#### CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

# Gallant<sup>™</sup> HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D) CDHFA500Q



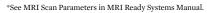
# **Product Highlights**

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- MultiPoint<sup>™</sup> pacing delivers multiple LV pacing pulses per cardiac cycle in both LV only and BiV pacing modes
- SyncAV<sup>™</sup> Plus CRT technology offers dynamic AV timing with adaptive programming to ensure BiV pacing with or without MultiPoint pacing
- · Improved shape with reduced volume and thickness
- 40J delivered energy safety shock option for enhanced safety margin
- DeFT Response<sup>™</sup> 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 algorithm 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 enhances SVT and VT discrimination for reduced inappropriate therapies
- SenseAbility™ sensing algorithm feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity

- The Gallant<sup>™</sup> HF CRT-D and Quartet<sup>™</sup> quadripolar LV lead feature four pacing electrodes and 13 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<sup>™</sup> 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<sup>†</sup> 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
- The CorVue<sup>™</sup> congestion monitoring feature measures transthoracic impedance changes over time to provide additional insight into the patient's heart failure condition
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- Premature Atrial Contraction (PAC) Response to avoid pacing the atrium in a vulnerable zone
- Physiologic rate responsive AV Delay and PVARP
- QuickOpt<sup>™</sup> 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

| MODEL NUMBER | DIMENSIONS (H × W × T, MM) | WEIGHT (G) | VOLUME (CC) | CONNECTOR        |
|--------------|----------------------------|------------|-------------|------------------|
| CDHFA500Q    | 74 × 51 × 12               | 76         | 34          | DF-4, IS-4, IS-1 |





## Cardiac Resynchronization Therapy Defibrillator (CRT-D) CDHFA5000

### Product Specifications

| PHYSICAL SPECIFICATIONS  |  |
|--|--|
| Model  | CDHFA500Q  |
| Telemetry<br>Delivered/Stored Energy   | Bluetooth® LE Communication<br>40/45 J   |
| Volume   | 40/45 J<br>34 cc   |
| Weight   | 76 g   |
| Size   | 74 × 51 × 12 mm  |
| Defibrillation Lead Connections  | DF4-LLHH   |
| LV Lead Connections  | IS4-LLLL   |
| Atrial Sense/Pace Lead Connections   | IS-1   |
| High Voltage Can PARAMETER   | Electrically active titanium can SETTINGS  |
| Biventricular Pacing   | JETTINGS   |
| Divertique a racing<br>VectSelect Quartet™ Programmable<br>LV Pulse Configuration                | Distal Tip 1 - Mid 2; Distal Tip 1 - Proximal 4;<br>Distal Tip 1 - Mid 3; Distal Tip 1 - RV Coil;<br>Mid 2 - Mid 3; Mid 2 - Proximal 4; Mid 2 - RV<br>Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 -<br>RV Coil; Proximal 4 - Mid 2; Proximal 4 - Mid 3:<br>Proximal 4 - RV Coil |
| MultiPoint™ Pacing   | LV1, LV2   |
| Delay MultiPoint Pacing  | Delay 1: 5; 10; 80 ms  |
| T. m. ' '  | Delay 2: 5; 10; 50 ms  |
| V. Triggering  | On; Off<br>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; LV only; Biventricular  |
| SyncAV™ <i>Plus</i> CRT Technology Delta   | If Type = Percentage: -10; -15;70%<br>If Type = Fixed: -10; -20;120 ms; Off  |
| MPP PVAB   | 125-260 ms   |
| AF Commencian IM Decime  | O Off  |
| AF Suppression™ Pacing<br>No. of Overdrive Pacing Cycles   | On; Off<br>15–40   |
| Maximum AF Suppression Rate  | 80–150 min <sup>-1</sup>   |
| Sensing/Detection  |  |
| SenseAbility™ Sensing Algorithm  | Automatic sensitivity control adjustment for   |
| T F A+   | atrial and ventricular events  |
| Low Frequency Attenuation<br>Threshold Start   | On; Off<br>Post-Sensed: 50; 62,5; 75; 100%;  |
| Threshold Start  | Post-Paced, Atrial: 0,2-3,0 mV   |
| Decay Delay  | Post-Paced, Ventricular: Auto, 0,2-3,0 mV<br>Post-Sensed: 0–220 ms   |
| Decay Belay  | 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<br>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 <sup>TM</sup> Morphology Discrimination or Original MD) with Automatic Template Update   |
| Monitor Mode   | Detection, discrimination and diagnostics, no<br>therapy delivery (VT or VT-1 zone)  |
| Discrimination Modes   | On; Passive; Off   |
| SVT Upper Limit  | 150-240 min <sup>-1</sup>  |
| SVT Discrimination Timeout   | 20s - 60 min; Off  |
|  | Continuous sensing during charging   |
| Reconfirmation SecureSense™ RV Lead Noise  |  |
| SecureSense™ RV Lead Noise   | On; On with Timeout; Passive; Off  |
| Reconfirmation<br>SecureSense™ RV Lead Noise<br>Discrimination Algorithm<br>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 Mode

Temporary Modes

Activity Sensor Programmable Rate and Delay Parameters

Pulse Amplitude Pulse Width LVCap™ 1 Confirm Feature, LVCap™ 2 Confirm Feature On: Off

