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ICD AND CRT-D DEVICES

Gallant™ and Entrant™ ICDs and CRT-Ds
U.S. Champ Document

Customer Launch Letter

Gallant™ VR ICD Catalog Page

Gallant™ DR ICD Catalog Page

Gallant™ HF CRT-D Catalog Page

Entrant™ VR ICD Catalog Page

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Durata™ Defibrillation Leads Catalog Page

Optisure™ Defibrillation Leads Catalog Page

Quartet™ Pacing Leads Catalog Page

Tendril™ Pacing Leads Catalog Page

FDA Approval

Abbott Medical Device Representative

Contact Information

June 2020

Dear Health Care Provider,

Abbott is committed to bringing you innovative solutions designed to improve patient outcomes, increase clinic efficiency, and reduce costs. In that spirit, we are proud to announce FDA approval of our new high-voltage platform with Bluetooth® wireless technology. Abbott's Gallant™ and Entrant™ ICD and CRT-D solutions combine **powerfully connected** smartphone connectivity with **dynamic technology** that is designed to optimize **patient-centric outcomes**.

Platform Components

PRODUCT TYPE	PRODUCT NAME	MODEL NUMBER
Device	Gallant™ ICD	CDVRA500Q, CDDRA500Q
	Gallant™ CRT-D	CDHFA500Q
	Entrant™ ICD	CDVRA300Q, CDDRA300Q
	Entrant™ CRT-D	CDHFA300Q
Patient Application	myMerlinPulse™ mobile app	APP1004 (Android‡) and APP1005 (iOS‡)

Platform Highlights Include:

- Bluetooth® Low Energy communication enables data encrypted smartphone connectivity
- SyncAV™ *Plus* CRT technology offers dynamic AV timing with adaptive programming to ensure BiV pacing with or without MultiPoint™ pacing
- VF Therapy Assurance decreases time to treatment for arrhythmias in patients who are likely to be hemodynamically unstable
- 3T & 1.5T MR Conditional labeling facilitates patient access to the care they need
- Powerful therapy and superior longevity packaged in a small, contoured design

Abbott is excited to partner with your organization to provide industry-leading ICD and CRT-D options for your patients. It is our mission to deliver solutions that improve patient outcomes, increase clinic efficiency and deliver value to your health care facilities. Please contact me if I can answer any questions regarding the importance of having access to this technology.

Sincerely,

Your Abbott Sales Representative

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICE

Gallant™ Single-Chamber ICD

CDVRA500Q

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*
- 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
- 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.

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Gallant™ Single-Chamber ICD

CDVRA500Q

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	
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 (+)
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 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
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 Thoracic Impedance	On; Off
CorVue Thoracic Impedance Threshold	8-18 days
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			
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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Rx Only
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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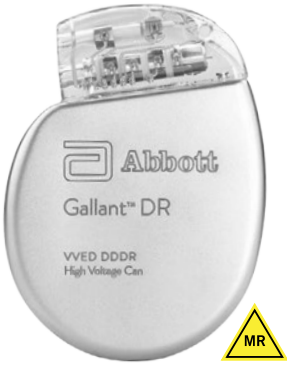
IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICE

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 (H × W × T. 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.

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Gallant™ Dual-Chamber ICD

CDDRA500Q

PHYSICAL SPECIFICATIONS

Models	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
Ventricular Sense/Pace Lead Connection	DF4
High-Voltage Can	Electrically active titanium can

PARAMETER	SETTINGS
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40
Maximum AF Suppression Rate	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
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
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

MRI Scan Parameters†

LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Durata™ Defibrillation Lead 7120Q (lead lengths: 58, 65 cm) 7122Q (lead lengths: 58, 65 cm)	1.5T / 3T	Normal Operating Mode	Full-body
Optisure™ Lead LDA220Q (lead lengths: 58, 65 cm) LDA210Q (lead lengths: 58, 65 cm)	1.5T / 3T		
Tendril™ STS Pacing Lead 2088TC (lead lengths: 46, 52 cm)	1.5T / 3T		
Tendril MRI™ Lead LPA1200M (lead lengths: 46, 52 cm)	1.5 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.

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Rx Only
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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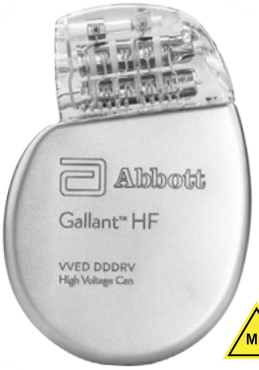
CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

Gallant™ HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D)
CDHFA500Q



MR Compatible with myMerlinPulse™ App

Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- MultiPoint™ pacing delivers multiple LV pacing pulses per cardiac cycle in both LV only and BiV pacing modes
- SyncAV™ *Plus* CRT technology offers dynamic AV timing with adaptive programming to ensure BiV pacing with or without MultiPoint pacing
- Improved shape with reduced volume and thickness
- 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 further 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 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 enhances 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
- The Gallant™ HF CRT-D and Quartet™ quadripolar LV lead feature four pacing electrodes and 13 pacing vectors to provide more options and greater control to address implant complications such as diaphragmatic stimulation and high pacing thresholds
- Easily test and program with Auto VectSelect Quartet™ multivector testing, offering an efficient workflow for complete results and programming
- 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
- The CorVue™ thoracic impedance feature measures transthoracic impedance changes over time to provide additional insight into the patient's heart failure condition
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- Premature Atrial Contraction (PAC) Response to avoid pacing the atrium in a vulnerable zone
- Physiologic rate responsive AV Delay and PVARP
- QuickOpt™ timing cycle optimization provides quick and effective optimization at the push of a button
- Dual patient notification: audio notification through the device and visual notification via myMerlinPulse™ app

Ordering Information

MODEL NUMBER	DIMENSIONS (H × W × T. MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
CDHFA500Q	74 × 51 × 12	76	34	DF-4, IS-4, IS-1

*See MRI Scan Parameters in MRI Ready Systems Manual.

