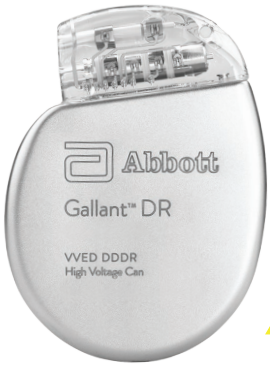
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICE

Gallant™ Dual Chamber ICD

CDDRA500Q



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 algorithm 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 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
- 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
- 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
- Premature Atrial Contraction (PAC) Response to avoid pacing the atrium in a vulnerable zone
- Physiologic rate responsive AV Delay and PVARP
- Dual patient notification: audio notification through the device and visual notification via myMerlinPulse app

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (L X W X H) (MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CDDRA500Q	69 × 51 × 12	71	31	DF4	IS-1; DF4

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

Abbott

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Product Specifications

PARAMETER SPECIFICATIONS	
Model	**CDDRA500Q**
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	40/45 J
Volume	31 cc
Weight	71 g
Size	69 × 51 × 12 mm
Defibrillation Lead Connection	DF4
Atrial Sense/Pace Lead Connection	IS-1 in-line bipolar
Ventricular Sense/Pace Lead Connection	DF4
High-Voltage Can	Electrically active titanium can
Parameter	**Settings**
AF Management	
AF Suppression™ Pacing No. of Overdrive Pacing Cycles Maximum AF Suppression Rate	On; Off 15-40 80-150 bpm
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%; Post-Paced, Atrial: 0.2-3.0 mV Post-Paced, Ventricular: Auto, 0.2-3.0 mV
Decay Delay	Post-Sensed: 0-220 ms Post-Paced, Atrial: 0-220 ms 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 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

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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; DDD(R); DDI(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO
Activity Sensor	On; Passive; Off
Programmable Rate and Delay Parameters	Base Rate (bpm); Rest Rate (bpm); Maximum Tracking 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 ms, 0.1-1.5 ms
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm Feature	On; Monitor; Off
QuickOpt™ Timing Cycle Optimization	Sensed/Paced AV delay
Auto Mode Switch (AMS)	DDI(R); VVI(R); Off
Atrial Tachycardia Detection Rate	110-300 bpm
AMS Base Rate	40; 45; ... 135 bpm
Rate Responsive PVARP	Low; Medium; High; Off
Rate Responsive V Pace Refractory	On; Off
PAC Response	On; Off
PAC Response Interval	200-400 ms
PMT Detection/Termination	Atrial Pace; Passive; Off
Ventricular Intrinsic Preference (VIP™)	On (50-200 ms); Off
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	AAI; VVI; DDI; 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
Burst Fibber Cycle Length	20-100 ms
Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to three extra stimuli

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Product Specifications

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 pacing lead impedance out of range. Ventricular pacing 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, 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 (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	Multi-Vector Trend Data
Histograms and Trends	Event Histogram; AV Interval Histogram; Mode Switch or AT/AF Duration Histogram; Peak Filtered Atrial Rate during Atrial Arrhythmia 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	
Tachy Therapy	Disabled
MRI Mode	DOO; VOO; AOO; Pacing Off
MRI Base Rate	30-100 bpm
MRI Paced AV Delay	25-120 ms
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

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MRI SCAN PARAMETERS†			
Lead Model	**Magnet (Tesla)**	**RF Transmit Conditions**	**Scan Region**
Durata™ Defibrillation Lead		Normal Operating Mode	Full-body
7120Q (lead lengths: 58, 65 cm)	1.5 T / 3 T		
7122Q (lead lengths: 58, 65 cm)			
Optisure™ Lead			
LDA220Q (lead lengths: 58, 65 cm)	1.5 T / 3 T		
LDA210Q (lead lengths: 58, 65 cm)			
Tendril™ STS Pacing Lead			
2088TC (lead lengths: 46, 52 cm)	1.5 T / 3 T		
Tendril MRI™ Lead			
LPA1200M (lead lengths: 46, 52 cm)	1.5 T		
UltiPace Pacemaker™ Lead			
LPA1231 (Lead lengths: 46, 52 cm)	1.5 T / 3 T		

†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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