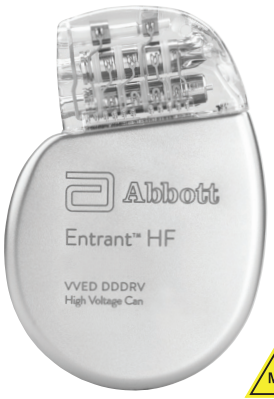
CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

# 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
- The CorVue™ thoracic impedance feature measures transthoracic impedance changes over time to provide additional insight into the patient's heart failure condition

## 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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## 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%;<br>Post-Paced, Atrial: 0.2-3.0 mV<br>Post-Paced, Ventricular: Auto: 0.2-3.0 mV |
| Decay Delay | Post-Sensed: 0-220 ms<br>Post-Paced, Atrial: 0-220 ms<br>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<br>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 |
| CorVue Thoracic Impedance | On; Off |
| CorVue Thoracic Impedance | Threshold 8-18 days |

| 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 Scan Parameters§**

| LEAD MODEL | MAGNET (TESLA) | RF TRANSMIT CONDITIONS | SCAN REGION |
|---|---|---|---|
| **Quartet™ LV Lead**<br>1456Q (lead lengths: 86 cm)<br>1457Q (lead lengths: 86 cm)<br>1458Q (lead lengths: 86 cm)<br>1458QL (lead lengths: 86 cm) | 1.5T / 3T | Normal Operating Mode | Full-body |
| **Durata™ Defibrillation Lead**<br>7120Q (lead lengths: 58, 65 cm)<br>7122Q (lead lengths: 58, 65 cm) | 1.5T / 3T | | |
| **Optisure™ Lead**<br>LDA220Q (lead lengths: 58, 65 cm)<br>LDA210Q (lead lengths: 58, 65 cm) | 1.5T / 3T | | |
| **Tendril™ STS Pacing Lead**<br>2088TC (lead lengths: 46, 52 cm) | 1.5T / 3T | | |
| **Tendril MRI™ Lead**<br>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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