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Gallant™ HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D)
CDHFA500Q

Product Specifications

PHYSICAL SPECIFICATIONS

Model	CDHFA500Q
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	40/45 J
Volume	34 cc
Weight	76 g
Size	74 × 51 × 12 mm
Defibrillation Lead Connections	DF4-LLHH
LV Lead Connections	IS4-LLLL
Atrial Sense/Pace Lead Connections	IS-1
High Voltage Can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ Programmable LV Pulse Configuration	Distal Tip 1 - Mid 2; Distal Tip 1 - Proximal 4; Distal Tip 1 - Mid 3; Distal Tip 1 - RV Coil; Mid 2 - Mid 3; Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - Mid 3: Proximal 4 - RV Coil
MultiPoint™ Pacing	LV1, LV2
Delay MultiPoint Pacing	Delay 1: 5; 10; ... 80 ms Delay 2: 5; 10; ... 50 ms
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/Paced AV delay, Interventricular pace delay
V-V Timing	Simultaneous†; RV First; LV First
Interventricular Pace Delay	RV First 10–80/LV First 15–80 ms
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; LV only; Biventricular
SyncAV™ *Plus* CRT Technology Delta	If Type = Percentage: -10; - 15;...-70% If Type = Fixed: -10; -20;...-120 ms; Off
MPP PVAB	125-260 ms
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40
Maximum AF Suppression Rate	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 in increments of 5 ms
Readaptive	On; Off
Number of Bursts/Stimuli	1-15 with 2–20 Stimuli
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	DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); Off
Temporary Modes	DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO; Off
Activity Sensor	On; Passive; Off
Programmable Rate and Delay Parameters	Base Rate (bpm); Rest Rate (bpm); Maximum Tracking Rate (bpm); Max Trigger 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, 0.1-1.5 ms
LVCap™ 1 Confirm Feature, LVCap™ 2 Confirm Feature	Setup; On; Monitor; Off
RVCap™ Confirm Feature	Setup; On; Monitor; Off
ACap™ Confirm Feature	On; Monitor; Off
Auto Mode Switch (AMS)	DDI(R); DDT(R); VVI(R); VVT(R); Off
Atrial Tachycardia Detection Rate	110-300 bpm
AMS Base Rate	40; 45; ... 135 bpm
PMT Detection/Termination	Atrial Pace; Passive; Off
Rate Responsive PVARP	Low; Medium; High; Off
Rate Responsive V Pace Refractory	On; Off
PAC Response	On; Off
PAC Response interval	200-400 ms
Shortest AV Delay	25-120 ms
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	AAI; VVI; DDI; or 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
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 lead impedance out of range, Right ventricular pacing lead impedance out of range, Left ventricular 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, Biventricular/Left ventricular pacing percentage lower 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 Trend	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	Setting
Tachy Therapy	Disabled
MRI Mode	DOO; VOO; AOO; Pacing Off
MRI Base Rate	30-100 bpm
MRI Paced AV Delay	25-110 ms
MRI RA and RV Pulse Amplitude	5.0 or 7.5 V
MRI RA and RV Pulse Width	1.0 ms
MRI RA and RV Pulse Configuration	Bipolar
MRI LV Pulse Amplitude	0.25-7.5 V
MRI LV Pulse Width	0.05-1.5 ms
MRI LV Pulse Configuration	D1-M2, D1-M3, D1-P4, M2-M3, M2-P4, M3-M2, M3-P4, P4-M2, P4-M3
MRI V Pacing Chamber	RV Only, LV+RV (Simultaneous)
MRI Timeout	3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters§

LEAD MODEL	LEAD LENGTHS	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Quartet™ LV Lead 1456Q, 1457Q, 1458Q, 1458QL	86 cm	1.5T / 3T	Normal Operating Mode	Full-body
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm	1.5T / 3T		
Optisure™ Lead LDA220Q, LDA210Q	58, 65 cm	1.5T / 3T		
Tendril™ STS Pacing Lead 2088TC	46, 52 cm	1.5T / 3T		
Tendril MRI™ Lead LPA1200M	46, 52 cm	1.5T		

†LV first with 10 ms interventricular delay.

§ For additional information about specific MR Conditional CRT-Ds 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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Rx Only
Intended Use: The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended to resynchronize the right and left ventricles.

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 CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

In addition, dual chamber CRT-D 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 CRT-Ds 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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IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICE

Entrant™ Single-Chamber ICD

CDVRA300Q

MR Compatible with myMerlinPulse™ App

Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- 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*
- 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
- 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
CDVRA300Q	63 x 51 x 12	69	30	DF4	DF4

*See MRI Scan Parameters in MRI Ready Systems manual.

