

Medtronic

EV ICD DVEX3E4



Digital single chamber extravascular implantable cardioverter defibrillator (VVE-VVI) with Antitachycardia Pacing (ATP), Pause Prevention, and Post-Shock Pacing

MR Conditional with PhysioCurve™ Design

Device Manual

Caution: Investigational device. Limited by Federal law (USA) to investigational use.

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1 System overview

1.1 Introduction

This manual describes the Medtronic EV ICD Model DVEX3E4 single chamber, extravascular 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 MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine. When programmed to On, MRI SureScan operation disables pacing, arrhythmia detection and all user-defined diagnostics. Before performing an MRI scan, refer to the MRI Technical Manual.

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

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

Reference manual – This manual contains information about device features and describes how to use a programmer to conduct a session. The reference manual applies to multiple models of ICD devices.

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

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

1.2 Investigational notice

The Medtronic EV ICD model DVEX3E4 implantable cardioverter defibrillator is under clinical investigation. The procedures for using the device, as well as its safety and effectiveness, will be evaluated according to the Clinical Investigation Plan. Therefore, the indications in this manual are based on the experience Medtronic has had with similar devices. No claims of safety and effectiveness can be made for the model DVEX3E4 device during clinical evaluation. Physicians should advise their patients that the model DVEX3E4 device is under clinical investigation.

1.3 System description

The Medtronic EV ICD model DVEX3E4 single chamber, implantable cardioverter defibrillator (ICD) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate. It provides ventricular tachyarrhythmia detection and therapy, post-shock pacing, and prolonged pause detection and therapy (Pause Prevention pacing).

The device also provides diagnostic and monitoring features to assist with system evaluation and patient care.

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

1.3.1 Usage environments

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

- The device must be implanted in a properly equipped, staffed, and sterile surgical environment.
- The device must be implanted under standard surgical protocols and in the patient population for which the device is indicated.
- Post-surgical patient and device follow-up care must be conducted in a properly equipped and staffed cardiology clinic or office.
- MRI procedures for patients with this device must be conducted in a properly equipped and staffed MR facility, and in consideration of the conditions and requirements described in Section 1.7.

- After the device and lead are implanted, patients can resume their lives at home, at work, and in other environments with consideration of the advice and restrictions documented in Section 2.6, "Warnings, precautions, and guidance for clinicians performing medical procedures on cardiac device patients", page 13, Section 2.7, "Warnings, precautions, and guidance related to electromagnetic interference (EMI) for cardiac device patients", page 16, and in the patient literature.

1.3.2 System components and accessories

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

Connector – The device has a Medtronic EV4 quadripolar inline connector. This connector facilitates the connection of a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead. EV4-LLHH is a Medtronic proprietary design where the lead connector contacts are defined as low voltage (L) and high voltage (H). The mechanical specifications for the EV4-LLHH connector are defined by the Medtronic EV4 connector specification.

Lead – The device is intended for implant with a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead. The Medtronic Model DVEX3E4 device can be used with EV4 labeled leads only. See Section 3.2, "Implanting the lead", page 20 for more information.

Implantable device system – The implantable device system includes the Medtronic EV ICD Model DVEX3E4 device connected to a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead.

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

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

Medtronic pacing system analyzer – A pacing system analyzer can be used to measure some electrical characteristics of the implanted lead prior to its attachment to the device.

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

1.4 Indications for use

The Medtronic EV ICD model DVEX3E4 device is indicated for the automated treatment of patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias.

1.5 Contraindications

The Medtronic EV ICD model DVEX3E4 device is contraindicated for patients with the following issues:

- Ventricular tachyarrhythmias due to transient or reversible causes
- Incessant VT or VF
- Concomitant implant of a device delivering unipolar pacing
- Concomitant implant of a device delivering dual-chamber or triple-chamber (CRT) pacing
- Concomitant implant of a device delivering anti-tachyarrhythmia therapies
- Symptomatic bradycardia

1.6 Pre-implant consideration

Patient evaluation for the implant of EV ICD model DVEX3E4 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 Medtronic Technical Services or their Medtronic representative before implanting the patient with the second device. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant procedure. For information about how to contact Medtronic, see the telephone numbers and addresses provided on the back cover of this manual.

1.7 MRI conditions for use

A complete SureScan defibrillation system is required for use in the MR environment. Before performing an MR scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

A complete SureScan system only includes components that have been certified by Medtronic as being MRI conditional. To verify that components are part of a SureScan system, visit <http://www.mrisurescan.com>. Any other combination may result in a hazard to the patient during an MRI scan.

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

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

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

Cardiology requirements

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history.
- The SureScan device is operating within the projected service life.
- The device does not provide pacing therapy when SureScan mode is programmed to On. Do not scan pacemaker-dependent patients.

Notes:

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

Patient monitoring and rescue requirements

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

In the event that patient rescue is required, an external defibrillator must be immediately available.

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 6, "Device parameters", page 34.

1.8.1 Programmer software features

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

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

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

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

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

1.8.2 Diagnostic data features

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

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

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

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

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.

Medtronic CareAlert events – If the device identifies any CareAlert programmed or automatic alert conditions, this feature sounds a Patient Alert tone to notify the patient to seek medical attention.

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

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

1.8.3 Tachyarrhythmia detection features

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

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

Auto-adjusting sensitivity – This feature automatically adjusts sensitivity thresholds following specific paced events and sensed events, according to configured parameters.

Feature Match – This feature prevents ventricular tachyarrhythmia detection for rapidly conducted SVTs whose morphology features are similar to a template collected during sinus rhythm.

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

Morphology Noise – This feature withholds detection of ventricular tachyarrhythmias when the morphology on the EGM2 channel shows noise.

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

Rapid AF – This feature withholds detection for rapid atrial fibrillation conducted into the ventricles with periodic slow intervals that have consistent morphology and amplitudes.

Sensed EMI – This feature withholds ventricular tachyarrhythmia detection when noise is sensed during the blanking periods.

Sensed Noise – This feature withholds ventricular tachyarrhythmia detection when the device sees sensed noise, but the EGM2 signal is free of noise.

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

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

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.

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

1.8.4 Tachyarrhythmia therapy features

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

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

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 antitachycardia pacing (ATP) therapies – ATP 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 and Ramp, each with a programmable number of sequences.

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

Ventricular defibrillation (VF Therapies) – Programmable defibrillation therapy is available to treat VF episodes. The first defibrillation therapy requires VF confirmation before delivery. If synchronization fails following delivery of the first defibrillation therapy, subsequent therapies are delivered asynchronously.

1.8.5 Pacing features

When MRI SureScan is programmed to On, pacing features are suspended. Before performing an MRI scan, refer to the MRI Technical Manual for MRI-specific warnings and precautions.

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

Pause Prevention pacing – This feature monitors for prolonged pauses of programmed duration between intrinsic ventricular events in OVO mode. If a pause is detected, the device switches to VVI pacing. After 30 s of VVI pacing, the device switches back to OVO mode and resumes monitoring for prolonged pauses between intrinsic ventricular events.

Post Shock pacing – This feature provides VVI pacing for 30 s following a defibrillation or cardioversion therapy.

1.8.6 Testing features

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

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

EP Study tests – This set of protocols allows clinicians to induce arrhythmias and deliver on-demand tachyarrhythmia therapies during electrophysiology studies. The available protocols are T-Shock, Burst Induction, Programmed Electrical Stimulation (PES), Defibrillation, Cardioversion, and Burst ATP.

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.

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, pulse width, and temperature sensitivity settings that ensure capture and minimize output.

Sensing test – This feature measures R-wave amplitudes to help the clinician assess lead integrity and sensing performance.

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

1.8.7 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 EV ICD model DVEX3E4 device.

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

Long range wireless telemetry communication system – The Medtronic long range wireless telemetry communication system is used with the clinician programmer to interrogate and program the device. This system uses RF telemetry for wireless communications between the device and the programmer. During a wireless telemetry session, all other programmers are locked out from communications with the patient's implanted device to protect patient information and device data.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

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

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 arrhythmias are possible or intentionally induced during post-implant testing.

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

Prior sternotomy – Use of the EV ICD model DVEX3E4 device has not been evaluated in patients who have undergone a prior sternotomy.

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, then disable tachyarrhythmia detection and Pause Prevention detection and therapy before explanting, cleaning, or shipping the device.
- Explant the implanted device postmortem. In some countries, explanting battery-operated implanted devices is mandatory because of environmental concerns; check the local regulations. In addition, the device can explode if subjected to incineration or cremation temperatures.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Contact Medtronic for return mailer kits to return explanted devices for analysis and disposal. See the back cover for addresses.

Note: Observe all local laws and regulations regarding the disposal of explanted devices or leads.

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.

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

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

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

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

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

2.3.2 Device storage

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

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

2.4 Lead evaluation and lead connection

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

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

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

- Cap abandoned leads to avoid transmitting electrical signals.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.

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

- Ensure that the defibrillation lead impedance is greater than 30 Ω . An impedance of less than 30 Ω may damage the device or prevent delivery of high-voltage therapy.
- The impedance range for therapies delivered at ≤ 8 V is 100 - 1500 Ω .
- The impedance range for therapies delivered at ≥ 10 V is 30 - 250 Ω .
- Prior to 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 a lead and an active implantable device, causing electrical current to bypass the heart and possibly damage the implantable device and lead.