150-300 min<sup>-1</sup>

1-15 with 2-20 Stimuli

On: Off

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

Ramp; Burst; Scan; 1 or 2 schemes per VT zone

1-15 With 2-20 Stimuli
On; Off
7,5 V independent from Bradycardia and
Post-Therapy Pacing
1,0 or 1,5 ms independently programmable from
Bradycardia and Post-Therapy Pacing

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

ATP While Charging; ATP Prior to Charging; Off

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; Passive; Off On; Passive; Oil
Base Rate (min¹); Rest Rate (min¹); Maximum
Tracking Rate (min¹); Max Trigger Rate (min¹);
Maximum Sensor Rate (min¹); Paced AV Delay (ms);
Sensed AV Delay (ms); Rate Responsive AV Delay;
Hysteresis Rate (min¹); Rate Hysteresis with Search

0,25 - 7,5 V 0,05, 0,1 - 1,5 ms Setup; On; Monitor; Off RVCap™ Confirm Feature ACap™ Confirm Feature Auto Mode Switch (AMS) Setup; On; Monitor; Off On; Monitor; Off DDI(R); DDT(R); VVI(R); VVT(R); Off Atrial Tachycardia

Detection Rate 110-300 min 40; 45; ... 135 min<sup>-1</sup> Atrial Pace; Passive; Off AMS Base Rate PMT Detection/Termination Rate Responsive PVARP Rate Responsive V Pace Refractory Low; Medium; High; Off On; Off PAC Response PAC Response interval Shortest AV Delay On; Off 200-400 ms

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

25-120 ms

Post-Shock Pacing Mode Post-Shock Base Rate AAI; VVI; DDI; or DDD; Off 30–100 min<sup>-1</sup> Post-Shock Pacing Duration 0,5; 1; 2,5; 5; 7,5; or 10 min; Off

**Device Testing/Induction Methods**DC Fibber™ Induction Method 0,5-5,0 sec Pulse Duration
Burst Fibber Cycle Length 2-25 stimuli with up to three extra stimuli

Noninvasive Programmed Stimulation (NIPS)

**Patient Notifiers** Programmable Notifiers (On; Off)

BatteryAssurance™ alert, Possible HV circuit damage, HV charge timeout, Long charge time for Capacitor Maintenance, Device at ERI, Atrial lead impedance out of range, Right ventricular pacing lead impedance out of range, Left ventricular lead impedance out of range, High-voltage 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, Nonsustained ventricular oversensing, Biventricular/Left ventricular pacing percentage lower than limit, CorVue™ congestion monitoring On

Device Parameter Reset Entry into Backup VVI Mode Auditory Duration Number of Audio Alerts per Notification

Number of Notifications Time Between Notifications

**Electrograms and Diagnostics** Stored Electrograms

On

1–16 10; 22 hours

30 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 bradvcardia events and device-

2; 4; 6; 8; 10; 12; 14; 16 sec 2

Therapy Summary Episodes Summary Lifetime Diagnostics History of bradycardia events and device-initiated charging Trend data and counts

AT/AF Burden Trend Ventricular HV Lead Impedance Trend Histograms and Trends

Trend data and counts
Multi-Vector Trend Data
Event Histogram; AV Interval Histogram; Mode
Switch or AT/AF Duration Histogram; Peak
Filtered Atrial Rate during Atrial Arrhythmia
Histogram; Atrial Heart Rate Histogram; AT/AF
Burden; Exercise and Activity Trending; V Rates
during AMS; DirectTrend" reports up to 1 year
Information regarding PMT detections
Pacing lead impedances; high-voltage lead
impedances; and signal amplitudes
On: Off

PMT Data Real-Time Measurements (RTM)

CorVue Congestion Monitoring On: Off CorVue Congestion Monitoring Threshold 8-18 days MRI Settings Setting

Tachy Therapy MRI Mode MRI Base Rate Disabled DOO; VOO; AOO; Pacing Off 30-100 min 25–110 ms 5,0 or 7,5 V

MRI Base Kate
MRI Paced AV Delay
MRI RA and RV Pulse Amplitude
MRI RA and RV Pulse Width
MRI RA and RV Pulse Configuration
MRI LV Pulse Amplitude 1,0 ms Bipolar 0,25-7,5 V MRI LV Pulse Width 0.05-1.5 ms MRI LV Pulse Configuration

0,05-1,3 nis D1-M2, D1-M3, D1-P4, M2-M3, M2-P4, M3-M2, M3-P4, P4-M2, P4-M3 RV Only, LV+RV (Simultaneous)

MRI V Pacing Chamber 3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters

#### MAGNET RF TRANSMIT LEAD MODEL **LEAD LENGTHS** (TESLA) CONDITIONS **SCAN REGION** Ouartet™ LV Lead 1456Q, 1457Q, 1458Q, 1458QL 1,5T / 3T 86 cm Durata™ Defibrillation Lead 7120Q, 7122Q 1,5T / 3T 58, 65 cm Normal Optisure™ Lead Operating Mode Full-body LDA220Q, LDA210Q 58, 65 cm 1,5T / 3T Tendril™ STS Pacing Lead 1,5T / 3T 2088TC 46, 52 cm Tendril MRI™ Lead 46, 52 cm 1.5T LPA1200M

†LV first with 10 ms interventricular delay.

§ 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.

**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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