Ellipse™
Tiered-therapy Cardioverter/Defibrillator

Fortify Assura™
Tiered-therapy Cardioverter/Defibrillator

Quadra Assura™, Quadra Assura MP™
Cardiac Resynchronization Device, Tiered-therapy Cardioverter/Defibrillator

Unify Assura™
Cardiac Resynchronization Device, Tiered-therapy Cardioverter/Defibrillator

Device Description

This manual describes the following St. Jude Medical™ pulse generators[1]:

CAUTION: Not all device models are available in all countries.

Not all of the products listed as MR Conditional are approved for MR Conditional use in all countries or regions.

Before performing an MRI scan on patients implanted with any of these devices, contact St. Jude Medical or consult your regulatory authorities to determine if the products have been certified as MR Conditional.

Table 1. Single-chamber pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Ellipse VR	CD1275-36	Single-chamber ICD with RF telemetry	DF-1/IS-1	36 J	Untested

[1] Not all device models are available in all countries.

Table 1. Single-chamber pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Ellipse VR	CD1275-36Q	Single-chamber ICD with RF telemetry	DF4-LLHH[2]	36 J	Untested
Fortify Assura VR	CD1359-40	Single-chamber ICD with RF telemetry	DF-1/IS-1	40 J	Untested
Fortify Assura VR	CD1359-40C	Single-chamber ICD with RF telemetry, Parylene coating	DF-1/IS-1	40 J	Untested
Fortify Assura VR	CD1359-40Q	Single-chamber ICD with RF telemetry	DF4-LLHH	40 J	MR Conditional
Fortify Assura VR	CD1359-40QC	Single-chamber ICD with RF telemetry, Parylene coating	DF4-LLHH	40 J	MR Conditional
Ellipse VR	CD1377-36	Single-chamber ICD with RF telemetry	DF-1/IS-1	36 J	Untested

[2] SJ4-LLHH is equivalent to DF4-LLHH. SJ4-LLLL is equivalent to IS4-LLLL. St. Jude Medical's SJ4 and DF4 connector cavities comply with ISO 27186:2010(E).

Table 1. Single-chamber pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Ellipse VR	CD1377-36C	Single-chamber ICD with RF telemetry, Parylene coating	DF-1/IS-1	36 J	Untested
Ellipse VR	CD1377-36Q	Single-chamber ICD with RF telemetry	DF4-LLHH	36 J	MR Conditional
Ellipse VR	CD1377-36QC	Single-chamber ICD with RF telemetry, Parylene coating	DF4-LLHH	36 J	MR Conditional

Table 2. Dual-chamber pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Ellipse DR	CD2275-36	Dual-chamber ICD with RF telemetry	DF-1/IS-1	36 J	Untested
Ellipse DR	CD2275-36Q	Dual-chamber ICD with RF telemetry	DF4-LLHH[3]/IS-1	36 J	Untested
Fortify Assura DR	CD2359-40	Dual-chamber ICD with RF telemetry	DF-1/IS-1	40 J	Untested
Fortify Assura DR	CD2359-40C	Dual-chamber ICD with RF telemetry, Parylene coating	DF-1/IS-1	40 J	Untested
Fortify Assura DR	CD2359-40Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/IS-1	40 J	MR Conditional

[3] SJ4-LLHH is equivalent to DF4-LLHH. SJ4-LLLL is equivalent to IS4-LLLL. St. Jude Medical's SJ4 and DF4 connector cavities comply with ISO 27186:2010(E).

Table 2. Dual-chamber pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Fortify Assura DR	CD2359-40QC	Dual-chamber ICD with RF telemetry, Parylene coating	DF4-LLHH/IS-1	40 J	MR Conditional
Ellipse DR	CD2377-36	Dual-chamber ICD with RF telemetry	DF-1/IS-1	36 J	Untested
Ellipse DR	CD2377-36C	Dual-chamber ICD with RF telemetry, Parylene coating	DF-1/IS-1	36 J	Untested
Ellipse DR	CD2377-36Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/IS-1	36 J	MR Conditional
Ellipse DR	CD2377-36QC	Dual-chamber ICD with RF telemetry, Parylene coating	DF4-LLHH/IS-1	36 J	MR Conditional

Table 3. CRT-D pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Unify Assura	CD3361-40	CRT-D with RF telemetry	DF-1/IS-1	40 J	Untested
Unify Assura	CD3361-40C	CRT-D with RF telemetry, Parylene coating	DF-1/IS-1	40 J	Untested
Unify Assura	CD3361-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS-1	40 J	Untested
Unify Assura	CD3361-40QC	CRT-D with RF telemetry, Parylene coating	DF4-LLHH/ IS-1	40 J	Untested
Quadra Assura	CD3367-40	CRT-D with RF telemetry	DF-1/IS-1/ IS4-LLLL	40 J	Untested

Table 3. CRT-D pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Quadra Assura	CD3367-40C	CRT-D with RF telemetry, Parylene coating	DF-1/IS-1/ IS4-LLLL	40 J	Untested
Quadra Assura	CD3367-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional
Quadra Assura	CD3367-40QC	CRT-D with RF telemetry, Parylene coating	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional
Quadra Assura MP	CD3371-40	CRT-D with RF telemetry	DF-1/IS-1/ IS4-LLLL	40 J	Untested
Quadra Assura MP	CD3371-40C	CRT-D with RF telemetry, Parylene coating	DF-1/IS-1/ IS4-LLLL	40 J	Untested

Table 3. CRT-D pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Quadra Assura MP	CD3371-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional
Quadra Assura MP	CD3371-40QC	CRT-D with RF telemetry, Parylene coating	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional

These devices can be programmed with Merlin™ Patient Care System equipped with Model 3330 version 17.2 (or greater) software. For information on programming, refer to the programmer's on-screen help.

Indications

The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronization Therapy

devices (CRT-Ds) are also intended to resynchronize the right and left ventricles in patients with congestive heart failure.

AT/AF Detection Algorithm. The AT/AF detection algorithm is indicated for detecting atrial tachyarrhythmias which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF.

Table 4. Accessories and their intended uses

Accessory	Intended use
Torque driver	Secure lead connectors and port plugs within the device header.
Silicone oil	Lubricant
Medical adhesive	Sealant
Magnet	Place over the device to inhibit tachyarrhythmia therapy
DF-1 Receptacle Plug	Seal unused lead receptacles
IS-1 Receptacle Plug	Seal unused lead receptacles
IS4/DF4 Port Plug	Seal unused lead receptacles

MR Conditional System

An MR Conditional ICD or CRT-D are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI Procedure document for the St. Jude Medical™ MR Conditional System.

Contraindications

Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Warnings

Implantation Procedure

- The physician should be familiar with all components of the system and the material in this manual before beginning the procedure.
- Ensure that a separate standby external defibrillator is immediately available.
- Implant the pulse generator no deeper than 50 mm to ensure reliable data transmission. For patient comfort, do not implant the pulse generator within 12.5 mm of bone unless you cannot

avoid it.

