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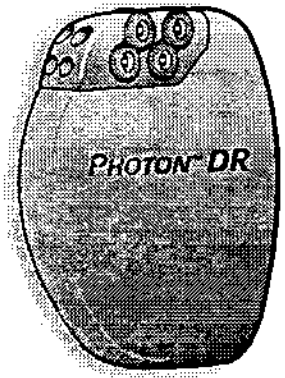

PHOTON™ DR

Implantable Cardioverter-Defibrillator

USER'S MANUAL

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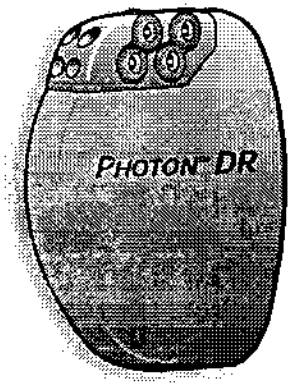

PHOTON™ DR
Implantable Cardioverter-Defibrillator

CAUTION
Federal (USA) law restricts this device to sale by or on order of a physician with appropriate training.

PREFACE

This booklet describes the St. Jude Medical™ Photon™ DR (Model V-230HV) Implantable Cardioverter-Defibrillator (also referred to as the "Photon DR pulse generator") and its implantation instructions. For information on programming the pulse generator, refer to the appropriate reference manual.

Typographic Conventions

This manual uses different formats to distinguish tasks, notes, cautions, and warnings.

1. **Numbered paragraphs contain instructions.**

   Paragraphs like this one provide explanations of the paragraph above it as well as additional information that might be useful at that point in the procedure.

NOTE:
Notes provide useful or important information.

CAUTION:
Precautions flag conditions that may damage the pulse generator or that may prevent its safe and effective use.

WARNING:
Warnings call attention to potential safety hazards and situations that may cause personal injury.

DEVICE DESCRIPTION

The St. Jude Medical™ Photon™ DR (Model V-230HV) implantable cardioverter-defibrillator (ICD) monitors and regulates a patient's heart rate by providing ventricular tachyarrhythmia therapy and single- or dual-chamber bradycardia pacing.

The pulse generator, along with compatible, commercially available sense/pace leads and cardioversion/defibrillation leads, constitutes the implantable portion of the ICD system. The lead systems are implanted using either transvenous or transthoracic techniques. The St. Jude Medical Model 3510 Programmer, the version 3307 (or greater) software, and a telemetry wand constitute the external portion of the ICD system.

INDICATIONS AND USAGE

The Photon DR pulse generator is indicated for use in patients with a history of hemodynamically compromising ventricular tachyarrhythmias. These patients may have experienced a cardiac arrest not associated with acute myocardial infarction or have ventricular tachyarrhythmias. In addition, the pulse generator can be used in patients whose primary therapy for hemodynamically significant, sustained ventricular tachycardia is antitachycardia pacing; the defibrillation capabilities of the device provide high-energy therapy in the event that the arrhythmia accelerates. The pulse generator can be implanted in either the pectoral region or the abdominal region, at the physician's discretion.

CONTRAINDICATIONS

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

The Photon DR pulse generator provides dual-chamber 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.

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. (See "Lead Compatibility" on page 18.)

Avoiding shock during handling. Program the device to Defib Off mode 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.

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 (See "Environmental and Medical Therapy Hazards" on page 4.) to avoid device damage. Store the device between 10° and 45°C (50 to 113°F) 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.

Implantation and Device Programming

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

Replace the device when the battery voltage reaches 2.45V.

Program device parameters such as sensitivity threshold and VT- and VF-detection intervals as specified in the reference manual.

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 non-conversion of the arrhythmia. Successful conversion of ventricular fibrillation or ventricular tachycardia during

arrhythmia conversion testing is no assurance that conversion will occur post-operatively.

Pulse Generator Explant and Disposal

Interrogate the device and program the pulse generator to Defib Off and Pacer 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. The device must be explanted before cremation.

Environmental and Medical Therapy Hazards

Patients should be directed 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 5 inches [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 and diathermy. Lithotripsy and diathermy may permanently damage the pulse generator. Avoid them unless the therapy site is not near the pulse generator and leads.

Magnetic resonance imaging (MRI). MRI may cause device malfunction or damage. If MRI must be used, patients should be closely monitored and programmed parameters should be verified upon cessation of MRI.

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 ICD function. To reduce interference, place the TENS electrodes close to one another and as far from the ICD/lead system as possible. Monitor cardiac activity during TENS use.

Radio frequency ablation. Radio frequency ablation in a patient with a pulse generator may cause device malfunction or damage.

Minimize RF ablation risks by:

- Programming the device to Defib Off and Pacer 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.

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 (EAS)

Advise patients that the EAS or anti-theft systems such as those used at the point of sale and entrances/exits of stores, libraries, banks, etc. may interact with the pulse generator. Advise patients to walk at a normal pace when passing through these areas and not to linger longer than necessary.

