Ellipse™
Tiered-therapy Cardioverter/Defibrillator

Fortify Assura™
Tiered-therapy Cardioverter/Defibrillator

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

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

Covered by one or more of the following US patents: 5,318,591

Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

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

Device Description

This manual describes the following St. Jude Medical® pulse generators:

Table 1. Single-chamber pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Ellipse VR	CD1275-36	Single-chamber ICD with RF telemetry	DF-1/IS-1	36 J
Ellipse VR	CD1275-36Q	Single-chamber ICD with RF telemetry	DF4-LLHH	36 J
Ellipse VR	CD1311-36	Single-chamber ICD with RF telemetry	DF-1/IS-1	36 J
Ellipse VR	CD1311-36Q	Single-chamber ICD with RF telemetry	DF4-LLHH	36 J

Table 1. Single-chamber pulse-generator descriptions

Fortify Assura VR	CD1257-40	Single-chamber ICD with RF telemetry	DF-1/IS-1	40 J
Fortify Assura VR	CD1257-40Q	Single-chamber ICD with RF telemetry	DF4-LLHH	40 J

Table 2. Dual-chamber pulse-generator descriptions

Name	**Model Number**	**Description**	**Connector Type**	**Delivered Energy (approx.)**
Ellipse DR	CD2275-36	Dual-chamber ICD with RF telemetry	DF-1/IS-1	36 J

Table 2. Dual-chamber pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Ellipse DR	CD2275-36Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/ IS-1	36 J
Ellipse DR	CD2311-36	Dual-chamber ICD with RF telemetry	DF-1/IS-1	36 J
Ellipse DR	CD2311-36Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/ IS-1	36 J
Fortify Assura DR	CD2257-40	Dual-chamber ICD with RF telemetry	DF-1/IS-1	40 J
Fortify Assura DR	CD2257-40Q	Dual-chamber ICD with RF telemetry	DF4-LLHH/ IS-1	40 J

Table 3. CRT-D pulse-generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)
Quadra Assura	CD3265-40	CRT-D with RF telemetry	DF-1/IS-1/ IS4-LLLL	40 J
Quadra Assura	CD3265-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J
Unify Assura	CD3257-40	CRT-D with RF telemetry	DF-1/IS-1	40 J
Unify Assura	CD3257-40Q	CRT-D with RF telemetry	DF4-LLHH/ IS-1	40 J

The pulse generator, along with compatible, commercially available leads, constitutes the implantable portion of the ICD and CRT-D systems. The lead systems are implanted using either transvenous or transthoracic techniques. The St. Jude Medical Merlin® Patient Care System (PCS) with software model 3330 version 14.1 (or greater), a Merlin® Antenna (for devices with RF communication), and a telemetry wand constitute the external portion of the ICD and CRT-D

systems.

Models with the “Q” suffix” are functionally equivalent in all respects to the same model without the “Q” suffix, except for the header. Models without the Q” suffix use DF-1 lead connectors for the high-voltage leads, and models with the Q” suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead.

SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connectors comply with ISO 27186:2010(E).SJ4-LLLL is equivalent to IS4-LLLL. SJ4 and IS4 connectors comply with ISO 27186:2010(E).

Indications and Usage

St. Jude Medical® ICDs and CRT-Ds are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

AF Suppression™ pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction.

In patients indicated for an ICD, CRT-Ds are also intended:

- to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical

therapy (as defined in the clinical trials section included in the Merlin PCS on-screen help) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration

- to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure

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 and Precautions

Resuscitation Availability. Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

Lead system. Do not use another manufacturer's lead system without demonstrated compatibility as undersensing cardiac activity and failure to deliver necessary therapy may result.

Avoiding shock during handling. Disable tachyarrhythmia therapy (Enable/ Disable Tachy Therapy) or program tachyarrhythmia therapies Off during surgical implant and explant or post-

mortem procedures as well as when disconnecting leads as the device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.

Additional pacemaker implanted. 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.

Modifying the device. 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.

Suboptimal radio frequency (RF) communication. The Merlin PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the Merlin PCS and the Merlin Antenna. Below is a list of potential causes to suboptimal radio communication:

Table 4. 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.

Table 4. Possible causes and solutions for suboptimal RF communication

Possible Causes	Solutions
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.

Sterilization, Storage and Handling

Resterilization. Do not resterilize and re-implant explanted pulse generators.