Device Replacement

- Replace the pulse generator within three months of reaching ERI. **Replace the pulse generator immediately upon reaching ERI if there is frequent high-voltage charging and/or one or more of the pacing outputs are programmed above 2.5 V. See Battery Information (page 59).**

Battery Incineration

- Do not incinerate pulse generators as they contain sealed chemical power cells and capacitors that may explode. Return explanted devices to St. Jude Medical.

High-Voltage Can

- Ensure that tachyarrhythmia therapy is programmed Off before handling the pulse generator to avoid any risk of accidental shock. Do not program tachyarrhythmia therapies On until the pulse generator is inserted in the pocket.
- For effective defibrillation, perform all defibrillation testing with the can in the pocket.

Magnetic Resonance Imaging (MRI)

- MR Conditional ICDs and CRT-Ds. Testing has demonstrated that the St. Jude Medical™ MR Conditional system is conditionally safe for use in the MRI environment when used according

to the instructions in the MRI Procedure Information document. The St. Jude Medical MR Conditional system includes a St. Jude Medical MR Conditional pulse generator connected to one or more St. Jude Medical MR Conditional leads.

- MR Untested ICDs and CRT-Ds. "Untested" indicates that the device has not been tested and its use in an MR environment is not determined. For more information, please consult the MRI Procedure Information document.

Precautions

Device Modification

- This device has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by St. Jude Medical Inc. could void the user's authority to operate this device.

Device Storage

- Store the pulse generator at temperatures between 10° and 45°C. Do not subject it to temperatures below -20° or over 60°C.
- After cold storage, allow the device to reach room temperature before charging the capacitors, programming, or implanting the device because cold temperature may affect initial device function.

Lead Impedance

- Do not implant the pulse generator if the acute defibrillation lead impedance is less than 20 Ω or the lead impedance of chronic leads is less than 15 Ω. Damage to the device may result if high-voltage therapy is delivered into an impedance less than 15 Ω.

Device Communication

- Communication with the device can be affected by electrical interference and strong magnetic fields. If this is a problem, turn off nearby electrical equipment or move it away from the patient and the programmer. If the problem persists, contact St. Jude Medical.

Suboptimal RF Communication

- The Merlin™ PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin™ Antenna. Below is a list of potential causes to suboptimal radio communication.

Table 5. Possible causes and solutions for suboptimal RF communication

Possible Causes	Solutions
The Merlin Antenna orientation/location is suboptimal.	Move or reorient the Merlin Antenna slightly. Make sure that the front of the Merlin Antenna faces the implantable device.
People or objects interfere with the communication between the Merlin Antenna and the device.	Make sure that the space between the Merlin Antenna and the device is free from interfering objects/people.
The Merlin Antenna is too far away from the device.	Move the Merlin Antenna closer to the device.
Someone is holding the Merlin Antenna.	Place the Merlin Antenna on a flat surface. Do not hold the Merlin Antenna.
Other products in the vicinity are causing electromagnetic interference (EMI).	Power off or remove equipment that could cause EMI.
The Merlin Antenna cable is wound around the Merlin Antenna.	Make sure the Merlin Antenna cable is not wound around the Merlin Antenna.

Disconnecting Leads

- Connecting or disconnecting sense/pace leads can produce electrical artifacts that can be sensed by the pulse generator. To prevent detection of artifacts, reprogram the pulse generator to tachyarrhythmia therapy Off:
  - Before disconnecting the leads from a pulse generator in the operating room
  - Before a post-mortem examination
  - Whenever there are no leads connected to it
  - When sense/pace leads are connected but are not implanted in a patient

  If a programmer is not available, use a magnet to prevent delivery of tachyarrhythmia therapy in response to detected disconnection artifacts. Place the magnet over the pulse generator before disconnecting the leads. Do not remove it until the leads are reconnected.

  CAUTION: The Magnet Response parameter must be set to Normal for the magnet to prevent the delivery of tachyarrhythmia therapy. For more information, see Using a Magnet.

External Equipment for Arrhythmia Induction

- If external equipment is used for arrhythmia induction through the pulse generator header and leads, apply rectified AC current through the high-voltage ports, not the sense/pace ports, to avoid

damaging the sense/pace function.

- Disconnect the external equipment from the pulse generator before any therapy is delivered; otherwise, damage to the device is likely to occur. Place a magnet over the device until the external equipment can be disconnected.

Antiarrhythmic Drugs

- Antiarrhythmic drugs may alter the defibrillation energy threshold, rendering the pulse generator's countershock ineffective or causing the shock to induce a clinically significant arrhythmia. In addition, changing cardiac electrical characteristics may prevent detection of a tachyarrhythmia or may cause the pulse generator to misinterpret a normal rhythm as a clinically significant arrhythmia. Changes in medication may require defibrillation threshold testing, updating the morphology template, and reprogramming of the device.

Sterilization

- The package contents have been sterilized with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.

Environmental Hazards

- External devices generating strong electromagnetic fields can cause operational problems in the

pulse generator that include: cessation of or intermittent bradycardia pacing, and inadvertent antitachycardia pacing, cardioversion, or defibrillation. Additionally, high-energy induced or conducted currents can reset the programmed parameters and damage the pulse generator and tissue surrounding the implanted lead electrodes.

Additional Pacemaker

- These devices provide bradycardia pacing. If another pacemaker is used, it should have a bipolar pacing reset mode and be programmed for bipolar pacing to minimize the possibility of the output pulses being detected by the device.

External Defibrillators

- Shocks of sufficient strength can reset the programmed parameters or damage the pulse generator and/or the tissue around the lead electrodes. Whenever possible, disconnect the pulse generator from its leads before applying defibrillator paddles.
- The effectiveness of external defibrillation may be reduced due to the insulating effect of the implanted defibrillation electrodes. Minimize this with proper external paddle placement relative to the orientation of the implanted defibrillation electrodes. Deliver the energy perpendicular to a line between the two implanted electrodes.
- As soon as possible after external/internal defibrillation, check the pulse generator by verifying that:

- Programmed parameters remain as previously programmed
- Measurements (battery voltage, lead impedances, etc.) are appropriate
- Real-time EGM and status information indicate appropriate sensing of cardiac signals
- Capture is maintained during bradycardia pacing

- Verify the proper functioning of the output circuitry by delivering a synchronous emergency shock.
- External defibrillation may reprogram the device to its reset values. Assess any device parameter reset in conjunction with St. Jude Medical Technical Service personnel.

Electrosurgical Instruments

- The pulse generator may detect electrocautery energy as cardiac events and deliver tachyarrhythmia therapy. Electrocautery can also cause tissue damage near the implanted electrodes, damage the pulse generator, or reprogram the device to its reset values. Position the electrocautery ground electrode to minimize current flow through the implanted electrode system. Do not apply electrocautery directly to the pulse generator.
- During electrosurgery, disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapy Off. If a programmer is unavailable, use a magnet to inhibit delivery of tachyarrhythmia therapy.

Therapeutic Radiation

- Use devices emitting ionizing radiation with caution as they can cause damage to the CMOS

circuitry in the pulse generator that might not be immediately detectable. Devices such as linear accelerators, betatrons and cobalt machines can be used with proper therapeutic planning to minimize cumulative dosage levels to the pulse generator. Diagnostic X-rays, although a source of ionizing radiation, generally produce much lower levels and are not contraindicated. Consultation with clinical physicists and St. Jude Medical is recommended.