Metal Detectors

Advise patients that it is safe to pass through the archways of metal detector security systems like those found in airports and government buildings. However, these systems may detect the metal in the pulse generator and sound the alarm. Under these circumstances, patients should present security personnel with their ICD identification card. If a hand-held wand search is done, patients should ensure that it is done quickly and that the wand is not held directly over the implanted device for a prolonged period.

Cellular Phones

The pulse generator has been tested to the frequency ranges used by the cellular phones included in Table 1. Based on this testing, these pulse generators should not be affected by the normal operation of such cellular phones.

These transmission technologies represent most of the cellular phones in use worldwide. Patients can contact

their local cellular phone service provider to confirm that the provider uses one of these technologies.

Type	Description
NADC (TDMA 50)	North American Digital Cellular (Time Division Multiple Access 50 Hz)
MIRS (TDMA 11)	Motorola Integrated Radio System (Time Division Multiple Access 11 Hz)
CDMA (Cellular)	Code Division Multiple Access
PCS 1900 (TDMA 217 Hz)	Personal Communication System (Time Division Multiple Access 217 Hz)
GSM	Global System for Mobile Communication
DCS 1800	Digital Communication System—1800

Table 1. Cellular phone standards tested

ADVERSE EVENTS

The Photon DR implantable cardioverter-defibrillator (ICD) clinical trial involved 106 patients with implanted systems and 16,198 cumulative implant days (44.4 years). The mean implant duration was 151 days (ranging from <1 day to 211 days). One additional patient had an attempted Photon DR implant; however, the device was not implanted because of high defibrillation thresholds and the patient received a higher output Contour® MD pulse generator.

Eight patients died during the course of the clinical study. An independent Events Committee felt that none of the deaths were attributable to the Photon device. There were no deaths classified as cardiac-arrhythmic/sudden. One death was classified as unknown/sudden. Three deaths were classified as cardiac arrhythmic/non-sudden. Three deaths were classified as cardiac non-arrhythmic/non-sudden. One death was classified as non-cardiac/non-sudden. Three of the eight deaths (38%) were considered to be procedure related, and four of the eight (50%) were considered to be peri-operative mortalities (i.e., occurred ≤ 30 days post-implantation).

Four additional patients were withdrawn from the study. One patient had the Photon DR system removed for infection. Another patient had the Photon DR system explanted prior to receiving a heart transplant. In one patient, the implant attempt was abandoned due to unacceptably high defibrillation thresholds and the patient received a higher output Contour MD device. One additional patient had their device removed for suspected pulse generator failure. All of these four patients are known to be alive.

Observed Adverse Events

Table 2 lists the observations and complications reported from this clinical trial. For the purposes of this discussion, a complication is defined as a clinical event with potential adverse effects that requires invasive intervention to treat or resolve. Observations are those clinical events with potential adverse effects that do not require invasive intervention. A total of 8 complications and 33 observations were reported in 28 patients during the Photon DR clinical investigation. The three-month complication-free survival for the Photon DR population was 94.2%.

	# Pts with AEs (n = 107)	% of Pts with AEs	# of AEs	AE/pt-years (n = 44.4 yrs)
Complications (total)	**7**	**6.5%**	**8**	**0.18**
Lead dislodgment	2	1.9%	2	0.045
Infection	2	1.9%	2	0.045
Bleeding/hematoma	1	0.9%	1	0.023
Pneumothorax	1	0.9%	1	0.023
Surgical removal of Jelco catheter	1	0.9%	1	0.023
Suspected generator malfunction	1	0.9%	1	0.023
Observations (total)	**24**	**22.4%**	**33**	**0.74**
Inappropriate device mode switching due to Far-R sensing	9	8.4%	15	0.338
Inappropriate therapy delivery due to misdiagnosis of SVT as VT[1]	4	3.7%	5	0.113
Elevated ventricular pacing threshold	3	2.8%	3	0.068
Bleeding/hematoma	2	1.9%	2	0.045
Elevated defibrillation threshold (DFT)	2	1.9%	2	0.045
Sensing of external stimuli/noise resulting in aborted therapy delivery	2	1.9%	2	0.045
Device reset during inductions	2	1.9%	2	0.045
Pericardial effusion	1	0.9%	1	0.023
Hex wrench broke off in device header	1	0.9%	1	0.023

Table 2. Observed Adverse Events

1 These observations include inappropriate therapies delivered when the device was programmed to "Monitor".

Potential Adverse Events

Adverse events (in alphabetical order) associated with ICD systems include:

- Acceleration of arrhythmias (caused by device)
- Air embolism
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- 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 system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking (phantom shock).

CLINICAL STUDIES

The purpose of the clinical study was to evaluate the safety and effectiveness of the Photon DR device possessing dual-chamber sensing/discrimination capabilities.

PATIENTS STUDIED

One hundred six (106) patients were implanted with the Photon DR device. An additional patient was enrolled in the study, but received a higher output Contour MD device due to high defibrillation thresholds. The population was predominantly male (80.4%) with a mean age of 66.4 years. The arrhythmia diagnosis was ventricular fibrillation (VF) in 14% of patients, ventricular tachycardia (VT) in 56% of patients, and both VT and VF in 30% of patients. Coronary artery disease was the primary disease process in 78.5% of patients, and the mean ejection fraction was 33.5%.

