CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

Quadra Assura™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI ready device has been tested for safe performance of an MRI scan using a 1,5 T (Tesla) field-strength MRI scanner when used in combination with MR Conditional leads[1,2]
- The Quadra Assura 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
- Elevate response easily with Auto VectSelect Quartet™ test offering an efficient workflow for complete results and programming at the touch of a button
- SyncAV™ CRT technology dynamically adjusts AV delays based on patient's intrinsic conduction to encourage patient-tailored biventricular pacing
- DynamicTx™ over-current detection algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Parylene coating for improved abrasion resistance
- 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 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

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
CD3367-40QC	75 x 41 x 14	80	38	DF-4, 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 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.

Quadra Assura™

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD3367-40QC
Telemetry	RF
Delivered/Stored Energy (J)	40/45
Volume (cc)	38
Weight (g)	80
Size (mm)	75 × 41 × 14
Defibrillation Lead Connections	DF4-LLHH
LV Lead Connections	IS4-LLLL
Sense/Pace Lead Connections	IS-1
High-Voltage Can	Electrically active titanium can
MR Conditional	Yes, MRI Ready

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ LV	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; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous[3]; 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
SyncAV™ CRT Delta	Off; -10 to -120
Shortest AV Delay (ms)	25–120
AF Management	
AF Suppression™ Pacing algorithm	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Rate	80–150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV; 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; Atrial/Ventricular) 0–220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming - 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD™ or Original MD) with Manual (original MD only) or Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0; 25–5 min
Reconfirmation	Continuous sensing during charging
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 in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 min^{-1}
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
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	
DynamicTx™ Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
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; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDT; DDI; VVT; VVI; AAI; 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
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	Setup; On; Monitor; Off
QuickOpt™ Timing Cycle Optimization	Interventricular Pace Delay
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; On (50–200)
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
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; AT/AF Episode Duration; % V Pacing; CorVue™ Congestion Trigger, SecureSense algorithm — lead noise detected, nonsustained 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 (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 25 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, nonsustained 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	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, DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8–18 days
MRI Scan Parameters	

If the implanted system is comprised of a combination of leads that have differing RF Power (SAR), scan region and/or additional considerations, use the most restrictive of each to determine the overall set of scan conditions applicable for the total system.

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril™ STS Pacing Lead		Normal Operating Mode*	Full-body
2088TC	46, 52 cm		
IsoFlex™ Optim™ pacing leads			
1944	46, 52 cm		
Durata™ Defibrillation Lead			
7122Q, 7120Q	58, 65 cm		
Optisure™ Lead			
LDA210Q, LDA220Q	58, 65 cm		
Quartet™ LV Lead			
1456Q; 1457Q; 1458Q; 1458QL	86 cm		

*As defined in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: ≤ 2 W/kg, Head SAR ≤ 3.2 W/kg

1. MR Conditional Field Strength: 1,5 Tesla
2. See MRI-Ready Systems Manual for approved MR Conditional Systems Device/Lead combinations and scan parameters
3. LV first with 10 ms interventricular delay

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.

30025-SJM-QD-1015-0027(5) | Item approved for international use only.

Abbott