Avant™, Neutrino™ NxT, Gallant™, Entrant™

Cardiac Resynchronization Therapy Defibrillator, Implantable Cardioverter Defibrillator

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

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

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Pat. http://www.abbott.com/patents

Device Description

This manual describes the following Abbott Medical pulse generators:

Table 1. Single-chamber pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Avant™ VR	CDVRA700Q	Single-chamber ICD with BLE telemetry	DF4-LLHH	40 J	MR Conditional
Neutrino™ NxT VR	CDVRA800Q CDVRA600Q	Single-chamber ICD with BLE telemetry	DF4-LLHH	40 J	MR Conditional
Gallant™ VR	CDVRA500Q	Single-chamber ICD with BLE telemetry	DF4-LLHH	40 J	MR Conditional
Entrant™ VR	CDVRA300Q	Single-chamber ICD with BLE telemetry	DF4-LLHH	36 J	MR Conditional

Abbott Medical 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
Avant™ DR	CDDRA700Q	Dual-chamber ICD with BLE telemetry	DF4-LLHH/IS-1	40 J	MR Conditional
Neutrino™ NxT DR	CDDRA800Q	Dual-chamber ICD with BLE telemetry	DF4-LLHH/IS-1	40 J	MR Conditional
	CDDRA600Q				
Gallant™ DR	CDDRA500Q	Dual-chamber ICD with BLE telemetry	DF4-LLHH/IS-1	40 J	MR Conditional
Entrant™ DR	CDDRA300Q	Dual-chamber ICD with BLE telemetry	DF4-LLHH/IS-1	36 J	MR Conditional

Abbott Medical DF4 connector cavities comply with ISO 27186:2010(E).

Abbott Medical IS-1 connector cavities comply with the international connector standard: ISO 5841-3.

Table 3. CRT-D pulse generator descriptions

Name	Model Number	Description	Connector Type	Delivered Energy (approx.)	MRI Status
Avant™ HF	CDHFA700Q	CRT-D with BLE telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional
Neutrino™ NxT HF	CDHFA800Q CDHFA600Q	CRT-D with BLE telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional
Gallant™ HF	CDHFA500Q	CRT-D with BLE telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	40 J	MR Conditional
Entrant™ HF	CDHFA300Q	CRT-D with BLE telemetry	DF4-LLHH/ IS4-LLLL/ IS-1	36 J	MR Conditional

Abbott Medical DF4 and IS4 connector cavities comply with ISO 27186:2010(E).

Abbott Medical IS-1 connector cavities comply with the international connector standard: ISO 5841-3.

These devices can be programmed with Merlin™ Patient Care System equipped with Model 3330 version 25.0.2 (or greater) software. For information on programming, refer to the programmer's on-screen help.

Intended Use

The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. CRT-D devices are also intended to resynchronize the right and left ventricles.

Indications

The ICD and CDT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated in certain patients with congestive heart failure.

In addition, dual chamber ICD and CRT-D devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias.

Table 4. Accessories and their intended uses

Accessory	Intended use
Torque wrench	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
IS-1 Receptacle Plug	Seal unused lead receptacles
IS4/DF4 Port Plug	Seal unused lead receptacles

Intended Clinical Benefits

The intended clinical benefits of the Avant™, Neutrino™ NxT, Gallant™ and Entrant™ Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) may include the following:

- Effective management of ventricular tachycardia (VT) and ventricular fibrillation (VF)
- Reduction in morbidity and mortality, including risk of sudden cardiac death

The intended clinical benefits of the Avant™, Neutrino™ NxT, Gallant™ and Entrant™ Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) may also include the following:

- Improvement in cardiac function and performance, heart failure symptoms, exercise tolerance, health-related quality of life and well-being, NYHA classification, and functional mitral regurgitation
- Reduction in heart failure hospitalizations

MRI Safety Information

MR Conditional ICDs and CRT-Ds are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction.

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, and with the sterile pulse generator implant procedure. The physician should also be familiar with follow-up evaluation and management of patients with an ICD or CRT-D before beginning the procedure. If not, the physician should refer the patient to such a physician.
- Ensure that an external defibrillator is immediately available during implant, electrophysiology testing, or MRI scan.

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 or one or more of the pacing outputs are programmed above 2.5 V. See Battery Information (page 56).**

Battery Incineration

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

Storage and Handling

- Disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapies Off during surgical implant and explant or post-mortem procedures, and when disconnecting leads. The device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.
- 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 ISO 14117 clause 4.5.2. The devices comply with the electromagnetic compatibility requirements of ISO 14117 clause 4.5.2 at atrial and ventricular sensitivities of 0.3 mV and less sensitive settings.