METHODS

The primary objective of the study was to determine whether the dual-chamber sensing/discrimination capabilities affected the ability of the defibrillator to detect and redetect ventricular fibrillation. The detection and redetection times of the Photon DR device were compared to a recent historical control group in order to demonstrate equivalent performance. For this comparison, data from the Contour MD/Angstrom MD defibrillator clinical investigation (PMA File Number P910023/S33, approved October 21, 1998) was used. A comparison of demographic information for the 107 patients in the Photon DR study population and the 161 patients in the MD historical control group indicated that the Photon DR study population was not statistically significantly different from the control group in any respect, except age (the Photon DR study group was on average slightly older by 3.4 years). Additional data, including supraventricular arrhythmia discrimination performance, complication and observation rates, and patient demographics, was also collected and summarized.

RESULTS

The study hypothesis was that, for both detection and redetection, dual-chamber sensing and discrimination capabilities do not affect the defibrillator's ability to

appropriately detect an episode of ventricular fibrillation (VF), where $\delta = 0.6$ seconds was chosen as the clinically important difference to detect. Stored electrograms were used to calculate detection and redetection times to within one-tenth of a second. The results are summarized in Table 3. The mean detection and redetection times were lower in the Photon DR study population. The Photon DR group had statistically equivalent median detection and redetection times to the control group.

	Photon DR	Control
Detection Time		
No. of episodes	374	200
Mean ± s.d.	2.8 ±0.5 sec	3.3 ±1.0 sec
Median	2.8 sec	3.0 sec
Range	1.7 to 6.0 sec	1.8 to 12.0 sec
Redetection Time		
No. of episodes	128	200
Mean ± s.d.	1.3 ±0.3 sec	1.8 ±1.0 sec
Median	1.3 sec	1.4 sec
Range	0.2 to 2.4 sec	0.9 to 5.8 sec

Table 3. Detection and Redetection Times

The dual-chamber discrimination algorithm's ability to differentiate between ventricular and supraventricular tachyarrhythmias was also assessed during the study. The data was analyzed for the parameters set to the nominal settings: 60% with 5 out of 8 matches for morphology discrimination, 80 ms for interval stability

and 100 ms for sudden onset. Performance of the SVT discriminators did not affect the detection of any ventricular fibrillation episodes; one hundred percent (100%) of VF episodes were appropriately diagnosed by the Photon DR device. A total of 160 tachycardia episodes were evaluated where the clinical diagnosis, based on review of two-channel stored electrograms, was VT in 83 cases and SVT in 77 cases. Episodes included simultaneous AF with VT, as well as 1:1 retrograde VT. SVT/VT discriminator performance showed a sensitivity of 100% and a specificity of 84%.

The mean defibrillation threshold for the Photon DR population was 10.0 joules (431 volts). The DC Fibber method was used in to induce ventricular fibrillation 420 times and was successful on the first attempt 96.4% of the time. The brady pacing function of the device was also evaluated; in all cases, the pacing function and timing was observed to be appropriate for the programmed settings, demonstrating appropriate dual-chamber brady-pacing function.

Patient Selection and Treatment

Pectoral or abdominal implant site. Evaluate the prospective patient's size and activity level to determine whether a pectoral or abdominal implant is suitable.

Exercise stress testing. If the patient's condition permits, use exercise stress testing to:

- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachyarrhythmias
- Identify exercise-induced tachyarrhythmias.

The maximum exercise rate or the presence of supraventricular tachyarrhythmias may influence selection of programmable parameters. Holter monitoring or other extended ECG monitoring also may be helpful.

Electrophysiologic (EP) testing. It is strongly recommended that candidates for ICD therapy have a complete cardiac evaluation, including EP testing. EP testing should identify the classifications and rates of all

the ventricular and atrial arrhythmias, whether spontaneous or during EP testing.

Drug-resistant supraventricular tachyarrhythmias (SVTs) may initiate frequent unwanted device therapy. A careful choice of programming options is necessary for such patients.

Antiarrhythmic drug therapy. If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose, rather than a loading dose, at the time of pulse generator implantation. Changes in a patient's antiarrhythmic drug (or any other medication that affects the patient's normal cardiac rate or conduction) can affect the rate of tachyarrhythmias and/or efficacy of therapy. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator may also need to be reprogrammed.

Direct any questions regarding the individualization of patient therapy to St. Jude Medical.

Patient Counseling Information

Physicians should consider the following points in counseling the patient about this device:

- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's ICD system delivers a shock
- Encourage patients to use ID cards (issued by St. Jude Medical) and/or ID bracelets documenting their ICD system.

Discuss the information in the patient manual with patients and their families before and after pulse generator implantation so they are fully familiar with operation of the device.

CLINICIAN USE INFORMATION

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 should refer the patient to such a physician).

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.

MAINTAINING DEVICE EFFECTIVENESS

Device storage

FOR SINGLE USE ONLY. Do not resterilize and reimplant 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 not green, 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 (50° to 113°F).

