Medtronic

Cobalt™ XT VR MRI SureScan™ DVPA2D4

MR Conditional implantable single chamber cardioverter defibrillator with SureScan™ technology and Bluetooth® wireless telemetry (VVE-VVIR)

Device Manual

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1 System overview

1.1 CE mark of conformity

CE 0123

2019

1.2 Introduction

This manual describes the Medtronic Model DVPA2D4 Cobalt XT VR MRI SureScan single chamber, implantable cardioverter defibrillator (ICD). It contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

The following manuals and documents also contain information about the device:

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

Reference manual – This manual includes information about device features. The reference manual applies to multiple models of ICD devices.

Implantable device app help – The help explains how to use the implantable device app to program the device settings and view the stored device data.

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

Medical Procedure and EMI Warnings, Precautions, and Guidance 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. This manual also includes information about hazards from sources of electromagnetic interference (EMI) in the patient's home, recreational environments, and occupational environments.

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

1.3 System description

The Model DVPA2D4 single chamber, implantable cardioverter defibrillator (ICD) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate by providing single chamber, rate-responsive bradycardia pacing and ventricular tachyarrhythmia therapies. This device features Bluetooth wireless technology.[1]

The device can detect ventricular tachyarrhythmias (VT/VF) automatically and provide treatment with defibrillation, cardioversion, and antitachycardia pacing therapies. The device responds to bradyarrhythmias by providing bradycardia pacing therapy. The device automatically detects and records the occurrence of atrial fibrillation (AF) for diagnostic purposes.

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

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.

1.3.1 Usage environments

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

- The device will be implanted in a properly equipped, staffed, and sterile surgical environment. Implant will take place under standard surgical protocols and in the patient population for which the device is indicated.
- Post-surgical patient and device follow-up care will take place in a properly equipped and staffed cardiology clinic or office.
- MRI procedures for patients with this device will take place in a properly equipped and staffed MR facility, and in consideration of the conditions and requirements described in Section 1.6.
- After having an implant, patients may resume their lives at home, at work, and in other environments with consideration of the advice and restrictions documented in the Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals.

1.3.2 System components and accessories

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

Connectors – The device has a DF4 inline connector, which facilitates the connection of a DF4-LLHH right ventricular (RV) lead or a DF4-LLHO RV lead during 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 sensing, pacing, cardioversion, and defibrillation therapies to the right ventricle (RV). 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 3.2, “Selecting and implanting the leads”, page 17.

Implantable device system – The Model DVPA2D4 along with its pacing and defibrillation lead constitute the implantable portion of the device system.

Device manager – Healthcare professionals and Medtronic representatives use the device manager in a clinical or hospital environment to perform implant and follow-up procedures. The device manager consists of a base, a patient connector, and a device manager app installed on a tablet. The device manager app is the primary interface of the device manager and provides access to the implantable device app and the analyzer. For more information, refer to the device manager instructions for use, including the help.

Programmers from other manufacturers are not compatible with Medtronic devices, but they do not damage Medtronic devices.

Home communicator – Patients use the home communicator to gather information automatically from their implanted device and communicate the information to their physicians through the Medtronic CareLink Network. For information on using the home communicator, refer to the home communicator instructions for use.

Patient app – Patients use the patient app to transmit information from their implanted device to their physicians through the Medtronic CareLink Network. For information on using the patient app, refer to the patient app instructions for use.

1.4 Indications and usage

The Cobalt XT VR MRI SureScan device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular arrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies.

Note: For patient-specific recommendations such as primary and secondary preventions, refer to current clinical guidelines.

1.5 Contraindications

The Model DVPA2D4 device is contraindicated for use in the following situations:

- If implanted with a unipolar pacemaker
- If incessant VT or VF exists
- If the primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
- If tachyarrhythmias with transient or reversible causes exist, including the following known issues:
  - acute myocardial infarction
  - drug intoxication
  - drowning
  - electric shock
  - electrolyte imbalance
  - hypoxia
  - sepsis

1.6 MRI conditions for use

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

- The Model DVPA2D4 device
- A SureScan defibrillation lead

A complete SureScan system only includes components that have been certified by Medtronic as being MR Conditional. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

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

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

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

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

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- The SureScan system is implanted in the left or the 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 the MRI SureScan mode is programmed to On, no diaphragmatic stimulation is present when the paced leads have a pacing output of 5.0 V and a pulse width of 1.0 ms.

Caution: 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 the MRI SureScan mode is programmed to On.
- If patient rescue is required, an external defibrillator must be immediately available.

Note: For radiology requirements for an MRI scan, refer to the MRI technical manual.

1.7 Pre-implant consideration

Patient evaluation for the implant of the Model DVPA2D4 system 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, a pacemaker, a defibrillator, or a monitor). In this case, physicians (for example, a neurologist, a neurosurgeon, a cardiologist, and a cardiac surgeon) involved with either device should contact 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.

1.8 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 5, “Device parameters”, page 30.

For more information about these features, see the reference manual and the implantable device app help.

1.8.1 Tachyarrhythmia detection features

Note: When the MRI SureScan mode 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.

AF detection (TruAF Detection algorithm) – This feature analyzes variability in the ventricular rate to determine whether the patient is currently experiencing atrial fibrillation. Evidence of atrial fibrillation is based on ventricular rate variability assessed via a Lorenz plot.

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

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

SmartShock 2.0+ technology – A collection of VT/VF detection features designed to reduce the incidence of inappropriate and unnecessary shocks while maintaining sensitivity for VT/VF arrhythmias. The collection of features includes Confirmation+, Intrinsic ATP algorithm, RV Lead Integrity Alert, RV Lead Noise Discrimination, SVT Discriminators in VF Zone, TWave Discrimination, and Wavelet.

- **Confirmation+ –** The Confirmation+ feature identifies if a tachycardia has been terminated with ATP or has spontaneously ended during the charge. The Confirmation+ feature identifies and cancels a pending defibrillation shock. The Confirmation+ feature avoids inappropriate shocks for single PVCs or single fast events at the end of the charge.

- **Intrinsic ATP algorithm –** Intrinsic ATP (iATP) is an automated ATP therapy for reentrant ventricular tachycardia (VT). iATP uses heart rate history to design the first ATP sequence and analyzes the result of each ATP sequence in real-time to design the next ATP sequence, if necessary. iATP delivers ATP until it terminates VT or reaches its programmed number of ATP sequences. If iATP does not terminate VT, the device progresses to the next programmed therapy.
- **RV Lead Integrity Alert –** The RV Lead Integrity Alert feature sounds an alert tone when a potential lead problem is suspected. When the alert criteria are met, device settings are automatically adjusted to prevent delivery of inappropriate and unnecessary therapy.
- **RV Lead Noise Discrimination and Alert –** The RV Lead Noise Discrimination and Alert feature identifies lead noise due to a suspected lead problem. This feature withholds VT/VF detection to prevent delivery of inappropriate therapy. An alert tone can be programmed to notify the patient.
- **SVT Discriminators in VF Zone –** The SVT Discriminators in VF Zone feature limits nominal changes to 260 ms with high rate timeout.
- **TWave Discrimination –** The TWave Discrimination feature withholds VT/VF detection when a fast ventricular rate is detected due to sensed T-waves, avoiding delivery of inappropriate therapy.
- **Wavelet –** The Wavelet feature prevents detection of rapidly conducted SVTs as ventricular tachyarrhythmias by comparing the shape of each QRS complex during a fast ventricular rate to a template.

Stability – This feature helps to prevent the 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.

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.

1.8.2 Tachyarrhythmia therapy features

Note: When the MRI SureScan mode 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.

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.

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.

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. The ATP During Charging feature allows the device to deliver a sequence of ventricular antitachycardia pacing therapy while the device charges its capacitors for the first defibrillation therapy. The device can also be programmed to attempt an additional sequence of ATP therapy 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, Ramp+, and iATP. Burst, Ramp, and Ramp+ all have a programmable number of sequences, while iATP automatically sets ATP sequences tailored for the patient.