Medical Lithotripsy

- Avoid lithotripsy unless the therapy site is not near the pulse generator and leads as lithotripsy may damage the pulse generator.

Diathermy

- Avoid diathermy, even if the device is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the pulse generator.

Ultrasound Therapy

- The device should not be exposed to therapeutic levels of ultrasound energy, as the device can inadvertently concentrate the ultrasound field and cause harm that might not be immediately detectable. Diagnostic ultrasound treatment is not known to affect the function of the device.

Home and Industrial Environments

- A variety of devices produce electromagnetic interference (EMI) of sufficient field strength and modulation characteristics to interfere with proper operation of the pulse generator. These include:

high-powered radio, television, and radar transmitters/antennas; arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

- The patient should avoid strong magnetic fields since they are potentially capable of inhibiting tachyarrhythmia therapies. If a patient is frequently in a high-magnetic-field environment and therefore at risk of not having therapies delivered, you may choose to program the device to ignore magnetic fields. Therapies would then be delivered in the normal manner in response to detected arrhythmias. Magnet application would have no effect on operation.

Electronic Article Surveillance (EAS)

Advise patients that the Electronic Article Surveillance/Anti-theft systems or Electronic Article Surveillance (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with ICDs and CRT-Ds. It is very unlikely that these systems will interact with their device significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

Metal Detectors

Advise patients that metal detector security systems such as those found in airports and government buildings emit signals that may interact with ICDs and CRT-Ds. It is very unlikely that these systems will interact with their device significantly. To minimize the possibility of interaction, advise patients to

simply walk through these areas at a normal pace and avoid lingering. Even so, the ICD and CRT-D systems contain metal that may set off the airport security system alarm. If the alarm does sound, the patient should present security personnel with their patient identification card. If security personnel perform a search with a handheld wand, they should ask the security personnel to perform the search quickly, stressing that they should avoid holding the wand over the device for a prolonged period.

Cellular Phones

The pulse generator has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of AAMI PC69. This testing covered the operating frequencies (450 MHz - 3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. Based on the results of this testing, the pulse generator should not be affected by the normal operation of cellular phones.

Adverse Events

Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include:

- Acute hemorrhage/bleeding
- Air emboli
- Arrhythmia acceleration
- Cardiac or venous perforation

- Cardiogenic shock
- Cyst formation
- Death
- Erosion
- Exacerbation of heart failure
- Extrusion
- Fibrotic tissue growth
- Fluid accumulation
- Hematoma formation
- Histotoxic reactions
- Infection
- Keloid formation
- Myocardial irritability
- Nerve damage
- Pneumothorax
- Thromboemboli
- Venous occlusion

Other possible adverse effects include mortality due to:

- Component failure
- Device-programmer communication failure
- Lead abrasion
- Lead dislodgment or poor lead placement
- Lead fracture
- Inability to defibrillate
- Inhibited therapy for a ventricular tachycardia
- Interruption of function due to electrical or magnetic interference
- Shunting of energy from defibrillation paddles
- System failure due to ionizing radiation

Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by:

- Multiple counting of cardiac events including T-waves, P-waves, or supplemental pacemaker stimuli

Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Persons administering cardiopulmonary resuscitation (CPR) have reportedly been startled by voltage present on the patient's body surface during discharge of the pulse generator. The voltage decreases as

the discharge disperses toward the periphery of the body, and is weakest at the furthest extension of the limbs. Nevertheless, there is a highly remote possibility that an arrhythmia may be induced in someone administering CPR to the patient at the time a countershock is delivered.

Pulse Generator Header

The pulse generator headers are shown below and the legend for the lead receptacles are described in the table (page 30) below.

Table 6. Single-chamber ICD headers (see table (page 30) for legend)

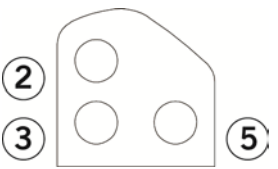
 Fortify Assura VR CD1359-40, CD1359-40C	 Fortify Assura VR CD1359-40Q, CD1359-40QC

Table 6. Single-chamber ICD headers (see table (page 30) for legend)

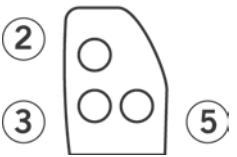
 Ellipse VR CD1275-36, CD1377-36, CD1377-36C	 Ellipse VR CD1275-36Q, CD1377-36Q, CD1377-36QC

Table 7. Dual-chamber ICD headers (see table (page 30) for legend)

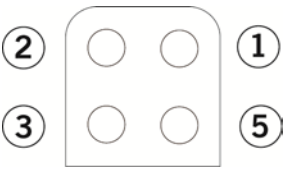
 Fortify Assura DR CD2359-40, CD2359-40C	 Fortify Assura DR CD2359-40Q, CD2359-40QC

Table 7. Dual-chamber ICD headers (see table (page 30) for legend)

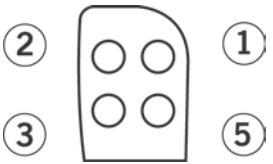
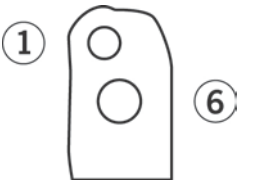
 Ellipse DR CD2275-36, CD2377-36, CD2377-36C	 Ellipse DR CD2275-36Q, CD2377-36Q, CD2377-36QC

Table 8. CRT-D headers (see table (page **30**) for legend)

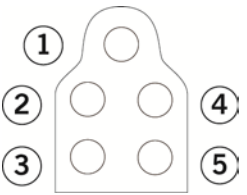
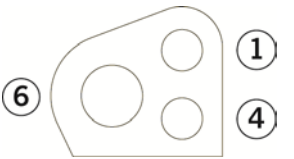
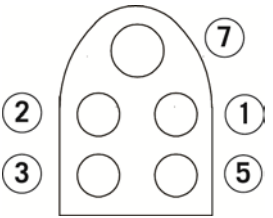
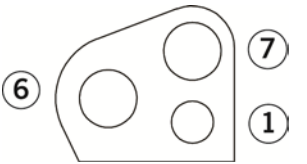
	
Unify Assura CD3361-40, CD3361-40C	Unify Assura CD3361-40Q, CD3361-40QC

Table 8. CRT-D headers (see table (page **30**) for legend)

 Quadra Assura CD3367-40, CD3367-40C Quadra Assura MP CD3371-40, CD3371-40C	 Quadra Assura CD3367-40Q, CD3367-40QC Quadra Assura MP CD3371-40Q, CD3371-40QC

Lead Receptacle Connector Types

Table 9. Lead receptacles

Legend Number	Receptacle	Lead type	Connector[4]
1	A (IS-1 Bi) SENSE/ PACE OR PLUG	Bipolar endocardial; IS-1 plug (when no atrial lead is used)	IS-1[5] in-line bipolar
2	SVC (DF-1) OR PLUG	Defibrillation; DF-1 plug (when only one defibrillation electrode is used)	DF-1[6]
3	RV (DF-1)	Defibrillation	DF-1
4	LV (IS-1 Bi) PACE OR PLUG	Bipolar or unipolar left ventricular; IS-1 plug (when no left ventricular lead is used)	IS-1 in-line bipolar or unipolar
5	V or RV (IS-1 Bi) SENSE/PACE	Bipolar endocardial	IS-1 in-line bipolar

[4] SJ4-LLHH is equivalent to DF4-LLHH. SJ4-LLLL is equivalent to IS4-LLLL. St. Jude Medical's SJ4 and DF4 connector cavities comply with ISO 27186:2010(E).
[5] St. Jude Medical IS-1 connector cavities comply with the international connector standard: ISO 5841-3.
[6] St. Jude Medical DF-1 connector cavities comply with the international connector standard: ISO 5841-3.

