## Cardiac Resynchronisation Therapy (CRT) Devices

# Unify Quadra<sup>™</sup>

### Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

## **Product Highlights**

- The Unify Quadra CRT-D and Quartet<sup>™</sup> quadripolar LV pacing lead feature four pacing electrodes and 10 pacing vectors to provide more options and greater control to minimise implant complications such as diaphragmatic stimulation and high pacing thresholds
- Downsized device for a smaller footprint
- The CorVue<sup>™</sup> Congestion Monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- ShockGuard<sup>™</sup> technology with DecisionTx<sup>™</sup> programming, designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- 40 J delivered energy provides unsurpassed energy for defibrillation
- Streamlined header connectors (IS4-LLLL/DF4-LLHH) reduce pocket bulk
- QHR<sup>™</sup>\* chemistry battery provides greater capacity for enhanced longevity and improved charge time performance



Ordering Information

Contents: Cardiac pulse generator

| Model Number | Dimensions (H x W x T, mm) | Weight (g) | Volume (cc) | Connector      |
|--------------|----------------------------|------------|-------------|----------------|
| CD3251-40    | 83 x 41 x 14               | 83         | 40          | DF1, IS4, IS-1 |
| CD3251-40Q   | 76 x 41 x 14               | 81         | 38          | DF4, IS4, IS-1 |

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with researching the televisers.

**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.

#### Adverse Events

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorthage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiagenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation,

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histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax nistotxic reactions, intection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboembolii, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including Twaves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate nulsings, and fear of losing nulse canability. inappropriate pulsing, and fear of losing pulse capability.

