Fortify[™] ST DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- The ST monitoring diagnostic provides information on significant ST segment changes for improved insight in decision making
- ShockGuard™ technology with DecisionTx™ programming, designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- Unique 40 J delivered energy safety shock option can provide a greater DFT safety margin
- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- QHR™* chemistry battery provides greater capacity for enhanced longevity and stable charge times
- 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
- The low frequency attenuation filter is designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- The SenseAbility™ feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity



Merlin@home1 Transmitter Compatible

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD2235-40	74 x 40 x 14	76	35	DF1	IS-1
CD2235-40Q	71 x 40 x 14	75	35	DF4	IS-1; DF4

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

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:

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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 hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax,

thromboemboli, 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 T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

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

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Biret Jummary: Prior to using these devices, piease review in instructions for use for a complete listing or indications, contraindications, contraindications, contraindications, contraindications, contraindications, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or noe of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All rights reserved.



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Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS				
Models	CD2235-40	CD2235-40Q		
Telemetry	RF	RF		
Delivered/Stored Energy (J)	40/45	40/45		
Volume (cc)	35	35		
Weight (g)	76	75		
Size (mm)	74 x 40 x 14	71 x 40 x 14		
Defibrillation Lead Connections	DF1	DF4		
Sense/Pace Lead Connections	IS-1	IS-1; DF4		
High-Voltage Can	Electrically active titanium can	Electrically active titanium can		
PARAMETERS	SETTINGS			
AF Management				
AF Suppression™ Pacing	On; Off			
No. of Overdrive Pacing Cycles	15-40 in increments of 5			
Maximum AF Suppression Rate	80-150 min ⁻¹			
Sensing/Detection				
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events On; Off			
Low Frequency Attenuation				
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75	(Post-Sensed; Atrial) 50; 62,5; 75; 100%;		
	(Post-Paced; Atrial) 0,2-3,0 mV;			
	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%;			
	(Post-Paced; Ventricular) Auto; 0,	2-3,0 mV		

(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220

Ramp; Burst; Scan; 1 or 2 schemes per VT zone

ATP While Charging; ATP Prior to Charging; Off

7,5 Independent from Bradycardia and Post-Therapy Pacing

1,0 or 1,5 Independently programmable from Bradycardia

Decay Delay Ventricular Sense Refractory (ms)

Detection Zones VT-1; VT-2; VF **SVT Discriminators** AV Rate Branch; Sudden Onset; Interval Stability; Morphology Discrimination (MD) with Manual or Automatic Template Update

125; 157

150-300 bpm

1-15

2-20

Adaptive; Readaptive or Fixed

150-400 in increments of 5

and Post-Therapy Pacing

Reconfirmation Continuous sensing during charging

Antitachycardia Pacing Therapy

ATP Configurations ATP in VF Zone ATP Upper Rate Cutoff Burst Cycle Length Min. Burst Cycle Length (ms) Number of Bursts

Number of Stimuli Add Stimuli per Burst

ATP Pulse Amplitude (V) ATP Pulse Width (ms) High-Voltage Therapy

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 Bradycardia Pacing Permanent Modes DDD(R); DDI(R); VVI(R); AAI(R); Pacer Off

Off: DDD: DDI: VVI: AAI: AAT: DOO: VOO: AOO Temporary Modes (Post-Sense/Post-Pace; Atrial/Ventricular) 0-220 Rate-Adaptive Sensor Off; Base Rate (min⁻¹); Rest Rate (min⁻¹); Maximum Tracking Rate (min⁻¹);

Rate and Delay Parameters Maximum Sensor Rate (min-1); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay: Pulse Amplitude (Atrial: RV) (V): Pulse Width (Atrial and RV) (ms); Hysteresis Rate (min-1); Rate Hysteresis with Search QuickOpt™ Timing Cycle Optimisation Sensed/Paced AV delay

Auto Mode Switch (AMS) Off: DDI(R): VVI(R) Atrial Tachycardia 110-300 Detection Rate (min-1)

AMS Base Rate (min-1) 40; 45; ... 135 Auto PMT Detection/Termination A Pace on PMT; Off; Passive Rate Responsive PVARP/VRFF Off: Low: Medium: High

Off; 50-200 (50-150 in increments of 25; 450 to 200 in increments of 10) Ventricular Intrinsic Preference (VIP

Ventricular AutoCapture™ Pacing System

ACap™ Confirm On; Monitor; Off

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)

Off: AAI: VVI: DDI: or DDD Post-Shock Pacing Mode 30-100 in increments of 5 Post-Shock Base Rate (min-1) Off; 0,5; 1; 2,5; 7,5; or 10 Post-Shock Pacing Duration (min)

Device Testing/Induction Methods

DC Fibber™ Pulse Duration (sec) Burst Fibber Cycle Length (ms)

Noninvasive Programmed Stimulation (NIPS) Patient Notifiers

0.5-5.0 20-100

2-25 stimuli with up to three extrastimuli

Programmable Notifiers (On: Off) Device at ERI: Charge Time Limit Reached: Possible HV Circuit Damage: Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue Congestion Trigger

Device Parameter Reset Entry into Backup VVI Mode Vibration Duration (sec) 2; 4; 6; 8; 10; 12; 14; 16 Number of Vibrations per Notification 1-16

Number of Notifications **Electrograms and Diagnostics**

Stored Electrograms

Up to 45 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; and morphology template verification

Diagram of therapies delivered
Directory listing of up to 60 episodes with access to more details including Therapy Summary **Episodes Summary**

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 Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;

Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V

Rates during AMS Information regarding PMT detections

Real-Time Measurements (RTM) Pacing lead impedances; high-voltage lead impedances; unloaded battery

voltage: and signal amplitudes

ST Histogram Data; ST Deviation Trend; ST Episode Log ST Monitoring

CorVue™ Congestion Monitoring CorVue Congestion Trigger 8-18 days

*QHR is a trademark of Greatbatch, LTD.



Item GMCRM777EN

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