

Unify Quadra™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- The Unify Quadra CRT-D and Quartet™ quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds.
- Downsized device for a smaller footprint.
- The CorVue™ Congestion Monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts.
- Enhanced tachycardia therapy nominal settings designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant.
- 40 J delivered energy provides unsurpassed energy for defibrillation.
- Streamlined header connectors (IS4-LLLL/DF4-LLHH) reduce pocket bulk.
- QHR™ chemistry battery provides greater capacity for enhanced longevity and improved charge time performance.



QHR is a trademark of Greatbatch Medical.

Ordering Information

Contents: Cardiac Resynchronisation Therapy Defibrillator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
CD3251-40	83 x 41 x 14	83	40	DF1, IS4, IS-1
CD3251-40Q	76 x 41 x 14	81	38	DF4, IS4, IS-1

DRAFT SPECIFICATIONS; CE MARK PENDING.

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise 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.

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.

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 trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2010 St. Jude Medical, Inc. All Rights Reserved.

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Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	CD3251-40	CD3251-40Q
Telemetry	RF	RF
Delivered Energy (J)	40	40
Volume (cc)	40	38
Weight (g)	83	81
Size (mm)	83 x 41 x 14	76 x 41 x 14
Defibrillation Lead Connections	DF-1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
PARAMETER SETTINGS		
Biventricular Pacing		
VectSelect Quartet™ LV Pulse Configuration	Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil	
V. Triggering (BIV Trigger Mode)	On; Off	
QuickOpt™ Timing Cycle Optimisation	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	
Negative AV Hysteresis/Search (ms)	Off; -10 to -120	
Shortest AV Delay (ms)	25-120	
AF Management		
AF Suppression™ Pacing	On; Off	
No. of Overdrive Pacing Cycles	15-40 in steps of 5	
Maximum AF Suppression Rate	80-150 min ⁻¹	
Sensing/Detection		
SenseAbility™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events	
Low Frequency Attenuation	On; Off	
Sense Filter 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-Sensed/Post-Paced; 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	
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off	
ATP Upper Rate Cutoff	150-300 bpm	
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); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay 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; Hysteresis Rate (min ⁻¹); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min ⁻¹)	110-300
AMS Base Rate (min ⁻¹)	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)
BIVCap™ Confirm; LVCap™ Confirm;	Setup; On; Monitor; Off
RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
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; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V Pacing; CorVue™ Congestion Trigger
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; 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; signal amplitudes
CorVue Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

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