Table 9. Lead receptacles

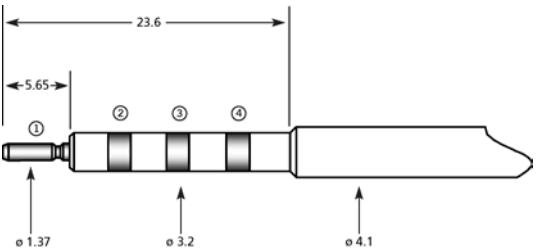
Legend Number	Receptacle	Lead type	Connector[4]
6	RV/SVC (DF4-LLHH) RV SENSE/ PACE RV/SVC DEFIB	Defibrillation and bipolar endocardial	DF4-LLHH
7	LV (IS4-LLLL) PACE	Four electrode, bipolar left ventricle	IS4-LLLL

NOTES:[7]

- When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct lead receptacle. For sensing and pacing, this is important to ensure that atrial and ventricular signals are correctly recorded and that pacing pulses are delivered in the desired chamber.
- The DF4-LLHH lead receptacle can only be used with DF4-LLHH leads that combine the RV and SVC defibrillation coils and the RV sense/pace electrode into a single connector.
- The IS4-LLLL lead receptacle can only be used with IS4-LLLL left heart leads.

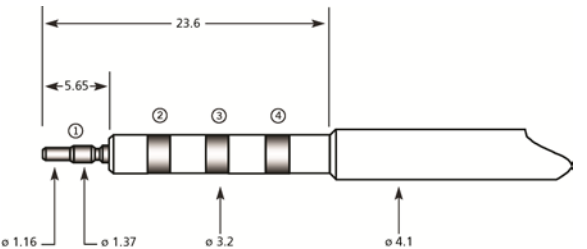
[7] SJ4-LLHH is equivalent to DF4-LLHH. SJ4-LLLL is equivalent to IS4-LLLL. St. Jude Medical's SJ4 and DF4 connector cavities comply with ISO 27186:2010(E).

Figure 1. Nominal dimensions of DF4-LLHH and SJ4-LLHH lead connector (mm)



1. V Tip
2. RV Ring
3. RV Coil
4. SVC Coil

Figure 2. Nominal dimensions of IS4-LLLL and SJ4-LLLL lead connector, in mm



1. Distal Tip 1
2. Mid 2
3. Mid 3
4. Proximal 4

Sensing

The pulse generator has an Automatic Sensitivity Control feature to allow accurate sensing in both the atrium and the right ventricle over a wide range of signal strengths.

NOTE: Ventricular sensing is done only in the right ventricle.

Table 10. Ranges for sensitivity settings

Parameter	Range
Atrial Maximum Sensitivity	0.2–1.0 mV
Ventricular Defibrillator Maximum Sensitivity	0.2–1.0 mV
Ventricular Pacemaker Maximum Sensitivity	0.2–2.0 mV

Radiopaque Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code.

Table 11. X-ray ID codes for the device models described in this manual

Device Model	X-ray ID Model Code
CD1359-40/40C/40Q/40QC, CD2359-40/40C/40Q/40QC, CD3361-40/40C/40Q/40QC, CD3367-40/40C/40Q/40QC, CD3371-40/40C/40Q/40QC	KC

Table 11. X-ray ID codes for the device models described in this manual

Device Model	X-ray ID Model Code
CD1275-36/36Q, CD1377-36/36C/36Q/36QC, CD2275-36/36Q, CD2377-36/36C/36Q/36QC	KF

Implanting the Pulse Generator

Training Personnel

Physicians should be familiar with all components of the system and the contents of this manual before beginning the procedure. St. Jude Medical provides physicians with comprehensive, on-site training and support. Physicians and support staff also receive training in follow-up and patient management.

Inspecting and Handling the Device

Inspect the packaging before removing the device. **Do not implant the pulse generator if:**

- The package is damaged or wet
- The dot on the ethylene oxide label is purple

Purple indicates that the package has not been sterilized.

- The Use Before Date on the outer box and the tray has been exceeded

  The Use Before Date reflects the minimum battery voltage required to support the calculated battery longevity shown in the programmer's on-screen help.

The pulse generator has been sterilized using ethylene oxide gas. Contact St. Jude Medical if resterilization is necessary.

CAUTION: The pulse generator should not be autoclaved, immersed in sterilant liquids, gamma-irradiated, or ultrasonically cleaned.

Sterile Package and Contents

The pulse generator is supplied in a sterile tray for introduction into the operating field. The tray contains:

- One pulse generator (with all therapies off) with pre-installed setscrews
- Torque driver

The outer box contains:

- Literature

Opening the Sterile Package

To open the package and remove the pulse generator:

1. Peel back the outer tray cover, starting with the corner labeled with an arrow.
2. Observing sterile technique, lift up the end of the inner tray that rests in the recess in the outer tray.
3. Peel off the inner tray cover, starting with the corner labeled with an arrow.
4. Use the recessed areas to facilitate removing the pulse generator and accessories from the tray.

Choosing the Implant Site

The pulse generator can be implanted in either the pectoral region or the abdominal region, at the physician's discretion.

Pectoral Placement

Before deciding to implant the pulse generator pectorally, assess patients on a case-by-case basis to ensure their suitability for pectoral implantation. If the device is implanted pectorally, a single incision may be used to form the pocket and provide access for transvenous lead placement. Use short leads of appropriate length to avoid the necessity of coiling extra lead length in the pocket.

Submuscular

For access to the cephalic and subclavian veins, make a single incision over the delta-pectoral groove. To avoid interfering with left shoulder motion, place the pulse generator medial to the humeral head.

Subcutaneous

For access to the cephalic vein, make a long, transverse incision. To ensure that the leads are far enough from the axilla, place the device as far medially as possible. Place the device in the pocket so that the upper edge is inferior to the incision. To prevent migration, anchor the device to the pectoral muscle using the suture holes in the device header.

Abdominal Placement

Abdominal placement is recommended for patients who have had previous pectoral surgery or for whom the physician decides that pectoral placement is undesirable for anatomical reasons. Use leads longer than 750 mm with devices implanted abdominally.

Implanting the Leads and Testing the Device

Forming the Pocket and Connecting the Leads

1. If it has not already been done, prepare a pocket for the pulse generator.

   WARNING: To avoid any risk of accidental shock, make sure that tachyarrhythmia therapies are off before handling the pulse generator. Do not program the pulse

generator on until it is inserted in the pocket.

