

Promote™ RF

with InvisiLink™ Wireless Telemetry

MODEL 3213-36

Cardiac Resynchronization Therapy Defibrillator (CRT-D)



SPECIFICATIONS

- **InvisiLink™** wireless telemetry frees the clinical team during implant, and streamlines follow-up. InvisiLink RF telemetry uses a dedicated range of frequencies designated for medical devices called the MICS (Medical Implant Communications Service) frequency band, which helps reduce the interference seen on frequencies used by common household electronics.
- **QuickOpt™** timing provides quick and effective optimization for more patients at the push of a button.¹
 - IEGM-based AV and V-V optimization allows optimized timing without need for echo-guided optimization.
 - **V-V timing optimization** may help improve patient outcomes. Because not all patients respond to simultaneous biventricular pacing, programmable timing of right and left ventricular outputs helps to ensure appropriate therapy and may reduce the number of non-responders.²
- **Advanced Biventricular Pacing Options include:**
 - Independently programmable RV and LV amplitude and pulse widths accommodate patients with different energy demands for each chamber, aiding in efficient maintenance of capture.
 - Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing.
 - Independent RV and LV threshold testing during follow-up enables you to check each lead independently, enabling you to determine each chamber's pacing threshold and program the outputs for consistent capture and battery longevity.
- Our exclusive **DeFT Response™** technology tools provide more clinically proven, non-invasive options for managing high DFTs.
 - Programmable pulse widths allow the user to tailor the shock to the individual patient, making shocks more efficacious.³
 - SVC shocking electrode can be quickly and non-invasively activated or deactivated with the press of a button.
 - 36 J delivered energy (model 3213-36) provides unsurpassed energy for defibrillation.
 - Four programmable tilt options are available because no one tilt is optimal for every patient.⁴
 - Together, these features may help to prevent additional surgeries.
- **The SenseAbility™** feature, with **Decay Delay** and **Threshold Start**, provides the flexibility to fine-tune sensing to individual patient needs and help eliminate oversensing of T waves, fractionated QRS complexes, and other extraneous signals.
- The exclusive **Morphology Discrimination plus AV Rate Branch** SVT discrimination feature helps reduce the risk of inappropriate ICD shocks and is intended to promote fast, accurate diagnosis and delivery of therapy. Clinical data states that this combination resulted in a sensitivity of 100% with a specificity of 85%.⁵
- **VectSelect™** programmable LV pulse configuration (LV ring-RV coil, LV tip - RV coil or LV bipolar) may be adjusted noninvasively via the programmer.
- Designed to Reduce Unnecessary Right Ventricular Pacing - The **VIP™** algorithm allows intrinsic conduction when possible and provides optimized ventricular support when needed.
- Exclusive **AF Suppression™** algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
 - Studies show a 25% decrease in symptomatic AF burden.⁶
- Our exclusive **DC Fibber™** induction has a documented 95.5% success rate for inducing fibrillation on the first induction as compared with a 72.7% success rate for Shock-on-T.⁷

- Exercise trend diagnostic provides insight into the patient's disease state progression and exercise activity.
- There are up to 45 minutes of continuous, fully annotated stored electrograms, including up to 60 seconds of pre-trigger information per electrogram.
- Preferential EGM storage capability allows you to prioritize the way episodes are stored.
- Exclusive vibratory **Patient Notifier** allows even patients with hearing problems to be alerted to a low battery, lead-related complications and more.
- Automatic Daily High Voltage Lead Test is designed to ensure optimal patient safety.
- Multiple hardware and software system safeguards for added security and patient comfort.
- The capability to program multiple ATP schemes per zone has the potential to increase the success of ATP prior to requiring a shock.

