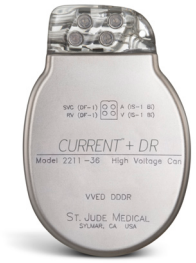
Current® Plus DR

Implantable Cardioverter Defibrillators (ICDs) with DF-1 and SJ4 Connectors

MODELS CD2211-36 and CD2211-36Q



SPECIFICATIONS

- The SJ4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws. The SJ4 connection reduces pocket bulk, which may provide increased comfort, particularly for patients who are thin or small in stature, and could lessen the risk of lead-to-can abrasion, a known complication.
- Triple Redundancy Safety Platform is designed to minimize risk and increase security and patient comfort through multiple hardware and software system safeguards.
- Vibratory Patient Notifier, proven superior to auditory notifier[1], enables patients with hearing problems to be alerted to a low battery, lead-related complications and more.
- *Tailored*Therapy™ features designed to customize therapy to each patient's unique needs.
  - QuickOpt® Timing Cycle Optimization provides quick and effective optimization for more patients at the push of a button.[2]
    - IEGM-based AV optimization allows optimized timing without need for echo-guided optimization.
  - VIP® (Ventricular Intrinsic Preference) algorithm limits unnecessary ventricular pacing, helps to restore and maintain AV synchrony and tailors the AV delay to optimize patient outcomes.
    - Studies show an 81% decrease in unnecessary RV pacing.[3]
    - Programming option allows AV delays up to 450 ms.
  - DeFT Response® Technology allows more non-invasive programming flexibility in the management of DFTs to ensure adequate safety margins with unsurpassed energy delivery.
    - Programmable pulse widths allow the user to tailor the shock to the individual patient, making shocks more efficacious.[4]
    - SVC shocking electrode can be quickly and noninvasively activated or deactivated with the press of a button.
    - 36 J delivered energy provides unsurpassed energy for defibrillation.
    - Four programmable tilt options are available to accommodate variances among patients.
  - The Sense*Ability*® 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.
  - Exclusive AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
    - Studies show a 25% decrease in symptomatic AF burden.[5]
- AT/AF Alerts notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode.
- Automatic Daily High-Voltage Lead Integrity Test is designed to ensure optimal patient safety.
- 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%.[6]
- Programming ATP schemes per zone may increase the success of ATP prior to requiring a shock.
- Exercise Trend Diagnostic provides insight into the patient's disease state progression and exercise activity.
- 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 prioritization of episode storage.
- InvisiLink® wireless telemetry, in conjunction with the Merlin@home™ transmitter and Merlin.net™ PCN, allows for seamless remote monitoring and 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.
- DC Fibber™ Induction has a documented 95.5% success rate for inducing fibrillation on the first induction.[7]

Indications and Usage:
The Current® pulse generators are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. AF Suppression pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction. In patients indicated for an ICD, the Promote pulse generators are also intended to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section included in the Merlin Patient Care System [PCS] on-screen help) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration; to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure.
Contraindications:
Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.
Warnings and Precautions:
Resuscitation Availability. Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.
Lead system. Do not use another manufacturer's lead system without demonstrated compatibility as undersensing cardiac activity and failure to deliver necessary therapy may result.
Avoiding shock during handling. Disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapies Off during surgical implant and explant or post-mortem procedures as well as when disconnecting leads as the device can deliver a serious shock if you touch the defibrillation terminals while the device is charged.
Additional pacemaker implanted. These devices provide bradycardia pacing. If another pacemaker is used, it should have a bipolar pacing reset mode and be programmed for bipolar pacing to minimize the possibility of the output pulses being detected by the device.
Modifying the device. This device has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by St. Jude Medical Inc. could void the user's authority to operate this device.
Suboptimal radio frequency (RF) communication. The Merlin PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the Merlin PCS and the Merlin Antenna. Please see the User's Manual for a list of potential causes to suboptimal radio communication.
Potential Adverse Events:
Possible adverse events (in alphabetical order) associated with the system, include, but are not limited to the following: acceleration of arrhythmias (caused by device), air embolism, allergic reaction, bleeding, cardiac tamponade, chronic nerve damage, death, erosion, exacerbation of heart failure, excessive fibrotic tissue growth, extracardiac stimulation (phrenic nerve, diaphragm, chest wall), extrusion, fluid accumulation, formation of hematomas or cysts, inappropriate shocks, infection, keloid formation, lead abrasion and discontinuity, lead migration/dislodgment, myocardial damage, pneumothorax, shunting current or insulating myocardium during defibrillation with internal, or external paddles, potential mortality due to inability to defibrillate or pace, thromboemboli, venous occlusion, venous or cardiac perforation. Patients susceptible to frequent shocks despite antiarrhythmic medical management, may develop psychological intolerance to an ICD or CRT-D system that may include the following: dependency, depression, fear of premature battery depletion, fear of shocking while conscious, fear of losing shock capability, imagined shocking (phantom shock).

