Gallant[™] Dual Chamber ICD



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 highvoltage 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*
- 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 × W × H) (MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CDDRA500T	73 × 51 × 12	76	35	DF-1	IS-1

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



Product Specifications

PARAMETER SPECIFICATIONS		
Model	CDDRA500T	
Telemetry	Bluetooth* LE Communication	
Delivered/Stored Energy	40/45 J	
Volume	35 cc	
Weight	76 g	
Size	73 × 51 × 12 mm	
Defibrillation Lead Connection	DF-1	
Atrial Sense/Pace Lead Connection	IS-1 in-line bipolar	
Ventricular Sense/Pace		
Lead Connection	IS-1 in-line bipolar	
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 <i>Ability</i> ™ 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; 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	

Product Specifications

PARAMETER SPECIFICATIONS			
High-Voltage Therapy			
DynamicTx [™] Over-current Detection Algorithm	On; Off		
$DeFT \; Response^{^{m}} \; Technology$	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 p	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 3 extra stimuli		

Product Specifications

PARAMETER 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 1 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; 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	

MRI SCAN PARAMETERS [†]					
Lead Model	Magnet (Tesla)	RF Transmit Conditions	Scan Region		
Durata ™ Defibrillation Lead					
7120 (lead lengths: 65 cm)	1.5 T / 3 T	Normal Operating Mode	Full-body		
7122 (lead lengths: 60, 65 cm)					
Optisure [™] Lead	15 T / 2 T				
LDA210 (lead lengths: 65 cm)	1.5 T / 3 T				
Tendril™ STS Pacing Lead	15 T / 2 T				
2088TC (lead lengths: 46, 52 cm)	1.5 T / 3 T				
UltiPace Pacemaker Lead	15 T / 2 T				
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 manuals.eifu.abbott.com.

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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