  Transportation limits: -20° to 60°C (-4° to 149°F).

  An electrical reset condition may occur at temperatures below -20°C (-4°F).

  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.

Patient Information

Information for the patient is available in a separate booklet packaged with each device from St. Jude Medical. Copies can be obtained by contacting St. Jude Medical. This information should be given to each patient with their first implantable defibrillator and/or at follow-up, as deemed appropriate.

Detailed Device Description

The St. Jude Medical Photon DR (Model V-230HV) is a cardioverter/defibrillator with dual-chamber sensing and bradycardia pacing. It can detect up to three different ventricular tachyarrhythmias based on rate criteria and, in response, deliver antitachycardia pacing, cardioversion or defibrillation therapy with programmable polarity in the ventricle.

The pulse generator can also be used for DDD(R) bradycardia pacing. It offers accelerometer-based, rate-responsive automatic mode switching and semi-automatic pacing capture testing.

The pulse generator stores detailed information on up to 60 events, including dates and times, initial SVT/VT discrimination results, therapies delivered, therapy results, total episode duration, cycle lengths at episode diagnosis and termination, as well as high-voltage shock and antitachycardia-pacing information. Summary diagnostic information, including initial diagnoses and therapies delivered, is presented in tree form. Lifetime diagnostic and patient information are also provided. Also available is the percentage of bradycardia pacing in the atrium and ventricle, as well as data on high-voltage

charging, high-voltage therapy, inhibited diagnoses, and capacitor-maintenance charging.

The device is capable of storing up to 25 minutes of fully annotated electrograms (EGMs) from one channel or up to 12 minutes from two channels with the waveform source programmable to either atrial bipolar, ventricular bipolar, or custom. The type of events to be stored, the criterion for storage, and the maximum duration are also programmable.

Real-time information is also available, including R- and P-wave amplitude, fully annotated EGMs, morphology scoring, battery voltage, residual high-voltage capacitor voltage, pacing lead impedance, and high-voltage lead impedance.

The pulse generator has non-invasive programmable stimulation and fibrillation induction features (including burst fibber, direct current, and shock-on-T-wave induction methods) for the induction of tachyarrhythmias and evaluation of therapy.

Pulse Generator Header

The Photon DR header is shown in Figure 1.

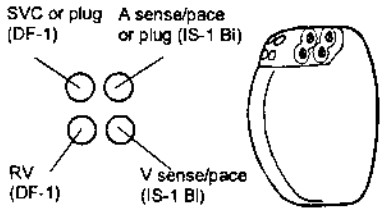

Figure 1. Photon DR pulse generator header

Bipolar Ventricular and Atrial Endocardial Sense/Pace Leads with IS-1[1] Connector
Defibrillation Leads with DF-1[2] (3.2 mm) Connector

The ventricular sense/pace receptacle of the header accepts a bipolar endocardial lead with an IS-1 in-line bipolar connector. The atrial sense/pace receptacle

1. St. Jude Medical IS-1 connector cavities conform to the international connector standard: ISO 5841-3: 1992.
2. St. Jude Medical DF-1 connector cavities conform to the international connector standard: ISO 11318: 1993.

accepts a bipolar endocardial lead with an IS-1 in-line bipolar connector or an IS-1 receptacle plug (when no atrial lead is used). The two high-voltage receptacles accept one or two defibrillation electrodes with DF-1 (3.2 mm) connectors (one RV, one SVC). A DF-1 receptacle plug seals the SVC receptacle when only one defibrillation electrode is used.

NOTE:
When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct port. 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.

Lead Compatibility

St. Jude Medical pulse generators are intended for use with the defibrillation lead systems with which they have been tested:

- Ventritex epicardial defibrillation leads
- Ventritex TVL® transvenous lead system
- Ventritex SPL® transvenous lead system
- CPI Endotak lead system
- Medtronic Transvene lead system

Sensing

The pulse generator has an Automatic Sensitivity Control feature to allow accurate sensing in both the atrium and the ventricle over a wide range of signal strengths. As shown in Figure 2 with nominal settings for the ventricle, Threshold Start begins at 50% of the measured R-wave (if the R-wave is between 2 and 6 mV) and decays linearly until the next sensed beat or until it reaches the Maximum Sensitivity Threshold. If the maximum R-wave amplitude is greater than 6 mV or less than 2 mV, Threshold Start is set to 3mV or 1mV, respectively. Sensing in the atrium is identical, with the

Threshold Start being 50% of the measured P-wave if the P-wave is between 0.6 and 3 mV. After a paced event, the Threshold Start is nominally set to 0.8 mV in the atrium and to adjust automatically based on the pacing rate in the ventricle.