Abbott

Entrant™ Single-Chamber ICD

CDVRA300Q

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CDVRA300Q
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	36/39 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	
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	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 (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	VVI(R); Off
Temporary Modes	VVI; VOO; Off
Activity Sensor	On; Passive; Off
Programmable Rate Parameters	Base Rate (bpm); Rest Rate (bpm); Maximum Sensor Rate (bpm); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); 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	VVI; Off
Post-Shock Base Rate	30-100 in increments of 5 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 extrastimuli
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	Up to 15 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
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	3; 6; 9; 12; 24 hours; Off

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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Rx Only
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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IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICE

Entrant™ Dual-Chamber ICD

CDDRA300Q

MR Compatible with myMerlinPulse™ App

Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- 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 further 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
- 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 (H × W × T. MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CDDRA300Q	69 × 51 × 12	71	31	DF4	IS-1; DF4

*See MRI Scan Parameters in MRI Ready Systems manual.

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Entrant™ Dual-Chamber ICD

CDDRA300Q

PHYSICAL SPECIFICATIONS

Models	CDDRA300Q
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	36/39 J
Volume	31 cc
Weight	71 g
Size	69 × 51 × 12 mm
Defibrillation Lead Connections	DF4
Atrial Sense/Pace Lead Connection	IS-1
Ventricular Sense/Pace Lead Connection	DF4
High-Voltage Can	Electrically active titanium can

PARAMETER	SETTINGS
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) 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)
Readaptive	On; Off
Min. Burst Cycle Length	150-400 ms
Number of Bursts	1-15
Number of Stimuli	2-20
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude	7.5V 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	DDD(R); DDI(R); VVI(R); AAI(R); Off
Temporary Modes	DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO; Off
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) Atrial Tachycardia	DDI(R); VVI(R); Off
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 extrastimuli
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	Up to 15 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
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	3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters†

LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Durata™ Defibrillation Lead 7120Q (lead lengths: 58, 65 cm) 7122Q (lead lengths: 58, 65 cm)	1.5T / 3T	Normal Operating Mode	Full-body
Optisure™ Lead LDA220Q (lead lengths: 58, 65 cm) LDA210Q (lead lengths: 58, 65 cm)	1.5T / 3T		
Tendril™ STS Pacing Lead 2088TC (lead lengths: 46, 52 cm)	1.5T / 3T		
Tendril MRI™ Lead LPA1200M (lead lengths: 46, 52 cm)	1.5 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.

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Rx Only
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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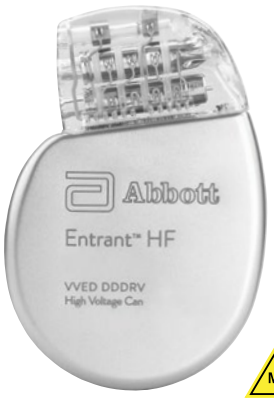
CARDIAC RESYNCHRONIZATION THERAPY (CRT) DEVICES

Entrant™ HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

CDHFA300Q



MR Compatible with myMerlinPulse™ App

Product Highlights

- Bluetooth® Low Energy (LE) communication enabling smartphone connectivity through data encryption
- SyncAV™ CRT technology offers dynamic AV timing with customizable programming to ensure BiV pacing
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- 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 further 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 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
- The Entrant™ HF CRT-D and Quartet™ quadripolar LV lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to address implant complications such as diaphragmatic stimulation and high pacing thresholds
- Easily test and program with Auto VectSelect Quartet™ multivector testing, offering an efficient workflow for complete results and programming
- 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
- Premature Atrial Contraction (PAC) Response to avoid pacing the atrium in a vulnerable zone
- Physiologic rate responsive AV Delay and PVARP
- QuickOpt™ timing cycle optimization provides quick and effective optimization at the push of a button
- 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
CDHFA300Q	74 x 51 x 12	76	34	DF-4, IS-4, IS-1

*See MRI Scan Parameters in MRI Ready Systems manual.

Abbott

Entrant™ HF

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

CDHFA300Q

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CDHFA300Q
Telemetry	Bluetooth® LE Communication
Delivered/Stored Energy	36/39 J
Volume	34 cc
Weight	76 g
Size	74 x 51 x 12 mm
Defibrillation Lead Connections	DF4-LLHH
LV Lead Connections	IS4-LLLL
Sense/Pace Lead Connections	IS-1
High-Voltage Can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
VectSelect Quartet™ Programmable Pulse Configuration	Distal Tip 1-Mid 2; Distal Tip I -Proximal 4; Distal Tip I - RV Coil; Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4; Mid 3 - RV Coil; Proximal 4 -Mid 2; Proximal 4 - RV Coil
V. Triggering	On; Off
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous†; RV First; LV First
Interventricular Pace Delay	RV First 10-80/LV First 15-80 ms
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; Biventricular
SyncAV™ CRT Technology Delta	-10 to -120 ms; Off
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 in increments of 5 ms
Readaptive	On; Off
Number of Bursts/Stimuli	1-15 with 2-20 Stimuli
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	DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); Off
Temporary Modes	DDD; DDT; DDI; VVT; VVI; AAI; AAT; DOO; VOO; AOO; Off
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (bpm); Rest Rate (bpm); Maximum Tracking Rate (bpm); Max Trigger 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; 0.1-1.5 ms
LVCap™ Confirm Feature	Setup; On; Monitor; Off
RVCap™ Confirm Feature	Setup; On; Monitor; Off
ACap™ Confirm Feature	On; Monitor; Off
Auto Mode Switch (AMS)	DDI(R); DDT(R); VVI(R); VVT(R); Off
Atrial Tachycardia Detection Rate	110-300 bpm
AMS Base Rate	40; 45; ... 135 bpm
Auto PMT Detection/Termination	Atrial Pace; Passive; Off
Rate Responsive PVARP	Low; Medium; High; Off
Rate Responsive V Pace Refractory	On; Off
PAC Response	On; Off
PAC Response Interval	200-400 ms
Shortest AV Delay	25-120 ms
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	AAI; VVI; DDI; or 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
BurstFibberCycle 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, Right ventricular pacing lead impedance out of range, Left ventricular 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, Biventricular pacing percentage lower 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	Up to 15 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 Trend	Multi-Vector Trend Data
Histograms and Trends	Event Histogram; AV Interval Histogram; Mode Switch or AT/AF Duration Histogram; Peak Filtered Atrial Rate 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

