IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICE

Gallant™ Single Chamber ICD

CDVRA500T

MR **Compatible with myMerlinPulse™ app**

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
- Sense*Ability*™ 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*
- Cold can programmability provides an additional RV-SVC Shock Configuration to decouple the can from the shocking vector parameters
- The CorVue™ thoracic impedance 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 (L × W × H) (MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CDVRA500T	73 × 51 × 12	72	35	DF-1	IS-1

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

Abbott

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Product Specifications

PARAMETER SPECIFICATIONS	
Model	**CDVRA500T**
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	40/45 J
Volume	35 cc
Weight	72 g
Size	73 × 51 × 12 mm
Defibrillation Lead Connections	DF-1
Ventricular Sense/Pace Lead Connections	IS-1 in-line bipolar
High-Voltage Can	Electrically active titanium can
Parameter	**Settings**
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm	Automatic Sensitivity Control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	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 bpm
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
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	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 (+)

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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 (bpm); Rest Rate (bpm); Maximum Sensor Rate (bpm); Hysteresis Rate (bpm); 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 bpm
Post-Shock Pacing Duration	Off; 0.5; 1; 2.5; 5; 7.5; or 10 min
Device Testing/Induction Methods	
DC Fibber™ Induction Method Pulse Duration	0.5-5.0 sec
Burst Fibber Cycle Length	20-100 ms
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to 3 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
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 1 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™ Thoracic Impedance	On; Off
CorVue Thoracic Impedance Threshold	8-18 days

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MRI Settings	
Tachy Therapy	Disabled
MRI Mode	VOO; Pacing Off
MRI Base Rate	30-100 bpm
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	1.5 T / 3 T	Normal Operating Mode	Full-body
7120 (lead lengths: 60, 65 cm)			
7122 (lead lengths: 60, 65 cm)			
Optisure™ Lead	1.5 T / 3 T		
LDA220 (lead lengths: 60, 65cm)			
LDA210 (lead lengths: 60, 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.

Rx Only

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.

Intended Use: The Implantable Cardioverter Defibrillator (ICD) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation.

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 ICD devices are indicated for automated treatment of life-threatening ventricular arrhythmias.

In addition, dual chamber ICD 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 ICDs 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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