High-Voltage Pulse Generator

- Perform all defibrillation testing with the pulse generator in the pocket.

Magnetic Resonance Imaging (MRI)

- MR Conditional ICDs and CRT-Ds. Testing has demonstrated that the Abbott Medical MR Conditional system is conditionally safe for use in the MRI environment when used according to the instructions in the MRI-Ready Systems manual. The Abbott Medical MR Conditional system includes an Abbott Medical MR Conditional device connected to one or more Abbott Medical MR Conditional leads.

Precautions

Implantation Procedure

- 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.

Device Modification

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

Storage and Handling

- Store the pulse generator at temperatures between 10° and 45°C. Do not subject it to temperatures below -20° or over 60°C. Storage outside of this range may result in device reset.
- Store the device in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage.
- Do not implant a device that has been dropped on a hard surface while outside of its intact shelf package, or from a height of more than 24 inches (61 cm) while within its intact shelf package. Sterility, integrity, or function cannot be guaranteed under these conditions, and the device should

be returned to Abbott Medical for inspection.

Temperature Equilibrium

- 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.

Suboptimal Bluetooth Communication

- Below is a list of potential causes to suboptimal Bluetooth communication.

Table 5. Possible causes and solutions for suboptimal BLE communication

Possible Causes	Solutions
The BLE dongle orientation or location is suboptimal.	Move or reorient the Merlin PCS slightly. Make sure that the BLE dongle faces the implantable device.
People or objects interfere with the communication between the Merlin PCS and the device.	Make sure that the space between the Merlin PCS and the device is free from interfering objects or people.
The BLE dongle is too far away from the device.	Move the Merlin PCS closer to the device.
Other products in the vicinity are causing electromagnetic interference (EMI).	Power off or remove equipment that could cause EMI.

Disconnecting Leads and Avoiding Shock While Handling

- Disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapies Off during surgical implant and explant or post-mortem procedures, and when disconnecting leads. The device can produce electrical artifacts that can be sensed by the pulse

generator or deliver a serious shock if you touch the defibrillation terminals while the device is charged.

- 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 (page 43).

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.
- Do not implant the device when the sterility indicator within the inner package is purple, because it might not have been sterilized, or when the storage package has been pierced or altered, because this could have rendered it non-sterile.

Damaged Package

- 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 Abbott 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.

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 Abbott Medical.

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

- External defibrillation may damage the pulse generator. It may also result in temporary or permanent myocardial damage at the electrode-tissue interface or 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 defibrillator paddles as far from the pulse generator as possible (a minimum of 13

cm).

- Use the lowest clinically appropriate energy output.
- Confirm the pulse generator is functioning following any external defibrillation.

- 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.
- External defibrillation may reprogram the device to its reset values. Assess any device parameter reset in conjunction with Abbott Medical Technical Support.

Electrosurgical Instruments

- The pulse generator may detect electrocautery energy as cardiac events and deliver tachyarrhythmia therapy, induce ventricular arrhythmias or fibrillation, 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, which 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 Abbott Medical is recommended.
- 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 the device is functioning after treatment.

Hospital and Medical Environments

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 the device is functioning after treatment.

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 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.

Environmental and Medical Therapy Hazards

- Advise patients to avoid devices that generate a strong electric or magnetic interference (EMI). EMI could cause malfunction of or damage to the pulse generator, 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.
- Advise patients to avoid any areas marked with a "No Pacer" symbol.

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; high-voltage transmission lines;

home appliances; arc or resistance welders; equipment with large motors; 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.
- Advise patients to not play sports or engage in activities where there is a risk of repetitive blows to the implanted device area.
- Twiddler's Syndrome: Caution patients against manipulating the implanted device as it may result in lead damage or lead displacement.

Transcutaneous Electrical Nerve Stimulation

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

Radiofrequency Ablation

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

Minimize radiofrequency 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. For example, place the groundplate under the patient's buttocks or legs
- Having external defibrillation equipment available

Electronic Article Surveillance (EAS)

- 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, or tag readers that include radio frequency identification (RFID) equipment emit signals that may interact with the device. 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. 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 ISO 14117. This testing covered the operating frequencies 385 MHz - 3 GHz, and pulsed modulation techniques of all digital cellular phone technologies in worldwide use today. Based on the results of this testing, the normal operation of cellular phones should not affect the pulse generator.

