

# Gallant™ Single-Chamber ICD

CDVRA500Q



## Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- 40J delivered energy safety shock option for enhanced safety margin
- 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 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 records short bursts of oversensing that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD™ morphology discrimination is designed to enhance 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
- 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 an MR Conditional lead 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
- Cold can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters
- The CorVue™ congestion monitoring feature measures transthoracic impedance changes over time to provide additional insight into the patient’s heart failure condition
- 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 DEFIBRILLATION	CONNECTOR SENSE/PACE
CDVRA500Q	63 x 51 x 12	69	30	DF4	DF4

\*See MRI Scan Parameters in MRI Ready Systems Manual.

Product Specifications

PHYSICAL SPECIFICATIONS	
Models	CDVRA500Q
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	40/45 J
Volume	30 cc
Weight	69 g
Size	63 x 51 x 12 mm
Defibrillation Lead Connections	DF4
Sense/Pace Lead Connections	DF4
High-Voltage Can	Electrically active titanium can
PARAMETER	SETTINGS
<b>Sensing/Detection</b>	
SenseAbility™ Sensing Algorithm	Automatic Sensitivity Control adjustment for ventricular events
Low Frequency Attenuation Threshold Start	On; Off Post-Sensed: 50; 62,5; 75; 100% Post-Paced: Auto; 0,2 - 3,0 mV
Decay Delay	Post-Sensed: 0-220 ms Post-Paced: 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	Sudden Onset, Interval Stability; Sinus Interval History; Morphology Discrimination (Far Field MD™ or Original MD) with Automatic Template Update
Discrimination Modes	On; Passive; Off
SVT Upper Limit	150-240 min <sup>1</sup>
SVT Discrimination Timeout	20s - 60 min; Off
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
SecureSense™ RV Lead Noise Discrimination Algorithm	On; On with Timeout; Passive; Off
VF Therapy Assurance	On; Off
<b>Antitachycardia Pacing Therapy</b>	
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 min <sup>1</sup>
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	1-15
Number of Stimuli	2-20
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
<b>High-Voltage Therapy</b>	
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
<b>Bradycardia Pacing</b>	
Permanent Modes	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Activity Sensor	On; Passive; Off
Programmable Rate Parameters	Base Rate (min <sup>-1</sup> ); Rest Rate (min <sup>-1</sup> ); Maximum Sensor Rate (min <sup>-1</sup> ); Hysteresis Rate (min <sup>-1</sup> ); Rate Hysteresis with Search
Pulse Amplitude	0,25 - 7,5 V
Pulse Width	0,05, 0,1 - 1,5 ms
Ventricular AutoCapture™ Pacing System	On; Off
Rate Responsive V Pace Refractory	On; Off

<b>Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)</b>			
Post-Shock Pacing Mode	Off; VVI		
Post-Shock Base Rate	30-100 in increments of 5 min <sup>1</sup>		
Post-Shock Pacing Duration	Off; 0,5; 1; 2,5; 5; 7,5; or 10 min		
<b>Device Testing/Induction Methods</b>			
DC Fibber™ Induction Method	0,5-5,0 sec		
Pulse Duration			
Burst Fibber Cycle Length	20-100 ms		
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to three extra stimuli		
<b>Patient Notifiers</b>			
Programmable Notifiers (On; Off)	BatteryAssurance™ alert, Possible HV circuit damage, HV charge timeout, Long charge time for Capacitor Maintenance, Device at ERI, Ventricular pacing lead impedance out of range, High-voltage lead impedance out of range, SecureSense™ lead noise detection, Non-sustained ventricular oversensing, Ventricular pacing percentage greater than limit, CorVue™ congestion monitoring		
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		
<b>Electrograms and Diagnostics</b>			
Stored Electrograms	30 minutes (1 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, 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		
Trends	HV lead impedance, Ventricular pacing lead impedance, Ventricular signal amplitude, Ventricular capture threshold, Exercise and activity trending, DirectTrend™ reports up to 1 year		
Histograms	Event Histogram; Ventricular Heart Rate Histogram;		
Real-Time Measurements (RTM)	Pacing lead impedances; High-voltage lead impedances; and Signal amplitudes		
CorVue Congestion Monitoring	On; Off		
CorVue Congestion Monitoring Threshold	8-18 days		
<b>MRI Settings</b>			
Tachy Therapy	Disabled		
MRI Mode	VOO; Pacing Off		
MRI Base Rate	30-100 min <sup>1</sup>		
MRI Pulse Amplitude	5,0 or 7,5 V		
MRI Pulse Width	1,0 ms		
MRI Pulse Configuration	Bipolar		
MRI Timeout	Off; 3; 6; 9; 12; 24 hours		
<b>MRI Scan Parameters<sup>†</sup></b>			
LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
<b>Durata™ Defibrillation Lead</b>			
7120Q (lead lengths: 58, 65 cm)	1,5T / 3T	Normal Operating Mode	Full-body
7122Q (lead lengths: 58, 65 cm)			
<b>Optisure™ Lead</b>			
LDA220Q (lead lengths: 58, 65 cm)	1,5T / 3T		
LDA210Q (lead lengths: 58, 65 cm)			

†For additional information about specific MR Conditional ICDs 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](http://medical.abbott/manuals).

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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