2.5 Device operation

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

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

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

Concomitant devices – If a single-chamber bipolar pacemaker is used concomitantly with the Model DVEX3E4 device, verify that the concomitant device accurately senses and paces the patient's heart:

- Verify that the concomitant device correctly senses all intrinsic ventricular rhythms, including normal sinus rhythm and all ventricular tachyarrhythmias.
- Verify that the concomitant device maintains pacing capture.

If the concomitant device does not correctly sense and pace the patient's heart, it can interfere with the normal operation of the Model DVEX3E4 device. This interference can lead to inappropriate tachyarrhythmia detection and therapy, or it can lead to undersensing of VF.

Note: The concomitant devices for which the Model DVEX3E4 device is contraindicated can be found in Section 1.5, "Contraindications", page 6.

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

Electrical reset – Electrical reset can be caused by exposure to temperatures below -18°C (0°F) or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a full reset occurs, the device operates in OVO mode. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation.

To restore the device to its previous operation, it must be reprogrammed. Inform a Medtronic representative if your patient's device has reset.

Emergency VVI button disabled – The red, mechanical Emergency VVI button on the Medtronic models 2090 and Encore programmers is disabled during programmer sessions with the EV ICD model DVEX3E4 device. If emergency therapy is needed during a programmer session, tap **Emergency** at the bottom of the programmer screen. That screen button opens the **Emergency** window from where you can deliver either defibrillation or cardioversion therapy to the patient.

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

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

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

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

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

Pacing and sensing safety margins – Lead maturation 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.

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

Sensing settings – If you change any sensing parameters, verify that the new settings provide adequate safety margins for the patient.

Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.075 mV.

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

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

This section is for health care professionals who perform medical procedures, in consultation with cardiologists, on patients who have a Medtronic EV ICD Model DVEX3E4 single chamber, extravascular implantable cardioverter defibrillator (ICD) system. The procedures in this section come with specific warnings, precautions, and guidance. Failure to follow medical procedure warnings, precautions, and guidance can interfere with or damage the implanted device system, or can lead to serious patient injury.

For guidance on medical procedures that are not addressed in this section, health care professionals can contact the following resources:

- Health care professionals within the United States can contact Medtronic Technical Services at +1 800 723 4636. You can also submit questions to tshelp@medtronic.com or to your Medtronic representative.
- Health care professionals outside of the United States can contact a Medtronic representative.

Ablation (RF ablation or microwave ablation) – Ablation is a surgical technique in which radiofrequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation used in cardiac device patients may result in, but is not limited to, induced ventricular tachyarrhythmias, oversensing, unintended tissue damage, device damage, or device malfunction. Pulse-modulated ablation systems may pose higher risk for induced ventricular tachyarrhythmias. Medtronic cardiac devices are designed to withstand exposure to ablation energy. To mitigate risks, observe the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the return electrode patch so that the electrical current pathway does not pass through or near the device and lead system.
- Always monitor the patient during ablation with at least two separate methods, such as arterial pressure display, ECG, manual monitoring of the patient's rhythm (taking pulse) or monitor by some other means such as ear or finger pulse oximetry, or Doppler pulse detection.

To avoid or mitigate the effects of oversensing, suspend tachyarrhythmia detection by using a magnet or a programmer. If a programmer is used and ablation causes a device reset, the cardiac device resumes detection. After the ablation procedure, remove the magnet or restore device parameters.

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

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

- Computerized axial tomography (CT or CAT scan)
- Fluoroscopy (an x-ray procedure that makes it possible to see internal organs in motion by producing a video image)
- Mammograms
- X-rays (radiography, such as chest x-rays)

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

CT scan – A CT scan is a computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. If the device is not directly in the CT scan beam, the device is not affected. If the device is directly in the CT scan beam, oversensing may occur for the duration of time the device is in the beam. If the device will be in the beam for longer than 4 s, to avoid or mitigate the effects of oversensing, suspend tachyarrhythmia detection by using a magnet or a programmer. After completing the CT scan, remove the magnet or restore device parameters.

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

Diathermy treatment (including therapeutic ultrasound) – Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and

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

Electrolysis – Electrolysis is the permanent removal of hair by using an electrified needle (AC or DC) that is inserted into the hair follicle. Electrolysis introduces electrical current into the body, which may cause oversensing. Evaluate any possible risks associated with oversensing with the patient's medical condition. To avoid or mitigate the effects of oversensing, suspend tachyarrhythmia detection by using a magnet or a programmer. After completing electrolysis, remove the magnet or restore device parameters.

Electrosurgery – Electrosurgery (including electrocautery, electrosurgical cautery, Medtronic Advanced Energy surgical incision technology, and hyfrecator) is a process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted tissue. Electrosurgery used on cardiac device patients may result in, but is not limited to, oversensing, unintended tissue damage, tachyarrhythmias, device damage, or device malfunction. If electrosurgery cannot be avoided, consider the following precautions:

- Ensure that temporary pacing and defibrillation equipment is available.
- Use a bipolar electrosurgery system or Medtronic Advanced Energy surgical incision technology, if possible. If a unipolar electrosurgery system is used, position the return electrode patch so that the electrical current pathway does not pass through or within 15 cm (6 in) of the device and lead system.
- Do not apply unipolar electrosurgery within 15 cm (6 in) of the device and lead system.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.
- Always monitor the patient during electrosurgery. If the ECG tracing is not clear due to interference, manually monitor the patient's rhythm (take pulse); alternatively, monitor by some other means such as ear or finger pulse oximetry, Doppler pulse detection, or arterial pressure display.

To avoid or mitigate the effects of oversensing, suspend tachyarrhythmia detection by using a magnet or a programmer. If a programmer is used and electrosurgery causes a device reset, the cardiac device resumes detection. After completing electrosurgery, remove the magnet or restore device parameters.

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

The EV ICD Model DVEX3E4 is designed to withstand exposure to external defibrillation and cardioversion. While damage to an implanted system from an external shock is rare, the probability increases with increased energy levels. These procedures can also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium. If external defibrillation or cardioversion are required, consider the following precautions:

- Use the lowest clinically appropriate energy.
- The EV ICD Model DVEX3E4 device is implanted in the left midaxillary region. Do not position the patches or paddles directly over the implanted device or lead.
- Do not position the patches or paddles closer than 15 cm (6 in) to the device.
- Position the patches or paddles perpendicular to the device and lead system.
- If an external defibrillation or cardioversion is delivered within 15 cm (6 in) of the device, use a Medtronic programmer to evaluate the device and lead system.

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

Lithotripsy – Lithotripsy is a medical procedure that uses mechanical shock waves to break up kidney or gallbladder stones. If the device is at the focal point of the lithotripter beam, lithotripsy may permanently damage the device. If lithotripsy is required, keep the focal point of the lithotripter beam a minimum distance of 2.5 cm (1 in) away from the device. To avoid or mitigate the effects of oversensing, suspend tachyarrhythmia detection by using

a magnet or a programmer. After completing lithotripsy treatment, remove the magnet or restore device parameters.

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

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

- **Oversensing** – If the patient undergoes radiotherapy treatment and the average dose rate at the device exceeds 1 cGy/min, the device may inappropriately sense direct or scattered radiation as cardiac activity for the duration of the procedure. To avoid or mitigate the effects of oversensing, suspend tachyarrhythmia detection by using a magnet or a programmer. After completing radiotherapy treatment, remove the magnet or restore device parameters.
- **Device damage** – Exposing the device to high doses of direct or scattered radiation from any source that results in an accumulated dose greater than 500 cGy may damage the device. Damage may not be immediately apparent. If a patient requires radiation therapy from any source, do not expose the device to radiation that exceeds an accumulated dose of 500 cGy. For patients who are undergoing multiple radiation treatments, consider the accumulated dose to the device from previous exposures.
Note: Normally, the accumulated dose from diagnostic radiology is not sufficient to damage the device. See "Diagnostic radiology" for precautions.
- **Device operational errors** – Exposing the device to scattered neutrons may cause electrical reset of the device, errors in device functionality, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment by using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of neutrons. If photon beam energies exceed 10 MV, Medtronic recommends interrogating the device immediately after radiotherapy treatment. An electrical reset requires reprogramming of device parameters. Electron beam treatments that do not produce neutrons do not cause electrical reset of the device.

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

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

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

General EMI guidelines for patients – Patients should observe the following general guidelines regarding electromagnetic interference (EMI) with their Medtronic EV ICD model DVEX3E4 implantable cardiac defibrillator (ICD):

- **Area restrictions** – Before you enter an area that is posted with warnings that prohibit entrance by persons with an ICD, consult with your doctor.