Adverse Events

Possible adverse events associated with the implantation of the pulse generator system include the following:

- Arrhythmia (for example, accelerated or induced)
- Bradycardia
- Cardiac or venous perforation
- Cardiac tamponade
- Cardiogenic shock

- Death
- Discomfort
- Embolism
- Endocarditis
- Erosion
- Exacerbation of heart failure
- Excessive fibrotic tissue growth
- Extracardiac stimulation (phrenic nerve, diaphragm, pectoral muscle)
- Extrusion
- Fluid accumulation within the device pocket
- Formation of hematomas, cysts, or seromas
- Heart block
- Hemorrhage
- Hemothorax
- Hypersensitivity, including local tissue reaction or allergic reaction
- Infection
- Keloid formation

- Myocardial damage
- Nerve damage
- Occlusion/Thrombus
- Pericardial effusion
- Pericarditis
- Pneumothorax
- Pulmonary edema
- Syncope
- Thrombosis
- Valve damage

Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death.

Among the psychological effects of device implantation are imagined pulsing, depression, dependency, fear of premature battery depletion, device malfunction, inappropriate pulsing, shocking while conscious, or losing pulse capability.

Possible adverse device effects include complications due to the following:

- Abnormal battery depletion
- Conductor fracture
- Device-programmer communication failure
- Elevated or rise in defibrillation/cardioversion threshold
- Inability to defibrillate or pace
- Inability to interrogate or program due to programmer or device malfunction
- Incomplete lead connection with pulse generator
- Inhibited therapy including defibrillation and pacing
- Inappropriate therapy (for example, shocks and antitachycardia pacing [ATP] where applicable, pacing)
- Interruption of function due to electrical or magnetic interference
- Intolerance to high rate pacing (for example dyspnea or discomfort)
- Lead abrasion
- Lead fracture
- Lead insulation damage

- Lead migration or lead dislodgement
- Loss of device functionality due to component failure
- Pulse generator migration
- Rise in DFT threshold
- Rise in pacing threshold and exit block
- Shunting of energy from defibrillation paddles
- System failure due to ionizing radiation

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include the following:

- Allergic reaction to contrast media
- Breakage or failure of implant instruments
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

Pulse Generator Header

The pulse generator headers are shown below and the legend for the lead receptacles are described in the table (page 28) below.

Table 6. Single-chamber ICD headers (see table (page **28**) for legend)

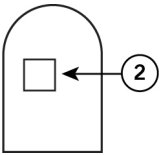
	Avant™ VR CDVRA700Q Neutrino™ NxT VR CDVRA800Q Neutrino™ NxT VR CDVRA600Q Gallant™ VR CDVRA500Q Entrant™ VR CDVRA300Q

Table 7. Dual-chamber ICD headers (see table (page 28) for legend)

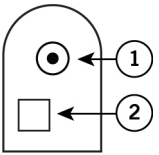
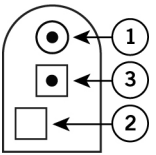
	Avant™ DR CDDRA700Q Neutrino™ NxT DR CDDRA800Q Neutrino™ NxT DR CDDRA600Q Gallant™ DR CDDRA500Q Entrant™ DR CDDRA300Q

Table 8. CRT-D headers (see table (page **28**) for legend)

	Avant™ HF CDHFA700Q Neutrino™ NxT HF CDHFA800Q Neutrino™ NxT HF CDHFA600Q Gallant™ HF CDHFA500Q Entrant™ HF CDHFA300Q

Lead Receptacle Connector Types

Table 9. Lead receptacles

Legend Number	Receptacle	Lead type	Connector
1	RA, IS-1 Bi	Bipolar endocardial; IS-1 plug (when no atrial lead is used)	IS-1 in-line bipolar
2	RV, DF4-LLHH	Defibrillation and bipolar endocardial	DF4-LLHH
3	LV, IS4-LLLL	Four electrode, bipolar left ventricle	IS4-LLLL

Abbott Medical IS-1 connector cavities comply with the international connector standard: ISO 5841-3

Abbott Medical DF4 and IS4 connector cavities comply with ISO 27186:2010(E).