MRI Settings	Setting
Tachy Therapy	Disabled
MRI Mode	DOO, VOO, AOO, Pacing Off
MRI Base Rate	30-100 bpm
MRI Paced AV Delay	25-120 ms
MRI RA and RV Pulse Amplitude	5.0 or 7.5 V
MRI RA and RV Pulse Width	1.0 ms
MRI RA and RV Pulse Configuration	Bipolar
MRI V Pacing Chamber	RV Only
MRI Timeout	3; 6; 9; 12; 24 hours; Off

MRI Scan Parameters§

LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Quartet™ LV Lead 1456Q (lead lengths: 86 cm) 1457Q (lead lengths: 86 cm) 1458Q (lead lengths: 86 cm) 1458QL (lead lengths: 86 cm)	1.5T / 3T	Normal Operating Mode	Full-body
Durata™ Defibrillation Lead 7120Q (lead lengths: 58, 65 cm) 7122Q (lead lengths: 58, 65 cm)	1.5T / 3T		
Optisure™ Lead LDA220Q (lead lengths: 58, 65 cm) LDA210Q (lead lengths: 58, 65 cm)	1.5T / 3T		
Tendril™ STS Pacing Lead 2088TC (lead lengths: 46, 52 cm)	1.5T / 3T		
Tendril MRI™ Lead LPA1200M (lead lengths: 46, 52 cm)	1.5T		

§ For additional information about specific MR Conditional CRT-Ds 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.

† LV first with 10 ms interventricular delay

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Rx Only
Intended Use: The Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended to resynchronize the right and left ventricles.

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 CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

In addition, dual chamber CRT-D 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 CRT-Ds 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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Durata™

Defibrillation Lead

MR

Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an MRI Ready device.[1,2] See Order Information below for specific MR Conditional leads.
- Optim™ insulation is a co-polymer that offers superior handling and durability[3-5]
- Two innovative designs are intended to help prevent tissue ingrowth — flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space
- Redundant conductors serve as a backup system in the unlikely event of a conductor failure
- Symmetrically aligned cables within the lead body and centrally located coil provide for additional protection to the inner coil[6]
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws

Ordering Information

Contents: Defibrillation lead

MODEL NUMBER	INSULATION	FIXATION	MIN. INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR	LENGTHS (CM)
7120	Optim™	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65, 75
7120Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	17	DF4	52; 58*; 65*
7121	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7121Q	Optim	Ext/Ret Helix	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7122	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	NA	DF1; IS-1	60; 65; 75
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	NA	DF4	52; 58*; 65*
7170	Optim	Passive/Tined	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65; 75
7170Q	Optim	Passive/Tined	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7171	Optim	Passive/Tined	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7171Q	Optim	Passive/Tined	7	Dual-coil	True bipolar	21	DF4	52; 58; 65

*Indicates lead lengths that are MRI Conditional (field strength of 1.5T or 3T, depending on MRI Ready device). See MRI Ready systems manual for more information.

Indications: The Durata™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

Contraindications: Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata leads are contraindicated for extra firm (red color knob) stylets.

Potential Complications: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

Abbott

Durata™
Defibrillation Lead

Product Specifications

TRUE BIPOLAR, ACTIVE-FIXATION DEFIBRILLATION LEADS

Models	7120	7120Q	7121	7121Q	7122	7122Q
Fixation	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF1; IS-1	DF4
Body Diameter	6.8 F	6.8 F	6.8 F	6.8 F	6.8 F	6.8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	n/a	n/a
Tip Electrode Area	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	n/a	n/a
MR Conditional	No	Yes (58 and 65 cm)[1,2]	No	No	No	Yes (58 and 65 cm)[1,2]

TRUE BIPOLAR, PASSIVE-FIXATION DEFIBRILLATION LEADS

Models	7170	7170Q	7171	7171Q
Fixation	Tines	Tines	Tines	Tines
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4
Body Diameter	6.8 F	6.8 F	6.8 F	6.8 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm
Tip Electrode Area	3.5 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2
MR Conditional	No	No	No	No

- Abbott DF1 lead connectors conform to the international connector standard ISO 11318/Amd.
- Abbott IS-1 lead connectors conform to the international connector standard ISO 5841.
- Abbott DF4 lead connectors conform to the international connector standard ISO 27186: 2010 (E).