- Symptoms of EMI – If you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The cardiac device should immediately return to normal operation. If symptoms do not improve when you move away from the item, consult with your doctor. If you receive a shock therapy from your ICD while using an electrical item, release the item or move away from it, then consult with your doctor.
- Proper grounding of electrical items – To avoid interference from electrical current that can leak from improperly grounded electrical items and pass through the body, observe the following precautions:
 - Make sure that all electrical items are properly wired and grounded.
 - Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

Wireless communication devices – Wireless communication devices and accessories can interfere with the function of an ICD. To avoid such interference, keep the following items at least 15 cm (6 in) away from an ICD:

- Cordless home telephones
- Laptop or tablet computers, keyboards; network routers; MP3 players; eReaders; gaming consoles; televisions, DVD/DVR players, and remote controls; wearable fitness monitors; smart watches
- Headsets, headphones, and earbuds
- Remote keyless entry and remote car starter devices
- Remote controller of radio-controlled toys
- Two-way walkie-talkies (less than 3 W)

For example, to avoid interference, do not carry a wireless device in a pocket over an ICD or in a shoulder bag near an ICD. **Note:** magnets in these wireless communication devices can interfere with an ICD; however transmitters in these wireless communication devices are not likely to interfere with an ICD.

Mobile telephones – Mobile telephones, including cellular telephones and smartphones, are not likely to affect an ICD. However, some accessories for mobile telephones contain magnets, such as cases with magnetic clasps. Keep these accessories at least 15 cm (6 in) away from an ICD.

Electronic article surveillance (EAS) – Electronic article surveillance equipment, such as retail theft prevention systems, may interact with devices and result in inappropriate therapy delivery. Advise patients to walk directly through an EAS system and not remain near an EAS system longer than necessary.

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

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such as handheld hair dryers, electric shavers, electric or ultrasonic toothbrushes (base charger), or back massagers
- Items that contain magnets, such as bingo wands, mechanic's extractor wands, magnetic bracelets, magnetic clasps, magnetic chair pads, speakers, or earphones

The following household and hobby items require special precautions:

- Boat motors – Keep the ICD at least 30 cm (12 in) away from electric trolling motors or gasoline-powered boat motors.
- Electronic body fat scale – Using this type of scale is not recommended for ICD patients because it passes electricity through the body and can interfere with the device.
- Electronic pet fences or invisible fences – Keep the ICD at least 15 cm (6 in) away from the collar, remote control, and indoor antenna of electronic pet fences or invisible fences.
- Recreational handheld metal detectors – Keep the ICD at least 60 cm (24 in) away from the detector end.
- Home-use electric kilns – Keep the ICD at least 60 cm (24 in) away from home-use electric kilns.
- Induction cook tops – An induction cook top uses an alternating magnetic field to generate heat. Keep the ICD at least 60 cm (24 in) away from the heating zone when the induction cook top is turned on.
- Magnetic mattress pads or pillows – Items containing magnets can interfere with the normal operation of the ICD if they are within 15 cm (6 in) of the device. Avoid using magnetic mattress pads or pillows because they cannot easily be kept away from the ICD.

- Portable electric generators up to 20 kW – Keep the ICD at least 30 cm (12 in) away from portable electric generators.
- UPS (uninterruptible power source) up to 200 A – Keep the ICD at least 30 cm (12 in) away from a UPS.

2.8 Potential adverse events

The following are foreseeable potential adverse events associated with the use of this device.

Note: Implant and usage of this product may result in adverse events which may lead to injury, death, or other serious adverse reactions.

- Acute tissue trauma
- Allergic reaction to implant
- Bradyarrhythmia
- Cardiac arrest
- Death
- Device migration
- Discomfort
- Discomfort associated with fibrotic growth
- Discomfort associated with product migration
- Dizziness
- Dyspnea
- Electrical or thermal tissue damage
- Erosion
- Extracardiac stimulation
- Failure to provide necessary therapy
- Hematoma
- Hemorrhage
- Hiccups
- Hospitalization
- Inappropriate shocks
- Infection
- Lethargy
- Mental anguish
- Pain
- Palpitations
- Return of cardiac symptoms
- Seroma
- Skeletal muscle twitching
- Syncope
- Tachyarrhythmia
- Toxic reaction to implant
- Twiddler's syndrome
- Wound dehiscence

Additional known potential adverse events associated with the use of ICD systems include the following events:

- Potential mortality due to inability to defibrillate
- Shunting current or insulating myocardium during defibrillation

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

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious

- Fear that shocking capability may be lost
- Imagined shocking (phantom shock)

3 Implant procedure

3.1 Preparing for an implant

To retain the ability to scan the SureScan system safely during MRI scans, the MRI conditions for use in Section 1.7 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.

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 components are used to support the device implant:

- Medtronic programmer.
- Programming head sleeve (if a programming head is used).
Note: If a sterilized programming head is used during an implant, a sterile programming head sleeve is not necessary.
- SW041 programmer software application for the EV ICD Model DVEX3E4 device.¹
- Medtronic pacing system analyzer and analyzer cables.
- External defibrillator.

3.1.2 Setting up the programmer and starting the application

See the reference manual for the Medtronic programmer for instructions about how to set up the programmer. The Model SW041 software must be installed on the programmer. 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: A Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead must be used with the Medtronic Model DVEX3E4 EV ICD device. If a lead other than a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead is used, the EV ICD system will present serious risks for adverse events to the patient.

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

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

Caution: The device is intended for implant in the left midaxillary region with a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead. No claims of safety and efficacy can be made about other acutely or chronically implanted device and lead systems that are not manufactured by Medtronic.

¹ Your Medtronic representative can install the Model SW041 software application.

Caution: Any device or lead coils or electrodes that are in contact with conductive materials during a high-voltage therapy can cause electrical current to bypass the heart. This current can damage the device and lead. Move objects made of conductive materials away from all coils and electrodes while the device is connected to the leads.

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

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

Determine ICD pocket location in the left mid-axillary region; it is recommended to use fluoroscopy (AP and lateral views) as guidance. It is recommended to confirm defibrillation vector based on lead placement and cardiac silhouette for final Medtronic Model DVEX3E4 EV ICD device implant location.

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 print an Initial Interrogation Report.
Caution: If the programmer reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.
2. To confirm that the device is acceptable for implant, check the status of the Remaining Longevity estimate on the Quick Look II 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 II screen is gray, indicating that the battery status is unacceptable, do not charge the capacitors.
3. Tap **Params > Data Collection Setup > Device Date/Time...** to set the device clock.
4. Program the device parameters to values that are appropriate for the patient. Make sure that VF detection, FVT detection, and VT detection are programmed to OFF.
Note: Additional parameters such as patient information typically is entered at the time of initial implant, but can be revised at any time.

3.2 Implanting the lead

A complete Medtronic EV ICD defibrillation system includes a Medtronic EV ICD Model DVEX3E4 device connected to a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead.

Consult the Medtronic extravascular lead technical manual for detailed implant instructions.

3.2.1 Lead and connector compatibility

Note: Do not use a lead adaptor with a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead. Only use the Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead with the Medtronic EV ICD Model DVEX3E4 device.

Table 1. Lead and connector

Connector port (electrodes)	Lead
V (Connector Pin, Ring 1, Ring 2, Ring 3)	EV4-LLHH quadripolar ^a

^a EV4-LLHH is a Medtronic proprietary design, where the lead connector contacts are defined as low voltage (L) or high voltage (H). The mechanical specifications for the EV4-LLHH connector are defined by the Medtronic EV4 connector specification.

3.2.2 Implanting the lead

Implant the Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead according to the instructions in the extravascular lead technical manual, supplied with the lead.

Warning: Pinching the lead can damage the lead conductor or insulation, which may cause unwanted high-voltage therapies or result in the loss of sensing or pacing therapy.

3.3 Testing the lead system

After the lead is implanted, test the lead system to verify that the sensing and pacing values are acceptable:

- You can use an implant support instrument such as a pacing system analyzer to evaluate sensing.
- Use the implantable device to evaluate pacing values.
- If you take lead measurements with an implant support instrument other than a pacing system analyzer, enter the measurements manually during the device session.

For information on how to use another implant support instrument, consult the product documentation for that device.

Note: See the Medtronic extravascular lead technical manual for supporting information to test the lead.

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

3.3.1 Testing the lead system sensing with a pacing system analyzer

To test the lead system sensing and impedance with a pacing system analyzer, perform the following procedure:

1. From the device session, launch a new analyzer session by tapping the analyzer icon on the task bar.



2. Measure the R Wave amplitude with the analyzer:
3. To confirm the measurement values, remeasure the R Wave amplitude if you choose.
4. Manually record the R Wave amplitude measurement to enter into the patient's record.
5. Tap the device icon on the task bar.
6. Tap **Patient > Patient Information > Implant...** field to display the **Implant** pop-up window.
7. Manually enter the measurements you recorded in Step 4 in the Lead Data from Analyzer fields.
8. To save the measurement values into device memory, tap **OK > Program**.

3.4 Connecting the lead to the device

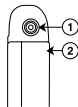
The following procedure describes how to connect the lead to the device, how to confirm that the lead connector is fully inserted in the connector block, and how to verify that the lead connection is secure.

Warning: After connecting the lead, verify that the lead connection is secure by gently tugging on the 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.

