Cardiac Rhythm Management International Product Catalog January 2012



A Comprehensive Portfolio of Cardiac Rhythm Management Products

St. Jude Medical offers comprehensive solutions for the diagnosis and treatment of cardiac arrhythmias. Our product portfolio ranges from proven pacemakers, implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy systems to innovative and reliable lead technologies. Additionally, we offer high-performance products for atrial fibrillation (AF), including mapping and surgical and catheter ablation systems. Other St. Jude Medical products include remote care solutions, heart valves and vascular closure devices.

High-performance devices with long-lasting batteries, expansive data storage and fast processors pave the way for disease management. These systems not only monitor device status but also take the patient and disease progression into account. In combination with telemedicine capabilities, patient monitoring can start in the patient's bedroom and extend beyond the parameters of rhythm management alone. Advanced disease management features include:

- ST segment monitoring
- CorVue[™] congestion monitoring
- AT/AF alerts

Our corporate mission is to develop medical technology and services that make it possible for physicians worldwide to treat cardiac and neurological diseases and chronic pain with more control. Reducing risk for every patient stands at the center of our efforts to advance medicine and improve therapeutic results.

To meet our objectives of more control and less risk, we partner with physicians to develop tools and techniques that simplify patient care and facilitate reproducible outcomes. Our efforts extend to physician training and education. We sponsor more than 170 programs with various themes geared toward physicians specialising in many areas of cardiology.

Descriptions and specifications for the St. Jude Medical comprehensive portfolio of cardiac rhythm management products can be found throughout this catalogue.



Left-Heart and Epicardial Leads

Implantable Cardioverter Defibrillator (ICD) Devices

Defibrillation Leads

Pacemakers

Pacing Leads

Accessories

Implantable Cardiac Monitors

Connectivity and Remote Care

Customer Support: 46-8-474-4756

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. 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 one 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.



CARDIAC RESYNCHRONISATION THERAPY (CRT) DEVICES

Exclusive St. Jude Medical Innovations Enable Delivery of Optimal Cardiac Resynchronisation Therapy

From design and development to market release, exclusive technical innovations reduce life-threatening risk and enable delivery of individually-tailored cardiac resynchronisation therapies (CRT-D and CRT-P). Simplified implantation and remote monitoring benefit physicians and patients alike.

More Control.

Comprehensive noninvasive programming techniques and algorithms such as QuickOpt[™] and DeFT Response[™] enable physicians to better meet the needs of their patients. These features provide the flexibility and control needed for individual therapy success. Improvements such as wireless telemetry help save time and improve efficiencies in the clinic.

Less Risk.

The latest functions of St. Jude Medical CRT devices provide the possibility to deliver optimal therapy to patients with less risk.



Unify Quadra[™]

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- The Unify Quadra CRT-D and Quartet[™] 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[™] 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[™] technology with DecisionTx[™] 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[™]* chemistry battery provides greater capacity for enhanced longevity and improved charge time performance



Compatible

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,

Customer Support: 46-8-474-4756

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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[™]

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); VV1(R); VV1(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 ⁻¹); Rest Rate (min ⁻¹); Maximum Tracking Rate (min ⁻¹);
Weight (g)	83	81	Delay Parameters	Maximum Sensor Rate (min ⁻¹); 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	DF1	DF4-LLHH	Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
LV Lead Connections	IS4-LLLL	IS4-LLLL	Atrial Tachycardia Detection Rate (min-1)	
Sense/Pace Lead Connections	IS-1	IS-1	AMS Base Rate (min-1)	40; 45; 135
High-Voltage Can	Electrically active titanium can	Electrically active titanium can	Auto PMT Detection/Termination	Atrial Pace; Off; Passive
PARAMETER	SETTINGS		Rate Responsive PVARP/VREF	Off; Low; Medium; High
Biventricular Pacing			Ventricular Intrinsic Preference (VIP™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
VectSelect Quartet™ LV	Distal Tip 1 - Mid 2, Distal Tip 1 -	Provimal 4. Distal Tip 1 - RV Coil:	BiVCap™ Confirm; LVCap™ Confirm;	Setup; On; Monitor; Off
Pulse Configuration		; Mid 3 - Mid 2; Mid 3 - Proximal 4;	RVCap™ Confirm	Setup; On; Monitor; Off
	Mid 3 - RV Coil; Proximal 4 - Mid 2		ACap™ Confirm	On; Monitor; Off
V. Triggering (BiV™ Trigger Mode)	On; Off		Post-Therapy Pacing (independently	y programmable from Bradycardia and ATP)
QuickOpt [™] Timing Cycle Optimisation		ricular nace delav		
V-V Timing	Simultaneous*; RV First; LV First		Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in	increments of 5	Post-Shock Base Rate (min-1)	30-100 in increments of 5
Ventricular Sensing	RV only (not programmable)		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 ⁻¹			
	00-130 mm		Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;
Sensing/Detection				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	Automatic Sensitivity Control adju	stment for atrial and ventricular events		Range; AT/AF Burden; V Rate During AT/AF; % V Pacing; CorVue™
Low Frequency Attenuation	On; Off			Congestion Trigger
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75	; 100%; (Post-Paced; Atrial) 0,2-3,0 mV;	Device Parameter Reset	On
Threshold Start	(Post-Sensed; Ventricular) 50; 62	,5; 75; 100%; (Post-Paced; Ventricular)	Entry into Backup VVI Mode	On
	Auto; 0,2-3,0 mV		Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Decay Delay	(Post-Sensed/Post-Paced; Atrial/	Ventricular) 0-220	Number of Vibrations per Notification	
Ventricular Sense Refractory (ms)	125; 157		Number of Notifications	1-16
Detection Zones	VT-1; VT-2; VF		Time Between Notifications (hours)	10:22
SVT Discriminators	AV Rate Branch; Sudden Onset; In Discrimination (MD) with Manual		Electrograms and Diagnostics	
Reconfirmation	Continuous sensing during chargi		Stored Electrograms	Up to 45 minutes; including up to 1 minute programmable pre-trigger
Antitachycardia Pacing Therapy				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 C	harging; Off	Therapy Summary	Diagram of therapies delivered
ATP Upper Rate Cutoff	150-300 bpm		Episodes Summary	Directory listing of up to 60 episodes with access to more details including
Burst Cycle Length	Adaptive; Readaptive or Fixed		-	stored electrograms
Min. Burst Cycle Length (ms)	150-400 in increments of 5		Lifetime Diagnostics	History of bradycardia events and device-initiated charging
Number of Bursts/Stimuli	1-15 with 2-20 Stimuli		AT/AF Burden Trend	Trend data and counts
Add Stimuli per Burst	On; Off		Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
High-Voltage Therapy			Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt			Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;
Waveform	Biphasic; Monophasic			V Rates During AMS
RV Polarity	Cathode (-); Anode (+)		PMT Data	
Electrode Configuration	RV to Can; RV to SVC/Can		PMT Data Real-Time Measurements (RTM)	Information regarding PMT detections Pacing lead impedances; high-voltage lead impedances;
			הכמו-ווווכ שכמגעופווופוונג (הוש)	signal amplitudes
			CorVue™ Congestion Monitoring	On; Off
			CorVue Congestion Trigger	8-18 days
			CorVue Congestion Trigger	8-18 days
			CorVue Congestion Trigger * QHR is a trademark of Greatbatch, L	

** LV first with 10ms interventricular delay

Customer Support: 46-8-474-4756

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Item GMCRM798EN

Promote Quadra[™] Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- The Promote Quadra CRT-D and Quartet[™] 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
- VectSelect Quartet[™] programmable LV pulse configuration (Distal Tip 1 Mid 2, Distal Tip 1 - Proximal 4, Distal Tip 1 - 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) may be adjusted noninvasively via the programmer
- The CorVue[™] congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- 40 J delivered energy provides unsurpassed energy for defibrillation
- Dual DF4 header option for defibrillation lead (DF4-LLHH) and LV pacing lead (IS4-LLLL) reduce pocket bulk
- QHR[™]* chemistry battery provides greater capacity for enhanced longevity and charge times
- Triggered pacing with BiV[™] Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event
- Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD3239-40	81 x 51 x 14	88	46	DF1	IS-1
CD3239-40Q	74 x 51 x 14	87	44	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. Cardiac Resynchronisation Therapy devices (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

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:

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,

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.



Merlin@home[™] Transmitter Compatible

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 emotality 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 tachorycardia, 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 adverse events.



Promote Quadra[™]

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS	CD2220 40	CD2220 400	rust-illerapy Pacing (Independenti	y programmable from Bradycardia and ATP)
Models		CD3239-40Q RF	Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Telemetry Delivered Energy (1)	RF 40	KF 40	Post-Shock Base Rate (min ⁻¹)	30-100 in increments of 5
Delivered Energy (J) Velume (co)			Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Volume (cc) Noight (g)	46	44	Device Testing/Induction Methods	
Weight (g)	88	87	Device resting/muuction methous	
Size (mm)	81x51x14	74x51x14	DC Fibber™ Pulse Duration (sec)	0,5-5,0
Defibrillation Lead Connections		DF4-LLHH	Burst Fibber Cycle Length (ms)	20-100
LV Lead Connections	IS4-LLLL	IS4-LLLL	Noninvasive Programmed	
Sense/Pace Lead Connections	IS-1	IS-1	Stimulation (NIPS)	2-25 stimuli with up to three extrastimuli
High-Voltage Can	Electrically active titanium can	Electrically active titanium can		
PARAMETER	SETTINGS		Patient Notifiers	
Biventricular Pacing			Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;
Diventification acting				Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range;
VectSelect Quartet™ LV Pulse Configuration	Distal Tip 1 - Mid 2; Distal Tip 1 - Proximal 4; Distal Tip 1 - 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		I	LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue™
		Proximal 4 - RV Coll		Congestion Trigger
V. Triggering (BiV™ Trigger Mode)	On; Off		Device Reset	On
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay, interventric	ular pace	Entry into Backup VVI Mode	On
V-V Timing	Simultaneous**; RV First; LV First		Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in in	crements of 5	Number of Vibrations per Notification	
Ventricular Sensing	RV only (not programmable)		Number of Notifications	1-16
Ventricular Pacing Chamber	RV only; biventricular		Time Between Notifications (hours)	10; 22
	Off; -10 to -120			10, 22
Shortest AV Delay (ms)	25-120		Electrograms and Diagnostics	
-			Stored Electrograms	Up to 45 minutes; including up to one minute programmable pre-trigger
AF Management			Stored Electrograms	
AF Suppression™ Pacing	On; Off			data per VT/VF diagnosis/detection electrograms; triggers include
				diagnosis; therapy; atrial episode; PMT termination; PC shock delivery;
No. of Overdrive Pacing Cycles	15-40 in steps of 5			noise reversion; magnet reversion; and morphology template verification
Maximum AF Suppression Rate	80-150 min ⁻¹		Therapy Summary	Diagram of therapies delivered
Sensing/Detection			Episodes Summary	Directory listing of up to 60 episodes with access to more details includi
			-	stored electrograms
Sense <i>Ability</i> ™ Technology		tment for atrial and ventricular events	Lifetime Diagnostics	History of bradycardia events and device-initiated charging
Low Frequency Attenuation	On; Off		AT/AF Burden Trend	Trend data and counts
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75;	100%; (Post-Paced; Atrial) 0,2-3,0 mV;	Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
	(Post-Sensed: Ventricular) 50: 62.5	; 75; 100%; (Post-Paced; Ventricular)		
	Auto; 0,2-3,0 mV	, , , (,	Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogra
Decay Delay	(Post-Sense/Post-Pace; Atrial/Vent	ricular) 0-220		Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular
Ventricular Sense Refractory (ms)	125; 157	100101/ 0-220		Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;
				V Rates During AMS
Detection Zones	VT-1; VT-2; VF		PMT Data	Information regarding PMT detections
SVT Discriminators	AV Rate Branch; Sudden Onset; Inter		Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances;
	Discrimination (MD) with Manual or	Automatic Template Update		signal amplitudes
Reconfirmation	Continuous sensing during charging	(CorVue™ Congestion Monitoring	On; Off
Antitachycardia Pacing Therapy			CorVue Congestion Trigger	8-18 days
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes			
ATP in VF Zone	ATP While Charging; ATP Prior to Cha	arging; Off	*QHR is a trademark of Greatbatch, LTD.	
ATP Upper Rate Cutoff	150-300 bpm		**LV first with 10 ms interventricular delay.	
Burst Cycle Length	Adaptive; Readaptive or Fixed			
Min. Burst Cycle Length (ms)	maapuve, maauapuve UI FIXEU			
	150-400 in increments of 5			
	150-400 in increments of 5			
Number of Bursts/Stimuli	150-400 in increments of 5 1-15 with 2-20 Stimuli			
Number of Bursts/Stimuli Add Stimuli per Burst	150-400 in increments of 5			
	150-400 in increments of 5 1-15 with 2-20 Stimuli			
Number of Bursts/Stimuli Add Stimuli per Burst <mark>High-Voltage Therapy</mark>	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (); Anode (+-)			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (); Anode (+-)			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(F			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(R Off; DDD(R); DDT(R); DDI(R); VVT(R	R); VVI(R); AAI(R) R); VVI(R); AAI(R); AAT; DOO; VOO; AOO		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Rate-Adaptive Sensor	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(F			
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-): Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(F Off; DDD(R); DDT(R); DD1(R); VVT(F Off; DDD(R); DDT(R); DD1(R); VVT(F Off; Base Rate (min ⁻¹); Rest Rate (m	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO nin ⁻¹); Maximum Tracking Rate (min ⁻¹)		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Rate-Adaptive Sensor	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-): Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(F Off; DDD(R); DDT(R); DD1(R); VVT(F Off; DDD(R); DDT(R); DD1(R); VVT(F Off; Base Rate (min ⁻¹); Rest Rate (m	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-): Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(F Off; DDD(R); DDT(R); DD1(R); VVT(F Off; DDD(R); DDT(R); DD1(R); VVT(F Off; Base Rate (min ⁻¹); Rest Rate (m	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO nin-1); Maximum Tracking Rate (min-1) d AV Delay (ms); Sensed AV Delay (ms);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(R Off; DDD(R); DDT(R); DDI(R); VVT(R Off; DDD(R); DDT(R); DDI(R); VVT(R Off; Base Rate (min ⁻¹); Rest Rate (min ⁻¹); Pacer Rate Responsive AV Delay; Pulse Am	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO nin ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); nplitude (Atrial; RV and LV) (V);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Andde (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(R Off; DDD(R); DDT(R); DDI(R); VVT(G Off; DDD(R); DDT(R); DDI(R); VVT(G Off; Base Rate (min ⁻¹); Rest Rate (m Maximum Sensor Rate (min ⁻¹); Pacet Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms)	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO nin ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); nplitude (Atrial; RV and LV) (V);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(F On; Off; DabD(R); DDT(R); DD1(R); VVT(F On; Off; Base Rate (min ⁻¹); Rest Rate (m Maximum Sensor Rate (min ⁻¹); Rest Rate Responsive AV Delay; Pulse Atter Rate Hysteresis with Search	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO 1in ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); plitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS)	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R Off; DDD(R); DDT(R); DD1(R); VVT(R Off; Dasc Rate (min ⁻¹); Rest Rate (m Maximum Sensor Rate (min ⁻¹); Pacet Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms) Off; DD1(R); DDT(R); VVT(R); VVT(R	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO 1in ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); plitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min ⁻¹)	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R Off; DDD(R); DDT(R); DD1(R); VVT(R Off; Base Rate (min ⁻¹); Rest Rate (m Maximum Sensor Rate (min ⁻¹); Pacer Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms) Rate Hysteresis with Search Off; DDT(R); DDT(R); VVT(R); VVT(R); 110-300	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO 1in ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); plitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min ⁻¹) AMS Base Rate	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Andde (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(R Off; DDD(R); DDT(R); DDI(R); VVT(R Off; Base Rate (min ⁻¹); Raset Rate (mi Maximum Sensor Rate (min ⁻¹); Pacet Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms) Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R); 110-300 40; 45;135	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO 1in ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); plitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Femporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min ⁻¹) AMS Detection Rate (min ⁻¹)	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Andde (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; Base Rate (min ⁻¹); Rest Rate (m Maximum Sensor Rate (min ⁻¹); Rest Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms) Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R); 110-300 40; 45;35 A Pace on PMT; Off; Passive	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO 1in ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); plitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min ⁻¹) AMS Base Rate Auto PMT Detection/Termination	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Andde (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DDI(R); VVT(R Off; DDD(R); DDT(R); DDI(R); VVT(R Off; Base Rate (min ⁻¹); Raset Rate (mi Maximum Sensor Rate (min ⁻¹); Pacet Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms) Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R); 110-300 40; 45;135	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO 1in ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); plitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; Bassive Off; Bassive Off; Bassive Off; Bassive Off; Bassive Off; DD1(R); DD1(R); VV1(R); VV1(R); 110-300 40; 45;135 A Pace on PMT; Off; Passive Off; Low; Medium; High	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO hin ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); uplitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);)		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min ⁻¹) AMS Bese Rate Auto PMI Detection/Termination Rate Responsive PVARP/VREF	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; Bassive Off; Bassive Off; Bassive Off; Bassive Off; Bassive Off; DD1(R); DD1(R); VV1(R); VV1(R); 110-300 40; 45;135 A Pace on PMT; Off; Passive Off; Low; Medium; High	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO hin ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); uplitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);)		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Dutput Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Temporary Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min ⁻¹) AMS Base Rate Auto PMT Detection/Termination Rate Responsive PVARP/VREF Ventricular Intrinsic Preference (VIP [™]) BiVCap [™] Confirm; LVCap [™] Confirm;	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Andde (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R Off; DDD(R); DDT(R); DD1(R); VVT(R Off; DD0(R); DDT(R); DD1(R); VVT(R) Off; Base Rate (min ⁻¹); Raset Rate (mi Maximum Sensor Rate (min ⁻¹); Paset Rate Responsive AV Delay; Pulse Am Pulse Width (Atrial; RV and LV) (ms) Rate Hysteresis with Search Off; DD1(R); DDT(R); VV1(R); VVT(R); 110-300 40; 45;135 A Pace on PMT; Off; Passive Off; Low; Medium; High) Off; 50-200 (50-150 in increments of	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO hin ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); uplitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);)		
Number of Bursts/Stimuli Add Stimuli per Burst High-Voltage Therapy High-Voltage Output Mode Waveform RV Polarity Electrode Configuration Bradycardia Pacing Permanent Modes Rate-Adaptive Sensor Programmable Rate and Delay Parameters Auto Mode Switch (AMS) AMS Detection Rate (min-¹) AMS Base Rate Auto PMT Detection/Termination Rate Responsive PVARP/VREF Ventricular Intrinsic Preference (VIP™)	150-400 in increments of 5 1-15 with 2-20 Stimuli On; Off Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic Cathode (-); Anode (+) RV to Can; RV to SVC/Can Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; DDD(R); DDT(R); DD1(R); VVT(R) Off; Bassive Off; Bassive Off; Bassive Off; Bassive Off; Bassive Off; DD1(R); DD1(R); VV1(R); VV1(R); 110-300 40; 45;135 A Pace on PMT; Off; Passive Off; Low; Medium; High	R); VVI(R); AAI(R); AAT; DOO; VOO; AOO hin ⁻¹); Maximum Tracking Rate (min ⁻¹) d AV Delay (ms); Sensed AV Delay (ms); uplitude (Atrial; RV and LV) (V); ; Hysteresis Rate (min ⁻¹);)		

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. 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 one 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.



Unify[™]

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- Smallest footprint of any HV device available
- The CorVue[™] congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- 40 J delivered energy provides unsurpassed energy for defibrillation
- ShockGuard[™] technology with DecisionTx[™] programming, designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
- DF connector is designed simplifies the implant by decreasing the defibrillation connections into a single terminal pin and reducing the number of set screws.
- QHR[™]* chemistry battery provides greater capacity for enhanced longevity and charge times
- Triggered pacing with BiV[™] Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event
- Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD3235-40	79 x 40 x 14	78	36	DF1	IS-1
CD3235-40Q	73 x 40 x 14	77	36	DF4	DF4; 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 congestive heart failure.

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:

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,

Customer Support: 46-8-474-4756

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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 dislogment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference. Shutting 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 acrdiac 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 adverse events.



Merlin@home™ Transmitter Compatible



Unify[™]

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS			Atrial Tachycardia Base Rate	40; 45; 135	
Models	CD3235-40	CD3235-40Q	Auto PMT Detection/Termination	A Pace on PMT; Off; Passive	
Telemetry	RF	RF	Rate Responsive PVARP/VREF	Off; Low; Medium; High	
Delivered/Stored Energy (J)	40/45	40/45	Ventricular Intrinsic Preference (VIP™		
Volume (cc)	36	36	LV Cap [™] Confirm; RV Cap [™] Confirm	Setup; On; Monitor; Off	
Weight (g)	78	77	ACap™ Confirm	On; Monitor; Off	
Size (mm)	79 x 40 x 14	73 x 40 x 14			
Defibrillation Lead Connections	DF1	DF4	Post-Therapy Pacing (Independent	y programmable from Bradycardia and ATP)	
Sense/Pace Lead Connections	IS-1	IS-1; DF4	Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD	
High Voltage Can	Can Electrically active titanium can Electrically active titanium can SETTINGS			30-100 in increments of 5	
PARAMETER			Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10	
Biventricular Pacing			Device Testing/Induction Methods		
V. Triggering (BiV™ Trigger Mode)	On; Off		DC Fibber™ Pulse Duration (sec)	0.5-5.0	
QuickOpt [™] Timing Cycle Optimisation	Sensed/paced AV delay; Interventricula	ar Pace delay	Burst Fibber Cycle Length (ms)	20-100	
V-V Timing	Simultaneous**; RV First; LV First		Noninvasive Programmed	2-25 stimuli with up to three extrastimuli	
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in incre	ments of 5	Stimulation (NIPS)		
Ventricular Sensing	RV only (not programmable)		Patient Notifiers		
Ventricular Pacing Chamber	RV only; biventricular				
Negative AV Hysteresis/Search (ms)	Off; -10 to -120		Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;	
Shortest AV Delay (ms)	25-120			Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range;	
VectSelect [™] LV Pulse Configuration AF Management	LV tip to RV coil; LV bipolar; LV ring to F	LV tip to RV coil; LV bipolar; LV ring to RV coil		LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue	
AF Supersonia TM Danian	0- 0#			Congestion Trigger	
AF Suppression™ Pacing No. of Overdrive Pacing Cycles	On; Off 15-40 in steps of 5		Device Parameter Reset	0n	
Maximum AF Suppression Rate	80-150 min ⁻¹		Entry into Backup VVI Mode Vibration Duration (sec)	On 2; 4; 6; 8; 10; 12; 14; 16 2	
Sensing/Detection	00 100 1111		Number of Vibrations per Notification		
Sensing/Detection			Number of Notifications	1-16	
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adjustme	ent for atrial and ventricular events	Time Between Notifications (hours)	10; 22	
Low Frequency Attenuation	On; Off		Electrograms and Diagnostics		
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100				
Threshold Start	(Post-Sensed; Ventricular) 50; 62,5; 7 Auto; 0,2-3,0 mV	5; 100%; (Post-Paceu; ventricular)	Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger	
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ventric	ular) 0.220		data per VT/VF diagnosis/detection electrograms; triggers include:	
Ventricular Sense Refractory (ms)	125; 157	ular) 0-220		diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; and morphology template verification	
Detection Zones	VT-1; VT-2; VF		Therapy Summary	Diagram of therapies delivered	
SVT Discriminators	AV Rate Branch; Sudden Onset; Interva	I Stability; Morphology	Episodes Summary	Directory listing of up to 60 episodes with access to more details includin	
	Discrimination (MD) with Manual or Au	tomatic Template Update		stored electrograms	
Reconfirmation	Continuous sensing during charging		Lifetime Diagnostics	History of bradycardia events and device-initiated charging	
Antitachycardia Pacing Therapy			AT/AF Burden Trend	Trend data and counts	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per		Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data	
ATP in VF Zone	ATP While Charging; ATP Prior to Charg		Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram	
ATP Upper Rate Cutoff	150-300 bpm	ilig; off		Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular	
Burst Cycle Length	Adaptive; Readaptive or Fixed			Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;	
Min. Burst Cycle Length (ms)	150-400 in increments of 5		PMT Data	V Rates During AMS	
Number of Bursts/Stimuli	1-15 with 2-20 Stimuli		PWI Data Real-Time Measurements (RTM)	Information regarding PMT detections Pacing lead impedances; high voltage lead impedances; unloaded	
Add Stimuli per Burst	On; Off		Real-Time weasurements (RTW)	battery voltage; and signal amplitudes	
High-Voltage Therapy			CorVue™ Congestion Monitoring	On; Off	
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt		CorVue Congestion Trigger	8-18 days	
Waveform	Biphasic; Monophasic				
RV Polarity	Cathode (-); Anode (+)				
Electrode Configuration	RV to Can; RV to SVC/Can		*QHR is a trademark of Greatbatch, **LV first with 10 ms interventricular d		
Bradycardia Pacing			Ly hist with 10 his interventicular u	ciay.	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R);	VVI(R); AAI(R)			
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R);				
Rate-Adaptive Sensor	On; Off; Passive				
Programmable Rate and	Off; Base Rate (min ⁻¹); Rest Rate (min ⁻	¹); Maximum Tracking Rate (min ⁻¹)			
Delay Parameters	Maximum Sensor Rate (min-1); Paced A				
	Rate Responsive AV Delay; Pulse Ampli				
	Pulse Width (Atrial; RV and LV) (ms); H	lysteresis Rate (min-1);			
Auto Mada Suutak (AMO)	Rate Hysteresis with Search				
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R) 110-300				
AMS Detection Rate (min ⁻¹)	110-300				

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Customer Support: 46-8-474-4756

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Promote Accel[™]

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- LV, RV and Atrial Capture Confirmation features ensure capture of the myocardium in response to pacing stimuli in the left ventricle, right ventricle and right atrium. LVCapTM, RVCapTM and ACapTM Confirm help ensure patient safety and therapy delivery by automatically monitoring and adjusting capture thresholds according to changing patient needs
- Advanced Biventricular Pacing options
 - Triggered Pacing with BiV Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event
 - VectSelect[™] programmable LV pulse configuration (LV ring-RV coil, LV tip-RV coil or LV bipolar) may be adjusted noninvasively via the programmer
 - Negative AV hysteresis with search promotes ventricular acing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- The Sense*Ability*TM feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD3215-36	81 x 50 x 14	82	43	DF1	IS-1
CD3215-36Q	75 x 50 x 14	82	42	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. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

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:

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,

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

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 adverse events.





Merlin@home™ Transmitter Compatible

Promote Accel

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

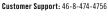
PHYSICAL SPECIFICATIONS				
Models	CD3215-36	CD3215-36Q		
Telemetry	RF	RF		
Delivered Energy (J)	36	36		
Volume (cc) Weight (g)	43 82	42 82		
Size (mm)	81 x 50 x 14	oz 75 x 50 x 14		
Defibrillation Lead Connections	DF1	DF4		
Sense/Pace Lead Connections	IS-1	IS-1; DF4		
High Voltage Can	Electrically active	Electrically active		
	titanium can	titanium can		
PARAMETER	SETTINGS			
V. Triggering (BiV Trigger Mode)	On; Off			
QuickOpt [™] Timing Cycle Optimisation		Interventricular Pace delay		
V-V Timing Interventricular Pace Delay (ms)	Simultaneous*; RV First; LV First RV First 10-80 / LV First 15-80 in increments of 5			
Ventricular Sensing	RV only (not programmab			
Ventricular Pacing Chamber	RV only; biventricular	,		
Negative AV Hysteresis/Search (ms)	Off; -10 to -120			
Shortest AV Delay (ms)	25-120			
VectSelect [™] LV Pulse Configuration	LV tip to RV coil; LV bipol	ar; LV ring to RV coil		
AF Management				
AF Suppression™ Pacing	On; Off			
No. of Overdrive Pacing Cycles	15-40 in steps of 5			
Maximum AF Suppression Rate	80-150 min ⁻¹			
Sensing/Detection				
Sense <i>Ability</i> ™ Technology Threshold Start	,	ntrol adjustment for atrial and ventricular events		
Threshold Start	(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	1) 50; 02,5; 75; 100 %; (1 0st-1 aced; Ventilculai)		
Decay Delay	(Post-Sense/Post-Pace;	Atrial/Ventricular) 0-220		
Ventricular Sense Refractory (ms)	125; 157			
Detection Zones	VT-1; VT-2; VF			
SVT Discriminators	AV Rate Branch; Sudden	Onset; Interval Stability; Morphology		
		Manual or Automatic Template Update		
Reconfirmation	Continuous sensing durir	ng charging		
Antitachycardia Pacing Therapy				
ATP Configurations	Ramp; Burst; Scan; 1 or 2			
Burst Cycle Length	Adaptive; Readaptive or I			
Min. Burst Cycle Length (ms)	150-400 in increments of	f 5		
Number of Bursts/Stimuli	1-15 with 2-20 Stimuli			
Add Stimuli per Burst	On; Off			
High-Voltage Therapy				
High-Voltage Output Mode	Fixed Pulse Width; Fixed	Tilt		
Waveform BV Polarity	Biphasic; Monophasic			
RV Polarity Electrode Configuration	Cathode (-); Anode (+) RV to Can; RV to SVC/Ca	n		
	N¥ tu Gali; N¥ tu S¥G/Gal	n		
Bradycardia Pacing				
Permanent Modes		I(R); VVT(R); VVI(R); AAI(R)		
Temporary Modes		I(R); VVT(R); VVI(R); AAI(R); AAT; DOO; VOO; AOO		
Rate-Adaptive Sensor	On; Off; Passive	est Rate (min ⁻¹); Maximum Tracking Rate (min ⁻¹)		
Programmable Rate and Delay Parameters		hin ⁻¹); Paced AV Delay (ms); Sensed AV Delay (ms);		
2010,1 0101101010		y; Pulse Amplitude (Atrial; RV and LV) (V);		
		nd LV) (ms); Hysteresis Rate (min ⁻¹);		
	Rate Hysteresis with Sea			
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI			
AMS Detection Rate (min-1)	110-300			
Atrial Tachycardia Base Rate	40; 45;135			
Auto PMT Detection/Termination	A Pace on PMT; Off; Pass	ive		
Rate Responsive PVARP/VREF	Off; Low; Medium; High			

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP) Post-Shock Pacing Mode Off; AAI; VVI; DDI; or DDD

Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹)	Off; AAI; VVI; DDI; or DDD 30-100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber [™] Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed	0,5-5,0 20-100
Stimulation (NIPS)	2-25 stimuli with up to three extrastimuli
Patient Notifiers	
Programmable Notifiers (On, Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range; LV Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22
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
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	
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
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; unloaded battery voltage; and signal amplitudes
*LV first with 10 ms interventricular delay.	
1 Mouchawar G, Kroll M, Val-Mejias JE pair-sampled multicenter study. PAG	et al. ICD waveform optimization: a randomized prospective, CE 2000; 23 (Part II):1992-1995.
2 Sweeney MO, Natale A, Volosin KJ et biphasic waveform on defibrillation	al. Prospective randomized comparison of 50%/50% versus 65%/65% tilt in humans. PACE 2001; 24:60-65.
method and echocardiogram for car	rammer-guided AV/PV and VV delay optimization comparing an IEGM diac resynchronization therapy in heart failure patients and dual-chamber ular Electrophysiology, Vol. 18 No. 2, Feb. 2007.
	ptimization of A-V and V-V delay of biventricular pacemaker improves on therapy in heart failure patients. J Cardiac Failure 2004; 10:4
5 Sperzel I Meine M et al. A new autor	matic undate function of the morphology template used for SVT/VT

5 Sperzel J, Meine M et al. A new automatic update function of the morphology template used for SVT/VT discrimination in an ICD. Europace Supplements; Vol. 3, July 2002; A 131, #1515.