WARNING: For reliable data transmission, implant the pulse generator at a depth not to exceed 50 mm. For patient comfort, do not implant the pulse generator within 12.5 mm of bone unless you cannot avoid it.

2. Insert the lead pins into their receptacles, past the setscrew opening.

   If necessary, use sterile lubricant on the insulated shoulder of the lead connectors. **Properly inserted, the plug heads protrude only a few millimeters from the header.** Do not use forceps or other tools to insert the plug as these can damage its silicone insulation.

   NOTE: When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct lead receptacle. For sensing and pacing, this is important to ensure that atrial and ventricular signals are correctly recorded and that pacing pulses are delivered in the desired chamber.

   WARNING: If you are using a single defibrillation lead with only one defibrillation coil, make sure that the lead is in the receptacle for the RV (DF-1) lead. Lubricate and insert the DF-1 plug into the receptacle for the SVC (DF-1) lead. If the lead is not in the RV receptacle, the can and the lead will have the same polarity and there will be no current flow.

   WARNING: When the DF4-LLHH lead receptacle is plugged, disable tachyarrhythmia

therapy.

NOTE: For IS4/DF4 leads and lead receptacles, do not use silicone oil, mineral oil, or any substance other than sterile saline, water, or heparinized saline as a lubricant. For IS-1 and DF-1 leads and lead receptacles the use of a lubricant is optional.

NOTE: Use and fasten the appropriate lead receptacle plug in an unused lead receptacle. Refer to Spare Parts and Accessories (page 66) for a list of available lead receptacle plugs.

NOTE: For dual-chamber and CRT-D devices, if you are not using an atrial sense/pace lead, lubricate and insert an IS-1 receptacle plug into the receptacle for the atrial sense/pace lead.

NOTE: For CRT-D devices, if you are not using a left ventricular pacing lead, lubricate and insert an IS-1 plug into the receptacle for the LV lead.

3. Carefully insert the tip of the torque driver into the setscrew and turn the handle clockwise until you hear at least three clicks.

   Setscrews are installed in the pulse generator at the time it is shipped. Exercise caution when turning the setscrew, which may be backed out of the connector if turned counterclockwise for more than two rotations.

4. Coil any excess lead length underneath the pulse generator in the implant pocket.

Managing and Following Patients

Patient Education

St. Jude Medical provides a booklet for patients to explain the device and its operation. You can use this to supplement your discussions with the patient and spouse or other interested persons. To obtain other available patient education materials, contact St. Jude Medical.

Implant/Patient Registration Form

Fill out and return both the Implant/Patient Registration Form and the device registration card to register the patient and facilitate patient tracking.

Patient Follow-Up

Patients who receive a pulse generator should be seen for follow-up every three months. If the patient experiences a spontaneous episode, it may be deemed appropriate for the patient to return for follow-up immediately.

A follow-up visit should include (at a minimum):

- Review of the FastPath™ Summary screen
- Review of stored and real-time EGMs
- Review of morphology template performance (if applicable)

- Review of sensing amplitude and pacing thresholds
- Confirmation that the final parameter settings are correct

Progression or changes over time in the patient's underlying heart or systemic disease may necessitate a re-evaluation of the patient's clinical arrhythmias and reprogramming of device detection and therapy parameters. Stored EGMs obtained during follow-up visits can help determine when to return to the electrophysiology laboratory, as in the case of an observed change in the VT rate. Device settings should be re-evaluated if the patient's antiarrhythmic medication is changed.

Depending on clinical circumstances and the patient's level of understanding, it may be advisable to give the patient a magnet for emergency use.

The delivery of a high-voltage shock into a damaged lead system may result in device failure, including the inability to deliver therapy or pace, inappropriate shocks, and/or premature battery depletion. Carefully monitor the lead system integrity during patient follow-up for insulation damage or fractures which may result in secondary device failure due to the arcing of current back to the device can.

Device Longevity

For estimated longevity calculations, see the programmer's on-screen help.

Elective Replacement Indicator

The programmer displays the remaining capacity to ERI percentage to help the clinician determine whether a pulse generator should be replaced. Check these figures at each follow-up visit.

Immediately following a high-voltage charge, the battery voltage may be much lower than its normal value. A battery voltage measured within approximately four hours of a high-voltage charge should, therefore, not be used for elective replacement determination unless it is at or below the elective replacement indicator (ERI) value. See Battery Information (page 59).

Normal Battery Condition (3.20 V to 2.59 V)

An unloaded battery voltage of more than ERI indicates that the device is not currently in need of replacement and that it will operate according to the specifications listed in this manual.

ERI to EOL Battery Condition (2.59 V to 2.54 V)

The pulse generator will continue to operate according to specifications in the ERI to end of life (EOL) voltage range, except for a change in the pacing amplitude and high-voltage charge time.

Careful monitoring of the battery status is strongly advised until the pulse generator can be replaced.

> **WARNING: Replace the pulse generator within three months of reaching the ERI indication. (This assumes that regular follow-up visits occur every three months, thereby taking into account the possibility that the battery reached the ERI level sometime in the previous three months and still has approximately three months remaining at this battery level.) Replace the pulse generator immediately after it reaches ERI if there is frequent high-voltage charging and/or one or more of the pacing outputs are programmed above 2.5 V.**

Past EOL Battery Condition (2.54 V to 2.40 V)

If the battery voltage is the EOL value or less, explant the pulse generator immediately or turn all therapies off until it can be replaced. **Below the EOL value, the pulse generator will continue to function, but some operating parameters will be out of specification.** Pacing lead impedance may read higher than actual, and the 2.5 V pacing setting is no longer regulated. High-voltage charge times will be extended. If the capacitors take longer than 28 s to reach the programmed voltage, charging stops and the pulse generator delivers whatever voltage is present on the capacitors. When the battery voltage drops below EOL the pulse generator could oversense; therefore, some device functions are automatically disabled, including ATP, arrhythmia induction, and capture testing.

There is no guarantee that the pulse generator will deliver a high-voltage shock with a battery voltage of less than the Past EOL value.

Using a Magnet

The pulse generator contains a giant magneto resistor (GMR) that, when activated, prevents delivery of tachyarrhythmia therapy. Bradycardia pacing is not affected.

The GMR is activated in the presence of a strong magnetic field. A magnet placed over the pulse generator can, therefore, be used to prevent the delivery of therapy if a programmer is not available to turn the device off.

The pulse generator can be programmed to ignore the GMR. Therapies would then be delivered in the normal manner in response to detected arrhythmias. Magnet application would have no effect on

operation.

The pulse generator does not emit an audible tone when a magnet is placed over it.

The effectiveness of magnets varies. If one magnet does not interrupt operation of the pulse generator, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the pulse generator may also help.

CAUTION:

- The magnet is for temporary inhibition of tachyarrhythmia therapy. If inhibition is required for longer than eight hours, disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapy Off.
- The presence of both a magnet and the programming wand near the implanted device may interfere with telemetry and cause a loss of communication with the programmer. If you need to communicate with the device and use a magnet simultaneously (for example, to confirm proper magnet placement by telemetry), first position the magnet over the device and then place the wand over the device. If the magnet is brought close to the device while communication is already in progress, the programmer may, in rare cases, not detect the presence of the magnet and a device reset may occur.