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

Figure 1. Lead connector port

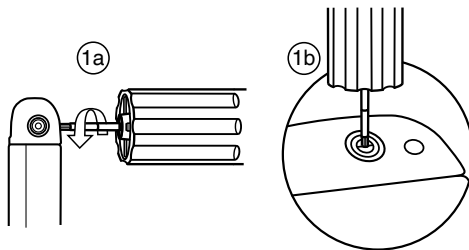


- 1 EV4-LLHH connector port
- 2 Device Active Can electrode

3.4.1 How to connect the lead to the device

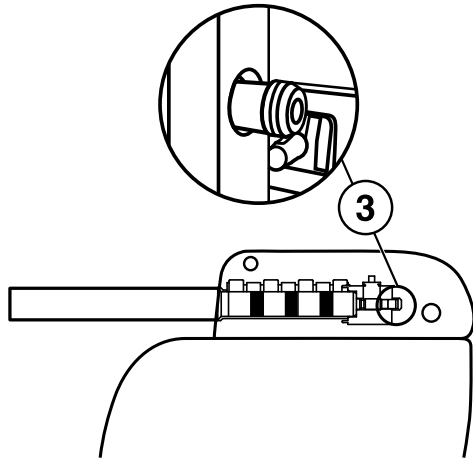
1. Insert the torque wrench into the appropriate setscrew.
 - a. If the setscrew obstructs the port, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see Figure 2).
 - b. To allow a pathway to vent trapped air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

Figure 2. Inserting the torque wrench into the setscrew



2. Insert the lead connector into the connector port, keeping twisting to a minimum. Insert the lead connector until the lead connector pin is visible in the pin viewing area. 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 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 EV4-LLHH 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 Positioning and securing the device

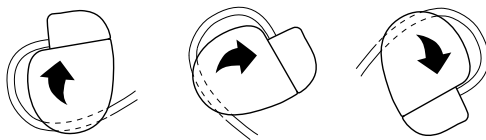
Caution: Program tachyarrhythmia detection to OFF to avoid inappropriate detection or therapy delivery while closing the surgical pocket.

Note: Implant the device under the patient's adipose tissue, against the muscle tissue. Face the side of the device engraved with the Medtronic logo toward the skin so the patient can better hear any alert tones. This orientation is also most compatible with the device PhysioCurve Design.

3.5.1 How to position and secure the device

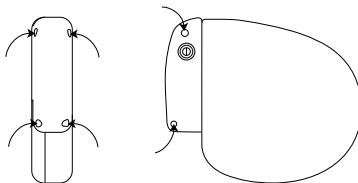
1. Verify that the lead connector pin is fully inserted into the connector port and that the setscrew is tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see Figure 4). Do not kink the lead body.

Figure 4. Rotating the device to wrap the lead



3. Place the device and the lead into the surgical pocket located in the left midaxillary region.
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.

3.6 Performing a Sensing Test

The sensing test enables you to measure R-wave amplitude on any programmed Sense Polarity.

Considerations for performing a sensing test:

- If no intrinsic events occur, the sensing test ends after a few seconds.
- Tachyarrhythmia detection is suspended during the sensing test.

3.6.1 Selecting a sense polarity to test

Use the following steps to select a Sense Polarity that you wish to test:

1. Tap **Params > Sensing... > Sense Polarity**
2. In the **Sense Polarity** pop-up window, click on the electrodes shown, or select from the list at the bottom of the window.
3. To program the selected polarity, tap **Close > OK > PROGRAM**

3.6.2 Performing a sensing test on the programmed polarity

Use the following steps to perform a sensing test on the programmed polarity:

1. Tap **Tests > Sensing**.
2. Tap **START Measurement**.
3. Observe the Live Rhythm Monitor for an intrinsic rhythm and amplitude measurements.

Notes:

- To abort the test, tap **STOP and Restore**.
- The device measures amplitudes only on intrinsic events. The maximum amplitude value that the sensing test can measure is 10 mV. If the amplitude is over 10 mV, the results are displayed as >10 mV.

The sensing test ends when it has measured 5 intrinsic events. When the test is complete, the R-Wave Amplitude value is updated on the test screen. This value represents the median measured R-wave amplitude.

3.7 Performing a pacing threshold test

The pacing threshold test is used to determine the minimum pacing output that consistently captures the heart. The results of this test also determine which **S1 Pathway** to use in the T-Shock defibrillation test in Section 3.8, "Performing ventricular defibrillation threshold tests", page 25.

3.7.1 How to measure pacing thresholds

1. Tap **Tests > Pacing Threshold**.
2. Select the Pace Polarity for the test, beginning with Ring 1 to Ring 2.
3. Select a Test Value for Lower Rate, Amplitude, and Pulse Width.
4. To change the value for V. Pace Blanking tap **Additional Settings...** to access the V. Pace Blanking | Test Value field. Tap the field and select a Temp. V. Pace Blanking value, then tap **OK**.
5. Select the **Enable** check box.

Note: When you are testing the Coil 2 to Coil 1 polarity, the **Energy Check - In Progress** pop-up appears briefly to determine the stored capacitor energy. If the energy on the capacitors is higher than the energy level you selected for the test, the programmer displays a warning. To clear this warning, tap either **DUMP** to dump the capacitors, or **CANCEL**.

6. Press and hold **TEST Press and Hold**.
7. Observe the Live Rhythm Monitor for capture or loss of capture.
8. If capture is lost, perform the following procedure. (If capture is not lost, go to Step 9.)
 - a. Release **TEST Press and Hold**. The device resumes OVO mode operation and displays the **Test - Pacing Threshold - Results** window.
 - b. Tap **Close** to return to the **Tests - Pacing Threshold** screen.
 - c. Repeat Step 3 through Step 7 using incrementally higher values until capture is not lost. These values comprise the pacing threshold for the Ring 1 to Ring 2 pace polarity.
9. If capture is not lost, perform the following procedure.
 - a. Release **TEST Press and Hold**. The device resumes OVO mode operation and displays the **Test - Pacing Threshold - Results** window.
 - b. Tap **Close** to return to the **Tests - Pacing Threshold** screen.
 - c. Repeat Step 3 through Step 7 using incrementally lower values until capture is lost. The lowest tested values at which capture is not lost comprise the pacing threshold for the Ring 1 to Ring 2 pace polarity.
10. To identify the pacing thresholds for the Ring 1 to Coil 2 and Coil 2 to Coil 1 pace polarities, repeat Step 3 through Step 9.

Note: The pacing amplitude range for the Ring 1 to Ring 2 and Ring 1 to Coil 2 pace polarities is 1.00 V to 8.00 V. If you are unable to capture the heart at a pacing amplitude of ≤ 8.00 V at any pulse width, you must pace from the Coil 2 to Coil 1 pace polarity. The pacing amplitude range for the Coil 2 to Coil 1 pace polarity is 10.00 V to 30.00 V for Post Shock pacing, 10.00 V to 30.00 V for ATP, and 10.00 V or 13.00 V for Pause Prevention pacing.

11. To print a Pacing Threshold test report at any time, tap **Print...** from the **Tests - Pacing Threshold - Results** window.

3.8 Performing ventricular defibrillation threshold tests

Test the operation and effectiveness of ventricular defibrillation by inducing VF with the T-Shock test or the Burst Induction test, and then allow the device to detect and treat the VF with programmed therapies. Establish an adequate sensing safety margin and an adequate defibrillation safety margin using your preferred method.

Carefully consider for each patient the decision to induce VF for testing ventricular defibrillation operation and effectiveness. Use discretion in your decision to test or how to test for an adequate safety margin.

3.8.1 High-voltage implant values

See Table 2 for information about the measured high-voltage therapy values that are recommended at implant.

Table 2. High-voltage (HV) therapy values recommended at implant

Measurement	Values
HV delivery pathway impedance	30–250 Ω
Demonstrated defibrillation success	30 J

3.8.2 How to prepare for defibrillation threshold testing

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

1. Establish telemetry between the device and programmer, and start a patient session. If you are using wireless telemetry, verify that at least 3 of the green lights on the wireless telemetry icon are illuminated. Interrogate the device if it has not been interrogated.
2. To verify that the device is sensing properly, observe the Marker Channel annotations. Tap **Params > Sensing...** to adjust the sensing parameters, if necessary.
3. Perform a manual Lead Impedance Test to verify defibrillation lead connections. For information about acceptable impedance values, refer to the Medtronic extravascular lead technical manual. Perform this test with the device in the surgical pocket. Keep the surgical pocket moist. If the lead impedance is out of range, perform one or more of the following tasks:
 - Recheck the lead connections and lead electrode placement.
 - Inspect the EGM for abnormalities.
 - Repeat the manual Lead Impedance Test.
4. If desired, enable post shock pacing before performing defibrillation threshold testing. To turn on post shock pacing, perform the following steps:
 - Tap **Params > Pacing...** > **Post Shock I Setting**. The **Post Shock Pacing Enable** pop-up displays.
 - Tap **Off**. The field will toggle to On.
5. Change the Amplitude, Pulse Width and Pace Polarity values, as desired.
6. Tap **OK > PROGRAM** to program your parameter changes into device memory.

3.8.3 How to perform defibrillation threshold testing using T-Shock

Note: During a wireless telemetry session, you cannot deliver a T-Shock induction when there is a magnet or programming head over the device.