- 6 Carlson MD et al. A new pacemaker algorithm for the treatment of atrial fibrillation: results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). JACC 2003; 42:627-633.
- 7 Sharma AD, O'Neill PG, Fain E et al. Shock on T versus DC for induction of ventricular fibrillation: a randomized prospective comparison. 21st Annual Scientific Session North American Society of Pacing and Electrophysiology (NASPE). Poster presentation published in meeting proceedings. Washington D.C., U.S.A. May 2000.



LV Cap[™] Confirm, RV Cap[™] Confirm Setup; On; Monitor; Off ACap[™] Confirm On; Monitor; Off

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Ventricular Intrinsic Preference (VIP™) Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)



Promote[™]+

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- Triple redundancy safety platform is designed to minimise risk and increase security and patient comfort through multiple hardware and software system safeguards
- Triggered pacing with BiV[™] Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event
- Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing
- AT/AF Alerts can be programmed to notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- QuickOpt[™] timing cycle optimisation provides quick and effective optimisation for more patients at the push of a button
- VectSelect[™] programmable LV pulse configuration (LV ring-RV coil, LV tip-RV coil or LV bipolar) may be adjusted noninvasively via the programmer
- DeFT Response[™] technology tools provide more clinically proven, noninvasive options for managing high DFTs

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD3211-36	81 x 50 x 14	82	43	DF1	IS-1
CD3211-36Q	75 x 50 x 14	82	42	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. Cardiac Resynchronisation Therapy Defibrillators (CRT-Ds) are also intended to resynchronise the right and left ventricles in patients with congestive heart failure.

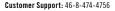
Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance or acute myocardial infarction.

Adverse Events:

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 emotality 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 adverse events.



Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.



Merlin@home™ Transmitter Compatible



Promote[™]+

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		Post-T	Therapy Pacing (independently	programmable from Bradycardia and ATP)		
Models	CD3211-36 CD3211-	io	Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD		
	RF RF		Shock Base Rate (min ⁻¹)	30-100 in increments of 5		
Delivered/Stored Energy (J)	36/42 36/42		Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10		
Volume (cc)	43 42		-	011; 0,5; 1; 2,5; 5; 7,5; 01 10		
Weight (g)	82 82	Device	e Testing/Induction Methods			
Size (mm)	81 x 50 x 14 75 x 50 x	DC Fib	ober™ Pulse Duration (sec)	0,5-5,0		
Defibrillation Lead Connections	DF1 DF4		Fibber Cycle Length (ms)	20-100		
Sense/Pace Lead Connections	IS-1 IS-1; DF4		vasive Programmed	2-25 stimuli with up to 3 extrastimuli		
High-Voltage Can	Electrically active titanium can Electrical	and the second s	lation (NIPS)			
	-	otimu				
PARAMETER Biventricular Pacing	SETTINGS	Patien	nt Notifiers			
		Progra	-	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;		
V. Triggering (BiV™ Trigger Mode)	On; Off			Atrial Lead Impedance Out of Range; RV Lead Impedance Out of Range;		
QuickOpt [™] Timing Cycle Optimisation	Sensed/paced AV delay; Interventricular Pace of	lay		LV Lead Impedance Out of Range; High-Voltage Lead Impedance		
V-V Timing	Simultaneous*; RV First; LV First			Out of Range; AT/AF Burden; V Rate During AT/AF; Backup VVI;		
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments o	5		Long AT/AF Episode		
Ventricular Sensing	RV only (not programmable)	Device	e Parameter Reset	On		
	RV only; biventricular	Entry i	into Backup VVI Mode	On		
-	Off; -10 to -120	Vibrati	ion Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16		
	25-120			2		
-	LV tip to RV coil; LV bipolar; LV ring to RV coil		er of Notifications	1-16		
-			Between Notifications (hours)	10; 22		
AF Management				10, 11		
AF Suppression™ Pacing	On; Off	Electr	rograms and Diagnostics			
	15-40 in steps of 5	Stored	l Electrograms	Up to 45 minutes including up to 1 minute programmable pre-trigger		
0,	80-150 min ⁻¹			data per VT/VF diagnosis/detection electrograms; triggers include:		
· · · · · · · · · · · · · · · · · · ·				diagnosis; therapy; atrial episode; PMT termination; PC shock delivery;		
Sensing/Detection	Jetection		diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; and morphology template verificatio			
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adjustment for al	al and ventricular events Therea	au Summary	Diagram of therapies delivered		
	(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)		Episodes Summary	· · ·		
				Directory listing of up to 60 episodes with access to more details including		
				stored electrograms		
	Auto; 0,2-3,0 mV		ne Diagnostics	History of bradycardia events and device-initiated charging		
	(Post-Sensed/Post-Paced; Atrial/Ventricular) (Burden Trend	Trend data and counts		
	(Post-Paced Ventricular), Auto	Ventric	cular HV Lead Impedance Trend	Multi-Vector Trend Data		
-	125; 157	Histog	rams	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;		
Detection Zones	VT-1; VT-2; VF			Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular		
SVT Discriminators	AV Rate Branch; Sudden Onset; Interval Stabili	; Morphology		Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;		
	Discrimination (MD) with Manual or Automatic	emplate Update		V Rates During AMS		
Reconfirmation	Continuous sensing during charging	PMT D	ata	Information regarding PMT detections		
Antitachycardia Pacing Therapy		Real-T	Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded battery		
	Dama Burst Case 1 as 2 ashamas assess			voltage; and signal amplitudes		
-	Ramp; Burst; Scan; 1 or 2 schemes per zone					
, ,	Readaptive or Fixed					
,	150-400 in increments of 5	*LV firs	st with 10 ms interventricular de	lay.		
	1-15 with 2-20 Stimuli					
Add Stimuli per Burst	On; Off					
High-Voltage Therapy						
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt					
	Biphasic; Monophasic					
	Cathode (-); Anode (+)					
-	RV to Can; RV to SVC/Can					
Bradycardia Pacing						
	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R);	AI(R); DOO(R);				
	V00(R); A00(R)					
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); A	(R); AAT(R); DOO; VOO; AOO				
	On; Off; Passive					
Programmable Rate and	Off; Base Rate (min-1); Rest Rate (min-1); Maxir	ım Tracking Rate (min-1);				
Delay Parameters	Maximum Sensor Rate (min-1); Paced AV Delay	is); Sensed AV Delay (ms);				
-	Rate Responsive AV Delay; Pulse Amplitude (At					
	Pulse Width (Atrial: RV and LV) (ms). Hysteresi					
	Pulse Width (Atrial; RV and LV) (ms); Hysteresi Rate Hysteresis with Search					
	Rate Hysteresis with Search					
Auto Mode Switch (AMS)	Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R)					
Auto Mode Switch (AMS) Atrial Tachycardia Detection Rate (min ⁻¹)	Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R) 110-300					
Auto Mode Switch (AMS) Atrial Tachycardia Detection Rate (min 1) AMS Base Rate (min 1)	Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R) 110-300 40; 45; 135					
Auto Mode Switch (AMS) Atrial Tachycardia Detection Rate (min ⁻¹) AMS Base Rate (min ⁻¹) Auto PMT Detection/Termination	Rate Hysteresis with Search Off, DDI(R); DDT(R); VVI(R); VVT(R) 110-300 40; 45; 135 Atrial Pace; Off; Passive					
Auto Mode Switch (AMS) Atrial Tachycardia Detection Rate (min ⁻¹) AMS Base Rate (min ⁻¹) Auto PMT Detection/Termination Rate Responsive PVARP/VREF	Rate Hysteresis with Search Off; DDI(R); DDT(R); VVI(R); VVT(R) 110-300 40; 45; 135					

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Anthem[™] RF

Cardiac Resynchronisation Therapy Pacemaker

Product Highlights

- InvisiLink[™] wireless telemetry, in conjunction with the Merlin@home[™] wireless transmitter and Merlin.net[™] Patient Care Network (PCN), allows for daily remote monitoring and follow-up
- AT/AF Alerts can be programmed to notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- Exclusive AF Suppression[™] algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF
- AT/AF burden trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 52 weeks
- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and simplify the diagnosis of complex ECG rhythms associated with heart failure

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM3212	58 x 52 x 6	25	13,71	IS-1

Indications: Implantation of Anthem and Anthem RF devices is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure, the reduction of the symptoms of moderate to severe heart failure (NYHA Class II or IV) in those patients who nemain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration, implantation of Accent[™], Accent RF, Anthem, and Anthem RF devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, or any combination of those symptoms. **Rate-Modulated Pacing** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased simulation rates concurrent with physical activity. **Duat-Chamber Pacing** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. **Atrial Pacing** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. **Ventricular Pacing** is indicated for patients with sinus rifts, with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation episodes in patients with one or more of the above pacing indications. **Contraindicated in patients** with seven a patients atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience anging or other symptoms of myocardial dystunction at higher sensor-driver rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerate by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. **Dual-Chamber Pacing**, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

patients. *Single-Chamber Ventricular Demand Pacing* is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blod pressure with the onset of ventricular pacing. *Single-Chamber Atrial Pacing* is relatively contraindicated in patients who have demonstrated compromise of AV conduction. *Atrial Fibrillation*. Anthem devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

specific contraindications associated with individual modes, refer to the programmer's on-screen help. Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead displacement, body reaction at electrode/ tissue interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phenic nerve stimulation, neuemothorax/hemothorax, endocarditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiate vein thrombosis.

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







Off; Low; Medium; High Off; Low; Medium; High

125–475 in steps of 25

Very Fast: Fast: Medium: Slow

Fast; Medium; Slow; Very Slow

80–150 in steps of 5; 160-180 in steps of 10

Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto +(2,0); 1-7 in steps of 0,5

Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16

On; Off; Passive

Anthem[™] RF

Cardiac Resynchronisation Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS Model Telemetry PM3212 RF Dimensions (mm) Weight (g) 58 x 52 x 6 25 13,71 Volume (cc)1 IS-1 Connector PARAMETER SETT **Resynchronisation Therapy** QuickOpt™ Timing Cycle Optimisation RV and LV Pulse Width (ms) Sensed/Paced AV Delay; Interventricular Paced Delay 0,05; 0,1-1,5 in steps of 0,1 0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5 Unipolar; Bipolar RV and LV Pulse Amplitude (V) RV Pulse Configuration Unipolar; Bipolar Unipolar; Bipolar; LV Tip-RV Ring; LV Ring-RV Ring BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; LV Unipolar Tip; LV Bipolar; RV Unipolar Ring; LV Tip-RV Tip LV Pulse Configuration Ventricular Sense Configuration Ventricular Pacing Chamber BV; RV only; LV only (temporary mode) First Chamber Paced Simultaneous²· RV· IV Interventricular Pace Delay (ms) 10-80 in steps of 5 Output/Sensing Negative AV Off; -10 to -120 in steps of 10 25–50 in steps of 5; 60–120 in steps of 10 On; Off; Monitor Hysteresis Search (ms) Shortest AV/PV Delay (ms) Atrial ACap[™] Confirm Primary Pulse Confirmation Backup Pulse Confirmation Bipolar Bipolar Backup Pulse Amplitude (V) 5.0 8:24 Searchable Intervals (hrs) Atrial Pulse Configuration Unipolar (tip-case); Bipolar (tip-ring) Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) 0,1–0,5 in steps of 0,1; 0,75–2,0 in steps of 0,25; 2,5–5,0 in steps of 0,5 0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5 Atrial Sense Configuration Atrial Sensitivity^{3,4} (Fixed) (mV) Atrial Pulse Amplitude (V) Atrial Pulse Width (ms) 0,05; 0,1-1,5 in steps of 0,1 RVCap[™] Confirm Searchable Interval (hrs) 0n; Off; Monitor 8; 24 On; Off; Monitor LVCap[™] Confirm Searchable Interval (hrs) SenseAbility™ Technology 8; 24 Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events) 0,2-1,0 in steps of 0 A Max Sensitivity (mV) V Max Sensitivity (mV) 0,2-2,0 in steps of 0,1 (Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2-3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2-3,0 in steps of 0,1 mV Threshold Start (Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220 Decay Delay (ms) Ventricular Sensitivity (fixed) (mV) 0,5-12,5 in steps of 0,53,4

Rate/Timing

Mode

A00(R); AAI(R); AAT(R); V00(R); VVI(R); VVT(R); D00(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off DDT Trigger⁵ R wave DDT Timing⁵ Base Rate (min⁻¹) DDI Hysteresis Rate (min-1) Search Interval (min) Cycle Count Intervention Rate (min-1) Intervention Duration (min-1) Recovery Time Rest Rate (min⁻¹) Maximum Tracking Rate (min⁻¹) Sensed AV Delay (ms) Paced AV Delay (ms) Ventricular Pace/Sense Refractory7 (Fixed) (ms) Atrial Pace Refractory Atrial Sense Refractory PVARP (ms) Atrial Protection Interval (ms)⁵ Far-Field Protection Interval (ms)⁵

30–130 in steps of 5; 140–170 in steps of 10 Off; 30-150 in steps of 56 Off; 1; 5; 10; 15; 30 1-16 Off: Same Base Rate: 80-120 in steps of 10 (Intrinsic +0: Intrinsic +10; Intrinsic +20; Intrinsic +30) 1-10 Fast: Medium: Slow: Very Slow ras; medulin; 30%; very 30% Off; 30-150 in steps of 5 90-130 in steps of 5; 140–180 in steps of 10 25; 30–200 in steps of 10; 225–325 in steps of 25 25; 30–200 in steps of 10; 225–300 in steps of 25; 350 125: 160-400 in steps of 30: 440: 4708 190-400 in steps of 30; 440; 470⁸ 93; 125; 157; 190-400 in steps of 30; 440; 470⁸ 125-500 in steps of 25

1 ± 0,5 cc 21 V first with 10 ms interventricular delay. 3 Sensitivity is with respect to a 20 ms havers test signal. 4 Values 0,1–4 An available is at Unipolar Sense Configuration. 5 This parameter is not programmable. 6 The highest available setting for hysteresis rate is 5 min ¹ below the programmed base rate. 7 In dual -chamber modes, the maximum Ventricular Refractory Period is 325 ms. 8 Programming options dependent on pacing mode. 9 Journa gatral MUPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay. 10 SI Burst Cycle is applied at the preprogrammed SI cycle length.

Customer Support: 46-8-474-4756

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Rate-Modulated

Rate Responsive AV/PV Delay Rate Responsive PVARP/VREF Shortest PVARP/VREF Max Sensor Rate (min-1) Threshold Slope Reaction Time **Recovery** Time

AF Management

AF Suppression™ Algorithm Lower Rate Overdrive (min⁻¹)⁵ Upper Rate Overdrive (min⁻¹)⁵ No. of Overdrive Pacing Cycles Rate Recovery (ms) Auto Mode Switch AMS Base Rate (min-1)

Off; On 10 5 15–40 in steps of 5 8; 12 Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R) 40-170 in steps of 5

Stored Electrograms

Options Priority Options Channel Triggers Advanced Hysteresis AMS Entry/AMS Exit/ AMS Entry and Exit AT/AF Detection Magnet Response High Atrial Rate Rate (min⁻¹) No. of Consecutive Cycles High Ventricular Rate Rate (min⁻¹) No. of Consecutive Cycles PMT Termination Consecutive PVCs No. of Consecutive PVCs Noise Reversion

Other

Magnet Response

Ventricular Intrinsic Preference, VIP[™] (ms) VIP Search Interval

VIP Search Cycles of the Atrial Tachycardia

Ventricular Safety Standby

PMT Detection Rate (min-1)

Stimulation Chamber Coupling Interval⁹ (ms)

Detection Rate (min-1) Post Vent. Atrial Blanking (PVAB) (ms)

PVC Response PMT Options

Lead Type NIPS Options

S1 Count

Off: Low: High Off; Low; High Off; Low; High Off; Low; High Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off: Low: High 2; 3; 4; 5 Off; Low; High

Off; Low; High

1; 2; 3

Off: Battery Test

Off; 50-150 in steps of 25; 160-200 in steps of 10 30 sec.; 1; 3; 5; 10; 30 min 1; 2; 3

110-200 in steps of 10: 225-300 in steps of 25

60-200 in steps of 10; 225; 250 Off: On Off; Atrial Pace⁸ Off; Passive; Atrial Pace⁸

90–180 in steps of 5 Uncoded; Unipolar; Bipolar

Atrial: Right Ventricula 200-800 in steps of 10 2-25 in steps of 1 Off; 100-800 in steps of 10 (Fixed or Adaptive)

Off; 30-95 in steps of 5 I-5 in steps of 1 AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold

Patient Notifiers

Support Rate (min⁻¹)

Programmable Notifiers (On: Off)

S1¹⁰; S2; S3 and S4 Cycle (ms) Right Ventricular

Sinus Node Recovery Delay (s) **Diagnostic Trends**

Device Reset Entry into Backup VVI Mode Audible Duration (sec) Number of Audible Alerts per Notification Number of Notifications Time Between Notifications (hours) Device at ERI: Atrial Lead Impedance Out of Range: Ventricular Lead Impedance Out of Range; LV Lead Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF

2: 4: 6: 8: 10: 12: 14: 16

1 - 16

10:22

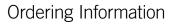


Anthem[™]

Cardiac Resynchronisation Therapy Pacemaker

Product Highlights

- AT/AF Alerts can be programmed to notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- Exclusive AF Suppression[™] algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF
- AT/AF burden trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 52 weeks
- Exclusive Sense *Ability*TM feature, with Decay Delay and Threshold Start, provides the flexibility to fine-tune sensing to individual patient needs and help eliminate oversensing of T waves, fractionated QRS complexes and other extraneous signals
- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and simplify the diagnosis of complex ECG rhythms associated with heart failure



Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM3112	52 x 52 x 6	21	11,51	IS-1

Indications: Implantation of Anthem and Anthem RF devices is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure, the reduction of the symptoms of moderate to severe heart failure (NYHA Class II or IV) in those patients who nemain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration, implantation of Accent[™], Accent RF, Anthem, and Anthem RF devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, or any combination of those symptoms. **Rate-Modulated Pacing** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased simulation rates concurrent with physical activity. **Dual-Chamber Pacing** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. **Atrial Pacing** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. **Ventricular Pacing** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation episodes in patients with one or more of the above pacing indications. **Contraindications:** Implanted Cardioverter-Defibrillator (ICD). Devices are contraindicated in patients

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dystunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerate by the patient. *Agust Sensor Rate Should be Sensor Rate Should be selected based on assessment of the highest stimulation rate tolerate by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. <i>Dual-Chamber Pacing*, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such

Customer Support: 46-8-474-4756

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patients. *Single-Chamber Ventricular Demand Pacing* is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. *Single-Chamber Atrial Pacing* is relatively contraindicated in patients who have demonstrated compromise of AV conduction. *Atrial Fibrillation*. Anthem devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

specific contraindications associated with individual modes, refer to the programmer's on-screen help. **Potential Adverse Events**: The following are potential complications associated with the use of any pacing system: air emblism, body rejection phenomena, cardiac tamponade or perforation. Hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead displacement, body reaction at electrode/ tissue interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaptragmatic atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis.

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





Off; Low; Medium; High Off; Low; Medium; High 125–475 in steps of 25

Very Fast: Fast: Medium: Slow

Fast; Medium; Slow; Very Slow

On; Off; Passive

Anthem™

Cardiac Resynchronisation Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS Model Telemetry PM3112 Inductive Dimensions (mm) 52 x 52 x 6 Weight (g) 11,51 Volume (cc) IS-1 Connector PARAMETER SETT **Resynchronisation Therapy** QuickOpt[™] Timing Cycle Optimisation RV and LV Pulse Width (ms) Sensed/Paced AV Delay; Interventricular Paced Delay 0,05; 0,1–1,5 in steps of 0,1 0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5 RV and LV Pulse Amplitude (V) **RV** Pulse Configuration Unipolar; Bipolar Unipolar; Bipolar; LV Tip-RV Ring; LV Ring-RV Ring BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; LV Unipolar Tip; LV Bipolar; RV Unipolar Ring; LV Tip-RV Tip LV Pulse Configuration Ventricular Sense Configuration Ventricular Pacing Chamber BV; RV only; LV only (temporary mode) First Chamber Paced Simultaneous²· RV· IV Interventricular Pace Delay (ms) 10-80 in steps of 5 Output/Sensing Negative AV Off; -10 to -120 in steps of 10 25–50 in steps of 5; 60–120 in steps of 10 On; Off; Monitor Hysteresis Search (ms) Shortest AV/PV Delay (ms) Atrial ACap[™] Confirm Primary Pulse Confirmation Backup Pulse Confirmation Bipolar Bipolar Backup Pulse Amplitude (V) 5.0 8:24 Searchable Intervals (hrs) Atrial Pulse Configuration Unipolar (tip-case); Bipolar (tip-ring) $\begin{array}{l} \text{Onpoint (tp-case); by low a (up-ning)}\\ \text{Unipolar Tip (tp-case); Bipolar (tip-ring); Unipolar Ring (ring-case)\\ 0.1-0.5 in steps of 0.1; 0.75-2.0 in steps of 0.25; 2.5-5.0 in steps of 0.5\\ 0.25-4.0 in steps of 0.25; 4.5-7.5 in steps of 0.5\\ \end{array}$ Atrial Sense Configuration Atrial Sensitivity^{3,4} (Fixed) (mV) Atrial Pulse Amplitude (V) Atrial Pulse Width (ms) 0,05; 0,1-1,5 in steps of 0,1 RVCap[™] Confirm Searchable Interval (hrs) 0n; Off; Monitor 8; 24 On; Off; Monitor LVCap[™] Confirm Searchable Interval (hrs) SenseAbility™ Technology 8; 24 Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events) 0,2-1,0 in steps of 0,1 0,2-2,0 in steps of 0,1 A Max Sensitivity (mV) V Max Sensitivity (mV) 0,2-2,0 m steps 0 0,1 (Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2-3,0 in steps of 0,1 mV (Ventricular Post-Pace) 0,2-3,0 in steps of 0,1 mV (Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220 Threshold Start Decav Delav (ms) Ventricular Sensitivity (fixed) (mV) 0,5-12,5 in steps of 0,53,4

Rate/Timing

Mode

A00(R); AAI(R); AAT(R); V00(R); VVI(R); VVT(R); D00(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off DDT Trigger⁵ R wave DDT Timing⁵ Base Rate (min⁻¹) וחח 30–130 in steps of 5; 140–170 in steps of 10 Off; 30-150 in steps of 56 Off; 1; 5; 10; 15; 30 Hysteresis Rate (min-1) Search Interval (min) 1-16 Cycle Count Off: Same Base Rate: 80-120 in steps of 10 (Intrinsic +0: Intervention Rate (min-1) Intrinsic +10; Intrinsic +20; Intrinsic +30) Intervention Duration (min-1) -10 Fast: Medium: Slow: Verv Slow Recovery Time Rest Rate (min⁻¹) Maximum Tracking Rate (min⁻¹) Sensed AV Delay (ms) 0ff; 30-150 in steps of 5 90–130 in steps of 5; 140–180 in steps of 10 25; 30–200 in steps of 10; 225–325 in steps of 25 Paced AV Delay (ms) Ventricular Pace/Sense 25; 30-200 in steps of 10; 225-300 in steps of 25; 350 125: 160-400 in steps of 30: 440: 4708 Refractory⁷ (Fixed) (ms) Atrial Pace Refractory Atrial Sense Refractory 190-400 in steps of 30; 440; 470⁸ 93; 125; 157; 190-400 in steps of 30; 440; 470⁸ PVARP (ms) 125-500 in steps of 25 Atrial Protection Interval (ms)⁵ Far-Field Protection Interval (ms)⁵ 125

1 ± 0,5 cc 21 Virfst with 10 ms interventricular delay. 3 Sensitivity is with respect to a 20 ms havers test signal. 4 Values 0,1-0 4 na vaniable in a Unipolar Sense Configuration. 5 This parameter is not programmable. 6 The highest available setting for hysteresis rate is 5 min ¹ below the programmed base rate. 7 In dual-thamber modes, the maximum Ventricular Refractory Period is 325 ms. 8 Programming options dependent on pacing mode. 9 Journg atrain MPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay. 10 SI Burst Cycle is applied at the preprogrammed SI cycle length.

Customer Support: 46-8-474-4756

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Rate-Modulated

Rate Responsive AV/PV Delay Rate Responsive PVARP/VREF Shortest PVARP/VREF Sensor Max Sensor Rate (min-1) Threshold Slope

Reaction Time Recovery Time

AF Management

AF Suppression™ Algorithm Lower Rate Overdrive (min⁻¹) Upper Rate Overdrive (min⁻¹) No. of Overdrive Pacing Cycles Rate Recovery (ms) Auto Mode Switch

Off; On 10 15-40 in steps of 5 8.12

Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (-1,5); Auto (+2,0); 1-7 in steps of 0,5 Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16

80–150 in steps of 5; 160-180 in steps of 10

Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R) 40-170 in steps of 5

AMS Base Rate (min-1) Stored Electrograms

Options . Priority Options Channel Triggers Advanced Hysteresis AMS Entry/AMS Exit/ AMS Entry and Exit AT/AF Detection Magnet Response High Atrial Rate Rate (min⁻¹) No. of Consecutive Cycles High Ventricular Rate Rate (min⁻¹) No. of Consecutive Cycles PMT Termination Consecutive PVCs No. of Consecutive PVCs Noise Reversion

Other

Magnet Response

1; 2; 3 Off: Low: High Off; Low; High Off; Low; High Off; Low; High Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off: Low: High 2; 3; 4; 5 Off; Low; High

Off; Low; High

Off: Battery Test

Ventricular Intrinsic Preference, VIP[™] (ms) VIP Search Interval VIP Search Cycles of the Atrial Tachycardia

Patient Notifiers

Programmable Notifiers (On: Off)

Device Reset Entry into Backup VVI Mode Audible Duration (sec) Number of Audible Alerts per Notification Number of Notifications Time Between Notifications (hours)

30 sec.; 1; 3; 5; 10; 30 min 1; 2; 3 110-200 in steps of 10: 225-300 in steps of 25

Off; 50-150 in steps of 25; 160-200 in steps of 10

60-200 in steps of 10; 225; 250 Off: On Off; Atrial Pace⁸ Off; Passive; Atrial Pace⁸

90–180 in steps of 5 Uncoded; Unipolar; Bipolar

Atrial: Right Ventricula 200-800 in steps of 10 2-25 in steps of 1 Off; 100-800 in steps of 10 (Fixed or Adaptive)

Off: 30-95 in steps of 5 1-5 in steps of 1 AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold

Device at ERI: Atrial Lead Impedance Out of Range: Ventricular Lead Impedance Out of Range; LV Lead Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF 0n

On 2: 4: 6: 8: 10: 12: 14: 16

1-16

10:22



Detection Rate (min-1) Post Vent. Atrial Blanking (PVAB) (ms) Ventricular Safety Standby PVC Response PMT Options PMT Detection Rate (min-1) Lead Type NIPS Options Stimulation Chamber Coupling Interval⁹ (ms) S1 Count S1¹⁰; S2; S3 and S4 Cycle (ms) Right Ventricular Support Rate (min⁻¹) Sinus Node Recovery Delay (s) **Diagnostic Trends**

Frontier[™] II

Cardiac Resynchronisation Therapy Pacemaker

Product Highlights

- QuickOpt[™] Timing Cycle Optimisation provides quick and effective AF optimization at the touch of a button
- Continuous Biventricular Pacing
 - AF Suppression[™] algorithm helps control atrial rhythm and maintains AV synchrony
 - Negative AV/PV Hysteresis is designed to ensure biventricular pacing by temporarily shortening the AV/PV delay upon sensing ventricular activity
 - DDT Biventricular Trigger Mode provides triggered pacing in the presence of intrinsic R-waves or PVCs to help promote biventricular pacing
 - Mode Switch Base Rate helps manage ventricular activity during AF episodes
- Exclusive AF SuppressionTM Algorithm is clinically proven to reduce AF burden¹ and improve quality of life^{2,3}
- AT/AF Burden Trend provides weekly count of the percent of time in AF and identifies long-term trends for device or drug management



- Carlson M et al. A new pacemaker algorithm for the treatment of atrial fibrillation, results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). JACC 2003; 42:627-33.
- Attuel P et al and the INOVA Study Group. Quality of life in permanently paced AF patients. The INOVA Study. *Europace* 2003; Abstract A42-6.
- Davy et al and the INOVA Study Group. Permanent atrial overdrive tolerance in patients with symptomatic paroxysmal AF. The INOVA Study *Europace* 2003; Abstract A42-3.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5596	49 x 52 x 6	25	11,5(±0,5)	IS-1

Indications: Implantation of Frontier II device is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure, the reduction of the symptoms of moderate to severe heart failure (NYHA Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction \leq 35% and a prolonged QRS duration, implantation of Accent **, Accent RF, Anthem, and Anthem RF devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation are sconcurrent with physical activity. *Dual-Chamber Pacing* is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with sinus oned dystunction and normal AV and intraventricular conduction systems. *Ventricular Pacing* is indicated for patients with sinus arrest, chronic atrial fibrillation episodes in patients with nor or more of the above pacing indications. Contraindicated in patients with son or more of the above pacing indications.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dystunction at higher sensor-driver rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerate by the patient. *Agustion as the should be selected based on assessment of the highest stimulation are tolerated by the patient. Bud <i>Chamber Pacing*, though not contraindicated for patients with cronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

patients. *Single-Chamber Ventricular Demand Pacing* is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. *Single-Chamber Atrial Pacing* is relatively contraindicated in patients who have demonstrated compromise of AV conduction. *Atrial Fibrillation*. Anthem devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead displacement, body reaction at the electrode interface, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, set and malfunction, fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax, hendoraditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vent intrombosis.

