ms	—	—
Other Enhancements			
Stability[a]	Off◈; 30; 40 …100 ms	Off	Off
Onset…			
Onset	Off◈; On; Monitor	Off	Off
Onset Percent	72; 75; 78; 81◈; 84; 88; 91; 94; 97%	—	—
High Rate Timeout…			
VF Zone Only	Off◈; 0.25; 0.5; 0.75; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5 min	Off	Off
All Zones	Off◈; 0.5; 1; 1.5 … 5; 6; 7 … 20; 22; 24; 26; 28; 30 min	—	—
TWave	On◈; Off	On	Off
RV Lead Noise…			
RV Lead Noise	On; On+Timeout◈; Off	On+Timeout	Off
Timeout	0.25; 0.5; 0.75◈ … 2 min	0.75 min	—
Sensitivity			
Atrial[c]	0.15; 0.30◈; 0.45; 0.60; 0.90; 1.20; 1.50; 1.80; 2.10; 4.00 mV; Off	0.3 mV	0.3 mV
RV[c]	0.15; 0.30◈; 0.45; 0.60; 0.90; 1.20 mV	0.3 mV	0.3 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 AF/Afl, Sinus Tach, and Wavelet features are automatically set to On when VF Detection is set to On.
[c] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

6.3 Atrial tachyarrhythmia therapy parameters

Table 12. Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
Anti-Tachy Pacing (ATP)			
AT/AF Rx Status	On; Off◈	Off	Off
Therapy Type	50 Hz; Ramp; Burst+ Rx1: Ramp◈ Rx2: Burst+◈ Rx3: 50 Hz◈	—	—
Fast AT/AF Rx Status	On; Off◈	—	—
Therapy Type	50 Hz; Ramp; Burst+ Rx1: Ramp◈ Rx2: Burst+◈ Rx3: 50 Hz◈	—	—
Patient Activated CV			
Patient Activated CV Status	On; Off◈	Off	Off
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J	—	—
Pathway[a]	AX>B; B>AX◈	—	—
Automatic CV			
AT/AF Automatic CV Status	On; Off◈	Off	Off
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J	—	—
Pathway[a]	AX>B; B>AX◈	—	—
Fast AT/AF Automatic CV Status	On; Off◈	—	—
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J	—	—
Pathway[a]	AX>B; B>AX◈	—	—
Shared CV			
Minimum R-R Interval[b]	400; 410 … 500◈ … 600 ms	500 ms	500 ms
Active Can/SVC Coil[c]	Can+SVC On◈; Can Off; SVC Off	Can+SVC On	Can+SVC On
Automatic CV Limits			
Delivery Window Start Time	00:00; 01:00; 02:00; 03:00◈ … 23:00	—	—
Delivery Window Length	1◈; 2; 3; 4; 6; 8; 10; 12; 16; 20; 24 hr	—	—
Maximum shocks per day	1◈; 2; 3; 4; 5; No Limit	—	—

Table 12. Atrial tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
Episode Duration Before Rx Delivery			
Episode Duration Before CV	0; 1; 2; 3; 4; 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6◈; 12; 24; 48; 72 hr; 7 days	—	—
50 Hz Burst parameters			
50 Hz Burst Duration	0.5; 1◈; 2; 3 s	—	—
# Sequences	1; 2◈ … 10	—	—
Burst+ parameters			
Initial # S1 Pulses	1; 2 … 15◈; 20; 25	—	—
A-S1 Interval (%AA)	28; 31; 34; 38; 41 … 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
S1-S2 (%AA)	28; 31; 34; 38; 41 … 59; 63; 66; 69 … 84◈; 88; 91; 94; 97%; Off	—	—
S2-S3 Decrement	0; 10◈; 20 … 80 ms; Off	—	—
Interval Decrement	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 6◈ … 10	—	—
Ramp parameters			
Initial # S1 Pulses	1; 2 … 6◈ … 15; 20; 25	—	—
A-S1 Interval (%AA)	28; 31; 34; 38; 41 … 59; 63; 66 … 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	—	—
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes◈; No	No	No
Duration to stop	12; 24; 48◈; 72 hr; None	—	—
Episode Duration Before Rx Delivery			
Episode Duration Before ATP	0; 1◈; 2; 3; 4; 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr	—	—
Reactive ATP			
Rhythm Change	On◈; Off	—	—
Time Interval	Off; 2; 4; 7◈; 12; 24; 36; 48 hr	—	—