1. Tap **Tests > EP Study > T-Shock**.
2. Tap **Adjust Permanent...** and make the following selections in the **Adjust Permanent** window:
 - a. Set the **Energy** parameter for **Rx1** to 30 J (or 10 J less than your desired final programmed value).
 - b. Set the **Energy** parameter for **Rx2, Rx3, Rx4, Rx5,** and **Rx6** to 40 J (or 10 J greater than the value you selected in Step 2a).
 - c. Tap the **Sensitivity** parameter and select a value for a safety margin for detecting VF that is at least 2x the final programmed sensitivity.

Note: For a final programmed sensitivity of 0.2 mV, an adequate safety margin typically is attained if you set the value to 0.45 mV during testing.
 - d. Set **VF Enable** to On.
 - e. Tap **PROGRAM**.
 - f. Tap **Close** to close the **Adjust Permanent** window.

3. Select the **S1 Pathway** based on the results of the pacing threshold test (see Section 3.7, "Performing a pacing threshold test", page 25) as follows:
 - If the pacing threshold is below 8 V, 8 ms, select **Ring 1 to Coil 2**.
 - If the pacing threshold is above 8 V, 8 ms, select **Coil 2 to Coil 1**.
4. Set the desired T-Shock parameters.
5. Check the **Enable** check box. (The **Energy Check - In Progress** pop-up appears briefly to determine the stored capacitor energy.)

Note: If the energy on the capacitors is higher than the energy level you selected for the test, the programmer displays a warning. To clear this warning, tap either **DUMP** to dump the capacitors, or **CANCEL**.
6. Tap **DELIVER T-Shock**. If necessary, tap **ABORT** to abort the induction.
7. Observe the Live Rhythm Monitor for proper detection, therapy, and post-shock sensing.
8. Tap **Retrieve Data...** to review the stored data for the induced episode. To view more details, tap **Print...** to print an EP Study T-Shock Induction Report, or tap **Data > Clinical Diagnostics > Arrhythmia Episodes** to view the induced episode data on the programmer.
9. Tap **Adjust Permanent...** to program new Therapy Energy levels or to change the Pathway, if desired.

Note: If sensing parameters other than Sensitivity need to be adjusted, tap **Params > Sensing...** to reprogram those parameters. The Last Induction (mm:ss) timer will continue to count while you do this.
10. Wait until the Last Induction (mm:ss) timer reaches at least 05:00, then repeat Step 1 through Step 10, as needed.

3.8.4 How to perform defibrillation threshold testing using Burst Induction

1. Tap **Tests > EP Study > Burst Induction**.
2. Tap **Adjust Permanent...** and make the following selections in the **Adjust Permanent** window:
 - a. Set the **Energy** parameter for **Rx1** to 30 J (or 10 J less than your desired final programmed value).
 - b. Set the **Energy** parameter for **Rx2, Rx3, Rx4, Rx5,** and **Rx6** to 40 J (or 10 J greater than the value you selected for **Rx1** in Step 2a).
 - c. Tap the **Sensitivity** parameter and select a value that results in an adequate safety margin for detecting VF. For a final programmed sensitivity of 0.2 mV, an adequate safety margin typically is attained by setting the value to 0.45 mV during testing.
 - d. Set **VF Enable** to On.
 - e. Tap **PROGRAM**.
 - f. Tap **Close** to close the **Adjust Permanent** window.
3. Select the **Enable** check box. (The **Energy Check - In Progress** window appears briefly to determine the stored capacitor energy.)

Note: If the energy reserved on the capacitors is greater than the energy that is required to perform the Burst Induction test, the programmer displays a warning. To clear this warning, tap either **DUMP** to dump the capacitors, or **CANCEL**.
4. Press and hold the touch pen on the **BURST Press and Hold** button. The test aborts if you lift the touch pen. If you do not lift the touch pen, the test times out after 10 s.
5. Observe the Live Rhythm Monitor for proper detection, therapy, and post-shock sensing.
6. Tap **Retrieve Data...** to review the stored data for the induced episode. To view more details, tap **Print...** to print an EP Study Burst Induction Report.
7. Tap **Adjust Permanent...** to program a new **Rx1** energy level or to change the **Pathway**, if desired.

Note: If sensing parameters other than Sensitivity need to be adjusted, tap **Params > Sensing...** to reprogram those parameters. The Last Induction (mm:ss) timer will continue to count while you do this.
8. Wait until the Last Induction (mm:ss) timer reaches at least 05:00, then repeat Step 3 through Step 8, as needed.

3.9 Completing the implant procedure

3.9.1 How to complete programming the device

1. Enable tachyarrhythmia detection and the desired tachyarrhythmia therapies.
2. Verify that the sensing, pacing, detection, and therapy parameters are programmed to values that are appropriate for the patient.

3. Perform a final VF induction, and allow the implanted system to detect and treat the tachyarrhythmia.
4. Enter the patient's information.
 - Note:** Enter complete information about the implanted lead in the **Patient Information** screen.
 - Note:** Enter complete information about other hardware implanted in the patient in the **MRI SureScan System/Other Hardware** screen. Include concomitant or abandoned devices or leads, and lead extenders or adaptors. This information is used 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.

3.9.2 How to assess the performance of the device and 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 lead.

1. Monitor the patient's electrocardiogram until the patient is discharged. If the lead migrates or 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 can induce tachyarrhythmias with one of the EP Study tests to assess further the performance of the system.
4. Check the pacing and sensing values, and adjust the values if necessary. Verify the safety margin for the pacing threshold, and verify the sensing safety margin for detecting VF.
5. Demonstrate the alert tones.
6. To document the postoperative programmed device status, interrogate the device and print a final report.

4 Replacement procedure

4.1 Replacing a device

To retain the ability to scan the SureScan system safely during future MRI scans, refer to the MRI technical manual for additional information.

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.

Warning: A Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead must be used with the Medtronic Model DVEX3E4 EV ICD device. If a lead other than a Medtronic Model EV2401 EV4-LLHH extravascular quadripolar lead is used, the EV ICD system will present serious risks for adverse events to the patient.

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

4.1.1 How to explant and replace a device

1. Disable tachyarrhythmia detection, Post Shock pacing and Pause Prevention detection to avoid potential inappropriate shocks to the patient or clinician while explanting the device.
2. Dissect the lead and the device free from the surgical pocket. Do not nick or breach the lead insulation.
3. Use a torque wrench to loosen the setscrew in the connector block.
4. Gently pull the lead out of the connector port.
5. Evaluate the condition of the lead (see Section 3.8, "Performing ventricular defibrillation threshold tests", page 25). Replace the 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.
6. Connect the lead to the replacement device (see Section 3.4, "Connecting the lead to the device", page 21).
7. Perform a sensing test on the replacement device. See Section 3.6, "Performing a Sensing Test", page 24.
8. Perform a pacing threshold test on the replacement device. See Section 3.7, "Performing a pacing threshold test", page 25.

9. Perform ventricular defibrillation threshold tests to evaluate the defibrillation effectiveness of the replacement device. See Section 3.8, "Performing ventricular defibrillation threshold tests", page 25.
10. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see Section 3.5, "Positioning and securing the device", page 23).
11. Contact Medtronic for return mailer kits to return explanted devices for analysis and disposal. See the back cover for addresses.

Note: Observe all local laws and regulations regarding the disposal of explanted devices or leads.

5 Product specifications

5.1 Physical characteristics

Table 3. Physical characteristics

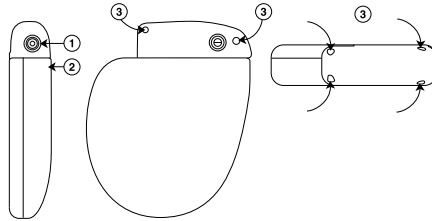
Volume ^a	33 cm ³
Mass	77 g
H x W x D	64 mm x 51 mm x 13 mm
Surface area of device can	57 cm ²
Connector	
Type	EV4-LLHH
Length	30 mm
Functional diameter	3.2 mm
Radiopaque ID ^b	REX
Materials in contact with human tissue ^c	Titanium, polyurethane, silicone rubber
Battery chemistry	Hybrid CFx lithium/silver vanadium oxide
Battery model	M970710A

^a Volume with connector ports unplugged.

^b The radiopaque ID and Medtronic radiopaque identifier 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

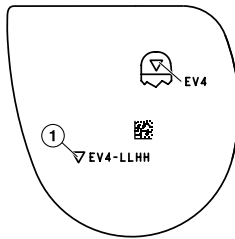


- 1 EV4-LLHH connector port
- 2 Device Active Can electrode

- 3 Suture holes

The EV ICD model DVE3E4 shield graphics are shown in Figure 7.

