

Current™ + VR

Single-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
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- 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
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety



Merlin@home™
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
CD1211-36	76 x 50 x 14	79	42	DF1	IS-1
CD1211-36Q	74 x 50 x 14	79	41	DF4	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, 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 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 adverse events.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, 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 one 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

PHYSICAL SPECIFICATIONS

Models	CD1211-36	CD1211-36Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/42	36/42
Volume (cc)	42	41
Weight (g)	79	79
Size (mm)	76 x 50 x 14	74 x 50 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETERS

PARAMETERS	SETTINGS
Sensing/Detection	
SenseAbility™ Technology	Automatic Sensitivity Control adjustment for ventricular events
Threshold Start	(Post-Sensed, Ventricular) 50; 62.5; 75; 100%; (Post-Paced, Ventricular) Auto; 0, 2-3, 0 mV
Decay Delay	(Post-Sensed/Post-Paced; Ventricular) 0-220; (Post-Paced Ventricular) Auto
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	VT-1; VT-2; VF
SVT Discriminators	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; 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; VVI(R); VOO(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate Parameters	Off; Base Rate (min ⁻¹); Rest Rate (min ⁻¹); Maximum Sensor Rate (min ⁻¹); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min ⁻¹); Rate Hysteresis with Search

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

Post-Shock Pacing Mode	Off; VVI
Post-Shock Base Rate (min ⁻¹)	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 3 extrastimuli

Patient Notifiers

Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; Backup VVI; Long AT/AF Episode
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 1 minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; therapy; 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
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded battery voltage; and signal amplitudes

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