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



# Unify Quadra<sup>™</sup>

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

## **Product Specifications**

| PHYSICAL SPECIFICATIONS                                       |  |   | Bradycardia Pacing   |  |  |
|---|--|---|--|--|--|
| Models  | CD3251-40  | CD3251-40Q  | Permanent Modes  | Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R)  |  |
| Telemetry   | RF   | RF  | Temporary Modes  | Off; DDD(R); DDT(R); VVI(R); VVI(R); AAI(R); AAT; DOO; VOO; AOO  |  |
| Delivered Energy (J)  | 40   | 40  | Rate-Adaptive Sensor   | On; Off; Passive   |  |
| Volume (cc)   | 40   | 38  | Programmable Rate and  | Off; Base Rate (min <sup>-1</sup> ); Rest Rate (min <sup>-1</sup> ); Maximum Tracking Rate (min <sup>-1</sup> ); |  |
| Weight (g)  | 83   | 81  | Delay Parameters   | Maximum Sensor Rate (min <sup>-1</sup> ); Paced AV Delay (ms); Sensed AV Delay (ms);                             |  |
| Size (mm)   | 83 x 41 x 14   | 76 x 41 x 14  |  | Rate Responsive AV Delay; Hysteresis Rate (min-1); Rate Hysteresis with Search                                   |  |
| Defibrillation Lead Connections<br>LV Lead Connections        | DF1<br>IS4-LLLL  | DF4-LLHH<br>IS4-LLLL  | Auto Mode Switch (AMS)   | Off; DDI(R); DDT(R); VVI(R); VVT(R)  |  |
| Sense/Pace Lead Connections                                   | IS4-LLLL<br>IS-1   | IS-1  | Atrial Tachycardia Detection Rate (min-1)                        | 110-300  |  |
| High-Voltage Can  | Electrically active titanium can   | Electrically active titanium can  | AMS Base Rate (min-1)  | 40; 45; 135  |  |
|   | -  | Liooti oun y dottro titumum oun   | Auto PMT Detection/Termination                                   | Atrial Pace; Off; Passive  |  |
| PARAMETER   | SETTINGS   |   | Rate Responsive PVARP/VREF                                       | Off; Low; Medium; High<br>Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)                  |  |
| Biventricular Pacing  |  |   | BiVCap <sup>™</sup> Confirm; LVCap <sup>™</sup> Confirm;         | Setup: On; Monitor; Off  |  |
| VectSelect Quartet <sup>™</sup> LV                            | Distal Tip 1 - Mid 2, Distal Tip 1 -   | Distal Tip 1 - Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - RV Coil;            |  | Setup: On; Monitor; Off  |  |
| Pulse Configuration   | Mid 2 - Proximal 4; Mid 2 - RV Coil; Mid 3 - Mid 2; Mid 3 - Proximal 4;<br>Mid 3 - RV Coil; Proximal 4 - Mid 2; Proximal 4 - RV Coil |   | RVCap™ Confirm<br>ACap™ Confirm                                  | On: Monitor; Off   |  |
|   |  |   |  |  |  |
| V. Triggering (BiV <sup>™</sup> Trigger Mode)                 | On; Off  | An Income the   | Post-Inerapy Pacing (Independenti                                | y programmable from Bradycardia and ATP)   |  |
| QuickOpt <sup>™</sup> Timing Cycle Optimisation<br>V-V Timing |  |   | Post-Shock Pacing Mode   | Off; AAI; VVI; DDI; or DDD   |  |
|   | Simultaneous*; RV First; LV First<br>RV First 10, 80 / LV First 15, 80 in  | incromonts of 5   | Post-Shock Base Rate (min <sup>-1</sup> )                        | 30-100 in increments of 5  |  |
| Interventricular Pace Delay (ms)<br>Ventricular Sensing       |  |   | Post-Shock Pacing Duration (min)                                 | Off; 0,5; 1; 2,5; 5; 7,5; or 10  |  |
| Ventricular Pacing Chamber                                    | RV only; biventricular   | Device Testing/Induction Methods  |  |  |  |
| Negative AV Hysteresis/Search (ms)                            | Off; -10 to -120   |   | DC Fibber™ Pulse Duration (sec)                                  | 0,5-5,0  |  |
| Shortest AV Delay (ms)  | 25-120   |   | Burst Fibber Cycle Length (ms)                                   | 20-100   |  |
| AF Management   |  |   | Noninvasive Programmed   | 2-25 stimuli with up to 3 extrastimuli   |  |
| AF Suppression™ Pacing  | On; Off  |   | Stimulation (NIPS)   |  |  |
| No. of Overdrive Pacing Cycles                                | 15-40 in steps of 5  |   | Patient Notifiers  |  |  |
| Maximum AF Suppression Rate                                   | 80-150 min <sup>-1</sup>   |   | Programmable Notifiers (On; Off)                                 | Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;  |  |
| Sensing/Detection   |  |   | riogrammable notifiers (oil, oil)                                | Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range;  |  |
|   |  |   |  | LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of   |  |
| Sense <i>Ability</i> ™ Technology                             |  | istment for atrial and ventricular events   |  | Range; AT/AF Burden; V Rate During AT/AF; % V Pacing; CorVue™  |  |
| Low Frequency Attenuation<br>Sense Filter                     | On; Off<br>(Post Seneed Atrial) 50, 62 5, 75   | 100% (Post Posed Atrial) 0.2.2.0 mV   |  | Congestion Trigger   |  |
| Threshold Start   |  | ; 100%; (Post-Paced; Atrial) 0,2-3,0 mV;<br>,5; 75; 100%; (Post-Paced; Ventricular) | Device Parameter Reset   | On   |  |
| The shou start  | Auto: 0.2-3.0 mV   | ,0, 73, 100%, (103t-12660, Ventileular)   | Entry into Backup VVI Mode                                       | On   |  |
| Decay Delay   | (Post-Sensed/Post-Paced; Atrial/Ventricular) 0-220   |   | Vibration Duration (sec)   | 2; 4; 6; 8; 10; 12; 14; 16   |  |
| Ventricular Sense Refractory (ms)                             | 125; 157   |   | Number of Vibrations per Notification<br>Number of Notifications | 2<br>1-16  |  |
| Detection Zones   | VT-1; VT-2; VF   |   | Time Between Notifications (hours)                               | 10;22  |  |
| SVT Discriminators  | AV Rate Branch; Sudden Onset; In   |   | Electrograms and Diagnostics                                     | 10;22  |  |
| Reconfirmation  | Discrimination (MD) with Manual<br>Continuous sensing during chargi  |   | Stored Electrograms  | Up to 45 minutes; including up to 1 minute programmable pre-trigger  |  |
| Antitachycardia Pacing Therapy                                | 0.00   |   | Stored Liectiograms  | data per VT/VF diagnosis/detection electrograms; triggers include  |  |
|   |  |   |  | diagnosis; therapy; atrial episode; PMT termination; PC shock delivery;  |  |
| ATP Configurations  | Ramp; Burst; Scan; 1 or 2 scheme   |   |  | noise reversion; magnet reversion; and morphology template verification  |  |
| ATP in VF Zone  |  | ATP While Charging; ATP Prior to Charging; Off                                      |  | Diagram of therapies delivered   |  |
| ATP Upper Rate Cutoff   |  | 150-300 bpm   |  | Directory listing of up to 60 episodes with access to more details including                                     |  |
| Burst Cycle Length<br>Min. Burst Cycle Length (ms)            | Adaptive; Readaptive or Fixed<br>150-400 in increments of 5  |   |  | stored electrograms  |  |
| Number of Bursts/Stimuli                                      | 1-15 with 2-20 Stimuli   |   | Lifetime Diagnostics   | History of bradycardia events and device-initiated charging  |  |
| Add Stimuli per Burst   | On; Off  |   | AT/AF Burden Trend   | Trend data and counts  |  |
|   | · · · ·  |   | · · · · · · · · · · · · · · · · · · ·                            | Multi-Vector Trend Data<br>Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;               |  |
| High-Voltage Therapy  |  |   | Histograms   | Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular   |  |
| High-Voltage Output Mode                                      | Fixed Pulse Width; Fixed Tilt  |   |  | Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;  |  |
| Waveform  | Biphasic; Monophasic   |   |  | V Rates During AMS   |  |
| RV Polarity   | Cathode (-); Anode (+)   |   | PMT Data   | Information regarding PMT detections   |  |
| Electrode Configuration                                       | RV to Can; RV to SVC/Can   |   | Real-Time Measurements (RTM)                                     | Pacing lead impedances; high-voltage lead impedances;  |  |
|   |  |   |  | signal amplitudes  |  |
|   |  |   | CorVue™ Congestion Monitoring                                    | On; Off  |  |
|   |  |   | CorVue Congestion Trigger  | 8-18 days  |  |
|   |  |   |  |  |  |
|   |  |   | * QHR is a trademark of Greatbatch, L                            |  |  |

\*\* LV first with 10ms interventricular delay

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