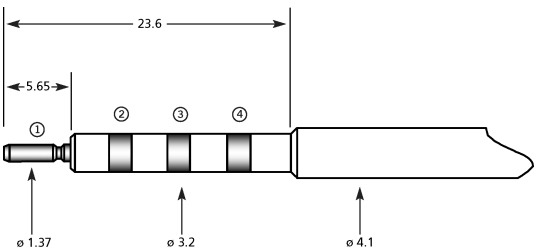
NOTE: When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct lead receptacle. For sensing and pacing, this is important to ensure that atrial and ventricular signals are correctly recorded and that pacing pulses are delivered in the desired chamber.

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.

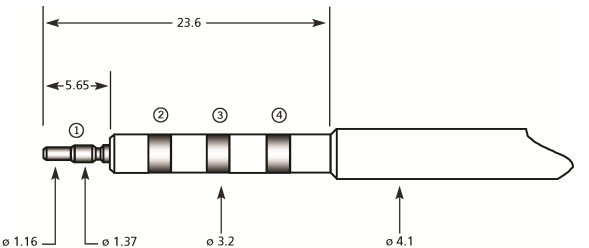
The IS4-LLLL lead receptacle can only be used with IS4-LLLL left heart leads.

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



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

Figure 2. Nominal dimensions of IS4-LLLL lead connector (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	0.3–1.0 mV
Ventricular Pacemaker Maximum Sensitivity	0.4–2.0 mV

Radiopaque Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the Abbott Medical logo 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
CDVRA300Q, CDVRA500Q, CDVRA600Q, CDVRA700Q, CDVRA800Q	KM
CDDRA300Q, CDDRA500Q, CDDRA600Q, CDDRA700Q, CDDRA800Q	
CDHFA300Q, CDHFA500Q, CDHFA600Q, CDHFA700Q, CDHFA800Q	

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. Abbott 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. If the sterile package has been compromised, return the device to Abbott Medical.

CAUTION: The device is for single use only and is not intended to be resterilized.

CAUTION: Do not submerge p**ulse generators in liquids or liquid baths.**

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 wrench

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 75 cm 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.

   CAUTION: 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.

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.

CAUTION: 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.

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.

CAUTION: 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 leads and lead receptacles the use of a lubricant is optional.

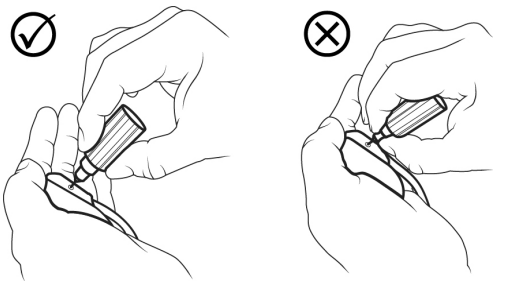
3. Use and fasten the appropriate lead receptacle plug in an unused lead receptacle. Refer to Spare Parts and Accessories (page 64) for a list of available lead receptacle plugs.

   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.
   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.
4. Carefully insert the tip of the torque wrench into the setscrew and turn the handle clockwise until

you hear at least three clicks.

Grip the torque wrench by the large part of the handle as shown in the figure on the left below. On applicable models, do not grip the torque wrench by the smaller, narrower part of the handle as shown on the right.

Figure 3. Correct vs. incorrect use of torque wrench



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

After implanting the leads, test the lead systems. Because of the difference in capacitance between the pulse generator and an external stimulation device, we strongly recommend device-based testing. However, you may want to use a single, initial test using an external stimulation device to screen for patients with a high defibrillation threshold before you open the pulse generator package.

Patient Notifier. Before setting Patient Notifier On, test and ensure patient awareness of the Patient Notifier feature.

Managing and Following Patients

Patient Education

Abbott 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 Abbott 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 (ERI)

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.

Normal Battery Condition

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 EOS Battery Condition

The pulse generator will continue to operate according to specifications in the ERI to end of service (EOS) range, except for the following:

- pacing amplitude and high-voltage charge time is changed
- ATP during charging is disabled
- CRT-Ds with MPP capability only: MPP is disabled

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 or one or more of the pacing outputs are programmed above 2.5 V.

Past EOS Battery Condition

The programmer displays an EOS battery alert to indicate that the pulse generator should be replaced immediately. **Below the EOS 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 EOS 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 after the EOS conditions is detected on the battery.

Using a Magnet

The pulse generator contains a giant magneto resistor that when activated prevents delivery of tachyarrhythmia therapy.

When the magnet is in place and the magnet response is set to Normal, an auditory tone will be present for 4 seconds. If a tone is not detected, the magnet should be moved or another magnet should be tried.