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



Frontier[™] II

Cardiac Resynchronisation Therapy Pacemaker

5596

25

11.5

IS-1

49 x 52 x 6

PHYSICAL SPECIFICATIONS

Model Number Dimensions (mm) Weight (g) Volume (cm3) Connector

PARAMETER

Resynchronization Therapy

QuickOpt[™] Timing Cycle Optimization RV and LV Pulse Width (ms) RV and LV Pulse Amplitude (V) **RV** Pulse Configuration LV Pulse Configuration Ventricular Sense Configuration

Ventricular Pacing Chamber First Chamber Paced Interventricular Pace Delay (ms) Ventricular Sensitivity (mV) Negative AV/PV Hysteresis Search (ms) Shortest AV/PV Delay (ms)

Atrial Output/Sensing

Atrial Pulse Configuration Atrial Sense Configuration

Atrial Sensitivity[‡] (mV)

Atrial Amplitude Atrial Pulse Width

Rate/Timing

Mode

DDT Trigger∆ DDT Timing² Base Rate (min-1) Hysteresis Rate (min-1) Search Interval (min-1) Cycle Count Intervention Rate (min-1)

Intervention Duration (min-1) Recovery Time Rest Rate (min-1) Maximum Tracking Rate (min-1) AV Delay (ms) PV Delay (ms) Ventricular Refractory[†] (ms) Atrial Refractory (PVARP) (ms) Ventricular Absolute Refractory Period (ms) Ventricular Blanking (ms) Atrial Absolute Refractory Period (ms) Atrial Protection Interval (ms) Far Field Protection Interval (ms) $^{\Delta}$

AF Management

AF Suppression™ Lower Rate Overdrive (min⁻¹)[△] Upper Rate Overdrive (min⁻¹)[△] No. of Overdrive Pacing Cycles Rate Recovery[∆] (ms) Auto Mode Switch

Sensed/paced AV delay, Interventricular Pace delay 0.05. 0.1-1.5 in steps of 0.1 0,0-4,0 in steps of 0,25, 4,5-7,5 in steps of 0,5 Unipolar, Bipolar Unipolar, Bipolar, LV Tip-RV ring BV Unipolar Tip, BV Bipolar, RV Unipolar Tip, RV Bipolar, LV Unipolar Tip, LV Bipolar, RV Unipolar Ring, LV tip-RV tip BV, RV only, LV only Simultaneous***, RV, LV 20-80 in steps of 5 0,5-5,0 in steps of 0,5, 6-10 in steps of 1,0, 12,5 Off, -10 to -110 in steps of 10 30-50 in steps of 5, 60-120 in steps of 10

Unipolar (tip-case), Bipolar (tip-ring) Unipolar Tip (tip-case), Bipolar (tip-ring), Unipolar Ring (ring-case) 0,1-0,5 in steps of 0,1, 0,75-2,0 in steps of 0,25, 2,5-5,0 in steps of 0,5 0,0-4,0 in steps of 0,25, 4,5-7,5 in steps of 0,5

0,05, 0,1-1,5 in steps of 0,1

A00(R), AAI(R), AAT(R), OAO, VOO(R), VVI(R), VVT(R), OVO, DOO(R), DVI(R), DDI(R), DDT(R), DDD(R), ODO R-wave DDD. DDI 30*, 40-130 in steps of 5, 140-170 in steps of 10 Off, 30–130 in steps of 5, 140, 150** Off, 5, 10, 15, 30 1-16 Off, 60, 80-120 in steps of 10 (Intrinsic +0, Intrinsic +10, Intrinsic +20, Intrinsic +30) 1 - 10Fast, Medium, Slow, Very Slow Off, 30-130 in steps of 5, 140, 150 90-130 in steps of 5, 140-180 in steps of 10 25, 30-200 in steps of 10, 225-300 in steps of 25, 350 25, 30-200 in steps of 10, 225-325 in steps of 25 125-500 in steps of 25 125-500 in steps of 25 60-240 in steps of 10 12-52 in steps of 4 60, 80, 100-350 in steps of 25 125 16

Off, DDDR to DDIR, DDD to DDI, DDT (D) to DDT (I),

Base Rate +0 to Base Rate +35 in steps of 5

DDT (D) to DDTR (I), DDTR (D) to DDTR (I), DDTR (D) to DDT (I),

Rate-Modulated

Rate Responsive AV/PV Delay Off. Low. Medium. High Rate Responsive PVARP/VREF Off. Low. Medium. High Shortest PVARP/VREF 120-350 in steps of 10 Sensor On, Off, Passive Max Sensor Rate (min-1) 80-150 in steps of 5, 160-180 in steps of 10 Threshold Auto (-0,5), Auto (+0,0), Auto (+0,5), Auto (+1,0), Auto (+1,5), Auto (+2,0), 1-7 in steps of 0,5 Auto (-1), Auto (+0), Auto (+1), Auto (+2), Auto (+3), 1-16 Slope Very Fast, Fast, Medium, Slow Reaction Time Fast, Medium, Slow, Very Slow Recovery Time Stored Electrograms Options Sampling Options Freeze, Continuous No. of Stored EGMs 1, 2, 4, 8, 12 Channel Single, Dual Triggers Magnet Placement On Off Off, 125-300 in steps of 25 High Atrial Rate (ms) No. of Consecutive Cycles 2, 3, 4, 5, 10, 15, 20 AMS Entry/Exit On, Off High Ventricular Rate (ms) Off, 125-300 in steps of 25 PVC On, Off No. of Consecutive PVCs 2.3.4.5 PMT Detection On, Off AT/AF Detection On. Off Advanced Hysteresis On, Off Other Magnet Response Off, Battery Test AutoIntrinsic Conduction Search (ms) Off, +10 to +120 in steps of 10 Atrial Tachycardia Detection Rate (min-1) 110-150 in steps of 5, 160-200 in steps of 10, 225-300 in steps of 25 60, 70, 80, 85, 95, 100, 110, 115, 125, 130, 140, 150, 155, 165, 170, 180, 185, 195, 200 Post Vent, Atrial Blanking (PVAB) (ms) Ventricular Safety Standby Off, On Off, +PVARP on PVC **PVC Options** PMT Options Off, 10 Beats > PMT, Auto Detect PMT Detection Rate (min-1) 90-150 in steps of 5, 160-180 in steps of 10 Lead Type Uncoded, Unipolar, Unipolar/Bipolar NIPS Options Atrial, Right Ventricular Stimulation Chamber Coupling Interval⁽⁾ (ms) 200-800 in steps of 10 1-25 in steps of 1 S1 Count S1*, S2, S3, and S4 Cycle (ms) 100-800 in steps of 10 Right Venticular Support Rate (min-1) Off, 30, 40-95 in steps of 5 Sinus Node Recovery Delay (s) 1-5 in steps of 1 ♦ ± 0,5 cm³ The actual pacing rate for the 30 min⁻¹ setting is 31 min⁻¹. The highest available setting for Hysteresis Rate is 5 $\rm min^{-1}$ below the programmed Base Rate. *** LV first with 10 ms interventricular delay.

- In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
- Sensitivity is with respect to a 20 ms haversine test signal.

Values 0,1-0,4 not available in a Unipolar Sense Configuration.

During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited \Diamond by the programmed AV/PV Delay.

¥ S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Δ This parameter is not programmable

AMS Base Rate (min-1)



Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binet Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

Off. On

15-40 in steps of 5

DDDR to DDI, DDD to DDIR

10

5

8.12

Item GMCRM889EN





LEFT-HEART AND EPICARDIAL LEADS

St. Jude Medical Left-Heart Lead Technology

We place great importance in left-heart leads, because they help ensure that the capabilities of the St. Jude Medical high-performance CRT-D and CRT devices are fully utilised.

Through a systematic development effort, St. Jude Medical has combined the safety of proven leads with innovative technology.

More Control.

When used with the Unify Quadra[™] CRT-D device and the Promote[™] Quadra CRT-D device, the Quartet[™] left ventricular pacing lead enables 10 pacing configuration options to provide better management of pacing complications intra- and post-operatively.

Less Risk.

Optim[™] lead insulation combines the biostability and flexibility of high-performance silicone and the strength, tear resistance and abrasion resistance of polyurethane. The combination enables an abrasion-resistant, thin diameter lead.



Left-Heart Leads

Quartet[™] Left-Heart Lead

Product Highlights

- Four 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 that blends the best features of polyurethane and silicone for improved handling and increased durability
- 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[™] placement through CPS Aim[™] SL inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire or stylet approaches

Ordering Information

Contents: Left-heart lead

Model Number	Insulation	S-Curve Height (mm)	Minimum Introducer (F)	Connector	Lengths (cm)
1458Q	Optim™	16	5	IS4-LLLL	75; 86; 92

Indications and Usage: The Quartet lead has application as part of a St. Jude Medical 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.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All rights reserved.





Quartet™ Left-Heart Lead

Product Specifications

MODEL	1458Q
Parameter	Description
Connector	IS4-LLLL
Lead Length	75; 86; 92 cm
Maximum Lead Size	5,1 F (1,70 mm/0,067") at the ring electrode
Lead Body Size	4,7 F (1,57 mm/0,062")
Tip Electrode Size	4,0 F (1,3 mm/0,052")
LV Lead Delivery System Introducer Size	Minimum 5 F ID
Minimum S-curve Height	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4,9 mm ²
Ring Electrode Surface Area	7,4 mm ²
Electrode Spacing	
Distal tip 1 - Mid 2	20 mm
Distal tip 1 - Mid 3	30 mm
Distal tip 1 - Proximal 4	47 mm
Lead Body Insulation	Optim [™] insulation
Lead Body Coating	Fast-Pass™ coating
Conductors	
Distal (coil)	MP35N™ LT*
Proximal (cables)	ETFE; MP35N LT
Suture Sleeve	Attached

*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

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Left-Heart Leads

QuickFlex[™] Left-Heart Lead

Product Highlights

- Superb deliverability combined with exceptional stability and performance
- Low profile 5,6 F proximal lead body; 5,0 F distal lead body; 4,0 F lead tip
- Steerable tip distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body
- Expanded tip-to-ring electrode spacing of 20 mm
- Shorter tip and ring electrodes reduce the length of rigid portions of the lead body
- Compatible with over-the-wire or stylet approaches
- Composite construction proximal polyurethane section and cable/coil conductors are designed to offer exceptional push and torque, while the flexible distal silicone portion is designed for improved tracking in tortuous anatomy

Ordering Information

Contents: Left-heart lead

Model Number	Insulation Proximal	Insulation Distal	S-Curve Height (mm)	Minimum Introducer (F)	Connector	Lengths (cm)
1156T	Polyurethane	Silicone	8	7	IS-1 bipolar	75; 86
1158T	Polyurethane	Silicone	16	7	IS-1 bipolar	75; 86

Indications and Usage: The QuickFlex lead has application as part of a St. Jude Medical biventricular system. Contraindications: The use of QuickFlex leads is contraindicated in patients who:

• Are expected to be hypersensitive to a single dose of 1,0 mg of dexamethasone sodium phosphate.

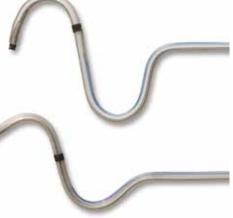
• Are unable to undergo an emergency thoracotomy procedure.

• Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

Customer Support: 46-8-474-4756

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QuickFlex™ Left-Heart Lead

Product Specifications

MODELS	1156T	1158T
Parameter	Description	Description
Connector	IS-1 Bipolar	IS-1 Bipolar
Lead Length	75 cm; 86 cm	75 cm; 86 cm
Maximum Lead Body Size	6,0 F (2 mm/0,079")	6,0 F (2 mm/0,079")
Proximal Polyurethane Lead Body Size	5,6 F (1,85 mm/0,073")	5,6 F (1,85 mm/0,073")
Distal Silicone Rubber Lead Body Size	5,0 F (1,68 mm/0,066")	5,0 F (1,68 mm/0,066")
Tip Electrode Size	4,0 F (1,33 mm/0,052")	4,0 F (1,33 mm/0,052")
LV Lead Delivery System Introducer Size	Minimum 7 F ID	Minimum 7 F ID
Minimum S-Curve Height	8 mm	16 mm
Tip Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves	Pt/Ir; TiN coated; ring-shaped; two grooves
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4,9 mm ²	4,9 mm ²
Ring Electrode Surface Area	7,4 mm ²	7,4 mm ²
Tip-to-Ring Electrode Spacing	20 mm	20 mm
Lead Body Insulation	Proximal: polyurethane 55D	Proximal: polyurethane 55D
Distal 7 cm: silicone rubber	Distal 7 cm: silicone rubber	
Lead Body Coating	Fast-Pass [™] coating	Fast-Pass™ coating
Conductors*		
Distal (coil)	MP35N™	MP35N™
Proximal (cables)	MP35N™	MP35N™
Suture Sleeve	Attached	Attached

*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

Brief Summary: Prior to a term in the set devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, 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 one 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.



Left-Heart Leads

QuickFlex[™] µ Left-Heart Lead

Product Highlights

- Superb deliverability combined with exceptional stability and performance
- Low profile 4,3 F lead body; 4,0 F lead tip
- Optim[™] lead insulation a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Steerable tip distal tip angle can be controlled to maneuver through venous anatomy
- Flexible lead body
- Tip-to-ring electrode spacing of 20 mm
- Shorter tip and ring electrodes reduce the length of rigid portions of the lead body
- Allows Direct-To-Target[™] placement through CPS Aim[™] SL inner catheter to deliver leads to small, acute venous anatomies that may have been unreachable in the past
- Compatible with over-the-wire or stylet approaches

Ordering Information

Contents: Left-heart lead

Model Number	Insulation	S-Curve Height (mm)	Minimum Introducer (F)	Connector	Lengths (cm)
1258T	Optim™	16	5	IS-1 bipolar	75; 86; 92

Indications and Usage: The QuickFlex lead has application as part of a St. Jude Medical biventricular system. Contraindications: The use of QuickFlex leads 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.

Customer Support: 46-8-474-4756

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. 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 one 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.





QuickFlex[™] µ Left-Heart Lead

Product Specifications

	1258T
rameter	Description
nnector	IS-1 Bipolar
ad Length	75 cm; 86 cm; 92 cm
ad Body Size	4,3 F (1,42 mm/0,056")
Electrode Size	4,0 F (1,33 mm/0,052")
Lead Delivery System Introducer Size	Minimum 5 F ID
nimum S-Curve Height	16 mm
Electrode	Pt/Ir; TiN coated; ring-shaped; two grooves
eroid	Dexamethasone sodium phosphate
Electrode Surface Area	5,0 mm ²
ig Electrode Surface Area	7,4 mm ²
-to-Ring Electrode Spacing	20 mm
ad Body Insulation	Optim [™] insulation
ad Body Coating	Fast-Pass™ coating
nductors*	
Distal (coil)	MP35N™
Proximal (cables)	MP35N™
ture Sleeve	Attached

Customer Support: 46-8-474-4756

Brief Summary: Prior to a term in the set devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, 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 one 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.



Left-Heart Leads

QuickSite[™] Left-Heart Lead

Product Highlights

- Superb deliverability combined with exceptional stability and performance
- Low profile 5,6 F proximal lead body; 5,0 F distal lead body
- Steerable tip the distal tip can be controlled to maneuver through venous anatomy
- Compatible with over-the-wire or stylet approaches
- Composite construction proximal polyurethane section and cable/coil conductors are designed to offer exceptional push and torque, while the flexible distal silicone portion is designed for improved tracking in tortuous anatomy



Ordering Information

Contents: Left-heart lead

Model Number	Insulation Proximal	Insulation Distal	S-Curve Height (mm)	Minimum Introducer (F)	Connector	Lengths (cm)
1056T	Polyurethane	Silicone	8	7	IS-1 bipolar	75; 86
1058T	Polyurethane	Silicone	16	7	IS-1 bipolar	75; 86

Indications and Usage: The QuickSite leads have application as part of a St. Jude Medical biventricular system.

Contraindications: The use of QuickSite leads 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.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with yours 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 one 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.



QuickSite[™] Left-Heart Lead

Product Specifications

PHYSICAL SPECIFICATIONS		
MODELS	1056T	1058T
Parameter	Description	Description
Connector	IS-1 Bipolar	IS-1 Bipolar
Lead Length	75 cm, 86 cm	75 cm, 86 cm
Maximum Lead Body Size	6,0 F (2 mm/0.079") at PU – SR transition	6,0 F (2 mm/0,079") at PU – SR transition
Proximal Polyurethane Lead Body Size	5,6 F (1,85 mm/0,073")	5,6 F (1,85 mm/0,073")
Distal Silicone Rubber Lead Body Size	5,0 F (1,68 mm/0,066")	5,0 F (1,68 mm/0,066")
LV Lead Delivery System Introducer Size	Minimum 7 F ID	Minimum 7 F ID
Minimum S-curve height	8 mm	16 mm
Tip Electrode	Pt/Ir, TiN coated, two grooves, blunt tip	Pt/Ir, TiN coated, two grooves, blunt tip
Steroid	Dexamethasone sodium phosphate	Dexamethasone sodium phosphate
Tip Electrode Surface Area	4,8 mm ²	4,8 mm ²
Ring Electrode Surface Area	14,7 mm ²	14,7 mm ²
Tip-to-Ring Electrode Spacing	15 mm	20 mm
Lead Body Insulation	Proximal: polyurethane 55D	Proximal: polyurethane 55D
	Distal 8 cm: silicone rubber	Distal 7 cm: silicone rubber
Conductors	Two ETFE-insulated low resistance cables,	Two ETFE-insulated low resistance cables,
	multifilar MP35N™*coil	multifilar MP35N™* coil
ACCESSORIES PACKAGED WITH THE QUICKS	ITE LEAD	
Stylets (6)	0,36 mm/0,014" (diameter) PTFE-coated stainles stylets, with 15 cm distal tapers:	s steel

Guidewire

Lead Flushing Tools (2) Stylet Guide (funnel) Vein Pick

*MP35N is a trademark of SPS Technologies, Inc.

0.36 mm/0.014 (ulameter) PTFE-coated stainless steel stylets, with 15 cm distal tapers: Soft – 0.15 mm/0.006' (diameter) – green knob (3 stylets) Firm – 0.20 mm/0.008' (diameter) – yellow knob (2 stylets) Extra Firm – 0.25 mm/0.010' (diameter) – red knob (1 stylet) PTFE-coated, 180 cm long, 0.36 mm/0.014'' (diameter) with 5 cm floppy tip; two torque tools included White ABS coupling with Luer Lock™ connector



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Myodex™

Bipolar, Steroid-eluting Epicardial Pacing Lead

Product Highlights

- Active-fixation, sutureless design
 - Full 3.5 mm helix penetration helps provide stable fixation
- Superb deliverability combined with exceptional stability and performance
- Low pacing thresholds with steroid elution
- Precise sensing and low polarisation
- Easy to implant with the FasTac[™] Lead Implant Tool



Ordering Information

Contents: Epicardial lead

Model Number	Insulation	Connector	Lengths (cm)
1084T	Silicone	IS-1 bipolar	25; 35; 54



Myodex™

Bipolar, Steroid-eluting Epicardial Lead

Product Specifications

MODELS	1084T (25 cm)	1084T (35 cm)	1084T (54 cm)
Electrode surface area	10 mm² cathode	10 mm ²	10 mm ²
	62 mm ² anode	62 mm ²	62 mm ²
Helix penetration depth	3,5 mm	3,5 mm	3,5 mm
Number of helix turns to implant	2,5	2,5	2,5
Lead resistance	20 ohms cathode	27 ohms	41 ohms
	38 ohms anode	46 ohms	75 ohms
Introducer length	27 cm	27 cm	27 cm
Tunneler length	27 cm	27 cm	27 cm
Connector type	IS-1 Bi	IS-1 Bi	IS-1 Bi
Electrode material	Titanium-nitride coated helix	Titanium-nitride coated	Titanium-nitride coated
	Platinum/Iridium	Platinum/Iridium	Platinum/Iridium
	Titanium-nitride coated anode plate	Titanium-nitride coated	Titanium-nitride coated
	titanium	titanium	titanium
Conductor material	MP35N™ (multifilar coil)	MP35N™ (multifilar coil)	MP35N™ (multifilar coil)
Insulation material	Silicone rubber	Silicone rubber	Silicone rubber
	(medical grade)	(medical grade)	(medical grade)
Connector pin material	316L stainless steel	316L stainless steel	316L stainless steel
Steroid plug	<1 mg dexamethasone	<1 mg dexamethasone	<1 mg dexamethasone
	sodium phosphate	sodium phosphate	sodium phosphate
Suture sleeve and pin cap material	Silicone rubber	Silicone rubber	Silicone rubber

ACCESSORIES PACKAGED WITH THE MYODEX LEAD

1 FasTac introducer

1 tunneler

1 bidirectional tunneler tip

1 connector pin cap 1 slit suture sleeve (detached from lead)



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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



IMPLANTABLE CARDIOVERTER Defibrillator (ICD) Devices

St. Jude Medical Implantable Cardioverter Defibrillators

Our new generation of implantable cardioverter defibrillators (ICDs) feature a triple redundancy safety platform designed to minimise risk and increase security and patient comfort through multiple hardware and software system safeguards.

More Control.

Individually tailored therapy helps ensure successful therapy. St. Jude Medical ICDs allow for comprehensive control over therapy delivery and make it possible to fine-tune programming to meet individual patient needs. Comfortable, simple controls along with advanced automaticity enable efficient patient care and help improve the patient's quality of life.

Less Risk.

A progressive approach to safety based on the concept of redundant proven designs along with innovative functions offers the best prospects for optimal patient therapy.



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 Sense*Ability*[™] feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity

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: 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,

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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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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 adverse events.



Fortify[™] ST DR Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS			Post-Therany Pacing (Independent	ly programmable from Bradycardia and ATP)
Models	CD2235-40	CD2235-40Q		
Telemetry	RF	RF	Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Delivered/Stored Energy (J)	40/45	40/45	Post-Shock Base Rate (min ⁻¹)	30-100 in increments of 5
Volume (cc)	35	35	Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 7,5; or 10
Weight (g)	76	75	Device Testing/Induction Methods	
Size (mm)	74 x 40 x 14	71 x 40 x 14	DC Fibber™ Pulse Duration (sec)	0,5-5,0
Defibrillation Lead Connections	DF1	DF4	Burst Fibber Cycle Length (ms)	20-100
Sense/Pace Lead Connections	IS-1	IS-1; DF4	Noninvasive Programmed	2-25 stimuli with up to three extrastimuli
High-Voltage Can	Electrically active titanium can	Electrically active titanium can	Stimulation (NIPS)	
PARAMETERS	SETTINGS		Patient Notifiers	
AF Management				
AF Suppression™ Pacing	On; Off		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
No. of Overdrive Pacing Cycles	15-40 in increments of 5			of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden;
Maximum AF Suppression Rate	80-150 min ⁻¹			V Rate During AT/AF; % V pacing; CorVue Congestion Trigger
	00 100 1111		Device Parameter Reset	On
Sensing/Detection			Entry into Backup VVI Mode	On
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adju	stment for atrial and ventricular events	Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Low Frequency Attenuation	On; Off		Number of Vibrations per Notification	
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75	; 100%;	Number of Notifications	2 1-16
	(Post-Paced; Atrial) 0,2-3,0 mV;	- •	Time Between Notifications (hours)	10; 22
	(Post-Sensed; Ventricular) 50; 62,	5: 75: 100%:		10; 22
	(Post-Paced; Ventricular) Auto; 0,		Electrograms and Diagnostics	
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ve		Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger
Ventricular Sense Refractory (ms)	125; 157	• • •		data per VT/VF diagnosis/detection electrograms; triggers include:
Detection Zones	VT-1; VT-2; VF			diagnosis; therapy; atrial episode; PMT termination; PC shock delivery;
SVT Discriminators	AV Rate Branch; Sudden Onset; In	terval Stability: Morphology		noise reversion; magnet reversion; and morphology template verification
	Discrimination (MD) with Manual		Therapy Summary	Diagram of therapies delivered
Reconfirmation	Continuous sensing during charging		Episodes Summary	Directory listing of up to 60 episodes with access to more details including
	continuous conoring during ondigin	'ð	Epicouco cuminary	stored electrograms
Antitachycardia Pacing Therapy			Lifetime Diagnostics	History of bradycardia events and device-initiated charging
ATP Configurations	Ramp; Burst; Scan; 1 or 2 scheme	s per VT zone	AT/AF Burden Trend	Trend data and counts
ATP in VF Zone	ATP While Charging; ATP Prior to C	harging; Off	Ventricular HV Lead Impedance Trend	
ATP Upper Rate Cutoff	150-300 bpm		Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;
Burst Cycle Length	Adaptive; Readaptive or Fixed		matograma	Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular
Min. Burst Cycle Length (ms)	150-400 in increments of 5			Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V
Number of Bursts	1-15			Rates during AMS
Number of Stimuli	2-20		PMT Data	Information regarding PMT detections
Add Stimuli per Burst	On; Off		Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded battery
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia	and Post-Therapy Pacing	Real-Time weasurements (RTW)	voltage; and signal amplitudes
ATP Pulse Width (ms)	1,0 or 1,5 Independently program		ST Monitoring	
	and Post-Therapy Pacing		ST Monitoring	ST Histogram Data; ST Deviation Trend; ST Episode Log
High-Voltage Therapy	and root morapy racing		CorVue™ Congestion Monitoring CorVue Congestion Trigger	On; Off 8-18 days
	Fixed Dulas Width Fixed Tilt			0 10 40,0
High-Voltage Output Mode Waveform	Fixed Pulse Width; Fixed Tilt Biphasic; Monophasic		*OUP is a tradomark of Greathatab 1	TD
			*QHR is a trademark of Greatbatch, L	10.
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); F			
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO			
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Atrial/Ve	ntricular) 0-220		
Programmable	Off; Base Rate (min ⁻¹); Rest Rate (min ⁻¹); Maximum Tracking Rate (min ⁻¹);		
Rate and Delay Parameters	Maximum Sensor Rate (min-1); Pac	ed AV Delay (ms); Sensed AV Delay (ms);		
	Rate Responsive AV Delay; Pulse A	mplitude (Atrial; RV) (V); Pulse Width		
	(Atrial and RV) (ms); Hysteresis R	ate (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/VREF	Off; Low; Medium; High			
	, , , ,	s of 25; 450 to 200 in increments of 10)		
Ventricular AutoCapture™	On; Off	, 100 to 200 morements of 10)		
Pacing System	, •			
ACap [™] Confirm	On; Monitor; Off			
noap oonnin	5.1, monitor, orr			

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Fortify[™] ST VR

Single-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
- The Sense*Ability*[™] feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD1235-40	73 x 40 x 14	76	35	DF1	IS-1
CD1235-40Q	71 x 40 x 14	75	35	DF4	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:

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, arrytythmia acceleration, cardiage or venous perforation, cardiagenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation,

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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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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 adverse events.



Fortify[™] ST VR Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS					
Models	CD1235-40	CD1235-40Q			
Telemetry	RF	RF			
Delivered/Stored Energy (J)	40/45	40/45			
Volume (cc)	35	35			
Weight (g)	76	75			
Size (mm)	73 x 40 x 14	71 x 40 x 14			
Defibrillation Lead Connections	DF1	DF4			
Sense/Pace Lead Connections	IS-1	DF4			
High-Voltage Can	Electrically active titanium can	Electrically active titanium can			
PARAMETERS	SETTINGS				
Sensing/Detection					
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adju	stment for atrial and ventricular events			
Low Frequency Attenuation	On; Off				
Threshold Start	(Post-Sensed; Ventricular) 50; 62	,5; 75; 100%;			
	(Post-Paced; Ventricular) Auto; 0,	2-3,0 mV			
Decay Delay	(Post-Sense/Post-Pace; Ventricul	ar) 0-220			
Ventricular Sense Refractory (ms)	125; 157				
Detection Zones	VT-1; VT-2; VF				
SVT Discriminators	Sudden Onset; Interval Stability; I	Norphology Discrimination (MD)			
	with Manual or Automatic Template Update				
Reconfirmation	Continuous sensing during charging				
Antitachycardia Pacing Therapy					
ATP Configurations	Ramp; Burst; Scan; 1 or 2 scheme	s per VT zone			
ATP in VF Zone	ATP While Charging; ATP Prior to C	harging; Off			
ATP Upper Rate Cutoff	150 - 300 bpm				
Burst Cycle Length	Adaptive; Readaptive or Fixed				
Min. Burst Cycle Length (ms)	150-400 in increments of 5				
Number of Bursts	1-15				
Number of Stimuli	2-20				
Add Stimuli per Burst	On; Off				
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia	and Post-Therapy Pacing			
ATP Pulse Width (ms)	1,0 or 1,5 Independently programm	nable from Bradycardia			
	and Post-Therapy Pacing				
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	VVI(R); Pacer Off				
Temporary Modes	Off; VVI; VOO				
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Ventricul	ar) 0-220			
Programmable		(min ⁻¹); Maximum Sensor Rate (min ⁻¹);			
Rate and Delay Parameters					
,	Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min ⁻¹);				

Rate Hysteresis with Search

On; Off

Post-Shock Pacing Mode	Off; VVI			
Post-Shock Base Rate (min-1)	30-100 in increments of 5			
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 7,5; or 10			
Device Testing/Induction Methods				
DC Fibber™ Pulse Duration (sec)	0,5-5,0			
Burst Fibber Cycle Length (ms)	20-100			
Noninvasive Programmed	2-25 stimuli with up to three extrastimuli			
Stimulation (NIPS)				
Patient Notifiers				
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;			
	Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; % V pacing; CorVue Congestion Trigger			
Device Parameter Reset	On			
Entry into Backup VVI Mode	On			
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16			
Number of Vibrations per Notification	2, 4, 6, 6, 10, 12, 14, 16			
Number of Notifications	1-16			
Time Between Notifications (hours)	10; 22			
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; PC shock delivery; noise reversion; magnet reversion			
	and morphology template verification			
Therapy Summary	Diagram of therapies delivered			
Episodes Summary	Directory listing of up to 60 episodes with access to more details includin stored electrograms			
Lifetime Diagnostics	History of bradycardia events and device-initiated charging			
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data			
Histograms	Event Histogram; Ventricular Heart Rate Histogram;			
	Exercise and Activity Trending			
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded batter			
	voltage; and signal amplitudes			
07.14 IL I	ST Histogram Data; ST Deviation Trend; ST Episode Log			
ST Monitoring CorVue™ Congestion Monitoring	On; Off			

*QHR is a trademark of Greatbatch, LTD.

Customer Support: 46-8-474-4756

Ventricular AutoCapture™

Pacing System

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Fortify[™] DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- 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 Sense*Ability*[™] feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Ventricular Intrinsic Preference (VIP[™]) algorithm automatically searches for intrinsic conduction

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector Defibrillation	Connector Sense/Pace
CD2233-40	74 x 40 x 14	76	35	DF1	IS-1
CD2233-40Q	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:

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, arrytythmia acceleration, cardiage or venous perforation, cardiagenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation,

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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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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 adverse events.



Fortify[™] DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS			Post-Therapy Pacing (Independent	ly programmable from Bradycardia and ATP)
Models	CD2233-40	CD2233-40Q	Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Telemetry	RF	RF	Post-Shock Base Rate (min ⁻¹)	30-100 in increments of 5
Delivered/Stored Energy (J)	40/45	40/45	Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Volume (cc)	35	35	Device Testing/Induction Methods	
Weight (g)	76 74 x 40 x 14	75 71 x 40 x 14		
Size (mm) Defibrillation Lead Connections	DF1	DF4	DC Fibber™ Pulse Duration (sec)	0,5-5,0
Sense/Pace Lead Connections	IS-1	DF4	Burst Fibber Cycle Length (ms)	20-100
High-Voltage Can	Electrically active titanium can	Electrically active titanium can	Noninvasive Programmed Stimulation (NIPS)	2-25 stimuli with up to three extrastimuli
0		···· , ··· , ··· · · · · · · · · · · ·		
PARAMETER	SETTINGS		Patient Notifiers	
AF Management			Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;
AF Suppression™ Pacing	On; Off			Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out
No. of Overdrive Pacing Cycles	15-40 in steps of 5			of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden;
Maximum AF Suppression Rate	80-150 min ⁻¹		Device Parameter Reset	V Rate During AT/AF; % V pacing; CorVue Congestion Trigger
Sensing/Detection			Entry into Backup VVI Mode	On On
			Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adjust	stment for atrial and ventricular events	Number of Vibrations per Notification	
Low Frequency Attenuation Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75;	100%	Number of Notifications	1-16
Theshold Start	(Post-Paced; Atrial) 0,2-3,0 mV;	, 100 %;	Time Between Notifications (hours)	10; 22
	(Post-Sensed; Ventricular) 50; 62,	5.75.100%.	Electrograms and Diagnostics	
	(Post-Paced; Ventricular) Auto; 0,2			The first off states that the state of the s
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ven		Stored Electrograms	Up to 45 minutes including up to one minute programmable pre-trigger
Ventricular Sense Refractory (ms)	125; 157			data per VT/VF diagnosis/detection electrograms; triggers include
Detection Zones	VT-1; VT-2; VF			diagnosis; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; and morphology template verification
SVT Discriminators	AV Rate Branch; Sudden Onset; Int		Therapy Summary	Diagram of therapies delivered
	Discrimination (MD) with Manual o		Episodes Summary	Directory listing of up to 60 episodes with access to more details including
Reconfirmation	Continuous sensing during chargin	g		stored electrograms
Antitachycardia Pacing Therapy			Lifetime Diagnostics	History of bradycardia events and device-initiated charging
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes	s per VT zone	AT/AF Burden Trend	Trend data and counts
ATP in VF Zone	ATP While Charging; ATP Prior to Cl		Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
ATP Upper Rate Cutoff	150 - 300 bpm		Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;
Burst Cycle Length	Adaptive; Readaptive or Fixed			Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular
Min. Burst Cycle Length (ms)	150-400 in increments of 5			Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;
Number of Bursts	1-15		PMT Data	V Rates during AMS
Number of Stimuli	2-20		Real-Time Measurements (RTM)	Information regarding PMT detections Pacing lead impedances; high-voltage lead impedances; unloaded battery
Add Stimuli per Burst	On; Off		Real-Time weasurements (RTW)	voltage; and signal amplitudes
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia		CorVue [™] Congestion Monitoring	On; Off
ATP Pulse Width (ms)	1,0 or 1,5 Independently programm and Post-Therapy Pacing		CorVue Congestion Trigger	8-18 days
High-Voltage Therapy	and rost-merapy racing		0.00	
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt		*QHR is a trademark of Greatbatch, L	TD.
Waveform	Biphasic; Monophasic			
RV Polarity Electrode Configuration	Cathode (-); Anode (+) RV to Can; RV to SVC/Can			
-	NV 10 Gall; NV 10 3VG/Gall			
Bradycardia Pacing				
Permanent Modes	DDD(R); DDI(R); VVI(R); AAI(R); P	acer Off		
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO;			
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Atrial/Ven			
Programmable Rate and		min ⁻¹); Maximum Tracking Rate (min ⁻¹);		
Delay Parameters		ed AV Delay (ms); Sensed AV Delay (ms);		
		mplitude (Atrial; RV) (V); Pulse Width		
ΩuickΩnt™ Timing Cuelo Ontimication		ate (min ⁻¹); Rate Hysteresis with Search		
QuickOpt™ Timing Cycle Optimisation 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/VREF	Off; Low; Medium; High			
) Off; 50-200 (50-150 in increments	of 25; 160-200 in increments of 10)		
Ventricular AutoCapture™	On; Off			
Pacing System				
ACap™ Confirm	On; Monitor; Off			

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Fortify[™] VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- 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
- The Sense*Ability*[™] feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more



Merlin@home[™] 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
CD1233-40	73 x 40 x 14	76	35	DF1	IS-1
CD1233-40Q	71 x 40 x 14	75	35	DF4	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:

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, cardiagenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation,

Customer Support: 46-8-474-4756

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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 adverse events.