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

ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

PHYSICAL SPECIFICATIONS

Models	CD2211-36	CD2211-36Q
Telemetry	RF	RF
Delivered Energy	36 J	36 J
Volume (cc)	42	41
Weight (g)	80	80
Size (mm)	77 x 50 x 14	74 x 50 x 14
Defibrillation Lead Connections	DF-1	SJ4
Sense/Pace Lead Connections	IS-1	IS-1
High Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER SETTINGS

QuickOpt® Timing Cycle Optimization	Sensed/paced AV delay, Interventricular Pace delay
Negative AV Hysteresis/Search (ms)	Off, -10, -20, -30, -40
Rate Responsive AV Delay	Off, Low, Medium, High

AF Management

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

Sensing/Detection

Sense*Ability*® 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; (Post-Pace Ventricular) Auto
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 Width, Fixed Tilt
Waveform	Biphasic, Monophasic
RV Polarity	Cathode (-), Anode (+)
Electrode Configuration	RV to Can, RV to SVC/Can

Bradycardia Pacing

Permanent Modes	DDD(R), DDI(R), DOO(R), VVI(R), VOO(R), AAI(R), AAT(R), AOO(R)
Temporary Modes	DDD, DDI, DOO, VVI, VOO, AAI, AAT, AOO
Rate-Adaptive Sensor	On, Off, Passive
Programmable Rate and Delay Parameters	Off, Base Rate (ppm), Rest Rate (ppm), Maximum Tracking Rate (ppm) Maximum Sensor Rate (ppm), Paced AV Delay (ms), Sensed AV Delay (ms), Rate Responsive AV Delay, Pulse Amplitude (Atrial, Ventricular) (V), Pulse Width (Atrial, Ventricular) (ms), Hysteresis Rate (ppm), Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off, DDI(R), DDT(R), VVI(R), VVT(R)
Atrial Tachycardia Detection Rate (ppm)	110-300
AMS Base Rate	40, 45, ...135
Auto PMT Detection/Termination	Atrial Pace, 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, AT/AF Burden, Backup VVI, HV Lead Impedance Out of Range
Device Parameter 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

1 Matthew T Bennett et al. The ICD alert is potentially an unreliable ICD warning feature. Canadian Cardiovascular Congress.

2 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.

3 Hanna G et al. Reduction of ventricular pacing in pacemaker patients using Ventricular Intrinsic Preference: Preliminary results from the VIP trial. Europace Supplement. July 2008; Sperzel J et al. First clinical experience with a new algorithm to avoid unnecessary right ventricular pacing in patients with preserved intrinsic conduction. World Congress, Rome, December 2007.

4 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.

5 Carlson MD et al. A new pacemaker algorithm for the treatment of atrial fibrillation: results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). JACC 2003; 42:627-633.

6 Sperzel J, Meine M et al. A new automatic update function of the morphology template used for SVT/VT discrimination in an ICD. Europace Supplements; Vol. 3, July 2002; A 131, #1515.

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.

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