If arrhythmia intervals were detected before the magnet was applied, detection is interrupted while the magnet is in place. Detection resumes when the magnet is removed.

Bradycardia pacing is not affected by magnet application.

Explanting the Pulse Generator

WARNING: Before explanting the system or disconnecting the leads from a pulse generator, disable Tachy Therapy or program the pulse generator to tachyarrhythmia therapy Off. In the event of the patient's death, deactivate the pulse generator before post-mortem examination.

Explant the device with standard surgical tools.

If a lead or adapter is explanted, be careful not to damage it during removal.

Before returning the explanted pulse generator to St. Jude Medical, clean it with disinfectant solution, but do not submerge it. Fluid in the lead receptacles of the pulse generator or adapter impedes analysis of the product.

WARNING: Pulse generators contain sealed chemical power cells and capacitors and therefore should never be incinerated.

Out-of-Service/Explant/Patient Death Form

Whenever a pulse generator is explanted, or if any of the leads or adapters are replaced or capped, complete an Out-of-Service/Explant/Patient Death form and return it to St. Jude Medical with the explanted products. If possible, send along a printout of the programmed settings of the pulse

generator. For information on printing reports, see the appropriate reference manual.

Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- manuals.sjm.com

For additional assistance, call your local St. Jude Medical representative.

Additional Information

For additional information on this device, see the programmer's on-screen help.

High-Voltage Waveforms

Table 12. High-voltage waveforms[8] for 36 J devices

	Energy Setting		
	Max	**Min**	**Mean**
Monophasic			
Delivered pulse energy (J) (first shock)	27.7	0.1	15.0
Peak ICD output voltage (V) (first shock)	779	64.0	576
Delivered pulse energy (J) (sequential shock)	32.2	0.1	15.0
Peak ICD output voltage (V) (sequential shock)	836	64.0	576
Biphasic			
Delivered pulse energy (J) (first shock)	30.7	0.1	14.8
First phase	27.2	0.1	13.2

[8] Monophasic and biphasic waveforms at 65% fixed tilt.

Table 12. High-voltage waveforms[8] for 36 J devices

	Energy Setting		
	Max	Min	Mean
Second phase	3.5	0.0	1.6
Peak ICD output voltage (V)(first shock)	771	47	540
First phase	771	47	540
Second phase	263	13	184
Delivered pulse energy (J) (sequential shock)	35.9	0.1	17.5
First phase	31.7	0.1	15.6
Second phase	4.2	0.0	1.9
Peak ICD output voltage (V)(sequential shock)	831	47	584
First phase	831	47	584
Second phase	291	13	201

Table 13. High-voltage waveforms[9] for 40 J devices

	Energy Setting		
	Max	**Min**	**Mean**
Monophasic			
Delivered pulse energy (J) (first shock)	32.0	0.1	15.0
Delivered pulse energy (J) (sequential shock)	36.0	0.1	15.0
Peak ICD output voltage (V) (first shock)	820	38.0	570
Peak ICD output voltage (V) (sequential shock)	852	38.0	570
Biphasic			
Delivered pulse energy (J) (first shock)	36.0	0.1	17.5
First phase	32.1	0.1	15.6
Second phase	3.9	0.0	1.9

[9] Monophasic and biphasic waveforms at 65% fixed tilt.

Table 13. High-voltage waveforms[9] for 40 J devices

	Energy Setting		
	Max	Min	Mean
Delivered pulse energy (J) (sequential shock)	40.0	0.1	17.5
First phase	35.6	0.1	15.6
Second phase	4.4	0.0	1.9
Peak ICD output voltage (V) (first shock)			
First phase	812	36	593
Second phase	283	7.0	191
Peak ICD output voltage (V) (sequential shock)			
First phase	855	36	593
Second phase	295	7.0	191

Physical Specifications

Device Measurements

Table 14. Device measurements, single-chamber ICDs

Model	Dimensions (l x w x h) (mm)	Weight (g)	Displaced volume (cm^3)	Stored energy (J)
CD1275-36	68 x 51 x 12	66	31	39
CD1275-36Q	66 x 51 x 12	67	30	39
CD1359-40	73 x 40 x 14	76	35	45
CD1359-40C	73 x 40 x 14	76	35	45
CD1359-40Q	71 x 40 x 14	75	35	45
CD1359-40QC	71 x 40 x 14	75	35	45
CD1377-36	68 x 51 x 12	66	31	39
CD1377-36C	68 x 51 x 12	66	31	39
CD1377-36Q	66 x 51 x 12	67	30	39
CD1377-36QC	66 x 51 x 12	67	30	39

Table 15. Device measurements, dual-chamber ICDs

Model	Dimensions (l x w x h) (mm)	Weight (g)	Displaced volume (cm^3)	Stored energy (J)
CD2275-36	69 x 51 x 12	66	31	39
CD2275-36Q	70 x 51 x 12	68	31	39
CD2359-40	74 x 40 x 14	76	35	45
CD2359-40C	74 x 40 x 14	76	35	45
CD2359-40Q	71 x 40 x 14	75	35	45
CD2359-40QC	71 x 40 x 14	75	35	45
CD2377-36	69 x 51 x 12	66	31	39
CD2377-36C	69 x 51 x 12	66	31	39
CD2377-36Q	70 x 51 x 12	68	31	39
CD2377-36QC	70 x 51 x 12	68	31	39

Table 16. Device measurements, CRT-Ds

Model	Dimensions (l x w x h) (mm)	Weight (g)	Displaced volume (cm^3)	Stored energy (J)
CD3361-40	79 x 40 x 14	78	36	45
CD3361-40C	79 x 40 x 14	78	36	45
CD3361-40Q	73 x 40 x 14	77	36	45
CD3361-40QC	73 x 40 x 14	77	36	45
CD3367-40	83.1 x 41 x 14	83	40	45
CD3367-40C	83.1 x 41 x 14	83	40	45
CD3367-40Q	75 x 41 x 14	80	38	45
CD3367-40QC	75 x 41 x 14	80	38	45
CD3371-40	83.1 x 41 x 14	83	40	45
CD3371-40C	83.1 x 41 x 14	83	40	45
CD3371-40Q	75 x 41 x 14	80	38	45

Table 16. Device measurements, CRT-Ds

Model	Dimensions (l x w x h) (mm)	Weight (g)	Displaced volume (cm^3)	Stored energy (J)
CD3371-40QC	75 x 41 x 14	80	38	45

Device Materials

Table 17. Device Materials

Model	Can	RF antenna[10]	Header	Septum
All devices	Titanium	Titanium	Epoxy	Silicone

[10] For devices with RF telemetry capability.

