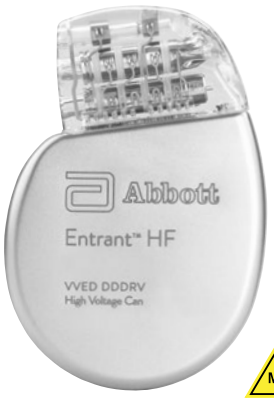
CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

Entrant™ HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

CDHFA300Q



MR Compatible with myMerlinPulse™ App

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.

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Cardiac Resynchronization Therapy Defibrillator (CRT-D)

CDHFA300Q

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™ Programmable Pulse Configuration	Distal Tip 1-Mid 2; Distal Tip I -Proximal 4; Distal Tip I - 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	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, interventricular pace delay
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	
Sense*Ability*™ 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 Post-Paced, Ventricular: Auto: 0.2-3.0 mV
Decay Delay	Post-Sensed: 0-220 ms Post-Paced, Atrial: 0-220 ms Post-Paced, Ventricular: Auto, 0-220 ms
Ventricular Sense Refractory	125; 157 ms
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™ Morphology Discrimination or Original MD) with Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination Modes	On; Passive; Off
SVT Upper Limit	150-240 bpm
SVT Discrimination Timeout	20s-60 min; Off
Reconfirmation	Continuous sensing during charging
SecureSense™ RV Lead Noise Discrimination Algorithm	On; On with Timeout; Passive; Off
VF Therapy Assurance	On; 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 bpm
Burst Cycle Length	Adaptive (50%-100%); Fixed (200-550 ms)
Min. Burst Cycle Length	150-400 in increments of 5 ms
Readaptive	On; Off
Number of Bursts/Stimuli	1-15 with 2-20 Stimuli
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude	7.5 V independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width	1.0 or 1.5 ms independently programmable from Bradycardia and Post-Therapy Pacing
High-Voltage Therapy	
DynamicTx™ Over-Current Detection 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	DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); Off
Temporary Modes	DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO; Off
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (bpm); Rest Rate (bpm); Maximum Tracking Rate (bpm); Max Trigger Rate (bpm) Maximum Sensor Rate (bpm); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (bpm); Rate Hysteresis with Search
Pulse Amplitude	0.25-7.5 V
Pulse Width	0.05; 0.1-1.5 ms
LVCap™ Confirm Feature	Setup; On; Monitor; Off
RVCap™ Confirm Feature	Setup; On; Monitor; Off
ACap™ Confirm Feature	On; Monitor; Off
Auto Mode Switch (AMS)	DDI(R); DDT(R); VVI(R); VVT(R); Off
Atrial Tachycardia Detection Rate	110-300 bpm
AMS Base Rate	40; 45; ... 135 bpm
Auto PMT Detection/Termination	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	200-400 ms
Shortest AV Delay	25-120 ms
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	AAI; VVI; DDI; or DDD; Off
Post-Shock Base Rate	30-100 bpm
Post-Shock Pacing Duration	0.5; 1; 2.5; 5; 7.5; or 10 min; Off
Device Testing/Induction Methods	
DC Fibber™ Induction Method Pulse Duration	0.5-5.0 sec
BurstFibberCycle Length	20-100 ms
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 Reset	On
Entry into Backup VVI Mode	On
Auditory Duration	2; 4; 6; 8; 10; 12; 14; 16 sec
Number of Audio Alerts per Notification	2
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
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 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
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; and signal amplitudes

MRI Settings	Setting
Tachy Therapy	Disabled
MRI Mode	DOO, VOO, AOO, Pacing Off
MRI Base Rate	30-100 bpm
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
MRI RA and RV Pulse Configuration	Bipolar
MRI V Pacing Chamber	RV Only
MRI Timeout	3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters§

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	Normal Operating Mode	Full-body
Durata™ Defibrillation Lead 7120Q (lead lengths: 58, 65 cm) 7122Q (lead lengths: 58, 65 cm)	1.5T / 3T		
Optisure™ Lead LDA220Q (lead lengths: 58, 65 cm) LDA210Q (lead lengths: 58, 65 cm)	1.5T / 3T		
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

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Rx Only
Intended Use: The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended to resynchronize the right and left ventricles.

The myMerlinPulse™ mobile application is intended for use by people who have an Abbott Medical implanted heart device and access to a mobile device. The app provides remote monitoring capability of the implanted heart device by transmitting information from the patient's implanted heart device to the patient's healthcare provider.

Indications: The CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

In addition, dual chamber CRT-D devices with the AT/AF detection algorithm are indicated in patients with atrial tachyarrhythmias or those patients who are at significant risk of developing atrial tachyarrhythmias.

MR Conditional CRT-Ds are conditionally safe for use in the MRI environment when used in a complete MR Conditional system and according to instructions in the MRI-Ready Systems manual. Scanning under different conditions may result in severe patient injury, death or device malfunction.

The myMerlinPulse™ mobile application is indicated for use by patients with supported Abbott Medical implanted heart devices.

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.

The myMerlinPulse™ mobile application is contraindicated for use with any implanted medical device other than supported Abbott Medical implanted heart devices.

Adverse Events: Possible adverse events associated with the implantation of the pulse generator system include the following: Arrhythmia (for example, accelerated or induced), Bradycardia, Cardiac or venous perforation, Cardiac tamponade, Cardiogenic shock, Death, Discomfort, Embolism, Endocarditis, Erosion, Exacerbation of heart failure, Excessive fibrotic tissue growth, Extracardiac stimulation (phrenic nerve, diaphragm, pectoral muscle), Extrusion, Fluid accumulation within the device pocket, Formation of hematomas, cysts, or seromas, Heart block, Hemorrhage, Hemothorax, Hypersensitivity, including local tissue reaction or allergic reaction, Infection, Keloid formation, Myocardial damage, Nerve damage, Occlusion/Thrombus, Pericardial effusion, Pericarditis, Pneumothorax, Pulmonary edema, Syncope, Thrombosis, Valve damage. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death. Among the psychological effects of device implantation are imagined pulsing, depression, dependency, fear of premature battery depletion, device malfunction, inappropriate pulsing, shocking while conscious, or losing pulse capability. Possible adverse device effects include complications due to the following: , Abnormal battery depletion, Conductor fracture, Device-programmer communication failure, Elevated or rise in defibrillation/cardioversion threshold, Inability to defibrillate or pace, Inability to interrogate or program due to programmer or device malfunction, Incomplete lead connection with pulse generator, Inhibited therapy including defibrillation and pacing, Inappropriate therapy (for example, shocks and antitachycardia pacing [ATP] where applicable, pacing), Interruption of function due to electrical or magnetic interference, Intolerance to high rate pacing (for example dyspnea or discomfort), Lead abrasion, Lead fracture, Lead insulation damage, Lead migration or lead dislodgement, Loss of device functionality due to component failure, Pulse generator migration, Rise in DFT threshold, Rise in pacing threshold and exit block, Shunting of energy from defibrillation paddles, System failure due to ionizing radiation. Additionally, potential adverse events associated with the implantation of a coronary venous lead system include the following: Allergic reaction to contrast media, Breakage or failure of implant instruments, Prolonged exposure to fluoroscopic radiation, Renal failure from contrast media used to visualize coronary veins. Refer to the User's Manual for detailed intended use, indications, contraindications, warnings, precautions and potential adverse events.

No potential adverse events have been identified with use of the myMerlinPulse™ mobile application.

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