Table 12. Atrial tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
Shared A. ATP			
A-A Minimum ATP Interval[b]	100; 110; 120; 130◈ … 400 ms	150 ms	150 ms
A. Pacing Amplitude	1; 2 … 6◈; 8 V	6 V	6 V
A. Pacing Pulse Width	0.1; 0.2 … 1.5◈ ms	1.5 ms	1.5 ms
VVI/VOO Backup Pacing[d]	Off; On (Always); On (Auto-Enable)◈	—	—
VVI/VOO Backup Pacing Rate	60; 70◈ … 120 bpm	—	—

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.
[b] 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.
[c] The Active Can/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock inductions.
[d] V. Backup Pacing is delivered to the RV chamber.

6.4 Ventricular tachyarrhythmia therapy parameters

Table 13. Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
VF Therapy parameters			
VF Therapy Status	On◈; Off	On	On
Energy	Rx1–Rx2: 0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J Rx3–Rx6: 10; 11 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J	35 J	35 J
Pathway[a]	AX>B; B>AX Rx1–Rx4: B>AX◈ Rx5–Rx6: AX>B◈	B>AX	B>AX
ATP…	During Charging◈; Before Charging; Off	During Charging	Off
Deliver ATP if last 8 R-R >=	200; 210 … 240◈ … 300 ms	240 ms	—
Therapy Type	Burst◈; Ramp; Ramp+	Burst	—
ChargeSaver…	On◈; Off	On	—
Switch when number of consecutive ATP successes equals	1◈; 2; 3; 4; 6; 8; 10	1	—
Smart Mode	On◈; Off	On	—

Table 13. Ventricular tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
VT/FVT Therapy parameters			
VT Therapy Status	On; Off◈	Off	Off
FVT Therapy Status	On; Off◈	Off	Off
Therapy Type	CV; Burst; Ramp; Ramp+ Rx1: Burst◈ Rx2–Rx6: CV◈	—	—
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J VT Rx1–Rx2: 20◈ J VT Rx3–Rx6: 35◈ J FVT Rx1–Rx6: 35◈ J	—	—
Pathway[a]	AX>B; B>AX Rx1–Rx4: B>AX◈ Rx5–Rx6: AX>B◈	—	—
Burst therapy parameters			
Initial # Pulses	1; 2 … 8◈ … 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%	—	—
Interval Dec	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 10 VT Therapies: 3◈ FVT Therapies: 1◈	—	—
Smart Mode[b]	On; Off◈	—	—
Ramp therapy parameters			
Initial # Pulses	1; 2 … 8◈ … 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
Interval Dec	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 10 VT Therapies: 3◈ FVT Therapies: 1◈	—	—
Smart Mode[b]	On; Off◈	—	—
Ramp+ therapy parameters			
Initial # Pulses	1; 2; 3◈ … 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 … 75◈ … 84; 88; 91; 94; 97%	—	—
S1S2(Ramp+)=(%RR)	50; 53; 56; 59; 63; 66; 69◈ … 84; 88; 91; 94; 97%	—	—
S2SN(Ramp+)=(%RR)	50; 53; 56; 59; 63; 66◈ … 84; 88; 91; 94; 97%	—	—

Table 13. Ventricular tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
# Sequences	1; 2 … 10 VT Therapies: 3◈ FVT Therapies: 1◈	—	—
Smart Mode[b]	On; Off◈	—	—
Shared Settings…			
V-V Minimum ATP Interval	150; 160 … 200◈ … 400 ms	200 ms	200 ms
V. Amplitude	1; 2 … 6; 8◈ V	8 V	8 V
V. Pulse Width	0.1; 0.2 … 1.5◈ ms	1.5 ms	1.5 ms
V. Pace Blanking	170; 180 … 240◈ … 450 ms	240 ms	240 ms
V. Pacing[c]	RV◈; RV+LV; LV	RV	RV
Active Can/SVC Coil[d]	Can+SVC On◈; Can Off; SVC Off	Can+SVC On	Can+SVC On
Progressive Episode Therapies	On; Off◈	Off	Off
Confirmation+	On◈; Off	On	On

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.
[b] Smart Mode is available only for Rx1– Rx4.
[c] If RV+LV is selected, the ATP therapy is delivered LV→RV with a 2.5 ms delay.
[d] The Active Can/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock inductions.