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

Off; VVI

30-100 in increments of 5

Off; 0,5; 1; 2,5; 7,5; or 10

Post-Shock Pacing Mode

Post-Shock Base Rate (min-1)

Post-Shock Pacing Duration (min)

Fortify[™] VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	CD1233-40	CD1233-40Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	73 x 40 x 14	71 x 40 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

SETTINGS

PARAMETERS Sensing/Detection

Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adjustment for ventricular events
, ,,	
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%;
	(Post-Paced; Ventricular) Auto; 0,2-3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	VT-1; VT-2; VF
SVT Discriminators	Sudden Onset, Interval Stability; Morphology Discrimination (MD) with
	Manual or Automatic Template Update
Reconfirmation	Continuous sensing during charging

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

150 - 300 bpm

1-15

2-20

On; Off

. Adaptive; Readaptive or Fixed

150-400 in increments of 5

and Post-Therapy Pacing

Fixed Pulse Width; Fixed Tilt

RV to Can; RV to SVC/Can

Biphasic; Monophasic Cathode (-); Anode (+)

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 Waveform **RV** Polarity Electrode Configuration

Bradycardia Pacing

Permanent Modes VVI(R): Pacer Off Off: VVI: VOO Temporary Modes Rate-Adaptive Sensor (Post-Sense/Post-Pace; Ventricular) 0-220 Programmable Off; Base Rate (min⁻¹); Rest Rate (min⁻¹); Maximum Sensor Rate (min⁻¹); Rate Parameters Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min-1); Rate Hysteresis with Search Ventricular AutoCapture™ On; Off Pacing System

Device Testing/Induction Methods DC Fibber[™] Pulse Duration (sec) 0.5-5.0 Burst Fibber Cycle Length (ms) 20-100 Noninvasive Programmed 2-25 stimuli with up to three extrastimuli Stimulation (NIPS) **Patient Notifiers** Programmable Notifiers (On: Off) Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; %V pacing; CorVue™ Congestion Trigger Device Parameter Reset 0n Entry into Backup VVI Mode On Vibration Duration (sec) 2; 4; 6; 8; 10; 12; 14; 16 Number of Vibrations per Notification 2 1-16 Number of Notifications Time Between Notifications (hours) 10; 22 **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; PC shock delivery; noise reversion; magnet reversion; and morphology template verification 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 Ventricular HV Lead Impedance Trend Multi-Vector Trend Data Histograms Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending Real-Time Measurements (RTM) Pacing lead impedances; high-voltage lead impedances; unloaded battery voltage; and signal amplitudes ST Monitoring ST Histogram Data; ST Deviation Trend; and ST Episode Log CorVue[™] Congestion Monitoring On: Off CorVue Congestion Trigger 8-18 days

ST. JUDE MEDICAL

More control. Less risk

*QHR is a trademark of Greatbatch, LTD.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binef Summary: Prior to using these devices, please review the instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Current Accel[™] DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- AutoCaptureTM Pacing System offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-BeatTM capture confirmation. The AutoCaptureTM Pacing System automatically delivers a 5,0 V backup safety pulse when noncapture is detected, and it may be programmed to either a bipolar or unipolar configuration
- ACapTM Confirm Pacing System periodically completes a threshold search and automatically adjusts amplitude to address patients' changing atrial thresholds
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- The Sense*Ability*TM feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety



Merlin@home™ 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
CD2215-36	77 x 50 x14	80	42	DF1	IS-1
CD2215-36Q	74 x 50 x 14	80	41	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: 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 includem ortality 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 adverse events.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.



Current Accel[™] DR Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

Models CD2215-58 CD2215-58 Post-Shock Pacing Mode Off. AAI: VVI; DDI, DDD Deliverac/Stroed Energy (1) 36/42 36/42 Post-Shock Pacing Mode Off. AAI: VVI; DDI, DDD Volume (cc) 42 41 Post-Shock Pacing Mode Off. AAI: VVI; DDI, DDD Volume (cc) 42 41 Post-Shock Pacing Mode Off. AAI: VVI; DDI, DDD Stee (mm) 77.50 x 14 DEvice Testing/Induction Methods Device Testing/Induction Methods Stee (mm) 77.50 x 14 DFA Burt Fibber Cycle Langth (ms) 20.100 Stars/Pace Lead Connections IS-1 Noninsvalve Porgrammed 2.25 stimuli with up to 3 extrastimuli High-Voltage Can Electrically active titanium can Electrically active titanium can Programmed 2.25 stimuli with up to 3 extrastimuli Ar Management	IYSICAL SPECIFICATIONS			Post-Therany Pacing (independent)	ly programmable from Bradycardia and ATP)
Jene etc. J.	odels lemetry	RF	RF	Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Weight (g) 80 80 Device Full grandical Methods Sign (mm) 77.50 140 74.50 1 74.50 1 20.100 Sign (mm) 77.50 140 74.50 1 20.100 20.100 Sign (mm) 7.50 140 74.50 1 20.100 20.100 Sign (mm) 5.1 Sign (mm) 20.50 minus (mm)					
Size (main) 7 x 30 x 14 7 x 30 x 14 0 x 30 x 14 Def Tabler Value (and the content) F1 Def Tabler Value (and the content) 0 x 30 x 14 Setes Pace (and Content) Si 1 Si 1 Si 14 Si 14 Setes Pace (and Content) Si 1 Si 1 Si 14 Manipace (and the content) Si 14 Setes Pace (and Content) Si 14 Si 14 Si 14 Si 14 Si 14 Setes Pace (and Content) Si 14 Si 14 <td< td=""><td></td><td></td><td></td><td>Device Testing/Induction Methods</td><td></td></td<>				Device Testing/Induction Methods	
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AF Management Programmable Notifiers (0n, 011) Noteward ER (1, change Time Lumit Reached, Possible W7 Center Management Pacing Option Programmable Notifiers (0n, 011) Noteward ER (1, change Time Lumit Reached, Possible W7 Center Management Assuppression Rate Programmable Notifiers (0n, 011) Noteward ER (1, change Time Lumit Reached, Possible W7 Center Management Assuppression Rate Programmable Notifiers (0n, 011) Noteward ER (1, change Time Lumit Reached, Possible W7 Center Management Assuppression Rate Programmable Notifiers (0n, 011) Stass.Adving V1 Mode Management Assuppression Rate Automatic Sensibility Control adjustment for atrial and ventricular events (Pars-Paceed, Atrial) 02-3,0 mV (Pars-Paced, Atrial) 02-3,0 mV (Pars-Paced, Particular) 0-220 Noteward ER (1, Varstan) 02-10 2 Ventricular Sames Retractory (ma) 25,157 Store Electrograms and Diagnostics 0,72 SVI Discriminators V1 / 1-2 vF (Pars-Paced, Varticular) 0-220 Wat Hoat management Singer Sin	DAMETED	SETTINGS		Patient Notifiers	
Ar July Field State Washing Matching Cycles State		1321111103		Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;
Saming Characterion On Sense Addity ¹⁰ Technology Automatic Sensitivity Control adjustment for atrial and ventricular events (Post-Sensed, Atrial) 05, 62, 57, 51, 00%; (Post-Sensed, Ventricular) 05, 62, 57, 52, 57, 50, 50%; (Post-Sensed, Ventricular) 05, 62, 57, 50, 50%;	o. of Overdrive Pacing Cycles	15-40 in steps of 5		Davies Decemeter Decot	
SenseAbily? Technology Automatic Sensitivity Control adjustment for atrial and ventricular events Vinitarion Durarios (ec) 2:4, 6; 8; 10; 12; 14; 16 Vinitarion Durarios (ec) 2:4, 6; 8; 10; 12; 14; 16 Vinitarion Durarios (ec) 10 Presended Start (Post-Sensed, Atrial) 50; 62, 5; 75; 100%; (Post-Peed, Ventricular) 50; 62, 5; 75; 100%; (Post-Peed, Ventricular) 40; 62, 25, 75; 100%; (Post-Peed, Ventricular) 40; 62, 25, 75; 100%; (Post-Peed, Ventricular) 40; 62, 23, 70; 100%; (Post-Peed, Ventricular) 40; 62, 23, 70; 100%; (Post-Sensed/Post-Peed, Ventricular) 0-220 Vinitarion Durarios (ec) 2:4, 6; 8; 10; 12; 14; 16 Vinitarion Durarios (ec) 2:4, 6; 8; 10; 12; 14; 16 Number of Vinitarios (ec) 10 Decay Delay (Post-Sensed/Post-Peed, Atrial) 40; 0:23 10 10; 22 Detection Zones V1-1; VT-2; VF data per VT/V diagonsis/ detection electrograms, trigges in diagonsis; therapy, atrial elposide, PM termination, PC shade noise reversion; majent reversion; and ner phology Discrement therapies delivered indigeness is therapy, atrial elposide, PM termination, PC shade noise reversion; majent reversion; and ner phology AP Configurations Ramp, Burst; Scan; 1 or 2 schemes per VT zone Lifetime Diagnostic Histogram, XM terval Ram, Moles and Counts AP Configurations Ramp, Burst; Scan; 1 or 2 schemes per VT zone Lifetime Diagnostic Histogram, XM terval Ram, Molescand counts AP Configuration <td>nsing/Detection</td> <td></td> <td></td> <td></td> <td></td>	nsing/Detection				
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(Past-Bacel, Arrial) Q.2-3 0 mV, (Past-Bacel, Ventricular) 50; 62; 57; 100%; (Past-Bacel, Ventricular) 50; 62; 57; 100%; (Past-Bacel, Ventricular) 40: 0, 2-3, 0 mV Number of Netricular) 50; 62; 57; 100%; (Past-Bacel, Ventricular) 6-220 Electrograms and Diagnostics Decay Delay (Past-Bacel, Ventricular) 6-220, 0 mV Electrograms and Diagnostics Up to 45 minutes including up to 1 minute programmable programmable programmable programs, triggers in diagnosis, therapy, atrial elpidode, PM Termination, PC show Discrimination Up to 45 minutes including up to 1 minute programmable programs, triggers in diagnosis, therapy, atrial elpidode, PM Termination, PC show Discrimination (MD) with Manual or Automatic Template Update Discrimination (MD) with Manual or Automatic Template Update Bard Copie Length Min. Bart Cipel Length Min. Bart Minus Minus Minus M					
(Past-Sensel, Ventricular) 50; 62; 57; 51:00%; (Past-Sensel, Ventricular) 50; 62; 57; 51:00%; (Past-Sensel, Ventricular) 0.2-30, mV Imme Betterwonk unditications (fours) 10; 22 Decay Delay (Past-Sensel, Ventricular) 0.2-30, mV Electrograms and Diagnostics Electrograms and Diagnostics Ventricular) 50: 57 Decay Intervention Up to 45 minutes including up to 1 minute programmable pre- diagnosis/detection electrograms. Triggers in diagnosis, therapy. string biology. MIT Annual on Automatic Template Update Discrimination (MUM) with Manual on Automatic Template Update Autitachycardia Pacing Therapy Up to 45 minutes including up to 1 minute programmable pre- stored dectograms. Triggers in diagnostics. Antitachycardia Pacing Therapy Diagram of therapise delectrograms. Trend y Summary Diagram of therapise delectrograms. Antitachycardia Pacing Therapy Antitachycardia Pacing Therapy Summary Directory listing of up to 60 episodes with access to more det. Stored dectograms Antitachycardia Pacing Therapy Antitachycardia Auto pacing therapy Pacing AlfAF Burden Trend Pacing Here Rate Histogram. Wold Switch Duration Histograms Histograms Histograms Alf Palsed Amplituding or Burst 0:n; 0f. 1:0; 0:1; 0:1; 0:0; 0:0; 0:0; 0:0; 0:0;			5, 100,00,	Number of Notifications	1-16
(Past-Peace), Ventricular Auto, 0.2-3,0 mV Electrograms and Diagnostics Decay Delay (Post-Sense/Post-Pace, Atrial/Ventricular) 0-220 Withicular Sense Refractory (ms) 125; 157 Attractory US; 157 Attractory Discriminators VR ate Branch, Sudden Onset, Interval Stability, Morphology Discriminators Discrimination (MD) with Manual or Automatic Template Update Treapy Summary Reconfirmation Continuous sensing during charging Treapy Summary Discriminators Ramp: Burst; Scan, 1 or 2 schemes per VT zone Burst Cycle Length Molative, Pleadaptive or Tixed Madaptive, Readaptive or Tixed Multi-Vector Tend data and counts Struct Schele Length Adaptive, Readaptive or Tixed Multi-Vector Tend data and counts Mine Burst Cycle Length Adaptive, Readaptive or Tixed Multi-Vector Tend data and counts Mine Burst Cycle Length Adaptive, Readaptive or Tixed Multi-Vector Tend data and counts Mine Burst Cycle Length Cycle Length Constructure on the cycle Schemes per VT zone Multi-Vector Tend data and counts Mine Burst Cycle Length On; Off The cycle Schemes per VIC and Heat Rate Histogram, Atrial Heat Rate Histogram, Atrial Heat Rate Histogram, Atria Heat Rate Histogram, Atrial Heat Rate Histog			2,5; 75; 100%;	Time Between Notifications (hours)	10; 22
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Auto PMT Detection/Termination Atrial Pace; Off; Passive Rate Responsive PVARP/VREF Off; Low; Medium; High					
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Ventoular inclusion relevance (m - y on; su-zuo (su-zuo in inclements of zu; sub-zuo in inclements of ru). Ventoular inclusione		5, 50 200 (50 150 m morellicits	5 5. 25, 100 200 m molementa 01 10)		
Venicular Auto-aprice Pacing System On; Off		On: Off			
ACap [™] Confirm On; Monitor; Off	∂ap™ Confirm	On; Monitor; Off			

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Current Accel[™] VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- ACapTM Confirm Pacing System periodically completes a threshold search and automatically adjusts amplitude to address patients' changing atrial thresholds
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- The Sense*Ability*TM feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety



Merlin@home™ 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
CD1215-36	76 x 50 x14	79	42	DF1	IS-1
CD1215-36Q	74 x 50 x 14	79	41	DF4	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: 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,

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

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 adverse events.



Current Accel[™] VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

Models	CD1215-36	CD1215-36Q
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/42	36/42
Volume (cc)	42	41
Weight (g)	79	79
Size (mm)	76 x 50 x 14	74 x 50 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can
PARAMETERS	SETTINGS	

Sensing/Detection	
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Threshold Start	(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
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220
Ventricular Sense Refractory (ms)	125; 157
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
Reconfirmation	Continuous sensing during charging
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 5
Number of Bursts	1-15
Number of Stimuli	2-20
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently programmable from Bradycardia
	and Post-Therapy Pacing
High-Voltage Therapy	
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic

Device Testing/Induction Methods

DC Fibber [™] Pulse Duration (sec) Burst Fibber Cycle Length (ms) Noninvasive Programmed Stimulation (NIPS)	0,5-5,0 20-100 2-25 stimuli with up to 3 extrastimuli		
Patient Notifiers			
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; Backup VVI; Long AT/AF Episode		
Device Parameter Reset	On		
Entry into Backup VVI Mode	On		
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16		
Number of Vibrations per Notification	2		
Number of Notifications	1-16		
Time Between Notifications (hours)	10;22		
Electrograms and Diagnostics			
Stored Electrograms	Up to 45 minutes including up to 1 minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; therapy; PC shock delivery; noise reversion; magnet reversion; and morphology template verification		
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		
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data		
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending		
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded battery		

voltage; and signal amplitudes

Waveform **RV** Polarity Electrode Configuration

Bradycardia Pacing

Permanent Modes	Off; VVI(R); VOO(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate Parameters	Off; Base Rate (min ⁻¹); Rest Rate (min ⁻¹); Maximum Sensor Rate (min ⁻¹);
	Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min ⁻¹);
	Rate Hysteresis with Search

or 10

Cathode (-); Anode (+) RV to Can; RV to SVC/Can

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

Post-Shock Pacing Mode	Off; VVI
Post-Shock Base Rate (min ⁻¹)	30-100 in increme
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5;

ost-Shock Pacing Mode	Off; VVI
ost-Shock Base Rate (min ⁻¹)	30-100 in increments of 5
ost-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10

Customer Support: 46-8-474-4756

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. 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 one 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.



Current[™]+ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- Triple redundancy safety platform is designed to minimise risk and increase security and patient comfort through multiple hardware and software system safeguards
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- The Sense*Ability*[™] feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety



Merlin@home™ 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
CD2211-36	77 x 50 x14	80	42	DF1	IS-1
CD2211-36Q	74 x 50 x 14	80	41	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: 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 adverse events.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.



Current[™]+ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS			Post-Therapy Pacing (independent)	y programmable from Bradycardia and ATP)
Models	CD2211-36	CD2211-36Q	Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Telemetry	RF 36/42	RF	Post-Shock Base Rate (min-1)	30-100 in increments of 5
Delivered/Stored Energy (J) Volume (cc)	42	36/42 41	Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Weight (g)	42 80	80	Device Testing/Induction Methods	
Size (mm)	77 x 50 x 14	74 x 50 x 14		
Defibrillation Lead Connections	DF1	DF4	DC Fibber™ Pulse Duration (sec)	0,5-5,0 20-100
Sense/Pace Lead Connections	IS-1	DF4	Burst Fibber Cycle Length (ms) Noninvasive Programmed	20-100 2-25 stimuli with up to 3 extrastimuli
High-Voltage Can	Electrically active titanium can	Electrically active titanium can	Stimulation (NIPS)	2-23 stilluli with up to 5 extrastilluli
PARAMETER	SETTINGS		Patient Notifiers	
AF Management			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
AF Suppression [™] Pacing	On; Off			of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden;
No. of Overdrive Pacing Cycles	15-40 in steps of 5			V Rate During AT/AF; Backup VVI; Long AT/AF Episode
Maximum AF Suppression Rate	80-150 min ⁻¹		Device Parameter Reset	On
Sensing/Detection			Entry into Backup VVI Mode	On
		and the state of the state of the state	Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Sense <i>Ability</i> ™ Technology		stment for atrial and ventricular events	Number of Vibrations per Notification	
Low Frequency Attenuation Threshold Start	On; Off	100%	Number of Notifications	1-16
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75	; 100%;	Time Between Notifications (hours)	10: 22
	(Post-Paced; Atrial) 0,2-3,0 mV; (Post-Sensed; Ventricular) 50; 62,	5. 75. 100%.	Electrograms and Diagnostics	
	(Post-Paced; Ventricular) 30; 02, (Post-Paced; Ventricular) Auto; 0,3			
Decay Delay	(Post-Sensed/Post-Paced; Atrial/		Stored Electrograms	Up to 45 minutes including up to 1 minute programmable pre-trigger
	(Post-Paced Ventricular) Auto	,		data per VT/VF diagnosis/detection electrograms; triggers include:
Ventricular Sense Refractory (ms)	125; 157			diagnosis; therapy; atrial episode; PMT termination; PC shock delivery;
Detection Zones	VT-1; VT-2; VF		The O	noise reversion; magnet reversion; and morphology template verification
SVT Discriminators	AV Rate Branch; Sudden Onset; Int	terval Stability; Morphology	Therapy Summary	Diagram of therapies delivered
	Discrimination (MD) with Manual of	or Automatic Template Update	Episodes Summary	Directory listing of up to 60 episodes with access to more details including
Reconfirmation	Continuous sensing during chargir	ng	Lifetime Diagnostics	stored electrograms History of bradycardia events and device-initiated charging
Antitachycardia Pacing Therapy			AT/AF Burden Trend	Trend data and counts
ATP Configurations	Romp Burat Soon 1 or 2 ophome	o por VT zopo	Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
ATP Configurations Burst Cycle Length	Ramp; Burst; Scan; 1 or 2 scheme Adaptive; Readaptive or Fixed	is per vi zone	Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram;
Min. Burst Cycle Length (ms)	150-400 in increments of 5			Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular
Number of Bursts				Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending;
Number of Stimuli	2-20			V Rates during AMS
Add Stimuli per Burst	0n: Off		PMT Data	Information regarding PMT detections
High-Voltage Therapy			Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded batter
				voltage; and signal amplitudes
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); DOO(R); VVI(R);	V00(R); AAI(R); A00(R)		
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; AAT(R); D00; V00; A00		
Rate-Adaptive Sensor	On; Off; Passive			
Programmable Rate and		(min ⁻¹); Maximum Tracking Rate (min ⁻¹);		
Delay Parameters		ced AV Delay (ms); Sensed AV Delay (ms);		
		mplitude (Atrial; RV) (V); Pulse Width		
		ate (min ⁻¹); Rate Hysteresis with Search		
QuickOpt [™] Timing Cycle Optimisation	,			
Auto Mode Switch (AMS)	DDD(R); DDI(R); DOO(R); VVI(R);	V00(R); AAI(R); A00(R)		
Atrial Tachycardia Detection Rate (min-1)				
AMS Base Rate (min-1)	40; 45;135			
Auto PMT Detection/Termination	Atrial Pace; Off; Passive			
Rate Responsive PVARP/VREF	Off; Low; Medium; High			
Ventricular Intrinsic Preference (VIP™) 011; 50-200 (50-150 in increments	s of 20; 160-200 in increments of 10)		

Customer Support: 46-8-474-4756

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Item GMCRM781EN

Current[™]+ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- Triple redundancy safety platform is designed to minimise risk and increase security and patient comfort through multiple hardware and software system safeguards
- Vibratory patient notifier enables patients with hearing problems to be alerted to a low battery, lead-related complications and more
- DeFT Response[™] technology offers the most noninvasive options for managing high DFTs
- The Sense*Ability*[™] feature provides the flexibility to fine-tune programming around T-wave oversensing without decreasing sensitivity
- Automatic daily high-voltage lead integrity test is designed to ensure optimal patient safety



Merlin@home™ 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
CD1211-36	76 x 50 x 14	79	42	DF1	IS-1
CD1211-36Q	74 x 50 x 14	79	41	DF4	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: 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, erosino, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax,

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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. Shutting 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 adverse events.



Current[™]+ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS			Patient Notifie	
Models	CD1211-36	CD1211-36Q	Programmable	
Telemetry	RF	RF		
Delivered/Stored Energy (J)	36/42	36/42		
Volume (cc)	42	41	Device Parame	
Weight (g)	79	79	Entry into Back	
Size (mm)	76 x 50 x 14	74 x 50 x 14	Vibration Durat	
Defibrillation Lead Connections	DF1	DF4	Number of Vibr	
Sense/Pace Lead Connections	IS-1	DF4	Number of Noti	
High-Voltage Can	Electrically active titanium can	Electrically active titanium can	Time Between	
PARAMETERS	SETTINGS		Electrograms	
Sensing/Detection			Stored Electro	
Sense <i>Ability</i> ™ Technology	Automatic Sensitivity Control adju	istment for ventricular events		
Threshold Start	(Post-Sensed; Ventricular) 50; 62	,5; 75; 100%;		
	(Post-Paced, Ventricular) Auto; 0,	2-3,0 mV		
Decay Delay	(Post-Sensed/Post-Paced; Ventri	cular) 0-220;	Therapy Summ	
	(Post-Paced Ventricular) Auto		Episodes Sumr	
Ventricular Sense Refractory (ms)	125; 157			
Detection Zones	VT-1; VT-2; VF		Lifetime Diagno	
SVT Discriminators	Sudden Onset; Interval Stability; I	Morphology Discrimination (MD) with	Ventricular HV	
	Manual or Automatic Template Up	date	Histograms	
Reconfirmation	Continuous sensing during chargi	Real-Time Mea		
Antitachycardia Pacing Therapy				
ATP Configurations	Ramp; Burst; Scan; 1 or 2 scheme	es per VT zone		
Burst Cycle Length	Adaptive; Readaptive or Fixed			
Min. Burst Cycle Length (ms)	150-400 in increments of 5			
Number of Bursts	1-15			
Number of Stimuli	2-20			
Add Stimuli per Burst	On; Off			
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	Off; VVI(R); VOO(R)			
Temporary Modes	Off; VVI; VOO			
Rate-Adaptive Sensor	On; Off; Passive			
Programmable Rate Parameters		(min ⁻¹); Maximum Sensor Rate (min ⁻¹);		
	Pulse Amplitude (RV) (V); Pulse W Rate Hysteresis with Search	/idth (RV) (ms); Hysteresis Rate (min ⁻¹);		
Post-Therapy Pacing (independen		ia and ATP)		
Post-Shock Pacing Mode	Off; VVI			
Post-Shock Pacing Mode Post-Shock Base Rate (min ⁻¹)	Off; VVI 30-100 in increments of 5			

Device Testing/Induction Methods

0,5-5,0
20-100
2-25 stimuli with up to 3 extrastimuli

Patient Notifiers

Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage;		
	Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance		
	Out of Range; Backup VVI; Long AT/AF Episode		
Device Parameter Reset	On		
Entry into Backup VVI Mode	On		
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16		
Number of Vibrations per Notification	2		
Number of Notifications	1-16		
Time Between Notifications (hours)	10; 22		
Electrograms and Diagnostics			
Stored Electrograms	Up to 45 minutes including up to 1 minute programmable pre-trigger		
	data per VT/VF diagnosis/detection electrograms; triggers include:		
	diagnosis thereasy DC shock delivery paiss reversion magnet reversion		

	data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; therapy; PC shock delivery; noise reversion; magnet reversion; and morphology template verification
erapy Summary	Diagram of therapies delivered
visodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
fetime Diagnostics	History of bradycardia events and device-initiated charging
ntricular HV Lead Impedance Trend	Multi-Vector Trend Data
stograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending
al-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded battery voltage; and signal amplitudes

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



DEFIBRILLATION LEADS

St. Jude Medical Defibrillation Leads

St. Jude Medical defibrillation leads have been designed to provide the highest level of safety.

All of our defibrillation leads feature Optim[™] insulation, which enables an abrasion-resistant, thin-diameter lead. Additional design features help prevent tissue ingrowth, and redundant conductors provide an added measure of security.



Defibrillation Leads

Durata[™] Defibrillation Lead

Product Highlights

- The DF4 connector is designed to simplify implants by streamlining defibrillation connections into a single terminal pin and reducing the number of set screws
- 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
- Optim[™] lead insulation a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Two innovative designs are intended to help prevent tissue ingrowth flatwire technology provides a low profile for the defibrillation coils, and silicone backfilling completely fills the shock coil space



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
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	N/A	DF1; IS-1	60; 65; 75
7122Q	Optim	Ext/Ret Helix	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65
7170	Optim	Tines	7	Dual-coil	True bipolar	17	DF1; IS-1	60; 65; 75
7170Q	Optim	Tines	7	Dual-coil	True bipolar	17	DF4	52; 58; 65
7171	Optim	Tines	7	Dual-coil	True bipolar	21	DF1; IS-1	60; 65; 75
7171Q	Optim	Tines	7	Dual-coil	True bipolar	21	DF4	52; 58; 65
7172Q	Optim	Tines	7	Single-coil	True bipolar	N/A	DF4	52; 58; 65

Indications for Use: The Durata[™] Models 7120, 71200, 7121, 71210, 7122, 71220, 7170, 71700, 7171, 71710 and 71720 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. A transvenous lead system may offer the patient the benefit of avoiding a thoracotomy for lead implantation. If the initial lead configuration is not effective, repositioning of the lead or other lead configurations should be attempted. In some patients, a nonthoracotomy lead configuration may not provide reliable conversion of arrhythmias, and the use of subcutaneous or epicardial patch defibrillation leads should be considered.

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 1202, 7120, 7120, 7120, 7171, 71710, and 71720 leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.

Customer Support: 46-8-474-4756

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

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, mycoarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, henothorax, infection, tissue necrosis and erosion of the skin. Specific events and effects are summarised below:

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.

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



Durata™ **Defibrillation Lead**

Product Specifications PHYSICAL SPECIFICATIONS

True Bipolar, Active-Fixation Defibrillation Leads

Models	7120	7120Q	7121	7121Q	7122	71220
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Heli
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 Bipola
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	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
True Bipolar, Passive-Fixation D						
		71700	7171	71710	71720	
True Bipolar, Passive-Fixation D Models	efibrillation Leads			7171Q Tines		
True Bipolar, Passive-Fixation D Models Fixation	lefibrillation Leads 7170	7170Q	7171		71720	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration	efibrillation Leads 7170 Tines	7170Q Tines	7171 Tines	Tines	7172Q Tines	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration	efibrillation Leads 7170 Tines Dual-Coil	7170Q Tines Dual-Coil	7171 Tines Dual-Coil	Tines Dual-Coil	71720 Tines Single-Coil	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer	efibrillation Leads 7170 Tines Dual-Coil True Bipolar	71700 Tines Dual-Coil True Bipolar	7171 Tines Dual-Coil True Bipolar	Tines Dual-Coil True Bipolar	71720 Tines Single-Coil True Bipolar	
True Bipolar, Passive-Fixation D	efibrillation Leads 7170 Tines Dual-Coil True Bipolar 7 F	7170Q Tines Dual-Coil True Bipolar 7 F	7171 Tines Dual-Coil True Bipolar 7 F	Tines Dual-Coil True Bipolar 7 F	71720 Tines Single-Coil True Bipolar 7 F	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer Lengths (cm) Connector	efibrillation Leads 7170 Tines Dual-Coil True Bipolar 7 F 60; 65; 75	7170Q Tines Dual-Coil True Bipolar 7 F 52; 58; 65	7171 Tines Dual-Coil True Bipolar 7 F 60; 65; 75	Tines Dual-Coil True Bipolar 7 F 52; 58; 65	7172Q Tines Single-Coil True Bipolar 7 F 52; 58; 65	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer Lengths (cm) Connector Body Diameter	efibrillation Leads 7170 Tines Dual-Coil True Bipolar 7 F 60, 65; 75 DF1; IS-1	71700 Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4	7171 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1	Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4	71720 Tines Single-Coil True Bipolar 7 F 52; 58; 65 DF4	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer Lengths (cm) Connector Body Diameter Tip-to-Anode Spacing	efibrillation Leads 7170 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1 6,8 F	71700 Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F	7171 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1 6,8 F	Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F	71720 Tines Single-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer Lengths (cm) Connector Body Diameter Tip-to-Anode Spacing Tip-to-Proximal Coil	efibrillation Leads 7170 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1 6,8 F 11 mm	71700 Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm	7171 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1 6,8 F 11 mm	Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6.8 F 11 mm	71720 Tines Single-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer Lengths (cm) Connector Body Diameter Tip-to-Anode Spacing Tip-to-Proximal Coil Tip Electrode Area	efibrillation Leads T170 Tines Dual-Coil True Bipolar 7 F 60, 65; 75 DF1; IS-1 6,8 F 11 mm 17 cm	71700 Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm 17 cm	7171 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1 6,8 F 11 mm 21 cm	Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6;8 F 11 mm 21 cm	71720 Tines Single-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm N/A 3.5 mm ² Yes	
True Bipolar, Passive-Fixation D Models Fixation Shock Configuration Sensing Configuration Min. Size Introducer Lengths (cm)	efibrilation Leads 7170 Tines Dual-Coil True Bipolar 7 F 60, 65, 75 DF1; IS-1 6,8 F 11 mm 17 cm 3.5 mm ²	7170Q Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm 17 cm 3.5 mm ²	7171 Tines Dual-Coil True Bipolar 7 F 60; 65; 75 DF1; IS-1 6,8 F 11 mm 21 cm 3.5 mm ²	Tines Dual-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm 21 cm 3.5 mm ²	71720 Tines Single-Coil True Bipolar 7 F 52; 58; 65 DF4 6,8 F 11 mm N/A 3.5 mm ²	

Customer Support: 46-8-474-4756

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. 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 one of its subsidinies. 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.



