CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

Entrant[™] HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D) CDHFA300Q



Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- SyncAV™ CRT technology offers dynamic AV timing with customizable programming to ensure BiV pacing
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- DeFT Response[™] technology offers noninvasive programming options to optimize rescue therapy to each patient's unique physiology and changing conditions
- VF Therapy Assurance decreases time to treatment for arrhythmias in patients who are likely to be hemodynamically unstable
- 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
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimize the need for programming adjustments at implant
 - SecureSense™ RV lead noise discrimination detects sustained lead noise and short bursts of oversensing that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
 - Far Field MD™ morphology discrimination and Chamber Onset discrimination enhance SVT and VT discrimination for reduced inappropriate therapies
- Sense*Ability*™ sensing algorithm feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity

- The Entrant™ HF CRT-D and Quartet™ quadripolar LV lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to address implant complications such as diaphragmatic stimulation and high pacing thresholds
- Easily test and program with Auto VectSelect Quartet™ multivector testing, offering an efficient workflow for complete results and programming
- DynamicTx[™] over-current detection algorithm automatically changes shock configurations to ensure delivery of high-voltage therapy when high current is detected
- MRI Ready device tested in combination with MR Conditional leads for full-body scans using a 1,5T or 3T (Tesla) field strength MRI Scanner*
- New battery provides higher capacity than previous QHR‡ batteries to offer superior longevity/volume ratio
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- Premature Atrial Contraction (PAC) Response to avoid pacing the atrium in a vulnerable zone
- Physiologic rate responsive AV Delay and PVARP
- QuickOpt[™] timing cycle optimization provides quick and effective optimization at the push of a button
- Dual patient notification: audio notification through the device and visual notification via myMerlinPulse™ app

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H x W x T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
CDHFA300Q	74 x 51 x 12	76	34	DF-4, IS-4, IS-1

^{*}See MRI Scan Parameters in MRI Ready Systems manual.



Entrant™ HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D) CDHFA3000

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CDHFA300Q		
Telemetry	Bluetooth® LE Communication		
Delivered/Stored Energy	36/39 J		
Volume	34 cc		
Weight	76 g		
Size	74 x 51 x 12 mm		
Defibrillation Lead Connections	DF4-LLHH		
LV Lead Connections	IS4-LLLL		
Sense/Pace Lead Connections	IS-1		
High-Voltage Can	Electrically active titanium can		
PARAMETER	SETTINGS		
Biventricular Pacing			
VectSelect Quartet™	Distal Tip I-Mid 2; Distal Tip I -Proximal 4; Distal Tip I - RV		
Programmable Pulse	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 - Mid 2 - RV Coil; Proximal 4 - Mid 2 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - Mid 2 - RV Coil; Proximal 4 - RV Coil; Proximal 4 - RV Coil; Proximal 4 - RV C		
Configuration	4 - RV Coil		
V. Triggering	On; Off		
QuickOpt™ Timing	Sensed/paced AV delay, interventricular pace delay		
Cycle Optimization			
V-V Timing	Simultaneous [†] ; RV First; LV First		
Interventricular Pace Delay	RV First 10-80/LV First 15-80 ms		
Ventricular Sensing	RV only (not programmable)		
Ventricular Pacing Chamber	RV only; Biventricular		
SyncAV™ CRT Technology Delta	-10 to -120 ms; Off		
Sensing/Detection			
SenseAbility™ Sensing Algorithm	Automatic sensitivity control adjustment for atrial and ventricular events		
Low Frequency Attenuation	On; Off		
Threshold Start	Post-Sensed: 50; 62,5; 75; 100%;		
	Post-Paced, Atrial: 0,2-3,0 mV		
p p1	Post-Paced, Ventricular: Auto: 0,2-3,0 mV		
Decay Delay	Post-Sensed: 0–220 ms Post-Paced, Atrial: 0-220 ms		
	POST-PACEU, AUTAI: U-220 IIIS		

Ventricular Sense Refractory Detection Zones

SVT Discriminators

Monitor Mode

Discrimination Modes SVT Upper Limit SVT Discrimination Timeout Reconfirmation SecureSense™ RV Lead Noise Discrimination Algorithm VF Therapy Assurance

Antitachycardia Pacing Therapy ATP Configurations ATP in VF Zone

ATP Upper Rate Cutoff Burst Cycle Length Min. Burst Cycle Length Readaptive

Number of Bursts/Stimuli Add Stimuli per Burst

ATP Pulse Amplitude ATP Pulse Width

High-Voltage Therapy DynamicTx™ Over-Current Detection Algorithm DeFT Response™ Technology High-Voltage Output Mode Waveform

RV Polarity Electrode Configuration Bradycardia Pacing

Permanent Modes

Parameters

Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay

Pulse Amplitude Pulse Ampittude
Pulse Width
LVCap™ Confirm Feature
RVCap™ Confirm Feature
ACap™ Confirm Feature
Auto Mode Switch (AMS)

Atrial Tachycardia Detection Rate AMS Base Rate Auto PMT Detection/ Termination Post-Paced, Atria: 0-220 ms Post-Paced, Ventricular: Auto, 0-220 ms 125; 157 ms

12-3, 17 Ins 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); Interval Stability; AV Association Morphology; Discrimination (Far Field MD" Morphology Discrimination or Original MD) with Automatic Template Lindate

