CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

Quadra Assura[™]

Cardiac Resynchronization Therapy Defibrillator (CRT-D)





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 highvoltage 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 $^{\text{\tiny TM}}$ 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.

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS

Coil; Pulse Configuration Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil V. Triggering On; Off Sensed/paced AV delay, interventricular pace delay Cycle Optimization V-V Timing Interventricular Pace Delay (ms) Ventricular Pace Delay (ms) Ventricular Pacing Chamber SyncAV*** CRT Delta Shortest AV Delay (ms) AF Suppression*** Pacing algorithm No. of Overdrive Pacing Cycles Maximum AF Suppression Rate Sensing/Detection Sense Ability*** Technology Low Frequency Attenuation Sense Filter On; Off (Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mly; Threshold Start (Post-Sensed; Ventricular) So; 62,5; 75; 100%; (Post-Paced; Atrial) 0-220 Ventricular Sense Refractory (ms) Detection Zones AV Rate Branch; Arrhythmia Onset (Chamber Onset or		
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High-Voltage Output Mode Fixed Pulse Width; Fixed Tilt Waveform Biphasic; Monophasic RV Polarity Cathode (-); Anode (+)		
RV Polarity Cathode (-); Anode (+)		
Electrode Configuration RV to Can; RV to SVC/Can; RV to SVC		
	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	Off; Base Rate (min ⁻¹); Rest Rate (min ⁻¹); Maximum Tracking Rate (min ⁻¹);		
Delay Parameters	Maximum Sensor Rate (min ⁴); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min ⁴); Rate Hysteresis with Search		
BiVCap™ Confirm; LVCap™	Setup; On; Monitor; Off		
Confirm; RVCap™ Confirm	•		
ACap™ Confirm	Setup; On; Monitor; Off		
QuickOpt™ Timing Cycle	Interventricular Pace Delay		
Optimization	- 22		
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)		
Atrial Tachycardia	110-300		
Detection Rate (min ⁻¹) 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	Off; On (50–200)		
(VIPTM) Post-Thorony Paging (Indopendent	ly programmable from Bradycardia and ATP)		
Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹)	Off; AAI; VVI; DDI; or DDD 30–100 in increments of 5		
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10		
Patient Notifiers	011, 0,0, 1, 2,0, 0, 7,0, 01 10		
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV		
Programmable Nouners (Oir; Oii)	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 TM Congestion Trigger, SecureSense algorithm — lead		
	noise detected, nonsustained lead noise detected		
Device Parameter Reset Entry into Backup VVI Mode	On On		
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16		
Number of Vibrations per	2, 4, 0, 0, 10, 12, 14, 10		
Notification	_		
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, NoSVT/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	Multi-Vector Trend Data		
Trend 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		

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.

On; Off 8-18 days

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril™ STS Pacing Lead			
2088TC	46, 52 cm		
IsoFlex™ Optim™ pacing leads			
1944	46, 52 cm		
Durata™ Defibrillation Lead		Normal Operating	Full-body
7122Q, 7120Q	58, 65 cm	Mode*	
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: \leq 2 W/kg, Head SAR \leq 3.2 W/kg

 $\begin{array}{l} \text{CorVue}^{\scriptscriptstyle{\text{TM}}} \operatorname{Congestion} \operatorname{Monitoring} \\ \operatorname{CorVue} \operatorname{Congestion} \operatorname{Trigger} \end{array}$

- MR Conditional Field Strength: 1,5 Tesla
 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.

 $^{\scriptscriptstyle\mathsf{TM}}$ Indicates a trademark of the Abbott group of companies.

 \ddagger Indicates a third party trademark, which is property of its respective owner.

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