Figure 7. Shield graphics: EV ICD model DVE3E4



- 1 EV4-LLHH marking

5.2 Electrical specifications

Table 4. Basic battery characteristics and battery and device specifications

Battery characteristics

Manufacturer	Medtronic Energy and Component Center
Model	M970710A
Chemistry	Hybrid CFx lithium/silver vanadium oxide

Battery electrical specifications

Nominal voltage	3.2 V
Mean capacity to RRT	1.0 Ah
Minimum capacity after RRT	0.1 Ah

Table 4. Basic battery characteristics and battery and device specifications (continued)

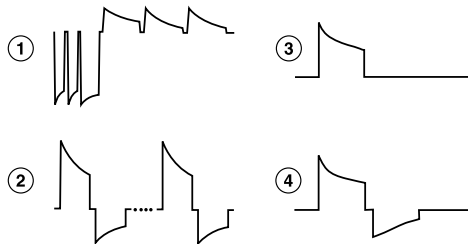
Device electrical specifications	
Input impedance	150 kΩ minimum

Table 5. 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)	71 V (±16%)	33 V (±30%)
Mean	20 J (±20%)	515 V (±10%)	255 V (±25%)
Maximum	40 J (±15%)	730 V (±10%)	360 V (±25%)

5.2.1 Output waveforms

Figure 8. Output waveform shapes



1 ≤8 V pace waveform (8 ms)

2 ≥10 V pace waveform (2 paces shown)

3 Monophasic high-voltage waveform (T-Shock inductions only)

4 Biphasic high-voltage waveform

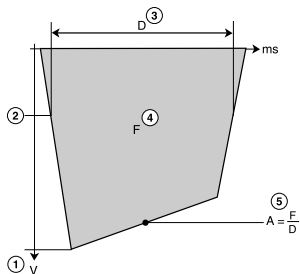
5.2.2 Measuring methods

Device parameters, such as pulse duration, pulse amplitude, and sensitivity, are measured at 37°C ±2°C and 500 Ω ±1% load according to standard ISO 14708-2:2012.

Pulse duration – Pulse duration is measured at 1/3 peak voltage levels according to standard ISO 14708-2:2012 (see Figure 9). When you apply this measurement method, the measured pulse width W depends on the load R_{load} (in ohms) and programmed pulse width W_p (in seconds) with tolerance $W \leq W_p + 34 \mu s$ and $W \geq$ the smaller of $(W_p - 16 \mu s)$ or $[124 \mu s + (4 \mu s \times R_{load})]$.

Amplitude – The pulse amplitude is calculated according to standard ISO 14708-2:2012 (see Figure 9). When you apply this measurement method, the measured amplitude A depends on the programmed amplitude A_p and programmed pulse width W_p : $A = A_p \times [0.9 - (W_p \times 0.145 \text{ ms}^{-1})]$. 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 .

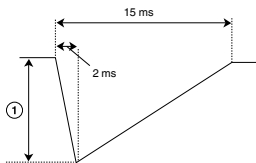
Figure 9. Measurement of pulse duration and amplitude



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

Sensitivity – Sensitivity is defined as the lowest voltage amplitude of a test signal that the device can sense. The programmable values for sensitivity assume a 40 ms sine² waveform. When using the test signal defined in ISO 14708-2:2012 (see Figure 10), the rated ventricular sensing threshold will be 1.5 times the programmed sensitivity value.

Figure 10. Measurement of sensitivity



- 1 Amplitude

Notes:

- If you measure pacing and sensitivity parameters with a pacing system analyzer, you may observe considerable variance from the specifications presented in this manual. If so, it is because the pacing system analyzers do not use the same measuring methods as defined in ISO 14708-2:2012.
- Electrocardiogram monitoring equipment can distort lead impedance measurements.

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.

5.2.3 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 (72°F to 113°F). Sensitivity at nominal conditions as measured at 37°C (98.6°F) can vary as much as ±1% per °C from 22°C to 45°C (72°F to 113°F).

5.3 Replacement indicators

The Remaining Longevity estimate, replacement status, and battery voltage appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT) and the End of Service (EOS) conditions are listed in Table 6.

Table 6. Replacement indicators

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

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

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

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

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

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

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS. The PSP is defined as 3 months assuming the following conditions: 0% pacing; 6 full-energy charges delivered, at the connector block, into a 50 Ω load. The EOS may be indicated before the end of 3 months if the device exceeds these conditions.

5.4 Projected service life

The service life projection for the device is 11.7 years, based on the following assumptions:

- Pacing at 0%.
- 2 high-voltage therapies per year.
- Pre-arrhythmia EGM storage programmed to On for 6-months, over life of device.
- Wireless telemetry:
 - 3 hours of telemetry enabled at implant.
 - 30 min of telemetry enabled for quarterly scheduled CareLink Monitor remote sessions (if available).
 - 1 hour of in-office wireless telemetry enabled annually.
- Shelf storage life of 5 months, before implant.

5.4.1 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 46 days.

Pre-arrhythmia EGM storage – Full-time use of Pre-arrhythmia EGM storage reduces projected service life by approximately 3.7 additional months per year, or 31%.

Medtronic patient monitor remote transmissions – Additional Medtronic patient monitor remote transmissions reduce projected service life. Projected service life reductions for more frequent remote transmission rates are as follows:

- Monthly transmissions over the life of the device reduce projected service life by 99 days, or 2%.
- Weekly transmissions over the life of the device reduce projected service life by 468 days, or 9%.
- Daily transmissions over the life of the device reduce projected service life by 2031 days, or 41%
- A single additional transmission reduces projected service life by approximately 0.8 days, or 0.02%.

Wireless telemetry – Each hour of wireless telemetry use (in-office or at implant) reduces the projected service life by approximately 11.7 days, or 0.27%.

Shelf storage time – Maximum shelf storage time of 18 months reduces projected service life by approximately 4.6%.

5.5 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 programmer display and on printed reports. You can evaluate charge time using the Charge/Dump Test.

Table 7. Maximum energy levels and typical full energy charge times

Maximum programmed energy	40 J
Maximum delivered energy ^{a,b}	48 J
Typical charge time at Beginning of Service (BOS) ^c	9.4 s
Typical charge time at Recommended Replacement Time (RRT) ^c	14.8 s

^a Energy delivered at connector block into a 75 Ω load.

^b Tolerance for delivered energy delivered into a 75 Ω load is $\pm 30\%$.

^c Charge time during a nonwireless telemetry session may be slightly higher.

5.6 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. The device ignores the magnet in the programmer head when telemetry communication is established through the programmer head. Before implant and for the first 6 hours after implant, the device does not sound audible tones when a magnet is placed over the device.

6 Device parameters

6.1 Emergency settings

Table 8. Emergency settings

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	STD

Table 8. Emergency settings (continued)

Parameter	Selectable values
Cardioversion	
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 J
Pathway	STD

6.2 Tachyarrhythmia detection parameters

Table 9. Ventricular tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
VF Detection ^a	On ϕ ; OFF	OFF	On
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40 ϕ ; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160	30/40	30/40
VF Beats to Redetect	6/8; 9/12; 12/16 ϕ ; 18/24; 21/28; 24/32; 27/36; 30/40	12/16	12/16
VF: Ventricular Interval (Rate) ^b	240; 250 ... 320 ϕ ... 400 ms	320 ms	320 ms
FVT Detection	OFF ϕ ; via VF	OFF	OFF
FVT: Ventricular Interval (Rate) ^b	200; 210 ... 240 ϕ ... 600 ms	—	—
VT Detection	On; OFF ϕ	OFF	OFF
VT Interval (Rate) ^b	280; 290 ... 360 ϕ ... 650 ms	360 ms	400 ms
VT Initial Beats to Detect	12; 16 ϕ ... 52; 76; 100	16	16
VT Beats to Redetect	8; 12 ϕ ... 52	12	12
Monitor	Monitor ϕ ; Off	Off	Off
Monitored VT Beats to Detect	16; 20; 24; 28; 32 ϕ ... 56; 80; 110; 130	32	32
Monitor: Ventricular Interval (Rate) ^b	280; 290 ... 450 ϕ ... 650 ms	450 ms	450 ms
Wavelet ...			
Wavelet	On ϕ ; Off; Monitor	On	Off
Template	[date]	None	None
Match Threshold	40; 43; 46 ... 61 ϕ ... 97%	61%	61%
Auto Collection	On ϕ ; Off	ON	OFF
Rapid AF	On ϕ ; Off	ON	OFF
Feature Match	On ϕ ; Off	ON	OFF
SVT V. Limit ^b	210; 220; ... 260 ϕ ... 650 ms	260 ms	260 ms

Table 9. Ventricular tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Reset
Other Enhancements			
Stability ^b	Off ϕ ; 30; 40 ... 100 ms	Off	Off
Onset	Off ϕ ; On; Monitor	Off	Off
Percent	72; 75; 78; 81 ϕ ; 84; 88; 91; 94; 97%	81%	81%
High Rate Timeout			
VF Zone Only (min)	Off; 0.25; 0.5; 0.75 ϕ ; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5 min	0.75 min	0.75 min
All Zones (min)	Off ϕ ; 0.5; 1; 1.5 ... 5; 6; 7 ... 20; 22; 24; 26; 28; 30 min	—	—
TWave	On ϕ ; Off	On	Off
Noise			
Sensed Noise	On ϕ ; Off	On	Off
Morphology Noise	On ϕ ; Off	On	Off
Sensed EMI	On ϕ ; Off	On	Off
Shared Noise Timeout ^c	Off; 0.25; 0.50; 0.75; ... 2.00; 2.503.0 ϕ ... 4.00 min	3 min	—

^a Reset does not happen in the box. Table shows Reset value when implanted.

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

^c Therapy can be withheld by noise oversensing enhancements for up to the total timeout period.