1. MRI Conditional Field Strength of 1.5T or 3T, depending on MRI Ready device.
2. See MRI Ready systems Manual for more information.
3. Jenney, C., Tan, J., Karicherla, A., Burke, J., & Helland, J. (2005). A new insulation material for cardiac leads with potential for improved performance. *Heart Rhythm, 2*(5), S318-S319.
4. Wilkoff B, et al. The biostability of cardiac lead insulation materials as assessed from longterm human implants. *J Biomed Mater Res B Appl Biomater. 2015 Apr 17.* doi: 10.1002/jbm.b.33405.
5. Cosgriff-Hernandez E, Tkatchouk E, Touchet T, Sears N, Kishan A, Jenney C, Padsalgikar AD, Chen E. Comparison of clinical explants and accelerated hydrolytic aging to improve biostability assessment of silicone-based polyurethanes. *J Biomed Mater Res A*. 2016 Jul;104(7):1805-16.
6. St. Jude Medical Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

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Abbott.com

Customer Support: 855-478-5833

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.

MAT-2006234 v2.0 | Item approved for U.S. use only.

Abbott

Optisure™

Defibrillation Lead

The Optisure™ lead expands on the Abbott high-voltage product portfolio, providing an additional system enhancement for addressing lead complications and improving system reliability.

Product Highlights

- Allows patients to safely undergo an MRI scan when used in combination with an MRI Ready device*,**
- Building on the proven 7 F Durata™ lead design, the Optisure lead features additional Optim™ insulation at the proximal end of the lead, and under the SVC coil resulting in an 8 F lead body.
  - Optim™ insulation is a chemical co-polymer that offers superior handling and durability.[1-3]
- Two innovative designs are intended to help prevent tissue ingrowth – flat-wire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space.
- Redundant conductors serve as a backup system in the unlikely event of a conductor failure.
- Symmetrically aligned cables within the lead body and centrally located coil provide for additional protection to the inner coil.[4]
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws.

Ordering Information

Contents: Defibrillation lead

MODEL NUMBER	INSULATION	FIXATION	MIN. INTRODUCER (F)	SHOCK CONFIGURATION	SENSING	TIP-TO-PROXIMAL COIL (CM)	CONNECTOR	LENGTHS (CM)
LDA220	Optim	Ext/Ret Helix	8	Dual-coil	True bipolar	17	DF1; IS-1	65
LDA220Q	Optim	Ext/Ret Helix	8	Dual-coil	True bipolar	17	DF4	52; 58*; 65*
LDA230Q	Optim	Ext/Ret Helix	8	Dual-coil	True bipolar	21	DF4	65
LDA210	Optim	Ext/Ret Helix	8	Single-coil	True bipolar	N/A	DF1; IS-1	65
LDA210Q	Optim	Ext/Ret Helix	8	Single-coil	True bipolar	N/A	DF4	52; 58*; 65*
LDP220Q	Optim	Tines	8	Dual-coil	True bipolar	17	DF4	65

*MRI Conditional Strength 1.5 Tesla
**See MRI Ready systems Manual for more information
***Indicates lead lengths that are MRI Conditional*,**

Indications for Use: The Optisure™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

Contraindications: Optisure™ leads are contraindicated in the following: Patients with tricuspid valvular disease or a mechanical tricuspid valve. Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. For use with extra firm (red color knob) stylets (models LDA220, LDA230, LDA210, LDA220Q, LDA230Q, and LDA210Q).

Potential Adverse Events: Possible adverse events associated with the use of transvenous lead systems include, but are not limited to: Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode fracture, or conductor discontinuity, cardiac perforation, venous perforation, myocardial irritability, transvenous implantation procedure, chronic (> 3 months) implantation, contamination, post-shock rhythm disturbances, threshold elevation or exit block, shunting or insulating of current during defibrillation with internal or external paddles.

Warning: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture, and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors. Use only battery-powered equipment when implanting and testing the lead to avoid fibrillation caused by alternating current. Ground all line-powered equipment used near the patient to avoid fibrillation caused by alternating current. Insulate lead connector pins from potential leakage currents from line-powered equipment to avoid fibrillation caused by the leakage current.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

Optisure™
Defibrillation Lead

Product Specifications

PHYSICAL SPECIFICATIONS

TRUE BIPOLAR, ACTIVE-FIXATION DEFIBRILLATION LEADS

Models	LDA220	LDA220Q	LDA230Q	LDA210	LDA210Q
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	8 F	8 F	8 F	8 F	8 F
Lengths (cm)	65	52; 58; 65	65	65	52; 58; 65
Connector	DF1; IS-1	DF4	DF4	DF1; IS-1	DF4
Maximum Diameter	7,6 F	7,6 F	7,6 F	7,3 F	7,3 F
Tip-to-Anode Spacing	11 mm	11 mm	11 mm	11 mm	11 mm
Tip-to-Proximal Coil	17 cm	17 cm	17 cm	17 cm	17 cm
Tip Electrode Area	6 mm^2	6 mm^2	6 mm^2	6 mm^2	6 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	642 mm^2	642 mm^2	642 mm^2	N/A	N/A
MRI Conditional	No	Yes[1,2]	No	No	Yes[1,2]

TRUE BIPOLAR, PASSIVE-FIXATION DEFIBRILLATION LEADS

Models	LDP220Q
Fixation	Tines
Shock Configuration	Dual-Coil
Sensing Configuration	True Bipolar
Min. Size Introducer	8 F
Lengths (cm)	65
Connector	DF4
Maximum Diameter	7,6 F
Tip-to-Anode Spacing	11 mm
Tip-to-Proximal Coil	17 cm
Tip Electrode Area	3.5 mm^2
Steroid Plug	Yes
Distal Shock Coil Area	367 mm^2
Proximal Shock Coil Area	642 mm^2
MRI Conditional	No

*MRI Conditional Strength 1.5 Tesla.
**See MRI Ready systems Manual for more information.