- 1 Baker, et al. "Acute Evaluation of Programmer-Guided AV/PV and VV Delay Optimization Comparing an IEGM Method and Echocardiogram for Cardiac Resynchronization Therapy in Heart Failure Patients and Dual-Chamber ICD Implants." *Journal of Cardiovascular Electrophysiology*, Vol. 18 No. 2, Feb. 2007.
- 2 Chan, et al. Tissue Doppler guided optimization of A-V and V-V delay of biventricular pacemaker improves response to cardiac resynchronization therapy in heart failure patients. *J Cardiac Failure* 2004; 10:4 (supplement); 572 (abstract 199).
- 3 Mouchawar G, Kroll M, Val-Mejias JE et al. ICD waveform optimization: a randomized prospective, pair-sampled multicenter study. *PACE* 2000; 23 (Part II):1992-1995.
- 4 Sweeney MO, Natale A, Volosin KJ, et al. Prospective randomized comparison of 50%/50% versus 65%/65% tilt biphasic waveform on defibrillation in humans. *PACE* 2001; 24:60-65.
- 5 Sperzel J, Meine M et al. A new automatic update function of the morphology template used for SVT/NT discrimination in anico. *Europace Supplements*; Vol. 3, July 2002:A 131, #1515.
- 6 Summary of Safety and Effectiveness, P88086/S83 and P830015/S76; St. Jude Medical.
- 7 Sharma AD, O'Neill PG, Fain E, et al. Shock on T versus DC for induction of ventricular fibrillation: a randomized prospective comparison. 21st Annual Scientific Session North American Society of Pacing and Electrophysiology (NASPE). Poster presentation published in meeting proceedings. Washington D.C., U.S.A. May 2000.

Indications and Usage

The Promote™ RF CRT-D is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronization Therapy devices (CRT-Ds) are also intended to resynchronize the right and left ventricles in patients with congestive heart failure.

Contraindications

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

Warnings

Implantation Procedure. The physician should be familiar with all components of the system and the material in this manual before beginning the procedure. Ensure that a separate standby external defibrillator is immediately available. Implant the pulse generator no deeper than 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 Replacement.** Replace the pulse generator within three months of reaching the 2.45 V indication. **Replace the pulse generator immediately upon reaching 2.45 V if there is frequent high-voltage charging and/or one or more of the pacing outputs are programmed above 2.5 V.**

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

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

Magnetic Resonance Imaging (MRI). Avoid MRI devices because of the magnitude of the magnetic fields and the strength of the radiofrequency (RF) fields they produce.

Precautions

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

Lead Impedance. 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 high-voltage therapy is delivered into an impedance less than 15 ohms.

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

Suboptimal RF Communication. The Merlin™ PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin Antenna. Please see the User's Manual for a list of potential causes to suboptimal radio communication.

Potential Adverse Events

Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionizing radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T-waves, P-waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability. Persons administering cardiopulmonary resuscitation (CPR) have reportedly been startled by voltage present on the patient's body surface during discharge of the pulse generator. The voltage decreases as the discharge disperses toward the periphery of the body, and is weakest at the furthest extension of the limbs. Nevertheless, there is a highly remote possibility that an arrhythmia may be induced in someone administering CPR to the patient at the time a countershock is delivered.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Promote™ RF Model 3213-36 Cardiac Resynchronization Therapy Defibrillator

MODEL NUMBER 3213-36

PHYSICAL SPECIFICATIONS

Telemetry	RF and Inductive
Delivered Energy	36 J
Volume (cc)	43
Weight (g)	82
Size (mm)	81 x 50 x 14
Defibrillation Lead Connections	DF-1
Sense/Pace Lead Connections	IS-1
High Voltage Can	Electrically active titanium can

PARAMETER SETTINGS

Resynchronization Therapy

QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, Interventricular Pace delay
V-V Timing	Simultaneous*, RV First, LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only, biventricular, LV only
Negative AV Hysteresis/Search (ms)	Off, -10 to -120
Shortest AV Delay (ms)	25-120
VectSelect™ LV Pulse Configuration	LV tip to RV coil, LV bipolar, LV ring to RV coil

AF Management

AF Suppression™ Pacing	Off; On
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Maximum AF Suppression Rate	80-150 ppm