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

1.8.3 Diagnostic data features

Note: When the MRI SureScan mode 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.

Quick Look – This feature 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, capture thresholds, and therapies provided.

Medtronic CareAlert Monitoring – If the device identifies any programmed or automatic CareAlert conditions, this feature sends a wireless alert signal to the home communicator or the patient app. The home communicator or the patient app then transmits the CareAlert event data to the Medtronic CareLink Network. If configured to do so, the Medtronic CareLink Network then sends an alert notification to the clinic.

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 alert tone sounds to notify the patient to seek medical attention.

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

Heart Failure Management Report – This report provides an overview of the patient's condition over the short term and the long term with a focus on heart failure management. The report includes graphs that show the OptiVol 2.0 fluid trends and the trends related to heart failure over the last 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 are episode and therapy counters 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 the date and time, the duration, the intervals and markers, the maximum ventricular rates, and an indication of whether the episode was part of a tachyarrhythmia.

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

1.8.4 Pacing features

Conducted AF Response – This feature helps to promote a regular ventricular rate during conducted AT/AF episodes by increasing the pacing rate in concert with the patient's intrinsic ventricular response.

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.

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

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 feature adjusts the pacing rate dynamically to eliminate the long pause that typically follows a premature ventricular contraction (PVC).

1.8.5 Testing features

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 stimulation thresholds. This information can be used to determine appropriate amplitude and pulse width settings that ensure capture and minimize output.

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.

1.8.6 Additional operations

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

1.9 Data security

Medtronic has designed safeguards to protect patient information and device data for the Model DVPA2D4 device.

BlueSync technology – The device uses Bluetooth wireless technology to communicate with the device manager, the patient app, and the home communicator. Critical data accepted or sent through the Bluetooth communication from the device is encrypted by the device before it is sent over the Bluetooth channel. The device responds only to authorized commands.

Inductive telemetry communication system – The Medtronic inductive telemetry communication system is used with the device manager to interrogate and program the device. This system uses short-range communication that protects patient information and device data.

1.10 Pacing mode information

Pacemaker modes are described using the NBG code. The five-letter NBG code, named after The North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG), describes the operation of implantable pulse generators. The NBG code, which supersedes the ICHD Code, is described in Table 1.

Table 1. The Revised NASPE/BPEG Generic Code for antibradycardia pacing

Position:	I	II	III	IV	V
Category:	Chamber(s) paced	Chamber(s) sensed	Response to sensing	Rate modulation	Multisite pacing[a]
	O = None A = Atrium V = Ventricle D = Dual (A + V)	O = None A = Atrium V = Ventricle D = Dual (A + V)	O = None T = Triggered I = Inhibited D = Dual (T + I)	O = None R = Rate modulation	O = None A = Atrium V = Ventricle D = Dual (A + V)
Manufacturers' designation only:	S = Single[b] (A or V)	S = Single[b] (A or V)			

[a] Medtronic devices do not use the multisite pacing code.
[b] The implantable device app displays A or V (not S) for chambers paced and sensed.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

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

- The Model DVPA2D4 device
- A SureScan defibrillation lead

A complete SureScan system only includes components that have been certified by Medtronic as being MR Conditional. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com.

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

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

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

Refer to the Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals 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.

Medical procedure warnings and precautions that pertain to the Medtronic implanted system are provided in the manual that is packaged with the device or on the Medtronic Manual Library website (www.medtronic.com/manuals).

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 during acute lead system testing, the implant procedure, or whenever tachyarrhythmias are possible or intentionally induced during post-implant testing.

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

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

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.
- The implantable device is intended for single use only. Do not resterilize and reimplant an explanted device.
- Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

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. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

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

Dropped device – Do not implant the device if it is dropped on a hard surface from a height of 30 cm 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.

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. Electrical reset may occur at temperatures below –18°C. Device longevity may decrease and performance may be affected at temperatures above +55°C.

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 torque wrench) have torque capabilities greater than the lead connector can tolerate.

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

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

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 the 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 a lead, causing electrical current to bypass the heart and possibly damage the device and the lead.

2.5 Device operation

Warning: Leads other than SureScan leads may be used with the DVPA2D4 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.

Battery depletion – Carefully monitor device longevity by checking the battery voltage and the replacement indicators. Battery depletion eventually causes the device to stop functioning.

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

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

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and implantable cardioverter defibrillators should generally be explanted.

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

Device reset – Electrical reset can be caused by exposure to temperatures below –18°C or to 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 min^{-1}. Electrical reset is indicated by a warning message that is immediately displayed on the implantable device app 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.

EOS (end of service) indicator – Replace the device immediately if the implantable device app displays an EOS indicator. The device may soon lose the ability to pace, to sense, and to deliver therapy adequately.

Defibrillation threshold testing – Changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold, 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.

Magnets – Placing a magnet over the device suspends tachyarrhythmia detection.

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.

Pediatric use – The device has not been tested specifically for pediatric use.

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

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

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

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.

Sensitivity setting – 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. When susceptibility to modulated interference is tested under the conditions specified in CENELEC standard EN 45502-2-2, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of clause 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher.

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.

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

OVO pacing mode – Pacing is disabled under OVO mode. Do not program the OVO 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:

- Allergic reaction
- Atrial fibrillation
- Bradyarrhythmia
- Cardiac arrest
- Device migration
- Discomfort
- Dizziness
- Dyspnea
- Erosion
- Excessive fibrotic tissue growth
- Hematoma
- Hemorrhage
- Inability to deliver therapy
- Inappropriate shock
- Infection
- Lead migration/dislodgement
- Lethargy
- Loss of pacing
- Mental anguish
- Necrosis
- Nerve damage
- Oversensing
- Palpitations
- Seroma
- Syncope
- Tachyarrhythmia
- Tissue damage due to heating of device
- Undersensing
- Wound dehiscence

3 Implant procedure

3.1 Preparing for an implant

To retain the ability to safely scan the SureScan defibrillation system during MRI scans, the MRI conditions for use in Section 1.6 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 3.8, “Replacing a device”, page 23.

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

3.1.1 Instruments, components, and accessories required for an implant

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

- Medtronic device manager
- External defibrillator

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

- Implantable device and lead system components
- Pacing system analyzer cables
- Lead introducers appropriate for the lead system
- Extra stylets of appropriate length and shape

3.1.2 Setting up and starting the device manager

Set up the device manager using the instructions for use provided with the system. Establish telemetry with the device and start a patient session.

3.1.3 Considerations for preparing for an implant

Review the following information before implanting the lead or device:

Warning: Leads other than SureScan leads may be used with the Model DVPA2D4 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 during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during postimplant 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 lead. While the device is connected to the lead, 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. Battery longevity could 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.

3.1.4 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 create an Initial Interrogation Report.
   Caution: If the implantable device app reports that a device reset occurred, do not implant the device. Contact a Medtronic representative.

2. To confirm that the device is acceptable for implant, check the status of the **REMAINING LONGEVITY** estimate on the **Quick Look** screen. 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 can be temporarily lower and the charge time can 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** screen is gray, indicating that the battery status is unacceptable, do not charge the capacitors.
3. On the implantable device app, set the **Time Zone** for the internal clock of the device.
4. Program the therapy and pacing parameters to values appropriate for the patient. Ensure that tachyarrhythmia detection is not programmed to On.
   Notes:
   - Do not enable a pacing feature that affects the pacing rate (for example, Ventricular Rate Stabilization) before implanting the device. Taking this action can cause 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.

3.2 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 defibrillation 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 single chamber SureScan defibrillation system includes the following components:

- The Model DVPA2D4 device
- A SureScan defibrillation lead

3.2.1 Selecting the leads

The device typically is implanted with 1 quadripolar/tripolar transvenous lead with a DF4-LLHH or DF4-LLHO connector in the right ventricle (RV) for sensing, pacing, and for cardioversion and defibrillation therapies. A dual-coil lead will increase P-wave amplitudes in a stored AF episode EGM.

