Ellipse™ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- New shape with reduced volume and thickness
- *Tailored*Therapy™ features are designed to customize treatment to each patient's unique needs, including: SecureSense™ RV lead noise discrimination, ShockGuard® technology, Sense*Ability*® sensing algorithm and DeFT Response® technology
- ShockGuard technology with DecisionTx® programming is designed to reduce inappropriate therapy and minimize the need for programming adjustments at implant
- SecureSense RV lead noise discrimination detects sustained and short bursts of lead noise for the reduction of inappropriate shocks
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high-voltage shock
- RV AutoCapture™ pacing system monitors and regulates right-ventricular pacing with beat-by-beat support
- The Low Frequency Attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- The Sense*Ability* sensing algorithm allows flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Streamlined DF4 connector simplifies implants and reduces pocket bulk
- 36 J delivered energy safety shock option can provide a greater defibrillation threshold (DFT) safety margin
- DeFT Response technology offers the most noninvasive options for managing high DFTs
- QHR®* battery chemistry provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries
- Unique vibratory notifier alerts patients to a low battery, lead-related complications and more

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD1311-36	68 x 51 x 12	66	31	DF1	IS-1
CD1311-36Q	66 x 51 x 12	67	30	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 pulse generator system use 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 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.

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

*QHR is a registered trademark of Greatbatch Medical.

U.S. Customer Support: 1-800-722-3774

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.

Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Unless otherwise noted, ® or ™ indicates a registered or unregistered trademark or service mark owned by, or licensed to, St. Jude Medical, Inc. 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. Item No. F00128

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Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD1311-36**	**CD1311-36Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	30
Weight (g)	66	67
Size (mm)	68 x 51 x 12	66 x 51 x 12
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
Sensing/Detection	
Sense*Ability*® Sensing Algorithm	Automatic Sensitivity Control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Ventricular) 50; 62.5; 75; 100%; (Post-Paced; Ventricular) Auto; 0.2-3.0 mV
Decay Delay (ms)	(Post-Sense/Post-Pace; Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone; 2 zones; 3 zones (VT-1; VT-2; VF)
SVT Discriminators	Sudden Onset; Interval Stability; Sinus Interval History; Morphology Discrimination
Discrimination Modes	On; Passive; Off
SVT Threshold	150-240 bpm
SVT Timeout	0.25-5 min
Monitor Mode	Provides detection, discrimination and diagnostics without therapy in the VT or VT-1 zone
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)
Antitachycardia Pacing (ATP) Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150-300 bpm
Burst Cycle Length	Adaptive; Readaptive; 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
ATP Pulse Amplitude (V)	7.5, Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1.0 or 1.5, Independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DeFT Response® Technology	Programmable pulse width or tilt for P1/P2
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)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate Parameters	Off; Base Rate (ppm); Rest Rate (ppm); Maximum Sensor Rate (ppm); Hysteresis Rate (ppm) with Search
Ventricular AutoCapture™ Pacing System	On; Off
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
Post-Shock Base Rate (ppm)	30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0.5; 1; 2.5; 7.5; 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; SecureSense RV lead noise detected/non-sustained lead noise detected
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 (hrs)	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; detection; therapy; PC shock delivery; noise reversion; magnet reversion; and morphology template verification; lead noise detected; non-sustained lead noise detected; non-sustained ventricular tachycardia (NSVT); morphology template update
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; DirectTrend® reports up to 1 year
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; signal amplitudes

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