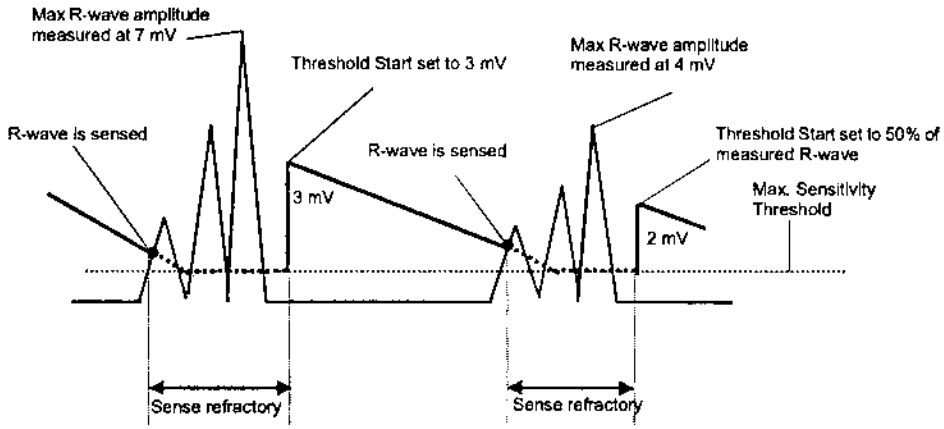

Figure 2. Automatic sensitivity control in the ventricle

Radiopaque Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification (see Figure 3). The model number is visible on a radiograph.

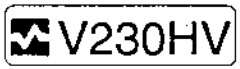

Figure 3. Photon DR X-ray marker

Package Contents

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

- One pulse generator with pre-installed setscrews
- Torque driver
- DF-1 receptacle plug
- IS-1 receptacle plug.

The outer box contains:

- *Photon* DR *User's Manual*
- Implant/Patient Registration form
- Out-of-Service/Explant Report form
- Patient Manual
- Temporary patient identification card
- One copy of the Limited Warranty
- Medic Alert enrollment form
- Hospital chart labels
- One package lubricant.

IMPLANTING THE PULSE GENERATOR

This section describes the recommended procedures for handling, implanting, and testing the pulse generator.

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 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

Refer to the information supplied with the leads for implantation information, indications, and possible complications.

Testing at Implant

Due to the nature of the implantation procedure, the physician and support staff should be familiar with all of the components of the system and the material in this manual before beginning the procedure.

After implanting the leads, test the lead systems. Because of the difference in capacitance between the pulse generator and the HVS®-02 electrophysiology device, we strongly recommend device-based testing. However, you may want to use a single, initial test using the HVS-02 device to screen for patients with a high defibrillation threshold before you open the pulse generator package.

For information on device-based testing, see "Performing Device-Based Testing" on page 23. If an implant support device is used, we strongly recommend that supplemental testing be done with the pulse generator.

WARNING:
Due to the nature of the procedure, a separate standby external defibrillator should always be immediately available.

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 the pulse generator is programmed to Defib Off before handling it. Do not program the pulse generator on until it is inserted into the pocket.

WARNING:
For reliable data transmission, implant the pulse generator at a depth not to exceed 7 cm.

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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.

NOTE:
When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct port. 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 only one defibrillation lead, make sure that the lead is in the receptacle marked "(DF-1) RV." Lubricate and insert the DF-1 plug into the receptacle marked "SVC or plug (DF-1)." 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.

NOTE:
If you are not using an atrial sense/pace lead, lubricate and insert the IS-1 plug into the receptacle marked "A sense/pace or plug (IS-1 Bi)."

   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.

3. **Carefully insert the tip of the torque driver through the center of the septum 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.

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

Performing Device-Based Testing

1. **Implant the leads and pulse generator. See "Forming the Pocket and Connecting the Leads" on page 22.**
2. **Use the programmer to interrogate the pulse generator.**

3. **Measure pacing capture thresholds, pacing lead impedance and R- and P-wave amplitude and store the data for trending analysis.**

   Ventricular pacing capture threshold should be less than 2 V (acute) or less than 5 V (chronic). Atrial pacing capture threshold should be less than 2 V (acute) or less than 5 V (chronic). R-wave amplitude should be greater than 5 mV (acute) or greater than 2 mV (chronic). P-wave amplitude should be greater than 2 mV (acute) or greater than 1 mV (chronic).

NOTE:
Very small-amplitude signals during tachycardia or fibrillation may result in prolonged arrhythmia detection times or inability to detect an arrhythmia.

4. **Check the bipolar lead real-time EGM for discontinuity or any artifact that might indicate lead damage.**

   Note that tapping the device header with an instrument or finger may produce artifacts on the real-time EGM.

5. **Set up the device configuration parameters as desired and program the device on.**
6. **Set the high-voltage waveform tilt or pulse width to the desired value.**

   If the waveform is Fixed PW, you should deliver a PC shock of at least 200 V to evaluate the lead impedance before programming the pulse width. If the waveform is Fixed Tilt, no impedance calculation is required.

   See "Suggested Pulse Widths For Measured Impedances For Fixed Pulse Width Mode" on page 41.

CAUTION:
Do not implant the pulse generator if the acute defibrillation lead impedance is less than 20 ohms or the lead impedance of chronic leads is less than 15 ohms. Damage to the device may result if the maximum output of 800 V is delivered into an impedance of less than 15 ohms.