Noise Detection

Table 18. Noise detection

Model	Noise Detection Rate
All devices	100 or more sensed events per second

Charge Time

Table 19. Charge Time

Model	Charge Time
All devices	Less than 10 seconds

Lead Compatibility

Table 20. Lead compatibility

Device	Lead compatibility
Single-chamber ICDs (DF-1, IS-1)	High voltage: one or two DF-1 3.2 mm lead connectors Low voltage: one IS-1 3.2 mm bipolar lead
Single-chamber ICDs (DF4-LLHH)	High voltage and RV low voltage: one DF4-LLHH lead connector
Dual-chamber ICDs (DF-1, IS-1)	High voltage: one or two DF-1 3.2 mm lead connectors Low voltage: one or two IS-1 3.2 mm bipolar leads
Dual-chamber ICDs (DF4-LLHH, IS-1)	High voltage and RV low voltage: one DF4-LLHH lead connector RA low voltage: one IS-1 3.2 mm bipolar lead
CRT-Ds (DF-1, IS-1)	High voltage: one or two DF-1 3.2 mm lead connectors Low voltage: one, two or three IS-1 3.2 mm bipolar (RA, RV, and LV) leads OR one or two IS-1 3.2 mm bipolar (RA and RV) leads and one IS-1 3.2 mm unipolar (LV) lead

Table 20. Lead compatibility

Device	Lead compatibility
CRT-Ds (DF4-LLHH, IS-1)	High voltage and RV low voltage: one DF4-LLHH lead connector RA and LV low voltage: one or two IS-1 3.2 mm bipolar leads OR one IS-1 3.2 mm bipolar (RA) lead and one IS-1 3.2 mm unipolar (LV) lead
CRT-Ds (DF-1, IS-1, IS4-LLLL)	High voltage: one or two DF-1 3.2 mm lead connectors Low voltage: one or two IS-1 3.2 mm bipolar (RA and RV) leads and one IS4-LLLL lead connector (LV) lead
CRT-Ds (IS-1, DF4-LLHH, IS4-LLLL)	High voltage and RV low voltage: one DF4-LLHH lead connector RA low voltage: one IS-1 3.2 mm bipolar lead LV low voltage: one IS4-LLLL lead connector (LV) lead

Battery Information

Table 21. Battery information

Device	36 J devices xxxx-36, xxxx-36Q	40 J devices xxxx-40, xxxx-40Q
Battery chemistry; Manufacturer; Model; Cells	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical; Model 2950; One cell	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical; Model 2850; One cell
Battery voltage (V)	3.20 (beginning of life)	3.20 (beginning of life)
Elective replacement voltage (unloaded) (V)	2.59	2.59
End of life voltage (unloaded) (V)	2.54	2.54
Past End of life voltage (unloaded) (V)	2.40	2.40

Device Configurations

Table 22. Device configuration, single-chamber ICDs

	Single-chamber ICDs
Tachyarrhythmia Configuration	Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off
Bradyarrhythmia Mode	VVI(R), Pacer Off; Additional modes available in the tachyarrhythmia therapy Off configuration: VOO; Additional modes available as temporary modes: VOO
SVT Discrimination Mode[11]	Ventricular Only
V Pulse & Sense Configuration	Bipolar (RV-tip to RV-ring)

[11] Sensing only in the right ventricle.

Table 23. Device configuration, dual-chamber ICDs

	Dual-chamber ICDs
Tachyarrhythmia Configuration	Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off
Bradyarrhythmia Mode[12]	AAI(R), VVI(R), VVT(R), DDI(R), DDD(R), DDT(R), Pacer Off; Additional modes available in the tachyarrhythmia therapy Off configuration: AOO, VOO, DOO; Additional modes available as temporary modes: AOO, VOO, DOO, AAT
SVT Discrimination Mode[13]	Ventricular Only, Dual Chamber
A Pulse & Sense Configuration	Bipolar (A-tip to A-ring)

[12] VVT(R) and DDT(R) modes are available in devices with Ventricular Triggering Capability. See the programmer's online help for a complete list.
[13] Sensing only in the right atrium and right ventricle.

Table 23. Device configuration, dual-chamber ICDs

	Dual-chamber ICDs
V Pulse & Sense Configuration	Bipolar (RV-tip to RV-ring)

Table 24. Device configuration, CRT-Ds without quadripolar lead support

	CRT-Ds without IS4-LLLL Lead Capability
Tachyarrhythmia Configuration	Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off

Table 24. Device configuration, CRT-Ds without quadripolar lead support

	CRT-Ds without IS4-LLLL Lead Capability
Bradyarrhythmia Mode[14]	AAI(R), VVI(R), VVT(R), DDI(R), DDD(R), DDT(R), Pacer Off; Additional modes available in the tachyarrhythmia therapy Off configuration: AOO, VOO, DOO; Additional modes available as temporary modes: AOO, VOO, DOO, AAT
SVT Discrimination Mode[15]	Ventricular Only, Dual Chamber
A Pulse & Sense Configuration	Bipolar (A-tip to A-ring)
RV Pulse & Sense Configuration	Bipolar (RV-tip to RV-ring)
LV Pulse Configuration	Bipolar (LV-tip to LV-ring), LV-tip to RV-coil, LV-ring to RV-coil

[14] VVT(R) and DDT(R) modes are available in devices with Ventricular Triggering Capability. See the programmer's online help for a complete list.
[15] Sensing only in the right atrium and right ventricle.

Table 25. Device configuration, CRT-Ds with quadripolar lead support

	CRT-Ds with IS4 Lead Capability
Tachyarrhythmia Configuration	Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off
Bradyarrhythmia Mode[16]	AAI(R), VVI(R), VVT(R), DDI(R), DDD(R), DDT(R), Pacer Off; Additional modes available in the tachyarrhythmia therapy Off configuration: AOO, VOO, DOO; Additional modes available as temporary modes: AOO, VOO, DOO, AAT
SVT Discrimination Mode[17]	Ventricular Only, Dual Chamber
A Pulse & Sense Configuration	Bipolar (A-tip to A-ring)
RV Pulse & Sense Configuration	Bipolar (RV-tip to RV-ring)

[16] VVT(R) and DDT(R) modes are available in devices with Ventricular Triggering Capability. See the programmer's online help for a complete list.
[17] Sensing only in the right atrium and right ventricle.

Table 25. Device configuration, CRT-Ds with quadripolar lead support

	CRT-Ds with IS4 Lead Capability
LV Pulse Configuration	Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil

RF Operating Frequencies

Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 301 839
- USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219.
- FCC ID: RIASJMRF.

The following is applicable to Canada only:

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Spare Parts and Accessories

Only the accessories listed here are approved for use with the pulse generators described in this manual.

Table 26. Spare parts and accessories

Model Number	Name/Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet

Table 26. Spare parts and accessories

Model Number	Name/Description
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[18]
AC-IS4PP	IS4/DF4 port plug

Detection Performance in the Presence of Electromagnetic Interference in Differential Mode

The Atrial Sensitivity setting of 0.2mV and Ventricular sensitivity 0.3mV (Low Frequency Attenuation Filter ON) may be more susceptible to EMI (as defined by the CENELEC standard EN45502-2-2).