When the magnet is removed, a higher audible tone will be present for 6 seconds once tachyarrhythmia detection has been restored.

When the magnet response is set to Ignore the device ignores the presence of a magnet and delivers therapy as usual.

Bradycardia pacing is not affected by a magnet placed over a CRT-D, single chamber ICD, or dual chamber ICD.

> **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.

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 Abbott 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 Abbott 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

Abbott 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)
- medical.abbott/manuals

For additional assistance, call your local Abbott 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[1] for 36 J devices

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

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

Table 12. High-voltage waveforms[1] for 36 J devices

	Energy Setting		
	Max	**Min**	**Mean**
Biphasic			
Delivered pulse energy (J) (first shock)	30.7	0.1	14.8
First phase	27.2	0.1	13.2
Second phase	3.5	0.0	1.6
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) (first shock)	771	47	540
First phase	771	47	540
Second phase	263	13	184

Table 12. High-voltage waveforms[1] for 36 J devices

	Energy Setting		
	Max	**Min**	**Mean**
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[2] for 40 J devices

	Energy Setting		
	Max	**Min**	**Mean**
Monophasic			
Delivered pulse energy (J) (first shock)	32.0	0.1	15.0

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

Table 13. High-voltage waveforms[2] for 40 J devices

	Energy Setting		
	Max	**Min**	**Mean**
Delivered pulse energy (J) (sequential shock)	35.6	0.1	15.0
Peak ICD output voltage (V) (first shock)	850	45	580
Peak ICD output voltage (V) (sequential shock)	890	45	580
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
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

Table 13. High-voltage waveforms[2] for 40 J devices

	Energy Setting		
	Max	Min	Mean
Peak ICD output voltage (V) (first shock)			
First phase	850	36	593
Second phase	281	7.0	191
Peak ICD output voltage (V) (sequential shock)			
First phase	890	36	593
Second phase	296	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)
CDVRA300Q	63 X 51 X 12	69	30	45
CDVRA500Q	63 X 51 X 12	69	30	45
CDVRA600Q	63 X 51 X 12	69	30	45
CDVRA700Q	63 X 51 X 12	69	30	45
CDVRA800Q	63 X 51 X 12	69	30	45

Table 15. Device measurements, dual-chamber ICDs

Model	Dimensions (l x w x h) (mm)	Weight (g)	Displaced volume (cm^3)	Stored energy (J)
CDDRA300Q	69 x 51 x 12	71	31	45
CDDRA500Q	69 x 51 x 12	71	31	45
CDDRA600Q	69 x 51 x 12	71	31	45
CDDRA700Q	69 x 51 x 12	71	31	45
CDDRA800Q	69 x 51 x 12	71	31	45

Table 16. Device measurements, CRT-Ds

Model	Dimensions (l x w x h) (mm)	Weight (g)	Displaced volume (cm^3)	Stored energy (J)
CDHFA300Q	74 x 51 x 12	76	34	45
CDHFA500Q	74 x 51 x 12	76	34	45
CDHFA600Q	74 x 51 x 12	76	34	45
CDHFA700Q	74 x 51 x 12	76	34	45
CDHFA800Q	74 x 51 x 12	76	34	45

Device Materials

Table 17. Device Materials

Model	Can	BLE antenna[3]	Header	Septum
All devices	Titanium	Titanium	Elasthane and Epoxy	Silicone

[3] For devices with BLE 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 (DF4-LLHH)	High voltage and RV low voltage: one DF4-LLHH lead connector
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 (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

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

Battery Information

Table 21. Battery information

Device	xxxxx300Q, xxxxx500Q, xxxxx600Q, xxxxx700Q, xxxxx800Q
Battery chemistry; Manufacturer; Model; Cells	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical®; Model 3451; One cell
Battery voltage (V)	3.20 (beginning of life)
Elective replacement voltage (unloaded) (V)	2.61
End of service voltage (unloaded) (V)	2.54
Past end of service voltage (unloaded) (V)	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[4]	Ventricular Only
V Pulse & Sense Configuration	Bipolar (RV-tip to RV-ring)

[4] 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[5]	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[6]	Ventricular Only, Dual Chamber

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

Table 23. Device configuration, dual-chamber ICDs

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

Table 24. 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[7]	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[8]	Ventricular Only, Dual Chamber
A Pulse & Sense Configuration	Bipolar (A-tip to A-ring)