7. **Induce ventricular fibrillation and monitor detection and therapy delivery. Adjust voltage and repeat until defibrillation threshold is determined.**

WARNING:
For effective defibrillation, place the device in the pocket before arrhythmia induction or defibrillation testing.

If you are using the programmer's device-based testing function, note that if the desired therapy voltage is not reached before the time delay has elapsed (in Timed mode) or therapy has been requested (in Manual mode), therapy delivery is postponed until the therapy voltage has been reached.

If energy requirements are excessive, the defibrillation leads may need to be repositioned, the waveform polarity reversed (by programming) or a different lead system chosen.

The energy requirement for reliable arrhythmia termination should be at least 10 J less than the pulse generator's maximum output. This equates to a voltage requirement for termination of no more than approximately 640 to 685 V, depending on programmed waveform, pulse width, and defibrillation lead impedance.

The choice of defibrillation lead system should be based on clinical factors and energy requirements. If energy requirements cannot be met with a given lead system, or if acute defibrillation lead impedance is low, a different lead system may alleviate the problem.

If the patient's condition permits, it is recommended that redetection be assessed after a failed shock at implant or predischarge testing.

If the R-wave amplitude is very small, detection times may be prolonged or the device may be unable to detect an arrhythmia.

If an arrhythmia is induced but the real-time EGM does not indicate that tachyarrhythmia intervals are being counted, the R-wave amplitude may be too low or the programmed tachyarrhythmia detection rate may be higher than the induced rate.

8. When testing is finished, go to the Capture Testing screen to evaluate the pacing capture thresholds. The capture threshold trends update automatically.

   The unloaded battery voltage, signal amplitude, and pacing lead impedance are automatically updated by the device once a month.

9. Set up the device configuration and parameters as described in the appropriate reference manual.

   Refer to the patient's electrophysiology (EP) study and documented spontaneous arrhythmia episodes for programming detection criteria.

10. Confirm bradycardia pacing as described in the next section.

Confirming Bradycardia Pacing

St. Jude Medical recommends that operating room testing include confirmation of bradycardia pacing at the programmed parameters.

1. Program the device to Defib Off and DDD or VVI pacing and set the pacing rate and (in DDD mode) AV Delay so the pulse generator paces 100% of the time.
2. If the real-time EGM shows T-waves that appear to be over half the size of the QRS complex and if the device is not pacing at the programmed rate (indicating T-wave sensing), increase the Decay Delay or Start Threshold.

Confirming Parameter Settings

At the end of the programming session, interrogate the device and check the Summary screen or Parameter Summary Report to confirm that the final parameter settings are correct.

Testing Before Hospital Discharge

The device's response to the patient's clinical arrhythmias should be re-evaluated before the patient's discharge from the hospital. If appropriate, use non-invasive stimulation to induce the clinical arrhythmias and confirm the appropriateness of the device's pro-

grammed settings. Review the performance of the morphology template, if applicable.

If appropriate, predischarge EP testing should be performed to verify proper system function. A chest X-ray taken at this time will provide a basis for comparison should later changes in shock efficacy or lead impedance make the lead system suspect.

Clinical and animal studies have shown that the high-voltage lead impedance drops significantly in the first seven days post-implant. Over the next few weeks, it gradually returns to near-implant level. In view of the recovery of the lead impedance level, no concomitant adjustment to the high-voltage pulse width is recommended during this period.

PATIENT FOLLOW-UP

Patients should be seen for follow-up every three months for the first six months, then every six months thereafter. As the battery approaches the elective replacement indicator, the follow-up frequency should be increased to 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 Detection Summary screen and Episodes screens
- Retrieval and review of stored and real-time EGMs
- Review of morphology template performance (if applicable)
- Measurement of the parameters on the Real-Time Measurements screen or the System Status area of the Summary screen
- Confirmation and storage in device memory of pacing capture thresholds
- Confirmation that the final parameter settings are correct. (Interrogate the device and check the Summary screen or Parameter Summary Report.)

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.

Device Longevity

Elective Replacement Indicator

The unloaded battery voltage determines whether a pulse generator should be replaced. The unloaded battery voltage appears on the Real-Time Measurements screen. Check the voltage at each follow-up visit. For a discussion of unloaded battery voltage, see the appropriate reference manual.

NOTE:
The *loaded* battery voltage is not used as an elective replacement indicator.

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 2.35 V.

Normal Battery Condition (3.20 V to 2.45 V)

An unloaded battery voltage of more than 2.45 V 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 (2.45 V to 2.35 V)

A battery voltage measurement of 2.45 V is the elective replacement indicator (ERI) for the device; however, the pulse generator will continue to operate according to specifications in the 2.45 to 2.35 V range, except for

a change in the pacing amplitude and high-voltage charge time.

A measurement of 2.35 V indicates that the battery is at end of life (EOL). Careful monitoring of the battery voltage 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 2.45 V level sometime in the previous three months and still has approximately three months remaining at this battery level.) Replace the pulse generator immediately upon reaching ERI if there is frequent high-voltage charging.