1. Jenney C, Tan J, Karicherla A, Burke J, Helland J. A New Insulation Material for Cardiac Leads with Potential for Improved Performance, *Heart Rhythm, 2*, S318-S319 (2005).

2. Wilkoff B, et al. The biostability of cardiac lead insulation materials as assessed from longterm human implants. *J Biomed Mater Res B Appl Biomater.* 2015 Apr 17. doi: 10.1002/jbm.b.33405.

3. Cosgriff-Hernandez E, Tkatchouk E, Touchet T, Sears N, Kishan A, Jenney C, Padsalgikar AD, Chen E. Comparison of clinical explants and accelerated hydrolytic aging to improve biostability assessment of silicone-based polyurethanes. *J Biomed Mater Res A. 2016* Jul;104(7):1805-16.

4. St. Jude Medical Engineering Report: Tension and Cable Shortening Comparison. Report 60032635.

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St. Jude Medical is now Abbott.

Rx Only
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.

23188-SJM-ELP-1017-0067 | Item approved for U.S. use only.

Abbott

Quartet™

Family of LV Leads

1458Q

1456Q

1457Q

1458QL

Product Highlights

- MRI Ready lead tested in combination with MR Conditional devices for full-body scans using a 1.5 T (Tesla) field strength scanner*
- Proven Quartet™ LV lead performance with additional Quadripolar lead options to match a patient's anatomy
- The Quartet™ Family of LV leads offers more distal shape options including the Large-S and Small-S as well as more total electrode spacing options including 40, 47 and 60 mm
- Four unique pacing electrodes to provide more options and greater control in pacing vector selection
- Superb deliverability with exceptional stability and performance
- Low profile — 4.7 F lead body; 4.0 F lead tip
- Optim™ lead insulation—a chemical co-polymer with proven strength and durability, demonstrating long-term abrasion resistance and biostability[1,2]
- Steerable tip — distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body — narrow ring electrodes provide lead tip flexibility
- Allows Direct-To-Target™ delivery placement through CPS Aim™ SL slittable inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire guidewire or stylet approaches

Ordering Information

Contents: Left-heart lead

MODEL NUMBER	SHAPE	TOTAL ELECTRODE SPACING (MM)	INSULATION	MINIMUM CURVE HEIGHT	LEAD BODY (F)	CONNECTOR	LENGTHS (CM)
1458Q	Traditional S	47	Optim™	16	4.7	IS4-LLLL	75, 86, 92
1456Q	Small-S	40	Optim™	8	4.7	IS4-LLLL	75, 86
1457Q	Double Bend	47	Optim™	16	4.7	IS4-LLLL	75, 86
1458QL	Traditional S	60	Optim™	16	4.7	IS4-LLLL	75, 86

*For additional information about specific MR conditional device and lead model numbers, including warnings, precautions, adverse conditions to MRI scanning, and potential adverse events please refer to Abbott's MRI Ready Systems Manual at manuals.sjm.com.

Indications and Usage: The Quartet lead has application as part of a Abbott's biventricular system.

Contraindications: The use of the Quartet lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1.0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Physical Specifications

MODELS	1458Q	1456Q	1457Q	1458QL
Parameter	**Description**	**Description**	**Description**	**Description**
Connector	IS4-LLLL	IS4-LLLL	IS4-LLLL	IS4-LLLL
Lead Length	75; 86; 92 cm	75; 86	75; 86 cm	75; 86
Maximum Lead Size	5.1 F (1.70 mm/0.067") at the ring electrode	5.1 F (1.70 mm/0.067") at the ring electrode	5.1 F (1.70 mm/0.067") at the ring electrode	5.1 F (1.70 mm/0.067") at the ring electrode
Lead Body Size	4.7 F (1.57 mm/0.062")	4.7 F (1.57 mm/0.062")	4.7 F (1.57 mm/0.062")	4.7 F (1.57 mm/0.062")
Tip Electrode Size	4.0 F (1.3 mm/0.052")	4.0 F (1.3 mm/0.052")	4.0 F (1.3 mm/0.052")	4.0 F (1.3 mm/0.052")
LV Lead Delivery System Introducer Size	Minimum 5.9 F ID	Minimum 5.9 F ID	Minimum 5.9 F ID	Minimum 5.9 F ID
Minimum Curve Height	16 mm	8 mm	16 mm	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4.9 mm^2	4.9 mm^2	4.9 mm^2	4.9 mm^2
Ring Electrode Surface Area	7.4 mm^2	7.4 mm^2	7.4 mm^2	7.4 mm^2
Electrode Spacing				
Distal tip 1 - Mid 2	20 mm	20 mm	20 mm	20 mm
Distal tip 1 - Mid 3	30 mm	30 mm	30 mm	47 mm
Distal tip 1 - Proximal 4	47 mm	40 mm	47 mm	60 mm
Lead Body Insulation	Optim™ insulation	Optim™ insulation	Optim™ insulation	Optim™ insulation
Lead Body Coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating	Fast-Pass™ coating
Conductors				
Distal (coil)	MP35N‡ LT	MP35N‡ LT	MP35N‡ LT	MP35N‡ LT
Proximal (cables)	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT	ETFE; MP35N LT
Suture Sleeve	Attached	Attached	Attached	Attached
MRI Ready	Yes, 86 cm only	Yes, 86 cm only	Yes, 86 cm only	Yes, 86 cm only