3.2.2 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.

Warning: Lead adaptors compromise the ability to safely perform an MRI scan on the SureScan defibrillation system in the future. Devices connected with lead adaptors are contraindicated for an MRI scan. Refer to the MRI technical manual for additional information.

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 2 to select a compatible lead.

Table 2. Lead and connector compatibility

Connector port (electrodes)	Primary lead
RV (RVtip, RVring, RVcoil, SVC coil)	DF4-LLHH or DF4-LLHO[a] quadripolar/tripolar

[a] 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).

3.2.3 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 the insulation, which may cause unwanted high-voltage therapies or 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.

3.3 Testing the lead system

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

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

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

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

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

3.3.1 How to verify and save the sensing and pacing values

Medtronic recommends that you use a Medtronic 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 instructions for use for detailed procedures about performing the lead measurements.

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

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

To perform lead measurements using the device manager, take the following actions:

1. From the device manager app, start an analyzer session.
2. Measure the EGM amplitude and capture threshold using the analyzer.
3. Use the information in Table 3 to verify that the measured values are acceptable.
   Note: The measured pacing lead impedance reflects the 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 the type of lead you are testing and save the measurements.

5. Select the saved measurements that you want to export. You can select a single measurement for each lead type.
   Note: The selected measurements are exported to the IMPLANT window, which is accessible from the PATIENT INFORMATION screen in the device session.
6. Program the imported values into the device memory.

Table 3. Acceptable sensing and pacing values

Measurements required	Acute transvenous leads	Chronic leads[a]
R-wave EGM amplitude (RV)	≥5 mV	≥3 mV
Capture threshold (0.5 ms pulse width)		
	≤1.0 V (RV)	≤3.0 V (RV)

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

3.4 Connecting the leads to the device

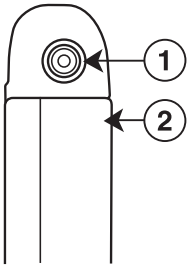
The following procedure describes how to connect the lead to the device, how to confirm that the lead connector is fully inserted in the connector block, and how to verify that the lead connection is secure.

Warning: After connecting the leads, verify that the lead connections are secure by gently tugging on each lead. A loose lead connection may result in inappropriate sensing, which can cause 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. Other torque wrenches (for example, a blue-handled or right-angled torque wrench) have torque capabilities greater than the lead connector can tolerate.

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

Figure 1. Lead connector ports

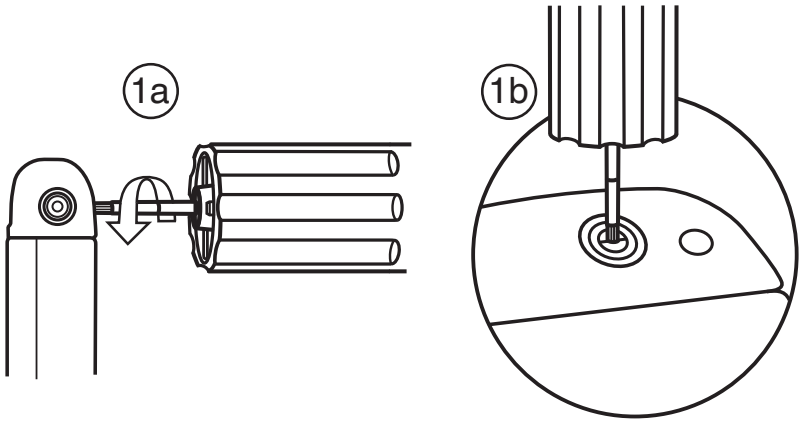


1 DF4-LLHH connector port, RV
2 Device Active Can electrode

3.4.1 How to connect a lead to the device

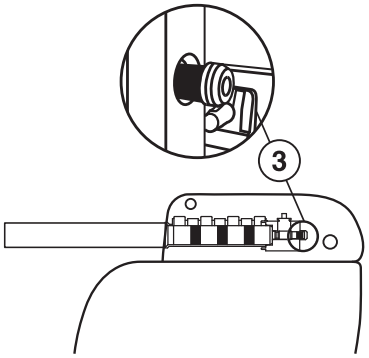
1. Insert the torque wrench into the appropriate setscrew.
   a. If the setscrew obstructs the port, retract the setscrew by turning it counterclockwise until the port is clear (see Figure 2). Do not remove the setscrew from the connector block.
   b. Leave the torque wrench in the setscrew until the 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 clearly visible in the pin viewing area. If necessary, sterile water may be used as a lubricant. No sealant is required.
3. Confirm that the lead is fully inserted into the connector pin cavity by viewing the device connector block from the side. 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



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.

3.5 Performing ventricular defibrillation threshold tests

You can test the operation of ventricular defibrillation and the effectiveness of the implanted lead system by using either the T-Shock method or the 50 Hz Burst method to induce VF. You can then use the programmed automatic therapies to detect and treat the VF. Use your preferred method to verify that you have established adequate safety margins for sensing and defibrillation.

Carefully consider the use of VF to test the operation of ventricular defibrillation and the effectiveness of the implanted lead system. Use your discretion to decide whether to test or how to test for an adequate safety margin.

3.5.1 High-voltage implant values

See Table 4 for information about the measured high-voltage therapy values that are recommended at implant.

Table 4. High-voltage (HV) therapy values recommended at implant

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

3.5.2 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 patient connector and the device.
2. Program the Active Can/SVC Coil parameter to On or Off, as appropriate for the patient.
3. Observe the markers on the Live Rhythm Monitor 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, see Table 4 and refer to the lead technical manual. 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.

For instructions on performing defibrillation threshold testing using T-Shock and 50 Hz Burst, refer to the implantable device app help.

3.6 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.

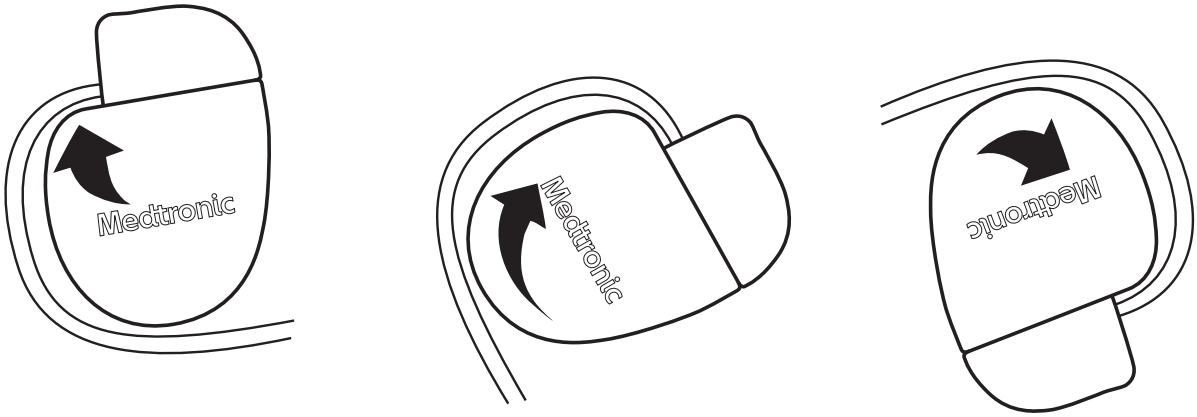
Note: Implant the device within 4 cm (1.6 in) of the surface of the skin to optimize the ability to connect to a wireless monitor.

Note: Implant the device with the engraved Medtronic logo side facing toward the skin to optimize the system performance. In addition, this orientation utilizes the PhysioCurve design to enhance patient comfort.