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	—
Lower Rate[a]	30; 35 … 50◈; 55; 60; 70; 75 … 150 bpm	50 bpm	65 bpm
Upper Tracking Rate	80; 85 … 130◈ … 175 bpm	130 bpm	—
Paced AV[b]	30; 40 … 130◈ … 350 ms	130 ms	—
Sensed AV[b]	30; 40 … 100◈ … 350 ms	100 ms	—
PVARP	Auto◈; 150; 160 … 500 ms	Auto	—
Minimum PVARP	150; 160 … 250◈ … 500 ms	250 ms	—
A. Refractory Period	150; 160 … 310◈ … 500 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	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[a]	0.15; 0.3◈; 0.45; 0.6; 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV; Off	0.3 mV	0.3 mV

[a] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

Table 16. RV parameters

Parameter	Programmable values	Shipped	Reset
RV Amplitude	0.5; 0.75 … 3.5◈ … 5; 5.5; 6; 8 V	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[a]	0.15; 0.3◈; 0.45; 0.6; 0.9; 1.2 mV	0.3 mV	0.3 mV
RV Pace Polarity	Bipolar; Tip to Coil	Bipolar	Bipolar
RV Sense Polarity	Bipolar; Tip to Coil	Bipolar	Bipolar

[a] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

Table 17. LV parameters

Parameter	Programmable values	Shipped	Reset
LV Amplitude	0.5; 0.75 … 4◈ … 5; 5.5; 6; 8 V	4 V	—
LV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4◈ … 1.5 ms	0.4 ms	—
LV Pace Polarity	LVtip to RVcoil; LVring to RVcoil; LVtip to LVring; LVring to LVtip	LVtip to RVcoil	—

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[a]	0◈; 10 … 80 ms	0 ms	—
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 and V-V Pace Delay cannot be selected or programmed.

Table 19. Atrial Capture Management parameters

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

Table 21. LV Capture Management parameters

Parameter	Programmable values	Shipped	Reset
LV Capture Management	Adaptive◈; Monitor; Off	Adaptive	—
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	—

Table 22. Blanking periods

Parameter	Programmable values	Shipped	Reset
PVAB Interval	10; 20 … 150◈ … 300 ms[a] 100; 110 … 150◈ … 300 ms[b]	150 ms	150 ms
PVAB Method	Partial◈; Partial+; Absolute[c]	Partial	Partial
A. Blank Post AP	150; 160 … 200◈ … 250 ms	200 ms	—
A. Blank Post AS	100◈; 110 … 170 ms	100 ms	100 ms
V. Blank Post VP	170; 180 … 230◈ … 450 ms	230 ms	240 ms
V. Blank Post VS	120◈; 130 … 170 ms	120 ms	120 ms

[a] When PVAB Method = Partial+ or Absolute
[b] When PVAB Method = Partial
[c] Programming the PVAB method to Absolute automatically resets the interval to 30 ms. If the PVAB method is programmed to Partial or Partial+, the interval resets to 150 ms.

Table 23. Rate Response Pacing parameters

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

Table 24. Rate Adaptive AV parameters

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

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

Table 25. Atrial Rate Stabilization parameters

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

Table 26. Atrial Preference Pacing parameters

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

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

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

Table 28. Conducted AF Response parameters

Parameter	Programmable values	Shipped	Reset
Conducted AF Response	On◈; Off	On	—
Response Level	Low; Medium◈; High	Medium	—
Maximum Rate	80; 85 … 110◈ … 130 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	—	—
Interval Increment	100; 110 … 150◈ … 400 ms	—	—

Table 30. Post VT/VF Shock Pacing parameters

Parameter	Programmable values	Shipped	Reset
Post VT/VF Shock Pacing	On; Off◈	Off	Off
Overdrive Rate	70; 75; 80◈ … 120 bpm	—	—
Overdrive Duration	0.5◈; 1; 2; 3; 5; 10; 20; 30; 60; 90; 120 min	—	—

Table 31. Post Shock Pacing parameters

Parameter	Programmable values	Shipped	Reset
Post Shock A. Amplitude	1; 2; 3; 4◈; 5; 6; 8 V	4 V	—
Post Shock A. Pulse Width	0.1; 0.2 … 1.5◈ ms	1.5 ms	—
Post Shock V. Amplitude[a]	1; 2 … 6◈; 8 V	6 V	6 V
Post Shock V. Pulse Width[a]	0.1; 0.2 … 1.5◈ ms	1.5 ms	1.5 ms

[a] Applies to all ventricular chambers paced.

