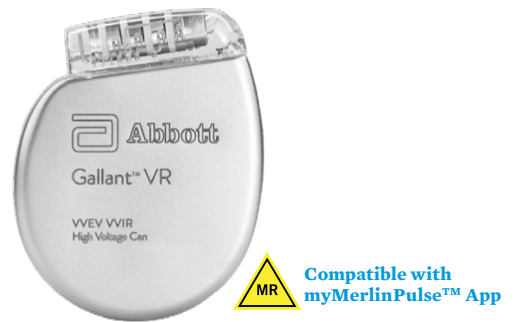


Gallant™ Single-Chamber ICD

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⁺ 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	
Sensing/Detection	
SenseAbility™ Sensing Algorithm	Automatic Sensitivity Control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	Post-Sensed: 50; 62,5; 75; 100%
Decay Delay	Post-Paced: Auto; 0,2 - 3,0 mV
Ventricular Sense Refractory	Post-Sensed: 0-220 ms
Detection Zones	Post-Paced: Auto; 0-220 ms
SVT Discriminators	125; 157 ms
Discrimination Modes	3 zone programming - 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Upper Limit	Sudden Onset, Interval Stability; Sinus Interval History; Morphology Discrimination (Far Field MD™ or Original MD) with Automatic Template Update
SVT Discrimination Timeout	On; Passive; Off
Monitor Mode	150-240 min ⁻¹
Reconfirmation	20s - 60 min; Off
SecureSense™ RV Lead Noise Discrimination Algorithm	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
VF Therapy Assurance	Continuous sensing during charging
	On; On with Timeout; Passive; Off
	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 min ⁻¹
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
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	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Activity Sensor	On; Passive; Off
Programmable Rate Parameters	Base Rate (min ⁻¹); Rest Rate (min ⁻¹); Maximum Sensor Rate (min ⁻¹); Hysteresis Rate (min ⁻¹); 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

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
Post-Shock Base Rate	30-100 in increments of 5 min ⁻¹
Post-Shock Pacing Duration	Off; 0,5; 1; 2,5; 5; 7,5; or 10 min

Device Testing/Induction Methods	
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

Patient Notifiers	
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

Electrograms and Diagnostics	
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

MRI Settings	
Tachy Therapy	Disabled
MRI Mode	VOO; Pacing Off
MRI Base Rate	30-100 min ⁻¹
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

MRI Scan Parameters†					
LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION		
Durata™ Defibrillation Lead					
7120Q (lead lengths: 58, 65 cm)	1,5T / 3T	Normal Operating Mode	Full-body		
7122Q (lead lengths: 58, 65 cm)					
Optisure™ Lead					
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.

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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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