3.6.1 How to position and secure the device

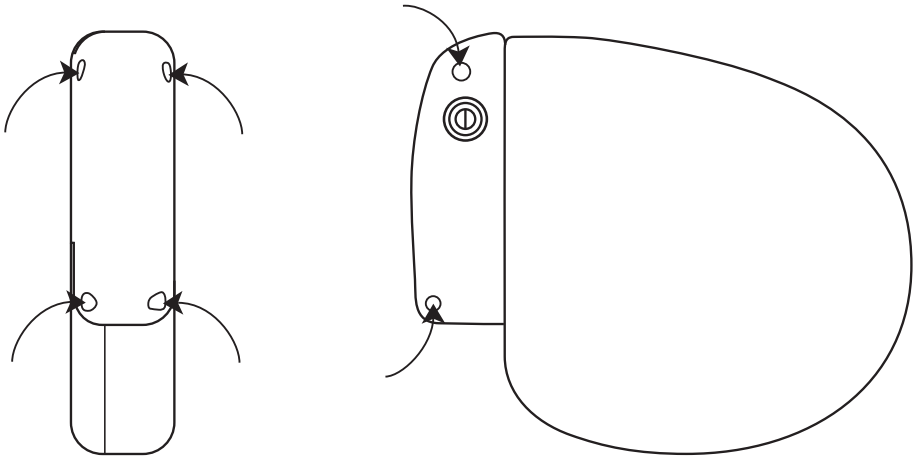
1. Verify that the lead connector pin is fully inserted into the connector port and that the setscrew is tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see Figure 4). Do not kink the lead body.

Figure 4. Rotating the device to wrap the lead



3. Place the device and the lead into the surgical pocket with the engraved Medtronic logo side facing toward the skin.
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 5).

Figure 5. Locating the suture holes



5. Suture the pocket incision closed.

3.7 Completing the implant procedure

3.7.1 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: Use the PATIENT INFORMATION screen to enter complete information about the implanted leads. Use the MRI SureScan SYSTEM/OTHER HARDWARE window 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.
   For more information about programming the device, see the implantable device app help.

3.7.2 How to assess the performance of the device and the lead

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 create a Final Report to document the postoperative programmed device status.

3.8 Replacing a device

To retain the ability to safely scan the SureScan defibrillation 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 Model DVPA2D4 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 defibrillation system during future MRI scans. When implanting a SureScan defibrillation system, consider the risks associated with removing previously implanted leads before removing the leads to maintain the ability to safely scan the SureScan defibrillation 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, you must use an adaptor. 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. Any capped or unused leads are considered abandoned leads in the MRI conditions for use, and their presence will contraindicate the system for MRI scanning. Contact your Medtronic representative for information about lead pin caps.

3.8.1 How to explant and replace a device

1. Disable tachyarrhythmia detection to avoid potential inappropriate shocks to the patient or the 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 3.3, “Testing the lead system”, page 18). 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 3.4, “Connecting the leads to the device”, page 19).
   Note: Lead adaptors may be needed to connect the leads to the replacement device. Contact a Medtronic representative for information about compatible lead adaptors.
   Warning: Lead adaptors compromise the ability to safely perform an MRI scan on the SureScan defibrillation system in the future. Devices connected 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 3.5, “Performing ventricular defibrillation threshold tests”, page 20).
9. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see Section 3.6, “Positioning and securing the device”, page 21).
10. Contact Medtronic for Return Mailer Kits to return explanted devices for analysis and disposal. See the back cover for addresses.

4 Product specifications

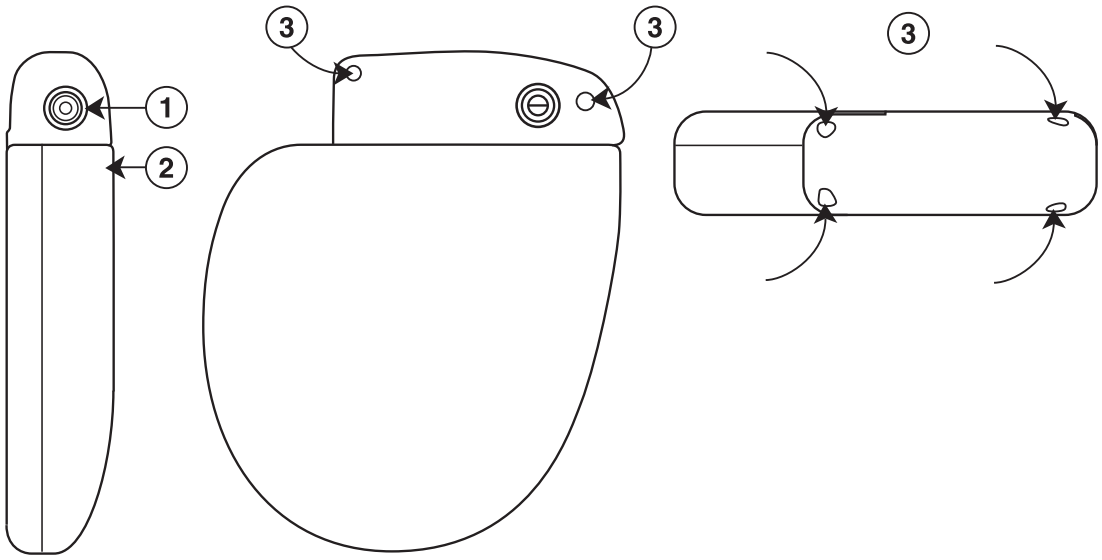
4.1 Physical characteristics

Table 5. Physical characteristics

Volume[a]	32.8 cm^3
Mass	79 g
H x W x D	64 mm x 51 mm x 13 mm
Surface area of device can	57 cm^2
Radiopaque ID[b]	PLS
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 6. Connector ports and suture holes

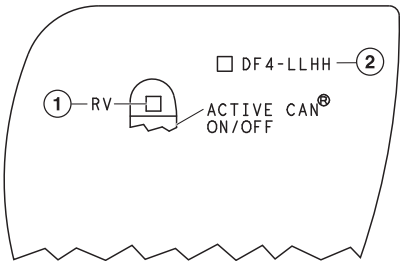


1 DF4-LLHH connector port, RV
2 Device Active Can electrode
3 Suture holes

The Model DVPA2D4 shield graphics are shown in Figure 7.

The DF4-LLHH marking in Figure 7 refers to the international standard ISO 27186, which defines the lead connector contacts as low voltage (L), high voltage (H), or open (O).

Figure 7. Shield graphics: Model DVPA2D4



1 RV = right ventricular
2 DF4-LLHH marking

4.2 Electrical specifications

Table 6. Basic battery characteristics and battery and device specifications

Battery characteristics	
Manufacturer	Medtronic Energy and Component Center
Model	Polaris
Chemistry	Hybrid CFx lithium/silver vanadium oxide
Number of cells	1

Table 6. Basic battery characteristics and battery and device specifications (continued)

Battery electrical specifications	
Nominal voltage	3.2 V
Mean capacity to RRT	1.13 Ah
Minimum capacity after RRT	0.1 Ah
Device electrical specifications	
Pacing rate limit (protective feature)[a]	200 min^{-1}
Input impedance	150 kΩ minimum

[a] Does not apply during ATP therapies or ventricular safety pacing.

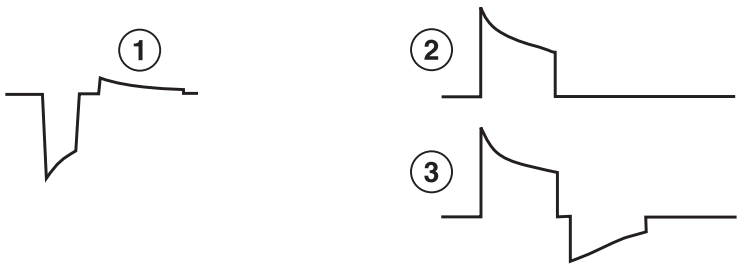
Table 7. Peak ICD output voltage during high-voltage shock delivery

Programmed energy	Peak voltage for first pulse phase	Peak voltage for second pulse phase
Minimum: 0.4 J (±0.25 J)	76 V (±16%)	36 V (±30%)
Mean: 20 J (±20%)	510 V (±10%)	255 V (±25%)
Maximum: 40 J (±15%)	728 V (±10%)	366 V (±25%)

Note: The stated values are for a 50 Ω load.