Table 32. Rate Drop Response parameters

Parameter	Programmable values	Shipped	Reset
Rate Drop Response[a]	On; Off◈	Off	Off
Detection Type	Drop◈; Low Rate; Both	—	—
Drop Size	10; 15 … 25◈ … 50 bpm	—	—
Drop Rate	30; 40 … 60◈ … 100 bpm	—	—

Table 32. Rate Drop Response parameters (continued)

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

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

Table 33. Sleep parameters

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

Table 34. Non-Competitive Atrial Pacing (NCAP) parameters

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

Table 35. MRI SureScan parameters

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

Table 36. Additional pacing features

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

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

6.6 Medtronic CareAlert parameters

Table 37. Clinical Management Alerts

Parameter	Programmable values	Shipped	Reset
OptiVol 2.0 Fluid Settings…			
Device Tone			
OptiVol Alert Enable	Off (Observation only)	Off (Observation only)	Off (Observation only)
OptiVol Threshold[a]	30; 40; 50; 60◈ … 180	60	60
AT/AF Burden and Rate Settings…			
Device Tone			
Alert Urgency[b]	High◈; Low	—	—
AT/AF Daily Burden Alert Enable	Off (Observation only)◈; On	Off (Observation only)	Off (Observation only)
Avg. V. Rate During AT/AF Alert Enable	Off (Observation only)◈; On	Off (Observation only)	Off (Observation only)
Patient Home Monitor			
AT/AF Daily Burden Alert Enable[c]	Off◈; On	—	—
Avg. V. Rate During AT/AF Alert Enable[c]	Off◈; On	—	—
Shared (Device Tone and Patient Home Monitor)			
AT/AF Daily Burden	0.5; 1; 2; 6◈; 12; 24 hours/day	6 hours/day	6 hours/day
Avg. V. Rate During AT/AF	90; 100◈ … 150 bpm	100 bpm	100 bpm
Daily Burden for Avg. V. Rate	0.5; 1; 2; 6◈; 12; 24 hours/day	6 hours/day	6 hours/day
Number of Shocks Delivered in an Episode…[d]			
Device Tone			
Alert Enable - Urgency	Off◈; On-Low; On-High	Off	Off
Patient Home Monitor			
Alert Enable[c]	Off◈; On	—	—
Shared (Device Tone and Patient Home Monitor)			
Number of Shocks Threshold[b]	1◈; 2; 3; 4; 5; 6	—	—
All Therapies in a Zone Exhausted for an Episode.			
Device Tone			
Alert Enable - Urgency	Off◈; On-Low; On-High	Off	Off

Table 37. Clinical Management Alerts (continued)

Parameter	Programmable values	Shipped	Reset
Patient Home Monitor			
Alert Enable[c]	Off◈; On	—	—

[a] 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.
[b] This parameter is displayed only if an associated alert has been enabled.
[c] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.
[d] Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

Table 38. Lead/Device Integrity Alerts

Parameter	Programmable values	Shipped	Reset
RV Lead…			
Device Tone			
Alert Urgency[a]	Low; High◈	High	—
RV Lead Integrity Enable	On◈; Off	On	Off
RV Lead Noise Enable	On◈; Off	On	Off
Patient Home Monitor			
RV Lead Integrity Enable[b]	On◈; Off	—	—
RV Lead Noise Enable[b]	On◈; Off	—	—
Lead Impedance Out of Range…			
Device Tone			
Alert Urgency[a]	Low; High◈	High	—
A. Pacing Impedance Enable	On◈; Off (Observation only)	On	Off (Observation only)
RV Pacing Impedance Enable	On◈; Off (Observation only)	On	Off (Observation only)
LV Pacing Impedance Enable	On◈; Off (Observation only)	On	Off (Observation only)
RV Defibrillation Impedance Enable	On◈; Off (Observation only)	On	Off (Observation only)
SVC Defibrillation Impedance Enable[c]	On◈; Off (Observation only)	On	Off (Observation only)
Patient Home Monitor			
A. Pacing Impedance Enable[b]	Off; On◈	—	—
RV Pacing Impedance Enable[b]	Off; On◈	—	—
LV Pacing Impedance Enable[b]	Off; On◈	—	—
RV Defibrillation Impedance Enable[b]	Off; On◈	—	—

