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
- SenseAbility™ sensing algorithm feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- DynamicTx™ over-current detection algorithm automatically changes shock configurations to ensure delivery of high-voltage therapy when high current is detected
- MRI Ready device tested in combination with 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

<table>
<thead>
<tr>
<th>MODEL NUMBER</th>
<th>DIMENSIONS (H×W×T. MM)</th>
<th>WEIGHT (G)</th>
<th>VOLUME (CC)</th>
<th>CONNECTOR DEFIBRILLATION</th>
<th>CONNECTOR SENSE/PACE</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDDRA500Q</td>
<td>69 × 51 × 12</td>
<td>71</td>
<td>31</td>
<td>DF4</td>
<td>IS-1; DF4</td>
</tr>
</tbody>
</table>

*See MRI Scan Parameters in MRI Ready Systems Manual.
### PHYSICAL SPECIFICATIONS

**Models**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDDRA500Q</td>
<td></td>
</tr>
</tbody>
</table>

#### AF Management

- **AF Suppression™ Pacing**
  - No. of Override Drive Cycles: 15-40
  - Maximum AF Suppression Rate: 80-150 bpm

- **Sensing/Detection**
  - SenseAbility™ 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%
  - Decay Delay: Post-Sensed: 0.220 ms
  - Ventricular Refractory: 125, 175 ms
  - Detection Zones: 3 zone programming – 1 zone, 2 zones or 3 zones
  - 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
  - Discrimination Modes: On; Off
  - SVT Upper Limit: 15-240 bpm
  - SVT Discrimination Timeout: 20-60 min, Off
  - Reconfirmation: Continuous sensing during charging
  - SecureSense™ RV Lead Noise: On; On with Timeout; Passive; Off
  - Discrimination Algorithm: On; Off
  - VF Therapy Assurance: On; Off

#### Antitachycardia Pacing Therapy

- **ATP Configurations**
  - Minimum ATP: 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: 150-400 ms
  - Min. Burst Cycle Length: 150-400 ms
  - Readaptive: On, Off
  - Number of Bursts: 1-15
  - Number of Stimulation: 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**
- **High-Voltage Output Mode**: Programmable pulse width for P1/P2 and tilt
- **Warpage**: Biphasic, Monophasic
- **BVP Polarity**: Cathode (-), Anode (+)
- **Electrode Configuration**: RV to Can, RV to SVC/Can, RV to SVC

### Bradydcardia Pacing

- **Permanent Modes**
  - OFF, DDD(D), DDIR(R), VVI(R), AAI(R)
- **Temporary Modes**
  - OFF, DDD, DDI, VVI, AA, AAI, DOO, VOO, AOO
- **Activity Sensor**: On, Off
- **Programmable Rate and Delay Parameters**
  - Base Rate (bps); Rest Rate (bps); Maximum Tracking Rate (bps); Maximum Sensor Rate (bps); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysterectomy Rate (bps); Rate Hysterectomy with Search
  - Pulse Amplitude: 0.25-7.5 V
  - Pulse Width: 0.05 ms, 0.1-1.5 ms
  - Ventricular AutoCapture™
  - PAC Sensing: On; Off
  - PAC Response Interval: 200-400 ms

### Implantable Cardioverter Defibrillator (ICD) Device

#### PMT Detection/Termination

- **Atrial Intrinsic Preference (VIP)**
  - PMT Detection/Termination: On (50-200 ms), Off
  - Ventricular Intrinsic Preference: On (30-100 ms), Off

#### Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)

- **Post-Shock Pacing Mode**
  - AAV: YVE, DDI: DDD: Off
  - Post-Shock Base Rate: 150-100 bpm
  - Post-Shock Pacing Duration: 0.5, 1.25, 5, 7.5, or 10 min, Off

#### Device Testing/Induction Methods

- **DC-Fiber™ Induction Method**
  - Pulse Duration: 0.5-5.0 sec
  - Burst Fiber 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 Management, 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

#### 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 episodes, PVT termination, PAC response, magnet reversion, noise reversion

#### Therapy Summary

- **Episodes Summary**
  - Directory listing of up to 60 episodes with access to more details including stored electrograms

#### Lifetime Diagnostics

- **AF Management**
  - History of bradydcardia events and device-initiated charging

#### Trend Data and Counts

- **AT/AF Burden Trend**
  - Multi-Vector Trend Data

#### 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**
  - DDD, VOO, AOO, PACING OFF
- **MRI Base Rate**
  - 30-100 bpm
- **MRI Paced AV Delay**
  - 125-157 ms
- **VF Therapy Assurance**
  - Off, On
- **CorV Thoracic Impedance**
  - Off, On
- **CorV Thoracic Impedance Threshold**
  - 8-18 days

#### MRI Scan Parameters†

- **Magnetic Resonance Imaging (MRI)•**
  - Duration: 8–18 days
  - **Scan Region**
  - Full-body

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† For additional information about specific MR Conditional ICDs and leads, including scan parameters, warnings, precautions, adverse conditions to MRI scanning, and potential adverse events, please refer to the Abbott MRI Ready Systems Manual at medical.abbott/manuals.
Rx Only

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 ICDs 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. 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, Cardiogenic shock, Death, Discomfort, Embolism, Endocardiitis, Erosion, Exacerbation of heart failure, Excessive friable 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, traumatic 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 malfunctions, inappropriate pulsing, shaking 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.