4.2.1 Output waveforms

Figure 8. Typical output waveform shapes



1 Pacing waveform
2 Monophasic high-voltage waveform (T-Shock inductions only), 50% tilt
3 Biphasic high-voltage waveform, 50% tilt

4.2.2 Measuring methods

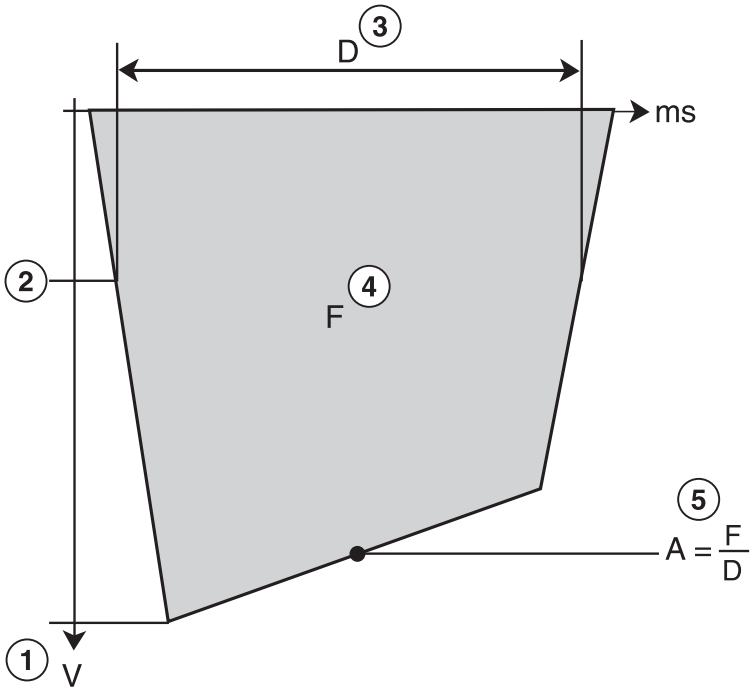
Device parameters, such as pulse duration, pulse amplitude, and sensitivity, are measured at the standard conditions of 37°C ±2°C and 500 Ω ±1% load.

Pulse duration – Pulse duration is measured at 1/3 peak voltage levels according to standard EN 45502-2-1 (see Figure 9). When applying this measurement method, the measured pulse width W depends on the load Rload (in ohms) and programmed pulse width W_p (in seconds) with tolerance $W \leq W_p + 34$ µs and $W \geq$ the smaller of (W_p - 16 µs) or [124 µs + (4 µs x Rload)].

Amplitude – The pulse amplitude is calculated according to standard EN 45502-2-1 (see Figure 9). When applying this measurement method, the measured amplitude A depends on the programmed amplitude A_p and

programmed pulse width W_p: $A = A_p \times [0.9 - (W_p \times 0.145\ ms^{-1})]$. The tolerance (+40%/-30% for voltages less than 2.0 V, and ±30% for voltages greater than or equal to 2.0 V) is applied not to the programmed setting, but to the calculated amplitude A.

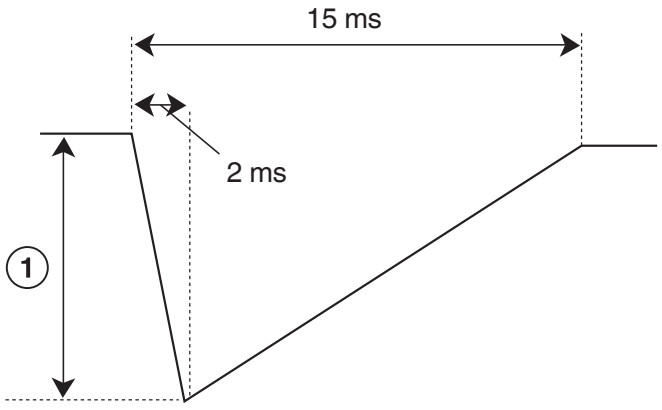
Figure 9. Measurement of pulse duration and amplitude



1 Maximum amplitude
2 1/3 maximum amplitude
3 Pulse duration (D)
4 Time integral over voltage (F)
5 Pulse amplitude (A)

Sensitivity – Sensitivity is defined as the voltage amplitude of a test signal that is just sufficient to be sensed by the device. The programmable values for RV sensitivity assume a 40 ms sine^2 waveform. When using the test signal defined in EN 45502-2-1 (see Figure 10), the rated ventricular sensing threshold will be 1.5 times the programmed RV Sensitivity value.

Figure 10. Measurement of sensitivity



1 Amplitude

Notes:

- When measuring the pacing and sensing parameters with pacing system analyzers, considerable differences may be observed with the specifications presented in this manual, because the measuring methods employed by such systems may differ from those described previously.
- Lead impedance measurement results may be distorted by electrocardiogram monitoring equipment.

Common mode rejection ratio – The common mode rejection ratio (CMRR) for frequencies 16.6 Hz, 50 Hz, and 60 Hz is at least 100 (40 dB). The calculation of the CMRR ratio was done based on measurements performed with the sinusoidal waveform injected directly into the device. The device and lead system CMRR ratio depends on several factors, such as the placement of the electrodes or electrode separation, and may be lower than the device CMRR ratio.

4.2.3 Variation with temperature

Basic rate, test pulse rate, pulse duration, and pulse amplitude remain within expected tolerances when the device temperature is between 22°C and 45°C. Sensitivity at nominal conditions as measured at 37°C can vary as much as ±1% per °C from 22°C to 45°C.

4.3 Replacement indicators

The Remaining Longevity estimate, the replacement status, and the battery voltage appear on the implantable device app and on reports. The Recommended Replacement Time (RRT) and the End of Service (EOS) conditions are listed in Table 8.

Table 8. Replacement indicators

Recommended Replacement Time (RRT)	< 2.80 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 implantable device app displays the RRT battery status to indicate that replacement of the device is recommended.

RRT date – The implantable device app displays the date when the battery reached RRT on the Quick Look and Battery and Lead Measurements screens.

EOS (End of Service) – The implantable device app 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 implantable device app 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% VVI pacing at 60 min^{-1}, 2.5 V RV pacing amplitude; 0.4 ms pulse width; 600 Ω pacing load; and 6 full-energy charges. The EOS may be indicated before the end of 3 months if the device exceeds these conditions.

4.4 Projected service life

The projected service life for the device is shown in years in Table 9. The data is based on pacing outputs programmed for the right atrium and right ventricle as specified, Pulse Widths at 0.4 ms, VVI mode, and Lower Rate at 60 min^{-1}.

The service life projections are based on the following assumptions:

- Semi-annual maximum energy charging frequency
- A quarterly schedule of remote telemetry transmissions
- Typical shelf storage time before implant
- 1 hour 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 9. Projected service life

RV Amplitude / Pace %	Projected service life per impedance
2.0 V / 0%	**500 Ω**
	13.6 years[a]
2.0 V / 0%	**RV 437 Ω**
	13.6 years[b]
2.0 V / 100%	**500 Ω**
	11.9 years[a]
2.5 V / 100%	11.2 years

[a] Per EN 45502-2-2 or ISO 14708-6 for paced percentage and lead impedance.
[b] Based on median CareLink settings for amplitude, paced percentage, and lead impedance.

4.4.1 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 37 days.