Table 38. Lead/Device Integrity Alerts (continued)

Parameter	Programmable values	Shipped	Reset
SVC Defibrillation Impedance Enable[b,c]	Off; On◈	—	—
Shared (Device Tone and Patient Home Monitor)			
A. Pacing Impedance Less than	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
A. Pacing Impedance Greater than	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω
RV Pacing Impedance Less than	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
RV Pacing Impedance Greater than	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω
LV Pacing Impedance Less than	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
LV Pacing Impedance Greater than	800; 1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω
RV Defibrillation Impedance Less than	20◈; 30; 40; 50 Ω	20 Ω	20 Ω
RV Defibrillation Impedance Greater than	100; 130; 160; 200◈ Ω	200 Ω	200 Ω
SVC Defibrillation Impedance Less than	20◈; 30; 40; 50 Ω	20 Ω	20 Ω
SVC Defibrillation Impedance Greater than	100; 130; 160; 200◈ Ω	200 Ω	200 Ω
Low Battery Voltage RRT…			
Device Tone			
Alert Enable - Urgency	Off; On-Low; On-High◈	On-High	Off
Patient Home Monitor			
Alert Enable[b]	Off; On◈	—	—
Excessive Charge Time EOS…			
Device Tone			
Alert Enable - Urgency	Off; On-Low; On-High◈	On-High	Off
Patient Home Monitor			
Alert Enable[b]	Off; On◈	—	—
VF Detection Off, 3+ VF or 3+ FVT Rx Off.			
Device Tone			
Alert Enable	Off; On-High◈	On-High	On-High
Patient Home Monitor			
Alert Enable[b]	Off; On◈	—	—

[a] This parameter is displayed only if an associated alert has been enabled.
[b] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.
[c] If an SVC lead is not implanted, the alert will not sound.

Table 39. Shared parameters

Parameter	Programmable values	Shipped	Reset
Patient Home Monitor	Yes; No◈	No	No
Alert Time…[a]	00:00; 00:10 … 08:00◈ … 23:50	08:00	08:00

[a] This parameter is displayed only if an associated alert has been enabled.

6.7 Data collection parameters

Table 40. Data collection parameters

Parameter	Programmable values	Shipped	Reset
LECG Source (Leadless ECG)[a]	Can to SVC◈[b,c]; RVcoil to Aring; Can to Aring	Can to SVC	Can to SVC
LECG Range (Leadless ECG)	±1; ±2◈; ±4; ±8; ±12; ±16; ±32 mV	±2 mV	±8 mV
EGM 1 Source	RVtip to RVcoil; RVtip to RVring; Atip to RVring; Atip to Aring◈; Aring to RVring; Aring to RVcoil	Atip to Aring	Atip to Aring
EGM 1 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 2 (Wavelet) Source	Can to RVcoil◈; Can to RVring; RVtip to RVcoil; RVtip to RVring; Can to SVC[b,c]; RVcoil to SVC[b]; LVtip to SVC[b]; Can to LVtip; RVtip to LVtip	Can to RVcoil	Can to RVcoil
EGM 2 (Wavelet) Range	±1; ±2; ±4; ±8; ±12◈; ±16; ±32 mV	±12 mV	±12 mV
EGM 3 Source	RVtip to RVcoil; RVtip to RVring; LVtip to LVring[d]; LVtip to RVring; LVtip to RVcoil◈; LVring to RVcoil	LVtip to RVcoil	LVtip to RVcoil
EGM 3 Range	±1; ±2; ±4; ±8; ±12; ±16◈; ±32 mV	±16 mV	±2 mV
Monitored	EGM1 and EGM2◈; EGM1 and EGM3; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG	EGM1 and EGM2	EGM1 and EGM2
Pre-arrhythmia EGM	Off◈; On - 1 month; On - 3 months; On Continuous	Off	Off
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[e]	(Enter time and date)	—	—
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off

[a] This EGM channel displays far-field signals. To display an approximation of a surface ECG signal, choose the Can to SVC EGM source.