Use before date. Do not implant the device after the "use before" date because the battery may have reduced longevity.

If package is damaged. Do not use the device or accessories if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to St. Jude Medical.

Device storage. Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage. Store the device between 10° and 45°C because temperatures outside this range may damage the device.

Temperature Equilibration. 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.

Follow-up Testing

Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

Be aware that the changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia. Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Implantation and Device Programming

Do not position a magnet over the device as that suspends detection and treatment (unless the device has been programmed to ignore the magnet).

Replace the device when the battery reaches the elective replacement indicator (ERI).

Implant the pulse generator no deeper than 5 cm to ensure reliable data transmission. For patient comfort, do not implant the pulse generator within 1.25 cm of bone unless you cannot avoid it.

Exercise caution when turning the setscrew, which may be backed out of the connector if turned counterclockwise for more than two rotations.

Program the device parameters as specified in the Merlin® PCS on-screen help.

The results of the DAVID Study demonstrated that, for patients with standard indications for ICD therapy, no indication for cardiac pacing and an EF < 40%, dual-chamber pacing offers no clinical advantage over backup VVI pacing and may be associated with worsening heart failure.[1] When programming the device to dual-chamber pacing modes, give particular attention to setting the pacing parameters (such as the A-V delay) to promote intrinsic conduction and minimize the amount of ventricular pacing.

Pulse Generator Explant and Disposal

Interrogate the device and turn all therapies off before explanting, cleaning or shipping the device to prevent unwanted shocks.

Return all explanted pulse generators and leads to St. Jude Medical.

Never incinerate the device because of the potential for explosion. Explant the device before cremation.

[1] Wilkoff BL, Cook JR, Epstein AE, Greene L, Hallstrom AP, Hsia H, Kutalek SP, Sharma A. Dual-Chamber Pacing or Ventricular Backup Pacing in Patients With an Implantable Defibrillator: The Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial. JAMA. December 25, 2002; Vol 288, No. 24:3115-3123.

Environmental and Medical Therapy Hazards

Instruct patients to avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause device malfunction or damage, resulting in non-detection or delivery of unneeded therapy. Moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

Hospital and Medical Environments

Electrosurgical cautery. Electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, or may cause device malfunction or damage. If electrocautery is necessary, keep the current path and groundplate as far away from the pulse generator and leads as possible.

External defibrillation. External defibrillation may damage the pulse generator or may result in temporary and/or permanent myocardial damage at the electrode-tissue interface as well as temporarily or permanently elevated pacing capture thresholds. Minimize current flowing through the pulse generator and lead system by following these precautions when using external defibrillation on a patient with a pulse generator:

- Position defibrillation paddles as far from the pulse generator as possible (minimum of 13 cm)
- Use the lowest clinically appropriate energy output
- Confirm pulse generator function following any external defibrillation

High radiation sources. Do not direct high radiation sources such as cobalt 60 or gamma radiation

at the pulse generator. If a patient requires radiation therapy in the vicinity of the pulse generator, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

Lithotripsy. Lithotripsy may permanently damage the pulse generator. Avoid it unless the therapy site is not near the pulse generator and leads.

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.

Magnetic resonance imaging (MRI). MRI for patients with implantable pulse generators has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decision to use MRI with ICD/CRT-D patients. MRI may cause device malfunction or injury to the patient.

Ultrasound therapy. Diagnostic and therapeutic ultrasound treatment is not known to affect the function of the pulse generator.

Transcutaneous Electrical Nerve Stimulation (TENS). TENS may interfere with device function. To reduce interference, place the TENS electrodes close to one another and as far from the device/lead system as possible. Monitor cardiac activity during TENS use.

Radiofrequency ablation. RF ablation in a patient with a pulse generator may cause device malfunction or damage.

Minimize RF ablation risks by:

- Programming all tachyarrhythmia therapies off

- Avoiding direct contact between the ablation catheter and the implanted lead or pulse generator
- Positioning the groundplate so that the current pathway does not pass near the pulse generator system, i.e., place the groundplate under the patient's buttocks or legs
- Having external defibrillation equipment available.

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 301 839-2
- USA: FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1221 Subpart I
- FCC ID: RIASJMRF.

WARNING
This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (that is.,transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations,

including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

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.