Remote transmissions – Additional Medtronic remote transmissions reduce projected service life. At the stated conditions in Table 9, the 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 14.7 days, or 0.4%.
- Weekly transmissions over the life of the device reduce projected service life by 88.3 days, or 2.1%.
- Daily transmissions over the life of the device reduce projected service life by 664.2 days, or 15.6%.
- A single additional transmission reduces projected service life by approximately 0.2 days, or 0.0%.

Shelf storage time – Maximum shelf storage time of 18 months reduces projected service life by approximately 4.4%.

Pre-arrhythmia EGM storage – These projections assume that Pre-arrhythmia EGM storage is programmed to On for the lifetime of the device. Programming Pre-arrhythmia EGM storage to Off increases the projected service life of the device by approximately 3.5% or 12.7 days per year.

Wireless telemetry – Each additional hour of wireless telemetry use (in-office or implant) reduces the projected service life by approximately 2.4 days, or 0.1%.

4.5 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 implantable device app and on reports. You can evaluate charge time using the Charge/Dump Test.

Table 10. Maximum energy levels and typical full energy charge times

Maximum programmed energy	40 J
Maximum delivered energy[a]	40 J
Maximum stored energy[b]	47 J
Typical charge time between Beginning of Service (BOS)[c] and Recommended Replacement Time (RRT)[c]	10.5 s

[a] Energy delivered at connector block into a 50 Ω ±1% load.
[b] Energy stored at charge end on capacitor.
[c] Charge time during a nonwireless telemetry session may be slightly higher.

Charge times per conditions specified in EN 45502-2-2 and ISO 14708-6 - Beginning of Service (BOS) is 8.8 s and Recommended Replacement Time (RRT) is 14.9 s.

4.6 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. 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 the MRI SureScan mode is programmed to On, tachyarrhythmia detection and Medtronic CareAlert notifications (including audible alerts) are suspended.

5 Device parameters

5.1 Emergency settings

Table 11. 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; 40◈ J
Pathway[a]	B>AX

Table 11. Emergency settings and default values (continued)

Parameter	Selectable values
MRI SureScan	Off
Cardioversion	
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40◈ J
Pathway[a]	B>AX
MRI SureScan	Off
Fixed Burst	
Interval	100; 110 … 350◈ … 600 ms
RV Amplitude	8.0 V
RV Pulse Width	1.5 ms
V. Pacing	RV
MRI SureScan	Off
VVI Pacing	
V. Pacing	RV
Pacing Mode	VVI
Lower Rate	70 min^{-1}
RV Amplitude[b]	6.0 V
RV Pulse Width[b]	1.5 ms
V. Blank Post VP	240 ms
V. Rate Stabilization	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.

5.2 AF detection parameters

Table 12. AF detection parameters

Parameter	Programmable values	Shipped	Reset
AF Detection	Monitor◈; Off	Monitor	Monitor
AF Sensitivity	Least Sensitive; Less Sensitive; Balanced Sensitivity◈; More Sensitive; Most Sensitive	Balanced Sensitivity	Balanced Sensitivity
Ectopy Rejection	On◈; Off	On	—
Record EGM for	Episodes ≥ 6 min◈; Episodes ≥ 10 min; Episodes ≥ 20 min; Episodes ≥ 30 min; Episodes ≥ 60 min	Episodes ≥ 6 min	Episodes ≥ 6 min

5.3 Tachyarrhythmia detection parameters

Table 13. Tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
VF DETECTION	On◈; Off	Off	On
VF: Ventricular Interval[a]	240 (250); 250 (240) … 320 (188)◈ … 400 (150) ms (min^{-1})	—	320 (188) ms (min^{-1})
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
VF Beats to Redetect	6/8; 9/12; 12/16◈; 18/24; 21/28; 24/32; 27/36; 30/40	—	12/16
FVT Enable	Off◈; via VF; via VT	Off	Off
FVT: Ventricular Interval[a]	200 (300); 210 (286) … 240 (250)◈ … 600 (100) ms (min^{-1})	—	—
VT DETECTION	On; Off◈	Off	Off
VT: Ventricular Interval[a]	280 (214); 290 (207) … 360 (167)◈ … 650 (92) ms (min^{-1})	—	—
VT Initial Beats to Detect	12; 16◈ … 52; 76; 100	—	—
VT Beats to Redetect	8; 12◈ … 52	—	—
Monitor	Monitor◈; Off	Off	Off
Monitor: Ventricular Interval [a]	280 (214); 290 (207) … 450 (133)◈ … 650 (92) ms (min^{-1})	—	—
Monitored VT Beats to Detect	16; 20 …32◈ … 56; 80; 110; 130	—	—
WAVELET			
Wavelet…[b]	On◈; Off; Monitor	Off	Off
Template Collected	[date][c]	—	—
Template Evaluated	[date][c]	—	—
Match Threshold	40; 43 …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…	Off◈; On; Monitor	Off	Off
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	0.75 min	Off
All Zones	Off◈; 0.5; 1; 1.5 … 5; 6; 7 … 20; 22; 24; 26; 28; 30 min	Off	Off

Table 13. Tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Reset
TWave	On◈; Off	On	Off
RV Lead Noise …			
RV Lead Noise	On◈; Off; On+Timeout	On	Off
Timeout	0.25; 0.50; 0.75◈ … 2.0 min	0.75 min	0.75 min
Sensitivity			
RV	0.15 mV (±75%); 0.30◈; 0.45; 0.60 mV (±50%); 0.90; 1.20 mV (±30%)	0.30 mV	0.30 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 Wavelet feature is automatically set to On when VF Detection is set to On.
[c] Date is auto-generated.

5.4 Ventricular tachyarrhythmia therapy parameters

Table 14. Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
VF THERAPIES			
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; 40◈ J RX3–RX6: 10; 11 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40◈ J	40 J	40 J
Pathway[a]	AX>B; B>AX RX1–RX4: B>AX◈ RX5–RX6: AX>B◈	B>AX	B>AX
VF ATP			
Therapy Status	On◈; Off	On	Off
Therapy Type	Ramp; Burst; Ramp+; iATP	—	—
Deliver ATP if last 8 R-R >=	200; 210 … 240◈ … 300 ms	—	—
# Sequences Before Charging	Ramp, Burst, Ramp+: 0◈; 1	—	—
	iATP: 1; 2◈; 3	—	—
# Sequences During Charging	1	—	—
S2/S3 Minimum	iATP: 150; 160◈; 170; 180 ms	—	—

Table 14. Ventricular tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
Initial # Pulses	Ramp, Burst: 1; 2 … 8◈ … 15	—	—
	Burst+: 1; 2; 3◈ … 15	—	—
R-S1 Interval=(%RR)	Ramp: 50; 53; 56; 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
	Burst: 50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%	—	—
	Ramp+: 50; 53; 56; 59; 63; 66; 69; 72; 75◈; 78; 81; 84; 88; 91; 94; 97%	—	—
Interval Dec	Ramp, Burst: 0; 10◈ … 40 ms	—	—
ChargeSaver[b]	On◈; Off	On	—
Smart Mode[c]	On◈; Off	On	—
S1S2(Ramp+)=(%RR)	50; 53; 56; 59; 63; 66; 69◈ … 81; 84; 88; 91; 94; 97%		
S2SN(Ramp+)=(%RR)	50; 53; 56; 59; 63; 66◈; 69 … 81; 84; 88; 91; 94; 97%		
FVT THERAPIES / VT THERAPIES			
FVT Therapy Status	On; Off◈	Off	Off
VT Therapy Status	On; Off◈	Off	Off
Therapy Type[d,e]	CV; Burst; Ramp; Ramp+; iATP	—	—
Smart Mode	RX1-RX4: On; Off	—	—
# Sequences	iATP: FVT therapies: 2; 3; 4; 5◈ …10 VT therapies: 2; 3 … 7◈; 8; 9; 10 Burst, Ramp, Ramp+: VT therapies: 1; 2; 3◈ …10 FVT therapies: 1◈; 2 …10		
S2/S3 Minimum	iATP: 150; 160◈; 170; 180 ms		
Initial # Pulses	Burst, Ramp: 1; 2 … 8◈ … 15	—	—
	Ramp+: 1; 2; 3◈ … 15	—	—