[b] An SVC electrode must be present for this configuration.

[c] If the Can to SVC source is selected, the EGM Range is automatically set to ±2 mV. The EGM Range is automatically set to ±8 mV for all other EGM Source options.
[d] A bipolar LV lead must be present for this configuration.
[e] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

6.8 System test parameters

Table 41. System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type (LV test)	Amplitude; Pulse Width; Phrenic Nerve Stim - Amplitude; Phrenic Nerve Stim - Pulse Width
Test Type (Atrium or RV test)	Amplitude; Pulse Width
Chamber	Atrium; RV; LV
Decrement after	2; 3 … 15 pulses
Pace Polarity (RV)	Bipolar; Tip to Coil
Pace Polarity (LV)	LVtip to RVcoil; LVring to RVcoil; LVtip to LVring; LVring to LVtip
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
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
AV Delay	30; 40 … 350 ms
V. Pace Blanking	150; 160 … 450 ms
A. Pace Blanking	150; 160 … 250 ms
PVARP[c]	150; 160 … 500 ms
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
CardioSync Optimization Test parameters	
Sensing Lower Rate	30; 35 … 60; 70; 75 … 90 bpm
Pacing Lower Rate	35; 40 … 60; 70; 75 … 95 bpm

Table 41. System test parameters (continued)

Parameter	Selectable values
Wavelet Test parameters	
Match Threshold	40; 43 … 70◈ … 97
Mode[a]	AAI; DDD; DDI; VVI; ODO
AV Delay	30; 40 … 350 ms
Lower Rate[b]	30; 35 … 60; 70; 75 … 120 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.
[c] The selectable values for this parameter depend on the programmed PVAB values.

6.9 EP study parameters

Table 42. T-Shock induction parameters

Parameter	Selectable values
Chamber[a]	RV◈; RV+LV; LV
Resume at Deliver	Enabled◈; Disabled
Enable	Enabled; Disabled◈
#S1	2; 3; 4; 5◈; 6; 7; 8
S1S1	300; 310 … 400◈ … 2000 ms
Delay	20; 30 … 300◈ … 600 ms
Energy	0.4; 0.6; 0.8; 1.0◈ … 1.8; 2; 3; 4 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J
Waveform	Monophasic◈; Biphasic
Pathway[b]	AX>B; B>AX◈

[a] If the chamber selected is RV+LV, the delay is set to 2.5 ms with LV pace delivered first.
[b] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Table 43. 50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled◈; Disabled
Chamber	Atrium; RV; LV
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms
VOO Backup (for atrial 50 Hz Burst)[a]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm

Table 43. 50 Hz Burst induction parameters (continued)

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

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

Table 44. 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
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 45. 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 … 400; 410 … 600 ms[b]
S3S4	Off◈; 100; 110 … 400; 410 … 600 ms[b]
Amplitude[c]	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width[c]	0.10; 0.20 … 0.50◈ … 1.50 ms
VVI Backup (for atrial PES)[d]	On; Off◈
Pacing Rate	60; 70◈ … 120 bpm

Table 45. PES induction parameters (continued)

Parameter	Selectable values
V. Amplitude[e,f]	0.50; 0.75 … 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[e]	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] Default value when parameter is On is 400 ms.
[c] Applies to all ventricular chambers paced.
[d] V. Backup Pacing is delivered to the RV chamber.
[e] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[f] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Table 46. Manual Defibrillation parameters

Parameter	Selectable values
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J
Pathway[a]	AX>B; B>AX◈

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Table 47. Manual Cardioversion parameters

Parameter	Selectable values
Chamber	Atrium; RV
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35◈ J
Pathway[a]	AX>B; B>AX◈
Minimum R-R (atrial CV only)	400; 410 … 500◈ … 600 ms

[a] If the Active Can/SVC Coil parameter is set to Can Off, the Active Can electrode is not used as part of the high-voltage delivery pathway. If the Active Can/SVC Coil parameter is set to SVC Off, the SVC Coil electrode is not used as part of the high-voltage delivery pathway.

Table 48. 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 48. 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 49. 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 50. 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 51. 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%
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%

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

Table 52. 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

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