Template Update Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
On; Passive; Off
150-240 min⁻¹

20s- 60 min; Off

Continuous sensing during charging On; On with Timeout; Passive; Off

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

150–300 min⁻¹ Adaptive (50%-100%); Fixed (200-550 ms) 150-400 in increments of 5 ms

On; Off 1-15 with 2-20 Stimuli

7,5 V independent from Bradycardia and Post-Therapy Pacing 1,0 or 1,5 ms independently programmable from Bradycardia and Post-Therapy Pacing

Programmable pulse width for P1/P2 and tilt Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic

Cathode (-); Anode (+) RV to Can; RV to SVC/Can; RV to SVC

DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); Off DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO;

Off
On; Off; Passive
Off; Base Rate (min⁻¹); Rest Rate (min⁻¹); Maximum Tracking
Rate (min⁻¹); Max Trigger 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
0.25 - 7,5 V

0,05; 0.1 -1,5 ms Setup; On; Monitor; Off Setup; On; Monitor; Off On; Monitor; Off
DDI(R); DDT(R); VVI(R); VVT(R); Off

110-300 min⁻¹ 40; 45; ... 135 min⁻¹ Atrial Pace; Passive; Off Rate Responsive PVARP Low; Medium; High; Off

Rate Responsive V Pace Refractory On; Off PAC Response On; Off PAC Response Interval Shortest AV Delay 25–120 i 200-400 ms 25-120 ms

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

Post-Shock Pacing Mode Post-Shock Base Rate AAI: VVI: DDI: or DDD: Off 30–100 min

Post-Shock Pacing Duration 0,5; 1; 2,5; 5; 7,5; or 10 min; Off

Device Testing/Induction MethodsDC Fibber™ Induction Method 0,
Pulse Duration 0,5 - 5,0 sec 20-100 ms

BurstFibberCycle Length Noninvasive Programmed Stimulation (NIPS) 2-25 stimuli with up to three extra stimuli

Patient Notifiers

Programmable Notifiers (On; Off)

BatteryAssurance™ alert, Possible HV circuit damage, HV charge timeout, Long charge time for Capacitor Maintenance, Device at ERI, Right ventricular pacing lead impedance out of range, Left ventricular lead impedance out of range, High-voltage lead impedance out of range, AT/AF episode duration, AT/AF Burden, High ventricular rate during AT/AF, SecureSense™ lead noise detection, Non-sustained ventricular oversensing, Biventricular pacing percentage lower than limit

Device Parameter Reser Entry into Backup VVI Mode

2; 4; 6; 8; 10; 12; 14; 16 sec Auditory Duration Number of Audio Alerts per Notification

Number of Notifications 1-16 Time Between Notifications 10; 22 hours

Electrograms and Diagnostics Stored Electrograms

Up to 15 minutes (2 user programmable + discrimination channel), up to one minute programmable pre-trigger data per VT/VF electrograms; additional triggers include lead noise detection, non-sustained ventricular oversensing, morphology template updates, atrial episode, PMT termination, PAC response, magnet reversion, noise reversion Diagram of therapies delivered Directory listing of up to 60 episodes with access to more details including stored electrograms. History of bradycardia events and device-initiated charging Trend data and counts Multi-Vector Trend Data

Therapy Summary Episodes Summary Lifetime Diagnostics AT/AF Burden Trend

Ventricular HV Lead Impedance Trend Multi-Vector Trend Data

Histograms and Trends

Event Histogram; AV Interval Histogram; Mode Switch or AT/AF Duration Histogram; Peak Filtered Atrial 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

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

MRI Settings Setting Tachy Therapy Disabled DOO, VOO, AOO, Pacing Off MRI Mode MRI Base Rate 30-100 min MRI Paced AV Delay 25-120 ms MRI RA and RV Pulse Amplitude 5.0 or 7.5 V MRI RA and RV Pulse Width 1,0 ms

Bipolar

MRI RA and RV Pulse Configuration MRI V Pacing Chamber RV Only MRI Timeout 3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters

PMT Data

LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Quartet™ LV Lead			
1456Q (lead lengths: 86 cm) 1457Q (lead lengths: 86 cm) 1458Q (lead lengths: 86 cm) 1458QL (lead lengths: 86 cm)	1,5T/3T		
Durata™ Defibrillation Lead			
7120Q (lead lengths: 58, 65 cm) 7122Q (lead lengths: 58, 65 cm)	1,5T / 3T	Normal	
Optisure™ Lead	Operating Mode	Full-body	
LDA220Q (lead lengths: 58, 65 cm) LDA210Q (lead lengths: 58, 65 cm)	1,5T / 3T	Mode	
Tendril™ STS Pacing Lead			
2088TC (lead lengths: 46, 52 cm)	1,5T / 3T		
Tendril MRI™ Lead LPA1200M (lead lengths: 46, 52 cm)	1,5T		

& For additional information about specific MR Conditional CRT-Ds and leads, including scan parameters, warnings, precautions, adverse conditions to MRI scanning, and potential adverse events, please refer to the Abbott MRI Ready Systems Manual at medical.abbott/manuals.

† LV first with 10 ms interventricular delay

Customer Support: 46-8-474-4756
Brief Summary: This product is intended for use by or under the direction of a Physician. 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.

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