Table 14. Ventricular tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
R-S1 Interval=(%RR)	Burst: 50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%	—	—
	Ramp: 50; 53; 56; 59; 63; 66 … 84; 88; 91◈; 94; 97%		
	Ramp+: 50; 53; 56; 59; 63; 66; 69; 72; 75◈; 78; 81; 84; 88; 91; 94; 97%		
S1S2(Ramp+)=(%RR)	50; 53; 56; 59; 63; 66; 69◈ … 81; 84; 88; 91; 94; 97%		
S2SN(Ramp+)=(%RR)	50; 53; 56; 59; 63; 66◈; 69 … 81; 84; 88; 91; 94; 97%		
Interval Dec	Burst, Ramp: 0; 10◈ … 40 ms	—	—
CV for FVT and VT therapies			
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 J VT RX1–RX2: 20◈ J VT RX3–RX6: 40◈ J FVT RX1–RX6: 40◈ J	—	—
Pathway[a]	AX>B; B>AX RX1–RX4: B>AX◈ RX5–RX6: AX>B◈	—	—
SHARED V. ATP			
V-V Minimum ATP Interval	150; 160 … 200◈ … 400 ms	200 ms	200 ms
V. Amplitude	1; 2 (+0.5%/-33%); 3 … 6; 7; 8◈ V(+20%/-33%)	8 V	8 V
V. Pulse Width	0.1; 0.2 … 1.5◈ ms(±0.025 ms)	1.5 ms	1.5 ms
V. Pace Blanking	170◈; 180; 190 … 450 ms (±5 ms)	170 ms	170 ms
SHARED V. THERAPIES			
Active Can/SVC Coil[f]	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] ChargeSaver is not available for iATP.
[c] Smart Mode is available for RX1– RX4.
[d] FVT therapies must be increasingly aggressive.

[e] Last therapy that is programmed to On must be a CV.
[f] The Active Can/SVC Coil parameter applies to all automatic, manual, and emergency high-voltage therapies. It also applies to T-Shock inductions.

5.5 Pacing parameters

Table 15. Modes, rates, and intervals

Parameter	Programmable values	Shipped	Reset
Mode	VVI◈; VVIR; VOO; OVO	VVI	VVI
Lower Rate[a]	30; 35; 40◈ … 60; 70; 75; 80 … 150 min^{-1} (±2 min^{-1})	40 min^{-1}	65 min^{-1}

[a] The corresponding Lower Rate Interval can be calculated as follows: Lower Rate Interval (ms) = 60,000/Lower Rate.

Table 16. RV pacing parameters

Parameter	Programmable values	Shipped	Reset
RV Amplitude	0.50; 0.75 … 1.25 V (+0.125 V/-33%); 1.50; 1.75 … 3.50◈ … 5.00; 5.50; 6.00; 8.00 V (+15%/-33%)	3.50 V	6.00 V
RV Pulse Width	0.03; 0.06 ms (±0.01 ms); 0.10; 0.20; 0.30; 0.40◈ … 1.50 ms (±0.025 ms)	0.40 ms	1.50 ms
RV Sensitivity	0.15; 0.30◈; 0.45; 0.60; 0.90; 1.20 mV (±55%)	0.30 mV	0.30 mV
Pace Polarity	Bipolar; Tip to Coil	Bipolar	Bipolar
Sense Polarity	Bipolar; Tip to Coil	Bipolar	Bipolar

Table 17. 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 18. Blanking periods

Parameter	Programmable values	Shipped	Reset
V. Blank Post VP	150; 160 … 200◈ … 450 ms (-30/+5 ms)	200 ms	240 ms
V. Blank Post VS	120◈; 130 … 170 ms (-30/+2 ms)	120 ms	120 ms

Table 19. Rate Response pacing parameters

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

Table 20. Conducted AF Response parameters

Parameter	Programmable values	Shipped	Reset
Conducted AF Response	On; Off◈	Off	Off
Response Level	Low; Medium◈; High	—	—
Maximum Rate	80; 85 … 110◈ … 130 min^{-1}	—	—

Table 21. Ventricular Rate Stabilization parameters

Parameter	Programmable values	Shipped	Reset
V. Rate Stabilization	On; Off◈	Off	Off
Maximum Rate	80; 85 … 100◈ …120 min^{-1}	—	—
Interval Increment	100; 110 … 150◈ … 400 ms	—	—

Table 22. 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 min^{-1}	—	—
Overdrive Duration	0.5◈; 1; 2; 3; 5; 10; 20; 30; 60; 90; 120 min	—	—

Table 23. Post Shock Pacing parameters

Parameter	Programmable values	Shipped	Reset
Post Shock V. Amplitude	1.0; 2.0 … 6.0◈; 8.0 V (+15%/-25%)	6.0 V	6.0 V
Post Shock V. Pulse Width	0.1; 0.2 … 1.5◈ (±0.025 ms)	1.5 ms	1.5 ms

Table 24. Sleep parameters

Parameter	Programmable values	Shipped	Reset
Sleep	On; Off◈	Off	Off
Sleep Rate	30; 35 … 50◈; 55; 60; 70; 75 … 100 min^{-1}	—	—
Bed Time	00:00; 00:10 … 22:00◈ … 23:50	—	—
Wake Time	00:00; 00:10 … 07:00◈ … 23:50	—	—

Table 25. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
MRI Pacing Mode	VOO (Asynchronous); OVO (Off)	—	—
MRI Pacing Rate	60; 70; 75… 120 min^{-1}	—	—

Table 26. Additional pacing features

Parameter	Programmable values	Shipped	Reset
Rate Hysteresis	Off◈; 30; 40 … 80 min^{-1}	Off	Off

5.6 Medtronic CareAlert parameters

Table 27. Clinical Management Alerts

Parameter	Programmable values	Shipped	Reset
OptiVol 2.0 Fluid Settings…			
DEVICE TONE and WIRELESS ALERT			
OptiVol Alert Enable			
DEVICE TONE	Off◈; On; Suspend 3 days; Suspend 5 days; Suspend 7 days; Suspend 14 days	Off	Off
WIRELESS ALERT	Off◈; On	Off	Off
OptiVol Threshold [b]	30; 40: 50; 60◈ … 180	60	60
AF Burden and Rate Settings…			
DEVICE TONE and WIRELESS ALERT			
AF Daily Burden	Off◈; On	Off	Off
Daily AF Burden	0.5; 1; 2; 6◈; 12; 24 h	—	—
Avg. V. Rate During AF	Off◈; On	Off	Off
Daily Burden for Avg. V. Rate	0.5; 1; 2; 6◈; 12; 24 h	—	—
Avg. V. Rate during AF	90; 100◈ … 150 min^{-1}	—	—

Table 27. Clinical Management Alerts (continued)

Parameter	Programmable values	Shipped	Reset
VT/VF Episodes and Therapies…			
DEVICE TONE and WIRELESS ALERT			
Monitored VT Episode Detected	Off◈; On	Off	Off
THRESHOLDS	1 episode	1 episode	1 episode
Daily VT/VF Episodes	Off◈; On	Off	Off
THRESHOLDS	3 episodes/day	3 episodes/day	3 episodes/day
Weekly ATP Delivered Episodes	Off◈; On	Off	Off
THRESHOLDS	1◈; 2; 3; 4; 5	3	3
Number of Shocks Delivered in an Episode[d]	Off◈; On	Off	Off
THRESHOLDS[c]	1◈; 2; 3; 4; 5; 6	1	1
Cumulative Right Ventricular Pacing > 40%			
DEVICE TONE and WIRELESS ALERT	Off◈; On [a]	Off	Off