6.3 Ventricular tachyarrhythmia therapy parameters

Table 10. Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
VF Therapies			
VF Therapy Status	On ϕ ; 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 ϕ J Rx3–Rx6: 10; 11 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 ϕ J	40 J	40 J
Pathway ^a	Rx1–Rx4: STD ϕ ; REV Rx5–Rx6: STD; REV ϕ	STD	STD
VT/FVT Therapies			
VT/FVT Therapy Status	Rx1–Rx6: On; Off ϕ	Off	Off
Therapy Type	Rx1: CV; Burst ϕ ; Ramp Rx2–Rx6: CV ϕ ; Burst; Ramp	—	—
Energy ^b	Rx2–Rx6: 0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 ϕ J	—	—

Table 10. Ventricular tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
Pathway ^a	Rx2–Rx4: STD ϕ ; REV Rx5–Rx6: STD; REV ϕ	—	—
Burst therapy parameters			
Initial # Pulses	1; 2 ... 8 ϕ ... 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 ... 84; 88 ϕ ; 91; 94; 97%	—	—
Interval Dec	0; 10 ϕ ... 40 ms	—	—
# Sequences	1; 2 ... 10 VT Therapies: 3 ϕ FVT Therapies: 1 ϕ	—	—
Smart Mode ^c	On; Off ϕ	—	—
Ramp therapy parameters			
Initial # Pulses	1; 2 ... 8 ϕ ... 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 ... 84; 88; 91 ϕ ; 94; 97%	—	—
Interval Dec	0; 10 ϕ ... 40 ms	—	—
# Sequences	1; 2 ... 10 VT Therapies: 3 ϕ FVT Therapies: 1 ϕ	—	—
Smart Mode ^c	On; Off ϕ	—	—
Shared Settings...			
Shared V. ATP			
V-V Minimum ATP Interval	150; 160 ... 200 ϕ ... 400 ms (\pm 12 ms ^d / \pm 60 ms ^e)	200 ms	200 ms
V. Amplitude	1; 2 ... 8; 10; 13; 16; 20; 30 V	10 V	10 V
V. Pulse Width	1; 2; 3; 4; 6; 8 ms (\pm 100 μ s)	2 ms	2 ms
V. Pace Blanking	150; 160 ... 250 ϕ ... 450 ms (\pm 5 ms)	250 ms	250 ms
ATP Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1	Coil 2 to Coil 1	Coil 2 to Coil 1

^a STD = Can to Coils; REV = Coils to Can.

^b This parameter is for CV (cardioversion).

^c Smart Mode is available only for Rx1– Rx4.

^d At \leq 8 V amplitude.

^e At \geq 10 V amplitude.

6.3.1 Delivered energy conditions and tolerances

This table lists the conditions and tolerances for delivered energy levels for high voltage therapies.

Table 11. Delivered energy conditions and tolerances

	30 Ω	50 Ω	75 Ω	200 Ω	250 Ω
22°C: 0.4 J - 35 J ^a	-35% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%
22°C: 40 J	-30% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%
37°C: 0.4 J - 4 J ^a	-30% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%
37°C: 5 J - 35 J	-30% / +20%	-20% / +20%	-20% / +20%	-30% / +20%	-50% / +50%
37°C: 40 J	-30% / +20%	-15% / +15%	-15% / +15%	-30% / +20%	-50% / +50%
45°C: 0.4 J - 40 J ^a	-30% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%

^a Tolerance is ± 0.25 J for energy levels for which ± 0.25 J is greater than the listed tolerance range.

6.4 Post shock pacing parameters

Table 12. Post Shock pacing parameters

Parameter	Programmable values	Shipped	Reset
Post Shock Pacing Enable	On; Off	Off	Off
Amplitude	1 V (+0.18 V / -35%); 2; 3 ... ; 7; 8 V (+15% / -35%) ^a 10; 13; 16; 20; 30 V (+20% / -45%) ^b	10 V	10 V
Pulse Width	2; 4 ms ($\pm 100 \mu\text{s}$); ^c 6; 8 ms ($\pm 10\%$) ^c 1; 2 ... 10 ms ($\pm 10\%$) ^d	—	—
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1	—	—
Lower Rate ^{e,f}	40 bpm (1500 ms)	—	—
Therapy Duration ^e	30 s	—	—

^a Ring 1 to Ring 2 or Ring 1 to Coil 2, nominal 500 Ω impedance.

^b Coil 2 to Coil 1, nominal 75 Ω impedance.

^c For ≤ 8 V amplitude, Ring 1 to Ring 2 or Ring 1 to Coil 2.

^d For ≥ 10 V amplitude, Coil 2 to Coil 1.

^e This parameter is nonprogrammable.

^f Escape interval at nominal pulse width of 8 ms is 992 ms.

6.5 Pause Prevention Detection — detection and pacing parameters

Table 13. Pause Prevention Detection — detection and pacing parameters

Parameter	Programmable values	Shipped	Reset
Setting			
Pause Prevention Detection Enable	On; Off; Monitor	Monitor	Monitor
Pause Prevention Detection Interval	5; 6 ... 15 s	5 s	10 s
Amplitude	1 V (+0.18 V / -35%) ^a 2; 3 ... 8 V (+15% / -35%) ^a 10; 13 V (+20% / -45%) ^b	—	—
Pulse Width	2; 4 ms ($\pm 100 \mu\text{s}$) ^c 6; 8 ms ^c 1; 2 ... 10 ($\pm 10\%$ / $\pm 20\%$) ms ^d	—	—
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1	—	—
Lower Rate ^{e,f}	40 bpm (1500 ms)	—	—
Therapy Duration ^e	30 s	—	—

^a Ring 1 to Ring 2 or Ring 1 to Coil 2.

^b Coil 2 to Coil 1.

^c For ≤ 8 V amplitude, Ring 1 to Ring 2 or Ring 1 to Coil 2.

^d For ≥ 10 V amplitude, Coil 2 to Coil 1. Within $\pm 10\%$ for impedance $\geq 50 \Omega$ and within $\pm 20\%$ for impedance $< 50 \Omega$.

^e This parameter is nonprogrammable.

^f Escape interval at nominal pulse width of 8 ms is 992 ms.

6.6 Sensing parameters

Table 14. Sensing parameters

Parameter	Programmable values	Shipped	Reset
Sensitivity ^{a,b,c}	0.075; 0.100; 0.150 ($\pm 75\%$); 0.200; 0.300; 0.450; 0.600 ($\pm 50\%$); 0.900; 1.200 mV ($\pm 30\%$)	0.300 mV	0.150 mV
Sense Polarity	Ring 1 to Ring 2; Ring 1 to Can; Ring 2 to Can	Ring 1 to Ring 2	Ring 1 to Ring 2
Blank after Sense	140; 150 ϕ ... 200 ms	150 ms	150 ms
Sensing Threshold Decay Delay	210; 260 ... 360 ϕ ... 650 ms	360 ms	360 ms
Sensing Threshold Drop Time	500; 680; 1000; 1100 ... 1500 ϕ ; 1600 ... 2500 ms	1500 ms	1500 ms

Table 14. Sensing parameters (continued)

Parameter	Programmable values	Shipped	Reset
Blank after Pace	200; 210 ... 250 [Ⓢ] ... 450 ms	250 ms	250 ms
Oversensing Prevention	Low - 1; 2; Medium - 3 [Ⓢ] ; 4; 5; High - 6; 7 ... 11; Max - 12	Medium - 3	Medium - 3

^a Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.075 mV. When susceptibility to modulated interference is tested under the conditions specified in standard ISO 14708-2:2012, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.075 mV. The device complies with the standard requirements when the sensitivity threshold is programmed 0.3 mV or higher.

^b There is no nominal value for this parameter.

^c Programming Sense Polarity to a unipolar setting (Ring 1 to Can or Ring 2 to Can) will result in increased susceptibility to EMI. Consider programming Sense Polarity to a bipolar setting whenever possible.

6.7 MRI SureScan parameters

Table 15. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
Timeout ^a	6 hr	—	—
Mode ^a	OVO	—	—
Detection/Therapies ^a	Off	—	—

^a This parameter is nonprogrammable when the MRI SureScan feature is programmed to On.

6.8 Medtronic CareAlert parameters

Table 16. Clinical Management Alerts

Parameter	Programmable values	Shipped	Reset
Number of Shocks Delivered in an Episode... ^a			
Device Tone			
Alert Enable - Urgency	Off [Ⓢ] ; On-Low; On-High	Off	Off
Number of Shocks Threshold ^b	1 [Ⓢ] ; 2; 3; 4; 5; 6	—	—
Patient Home Monitor ^c			
Alert Enable	Off [Ⓢ] ; On	Off	Off
Number of Shocks Threshold ^b	1 [Ⓢ] ; 2; 3; 4; 5; 6	—	—
All Therapies in a Zone Exhausted for an Episode.			
Device Tone			
Alert Enable - Urgency	Off [Ⓢ] ; On-Low; On-High	Off	Off
Patient Home Monitor			
Alert Enable	Off [Ⓢ] ; On	Off	Off
Number of Pause Prevention Episodes...			