Past EOL Battery Condition (2.35 V to 2.25 V)

If the battery voltage is 2.35 V or less, explant the pulse generator immediately or program it to Defib Off/Pacer Off until it can be replaced. Below 2.35 V, 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. [3]

There is no guarantee that the pulse generator will deliver a high-voltage shock with a battery voltage of less than 2.25 V.

Factors That Affect Device Longevity

The longevity of the pulse generator depends strongly on the frequency of high-voltage charging. An increase

3. In pulse generators with serial numbers under 24,000, ATP and the other device functions are not automatically disabled.

in pacing output parameters or a decrease in pacing lead impedance also decreases battery longevity.

Battery Voltage Range	Battery Condition	Approximate Duration[1]					Recommended Action
		4 Maximum Charges/Yr No Pacing	1 Maximum Charge/Month				
			No pacing	25% pacing[2]	50% pacing[2]	100% pacing[2]	
3.20–2.45	Normal	4.9 yr	4.0 yr	3.8 yr	3.6 yr	3.3 yr	None
2.45–2.35	ERI to EOL	4 mo	4 mo	4 mo	4 mo	4 mo	Replace within 3 mo, or immediately if frequently charging
2.35–2.30	past EOL	N/A	N/A	N/A	N/A	N/A	Replace immediately

Table 4. Battery longevity

1 The battery longevities listed for the normal battery range are for a device with nominal specifications. Shelf life duration is 9 months.

2 Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 ppm, 500 ohms.

Using A Magnet

The pulse generator contains a reed switch that, when closed, prevents delivery of tachyarrhythmia therapy. Bradycardia pacing is not affected.

The reed switch closes in the presence of a strong magnetic field (see "Environmental and Medical Therapy Hazards" on page 4). 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 position of the reed switch. 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, program the device to Defib Off.

CAUTION:
The magnet interferes with proper telemetry. If you want to communicate with the device, remove the magnet.

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 and non-invasive stimulation are not affected by magnet application.

Explanting the Pulse Generator

WARNING:
Before explanting the system or disconnecting the leads from a pulse generator, program the pulse generator to Defib Off.

In the event of the patient's death, deactivate the pulse generator before post-mortem examination.

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 Report

Whenever a pulse generator is explanted, or if any of the leads or adapters are replaced or capped, complete an Out-of-Service/Explant Report 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.

DEVICE SPECIFICATIONS

For a listing of programmable device parameters, see the appropriate reference manual.

Physical Specifications

Dimensions	73 mm x 62 mm x 12.7 mm
Weight	85 g
Displacement volume	46 cm^3
Can material	Titanium
Header material	Epoxy
Septum material	Silicone
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors Low voltage: one or two IS-1 3.2 mm bipolar leads
Stored Energy	37 J
Noise detection rate	40 or more sensed events per second

Power Source

Type	Lithium/silver vanadium oxide; Wilson Greatbatch Limited, Model 9610
Number of cells	One cell
Battery voltage	3.20 V (beginning of service)
Elective replacement voltage (unloaded)	2.45 V
End of life voltage (unloaded)	2.35 V

Device Configurations

Tachyarrhythmia configuration	Defibrillator with No Tachycardia Response (Defib Only) Defibrillator with Tachycardia Response/Single Tachycardia Discrimination (Tach) Defibrillator with Tachycardia Response/Tach A and Tach B Discrimination (Tach A & B)) Defibrillator Off (Defib Off)
Bradyarrhythmia mode	AAI(R), VVI(R), DDI(R), DDD(R), Pacer Off Additional modes available in the Defib Off configuration: AOO, VOO, DOO Additional modes available as temporary modes: AOO, VOO, and DOO, AAT
Arrhythmia sensing configuration	Ventricular Only Dual Chamber

Operating Parameters Tolerances

Footnotes begin on page 37.

Arrhythmia Detection Parameters	
Detection intervals	± 10 ms
MTD/MTF timers	± 3 ms
Interval stability delta	± 10 ms
AVA delta	± 10 ms
Sudden onset delta	± 10 ms
Sensing refractory period	± 5 ms
Pacing/Fibrillation Induction Parameters	
Bradycardia pacing interval	± 15 ms
Pacing refractory period	± 10 ms
Burst refractory period[1]	+ 10/ -25 ms
Pacing pulse width	± 30 µs
Pacing voltage	± 5% or 0.25 V, whichever is greater (open circuit) ± 10% (500 ohm load to ERI) ± 20% (500 ohm load ERI to EOL)
Burst fibber pacing pulse width	± 60µs
Burst fibber amplitude	± 10%
Pacing output impedance[2]	40 ohms, maximum
Pacing output droop[3]	< 5%

Post-therapy pacing pause	± 0.25 sec
Typical delivered pacing amplitude[4]	> 4.7 V
ATP interval (fixed)	± 5 ms
ATP interval (adaptive)	± 3%
ATP minimum burst cycle length	± 5 ms
NIPS intervals	± 5 ms
Burst fibber intervals[5]	± 5 ms
Shock-on-T fibber intervals	± 5 ms
Cardioversion/Defibrillation Parameters	
Stored voltage	± 5% or 20 V, whichever is greater
Pulse width	± 150 µs
Output impedance	3 ohms, maximum
Post-shock refractory period[6]	± 10 ms
Typical delivered cardioversion/ defibrillation amplitude[7]	760 V (when programmed to 800 V)
Cardioversion/Defibrillation Measurements	
Estimated impedance[8]	± 15% (from 25 to 75 ohms for >100 V)
Estimated delivered energy[9]	± 15%
Pulse width	± 250 µs
High-voltage charge time	± 0.15 sec