PACEMAKERS

St. Jude Medical Pacemakers

The most noteworthy characteristics of St. Jude Medical pacemakers include longevity, the avoidance of unnecessary right ventricular stimulation, and extensive automaticity including proven diagnostics. Additionally, our state-of-the-art pacemakers are efficient in that they save time and make it possible for patients to receive optimal therapy. Remote care options provide the possibility of home monitoring and increase patient safety.

More Control.

The MRI conditional pacing system provides full-featured pacing therapy with no zone restrictions and highpower, whole-body imaging allowing for superior quality MRI images. VIP[™] technology prevents unnecessary right ventricular pacing by continually monitoring a patient's rhythm and searching for intrinsic conduction. QuickOpt[™] timing cycle optimisation furthers delivery of right ventricular pacing only when necessary through AV interval optimisation.

Our advanced pacemakers feature individually programmable alerts that inform patients and/or their clinic about critical changes in device performance or arrhythmia status.

Less Risk.

The MRI conditional pacing system provides safe², full-body MRI scans. The AutoCapture[™] pacing system provides ventricular pacing security for every beat while minimising energy use. The ACap[™] confirm algorithm automatically measures the atrial pacing threshold and adapts the pulse amplitude. Together these features offer patient safety and enable quick intervention through a capture trend display.

High-quality, stored IEGM with histograms and trending provide further diagnostic insight.

The combination of automatic daily measurements, capture threshold and lead impedance monitoring offer safety and enable more time for patient care during follow-up. All necessary tests have already been performed before the patient comes to follow-up.

Customer Support: 46-8-474-4756

MRI conditional pacemaker system; an MRI conditional pacing system is conditionally safe for use in the MRI environment when used according to the instructions in this manual. See the St. Jude Medical MRI Procedure information document prior to performing an MRI scan: www.SJMprofessional.com/MRI



Pacemakers

88.1

ST. JUDE MEDICAL

CENT MRI"

PM2224 DDDR

Merlin@home[™]

Transmitter

Compatible

Accent MRI[™] DR

Dual-Chamber Pacemaker with Wireless Telemetry

Product Highlights

- The Accent MRI pacemaker has been designed and tested for safe performance of a full-body MRI scan, without zone restrictions,¹ using a 1,5 T (Tesla) field-strength MRI scanner.¹ The MRI conditional device:
 - Allows a maximum whole body averaged specific absorption rate (SAR) of 4 watts per kilogram (W/kg) for high image resolution
 - Must be used in conjunction with an MRI lead from St. Jude Medical
- An optional, easy-to-use hand-held device (SJM MRI Activator[™] device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency
- InvisiLink[™] wireless telemetry in conjunction with the Merlin@home[™] transmitter and Merlin.net[™] Patient Care Network (PCN), allows for daily remote monitoring and follow-up.
- AT/AF Alerts can be programmed to notify patients and/or their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- A suite of state-of-the-art features—complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP[™]) technology, QuickOpt[™] timing cycle optimisation, the AF Suppression[™] algorithm and SenseAbility[™] technology—is designed to deliver optimal therapy for patients at implant and throughout their lives
- Industry-leading longevity offers 9,1 years of service life,² which is supported by a 7-year warranty³

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2224 (RF)	52 x 53 x 6	24	13,1 (± 0,5)	IS-1

Radiopaque markers

St. Jude Medical identifier



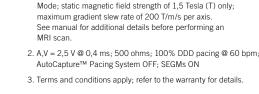
Device MRI symbol

Indications: Implantation of a dual-chamber pulse generator is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. MRI conditional pulse generator is safe for use in the MRI environment when used in a complete MRI conditional pacing system and according to the instructions in the MRI Procedure Information document for the SI. Jude Medical MRI conditional pacing system. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, esvere physical disability. AF Suppression algorithm is indicated for supression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Dual-chamber pulse generators are contraindicated in patients with an implanted cardioverter defibrillator (ICD). Rate-adaptive pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher senso-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. Af Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-chamber pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial

Customer Support: 46-8-474-4756

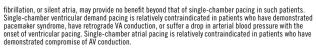
Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical 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 one 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.



1. The St. Jude Medical[™] MRI conditional pacing system

horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating

can be scanned in patients under the following conditions:



Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to batter failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, and phenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, and papitations with high-rate pacing.

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



Accent MRI[™] DR

Dual-Chamber Pacemaker with Wireless Telemetry

Product Specifications

Model	PM2224	Shortest PVARP/VREF (ms) Slope
Telemetry Dimensions (mm)	RF 52 x 53 x 6	
Weight (g) Volume (cc)	24 13,1 ¹	Threshold
Connector	IS-1	AF Management
PARAMETER SETTINGS		AF Suppression™ Algorithm
Rate/Timing		Lower Rate Overdrive (min Upper Rate Overdrive (min
Atrial Pace Refractory (ms)	190-400 in steps of 30; 440; 470 ²	No. of Overdrive Pacing Cy Rate Recovery (ms)
Atrial Sense Refractory (ms) Atrial Protection Interval (ms)	93; 125; 157; 190-400 in steps of 30; 440; 470; 500 ² 125 ³	Maximum AF Suppression Rate (min ⁻¹)
Paced AV Delay (ms) Base Rate (min ⁻¹)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350 30-130 in steps of 5; 140-170 in steps of 10	Atrial Tachycardia
Far-Field Protection Interval (ms)	16 ³	Detection Rate (min ⁻¹) Auto Mode Switch
Hysteresis Rate (min ⁻¹) Search Interval (min)	Off; 30 ⁴ -150 in steps of 5 Off; 1; 5; 10; 15; 30	AMS Base Rate (min ⁻¹)
Cycle Count Intervention Rate (min-1)	1-16 in steps of 1 Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0;	Stored Electrograms
	Intrinsic +10; Intrinsic +20; Intrinsic +30	
Intervention Duration (min) Recovery Time	1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow	Options Priority Options
Maximum Tracking Rate (min ⁻¹) Mode	90-130 in steps of 5; 140-180 in steps of 10 A00(R); AAI(R); AAT(R); V00(R); VVI(R);	Channel Triggers
	VVT(R); VDD(R); DOO(R); DVI(R); DDI(R);	Advanced Hysteresis AMS Entry/AMS Exit/
Post-Ventricular Atrial Blanking (ms)	DDD(R); Pacing Off 60-200 in steps of 10; 225; 250	AMS Entry and Exit
PVARP (ms) Sensed AV Delay (ms)	125-500 in steps of 25 25; 30-200 in steps of 10; 225-325 in steps of 25	AT/AF Detection Magnet Response
Rest Rate (min ⁻¹)	Off; 30-150 in steps of 5	High Atrial Rate Rate (min ⁻¹)
Shortest AV Delay (ms) Ventricular Blanking (ms)	25-50 in steps of 5; 60-120 in steps of 10 Auto; 12-52 in steps of 4	No. of Consecutive Cycle
Ventricular Pace/Sense Refractory ⁵ (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470 ²	High Ventricular Rate Rate (min ⁻¹)
MRI Settings	, , ,,,, ,, ,	No. of Consecutive Cycle PMT Termination
MRI Mode	A00; V00; D00; Pacing Off	Consecutive PVCs
MRI Base Rate	30-120 bpm in steps of 5 bpm	No. of Consecutive PVCs Noise Reversion
MRI Paced AV Delay	25 ms; 30-200 ms in steps of 10 ms; 225-300 ms in steps of 25 ms; 350 ms	Other
MRI Atrial Pulse Configuration MRI Atrial Pulse Amplitude	Bipolar 5,0 V; 7,5 V	A and V Lead Monitoring
MRI Atrial Pulse Width	1,0 ms	A and V Low Impedance Li A and V High Impedance Li
MRI RV Pulse Configuration MRI RV Pulse Amplitude	Bipolar 5,0 V; 7,5 V	Lead Type
MRI RV Pulse Width	1,0 ms	Magnet Response Negative AV Hysteresis Sear
Output/Sensing		NIPS Options Stimulation Chamber
ACap™ Confirm	On; Off; Monitor Bipolar	Coupling Interval (ms)
Primary Pulse Configuration Backup Pulse Configuration	Bipolar	S1 Count S1º; S2; S3 and S4 Cycle (i
Backup Pulse Amplitude (V) Search Interval (hours)	5,0 8: 24	Ventricular Support Rate (Sinus Node Recovery Delay
A or V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5	PMT Options
A or V Pulse Width (ms) A or V Pulse Configuration	0,05; 0,1-1,5 in steps of 0,1 Unipolar (tip-case); Bipolar (tip-ring)	PMT Detection Rate (min ⁻¹) PVC Response
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)	Ventricular Intrinsic Preference, VIP™ (ms)
Atrial Sensitivity (mV)	0,1-0,4 ⁶ in steps of 0,1; 0,5; 0,75-2,0 in steps of 0,25;	VIP Search Interval
Ventricular AutoCapture™	2,5-4,0 in steps of 0,5; 5,0 ⁷	VIP Search Cycles Ventricular Safety Standby
Pacing System Primary Pulse Configuration	On; Off Unipolar; Bipolar	Diagnostic Trends
Backup Pulse Configuration Backup Pulse Amplitude (V)	Unipolar; Bipolar 5,0³	Patient Notifiers
Search Interval (hours)	8; 24	Programmable Notifiers (On
AutoCapture Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100	
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,57	Device Reset
Sense <i>Ability</i> ™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events)	Entry into Backup VVI Mode
A Max Sensitivity (mV) V Max Sensitivity (mV)	0,2-1,0 in steps of 0,1 0,2-2,0 in steps of 0,1	Audible Duration (sec) Number of Audible Alerts
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2-3,0 in steps of 0,1 mV	per Notification Number of Notifications
	(Ventricular Post-Pace) Auto; 0,2-3,0 in steps of 0,1 mV	Time Between Notifications
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220	 ± 0,5 cc Programming options dependent
	(Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220	 This parameter is not program 4. The highest available setting for
Rate-Modulated Parameters		 In dual-chamber modes, the m Values 0,1-0,4 not available in
	80-150 in steps of 5; 160-180 in steps of 10	7. Sensitivity is with respect to a
Maximum Sensor Rate (min ⁻¹) Pata Rosponsivo AV Dalav		
Maximum Sensor Rate (min ⁻¹) Rate Responsive AV Delay Rate Responsive PVARP/VREF Reaction Time	Off; Low; Medium; High Off; Low; Medium; High Very Fast; Fast; Medium; Slow	8. During atrial NIPS in dual-char 9. S1 Burst Cycle is applied at the

> Management Suppression™ Algorithm *ower Rate Overdrive (min⁻¹)* Ipper Rate Overdrive (min⁻¹) Io. of Overdrive Pacing Cycles

Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5 Off; On 10

On; Off; Passive 125-475 in steps of 25

15-40 in steps of 5 8:123

80-150 in steps of 5; 160-180 in steps of 10

110-200 in steps of 10; 225-300 in steps of 25 Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R) 40-170 in steps of 5

red Electrograms

Off; Low; High 1; 2; 3 Off; Low; High Off: Low: High Off; Low; High Off; Low; High Off: Low: High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off: Low: High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off: Low: High Off; Low; High 2; 3; 4; 5 Off; Low; High

Monitor; Auto Polarity Switch

100-500 in steps of 25 750-2500 in steps of 250; 3000

Uncoded; Unipolar; Bipolar Off; Battery Test Off; -10 to -120 in steps of 10

Atrial; Ventricular

nd V Lead Monitoring and V Low Impedance Limit (Ω) and V High Impedance Limit (Ω) d Type gnet Response ative AV Hysteresis Search (ms) PS Options Stimulation Chamber Coupling Interval (ms) P1 Count P1', S2; S3 and S4 Cycle (ms) (inc) Options Detection Rate (min-1) Response tricular Intrinsic ference, VIP™ (ms) Search Interval Search Cycles tricular Safety Standby gnostic Trends

ient Notifiers

grammable Notifiers (On; Off)

rice Reset ry into Backup VVI Mode lible Duration (sec) nber of Audible Alerts Notification mber of Notifications ne Between Notifications (hours) 100-800 in steps of 10⁸ 2-25 in steps of 1 Off; 100-800 in steps of 10 (Fixed or Adaptive) Off; 30-95 in steps of 5 1; 2; 3; 4; 5 Off; Passive; Atrial Pace² 90-180 in steps of 5 Off; Atrial Pace² Off; 50-150 in steps of 25; 160-200 in steps of 10 30 sec; 1; 3; 5; 10; 30 min 1:2:3

Off- On AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold

Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; V Rate During AT/AF (High V Rate Threshold/ Total Time in High V Rate) 2

0n 0n 2; 4; 6; 8; 10; 12; 14; 16

1-16 10;22

0,5 cc ogramming options dependent on pacing mode.

is parameter is not programmable. ie highest available setting for hysteresis rate will be 5 min^{.1} below the programmed base rate.

he highest available setting for hystersist rate will be 5 min" below the programmed base rate. n dual-chamber modes, the maximum wentricular refractory period is 325 ms. alues 0,1-0,4 not available in a unipolar sense configuration. ensitivity is with respect to a 20 ms haversine test signal. uring atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay. 1 Burst Cycle is applied at the pre-programmed S1 cycle length.



Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of

Pacemakers

Accent MRI[™] DR

Dual-Chamber Pacemaker

Product Highlights

- The Accent MRI pacemaker has been designed and tested for safe performance of a full-body MRI scan, without zone restrictions,¹ using a 1,5 T (Tesla) field-strength MRI scanner.¹ The MRI conditional device:
 - Allows a maximum whole body averaged specific absorption rate (SAR) of 4 watts per kilogram (W/kg) for high image resolution
 - Must be used in conjunction with an MRI lead from St. Jude Medical
- An optional, easy-to-use hand-held device (SJM MRI Activator[™] device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency
- AT/AF Alerts can be programmed to notify patients and/or their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- A suite of state-of-the-art features—complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP[™]) technology, QuickOpt[™] timing cycle optimisation, the AF Suppression[™] algorithm and SenseAbility[™] technology—is designed to deliver optimal therapy for patients at implant and throughout their lives
- Industry-leading longevity offers 9,4 years of service life,² which is supported by a 7-year warranty³



- The St. Jude Medical[™] MRI conditional pacing system can be scanned in patients under the following conditions: horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating Mode; static magnetic field strength of 1,5 Tesla (T) only; maximum gradient slew rate of 200 T/m/s per axis. See manual for additional details before performing an MRI scan.
- 2. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON
- 3. Terms and conditions apply; refer to the warranty for details.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2124 (Inductive)	52 x 53 x 6	23	13,1 (± 0,5)	IS-1

Radiopaque markers

St. Jude Medical identifier



Device MRI symbol

Indications: Implantation of a dual-chamber pulse generator is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. MRI conditional pulse generator is safe for use in the MRI environment when used in a complete MRI conditional pulse generator is safe for use in the MRI environment when used in a complete MRI conditional pulse generator is safe for use in the MRI environment increased stimulation rates concurrent with physical activity. Dual-chamber pacing is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular pacing is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic artial fibrillation, esvere physical disability. AF Suppression algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indicators. **Contraindications**. Dual-chamber pulse generators are contraindicated in natients with an implanted

Contraindications: Dual-chamber pulse generators are contraindicated in patients with an implanted cardioverter defibrillator (ICD). Rate-adaptive pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-chamber pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-chamber atrial pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to batter failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, and phenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, and papitations with high-rate pacing.

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



Accent MRI[™] DR

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS Model	PM2124
Telemetry	Inductive
Dimensions (mm)	52 x 53 x 6
Weight (g)	23
Volume (cc)	13,11
Connector	IS-1
PARAMETER SETTINGS	
Rate/Timing	
Atrial Pace Refractory (ms)	190-400 in steps of 30; 440; 470 ²
Atrial Sense Refractory (ms)	93; 125; 157; 190-400 in steps of 30; 440; 470; 500 ²
Atrial Protection Interval (ms) Paced AV Delay (ms)	125 ³ 25 20 200 in store of 10, 225, 200 in store of 25, 250
Base Rate (min ⁻¹)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350 30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16 ³
Hysteresis Rate (min-1)	Off; 304-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count Intervention Rate (min ⁻¹)	1-16 in steps of 1 Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0;
Intervention Nate (IIIII)	Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1-10 in 1-minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Maximum Tracking Rate (min ⁻¹)	90-130 in steps of 5; 140-180 in steps of 10
Mode	A00(R); AAI(R); AAT(R); V00(R); VVI(R); VVT(R); VDD(R); D00(R); DVI(R); DDI(R);
	DDD(R); Pacing Off
Post-Ventricular Atrial Blanking (ms)	60-200 in steps of 10; 225; 250
PVARP (ms)	125-500 in steps of 25
Sensed AV Delay (ms) Rest Rate (min ⁻¹)	25; 30-200 in steps of 10; 225-325 in steps of 25 Off; 30-150 in steps of 5
Shortest AV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
Ventricular Blanking (ms)	Auto; 12-52 in steps of 4
Ventricular Pace/Sense Refractory ⁵	
(Fixed) (ms)	125; 160-400 in steps of 30; 440; 470 ²
MRI Settings	
MRI Mode	A00; V00; D00; Pacing Off
MRI Base Rate MRI Paced AV Delay	30-120 bpm in steps of 5 bpm 25 ms; 30-200 ms in steps of 10 ms;
	225-300 ms in steps of 25 ms; 350 ms
MRI Atrial Pulse Configuration	Bipolar
MRI Atrial Pulse Amplitude	5,0 V; 7,5 V
MRI Atrial Pulse Width MRI RV Pulse Configuration	1,0 ms Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V) Search Interval (hours)	5,0 8; 24
A or V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring);
Atrial Sensitivity (mV)	Unipolar Ring (ring-case) 0,1-0,4 ⁶ in steps of 0,1; 0,5; 0,75-2,0 in steps of 0,25;
-	2,5-4,0 in steps of 0,5; 5,0 ⁷
Ventricular AutoCapture™	0.00
Pacing System Primary Pulse Configuration	On; Off Uninglar, Ringlar
Primary Pulse Configuration Backup Pulse Configuration	Unipolar; Bipolar Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0 ³
Search Interval (hours)	8; 24
AutoCapture	
Paced/Sensed AV Delay (ms) Ventricular Sensitivity (mV)	50/25; 100/70; 120/100 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5 ⁷
Sense <i>Ability</i> [™] Technology	Off; On (Automatic Sensitivity Control adjustment for atrial
	and ventricular events)
A Max Sensitivity (mV)	0,2-1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2-2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2-3,0 in steps of 0,1 mV
	(Ventricular Post-Pace) Auto; 0,2-3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220
	(Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220
	(Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Rate-Modulated Parameters	
	80-150 in steps of 5; 160-180 in steps of 10
Maximum Sensor Rate (min ⁻¹) Rate Responsive AV Delay	80-150 in steps of 5; 160-180 in steps of 10 Off; Low; Medium; High
Rate-Modulated Parameters Maximum Sensor Rate (min ⁻¹) Rate Responsive AV Delay Rate Responsive PVARP/VREF Reaction Time	

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of

Sensor Shortest PVARP/VREF (ms) Slope Threshold

AF Management AF Suppression™ Algorithm

Lower Rate Overdrive (min⁻¹) Upper Rate Overdrive (min⁻¹) No. of Overdrive Pacing Cycles Rate Recovery (ms) Maximum AF Suppression Rate (min⁻¹) Atrial Tachycardia Detection Rate (min⁻¹) Auto Mode Switch

On; Off; Passive 125-475 in steps of 25 Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0.5): Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5

Off: On 10 15-40 in steps of 5 8:123

80-150 in steps of 5; 160-180 in steps of 10

110-200 in steps of 10; 225-300 in steps of 25 Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R) 40-170 in steps of 5

AMS Base Rate (min-1) Stored Electrograms

Options Priority Options Channel Triggers Advanced Hysteresis AMS Entry/AMS Exit/ AMS Entry and Exit AT/AF Detection Magnet Response High Atrial Rate Rate (min⁻¹) No. of Consecutive Cycles High Ventricular Rate Rate (min⁻¹) No. of Consecutive Cycles PMT Termination Consecutive PVCs No. of Consecutive PVCs Noise Reversion

Off; Low; High 1:2:3 Off; Low; High Off; Low; High Off; Low; High Off: Low: High Off; Low; High Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High 125-300 in steps of 25 2:3:4:5:10:15:20 Off; Low; High Off; Low; High 2.3.4.5 Off; Low; High

Monitor; Auto Polarity Switch

Off; -10 to -120 in steps of 10

Off; 100-800 in steps of 10 (Fixed or Adaptive) 0ff; 30-95 in steps of 5 1; 2; 3; 4; 5

Off; 50-150 in steps of 25; 160-200 in steps of 10

AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold

100-500 in steps of 25 750-2500 in steps of 250; 3000 Uncoded; Unipolar; Bipolar

Off: Battery Test

Atrial: Ventricular

100-800 in steps of 10⁸ 2-25 in steps of 1

Off; Passive; Atrial Pace² 90-180 in steps of 5

30 sec; 1; 3; 5; 10; 30 min

Off; Atrial Pace2

1; 2; 3 Off; On

Other

A and V Lead Monitoring A and V Low Impedance Limit (Ω) A and V High Impedance Limit (Ω) Lead Type Magnet Response Negative AV Hysteresis Search (ms) NIPS Options Stimulation Chamber Coupling Interval (ms) S1 Count *S1⁹; S2; S3 and S4 Cycle (ms) Ventricular Support Rate (min⁻¹) Sinus Node Recovery Delay (sec)* PMT Options PMT Detection Rate (min⁻¹) **PVC** Response Ventricular Intrinsic Preference, VIP™ (ms) VIP Search Interval VIP Search Cycles Ventricular Safety Standby Diagnostic Trends

Patient Notifiers

Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; V Rate During AT/AF (High V Rate Threshold/ Programmable Notifiers (On; Off) Total Time in High V Rate) Device Reset On Entry into Backup VVI Mode Audible Duration (sec) Number of Audible Alerts 0n 2; 4; 6; 8; 10; 12; 14; 16 per Notification Number of Notifications 1-16 Time Between Notifications (hours) 10:22 I line Detween roundations (nearly - --,
1. ± 0,5 cc
2. Programming options dependent on pacing mode.
3. This parameter is not programmable.
4. The highest available setting for hysteresis rate will be 5 min⁻¹ below the programmed base rate.
5. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.
6. Values (1-0 And available) an unipolar sense configuration.
7. Sensitivity is with respect to a 20 ms haversine test signal.
8. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.
9. S1 Burst Cycle is applied at the pre-programmed S1 cycle length.

ST. JUDE MEDICAL More control. Less risk

Customer Support: 46-8-474-4756

Pacemakers

Accent MRI[™] SR

Single-Chamber Pacemaker with Wireless Telemetry

Product Highlights

- The Accent MRI pacemaker has been designed and tested for safe performance of a full-body MRI scan, without zone restrictions,¹ using a 1,5 T (Tesla) field-strength MRI scanner.¹ The MRI conditional device:
 - Allows a maximum whole body averaged specific absorption rate (SAR) of 4 watts per kilogram (W/kg) for high image resolution
 - Must be used in conjunction with an MRI lead from St. Jude Medical
- An optional, easy-to-use hand-held device (SJM MRI Activator[™] device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency
- InvisiLink[™] wireless telemetry in conjunction with the Merlin@home[™] transmitter and Merlin.net[™] Patient Care Network (PCN), allows for daily remote monitoring and follow-up
- State-of-the-art features—such as automaticity, Ventricular AutoCapture[™] Pacing System and Sense*Ability*[™] technology—are designed to deliver optimal therapy for patients at implant and throughout their lives
- Industry-leading longevity offers 13,7 years of service life,² which is supported by a 7-year warranty³





- The St. Jude Medical[™] MRI conditional pacing system can be scanned in patients under the following conditions: horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating Mode; static magnetic field strength of 1,5 Tesla (T) only; maximum gradient slew rate of 200 T/m/s per axis. See manual for additional details before performing an MRI scan.
- 2. V = 2,5 V @ 0,4 ms; 500 ohms; 100% VVI pacing @ 60 bpm; AutoCapture Pacing System OFF; SEGMs ON
- 3. Terms and conditions apply; refer to the warranty for details.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1224 (RF)	52 x 53 x 6	24	13,1 (± 0,5)	IS-1

Radiopaque markers

St. Jude Medical identifier



Device MRI symbol

Indications: Implantation of a single-chamber pulse generator is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. MRI conditional pulse generator is safe for use in the MRI environment When used in a complete MRI conditional pacing system and according to the instructions in the MRI Procedure Information document for the St. Jude Medical MRI conditional pacing system. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Atrial pacing is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: Single-chamber pulse generators are contraindicated in patients with an implanted cardioverter defibrillator (ICD). Rate-adaptive pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-chamber atrial pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program a device because of programmer maffunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component maffunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, and phrenic nerve or disphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, and palpitations with high-rate pacing.

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



Accent MRI[™] SR

PHYSICAL SPECIFICATIONS

Single-Chamber Pacemaker with Wireless Telemetry

Product Specifications

Model Telemetry Dimensions (mm) Weight (g) Volume (cc) Connector PARAMETER SETTINGS Rate/Timing Ventricular Pace/Sense Refractory (Fixed) (ms)	PM1224 RF 52 x 53 x 6 24 13,1' IS-1 125; 160-400 in steps of 30; 440; 470; 500 ²	Options Priority Options Channel Triggers Magnet Response High Ventricular Rate Rate (min ⁻¹) No. of Consecutive Cycles Advanced Hysteresis Noise Reversion Other	Off; Low; High 1; 2; 3 Off; Low; High 0ff; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off; Low; High
(Fixed) (itis) Base Rate (min ⁻¹) Mode Hysteresis Rate (min ⁻¹) Search Interval (min ⁻¹) Cycle Count Intervention Rate (min ⁻¹) Intervention Duration (min) Recovery Time Rest Rate (min ⁻¹) MRI Settings	123; 180-400 in steps of 5; 140-170 in steps of 10 VOO(R); VVI(R); VVT(R); Pacing Off Off; 30'-150 in steps of 5 Off; 1; 5; 10; 15; 30 1-16 by1 Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30 1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow Off; 30-150 in steps of 5	Lead Monitoring V Low Impedance Limit (Ω) V High Impedance Limit (Ω) Magnet Response Lead Type NIPS Options Stimulation Chamber Coupling Interval (ms) SI Count SI ^F , S2; S3 and S4 Cycle (ms) Diagnostic Trends	Monitor; Auto Polarity Switch 100-500 in steps of 25 750-2500 in steps of 250; 3000 Off; Battery Test Uncoded; Unipolar; Bipolar Ventricular 100-800 in steps of 10 2-25 in steps of 1 100-800 in steps of 10 (Fixed or Adaptive) Exercise; Lead Impedance; R Wave; V Threshold
MRI Mode MRI Base Rate MRI RV Pulse Configuration MRI RV Pulse Amplitude MRI RV Pulse Width Output/Sensing	VOO; Pacing Off 30-120 bpm in steps of 5 bpm Bipolar 5,0 V; 7,5 V 1,0 ms	Patient Notifiers Programmable Notifiers (On; Off) Device Reset Entry into Backup VVI Mode Audible Duration (sec) Number of Audible Alerts	Device at ERI; Ventricular Lead Impedance Out of Range On On 2; 4; 6; 8; 10; 12; 14; 16
V Pulse Amplitude (V) V Pulse Width (ms) V Sensitivity (mV) V Pulse Configuration V Sense Configuration Ventricular AutoCapture TM Pacing System Primary Pulse Configuration Backup Pu	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5 0,05; 0,1-1,5 in steps of 0,1 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5 ⁴ Unipolar (tip-case); Bipolar (tip-ring) Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) On; Off Unipolar; Bipolar Unipolar; Bipolar Unipolar; Bipolar Unipolar; Bipolar 5,0 ⁵ 8; 24 Off; On (Automatic Sensitivity Control adjustment for ventricular events) 0,2-2,0 in steps of 0,1 (Ventricular Post-Sense) 50; 62,5; 75; 100% (Ventricular Post-Sense) 50; 62,5; 75; 100% (Ventricular Post-Sense) 0,30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220	per Notification Number of Notifications Time Between Notifications (hours) 1. ± 0.5 cc 2. Programming options dependent on pacin 3. The highest available setting for hysteres 4. Sensitivity is with respect to a 20 ms have 5. This parameter is not programmable. 6. S1 Burst Cycle is applied at the preprogra	is rate will be 5 min $^{\rm 1}$ below the programmed base rate. ersine test signal.
Maximum Sensor Rate (min ⁻¹) Rate Responsive VREF Shortest VREF Reaction Time Recovery Time Sensor Stensor	80-150 in steps of 5; 160-180 in steps of 10 Off; Low; Medium; High 125-475 in steps of 25 Very Fast; Fast; Medium; Slow Fast; Medium; Slow; Very Slow On; Off; Passive Arto(1), Arto(2), Arto(2), Arto(2), Arto(2), 116 in steps of 1		

Stored Electrograms

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

01; 01; rassive Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5

Slope Threshold



Pacemakers

Accent MRI[™] SR

Single-Chamber Pacemaker

Product Highlights

- The Accent MRI pacemaker has been designed and tested for safe performance of a full-body MRI scan, without zone restrictions,¹ using a 1,5 T (Tesla) field-strength MRI scanner.¹ The MRI conditional device:
 - Allows a maximum whole body averaged specific absorption rate (SAR) of 4 watts per kilogram (W/kg) for high image resolution
 - Must be used in conjunction with an MRI lead from St. Jude Medical
- An optional, easy-to-use hand-held device (SJM MRI Activator[™] device) can be used to program the device to pre-approved MRI settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency
- State-of-the-art features—such as automaticity, Ventricular AutoCapture[™] Pacing System and SenseAbility[™] technology—are designed to deliver optimal therapy for patients at implant and throughout their lives
- Industry-leading longevity offers 14,2 years of service life,² which is supported by a 7-year warranty³



- The St. Jude Medical[™] MRI conditional pacing system can be scanned in patients under the following conditions: horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating Mode; static magnetic field strength of 1,5 Tesla (T) only; maximum gradient slew rate of 200 T/m/s per axis. See manual for additional details before performing an MRI scan.
- 2. V = 2,5 V @ 0,4 ms; 500 ohms; 100% VVI pacing @ 60 bpm; AutoCapture Pacing System OFF; SEGMs ON
- 3. Terms and conditions apply; refer to the warranty for details.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1124 (Inductive)	46 x 52 x 6	22	12 (± 0,5)	IS-1

Radiopaque markers

St. Jude Medical identifier



Device MRI symbol

Indications: Implantation of a single-chamber pulse generator is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. MRI conditional pulse generator is safe for use in the MRI environment when used in a complete MRI conditional pacing system and according to the instructions in the MRI Procedure Information document for the St. Jude Medical MRI conditional pacing system. Rate-modulated pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Atrial pacing is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: Single-chamber pulse generators are contraindicated in patients with an implanted cardioverter defibrillator (ICD). Rate-adaptive pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-chamber atrial pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program a device because of programmer maifunction, infection, interruption of desired device function due to electrical interfreence, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, and phrenic nerve or disphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, and palpitations with high-rate pacing.

