Quadra Assura MP™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- MultiPoint™ pacing delivers multiple LV pacing pulses per cardiac cycle and is designed to improve hemodynamic and clinical response
- The Quadra Assura MP CRT-D and QuartetTM 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
- VectSelect Quartet[™] multivector testing feature offers a streamlined workflow to identify, test and program the patient's pacing vector
- Parylene coating for improved abrasion resistance
- DynamicTx[™] Over-Current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold Can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- SecureSense™ RV lead noise discrimination detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
- Far Field MD™ morphology discrimination and Chamber Onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- 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
- Low Frequency Attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T-waves
- Sense Ability™ feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- QHR^{™*} chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- 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
- QuickOpt™ timing cycle optimisation provides quick and effective optimisation at the push of a button

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector	
CD3371-40C	83 x 41 x 14	83	40	DF1, IS4, IS-1	
CD3371-40QC	75 x 41 x 14	80	38	DF4, IS4, IS-1	

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 connective 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, 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 adiation. 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 trademark of Greatbatch Medical

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Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	CD3371-40C	CD3371-40QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	40	38
Weight (g)	83	80
Size (mm)	83 x 41 x 14	75 x 41 x 14
Defibrillation Lead Connections	DF1	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
Coating	Parylene	Parylene

PARAMETER	SETTI

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Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2 VectSelect Quartet

Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil

MultiPoint Pacing LV1: LV2

Delay 1: 5; 10; ...80 ms Delay 2: 5; 10; ... 50 ms Delay MultiPoint Pacing

V. Triggering QuickOpt™ Timing

Cycle Optimisation Sensed/paced AV delay, interventricular pace delay

V-V Timing Simultaneous*; RV First; LV First RV First 10-80 / LV First 15-80 in increments of 5 Interventricular Pace Delay (ms)

Ventricular Sensing
Ventricular Pacing Chamber RV only (not programmable) 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 Maximum AF Suppression Rate 15-40 in steps of 5 80-150 min

Sensing/Detection

Sense Ability™ Technology Automatic Sensitivity Control adjustment for atrial and ventricular

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-Sense/Post-Pace; Atrial/Ventricular) 0-220 Decay Delay

Ventricular Sense Refractory (ms)

Detection Zones 3 zone programming - 1 zone; 2 zones or 3 zones (VT-1; VT-2; VF) AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); SVT Discriminators

Interval Stability; AV Association; Morphology Discrimination (Far Field MD or Original MD) with Manual (original MD only) or Automatic Template Update

Detection, discrimination and diagnostics, no therapy delivery (VT or Monitor Mode

Discrimination modes On: Passive: Off 150-240 min SVT Threshold SVT Timeout 0.25-5 min

Continuous sensing during charging Reconfirmation Lead Noise Discrimination SecureSense™ RV lead noise discrimination (On; On with Timeout; Passive; Off)

Antitachycardia Pacing Therapy

ATP Configurations Ramp; Burst; Scan; 1 or 2 schemes per VT zone ATP While Charging; ATP Prior to Charging; Off ATP in VF Zone

ATP Upper Rate Cutoff Burst Cycle Length 150 - 300 min-1 Adaptive; Readaptive or Fixed Min. Burst Cycle Length (ms) 150-400 in increments of 51-15 with 2-20 Stimuli Number of Bursts/Stimuli 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 Bradycardi

and Post-Therapy Pacing

High-Voltage Therapy

DynamicTx™ Algorithm On: Off

Programmable pulse width for P1/P2 and tilt DeFT Response™ Technology Fixed Pulse Width: Fixed Tilt

High-Voltage Output Mode Biphasic; Monophasic **RV** Polarity Cathode (-); Anode (+) Electrode Configuration RV to Can; RV to SVC/Can; RV to SVC **Bradycardia Pacing**

Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)Permanent Modes Temporary Modes Off; DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO; On, Off, Passive

Rate-Adaptive Sensor 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; Hysteresis Rate (min-1); Rate Hysteresis

BiVCap™ Confirm; LVCap™ Confirm;

RVCap™ Confirm Setup; On; Monitor; Off ACap[™] Confirm QuickOpt[™] Timing Cycle Optimisation On; Monitor; Off Interventricular Pace Delay Auto Mode Switch (AMS) Off; DDI(R); DDT(R); VVI(R); VVT(R) Atrial Tachycardia

Detection Rate (min-1) 110-300 40; 45; ... 135 Atrial Pace; Off; Passive AMS Base Rate (min-1) Auto PMT Detection/Termination Rate Responsive PVARP/VREF Off; Low; Medium; High Ventricular Intrinsic Preference (VIP¹ M) Off; On (50-200)

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

Off; AAI; VVI; DDI; or DDD Post-Shock Pacing Mode 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 three extrastimuli

Patient Notifiers

Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; Programmable Notifiers (On: Off)

LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; AT/AF Episode Duration; % V pacing; CorVue Congestion Trigger; SecureSense -– lead noise detected.

non-sustained lead noise detected

Device Parameter Reset Entry into Backup VVI Mode Ωn

Vibration Duration (sec) 2; 4; 6; 8; 10; 12; 14; 16

Number of Vibrations per Notification 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; morphology template verification; lead noise detected, non-sustained lead noise detected, NSVT/NSVF

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 Frend 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; DirectTrend™ reports up to 1 year

Information regarding PMT detections

Pacing lead impedances; high-voltage lead impedances; and signal Real-Time Measurements (RTM)

amplitudes CorVue™ Congestion Monitoring On; Off CorVue Congestion Trigger 8-18 days

* LV first with 10 ms interventricular delay

PMT Data

Customer Support: 46-8-474-4756

Item GMCRM1076EN

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.

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