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

Table 24. Device configuration, CRT-Ds with quadripolar lead support

	CRT-Ds with IS4 Lead Capability
RV Pulse & Sense Configuration	Bipolar (RV-tip to RV-ring)
LV Pulse Configuration	Distal tip 1-Mid 2; Distal tip 1-Mid 3; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Mid 3; 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-Mid 3; Proximal 4-RV Coil

Inductive Communication

While you are conducting the Fibber and NIPS tests using inductive telemetry, ensure that the telemetry wand is at least 2 cm away from and centered over the device. Charging while the telemetry wand is too close may result in a loss of communication when the device charges or dumps the capacitor. If this occurs, the test ends and the device returns to the permanently programmed parameters.

BLE Operating Frequencies

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

Bluetooth®[9] Low Energy wireless communication operates:

- At 2.402 to 2.4835 GHz at 1 megabits/s or lower
- Over a short range (within 2 meters in normal use)

The effective radiated power is below the limits as specified in:

- Europe: EU EN 300 328

[9] Bluetooth® and the Bluetooth logo are registered trademarks of Bluetooth SIG, Inc.

- USA: FCC Part 15 Subpart C paragraph 15.247

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device complies with Industry Canada licence-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.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. l'appareil ne doit pas produire de brouillage, et
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Spare Parts and Accessories

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

Table 25. Spare parts and accessories

Model Number	Name/Description
442-2	Torque wrench
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-IP-2	IS-1 receptacle plug[10]
AC-IS4PP	IS4/DF4 port plug

[10] Dual-chamber ICDs and CRTDs only.

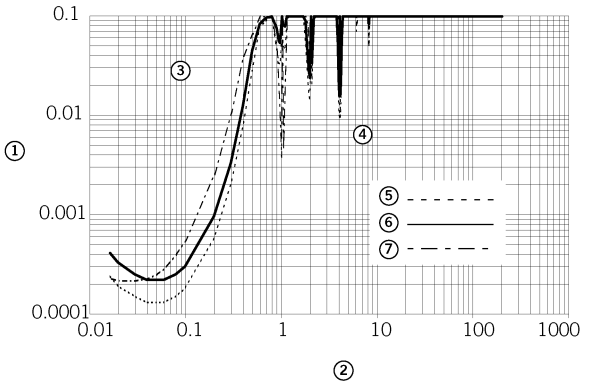
Detection Performance in the Presence of Electromagnetic Interference in Differential Mode

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 ISO 14117 clause 4.5.2).

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 ISO 14117 clause 4.5.2, 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 to change the therapeutic behavior of the implantable pulse generator.

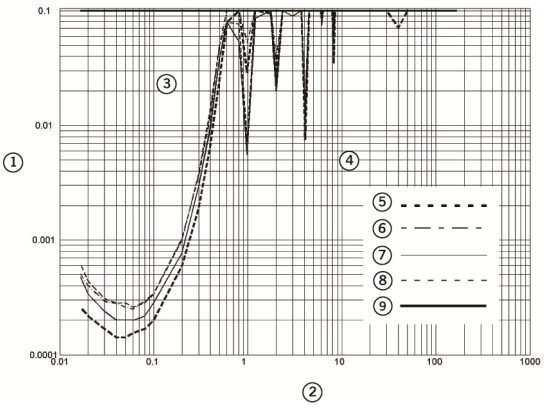
The common mode rejection ratio for this device for 16.6 Hz, 50 Hz and 60 Hz is higher than a factor of 100.

Figure 4. 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 5. Detection performance in the presence of EMI in differential mode (with Low Frequency Attenuation Filter On[11])



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

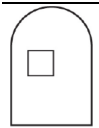
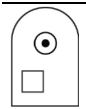
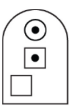
[11] For devices with the Low Frequency Attenuation Filter only.

Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://medical.abbott/manuals.

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)

Symbol	Description
LLLL	Quadripolar connector (low voltage, low voltage, low voltage, low voltage)
	Shipped settings. The pulse generator is shipped with all functions off
	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-ICDRF	Industry Canada certification
	Accessories
	Product literature

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

Symbol	Description
UDI	Unique device identification number
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 2.4-2.4835 GHz band with an effective radiated power of less than 0.2 mW ERP.

Symbol	Description
	Follow instructions for use on this website
	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 Abbott Medical when explanted or dispose as potentially biohazardous material in accordance with medical practice and applicable local, state, and federal laws and regulations.

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

EC REP

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

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