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



Accent MRI[™] SR

PHYSICAL SPECIFICATIONS

Single-Chamber Pacemaker

Product Specifications

Model Telemetry PM1124 Options Inductive Off; Low; High 1; 2; 3 Priority Options Dimensions (mm) 46 x 52 x 6 Channel Weight (g) 22 12¹ Triggers Magnet Response High Ventricular Rate Volume (cc) Off; Low; High Connector IS-1 Off; Low; High Rate (min⁻¹) No. of Consecutive Cycles 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High PARAMETER SETTINGS Rate/Timing Advanced Hysteresis Noise Reversion Off; Low; High Ventricular Pace/Sense Refractory Other 125: 160-400 in steps of 30: 440: 470: 5002 (Fixed) (ms) 30-130 in steps of 5; 140-170 in steps of 10 VOO(R); VVI(R); VVT(R); Pacing Off Base Rate (min-1) Monitor; Auto Polarity Switch 100-500 in steps of 25 750-2500 in steps of 250; 3000 Lead Monitoring V Low Impedance Limit (Ω) Mode Hysteresis Rate (min-1) Off; 30³-150 in steps of 5 Off; 1; 5; 10; 15; 30 Search Interval (min⁻¹) V High Impedance Limit (Q) Magnet Response Off; Battery Test Cvcle Count 1-16 by 1 Uncoded: Unipolar: Bipolar Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30 Intervention Rate (min-1) Lead Type NIPS Options Stimulation Chamber Ventricular Intervention Duration (min) 1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow Recovery Time Coupling Interval (ms) 100-800 in steps of 10 S1 Count S1⁶; S2; S3 and S4 Cycle (ms) 2-25 in steps of 1 Rest Rate (min-1) Off; 30-150 in steps of 5 100-800 in steps of 10 (Fixed or Adaptive) **MRI Settings Diagnostic Trends** Exercise; Lead Impedance; R Wave; V Threshold MRI Mode **Patient Notifiers** VOO; Pacing Off MRI Base Rate 30-120 bpm in steps of 5 bpm Programmable Notifiers (On; Off) Device at ERI; Ventricular Lead Impedance Out of Range MRI RV Pulse Configuration Bipolar Device Reset MRI RV Pulse Amplitude . 5,0 V; 7,5 V Entry into Backup VVI Mode 0n MRI RV Pulse Width 1,0 ms Audible Duration (sec) Number of Audible Alerts 2; 4; 6; 8; 10; 12; 14; 16 Output/Sensing per Notification 2 Number of Notifications 1-16 V Pulse Amplitude (V) 0.25-4.0 in steps of 0.25: 4.5-7.5 in steps of 0.5 Time Between Notifications (hours) 10:22 V Pulse Width (ms) 0,05; 0,1-1,5 in steps of 0,1 V Sensitivity (mV) 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,54 1. + 0.5 cc ± 0, 2 c
 2. Programming options dependent on pacing mode.
 3. The highest available setting for hysteresis: rate will be 5 min⁻¹ below the programmed base rate.
 4. Sensitivity is with respect to a 20 ms haversine test signal.
 5. This parameter is not programmable.
 6. S1 Burst Cycle is applied at the proprogrammed S1 cycle length. V Pulse Configuration Unipolar (tip-case); Bipolar (tip-ring) V Sense Configuration Unipolar Tip (tip-case): Bipolar (tip-ring): Unipolar Ring (ring-case) Ventricular AutoCapture™ Pacing System On; Off Primary Pulse Configuration Unipolar; Bipolar Backup Pulse Configuration Unipolar: Bipolar Backup Pulse Amplitude (V) 5,05 Search Interval (hours) 8;24 Sense*Ability*™ Technology Off: On (Automatic Sensitivity Control adjustment for ventricular events) Max Sensitivity (mV) 0,2-2,0 in steps of 0,1 Threshold Start (Ventricular Post-Sense) 50; 62,5; 75; 100% (Ventricular Post-Pace) Auto; 0,2-3,0 in steps of 0,1 mV Decay Delay (ms) (Ventricular Post-Sense) 0 · 30 · 60 · 95 · 125 · 160 · 190 · 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220 **Rate-Modulated Parameters** Maximum Sensor Rate (min-1) 80-150 in steps of 5; 160-180 in steps of 10 Rate Responsive VREF Shortest VREF Off; Low; Medium; High 125-475 in steps of 25 Reaction Time Very Fast: Fast: Medium: Slow Fast; Medium; Slow; Very Slow On; Off; Passive Recovery Time Sensor Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Slope Threshold

Stored Electrograms

Customer Support: 46-8-474-4756

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. 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 one 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.

Auto (+2.0): 1-7 in steps of 0.5



SJM MRI Activator[™]

Handheld Device

Product Highlights

- The SJM MRI Activator[™] handheld device, model EX4000, is an external device that uses radio waves to communicate with a St. Jude Medical MRI conditional implanted pulse generator
- The SJM MRI Activator device streamlines MRI patient workflow by allowing previously stored MRI settings to be easily:
 - Enabled before an MRI scan1
 - Disabled after an MRI scan¹
 - Verified at any time



Ordering Information

Contents: SJM MRI Activator device

Reorder Number	Description
EX4000	SJM MRI Activator EX4000

Intended Use: The SIM MRI Activator[™] handheld device is used to evaluate the status of, and to enable and disable, the previously stored MRI settings. The activator is intended for use with St. Jude Medical[™] MR Conditional pulse generators.

Contraindications: There are no contraindications.

Warnings and Precautions: Electromagnetic interference. The activator is not magnetic and has no moving parts. However, you should avoid equipment which generates a strong electromagnetic interference (CMI). EMI could interfere with communication between the activator and the implanted St. Jude Medical ¹⁴ MR conditional pulse generator. Moving away from the source of EMI or turning it off will usually allow the activator to return to its normal mode of operation. Communication equipment. Summinication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

with the performance of the activator if you are too close to the source of EMI. Wireless communication devices. Wireless communication devices such as computers that operate on a wireless network, handheld personal computers (PDA), cellular phones, and even cordless telephones may generate enough EMI to interfere with the performance of the activator if it is used too close to the source of EMI. Hospital and Medical equipment. A variety of standard hospital and medical equipment, external defibrillation equipment, x-ray machines. Office equipment. A variety of standard hospital and medical equipment may generate enough EMI to interfere equipment may generate enough EMI to interfere and the performance of the activator. These include, but are not limited to: blood pressure monitors, ECG equipment, external defibrillation equipment, x-ray machines. Office equipment. A variety of standard office equipment interfere with the performance of the activator. These include, but are not limited to: elsktop or laptop computers, fax machines, phone systems. Industrial equipment. A variety of industrial equipment may generate enough EMI to interfere with the performance of your activator. These include, but are not limited to: are welders, induction furnaces, very large or detective electric motors; and internal combustion engines with poorly shielded ignition systems.



SJM MRI Activator™

Handheld Device

Product Specifications

PHYSICAL SPECIFICATIONS			
Model	EX4000		
Dimensions (cm)	7,1 x 5,6 x 1,8		
Case material	High-impact plastic		
Power source	1 cell; 3,6 V (nominal); Chemistry:		
	Lithium Thionyl Chloride		
Battery longevity	3 years from manufacturing date		
Audible output level	60 dB (minimum) at 10,0 cm		
Classification with respect to			
electric shock	Internally powered		
Protection from electric shock			
(IEC 60601-1)	Туре BF		
Protection against ingress			
of liquids	Ordinary equipment		
Mode of operation	Non-continuous		

 The SJM MRI Activator device is designed to enable/disable pre-programmed MRI mode quickly and easily pre- and post-scan; do not take the SJM MRI Activator device into the MRI magnet/scanner room.



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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

Item GMCRM855EN



Accent[™] DR RF

Dual-Chamber Pacemaker

Product Highlights

- InvisiLink[™] wireless telemetry, in conjunction with the Merlin@home[™] transmitter and Merlin.net[™] Patient Care Network (PCN), allows for daily remote monitoring and follow-up
- AT/AF alerts can be programmed to notify patients and their clinics when a programmed AT/AF threshold or can be programmed to continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- A suite of state-of-the-art features—complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP[™]) technology, QuickOpt[™] timing cycle optimisation, the AF Suppression[™] algorithm and SenseAbility[™] technology—is designed to deliver optimal therapy for patients at implant and throughout their lives.
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2212	52 x 52 x 6	23	12,8 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with hybrical activity. *Dual-Chamber Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with hybrical activity. *Dual-Chamber Pacing* is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with sinus node dysfunction and normal aix usn tythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression algorithm is indicated for suppression of paroxysmal or persistent atrial librillation episodes in patients with one or more of the above pacing indications.

Contraindications: Dual-chamber pulse generators are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-Chamber Pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, papitations with high-rate pacing.

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





Merlin@home™ Transmitter Compatible

Accent[™] DR RF

Dual-Chamber Pacemaker

Product Specifications

PM2212

RF 52 x 52 x 6

23

12,8¹ IS-1

SETTI

PHYSICAL SPECIFICATIONS Model Telemetry Dimensions (mm) Weight (g) Volume (cc) Connecto

PARAMETER Rate/Timing

Atrial Pace Refractory (ms) Atrial Sense Refractory (ms) Atrial Protection Interval (ms) Paced AV Delay (ms) Base Rate (min⁻¹) Far-Field Protection Interval (ms) Hysteresis Rate (min-1) earch Interval (min) Cycle Count Intervention Rate (min-1)

Intervention Duration (min) Recovery Time Maximum Tracking Rate (min⁻¹) Mode

Post Ventricular Atrial Blanking (ms) PVARP (ms) Sensed AV Delay (ms) Rest Rate (min⁻¹) Shortest AV Delay (ms) Ventricular Blanking (ms) Ventricular Pace/Sense Refractory (Fixed) (ms)

Output/Sensing

ACap[™] Confirm Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours) A or V Pulse Amplitude (V) A or V Pulse Width (ms) A or V Pulse Configuration A or V Sense Configuration

Atrial Sensitivity (mV)

Ventricular AutoCapture" Pacing System Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours) AutoCapture Paced/Sensed AV Delav (ms) Ventricular Senseti AV Denay SenseAbility™ Technology

A Max Sensitivity (mV) V Max Sensitivity (mV) Threshold Start

Decay Delay (ms)

Rate-Modulated Parameters

Maximum Sensor Rate (min-1) Rate Responsive AV Delay Rate Responsive PVARP/VREF Reaction Time Recovery Time Sensor Shortest PVARP/VRFF (ms) Slope

Threshold

190-400 in steps of 30; 440; 470² 93; 125; 157; 190-400 in steps of 30; 440; 470² 1253 25; 30-200 in steps of 10; 225-300 in steps of 25; 350 30-130 in steps of 5; 140-170 in steps of 10 163 Off: 304-150 in steps of 5 Off; 1; 5; 10; 15; 30 1-16 in steps of 1 Off, Same Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30 1-10 in 1 minute intervals
 Fast; Medium; Slow; Very Slow

 90-130 in steps of 5; 140-180 in steps of 10

 A00(R); AAI(R); AAT(R); V00(R); VVI(R);

 VVT(R); VDD(R); D00(R); DVI(R); DDI(R);
 DDD(R); Pacing Off 60-200 in steps of 10; 225; 250 125-500 in steps of 25 25; 30-200 in steps of 10; 225-325 in steps of 25 0f; 30-150 in steps of 5 25-50 in steps of 5; 60-120 in steps of 10 Auto: 12-52 in steps of 4

125; 160-400 in steps of 30; 440; 5002

On: Off: Monitor Bipolar Bipolar 5.0 8.24 0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5 0,05; 0,1-1,5 in steps of 0,1 Unipolar (tip-case); Bipolar (tip-ring) Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) 0,1-0,4 6 in steps of 0,1; 0,5; 0,75-2,0 in steps of 0,25; 2,5-4,0 in steps of 0,5; 5,0 7 0n · Off Unipolar; Bipolar Unipolar; Bipolar 8;24 50/25 100/70 120/100 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5⁷ Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events) 0,2-1,0 in steps of 0,1 0,2-2,0 in steps of 0,1 (Atrial and Ventricular Post-Sense) 50: 62.5: 75: 100% (Atrial and Ventricular Yost-Sense) 30; 52,5; 75; 100% (Atrial Post-Pace) (0,-3,0) in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2-3,0 in steps of 0,1 mV (Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 120; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220 **AF Management**

```
AF Suppression<sup>™</sup> Algorithm
Lower Rate Overdrive (min<sup>-1</sup>
         Unner Rate Overdrive (min-1)
        No. of Overdrive Pacing Cycles
Rate Recovery (ms)
Maximum AF
        Suppression Rate (min<sup>-1</sup>)
Atrial Tachycardia
Detection Rate (min<sup>-1</sup>)
Auto Mode Switch
AMS Base Rate (min<sup>-1</sup>)
```

Stored Electrograms

Options Priority Options Channel Triggers Advanced Hysteresis AMS Entry/AMS Exit/ AMS Entry and Exit AT/AF Detection Magnet Response High Atrial Rate Rate (min-1) No. of Consecutive Cycles High Ventricular Rate Rate (min-1) No. of Consecutive Cycles PMT Termination Consecutive PVCs No. of Consecutive PVCs Noise Reversion

Off; Low; High 1; 2; 3 Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off; Low; High 2.3.4.5 Off; Low; High

Monitor; Auto Polarity Switch

Off; On 10³ 5³

15-40 in steps of 5 8; 12³

80-150 in steps of 5; 160-180 in steps of 10 110-200 in steps of 10; 225-300 in steps of 25

Off; DDD(R) to DDI(R); DDD(R) to VVI(R); VDD(R) to VVI(R) 40-170 in steps of 5

Other

A and V Lead Monitoring A and V Low Impedance Limit (Ω) A and V High Impedance Limit (Ω) Lead Type Magnet Response Negative AV Hysteresis Search (ms) NIPS Options Stimulation Chamber Coupling Interval (ms) S1 Count S1⁹; S2; S3 and S4 Cycle (ms) Ventricular Support Rate (min⁻¹) Sinus Node Recovery Delay (sec) PMT Options PMT Detection Rate (min⁻¹) PVC Response Ventricular Intrinsic Preference, VIP™ (ms) VIP Search Interval VIP Search Cycles Ventricular Safety Standby

100-500 in steps of 50 750-2500 in steps of 250; 3000 Uncoded; Unipolar; Bipolar Off: Battery Test Off; -10 to -120 in steps of 10 Atrial: Ventricular 100-800 in steps of 10⁸ 2-25 in steps of 1 Off: 100-800 in steps of 10 (Fixed or Adaptive) Off; 30-95 in steps of 5 1; 2; 3; 4; 5 Off; Passive; Atrial Pace² 90-180 in steps of 5 Off; Atrial Pace² Off: 50-150 in steps of 25: 160-200 in steps of 10 30 sec.; 1; 3; 5; 10; 30 min. 1; 2; 3

Off On Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold

Diagnostic Trends AT/AF **Patient Notifiers**

Programmable Notifiers

Device Reset Entry into Backup Audible Duration (sec) Number of Audible Alerts per Notification Number of Notifications Time Between Notifications (hours)

(On; Off) Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range: AT/AF Burden AT/AF Episode Duration; High V Rate During AT/AF VVI Mode On 2; 4; 6; 8; 10; 12; 14; 16

 $1.\pm0,5~{\rm cc}$

2. Programming options dependent on pacing mode

A. This parameter is not programmable.
 A. The highest available setting for hysteresis rate will be 5 min-1 below the programmed base rate.
 5. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.

1-16

10;22

6. Values 0.1-0.4 not available in a uninolar sense configuration

 Sensitivity is with respect to a 20 ms haversine test signal.
 During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay. 9. S1 Burst Cycle is applied at the preprogrammed S1 cycle length

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binef Summary: Prior to using these devices, please review the instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

80-150 in steps of 5; 160-180 in steps of 10 Off; Low; Medium; High Off; Low; Medium; High

125-475 in steps of 25 Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1

Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5

Auto (+0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0);

Very Fast; Fast; Medium; Slow Fast; Medium; Slow; Very Slow On; Off; Passive



Pacemakers

Accent[™] DR

Dual-Chamber Pacemaker

Product Highlights

- Inductive remote follow-up utilising a wand, in conjunction with the Merlin@home™ transmitter and Merlin.net[™] Patient Care Network (PCN), allows patients to download information and provide the clinic with access to device measurements
- A two-tone audible alert allows programming to notify the patient of changes in device performance or arrhythmia status, which can provide earlier insight into actionable clinical events
- AT/AF alerts can be programmed to notify patients and their clinics when a programmed AT/AF threshold or can be programmed to continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- A suite of state-of-the-art features—complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP[™]) technology, QuickOpt[™] timing cycle optimisation, the AF Suppression[™] algorithm and SenseAbility[™] technology—is designed to deliver optimal therapy for patients at implant and throughout their lives
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2112	46 x 52 x 6	19	10,5 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. *Dual-Chamber Pacing* is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. *Ventricular Pacing* is indicated for superssion of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Dual-chamber pulse generators are contraindicated in patients with an implanted cardioverter-defibrillator, Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-Chamber Pacing, though not contraindicated for patients with chronic atrial fulter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arthythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of bitoric tissue/local tissue reaction, inability to interrogate or program and edvice because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, paloitations with high-rate pacing.

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





Accent[™] DR

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS Model PM2112 Telemetry Inductive 46 x 52 x 6 Dimensions (mm) Weight (g) 19 10,51 Volume (cc) Connector IS-1 PARAMETER SETTIN Rate/Timing Atrial Pace Refractory (ms) Atrial Sense Refractory (ms) Atrial Protection Interval (ms) 190-400 in steps of 30; 440; 470^2 93; 125; 157; 190-400 in steps of 30; 440; 470^2 125^3 $\,$ Paced AV Delay (ms) Base Rate (min⁻¹) 25; 30-200 in steps of 10; 225-300 in steps of 25; 350 30-130 in steps of 5; 140-170 in steps of 10 Far-Field Protection Interval (ms) 16³ Hysteresis Rate (min⁻¹) Search Interval (min) Off; 30⁴-150 in steps of 5 Off; 1; 5; 10; 15; 30 Cvcle Count 1-16 in steps of 1 Off; Same as Base Rate; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30 Intervention Rate (min-1) 1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow 90-130 in steps of 5; 140-180 in steps of 10 Intervention Duration (min) Recovery Time Maximum Tracking Rate (min⁻¹) AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(R); DVI(R); DDI(R); DDD(R); Pacing Off Mode 00-200 in steps of 10; 225; 250 125-500 in steps of 25 25; 30-200 in steps of 25 Post Ventricular Atrial Blanking (ms) PVARP (ms) Sensed AV Delay (ms) Rest Rate (min⁻¹) Shortest AV Delay (ms) Off; 30-150 in steps of 5 25-50 in steps of 5; 60-120 in steps of 10 Ventricular Blanking (ms) Ventricular Pace/Sense Refractory⁵ Auto, 12-52 in steps of 4 (Fixed) (ms) 125; 160-400 in steps of 30; 440; 4702 Output/Sensing ACap[™] Confirm On; Off; Monitor Primary Pulse Configuration Binolar Backup Pulse Configuration Bipolar Backup Pulse Amplitude (V) 5.0³ Search Interval (hours) A or V Pulse Amplitude (V) 8:24 0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5 A or V Pulse Width (ms) 0.05: 0.1-1.5 in steps of 0.1 Unipolar (tip-case); Bipolar (tip-ring) Unipolar Tip (tip-case); Bipolar (tip-ring); A or V Pulse Configuration A or V Sense Configuration Unipolar Ring (ring-case) 0,1-0,4 6 in steps of 0,1; 0,5; 0,75-2,0 in steps of 0,25; 2,5-4,0 in steps of 0,5; 5,0 7 Atrial Sensitivity (mV) Ventricular AutoCapture™ Pacing System Primary Pulse Configuration On; Off Unipolar; Bipolar Backup Pulse Configuration Backup Pulse Amplitude (V) Unipolar; Bipolar 5,03 8;24 Search Interval (hours) AutoCanture 50/25; 100/70; 120/100 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5⁷ Paced/Sensed AV Delay (ms) Ventricular Sensitivity (mV) Sense*Ability*™ Technology off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events) 0,2-1,0 in steps of 0,1 A Max Sensitivity (mV) 0,2-1,0 in steps of 0,1 0,2-2,0 in steps of 0,1 (Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2-3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2-3,0 in steps of 0,1 mV (Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 V Max Sensitivity (mV) Threshold Start Decay Delay (ms) (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220 Rate-Modulated Parameters 80-150 in steps of 5; 160-180 in steps of 10 Off; Low; Medium; High Maximum Sensor Rate (min⁻¹) Rate Responsive AV Delay Off; Low; Medium; High Very Fast; Fast; Medium; Slow Fast; Medium; Slow; Very Slow Rate Responsive PVARP/VREF Reaction Time Recovery Time Sensor Shortest PVARP/VREF (ms) On; Off; Passive 125-475 in steps of 25 Auto (-1); Auto (+0); Auto (+1); Auto (+2); Slope Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Threshold

AF Management

Ontions

AF Suppression™ Algorithm Lower Rate Overdrive (min⁻¹) Upper Rate Overdrive (min-1) No. of Overdrive Pacing Cycles Rate Recovery (ms) Maximum AF Suppression Rate (min⁻¹) Atrial Tachycardia Detection Rate (min⁻¹) Auto Mode Switch AMS Base Rate (min-1) Stored Electrograms

Priority Options Channel Triggers Advanced Hysteresis AMS Entry/AMS Exit/ AMS Entry and Exit AT/AF Detection Magnet Response High Atrial Rate Rate (min⁻¹) No. of Consecutive Cycles High Ventricular Rate Rate (min⁻¹) No. of Consecutive Cycles PMT Termination Consecutive PVCs No. of Consecutive PVCs Noise Reversion

Off; Low; High 1:2:3 Off; Low; High Off: Low: High Off; Low; High Off: Low: High Off; Low; High Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off: Low: High 2; 3; 4; 5 Off; Low; High

Off: On

15-40 in steps of 5

40-170 in steps of 5

80-200 in steps of 10; 225-300 in steps of 25

110-200 in steps of 10: 225-300 in steps of 25

Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)

5

8:12

Other

A and V Lead Monitoring A and V Low Impedance Limit (Ω) A and V High Impedance Limit (Ω) Lead Type Magnet Response Negative AV Hysteresis Search (ms) NIPS Options Stimulation Chamber Coupling Interval (ms) S1 Count S1⁹; S2; S3 and S4 Cycle (ms) Ventricular Support Rate (min⁻¹) Sinus Node Recovery Delay (sec) PMT Options PMT Detection Rate (min⁻¹) PVC Response Ventricular Intrinsic Preference, VIP™ (ms) VIP Search Interval VIP Search Cycles Ventricular Safety Standby Diagnostic Trends

Monitor: Auto Polarity Switch 100-500 in steps of 25 750-2500 in steps of 250; 3000 Uncoded: Unipolar: Bipolar Off; Battery Test Off; -10 to -120 in steps of 10 Atrial; Ventricular

100-800 in steps of 10⁸ 2-25 in steps of 1 Off; 100-800 in steps of 10 (Fixed or Adaptive) Off; 30-95 in steps of 5 1: 2: 3: 4: 5 Off; Passive; Atrial Pace² 90-180 in steps of 5 Off: Atrial Pace2 Off, 50-150 in steps of 25; 160-200 in steps of 10 30 sec.; 1; 3; 5; 10; 30 min. 1; 2; 3 Off; On

AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold

Patient Notifiers

Programmable Notifiers (On; Off) Device Reset Entry into Backup VVI Mode 0n Audible Duration (sec) Number of Audible Alerts per Notification Number of Notifications 1 - 16

Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF

2; 4; 6; 8; 10; 12: 14: 16

Time Between Notifications (hours) 10; 22 1 ± 0,5 cc 2 Programming options dependent on pacing mode.

The parameters is not programmable.
 The highest available setting for hysteresis rate will be 5 min⁻¹ below the programmed base rate.
 S In dual-chamber modes, the maximum ventricular refractory period is 325 ms.

5 in user families in market in a unipolar sense configuration. 7 Sensitivity is with respect to a 20 ms haversine test signal. 8 Jouring atrial NUPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay. 9 SI Burst Cycle is applied at the preprogrammed SI cycle length.



Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binef Summary: Prior to using these devices, please review the instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5



Pacemakers

Accent[™] SR RF

Single-Chamber Pacemaker

Product Highlights

- InvisiLink[™] wireless telemetry, in conjunction with the Merlin@home[™] transmitter and Merlin.net[™] Patient Care Network (PCN), allows for daily remote monitoring and follow-up
- A two-tone audible alert allows programming to notify the patient of changes in device performance, or information can be remotely transmitted to the clinician through the Merlin.net PCN without patient interaction
- State-of-the-art features—such as automaticity, Ventricular AutoCapture[™] pacing system and SenseAbility[™] technology—are designed to deliver optimal therapy for patients at implant and throughout their lives
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options
- Weekly lead impedance trend displays the current measurement, historical test results, pacing polarity and any polarity switches



Merlin@home™ Transmitter Compatible

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1210	52 x 52 x 6	23	12,8 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. *Atrial Pacing* is indicated for patients with chronotropic incompetence, and patients with sinus node dysfunction and normal AV and intraventricular conduction systems. *Ventricular Pacing* is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: Single-chamber pulse generators are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients with experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction. or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction. For specific contraindications associated with individual modes, refer to the programmer's on -screen help.

Customer Support: 46-8-474-4756

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Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air emblism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, paplitations with high-rate pacing.



100-800 in steps of 10 (Fixed or Adaptive) Exercise; Lead Impedance; R Wave; V Threshold

Device at ERI; Ventricular Lead Impedance Out of Range

Accent[™] SR RF

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS		Stored Electrograms	
Model Telemetry Dimensions (mm) Weight (g) Volume (cc) Connector PARAMETER Rate/Timing	PM1210 RF 52 x 52 x 6 23 12,8 ¹ IS-1 SETTINGS	Options Priority Options Channel Triggers Magnet Response High Ventricular Rate Rate (min ⁻¹) No. of Consecutive Cycles Advanced Hysteresis Noise Reversion	Off; Low; High 1; 2; 3 Off: Low; High Off: Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off; Low; High
Ventricular Pace/Sense Refractory (Fixed) (ms) Base Rate (min ⁻¹) Mode Hysteresis Rate (min ⁻¹) Search Interval (min ⁻¹) Cycle Count Intervention Rate (min ⁻¹) Intervention Duration (min) Recovery Time Rest Rate (min ⁻¹) Dutput/Sensing	125: 160-400 in steps of 30: 440: 470 ² 30-130 in steps of 5: 140-170 in steps of 10 VO0(R); VV1(R); VVT(R); Pacing Off Off, 30 ³ -150 in steps of 5 Off; 1; 5: 10: 15: 30 1-16 by 1 Off; 80-120 in steps of 10: Intrinsic +0: Intrinsic +10: Intrinsic +20: Intrinsic +30: Same as Base Rate 1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow Off; 30-150 in steps of 5	Other Lead Monitoring V Low Impedance Limit (Ω) V High Impedance Limit (Ω) Magnet Response Lead Type NIPS Options Stimulation Chamber Coupling Interval (ms) SI Count SI ^C , S2; S3 and S4 Cycle (ms) Diagnostic Trends	Monitor; Auto Polarity Switch 100-500 in steps of 225 750-2500 in steps of 250; 3000 Off; Battery Test Uncoded; Unipolar; Bipolar Ventricular 100-800 in steps of 10 2-25 in steps of 10 100-800 in steps of 10 (Fixed or Adaptive) Exercise; Lead Impedance; R Wave; V Thres
V Pulse Amplitude (V) V Pulse Width (ms) V Sensitivity (mV) V Pulse Configuration V Sense Configuration Ventricular AutoCapture™ Pacing System Primary Pulse Configuration Backup Pulse Pulse Pulse Configuration Backup Pulse Puls	0.25-4.0 in steps of 0.25; 4,5-7,5 in steps of 0,5 0.05; 0,1-1,5 in steps of 0,1 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5 ⁴ Unipolar (tip-case); Bipolar (tip-ring) Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) 0n; Off Unipolar; Bipolar Unipolar; Bipolar Unipolar; Bipolar 5,0 ⁵ 8; 24 Off; On (Automatic Sensitivity Control adjustment for ventricular events) 0,2-2,0 in steps of 0,1 (Ventricular Post-Sense) 50; 62,5; 75; 100% (Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220	Patient Notifiers Programmable Notifiers (On; Off) Device Reset Entry into Backup VVI Mode Audible Duration (sec) Number of Notifications Time Between Notifications (hours) 1 ± 0.5 cc 2 Programming options dependent on pacing 3 The highest available setting for hysteresis 4 Sensitivity is with respect to a 20 ms have 5 This parameter is not programmable. 6 SI Burst Cycle is applied at the preprogram	s rate will be 5 min ⁻¹ below the programmed base rate. rsine test signal.
Maximum Sensor Rate (min ⁻¹) Rate Responsive VREF Shortest VREF Reaction Time Recovery Time Sensor Slope Threshold	80-150 in steps of 5; 160-180 in steps of 10 Off; Low; Medium; High 125-475 in steps of 25 Very Fast; Fast; Medium; Slow Fast; Medium; Slow; Very Slow On; Off; Passive Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5		



Customer Support: 46-8-474-4756

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Pacemakers

Accent[™] SR Single-Chamber Pacemaker

Product Highlights

- Inductive remote follow-up utilising a wand, in conjunction with the Merlin@home[™] transmitter and Merlin.net[™] Patient Care Network (PCN), allows patients to download information and provide the clinic with access to device measurements
- A two-tone audible alert allows programming to notify the patient of changes in device performance or arrhythmia status, which can provide earlier insight into actionable clinical events
- State-of-the-art features—such as automaticity, Ventricular AutoCapture[™] pacing system and Sense*Ability*[™] technology—are designed to deliver optimal therapy for patients at implant and throughout their lives
- Real-time electrogram (EGM) waveform, as well as the associated event markers that precede and follow a specific triggering event, can be programmed to automatically record up to 14 minutes of stored EGMs when encountering one or more programmable trigger options
- Weekly lead impedance trend displays the current measurement, historical test results, pacing polarity and any polarity switches



Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1110	42 x 52 x 6	18	9,5 (± 0,5)	IS-1

Indications: Implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. *Atrial Pacing* is indicated for patients with chronotropic incompetence, and for those. *Neutricular Pacing* is indicated for patients with chronicate for patients with chronicate for apatients with since and edystunction and normal AV and intraventricular conduction systems. *Ventricular Pacing* is indicated for patients with segments with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: Single-chamber pulse generators or pulsed indicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction. or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Customer Support: 46-8-474-4756

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Potential Adverse Events: The following are potential complications associated with the use of any pacing system: arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air emblism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue/local tissue reaction, inability to interrogate or program a device because of programmer malfunction, infection, interruption of desired device function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, paplitations with high-rate pacing.