Real-Time Measurements	
Unloaded battery voltage	± 1% at 2.45 V (ERI)
Battery impedance	< 0.5 ohms
Pacing lead impedance	± 10% (at 500 ohms)
Residual capacitor voltage	± 5% (100 to 750 V)
Signal amplitude[10]	± 10% or 0.2mV, whichever is greater
Diagnostics/Real-Time Status Data	
Sensed intervals (cycle length)	± 10 ms
Min/max tachyarrhythmia cycle length	± 10 ms
Last successful ATP BCL	± 5 ms
Near-field EGM sensitivity[11]	± 10% or 0.2 mV, whichever is greater

1 Measured using a 10 ms haversine test signal
2 Measured with a 500 ohm load with an output voltage of 5.0 V.
3 Measured with a 500 ohm load with a burst cycle length of 200 ms.
4 Measured with a 500 ohm load with an output voltage of 5.0 V.
5 Initial S1 (synchronous interval) is ± 5 ms
6 Measured using a 10 ms haversine test signal
7 Measured with a 50 ohm load with an output voltage of 800 V.
8 Measured at voltages greater than or equal to 200 V with a monophasic pulse at the pulse width suggested by the programmer.
9 At 50 ohms for a fixed pulse width above 200V.
10 Measured using a 33 ms (30 Hz) haversine test signal
11 Measured using a 33 ms (30 Hz) haversine test signal

EMERGENCY VVI AND RESET PACING PARAMETERS

Parameter	Emergency	Software Reset	Hardware Reset
Pacing Mode	VVI	VVI	VVI
Ventricular Pulse Amplitude	5.0 V	5.0 V	7.5 V
Ventricular Pulse Width	0.6 ms	0.5 ms	0.75 ms
Sense Configuration	Bipolar	Bipolar	Bipolar
Pulse Configuration	Bipolar	Bipolar	Bipolar
Ventricular Pacing Rate	70 ppm	60 ppm	60 ppm
Paced Ventricular Refractory Period	400 ms	440 ms	312.5 ms
Ventricular Sensitivity	Not affected	0.3 mV	2.2 mV
Rate Hysteresis	Off	Off	Off
Sensor	Off	Off	Off

RESET VALUES

Arrhythmia sensing mode	Ventricular only
Tachyarrhythmia configuration	Defibril'ator with No Tachycardia Response (Defib Only)
Fibrillation detection	410 ms (146 bpm)
Fibrillation detection time	Nominal
Fibrillation therapies	Therapy 1–800 V Therapy 2–800 V Therapy 3–800 V
Post-shock fibrillation detection interval	410 ms (146 bpm)
Device sinus redetection time	Nominal
High-voltage waveform	Biphasic
High-voltage waveform mode	Fixed Tilt
RV polarity	Anode (+)
High-voltage pulse width	65%
Bradyarrhythmia mode	VVI
Bradycardia sensor	Off
Bradycardia pacing rate	60 ppm
Bradycardia pacing rest rate	Off
Bradycardia ventricular pacing pulse amplitude	5 V

Bradycardia ventricular pacing pulse width	0.50 ms
Post-therapy pause before bradycardia pacing	2 s
Bradycardia pacing hysteresis rate and search	Off
Bradycardia pacing noise reversion mode	VOO
Bradycardia ventricular pacing refractory period	440 ms
EGM storage	On
Type of EGM events stored	Fib, PC shock, magnet reversion, noise reversion, activation of morphology template
Trigger for EGM event storage	Diagnosis of fibrillation
Capacitor maintenance	3 months; 800 V
Magnet mode	Normal

Suggested Pulse Widths For Measured Impedances For Fixed Pulse Width Mode

Measured Impedance (ohms)	Monophasic Waveform Suggested Pulse Width (ms)	Biphasic Waveform Suggested Pulse Width (Phase 1 = Phase 2) (ms)
0-30	3.0	3.0
31-34	3.5	3.5
35-39	4.0	4.0
40-43	4.5	4.5
44-48	5.0	5.0
49-52	5.5	5.5
53-57	6.0	6.0
58-62	6.5	6.5
63-66	7.0	7.0
67-71	7.5	7.5
72-75	8.0	8.0
76-80	8.5	8.5

Measured Impedance (ohms)	Monophasic Waveform Suggested Pulse Width (ms)	Biphasic Waveform Suggested Pulse Width (Phase 1 = Phase 2) (ms)
81-85	9.0	9.0
86-89	9.5	9.5
90-94	10.0	10.0
95-98	10.5	10.0
99-103	11.0	10.0
104-107	11.5	10.0
>108	12.0	10.0

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