Sensing/Detection

SenseAbility™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Threshold Start	(Post-Sensed, Atrial) 50, 62.5, 75, 100%; (Post-Paced, Atrial) 0.2-3.0 mV; (Post-Sensed, Ventricular) 50, 62.5, 75, 100%; (Post-Paced, Ventricular) Auto, 0.2-3.0 mV
Decay Delay	(Post-Sense/Post-Pace, Atrial/Ventricular) 0-220
Ventricular Sense Refractory (ms)	125, 157
Detection Zones	VT-1, VT-2, VF
SVT Discriminators	AV Rate Branch, Sudden Onset, Interval Stability, Morphology Discrimination (MD) with Manual or Automatic Template Update
Reconfirmation	Continuous sensing during charging

Antitachycardia Pacing Therapy

ATP Configurations	Ramp, Burst, Scan; 1 or 2 schemes per zone
Burst Cycle Length	Adaptive, Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts/Stimuli	1-15 with 2-20 stimuli
Add Stimuli per Burst	On, Off

High Voltage Therapy

High Voltage Output Mode	Fixed Pulse Width, Fixed Tilt
Waveform	Biphasic, Monophasic
RV Polarity	Cathode (-), Anode (+)
Electrode Configuration	RV to Can, RV to SVC/Can

Bradycardia Pacing

Permanent Modes	Off, DDD(R), DDI(R), VVI(R), AAI(R), Pacer Off
Temporary Modes	Off, DDD, DDI, VVI, AAI, AAT, DDO, VOO, AOO
Rate-Adaptive Sensor	On, Off, Passive
Programmable Rate Parameters	Off, Base Rate (min ⁻¹), Rest Rate (min ⁻¹), Maximum Tracking Rate (min ⁻¹), Maximum Sensor Rate (min ⁻¹), Paced AV Delay (ms), Sensed AV Delay (ms), Rate Responsive AV Delay, Pulse Amplitude (Atrial, RV and LV) (V), Pulse Width (Atrial, RV and LV) (ms), Hysteresis Rate (min ⁻¹), Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off, DDI(R), VVI(R)
AMS Detection Rate (ppm)	110-300
AMS Base Rate	40, 45, ...135
Auto PMT Detection/Termination	A Pace on PMT, Off, Passive
Rate Responsive PVARP/VREF	Off, Low, Medium, High
Ventricular Intrinsic Preference (VIP™)	Off, 50-200 (50-150 in increments of 25; 160-200 in increments of 10)

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)

Post-Shock Pacing Mode	Off, AAI, VVI, DDI, or DDD
Post-Shock Base Rate (ppm)	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off, 0.5, 1, 2.5, 5, 7.5, or 10

Device Testing/Induction Methods

DC Fibber™ Pulse Duration (sec)	0.5-5.0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to three extrastimuli

Patient Notifiers

Programmable Notifiers (On, Off)	Device at ERI, Charge time Limit Reached, Possible HV Circuit Damage, Atrial Lead Impedance out of range, Ventricular Lead Impedance out of range
Device Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2, 4, 6, 8, 10, 12, 14, 16
Number of Vibrations per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10, 22

Electrograms and Diagnostics

Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include diagnosis, therapy, atrial episode, PMT termination, PC shock delivery, noise reversion, magnet reversion, and morphology template verification
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram, AV Interval Histogram, Mode Switch Duration Histogram, Peak Filtered Rate Histogram, Atrial Heart Rate Histogram, Ventricular Heart Rate Histogram, AT/AF Burden, Exercise and Activity Trending, V Rates During AMS
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances, High voltage lead impedances, unloaded battery voltage and signal amplitudes.

*LV first with 10 ms interventricular delay.



Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362-6822
+1 818 362-7182 Fax

St. Jude Medical AB
Veddestavägen 19
SE-175 84 Järfälla
SWEDEN
+46 8 474 4000
+46 8 760 9542 Fax

St. Jude Medical Coordination Center
The Corporate Village
Building Figueras
Avenue Da Vinci Iaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

www.sjm.com

Ordering No. E1662 Printed in Brussels 080710
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

Consult the User's Manual for information on indications, contraindications, warnings and precautions. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical, or one of its subsidiaries. © 2007 St. Jude Medical Cardiac Rhythm Management Division. All rights reserved.