[a] Alert triggered if percent of cumulative right ventricular pacing is greater than 40% for 7 consecutive days.
[b] Decreasing the OptiVol Threshold makes the device more sensitive to changes in the patient's thoracic fluid status. Increasing the OptiVol Threshold could delay or prevent device observation of significant changes in the patient's thoracic fluid status.
[c] This parameter is displayed only if an associated alert has been enabled.
[d] Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

Table 28. Lead/Device Integrity Alerts

Parameter	Programmable values	Shipped	Reset
RV Lead…			
DEVICE TONE and WIRELESS ALERT			
RV Lead Integrity	On◈; Off	On	On
RV Lead Noise	On◈; Off	On	Off
Lead Impedance Out of Range…			
DEVICE TONE and WIRELESS ALERT			
RV Pacing ENABLE	On◈; Off	On	On
RV Pacing LESS THAN	200◈; 300; 400; 500 Ω	200 Ω	200 Ω
RV Pacing GREATER THAN	1000; 1500; 2000; 3000◈ Ω	3000 Ω	3000 Ω
RV Defibrillation ENABLE	On◈; Off	On	On
RV Defibrillation LESS THAN	20◈; 30; 40; 50 Ω	20 Ω	20 Ω
RV Defibrillation GREATER THAN	100; 130; 160; 200◈ Ω	200 Ω	200 Ω

Table 28. Lead/Device Integrity Alerts (continued)

Parameter	Programmable values	Shipped	Reset
SVC Defibrillation ENABLE[a]	On◈; Off	On	On
SVC Defibrillation LESS THAN	20◈; 30; 40; 50 Ω	20 Ω	20 Ω
SVC Defibrillation GREATER THAN	100; 130; 160; 200◈ Ω	200 Ω	200 Ω
Capture Management High Threshold…			
DEVICE TONE and WIRELESS ALERT			
RV Capture	Off◈; On	Off	Off
Low Battery Voltage RRT			
DEVICE TONE and WIRELESS ALERT	On◈; Off	On	On
Excessive Charge Time EOS			
DEVICE TONE and WIRELESS ALERT	On◈; Off	On	On
VF Detection Off, 3+ VF or 3+ FVT Rx Off			
DEVICE TONE and WIRELESS ALERT	On◈; Off	On	On

[a] If an SVC lead is not implanted, the alert will not sound.

Table 29. Shared parameters

Parameter	Programmable values	Shipped	Reset
Wireless Telemetry with Monitor	On◈;Off	On	On
Alert Time (OptiVol)…[a]	00:00; 00:10 … 10:10◈ … 23:50[b]	10:10	10:10
Alert Time (all others)…[a]	00:00; 00:10 … 08:00◈ … 23:50[b]	08:00	08:00

[a] This parameter is displayed only if an associated alert has been enabled.
[b] The implantable device app expresses time in the 24-hour format or in the 12-hour format, depending on your tablet settings.

5.7 Data collection parameters

Table 30. Data collection parameters

Parameter	Programmable values	Shipped	Reset
LECG Source[a]	Can to SVC; Can to RVcoil◈; RVcoil to SVC	Can to RVcoil	Can to RVcoil
LECG Range	±1; ±2◈; ±4; ±8; ±12; ±16; ±32 mV	±2 mV	±2 mV
EGM 1 Source	RVtip to RVcoil; RVtip to RVring◈	RVtip to RVring	RVtip to RVring
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]	Can to RVcoil	Can to RVcoil

Table 30. Data collection parameters (continued)

Parameter	Programmable values	Shipped	Reset
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; Can to RVcoil	RVtip to RVcoil	RVtip to RVcoil
EGM 3 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
Stored (Ventricular)	EGM1 and EGM2◈; EGM1 and EGM3; EGM2 and EGM3; EGM1 and LECG; EGM2 and LECG; EGM3 and LECG	EGM1 and EGM2	EGM1 and EGM2
Stored (Atrial)	EGM1 and LECG; EGM2 and LECG◈; EGM3 and LECG	EGM2 and LECG	EGM2 and EGM4
Pre-arrhythmia EGM	Off On - 1 month; On - 3 months◈; On Continuous	On - 3 months	Off
Device Date/Time[d]	(select Time Zone)	—	—
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 h	Off	Off

[a] This EGM channel displays far-field signals.
[b] An SVC electrode must be present for this configuration.
[c] If Can to SVC 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] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

5.8 System test parameters

Table 31. System test parameters

Parameter	Selectable values
PACING THRESHOLD test parameters	
Test Type	Amplitude◈; Pulse Width
Chamber	RV
Decrement After	2; 3◈ … 15 pulses
RV Pace Polarity	Bipolar; Tip to Coil
Mode[a]	VVI; VOO
Lower Rate	30; 35 … 60; 70; 75 … 150 min^{-1}
RV Amplitude	0.25; 0.50 … 5.00; 5.50; 6.00; 8.00 V
RV Pulse Width	0.03; 0.06; 0.10; 0.20 … 1.50 ms
Additional Settings…	
V. Pace Blanking	150; 160 … 450 ms
SENSING test parameters	
Mode[a]	VVI; OVO
Lower Rate	30; 35 … 60; 70; 75 … 120 min^{-1}

Table 31. System test parameters (continued)

Parameter	Selectable values
WAVELET test parameters	
PERMANENT VALUES[b]	
Wavelet	On; Off; Monitor
Match Threshold	40; 43 … 70◈ … 97 %
Auto Collection	On◈; Off
TEMPORARY VALUES	
Mode[a]	OVO; VVI
Lower Rate	30; 35 … 60; 70; 75 … 120 min^{-1}

[a] The selectable values for this parameter depend on the programmed pacing mode.
[b] Tap ADJUST PERMANENT to change the values for these parameters.

5.9 EP Study parameters

Table 32. T-Shock induction parameters

Parameter	Selectable values
Resume at DELIVER	Enabled◈; Disabled
Enable	Enabled; Disabled◈
Chamber	RV
#S1	2; 3; 4; 5◈; 6; 7; 8
S1S1	300; 310 … 400◈ … 2000 ms
Delay	20; 30 … 300◈ … 600 ms
Energy/Pathway	
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; 40 J
Pathway[a]	AX>B; B>AX◈
Waveform	Monophasic◈; Biphasic

[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 33. 50 Hz Burst induction parameters

Parameter	Selectable values
Resume at BURST	Enabled◈; Disabled
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms

Table 34. Fixed Burst induction parameters

Parameter	Selectable values
Resume at BURST	Enabled◈; Disabled
Interval	100; 110 … 600◈ ms
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms

Table 35. PES induction parameters

Parameter	Selectable values
Resume at DELIVER	Enabled◈; Disabled
Chamber	RV
#S1	1; 2 … 8◈ … 15
S1S1	100; 110 … 600◈ … 2000 ms
S1S2	On; Off; 100; 110 … 400◈; … 600 ms
S2S3	On; Off◈; 100; 110 … 600 ms[a]
S3S4	On; Off◈; 100; 110 … 600 ms[a]
Amplitude	1; 2; 3; 4◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 … 0.50◈ … 1.50 ms

[a] Default value when parameter is programmed to On is 400 ms.

Table 36. Defibrillation parameters

Parameter	Selectable values
Chamber	RV
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40◈ 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 37. Cardioversion parameters

Parameter	Selectable values
Chamber	RV
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40◈ 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 38. Shared ATP parameters

Parameter	Selectable values
Minimum Interval	150; 160 … 200◈ … 400 ms
Amplitude	1; 2 … 6◈; 8 V
Pulse Width	0.10; 0.20 … 1.50◈ ms

Table 39. Ramp parameters

Parameter	Selectable values
Chamber	RV[a]
#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

[a] This value is non-programmable.

Table 40. Burst parameters

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

[a] This value is non-programmable.

Table 41. Ramp+ parameters

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

[a] This value is non-programmable.

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