1. Hayes, D., Freedman, R., Porterfield, J.G., Porterfield, L.M., Dinerman, J., Styperek, R.,Machell, C., Kim, G., Curtis A.B. (2015). Absence of externalized conductors and electricaldysfunction in Durata leads: results from a prospective, multicenter study [abstract]. Presented at Heart Rhythm 2015. Boston, Massachusetts.
2. Wilkoff, B. L., Rickard, J., Tkatchouk, E., Padsalgikar, A. D., Gallagher, G., & Runt, J. (2015).The biostability of cardiac lead insulation materials as assessed from long-term humanimplants. *Journal of Biomedical Materials Research Part B: Applied Biomaterials.,104(2)*, 411–421.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing indications, contraindications, warnings, precautions, potential adverse events and directions for use.

23198-SJM-QRT-0216-0025(6) | Item approved for U.S. use only.

Abbott

PACING LEAD

Tendril™ STS

2088TC

Product Highlights

- The Tendril STS™ pacing lead is designed to allow patients to undergo MRI scans when used with an MRI Ready device if conditions for use as described in MRI-Ready Systems manual are met and followed
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface
- Small diameter lead offers improved ease of venous passage, reduced risk of venous thrombosis or rib-clavicle crush and ability to accommodate additional leads more easily
- Optim™ lead insulation — a chemical copolymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Titanium nitride (TiN) fractal coating on the tip and ring electrodes is designed to promote precise sensing and to provide improved contact with the myocardium
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer and veins to ease implantation
- Fits through a 6 F introducer

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTH (CM)
2088TC	Tendril™ STS Pacing Lead	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 52, 58

Indications: Tendril™ STS lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril STS lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: Tendril STS lead is contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of Tendril STS lead are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. 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.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Tendril™ STS

Product Specifications

PHYSICAL SPECIFICATIONS

Model	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, bipolar, steroid-eluting, endocardial, pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46, 52, 58, 65,* 100 cm*
Fixation Mechanism	Extendable/retractable helix
Typical Number of Rotations for Helix Extension	6–11 (straight stylet)
Lead Body Diameter	1.9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active TiN-coated Pt/Ir helix (2.0 mm extension)
Tip Electrode Surface Area	6.9 mm^2
Ring Electrode (Anode)	TiN-coated Pt/Ir
Ring Electrode Surface Area	16 mm^2
Mapping	Capable with TiN-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/ Outer Conductor	MP35N‡ coil
Inner Insulation	Silicone
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

In Pack	
Straight Stylets	1 x-soft in lead, 1 x-soft, 1 soft
J-curved Stylets	2 soft
Helix Extension/Retraction Clip-on Tools	2 clip-on tools

ACCESSORY KITS

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DSO6002 with appropriate length designation	46, 52, 58, 65, 100 cm	1 fixation tool, 1 clip-on tool, 1 J-shaped soft, 1 x-soft, 1 soft, 1 firm, 1 x-firm
	DSO6003 with appropriate length designation	46, 52, 58, 65, 100 cm	1 clip-on tool, 1 J-shaped soft, 1 x-soft, 1 soft, 1 firm, 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46, 52, 58, 65 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46, 52, 58, 65 cm	

*Not MRI approved.

For additional information about MR Conditional pacemakers and leads, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the Abbott MRI-Ready Systems Manual at manuals.sjm.com or check our MRI Ready resources at sjm.com/mriready.

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U.S. Customer Support: 1-800-722-3774

Rx Only
Brief Summary: 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.

29003-SJM-TND-0115-0004(3) | Item approved for U.S. use only.

Abbott

June 30, 2020

St. Jude Medical
% Juni Sarkar
Senior Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, California 91335

Re: P910023/S423
Trade/Device Name: Avant, Neutrino NxT, Gallant, Entrant, Current, Current Accel, Current+, Ellipse, Fortify, Fortify Assura, Epic/Epic+, Atlas/II/+ families of ICDs; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8
Product Code: LWS, OSR

P030054/S374
Trade/Device Name: Avant, Neutrino NxT, Gallant, Entrant, Promote/+/RF/Q, Promote Accel, Promote Quadra, Unify, Unify Assura, Unify Quadra, Quadra Assura, Epic+/HF/HF+/II HF/II+ HF, Atlas+HF/II HH/II+ HF families of CRT-Ds
Product Code: NIK

P030035/S178
Trade/Device Name: Anthem, Allure/RF, Allure Quadra/RF families of CRT-Ps
Product Code: NKE

P880086/S308
Trade/Device Name: Assurity, Assurity+, Endurity, Accent families of Pacemakers
Product Code: LWP