Accent[™] SR

PHYSICAL SPECIFICATIONS

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS		Stored Electrograms
Model Telemetry Dimensions (mm) Weight (g) Volume (cc) Connector	PM1110 Inductive 42 x 52 x 6 18 9,5 ¹ IS-1	Options Priority Options Channel Triggers Magnet Response High Ventricular Rate
PARAMETER	SETTINGS	Rate (min ⁻¹) No. of Consecutive Cycles
Rate/Timing		Advanced Hysteresis Noise Reversion
Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470 ²	Other
Base Rate (min ⁻¹) Mode Hysteresis Rate (min ⁻¹) Search Interval (min ⁻¹) Cycle Count Intervention Rate (min ⁻¹) Intervention Duration (min) Recovery Time Rest Rate (min ⁻¹)	30-130 in steps of 5; 140-170 in steps of 10 VO0(R); VVI(R); VVT(R); Pacing Off Off; 30 ³⁻¹ 50 in steps of 5 Off; 1; 5; 10; 15; 30 1-16 by 1 Off; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30; Same as Base Rate 1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow Off; 30-150; in steps of 5	Lead Monitoring V Low Impedance Limit (Ω) V High Impedance Limit (Ω) Magnet Response Lead Type NIPS Options Stimulation Chamber Coupling Interval (ms) SI Count SI ⁶ ; S2; S3 and S4 Cycle (ms Diagnostic Trends
Output/Sensing		0
V Pulse Amplitude (V) V Pulse Width (ms) V Sensitivity (mV) V Sense Configuration Ventricular AutoCapture [™] Pacing System Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours) Sense Ability [™] Technology Max Sensitivity (mV) Threshold Start Decay Delay (ms)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5 0,05; 0,1-1,5 in steps of 0,1 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5 ⁴ Unipolar (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) On; Off Unipolar; Bipolar Unipolar; Bipolar 5,0 ⁶ 8; 24 Off; On (Automatic Sensitivity Control adjustment for ventricular events) 0,2-2,0 in steps of 0,1 (Ventricular Post-Sense) 50; 62,5; 75; 100% (Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0, 30; 60; 95; 125; 160; 190; 220	Patient Notifiers Programmable Notifiers (On; (Device Reset Entry into Backup VVI Mode Audible Duration (sec) Number of Audible Alerts per Notifications Time Between Notifications (t 1 ± 0,5 cc 2 Programmig options dependent (3 The highest available setting for 4 Sensitivity is with respect to a 200 5 This parameter is not program 6 SI Burst Cycle is applied at the pr
Rate-Modulated Parameters		
Maximum Sensor Rate (min ⁻¹) Rate Responsive VREF Shortest VREF Reaction Time	80-150 in steps of 5; 160-180 in steps of 10 Off. Low: Medium: High 125-475 in steps of 25 Very Fast; Fast; Medium; Slow	

Fast; Medium; Slow; Very Slow On; Off; Passive Recovery Time Sensor Un; UT; rassive Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5 Slope Threshold

Stored Electrograms

Off; Low; High 1; 2; 3 Off; Low; High Off; Low; High 125-300 in steps of 25 2; 3; 4; 5; 10; 15; 20 Off; Low; High Off; Low; High

100-500 in steps of 25 750-2500 in steps of 250; 3000 Off; Battery Test Uncoded; Unipolar; Bipolar Ventricular 100-800 in steps of 10

Monitor; Auto Polarity Switch

2-25 in steps of 1 Off; 100-800 in steps of 10 (Fixed or Adaptive) Exercise; Lead Impedance; R Wave; V Threshold

On: Off) de ns (hours) Device at ERI; Ventricular Lead Impedance Out of Range On 0n 2; 4; 6; 8; 10; 12; 14; 16

2 1-16 10; 22

ident on pacing mode. g for hysteresis rate will be 5 min¹ below the programmed base rate. o a 20 ms haversine test signal. ammable. the preprogrammed S1 cycle length.



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ST. JUDE MEDICAL More control. Less risk.

Zephyr[™] XL DR

Dual-Chamber Pacemaker

Product Highlights

- Superior longevity when compared volume-for-volume with any other pacemaker on the market
- QuickOpt[™] timing cycle optimisation provides quick and effective optimisation for more patients at the touch of a button
- Powerful tools—including automatic daily measurements, follow-up EGM and trends, optimised in-clinic testing and lead impedance trend and polarity switch—save valuable clinic time
- The AutoCapture[™] pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation
- ACap[™] confirm feature periodically completes a threshold search and adjusts the pulse amplitude accordingly in the atrium
- Ventricular Intrinsic Preference (VIP[™]) algorithm automatically searches for intrinsic conduction
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event
- Multiple algorithms and diagnostics to assist physicians in therapy decisions including AF Suppression[™] algorithm, AT/AF diagnostic suite and Auto Mode Switch algorithm and diagnostic suite

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5826	44 x 52 x 6	23,5	11 (± 0,5)	IS-1

Indications and Usage: Implantation of Zephyr[™] pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. **Rate-Modulated Pacing** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. **Dual-Chamber Pacing (Models S2E5, 5820 only)** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second - and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarnythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. **Ventricular Pacing** is indicated for patients with significant bradycardia and. Normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. **AF Suppression (Models S826, 5820 only)** is indicated for suppression of parxysmal or persistent atrial fibrillation episodes in patients with more or more of the above pacing indications. For specific indications associated with individual modes, refer to Operating Modes.

Contraindications: Zephyr devices are contraindicated in patients with an implanted cardioverter-defibrillator. **Rate-Adaptive Pacing** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. **AF Suppression** (Models 5826, 5820 only) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Customer Support: 46-8-474-4756

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Dual-Chamber Pacing (Models 5826, 5820 only) though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. **Single-Chamber Atrial Pacing** is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, refer to Operating Modes

Potential Adverse Events: Adverse events associated with the use of any pacing system include: Air embolism, Bleeding Hematoma, Body rejection phenomena, Cardiac tamponade or perforation, Formation of fibrito tissue, local tissue reaction, Inability to interrogate or program due to programmer or device malfunction, Infection/erosion, Interruption of desired pulse generator function due to electrical interference, either electromygenic or electromagnetic, Lead malfunction due to conductor fracture or insulation degradation, Loss of capture or sensing due to lead dislodgement or reaction at the electrode/itsue interface, Loss of desired pacing and/or sensing due to lead dislodgement pody reaction at electrode/itsue interface, elead malfunction (fracture or damage to insulation), Loss of normal device function due to battery failure or component malfunction, Pacemaker migration, pocket erosion or hematoma, Pectoral muscle or diaphragmatic stimulation, Phenein enverse timulation, Pacemator elementhosy remembrava.





Zephyr[™] XL DR

Dual-Chamber Pacemaker

Product Specifications

Model Dimensions (mm) Weight (g) Volume (cc) Connector

PHYSICAL SPECIFICATIONS

5826 44 x 52 x 6 23.5 11^{1} IS-1 compatible

SETTINGS

125²

16²

Off; 5; 10; 15; 30

1-16 in steps of 1

DDD(R): 0D0

1-10 in 1 minute intervals

Fast; Medium; Slow; Very Slow

155; 165; 170; 180; 185; 195; 200

Off; 30-130 in steps of 5; 140; 150

Auto: 12-52 in steps of 4: 12

0,05; 0,1-1,5 in steps of 0,1

Unipolar Ring (ring-case)

2,0-4,0 in steps of 0,5; 5,07

Unipolar (tip-case); Bipolar (tip-ring)

Unipolar Tip (tip-case); Bipolar (tip-ring);

0,1-0,4⁶; 0.5 by 0,1, 0,75-2,0 in steps of 0,25;

0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,57

125-500 in steps of 255

On; Off; Monitor

Bipolar²

Binolar

5,0

8;24

On · Off

5.0²

8;24

Unipolar; Bipolar

Unipolar; Bipolar

30-50 in steps of 5; 60-120 in steps of 10

0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5

125-500 in steps of 25

60: 80: 100-350 in steps of 25

Off: 303-130 in steps of 5: 140: 1504

25; 30-200 in steps of 10; 225-300 in steps of 25; 350

303; 40-130 in steps of 5; 140-170 in steps of 10

Off; 60; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30

90-130 in steps of 5; 140-180 in steps of 10

A00(R); AAI(R); AAT(R); 0A0; V00(R); VVI(R);

VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R);

60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140;

25; 30-200 in steps of 10; 225-325 in steps of 25

PARAMETER Rate/Timing

Atrial Absolute Refractory Period Atrial Protection Interval (ms) Paced AV Delay (ms) Base Rate (min-1) Far-Field Protection Interval (ms) Hysteresis Rate (min-1) Search Interval (min) Cvcle Count Intervention Rate (min⁻¹)

Intervention Duration (min) Recovery Time Maximum Tracking Rate (min-1)

Post Ventricular Atrial Blanking (ms)

PVARP (ms) Sensed AV Delay (ms) Rest Rate (min-1) Shortest AV Delay (ms) Ventricular Blanking (ms) Ventricular Refractory (ms)

Output/Sensing ACap™ Confirm Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours) A or V Pulse Amplitude (V) A or V Pulse Width (ms)

A or V Pulse Configuration A or V Sense Configuration Atrial Sensitivity (mV)

Ventricular AutoCapture[™] Pacing System Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours) AutoCapture Paced/Sensed AV Delay (ms) 50/25; 100/70; 120/100 Ventricular Sensitivity (mV)

Rate-Modulated Parameters

Reaction Time

Recovery Time

Sensor

Slope

Threshold

Maximum Sensor Rate (min-1) 80-150 in steps of 5, 160-180 in steps of 10 Rate Responsive AV Delay Off; Low; Medium; High Rate Responsive PVARP/VREF Off; Low; Medium; High Very Fast: Fast: Medium: Slow Fast; Medium; Slow; Very Slow On; Off; Passive 120-350 in steps of 10 Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); Shortest PVARP/VRFF 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1.0): Auto (+1.5): Auto (+2.0): 1-7 in steps of 0.5

AF Management AF Suppression™ Algorithm

Lower Rate Overdrive (min-1)

Upper Rate Overdrive (min-1) 5^{2} No. of Overdrive Pacing Cycles 15-40 in steps of 5 Rate Recovery (ms) 8; 12² Maximum AF Suppression Rate (min⁻¹) 80-150 in steps of 5; 160-180 in steps of 10 110-150 in steps of 5; 160-200 in steps of 10; Atrial Tachycardia Detection Rate (min-1) 225-300 in steps of 25 Off; DDDR to DDIR; DDD to DDI; VDDR to VVIR; VDD to VVI; Auto Mode Switch DDDR to DDI; DDD to DDIR; VDDR to VVI; VDD to VVIR; DDIR AMS Base Rate (min-1) Base Rate +0 to Base Rate +35 in steps of 5 Stored Electrograms Options Sampling Options No. of Stored EGMs Channel Triggers Advanced Hysteresis On; Off AMS Entry/AMS Exit On; Off AT/AF Detection On; Off Magnet Placement On; Off High Atrial Rate No. of Consecutive Cycles High Ventricular Rate No. of Consecutive Cycles PMT Termination **PVC** Detection On: Off No. of Consecutive PVCs

Freeze; Continuous 1: 2: 4: 8: 12 Atrial: Ventricular: Dual: Cross-Channel

Off; On

10²

 $0ff;\,125;\,150;\,175;\,200;\,225;\,250;\,275;\,300$ 2; 3; 4; 5; 10; 15; 20 Off; 125; 150; 175; 200; 225; 250; 275; 300 2; 3; 4; 5; 10; 15; 20 On; Off 2; 3; 4; 5 Off; Monitor; Auto Polarity Switch

2002 750; 1000; 1250; 1500; 1750; 2000 Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar Off; Battery Test Off; -10 to -110 in steps of 10

Atrial; Ventricular 100-800 in steps of 108 1-25 in steps of 1 100-800 in steps of 10 Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95 1; 2; 3; 4; 5 Off: 10 Beats > PMT: Auto Detect 90-150 in steps of 5: 160-180 in steps of 10 Off; A Pace on PVC; +PVARP on PVC (VDD mode only) Off: On

Off; On Off; 50-150 in steps of 25; 160-200 in steps of 10 30 sec.; 1; 3; 5; 10; 30 min. 1:2:3 Off; Or

1. ± 0.5 cc

Other

Lead Type

NIPS Options

S1 Count

PMT Options

PVC Options

Magnet Response

A and V Lead Monitoring

A and V Low Impedance Limit ($\Omega\!)$

A and V High Impedance Limit (Ω)

Negative AV Hysteresis Search (ms)

S19: S2: S3 and S4 Cycle (ms)

Ventricular Support Rate (min-1)

Sinus Node Recovery Delay (sec)

Ventricular Intrinsic Preference, VIP™ (ms)

PMT Detection Rate (min-1)

Signal Amplitude Monitoring

P-Wave Monitoring

R-Wave Monitoring

VIP Search Interval

Ventricular Safety Standby

VIP Search Cycles

Stimulation Chamber

Coupling Interval

2. This parameter is not programmable.

3. The actual pacing rate for the 30 min⁻¹ is 31 min⁻¹

The bighest available setting for Hysteresis Rate will be 5 min-1 below the programmed Base Rate.
 In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.

6. Values 0.1-0.4 not available in a Unipolar Sense Configuration

Sensitivity is with respect to a 20 ms haversine test signal.

8. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.

9. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binef Summary: Prior to using these devices, please review the instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Zephyr[™] DR

Dual-Chamber Rate-Responsive Pacemaker

Product Highlights

- QuickOpt[™] timing cycle optimisation provides quick and effective optimisation for more patients at the touch of a button
- Powerful tools—including automatic daily measurements, follow-up EGM and trends, optimised in-clinic testing and lead impedance trend and polarity switch—save valuable clinic time
- The AutoCapture[™] pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation
- ACap[™] confirm feature periodically completes a threshold search and adjusts the pulse amplitude accordingly in the atrium
- Ventricular Intrinsic Preference (VIP[™]) algorithm automatically searches for intrinsic conduction
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event
- Multiple algorithms and diagnostics to assist physicians in therapy decisions including AF Suppression[™] algorithm, AT/AF diagnostic suite and Auto Mode Switch algorithm and diagnostic suite

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5820	43 x 44 x 6	18	8,5 (± 0,5)	IS-1

Indications and Usage: Implantation of Zephyr²⁰ pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. *Dual-Chamber Pacing (Models 5826, 5820 only)* is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, syndrome, syntrome, systems. *Ventricular Pacing* is indicated for patients with sinus node dystunction and normal AV and intraventricular conduction systems. *Ventricular Pacing* is indicated for patients with sinus ande dystunction and normal AV and intraventricular disability. *AF Suppression (Models 5826, 5820 only)* is indicated for suppression of paroxysmal or persistent atrial fibrillation persodes in patients with one or more of the above pacing indications. For specific indications associated with individual modes, refer to Operating Modes.

Contraindications: Zephyr devices are contraindicated in patients with an implanted cardioverter-Contraindications: Zeptity devices are contraindicated in patients with an implanted cardioverel-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression (Models S26, 5820 only) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binet 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. 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 one 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.

Dual-Chamber Pacing (Models 5826, 5820 only) though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. **Single-Chamber Atrial Pacing** is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, refer to Operating Modes

Por specific contrainfucations associated with individual modes, refer to operating modes. Potential Adverse Events: Adverse events associated with the use of any pacing system include: Air embolism, Bleeding Hematoma, Body rejection phenomena, Cardiac tamponade or perforation, Formation of fibrotic tissue, local tissue reaction, Inability to interrogate or program due to programmer or device malfunction, Infection/rerosion, Interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, Lead malfunction due to conductor fracture or insulation degradation, Loss of capture or sensing due to lead displacement, body reaction at electrode/tissue interface, Loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), Loss of normal device function due to battery failure or component malfunction, Premeiton, Preumothorax/hemothorax.





Zephyr[™] DR

Dual-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS AF Management Model 5820 AF Suppression™ Algorithm Off, On Dimensions (mm) 43 x 44 x 6 Lower Rate Overdrive (min⁻¹) 10² Upper Rate Overdrive (min-1) Weight (g) 18 5^{2} 8,51 No. of Overdrive Pacing Cycles 15-40 in steps of 5 Volume (cc) Connector IS-1 Rate Recovery (ms) 8; 12² Maximum AF Suppression Rate (min-1) 80-150 in steps of 5; 160-180 in steps of 10 PARAMETER Atrial Tachycardia Detection Rate (min-1) SETTINGS 110-150 in steps of 5; 160-200 in steps of 10; 225-300 in steps of 25 Rate/Timing Off; DDDR to DDIR; DDD to DDI; VDDR to VVIR; VDD to VVI; Auto Mode Switch Atrial Absolute Refractory Period 60; 80; 100-350 in steps of 25 DDDR to DDI; DDD to DDIR; VDDR to VVI; VDD to VVIR; DDIR AMS Base Rate (min-1) Base Rate +0 to Base Rate +35 in steps of 5 Atrial Protection Interval (ms) 125² 25; 30-200 in steps of 10; 225-300 in steps of 25 Paced AV Delay (ms) 303; 40-130 in steps of 5; 140-170 in steps of 10 Stored Electrograms Base Rate (min⁻¹) Far-Field Protection Interval (ms) 16² Options Hysteresis Rate (min-1) Off: 303-130 in steps of 5: 140: 1504 Sampling Options Freeze, Continuous Search Interval (min) Off; 5; 10; 15; 30 No. of Stored EGMs 1; 2; 4; 8; 12 Cycle Count 1-16 in steps of 1 Channel Atrial; Ventricular; Dual; Cross-Channel Intervention Rate (min⁻¹) Off; 60; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30 Triggers Advanced Hysteresis On; Off Intervention Duration (min) 1-10 in 1 minute intervals AMS Entry/AMS Exit On; Off Fast; Medium; Slow; Very Slow Recovery Time AT/AF Detection On; Off 90-130 in steps of 5; 140-180 in steps of 10 AOO(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); VDD(R); OVO; Maximum Tracking Rate (min-1) Magnet Placement On; Off Mode High Atrial Rate $0ff;\,125;\,150;\,175;\,200;\,225;\,250;\,275;\,300$ DOO(R); DVI(R); DDI(R); DDD(R); ODO No. of Consecutive Cycles 2: 3: 4: 5: 10: 15: 20 PVARP (ms) 125-500 in steps of 25 Off; 125; 150; 175; 200; 225; 250; 275; 300 High Ventricular Rate 60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 150; 165; 170: 180: Post Ventricular Atrial Blanking (ms) No. of Consecutive Cycles 2; 3; 4; 5; 10; 15; 20 185; 195; 200 PMT Termination On; Off 25; 30-200 in steps of 10; 225-325 in steps of 25 Sensed AV Delay (ms) **PVC** Detection On; Off Rest Rate (min⁻¹) Off; 30-130 in steps of 5; 140; 150 No. of Consecutive PVCs 2; 3; 4; 5 30-50 in steps of 5: 60-120 in steps of 10 Shortest AV Delay (ms) Auto, 12-52 in steps of 4 Ventricular Blanking (ms) Ather Ventricular Refractory (ms) 125-500 in steps of 255 A and V Lead Monitoring Off; Monitor; Auto Polarity Switch **Output/Sensing** A and V Low Impedance Limit (Ω) 2002 A and V High Impedance Limit (Ω) 750; 1000; 1250; 1500; 1750; 2000 ACap[™] Confirm On; Off; Monitor Lead Type Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar Primary Pulse Configuration Bipolar⁴ Magnet Response Off; Battery Test Backup Pulse Configuration Bipolar Negative AV Hysteresis Search (ms) Off; -10 to -110 in steps of 10 Backup Pulse Amplitude (V) 5;0² NIPS Options Search Interval (hours) 8:24 Stimulation Chamber Atrial: Ventricular A or V Pulse Amplitude (V) 0.0-4.0 in steps of 0.25: 4.5-7.5 in steps of 0.5 Coupling Interval (ms) 100-800 in steps of 108 A or V Pulse Width (ms) 0,05; 0,1-1,5 in steps of 0,1 S1 Count 1-25 in steps of 1 A or V Pulse Configuration Unipolar (tip-case), Bipolar (tip-ring) S1º, S2, S3 and S4 Cycle (ms) 100-800 in steps of 10 A or V Sense Configuration Unipolar Tip (tip-case), Bipolar (tip-ring), Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95 Ventricular Support Rate (min-1) Unipolar Ring (ring-case) Sinus Node Recovery Delay (sec) 1: 2: 3: 4: 5 0,1-0,46; 0,5 by 0,1; 0,75-2,0 in steps of 0,25; 2,0-4,0 in steps of 0,5; 5,07 Atrial Sensitivity (mV) PMT Options Off: 10 Beats > PMT. Auto Detect Ventricular AutoCapture™ Pacing System On; Off PMT Detection Rate (min⁻¹) 90-150 in steps of 5; 160-180 in steps of 10 Primary Pulse Configuration Unipolar; Bipolar PVC Options Off; A Pace on PVC; +PVARP on PVC (VDD mode only) Backup Pulse Configuration Unipolar: Bipolar Signal Amplitude Monitoring Backup Pulse Amplitude (V) 5,0² Off: On P-Wave Monitoring Search Interval (hours) 8; 24 R-Wave Monitoring Off; On AutoCanture Paced/Sensed AV Delay (ms) 50/25-100/70-120/100 Ventricular Intrinsic Preference, VIP™ (ms) Off; 50-150 in steps of 25; 160-200 in steps of 10 Ventricular Sensitivity (mV) 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,55; 2,0 VIP Search Interval 30 sec.; 1; 3; 5; 10; 30 min. **VIP Search Cycles** 1; 2; 3 Rate-Modulated Parameters Ventricular Safety Standby Off; On Maximum Sensor Rate (min-1) 80-150 in steps of 5; 160-180 in steps of 10 1. ± 0,5 cc Rate Responsive AV Delay Off: Low: Medium: High 2. This parameter is not programmable.
 3. The actual pacing rate for the 30 min⁻¹ is 31 min⁻¹ Rate Responsive PVARP/VREF Off; Low; Medium; High Very Fast; Fast; Medium; Slow Reaction Time The highest available setting for Hysteresis Rate will be 5 min-1 below the programmed Base Rate.
 In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms. Fast; Medium; Slow; Very Slow Recovery Time Sensor On; Off; Passive 6. Values 0.1-0.4 not available in a Unipolar Sense Configuration. 120-350 in steps of 10 Shortest PVARP/VREF

Sensitivity is with respect to a 20 ms haversine test signal.
 During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.

9. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All rights reserved.

Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3);

Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5);

1-16 in steps of 1

Auto (+2,0); 1-7 in steps of 0,5

Item GMCRM816EN

Slope

Threshold



Pacemakers

Zephyr[™] XL SR

Single-Chamber Rate-Responsive Pacemaker

Product Highlights

- Superior longevity when compared volume-for-volume with any other pacemaker on the market
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and threshold tests, resulting in 100% of follow-up completed before the patient arrives at the clinic
- The AutoCapture[™] pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation
- ACap[™] confirm feature periodically completes a threshold search and adjusts the pulse amplitude accordingly in the atrium
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event
- Automatic daily measurement and weekly trending of intrinsic P- or R-waves
- Automatic lead impedance measurement. Display of weekly lead impedance trend, historical test results, pacing polarity and any polarity switches
- Physiologic-based rest rate not subject to changes in time zone, daylight savings time or the patient's schedule
- Advanced hysteresis maximises opportunities for the patient's own rhythm to prevail and addresses abrupt rate drops

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5626	42 x 52 x 6	23,5	10,4 (± 0,5)	IS-1

Indications and Usage: Implantation of Zephyr[™] pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with physical activity. *Dual-Chamber Pacing (Models 5826, 5820 only)* is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic branch by when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with syndrome, syndrome,

Contraindications: Zephyr devices are contraindicated in patients with an implanted cardioverterdefibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression (Models 5826, 5820 only) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Customer Support: 46-8-474-4756

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. 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 one 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.

Dual-Chamber Pacing (Models 5826, 5820 only) though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, refer to Operating Modes

Potential Adverse Events: Adverse events associated with the use of any pacing system include: Air embolism, Bleeding Hematoma, Body rejection phenomena, Cardiac tamponade or perforation, Formation of fibrotic tissue, local tissue reaction, Inability to interrogate or porgrand use to programmer or device malfunction, Infection/rension, Interruption of desired pulse generator function due to electrical interference, either electromygenic or electromagnetic, Lead malfunction due to advuctor fracture or insulation degradation, Loss of capture or sensing due to lead dislodgement to reaction at the electrode/interface, or lead malfunction (fracture or damage to insulation), Loss of one advice function due to advice function due to battery failure or component malfunction, Racemaker migration, pocket ension or hematoma, Pectoral muscle or diaphragmatic stimulation, Phenein cerve stimulation, Penemothorax/hemothorax.





Zephyr[™] XL SR

PHYSICAL SPECIFICATIONS

Single-Chamber Rate-Responsive Pacemaker

Product Specifications

PHISICAL SPECIFICATIONS		Utiler
Model	5626	Lead Monitoring
Dimensions (mm)	42 x 52 x 6	A or V Low Impedance
Weight (g)	23,5	A or V High Impedanc
Volume (cc)	10,4	A or V Signal Amplitude
Connector	IS-1	Magnet Response
5161115755		Lead Type
PARAMETER	SETTINGS	NIPS Options Stimulation Chamber
Rate/Timing		Coupling Interval (m
A or V Refractory (ms)	125-500 in steps of 25	S1 Count
Base Rate (bpm)	30 ² ; 40-130 in steps of 5; 140-170 in steps of 10	S1 ⁶ ; S2; S3 and S4 C
Mode	A00(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R)	Sinus Node Recovery
Hysteresis Rate (bpm)	Off; 30-130 in steps of 5; 140; 150 ³	
Search Interval (bpm)	Off; 5; 10; 15; 30	1. ± 0,5 cc
Cycle Count	1-16 by 1	2. The actual pacing rate
Intervention Rate (bpm)	Off; 60; 80-120 in steps of 10; Intrinsic +0;	The highest available
Internetice Densities (min)	Intrinsic +10; Intrinsic +20; Intrinsic +30	 Sensitivity is with res This parameter is not
Intervention Duration (min)	1-10 in 1 minute intervals	6. S1 Burst Cycle is appl
Recovery Time	Fast; Medium; Slow; Very Slow	
Rest Rate (bpm)	Off; 30-130 in steps of 5; 140; 150	
Output/Sensing		
A or V Pulse Amplitude (V)	0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5	
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1	
A or V Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,54	
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)	
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring);	
	Unipolar Ring (ring-case)	
Ventricular AutoCapture [™] Pacing System	On; Off	
Primary Pulse Configuration	Unipolar; Bipolar	
Backup Pulse Configuration	Unipolar; Bipolar	
Backup Pulse Amplitude (V)	5,0 ⁵	
Search Interval (hours)	8; 24	
Rate-Modulated		
Maximum Sensor Rate (bpm)	80-150 in steps of 5; 160-180 in steps of 10	
Rate Responsive VREF	Off; Low; Medium; High	
Shortest VREF	120-350 in steps of 10	
Reaction Time	Very Fast; Fast; Medium; Slow	
Recovery Time	Fast; Medium; Slow; Very Slow	
Sensor	On; Off; Passive	
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2);	
	Auto (+3); 1-16 in steps of 1	
Threshold	Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0); Auto (+1.5); Auto (+2.0); 1-7 in steps of 0,5	
Stored Electrograms		
Options		
Options Sampling Options	Freeze; Continuous	
	Freeze; Continuous 1; 2; 4; 8; 12	
Sampling Options		
Sampling Options No. of Stored EGMs Channel	1; 2; 4; 8; 12	
Sampling Options No. of Stored EGMs Channel	1; 2; 4; 8; 12	
Sampling Options No. of Stored EGMs Channel Triggers	1; 2; 4; 8; 12 Atrial or Ventricular	
Sampling Options No. of Stored EGMs Channel Triggers Magnet Placement	1; 2; 4; 8; 12 Atrial or Ventricular On; Off	
Sampling Options No. of Stored EGMs Channel Triggers Magnet Placement High Atrial Rate (bpm)	1; 2; 4; 8; 12 Atrial or Ventricular On; Off Off; 125; 150; 175; 200; 225; 250; 275; 300	
Sampling Options No. of Stored EGMs Channel Triggers Magnet Placement High Atrial Rate (bpm) No. of Consecutive Cycles	1; 2; 4; 8; 12 Atrial or Ventricular On; Off Off; 125; 150; 175; 200; 225; 250; 275; 300 2; 3; 4; 5; 10; 15; 20	

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

ce Limit (Ω) nce Limit (Ω) Monitoring er ns) Cycle (ms) ry Delay (sec)

Other

Off; Monitor; Auto Polarity Switch 200⁵ 750; 1000; 1250; 1500; 1750; 2000 Off; On Off; Battery Test Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar

Atrial or Ventricular 100-800 in steps of 10 1-25 in steps of 1 100-800 in steps of 10 1-5 in steps of 1

- ate for the 30 ppm is 31 ppm. le setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate. espect to a 20 ms haversine test signal. ot programmable. splied at the preprogrammed S1 cycle length.

Item GMCRM815EN



Zephyr[™] SR

Single-Chamber Rate-Responsive Pacemaker

Product Highlights

- Small, physiologic-shaped device maximises longevity without compromising size
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and threshold tests, resulting in 100% of follow-up completed before the patient arrives at the clinic
- The AutoCapture[™] pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation
- ACap[™] confirm feature periodically completes a threshold search and adjusts the pulse amplitude accordingly in the atrium
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event
- Automatic daily measurement and weekly trending of intrinsic P- or R-waves
- Automatic lead impedance measurement. Display of weekly lead impedance trend, historical test results, pacing polarity and any polarity switches
- Physiologic-based rest rate not subject to changes in time zone, daylight savings time or the patient's schedule
- Advanced hysteresis maximises opportunities for the patient's own rhythm to prevail and addresses abrupt rate drops

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5620	41 x 44 x 6	17	8 (± 0,5)	IS-1

Indications and Usage: Implantation of Zephyr[™] pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. *Dual-Chamber Pacing (Models S226, S20 only)* is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic blareral bundle branch block when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. *Ventricular Pacing* is indicated for patients with significant bradycardia and. Normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. *AF Suppression (Models S826, S820 only)* is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. For specific indications associated with individual modes, refer to Operating Modes.

Contraindications: Zephyr devices are contraindicated in patients with an implanted cardioverterdefibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression (Models 5826, 5820 only) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a completel listing of indications, contraindications, warnings, 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 one 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.

Dual-Chamber Pacing (Models 5826, 5820 only) though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. *Single-Chamber Atrial Pacing* is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, refer to Operating Modes

Potential Adverse Events: Adverse events associated with the use of any pacing system include: Air embolism, Bleeding Hematoma, Body rejection phenomena, Cardiac tamponade or perforation, formation of fibrotic tissue, local tissue reaction, Inability to interrogate or program due to programmer or device malfunction, Infection/erosion, Interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, Lead malfunction due to conductor fracture or insulation degradation, Loss of capture or sensing due to lead disjdagement or reaction at the electrode/tissue interface, Loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), Loss of normal device function due to battery failure or component malfunction, Pacemaker migration, pocket erosion or hematoma, Pectoral muscle or diaphragmatic stimulation, Phrenic nerve stimulation, Pneumothorax.