Table 16. Clinical Management Alerts (continued)

Parameter	Programmable values	Shipped	Reset
Device Tone			
Alert Enable - Urgency	Off \diamond ; On-Low; On-High	Off	Off
Number of Pause Prevention Episodes Threshold ^b	1; 2; 3; 4; 5 \diamond	—	—
Patient Home Monitor			
Alert Enable	Off; On	Off	Off
Number of Pause Prevention Episodes Threshold ^b	1; 2; 3; 4; 5 \diamond	—	—
Alert Time (all others)...	00:00; 00:10 ... 08:00 \diamond ... 23:50	08:00	08:00

^a Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

^b This parameter is displayed only when its related alert is enabled; a single parameter is shared between the Device Tone and Patient Home Monitor alerts.

^c Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Table 17. Lead/Device Integrity Alerts

Parameter	Programmable values	Shipped	Reset
Lead Impedance Out of Range...			
Device Tone			
Alert Urgency ^a	Low; High \diamond	High	Off
Lead Impedance Enable			
Ring 1 to Ring 2	On; Off (Observation only)	On	Off (Observation only)
Ring 1 to Coil 2	On; Off (Observation only)	On	Off (Observation only)
High Voltage	On; Off (Observation only)	On	Off (Observation only)
Patient Home Monitor			
Lead Impedance Enable ^b			
Ring 1 to Ring 2	On; Off \diamond	Off	Off
Ring 1 to Coil 2	On; Off \diamond	Off	Off
High Voltage	On; Off \diamond	Off	Off
Low Battery Voltage RRT...			
Device Tone			
Alert Enable - Urgency	Off; On-Low; On-High \diamond	On-High	Off
Patient Home Monitor			
Alert Enable ^b	Off; On	On	Off

Table 17. Lead/Device Integrity Alerts (continued)

Parameter	Programmable values	Shipped	Reset
Excessive Charge Time EOS...			
Device Tone			
Alert Enable - Urgency	Off; On-Low; On-High ϕ	On-High	Off
Patient Home Monitor			
Alert Enable ^b	Off; On	On	Off
VF Detection Off, 3+ VF or 3+ FVT Rx Off.			
Device Tone			
Alert Enable	Off; On-High ϕ	On-High	On-High
Patient Home Monitor			
Alert Enable ^b	Off; On	On	Off

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

^b Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Table 18. Shared parameters

Parameter	Programmable values	Shipped	Reset
Patient Home Monitor	Yes; No ϕ	No	No
Alert Time... ^a	00:00; 00:10 ... 08:00 ϕ ... 23:50	08:00	08:00

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

6.9 Data collection parameters

Table 19. Data Collection Setup parameters

Parameter	Programmable values	Shipped	Reset
LECG Source ^a	Ring 1 to Ring 2; Ring 2 to Can ϕ ; Coil 2 to Ring 2	Ring 2 to Can	Ring 2 to Can
LECG Range	± 1 ; ± 2 ; ± 4 ; $\pm 8\phi$; ± 12 ; ± 16 ; ± 32 mV	± 8 mV	± 8 mV
EGM 1 Source	Ring 1 to Ring 2 ϕ ; Ring 1 to Can; Ring 2 to Can; Coil 2 to Coil 1	Ring 1 to Ring 2	Ring 1 to Ring 2
EGM 1 Range	± 2 ; ± 4 ; $\pm 8\phi$; ± 12 ; ± 16 ; ± 32 mV	± 8 mV	± 8 mV
EGM 2 (Wavelet) Source	Ring 1 to Ring 2; Ring 1 to Coil 1; Ring 1 to Coil 2; Coil 2 to Can ϕ ; Coil 1 to Can; Ring 1 to Can; Ring 2 to Can; Coil 2 to Coil 1	Coil 2 to Can	Coil 2 to Can
EGM 2 (Wavelet) Range	± 1 ; ± 2 ; ± 4 ; $\pm 8\phi$; ± 12 ; ± 16 ; ± 32 mV	± 8 mV	± 8 mV
EGM 3 Source	Coil 2 to Coil 1 ϕ ; Ring 1 to Ring 2; Coil 2 to Ring 2	Coil 2 to Coil 1	Coil 2 to Coil 1
EGM 3 Range	± 1 ; ± 2 ; ± 4 ; $\pm 8\phi$; ± 12 ; ± 16 ; ± 32 mV	± 8 mV	± 8 mV

Table 19. Data Collection Setup parameters (continued)

Parameter	Programmable values	Shipped	Reset
Stored (Ventricular)	EGM1 and EGM2 [Ⓢ] ; EGM1 and EGM3; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG	EGM1 and EGM2	EGM1 and EGM2
Pre-arrhythmia EGM	Off [Ⓢ] ; On - 1 month; On - 3 months; On Continuous	Off	Off
Device Date/Time... ^b	(Enter time and date)	On	On
Holter Telemetry	Off [Ⓢ] ; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off

^a LECG: this EGM channel displays morphology channel signals.

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

6.10 System test parameters

Table 20. System Test parameters

Parameter	Selectable values
Tests – Sensing	
Mode	
Test Value	OVO
Permanent	OVO
Tests – Pacing Threshold	
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Mode	
Test Value	VVI
Permanent	OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 150 bpm
Amplitude	1.00; 1.50; ... 8.00 V
Pulse Width	2.00; 4.00; 6.00; 8.00 ms
Additional Settings...	
V. Pace Blanking	150; 160 ... 450 ms
Tests – Wavelet	
Wavelet enable	Off; On [Ⓢ] ; Monitor
Match Threshold	40; 43 ... 61 [Ⓢ] ... 97
Auto Collection	On [Ⓢ] ; Off
Mode	OVO

6.11 EP Study parameters

Table 21. T-Shock parameters

Parameter	Selectable values
Enable	(checked); (unchecked)⊕
#S1	2; 3; 4; 5⊕; 6 ... 15
S1S1	300; 310 ... 400⊕ ... 2000 ms
S1 Pathway	Ring 1 to Coil 2⊕; Coil 2 to Coil 1
Delay	120; 130 ... 300⊕ ... 600 ms
T Energy	1⊕; 1.2; 1.4 ... 2; 3 ... 16; 18; 20 J
Waveform ^a	Monophasic

^a This parameter is nonprogrammable.

Table 22. Burst Induction parameters

Parameter	Selectable values
Enable	(checked); (unchecked)⊕

Table 23. PES parameters

Parameter	Selectable values
Enable	(checked); (unchecked)⊕
#S1	1; 2 ... 8⊕; 9 ... 15
S1S1	150; 160 ... 600⊕; 610 ... 2000 ms
S1S2	150; 160 ... 400⊕; 410 ... 600 ms
S2S3	150; 160 ... 400⊕; 410 ... 600 ms ^a
S3S4	150; 160 ... 400⊕; 410 ... 600 ms ^a
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Amplitude	Ring 1 to Coil 1, Ring 1 to Coil 2: 8 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Coil 1, Ring 2 to Coil 2: 2; 4; 6; 8⊕ ms Coil 2 to Coil 1: 1; 2; 3; 4 ms

^a Default value when parameter is On is 400 ms.

Table 24. Defibrillation parameters

Parameter	Selectable values
Enable	(checked); (unchecked)⊕
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40⊕ J

Table 24. Defibrillation parameters (continued)

Parameter	Selectable values
Waveform ^a	Biphasic
Pathway	STD ϕ ; REV

^aThis parameters is nonprogrammable.

Table 25. Cardioversion parameters

Parameter	Selectable values
Enable	(checked); (unchecked) ϕ
Energy	0.4; 0.6 ... 1.8; 2; 3 ... 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 ϕ J
Pathway	STD ϕ ; REV

Table 26. Burst ATP parameters

Parameter	Selectable values
Enable	(checked); (unchecked) ϕ
# Pulses	1; 2 ... 8 ϕ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88 ϕ ; 91; 94; 97%
Minimum Interval	150; 160 ... 400 ms
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Amplitude ^a	Ring 1 to Coil 1, Ring 1 to Coil 2: 8 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Coil 1, Ring 2 to Coil 2: 2; 4; 6; 8 ms Coil 2 to Coil 1: 1; 2; 3; 4 ms

^aThis parameter is nonprogrammable.

7 Explanation of symbols

The following symbols and abbreviations are printed on the Medtronic EV ICD Model DVEX3E4 package label.

Table 27. Explanation of symbols on package labeling



Symbol	Explanation
	SureScan symbol
	MR Conditional. The Medtronic SureScan pacing system is safe for use in the MRI environment when used according to the instructions in the SureScan technical manual.

Table 27. Explanation of symbols on package labeling (continued)











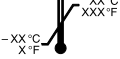






Symbol	Explanation
	Open here
	Open here
	Do not use if package is damaged
	Do not reuse
	Sterilized using ethylene oxide
	Consult instructions for use
	Date of manufacture
	Use by
	Reorder number
	Serial number
	Temperature limitation
	Package contents
	Implantable device

Table 27. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Implantable device, MR
	ICD (single chamber, RV)
	Non-standard connector cavity
	Product documentation
	Torque wrench
	Sensitivity, RV
	Therapies (delivered and stored), VF
	Therapies (RV), VT, FVT
	Detection, VT, FVT, VF
	Burst: RV
	Ramp: RV
	Defibrillation
	V cardioversion

Table 27. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Active Can
	Diameter
	Use with
	Extra-vascular lead

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Technical manuals

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