P970013/S082
Trade/Device Name: Microny family of Pacemakers
Produce Code: LWO

P140033/S050
Trade/Device Name: Assurity MRI, Endurity MRI families of Pacemakers
Product Code: DXY

Filed: November 8, 2019
Amended: November 13, 2019; April 1, 2020

Dear Juni Sarkar:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) 180-day supplement, which requested approval for Avant, Neutrino NxT, Gallant, and Entrant families of ICDs and CRT-Ds; myMerlinPulse mobile application; Merlin PCS 3650 Programmer Software Model 3330 v25.0.1; and Merlin.net MN5000 v7.8. Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition, because your device is a pacemaker, implantable cardioverter-defibrillator (ICD), or cardiac lead, FDA has determined that the following additional information is necessary to provide continued reasonable assurance of the safety and effectiveness of the device. In the Annual Report, provide the following information known by or reported to the applicant:

1. The number of ICDs domestically implanted and the number of reported explants and deaths.

2. A breakdown of the reported deaths into ICD related and non-ICD related.

3. A breakdown of the reported explants into the number reported that were:

a. For pacemakers and pulse generators: at end of battery life, the number that had complications not resolvable by programming, and, as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise, or

b. For leads: associated with mechanical failure, associated with clinical complications, and as applicable, the numbers that experienced other safety and effectiveness complications as ascertained by the user, applicant, or otherwise.

4. The number of ICDs returned to the applicant for cause from domestic sources, with a breakdown into:

a. For pacemakers and pulse generators: the number currently in analysis, the number operating properly, and the number at normal battery depletion and failed (with the failure mechanisms described).

b. For leads: the number currently in analysis, the number operating properly, the number failed (with failure mechanisms described); broken down into groupings for full leads and partial leads.

5. A cumulative survival table for the ICDs.

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product postmarketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the postmarketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Alexandra Manaras at 301-796-4042 or Alexandra.Manaras@fda.hhs.gov.

Sincerely,

Jessica E. Paulsen -S

Jessica Paulsen
Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Abbott
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Rx Only
Intended Use: The Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronization Therapy Defibrillator (CRT-D) devices are intended to provide ventricular antitachycardia pacing and ventricular cardioversion/defibrillation. The CRT-D devices are also intended to resynchronize the right and left ventricles.

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 and CRT-D devices are indicated for automated treatment of life-threatening ventricular arrhythmias. CRT-D devices are also indicated to treat symptoms in patients who have congestive heart failure with ventricular dyssynchrony.

In addition, dual chamber ICD and CRT-D 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 and CRT-Ds 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.

Durata™ Leads

Indications: The Durata™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

Contraindications: Contraindications for use of the Durata leads with an implantable pulse generator include ventricular tachyarrhythmias resulting from transient or reversible factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Transvenous lead systems are contraindicated for patients with tricuspid valvular disease or a mechanical heart valve. Durata leads are contraindicated for patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. The Durata leads are contraindicated for extra firm (red color knob) stylets.

Potential Complications: Possible complications of the use of transvenous lead systems include, but are not limited to, supraventricular or ventricular arrhythmias, conduction disturbances, cardiac perforation, cardiac tamponade, loss of contractility, air embolism, heart wall rupture, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

Optisure™ Leads

Indications for Use: The Optisure™ transvenous leads are indicated for use with compatible pulse generators (refer to the applicable defibrillator manual for system indications). They provide pacing and sensing and deliver cardioversion/defibrillation therapy to the heart.

Contraindications: Optisure™ leads are contraindicated in the following: Patients with tricuspid valvular disease or a mechanical tricuspid valve. Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction. Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated. For use with extra firm (red color knob) stylets (models LDA220, LDA230, LDA210, LDA220Q, LDA230Q, and LDA210Q).

Potential Adverse Events: Possible adverse events associated with the use of transvenous lead systems include, but are not limited to: Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode fracture, or conductor discontinuity, cardiac perforation, venous perforation, myocardial irritability, transvenous implantation procedure, chronic (> 3 months) implantation, contamination, post-shock rhythm disturbances, threshold elevation or exit block, shunting or insulating of current during defibrillation with internal or external paddles.

Warning: Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture, and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors. Use only battery-powered equipment when implanting and testing the lead to avoid fibrillation caused by alternating current. Ground all line-powered equipment used near the patient to avoid fibrillation caused by alternating current. Insulate lead connector pins from potential leakage currents from line-powered equipment to avoid fibrillation caused by the leakage current.

Refer to the defibrillator manual for additional complications and precautions specific to the pulse generator.

Quartet™ Leads

Indications and Usage: The Quartet lead has application as part of a Abbott's biventricular system.

Contraindications: The use of the Quartet lead is contraindicated in patients who:

• Are expected to be hypersensitive to a single dose of 1.0 mg of dexamethasone sodium phosphate.

• Are unable to undergo an emergency thoracotomy procedure.

• Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Tendril™ Leads

Indications: The Tendril™ STS Model 2088TC and Tendril MRI™ Model LPA1200M leads are designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS Model 2088TC and Tendril MRI™ Model LPA1200M leads may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of the screw-in leads such as Tendril STS Model 2088TC and Tendril MRI™ Model LPA1200M leads may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The Tendril STS Model 2088TC and Tendril MRI™ Model LPA1200M leads are contraindicated: in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of Tendril STS Model 2088TC and Tendril MRI™ Model LPA1200M leads are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions, and potential adverse events.

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