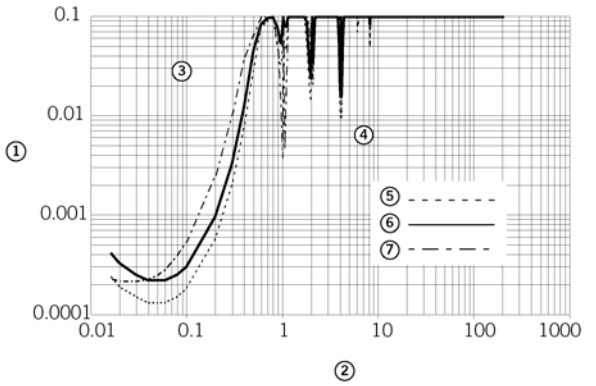
Atrial Sensitivity of 0.3mV (and less sensitive settings) and Ventricular Sensitivity of 0.3mV and less sensitive settings (Low Frequency Attenuation Filter Off) and 0.4 mV and less sensitive settings (Low Frequency Attenuation Filter On) comply with the requirements of clause 27.5.1 of the CENELEC standard EN45502-2-2, which requires that the implantable pulse generator shall be constructed so that commonly encountered electromagnetic signals are unlikely to be confused with sensed beats and

[18] Dual-chamber ICDs and CRTDs only.

to change the therapeutic behavior of the implantable pulse generator.

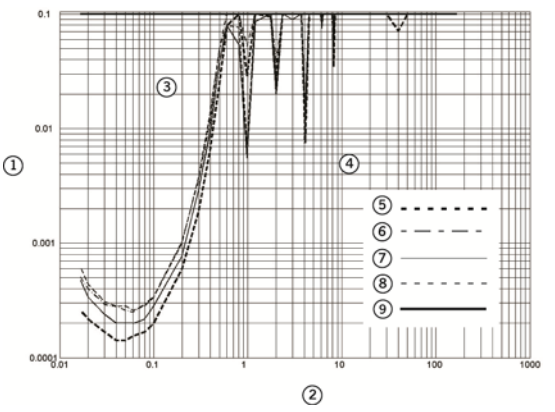
The common mode rejection ratio for this device for 16.6 Hz, 50 Hz and 60 Hz is higher than a factor of 100.

Figure 3. Detection performance in the presence of EMI in differential mode



1. Amplitude (V)
2. Frequency (kHz)
3. Detection Zone
4. No Interference
5. Atrium (0.2 mV)
6. Atrium (0.3 mV)
7. Right Ventricle (0.3 mV)

Figure 4. Detection performance in the presence of EMI in differential mode (with Low Frequency Attenuation Filter On[19])



1. Amplitude (V)
2. Frequency (kHz)
3. Detection Zone
4. No Interference
5. Atrium (0.2 mV)
6. Atrium (0.3 mV)
7. Right Ventricle (0.3 mV)
8. Right Ventricle (0.4 mV)
9. Maximum EMI

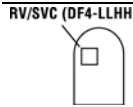
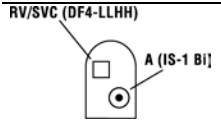
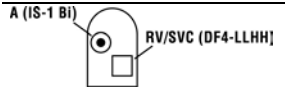
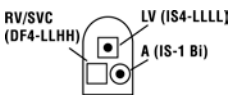
[19] For devices with the Low Frequency Attenuation Filter only.

Symbols

Symbol	Description
VVED - DDDR Dual-chamber ICDs	NBD - NBG Code; NBD - ventricular shocking, ventricular antitachycardia pacing, electrogram detection, dual-chamber bradycardia pacing; NBG - dual-chamber pacing, dual-chamber sensing, dual response, rate-modulated
VVEV - VVIR Single-chamber ICDs	NBD - NBG Code; NBD - ventricular shocking, ventricular antitachycardia pacing, electrogram detection, ventricular bradycardia pacing; NBG - ventricular pacing, ventricular sensing, inhibited response, rate-modulated
VVED - DDDRV CRT-Ds	NBD - NBG Code; NBD - ventricular shocking, ventricular antitachycardia pacing, electrogram detection, dual-chamber bradycardia pacing; NBG - dual-chamber pacing, dual-chamber sensing, dual response, rate-modulated, biventricular pacing
LLHH	Quadripolar connector (low voltage, low voltage, high voltage, high voltage)
LLLL	Quadripolar connector (low voltage, low voltage, low voltage, low voltage)

Symbol	Description
	Authorized EC Representative in the European Community
	Sterilized using ethylene oxide
	Caution, Consult Accompanying Documents
	Dangerous Voltage
	Shipped settings. The pulse generator is shipped with all functions off
	Implantable cardioverter defibrillator, single chamber, right ventricular
	Implantable cardioverter defibrillator, dual chamber, right atrial, right ventricular
	Implantable cardioverter defibrillator, cardiac resynchronization therapy, right atrial, right ventricular, left ventricular

Symbol	Description
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law
	Korea Certification mark for electrical devices
IC: 7067A-SJMRF	Industry Canada certification
	Contents
	Accessories
	Product literature
	Pulse generator

Symbol	Description
	RV/SVC (DF4-LLHH)- RV/SVC defibrillation port with quadripolar connector (low voltage, low voltage, high voltage, high voltage)
	RV/SVC (DF4-LLHH) - RV/SVC defibrillation port with quadripolar connector (low voltage, low voltage, high voltage, high voltage); A (IS-1 Bi) - Atrial pacing port with IS-1 bipolar connector
	A (IS-1 Bi) - Atrial pacing port with IS-1 bipolar connector; RV/SVC (DF4-LLHH) - RV/SVC defibrillation port with quadripolar connector (low voltage, low voltage, high voltage, high voltage)
	RV/SVC (DF4-LLHH) - RV/SVC defibrillation port with quadripolar connector (low voltage, low voltage, high voltage, high voltage); LV (IS4-LLLL) - LV pacing port with quadripolar connector (low voltage, low voltage, low voltage, low voltage); (A (IS-1 Bi) - Atrial pacing port with IS-1 bipolar connector
Made in USA	Made in USA

Symbol	Description
CE 0123	European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, St. Jude Medical declares that this device complies with the essential requirements and other relevant provisions of these directives. The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.sjmglobal.com/euconformity. This product operates between 9 and 200 kHz with an H-field strength of less than 25 dBµA/m at 10 m. This product operates in the 402-405 MHz band with an effective radiated power of less than 25 µW ERP.
	Date of Manufacture
	Manufacturer

Symbol	Description
	Country of manufacture; BE- Belgium, MY- Malaysia, US- United States
	Use by
	Temperature limitations
	Do not reuse
	Lot number
	Reorder number
	Consult instructions for use
	Follow instructions for use on this website

Symbol	Description
	Do not use if package is damaged
	Serial number
	The device contains a battery and the label is affixed to this device in accordance with European Council Directive 2006/66/EC. Return the device to St. Jude Medical when explanted or dispose as potentially biohazardous material in accordance with medical practice and applicable local, state, and federal laws and regulations.

The following symbols may appear on St. Jude Medical MR Conditional pulse generator labels.

Symbol	Description
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.

Manufacturer:
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

European Authorized Representative:
St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

Australian Sponsor:
St. Jude Medical Australia Pty. Limited
17 Orion Road
Lane Cove NSW 2066
Australia

Manufacturing Site:
St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5
Santana Industrial Park
Arecibo, PR 00612
USA

Manufacturing Site:
St. Jude Medical Operations (M) Sdn. Bhd.
Plot 102, Lebuhraya Kampung Jawa,
Bayan Lepas Industrial Zone
11900 Penang
Malaysia

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