Implantable Cardioverter Defibrillator (ICD) Devices

Current[™]+ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- Triple redundancy safety platform is designed to minimise risk and increase security and patient comfort through multiple hardware and software system safeguards
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- The SenseAbility™ feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety



Merlin@home^T Transmitter Compatible

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD2211-36	77 x 50 x14	80	42	DF1	IS-1
CD2211-36Q	74 x 50 x 14	80	41	DF4	IS-1; DF4

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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.

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, cardiagenic 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 ionising 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.

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

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Biret Jummary: Prior to using these devices, piease review in instructions for use for a complete listing or indications, contraindications, contraindications, contraindications, contraindications, contraindications, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or noe of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All rights reserved.



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Product Specifications

CD2211-36	CD2211-36Q	
RF	RF	
36/42	36/42	
42	41	
80	80	
77 x 50 x 14	74 x 50 x 14	
DF1	DF4	
IS-1	DF4	
Electrically active titanium can	Electrically active titanium can	
SETTINGS		
On; Off		
15-40 in steps of 5		
80-150 min ⁻¹		
	RF 36/42 42 80 77 x 50 x 14 DF1 IS-1 Electrically active titanium can SETTINGS On; Off 15-40 in steps of 5	

Sensing/Detection Sense*Ability*™ Technology Automatic Sensitivity Control adjustment for atrial and ventricular events Low Frequency Attenuation On: Off

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 (Post-Sensed/Post-Paced; Atrial/Ventricular) 0-220;

Decay Delay Ventricular Sense Refractory (ms) 125: 157 VT-1: VT-2: VF

Detection Zones 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 VT zone Burst Cycle Length Adaptive; Readaptive or Fixed Min. Burst Cycle Length (ms) 150-400 in increments of 5

Number of Bursts 1-15 Number of Stimuli 2-20 Add Stimuli per Burst On; Of

High-Voltage Therapy

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

Bradycardia Pacing

DDD(R): DDI(R): DOO(R): VVI(R): VOO(R): AAI(R): AOO(R) Permanent Modes Temporary Modes Off; DDD; DDI; VVI; AAI; AAT; AAT(R); DOO; VOO; AOO

Rate-Adaptive Sensor On; Off; Passive

Programmable Rate and Off; Base Rate (min-1); Rest Rate (min-1); Maximum Tracking Rate (min-1); **Delay Parameters** Maximum Sensor Rate (min⁻¹); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV) (V); Pulse Width (Atrial and RV) (ms); Hysteresis Rate (min-1); Rate Hysteresis with Search

QuickOpt™ Timing Cycle Optimisation Sensed/Paced AV delay $\label{eq:ddd} \texttt{DDD}(R); \texttt{DDI}(R); \\ \mbox{DOO}(R); \\ \mbox{VVI}(R); \\ \mbox{VOO}(R); \\ \mbox{AAI}(R); \\ \mbox{AOO}(R)$ Auto Mode Switch (AMS)

Atrial Tachycardia Detection Rate (min-1) 110-300 AMS Base Rate (min-1) 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)

${\bf Post-The rapy\ Pacing\ (independently\ programmable\ from\ Bradycardia\ and\ ATP)}$

Post-Shock Pacing Mode Off; AAI; VVI; DDI; DDD 30-100 in increments of 5 Post-Shock Base Rate (min-1) 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

2-25 stimuli with up to 3 extrastimuli Noninvasive Programmed Stimulation (NIPS)

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; High-Voltage Lead Impedance Out of Range; AT/AF Burden;

V Rate During AT/AF; Backup VVI; Long AT/AF Episode Device Parameter Reset

Entry into Backup VVI Mode 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 $45\,\mathrm{minutes}$ including up to $1\,\mathrm{minute}$ 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 Diagram of therapies delivered Therapy Summary **Episodes Summary** Directory listing of up to 60 episodes with access to more details including

stored electrograms History of bradycardia events and device-initiated charging

Lifetime Diagnostics AT/AF Burden Trend Trend data and counts

Ventricular HV Lead Impedance Trend Multi-Vector Trend Data Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Histograms

Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricula Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;

V Rates during AMS PMT Data Information regarding PMT detections

Pacing lead impedances; high-voltage lead impedances; unloaded battery Real-Time Measurements (RTM)

voltage; and signal amplitudes