Home and Occupational Environments

High-voltage power transmission lines. High-voltage power transmission lines may generate enough EMI to interfere with pulse generator operation if approached too closely.

Communication equipment. Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with pulse generator operation if approached too closely.

Home appliances. Home appliances in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

Industrial equipment. A variety of industrial equipment produce EMI of sufficient field strength and modulation characteristics to interfere with proper operation of the pulse generator. These include, but are not limited to: arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

Electronic Article Surveillance

Advise patients that the Electronic Article Surveillance/Anti-theft (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with the device. 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, the patient should ask that they 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.

Potential Adverse Events

Possible adverse events (in alphabetical order) associated with the system, include, but are not limited to the following:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Allergic reaction

- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Death
- Erosion
- Exacerbation of heart failure
- Excessive fibrotic tissue growth
- Extracardiac stimulation (phrenic nerve, diaphragm, chest wall)
- Extrusion
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion and discontinuity
- Lead migration/dislodgment
- Myocardial damage
- Pneumothorax
- Shunting current or insulating myocardium during defibrillation with internal or external paddles

- Potential mortality due to inability to defibrillate or pace
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation.

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychological intolerance to an ICD or CRT-D system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear of losing shock capability
- Imagined shocking (phantom shock).

Clinician Use Information

WARNING
For devices without the Low Frequency Attenuation Filter, the default Atrial Sensitivity setting and the lowest possible setting of Ventricular Sensitivity, 0.2 mV, may be more susceptible to EMI, according to testing required by CENELEC standard prEN45502-2-2. The devices comply with the electromagnetic

compatibility requirements of CENELEC standard prEN45502-2-2 at atrial and ventricular sensitivities of 0.3 mV and less sensitive settings.

For devices with the Low Frequency Attenuation Filter, the default Atrial Sensitivity setting, the lowest possible setting of Ventricular Sensitivity, 0.2 mV, and the Ventricular Sensitivity setting of 0.3 mV when the Low Frequency Attenuation Filter is On, may be more susceptible to EMI, according to testing required by CENELEC standard EN45502-2-2. The devices comply with the electromagnetic compatibility requirements of CENELEC standard EN45502-2-2 at atrial sensitivities of 0.3 mV, ventricular sensitivities of 0.3mV (Low Frequency Attenuation Filter OFF) or ventricular sensitivities of 0.4 mV (Low Frequency Attenuation Filter On), and less sensitive settings.

Physician Training

Physicians should be familiar with sterile pulse generator implant procedure and with follow-up evaluation and management of patients with an ICD or CRT-D (or should refer the patient to such a physician).

Maintaining Device Effectiveness

Device Storage

FOR SINGLE USE ONLY. Do not resterilize and re-implant explanted pulse generators.

St. Jude Medical has sterilized the pulse generator with ethylene oxide prior to shipment. Contact St. Jude Medical if resterilization is necessary.

Do not implant the device when:

- It has been dropped on a hard surface because this could have damaged pulse generator components.
- The sterility indicator within the inner package is purple, because it might not have been sterilized.
- Its storage package has been pierced or altered, because this could have rendered it non-sterile.
- It has been stored or transported outside the environmental temperature limits.
  Storage limits: 10° to 45°C.
  Transportation limits: -20° to 60°C.
  An electrical reset condition may occur at temperatures below -20°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.

- Its "use before" date has expired, because this can adversely affect pulse generator longevity or device sterility.

Do not resterilize the pulse generator using an autoclave, gamma-irradiation, organic cleaning agents (e.g., alcohol, acetone, etc.), or ultrasonic cleaners.

Sterilization Instructions

Contact St. Jude Medical if resterilization is necessary.

Directions for Use

Pulse generator operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the Patient Registration Form and return it to St. Jude Medical as it provides necessary information for warranty purposes and patient tracking.

Copies of this user's manual can be obtained by contacting your St. Jude Medical representative.

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

Device Model	X-ray ID Model Code
CD1275-36/36Q, CD1311-36/36Q, CD2275-36/36Q, CD2311-36/36Q	KF
CD1257-40/40Q, CD2257-40/40Q, CD3257-40/40Q, CD3265-40/40Q	KC

Package Contents

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

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

The outer box contains:

- Literature.

Technical Support

St. Jude Medical Cardiac Rhythm Management Division 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)

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.

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MORE CONTROL. LESS RISK.

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