Off; Monitor; Auto Polarity Switch 200⁵ 750; 1000; 1250; 1500; 1750; 2000

Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar

Off; On

Off; Battery Test

Atrial or Ventricular

1-25 in steps of 1 100-800 in steps of 10

1-5 in steps of 1

± 0.5 cc
 The actual pacing rate for the 30 ppm is 31 ppm.
 The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.
 Sensitivity is with respect to a 20 ms haversine test signal.
 This parameter is not programmable.
 SI Burst Cycle is applied at the preprogrammed S1 cycle length.

100-800 in steps of 10

Zephyr[™] SR

Single-Chamber Rate-Responsive Pacemaker

Other

Lead Monitoring

Magnet Response

Stimulation Chamber

Coupling Interval (ms)

S1 Count S1⁶; S2; S3 and S4 Cycle (ms)

Sinus Node Recovery Delay (sec)

Lead Type NIPS Options

A or V Low Impedance Limit ($\Omega\!\!\!\!\!\Omega$ A or V High Impedance Limit (Q) A or V Signal Amplitude Monitoring

Product Specifications PHYSICAL SPECIFICATIONS

PHYSICAL SPECIFICATIONS	
Model	5620
Dimensions (mm)	41 x 44 x 6
Weight (g)	17
Volume (cc)	81
Connector	IS-1
oomicetoi	10 1
PARAMETER	SETTINGS
Rate/Timing	
A or V Refractory (ms)	125-500 in steps of 25
Base Rate (bpm)	30 ² ; 40-130 in steps of 5; 140-170 in steps of 10
Mode	A00(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R)
Hysteresis Rate (bpm)	Off; 30-130 in steps of 5; 140; 150 ³
Search Interval (bpm)	Off; 5; 10; 15; 30
Cycle Count	1-16 by 1
Intervention Rate (bpm)	Off; 60; 80-120 in steps of 10; Intrinsic +0;
	Intrinsic +10; Intrinsic +20; Intrinsic +30
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (bpm)	Off; 30-130 in steps of 5; 140; 150
Output (Consing	
Output/Sensing	
A or V Pulse Amplitude (V) A or V Pulse Width (ms)	0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
	0,05; 0,1-1,5 in steps of 0,1
A or V Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5 ⁴
A or V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring);
	Unipolar Ring (ring-case)
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0 ^s
Search Interval (hours)	8; 24
Rate-Modulated	
Maximum Sensor Rate (bpm)	80-150 in steps of 5; 160-180 in steps of 10
Rate Responsive VREF	Off; Low; Medium; High
Shortest VREF	120-350 in steps of 10
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2);
	Auto (+3); 1-16 in steps of 1
Threshold	Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0);
The should	Auto (+1.5); Auto (+2.0); 1-7 in steps of 0,5
Stored Electrograms	
Options	
Sampling Options	Freeze; Continuous
No. of Stored EGMs	1; 2; 4; 8; 12
Channel	Atrial or Ventricular
Triggers	
Magnet Placement	On; Off
High Atrial Rate (bpm)	Off; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate (bpm)	Off; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	On; Off

Customer Support: 46-8-474-4756

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. 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 one 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.



More control. Less risk.

ST. JUDE MEDICAL

Sustain[™] XL DR

Dual-Chamber Rate-Responsive Pacemaker

Product Highlights

- Device features small, physiologic shape and offers superior longevity (9,8 years) without compromising size.¹
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and ventricular threshold tests.
- Ventricular Intrinsic Preference (VIP[™]) algorithm automatically searches for intrinsic conduction.
- The AutoCapture[™] Pacing System feature offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation.
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event.
- The system also includes the clinically proven Omnisense[™] accelerometer sensor, featuring auto rest rate (based on activity rather than on preset clock settings) and auto rate response.

1. A, V = 2,5 V/0,4 ms, A,V = 500 ohms, 100% DDD pacing @ 60 bpm, SEGMs ON; data on file.



Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2136	44 x 52 x 6	23,5	11	IS-1

Indications and Usage: Implantation of Sustain pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Dual-Chamber Pacing (Models PM2134 and PM2136 only) is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with significant bradycardia and: Normal sinus rhythm with only rare episodes of A-V block, cerus arrest, chronic atrial fibrillation, severe physical disability. AF Suppression" (Models PM2134 and PM2136 only) is indicated for suppression of parcoxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. For specific indications associated with individual modes, refer to the programmer's on-screen help.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Because Sustain pulse generators will be automatically programmed to a unipolar pulse configuration if the device initiates Backup VII pacing. Sustain devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highers stimulation rate tolerated by the patient. AF Suppression (Models PM2134 and PM2136 only) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Dual-Chamber Pacing (Models PM2134 and PM2136 only) though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of singlechamber pacing in such patients. *Single-Chamber Ventricular Demand Pacing* is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. *Single-Chamber Atrial Pacing* is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, see the programmer's on-screen help.

Potential Adverse Events: Arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue; local tissue reaction, inability to interrogate or program a pulse generator because of programmer malfunction, infection, inability to interrogate or program body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal pacemaker function due to battery failure or component malfunction, pacemaker migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.



Sustain[™] XL DR

Model

Mode

Dual-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS AF Management PM2136 AF Suppression™ Algorithm Dimensions (mm) 44 x 52 x 6 Lower Rate Overdrive (min-1) Weight (g) Upper Rate Overdrive (min-1) 23.5 111 No. of Overdrive Pacing Cycles Volume (cc) Connector IS-1 Rate Recovery (ms) Maximum AF Suppression Rate (min⁻¹) PARAMETER Atrial Tachycardia Detection Rate (min-1) SETTING Rate/Timing Auto Mode Switch Atrial Absolute Refractory Period 60; 80; 100-350 in steps of 25 Atrial Protection Interval (ms) AMS Base Rate (min-1) 125² Atrial Refractory (PVARP) (ms) 125-500 in steps of 25; 275 AV Delay (ms) 25; 30-200 in steps of 10; 225-300 in steps of 25; 350; 200Stored Electrograms 303; 40-130 in steps of 5; 140-170 in steps of 10; 60 Base Rate (bpm) Options Far-Field Protection Interval (ms) 16 Sampling Options **Off**; 30-130 in steps of 5; 140; 150⁴ Hysteresis Rate (min⁻¹) No. of Stored EGMs Search Interval (min) Off; 5; 10; 15; 30 Channel Cycle Count 1-16 in steps of 1 Triggers Intervention Rate (min-1) Off; 60; 80-120 in steps of 10; Intrinsic +0; Advanced Hysteresis Intrinsic +10; Intrinsic +20; Intrinsic +30 AMS Entry/AMS Exit Intervention Duration (min) 1-10 in 1 minute intervals AT/AF Detection Fast; Medium; Slow; Very Slow Recovery Time Magnet Placement Maximum Tracking Rate (min-1) 90-130 in steps of 5; 140-180 in steps of 10; 130 High Atrial Rate A00(R); AAI(R); AAT(R); 0A0; V00(R); VVI(R); No. of Consecutive Cycles VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R); High Ventricular Rate **DDD**(R): 0D0 60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; **150**; 155; 165; 170; 180; 185; 195; 200 No. of Consecutive Cycles Post Vent. Atrial Blanking (PVAB) (ms) PMT Termination **PVC** Detection PV Delay (ms) 25; 30-200 in steps of 10; 225-325 in steps of 25; 150 No. of Consecutive PVCs Rest Rate (min⁻¹) Off; 30-130 in steps of 5; 140; 150 Shortest AV/PV Delav (ms) 30-50 in steps of 5; 60-120 in steps of 10; 100 Ventricular Blanking (ms) 12-52 in steps of 4; 12 Ather Ventricular Refractory (ms) 125-500 in steps of 255; 250 A and V Lead Monitoring **Output/Sensing** Lead Type A or V Pulse Amplitude (V) 0.0-4.0 in steps of 0,25; 4,5-7,5 in steps of 0,5; 2,5 A or V Pulse Width (ms) 0,05; 0,1-1,5 in steps of 0,1; 0,4 Unipolar (tip-case); Bipolar (tip-ring) A or V Pulse Configuration NIPS Options A or V Sense Configuration Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) Atrial Sensitivity (mV) 0,1-0,4 in steps of 0,16; 0,5; 0,75-2,0 in steps of 0,25; 2,0-4,0 in steps of 0,5; 5,07; 0,5 S1 Count Ventricular AutoCapture™ Pacing System On: Off Primary Pulse Configuration Unipolar Backup Pulse Configuration Unipolar; Bipolar Backup Pulse Amplitude (V) 5 0² PMT Options 8:24 Threshold Search Interval (hours) Ventricular Sensitivity (mV) 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5; 2,0" PVC Options Rate-Modulated Parameters Maximum Sensor Rate (min-1) 80-150 in steps of 5, 160-180 in steps of 10; **130 Off**; Low; Medium; High Rate Responsive AV/PV Delay Rate Responsive PVARP/VREF Off; Low; Medium; High Reaction Time Very Fast; Fast; Medium; Slow Recovery Time Fast: Medium: Slow: Very Slow On; Off; Passive 1. ± 0,5 cc Shortest PVARP/VREF 120-350 in steps of 10; 170 Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3);

Slone Threshold

Sensor

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binet 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. 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

1-16 in steps of 1

Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0);

Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5

Off; DDDR to DDIR; DDD to DDI; VDDR to VVIR; VDD to VVI; DDDR to DDI; DDD to DDIR; VDDR to VVI; VDD to VVIR; DDIR Base Rate +0 to Base Rate +35 in steps of 5: Base Rate +20 Freeze; Continuous 1; 2; 4; 8; 12 Atrial; Ventricular; Dual; Cross-Channel On: Off On: Off 0n; **Off** 0n; **Off** $\pmb{0ff};\,125;\,150;\,175;\,200;\,225;\,250;\,275;\,300$ 2; 3; 4; 5; 10; 15; 20 **Off**; 125; 150; 175; 200; 225; 250; 275; 300 2; 3; 4; 5; 10; 15; 20 On; Off On; Off 2; 3; 4; 5

Off; Monitor; Auto Polarity Switch

Off; -10 to -110 in steps of 10

750; 1000; 1250; 1500; 1750; 2000

Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar

Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95

90-150 in steps of 5; 160-180 in steps of 10; Off; 110

Off; A Pace on PVC; + PVARP on PVC (VDD mode only)

Off; 50-150 in steps of 25; 160-200 in steps of 10

2002

Off; Battery Test

Atrial: Ventricula

1-25 in steps of 1

1-5 in steps of 1

Off. On

Off; On

1:2:3

Off: Or

100-800 in steps of 10⁸

. 100-800 in steps of 10

Off: 10 Beats > PMT: Auto Detect

30 sec.; 1; 3; 5; 10; 30 min.

Off; On

15-40 in steps of 5

225-300 in steps of 25; **180**

80-150 in steps of 5; 160-180 in steps of 10 110-150 in steps of 5; 160-200 in steps of 10;

102

 5^{2}

8;12

A and V Low Impedance Limit (Ω) A and V High Impedance Limit (Ω) Magnet Response Negative AV/PV Hysteresis Search (ms) Stimulation Chamber Coupling Interval S19; S2; S3 and S4 Cycle (ms) Ventricular Support Rate (min-1) Sinus Node Recovery Delay (sec) PMT Detection Rate (min-1) Signal Amplitude Monitoring P-Wave Monitoring R-Wave Monitoring Ventricular Intrinsic Preference (VIP™) (ms) VIP Search Interval

VIP Search Cycles Ventricular Safety Standby

2. This parameter is not programmable.

3. The actual pacing rate for the 30 bpm is 31 bpm

- The highest available setting for Hysteresis Rate will be 5 bpm below the programmed Base Rate
 In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
- 6. Values 0.1-0.4 not available in a Unipolar Sense Configuration

Sensitivity is with respect to a 20 ms haversine test signal.
 During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay.

9. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.





Item GMCRM874EN

Pacemakers

Sustain[™] XL SR

Single-Chamber Rate-Responsive Pacemaker

Product Highlights

- Device features small, physiologic shape and offers superior longevity (12,8 years) without compromising size.¹
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and ventricular threshold tests.
- The AutoCapture[™] Pacing System feature offers the maximum in threshold adaptability and patient safety with ventricular Beat[™] capture confirmation.
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event.
- The system also includes the clinically proven Omnisense[™] accelerometer sensor, featuring auto rest rate (based on activity rather than on preset clock settings) and auto rate response.
- 1. A, V = 2,5 V/0,4 ms, A,V = 500 ohms, 100% VVI pacing @ 60 bpm, SEGMs ON; data on file.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1136	42 x 52 x 6	23	10,4	IS-1

Indications and Usage: Implantation of Sustain pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia or any combination of those symptoms. *Rate-Modulated Pacing* is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and: Normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Because Sustain pulse generators will be automatically programmed to a unipolar pulse configuration if the device initiates Backup VVI pacing, Sustain devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Potential Adverse Events: Arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue; local tissue reaction, inability to interrogate or program a pulse generator because of programmer malfunction, infection, interruption of desired pulse generator function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal pacemaker function due to battery failure or component malfunction, pacemaker migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation. The following, in addition to the above, are potential complications associated with the use of rate-modulated pacing systems: inappropriate, rapid pacing rates due to sensor failure, palpitations with high-rate pacing.





Sustain[™] XL SR

Single-Chamber Rate-Responsive Pacemaker

Product Specifications

Model Dimensions (mm) Weight (g) Volume (cc) Connector

PHYSICAL SPECIFICATIONS

PM1136 42 x 52 x 6 23 10,41 IS-1

SETTINGS

125-500 in steps of 25: 325

Off; 5; 10; 15; 30 1-16 in steps of 1

0n; **Off**

5.05

8;24

Unipolar; Bipolar Unipolar; Bipolar

1-10 in 1 minute intervals

Fast; Medium; Slow; Very Slow

Off; 30-130 in steps of 5; 140; 150

0.05: 0.1-1.5 in steps of 0.1: 0.4

Unipolar (tip-case); Bipolar (tip-ring)

Off; 30-130 in steps of 5; 140; 1503

30²; 40-130 in steps of 5; 140-170 in steps of 10

Off; 60; 80-120 in steps of 10; Intrinsic +0;

0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5; 2,5

0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5⁴

Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)

Intrinsic +10; Intrinsic +20; Intrinsic +30

A00(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); OVO

PARAMETER Rate/Timing

A or V Refractory (ms) Base Rate (bpm) Mode Hysteresis Rate (bpm) Search Interval (bpm) Cycle Count Intervention Rate (bpm)

Intervention Duration (min) Recovery Time Rest Rate (bpm)

Output/Sensing

A or V Pulse Amplitude (V) A or V Pulse Width (ms) A or V Sensitivity (mV) A or V Pulse Configuration A or V Sense Configuration Ventricular AutoCapture™ Pacing System Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours)

Rate-Modulated Parameters

Maximum Sensor Rate (bpm) Rate Responsive VREF Shortest VREF Reaction Time Recovery Time Sensor Slope Threshold

80-150 in steps of 5; 160-180 in steps of 10; **130** Off; Low; Medium; High 120-350 in steps of 10 Very Fast; Fast; Medium; Slow Fast; Medium; Slow; Very Slow On: Off: Passive Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16 in steps of 1 Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto (+2,0); 1-7 in steps of 0,5

Stored Electrograms

Options Sampling Options No. of Stored EGMs Channel Triggers Magnet Placement High Atrial Rate No. of Consecutive Cycles High Ventricular Rate No. of Consecutive Cycles Advanced Hysteresis

Other

Lead Monitoring A or V Low Impedance Limit ($\Omega\!\!\!\!\!\Omega$ A or V High Impedance Limit (Ω) A or V Signal Amplitude Monitoring Magnet Response Lead Type NIPS Options Stimulation Chamber Coupling Interval (ms) S1 Count S16: S2: S3 and S4 Cycle (ms) Sinus Node Recovery Delay (sec)

750; 1000; 1250; 1500; 1750; 2000 Off; **On** Off; Battery Test

Off; Monitor; Auto Polarity Switch

Freeze; Continuous

Atrial or Ventricular

2; 3; 4; 5; 10; 15; 20

2; 3; 4; 5; 10; 15; 20

1:2:4:8:12

On · Off

On; Off

200

Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar

Off; 125; 150; 175; 200; 225; 250; 275; 300

 $\pmb{0ff};\,125;\,150;\,175;\,200;\,225;\,250;\,275;\,300$

Atrial or Ventricular 100-800 in steps of 10 1-25 in steps of 1 100-800 in steps of 10 1-5 in steps of 1

 ± 0,5 cc
 The actual pacing rate for the 30 ppm is 31 ppm.
 The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.
 Sensitivity is with respect to a 20 ms haversine test signal. 5. This parameter is not programmable. 6. S1 Burst Cycle is applied at the preprogrammed S1 cycle length

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binef Summary: Prior to using these devices, please review the instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Sustain[™] XL DC

Dual-Chamber Pacemaker

Product Highlights

- Device features small, physiologic shape and offers superior longevity (9,8 years) without compromising size.¹
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and ventricular threshold tests.
- The Ventricular Intrinsic Preference (VIP[™]) algorithm automatically searches for intrinsic conduction.
- The AutoCapture[™] Pacing System feature offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation.
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event.
- 1. A, V = 2,5 V/0,4 ms, A,V = 500 ohms, 100% DDD pacing @ 60 bpm, SEGMs ON; data on file.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2134	44 x 52 x 6	23,5	11	IS-1

Indications and Usage: Implantation of Sustain pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. *Dual-Chamber Pacing* (*Models PMZ134 and PMZ136 only*) is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second - and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with synical disability, six six six syndrome, chronic, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. *Atrial Pacing* is indicated for patients with significant bradycardia and. Normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrilition, severe physical disability. *JR Suppression* "*(Models PMZ134 and PMZ136 only*)'s indicated for suppression of parxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. For specific indications associated with individual modes, refer to the programmer's on-screen help.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Because Sustain pulse generators will be automatically programmed to a unipolar pulse configuration if the device initiates Backup VVI pacing. Sustain devices are contraindicated in patients with an implanted cardioverter-defibrillator. AF Suppression (Models PM2134 and PM2136 and)'s timulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-Chamber Pacing (Models PM2134 and PM2136 only) though not contraindicated for patients

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of singlechamber pacing in such patients. *Single-Chamber Ventricular Demand Pacing* is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. *Single-Chamber Atrial Pacing* is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, see the programmer's on-screen help. **Potential Adverse Events:** Arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myootential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue; local tissue reaction, inability to interrogate or program a pulse generator because of programmer maffunction, infertion, interruption of desired pulse generator function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead maffunction (fracture or damage to insulation), loss of normal pacemaker function due to battery failure or component maffunction, pacemaker migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation.





Sustain[™] XL DC

Dual-Chamber Pacemaker

Product Specifications

Model

PHYSICAL SPECIFICATIONS

PM2134 44 x 52 x 6 23,5 11^{1} IS-1

SETTINGS

PARAMETER Rate/Timing

Dimensions (mm)

Weight (g)

Volume (cc)

Connector

Atrial Absolute Refractory Period Atrial Protection Interval (ms) Atrial Refractory (PVARP) (ms) AV Delay (ms) Base Rate (bpm) Far-Field Protection Interval (ms) Hysteresis Rate (min-1) Search Interval (min) Cycle Count Intervention Rate (min-1)

Intervention Duration (min) Recovery Time Maximum Tracking Rate (min-1) Mode

Post Vent. Atrial Blanking (PVAB) (ms)

Rate Responsive AV/PV Delay Rate Responsive PVARP/VREF Shortest PVARP/VREF PV Delay (ms) Rest Rate (min⁻¹) Shortest AV/PV Delay (ms) Ventricular Blanking (ms) Ventricular Refractory (ms)

Output/Sensing

A or V Pulse Amplitude (V) A or V Pulse Width (ms) A or V Pulse Configuration A or V Sense Configuration

Atrial Sensitivity (mV)

Ventricular AutoCapture™ Pacing System Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Threshold Search Interval (hours) Ventricular Sensitivity (mV)

AF Management

AF Suppression™ Algorithm Lower Rate Overdrive (min⁻¹) Upper Rate Overdrive (min-1) No. of Overdrive Pacing Cycles Rate Recovery (ms) Maximum AF Suppression Rate (min-1) Atrial Tachycardia Detection Rate (min⁻¹)

Auto Mode Switch AMS Base Rate (min-1) 60; 80; **100**-350 in steps of 25 125² 125-500 in steps of 25; 275 25; 30-200 in steps of 10; 225-300 in steps of 25; 350; 200 $30^3;\,40\mathchar`-130$ in steps of 5; 140-170 in steps of 10; 6016 Off; 30-130 in steps of 5; 140; 1504 Off; 5; 10; 15; 30 1-16 in steps of 1 Off; 60; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30 1-10 in 1 minute intervals Fast; Medium; Slow; Very Slow 90-130 in steps of 5; 140-180 in steps of 10; 130 A00; AAI; AAT; OAO; VOO; VVI; VVT; VDD; OVO; DOO; DVI; DDI; DDD; ODO 60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; **150**; 155; 165; 170; 180; 185; 195; 200 Off; Low; Medium; High Off: Low: Medium: High 120-350 in steps of 10; 170 25; 30-200 in steps of 10; 225-325 in steps of 25; ${\bf 150}$ Off: 30-130 in steps of 5: 140: 150 30-50 in steps of 5; 60-120 in steps of 10; **100** 12-52 in steps of 4; **12** 125-500 in steps of 255; 250

0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5; **2,5** 0,05; 0,1-1,5 in steps of 0,1; 0,4 Unipolar (tip-case): Bipolar (tip-ring) Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case) 0,1-0,4 in steps of 0,1 6 ; 0,5; 0,75-2,0 in steps of 0,25; 2,0-4,0 in steps of 0,5; 5,0 On; Off Unipolar Unipolar; Bipolar 5,0² 8;24 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5; 2,0

Off; On 102 5^{2} 15-40 in steps of 5 8;12 80-150 in steps of 5; 160-180 in steps of 10 110-150 in steps of 5; 160-200 in steps of 10; 225-300 in steps of 25; 180 Off; DDD to DDI; VDD to VVI; DDI Base Rate +0 to Base Rate +35 in steps of 5; Base Rate +20

Stored Electrograms

Options Sampling Options No. of Stored EGMs Channel Triggers Advanced Hysteresis AMS Entry/AMS Exit AT/AF Detection Magnet Placement High Atrial Rate No. of Consecutive Cycles High Ventricular Rate No. of Consecutive Cycles PMT Termination PVC Detection No. of Consecutive PVCs

Other

A and V Lead Monitoring A and V Low Impedance Limit (Ω) A and V High Impedance Limit (Q) Lead Type Magnet Response Negative AV/PV Hysteresis Search (ms) NIPS Options Stimulation Chamber Coupling Interval S1 Count S19: S2: S3 and S4 Cycle (ms) Ventricular Support Rate (min-1) Sinus Node Recovery Delay (sec) PMT Options PMT Detection Rate (min-1) **PVC** Options Signal Amplitude Monitoring P-Wave Monitoring R-Wave Monitoring Ventricular Intrinsic Preference (VIP™) (ms) VIP Search Interval **VIP Search Cycles** Ventricular Safety Standby

Freeze; Continuous 1; 2; **4**; 8; 12 Atrial; Ventricular; **Dual**; Cross-Channel 0n; **Off**

0n; **Off** 0n; **Off** 0n; **Off** Off; 125; 150; 175; 200; 225; 250; 275; 300 2; 3; 4; 5; 10; 15; 20 Off; 125; 150; 175; 200; 225; 250; 275; 300 2; 3; 4; 5; 10; 15; 20 0n; **Off** On: Off 2:3:4:5

Off; Monitor; Auto Polarity Switch

200² 750: 1000: 1250: 1500: 1750: 2000 Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar Off; Battery Test Off; -10 to -110 in steps of 10

Atrial; Ventricular 100-800 in steps of 10⁸ 1-25 in steps of 1 . 100-800 in steps of 10 Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95 1-5 in steps of 1 Off; 10 Beats > PMT; Auto Detect 90-150 in steps of 5: 160-180 in steps of 10: Off: 110 Off; A Pace on PVC; + PVARP on PVC (VDD mode only)

Off: On Off: **On**

Off; 50-150 in steps of 25; 160-200 in steps of 10 30 sec.; 1; 3; 5; 10; 30 min. $1 \cdot 2 \cdot 3$ Off · On

1. + 0.5 cc

2. This parameter is not programmable.

3. The actual pacing rate for the 30 bpm is 31 bpm

4. The higher available setting for Hysteresis Rate will be 5 bpm below the programmed Base Rate 5. In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.

6. Values 0,1-0,4 not available in a Unipolar Sense Configuration.7. Sensitivity is with respect to a 20 ms haversine test signal.

8. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV delay. 9. S1 Burst Cycle is applied at the preprogrammed S1 cycle lengt



Customer Support: 46-8-474-4756

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Pacemakers

Sustain[™] XL SC

Single-Chamber Pacemaker

Product Highlights

- Device features small, physiologic shape and offers superior longevity (12,8 years) without compromising size.¹
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and ventricular threshold tests.
- The AutoCapture[™] Pacing System feature offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation.
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event.
- 1. A, V = 2,5 V/0,4 ms, A,V = 500 ohms, 100% VVI pacing @ 60 bpm, SEGMs ON; data on file

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1134	42 x 52 x 6	23	10,4	IS-1

Indications and Usage: Implantation of Sustain pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation due to arrythina/bradycardia or any combination of those symptoms. Symptomatic bilateral bundle branch block when tachy-arrhythmia and other causes have been ruled out.

Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing is indicated for patients with significant bradycardia and. Normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability.

Contraindications: *Implanted Cardioverter-Defibrillator (ICD)*. Because Sustain pulse generators will be automatically programmed to a unipolar pulse configuration if the device initiates Backup VVI pacing, Sustain devices are contraindicated in patients with an implanted cardioverter-defibrillator.

Customer Support: 46-8-474-4756

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Potential Adverse Events: Arrhythmia, heart block, thrombosis, threshold elevation, valve damage, pneumothorax, myopotential sensing, vessel damage, air embolism, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue; local tissue reaction, inability to interrogate or program a pulse generator because of programmer malfunction, infection, interplin of desired pulse generator function due to electrical interference, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal pacemaker function due to battery failure or component malfunction, pacemaker migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation.





Sustain[™] XL SC

Single-Chamber Pacemaker

Product Specifications

SETTINGS

125-500 in steps of 25; 325

Off; 5; 10; 15; 30

1-16 in steps of 1

1-10 in 1 minute intervals

Off; Low; Medium; High

120-350 in steps of 10

Fast: Medium: Slow: Very Slow

Off; 30-130 in steps of 5; 140; 150

302: 40-130 in steps of 5: 140-170 in steps of 10

A00; AAI; AAT; OAO; VOO; VVI; VVT; OVO

Off; 60; 80-120 in steps of 10; Intrinsic +0;

Intrinsic +10; Intrinsic +20; Intrinsic +30

Off; 30-130 in steps of 5; 140; 1503

PHYSICAL SPECIFICATIONS Model PM1134 Dimensions (mm) 42 x 52 x 6 Weight (g) 23 10,41 Volume (cc) Connector IS-1

PARAMETER Rate/Timing

A or V Refractory (ms) Base Rate (bpm) Mode Hysteresis Rate (bpm) Search Interval (bpm) **Cvcle Count** Intervention Rate (bpm)

Intervention Duration (min) Recovery Time Rate Responsive VREF . Rest Rate (bpm) Shortest VREF

Output/Sensing

A or V Pulse Amplitude (V) A or V Pulse Width (ms) A or V Sensitivity (mV) A or V Pulse Configuration A or V Sense Configuration Ventricular AutoCapture[™] Pacing System Primary Pulse Configuration Backup Pulse Configuration Backup Pulse Amplitude (V) Search Interval (hours)

0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5; 2,5 0,05; 0,1-1,5 in steps of 0,1; **0,4** 0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5^4 Unipolar (tip-case); **Bipolar (tip-ring)** Unipolar Tip (tip-case); **Bipolar (tip-ring)**; Unipolar Ring (ring-case) 0n; **Off** Unipolar; Bipolar Unipolar; Bipolar 5,05 8;24

Stored Electrograms

Options Sampling Options No. of Stored FGMs Channel Triggers Magnet Placement High Atrial Rate No. of Consecutive Cycles High Ventricular Rate No. of Consecutive Cycles Advanced Hysteresis Other

Lead Monitoring A or V Low Impedance Limit (Ω) A or V High Impedance Limit (Ω) A or V Signal Amplitude Monitoring Magnet Response Lead Type NIPS Options . Stimulation Chamber Coupling Interval (ms) S1 Count S16: S2: S3 and S4 Cycle (ms) Sinus Node Recovery Delay (sec) Off; Monitor; Auto Polarity Switch 2005

0n; Off Off; 125; 150; 175; 200; 225; 250; 275; 300

 $\pmb{0ff};\,125;\,150;\,175;\,200;\,225;\,250;\,275;\,300$

Freeze; Continuous

Atrial or Ventricular

2; 3; 4; 5; 10; 15; 20

2; 3; 4; 5; 10; 15; 20

On: Off

1:2:4:8:12

750; 1000; 1250; 1500; 1750; 2000 Off; **On**

Off; Battery Test Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar

Atrial or Ventricular 100-800 in steps of 10 1-25 in steps of 1 100-800 in steps of 10 . 1-5 in steps of 1

- ± 0,5 cc
 The actual pacing rate for the 30 ppm is 31 ppm.
 The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.
 Sensitivity is with respect to a 20 ms haversine test signal.
- 5. This parameter is not programmable.
- 6. S1 Burst Cycle is applied at the preprogrammed S1 cycle length



Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of Binet Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, procautions, 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, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.

Pacemakers

Microny[™] II SR+

Single-Chamber Pacemaker

Product Highlights

- The AutoCapture[™] pacing system offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat[™] capture confirmation
- Automatic P/R sensitivity test suggests a programmed value for the P/R sensitivity
- Accelerometer sensor provides reliable rate response with only one programmable parameter (Slope)
- Beat-by-Beat[™] lead impedance monitoring
- Comprehensive diagnostics and management tools, including measured data, rate prediction model, stimulation threshold vs. time, sensor indicated rate vs. time and others

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
2525T	33 x 33 x 6	12,8	5,9	IS-1 bipolar

Indications: The pulse generators are indicated for: Accepted Patient Conditions warranting chronic cardiac pacing, which include: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachy-arrhythmia and other causes have been ruled out.

Atrial Pacing in patients with sinus node dysfunction and normal AV and intraventricular conduction systems. Ventricular Pacing in patients with significant bradycardia and:

normal sinus rhythm with only rare episodes of A-V block or sinus arrest requiring short periods of pacing support, chronic atrial fibrillation, severe physical disability.

Rate-Modulated Pacing in patients who would benefit from increased pacing rates concurrent with physical activity.

Contraindications: The pulse generators are contraindicated for: single-Chamber Ventricular Demand Pacing in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or who suffer a drop in arterial blood pressure with the onset of ventricular pacing, single-Chamber Artial Pacing in patients who have demonstrated compromise of AV conduction, rate-Modulated Pacing in patients who experience angina or

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

other symptoms of myocardial dysfunction at higher sensor-driven rates, unipolar pacing in patients with an implanted cardioverter-defibrillator (ICD) since it may inhibit or trigger ICD therapy. The pulse generators are programmed to unipolar pacing and may be inappropriate for patients with an ICD.

Protential Adverse Events: A dverse events: A dverse event a saxoiated with the use of any pacing system include: air embolism, bleeding/hematoma, body rejection phenomena, cardiac tamponade or perforation, formation of fibrotic tissue; local tissue reaction, Inability to interrogate or program due to programmer or device maifunction, infection/reosin, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead maifunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead displacement, body reaction at the electrode/Hissue interface, or lead maifunction, pacemaker migration, pocket erosion, or hematoma, pectoral muscle or diapragmatic stimulation, phenic nerve stimulation, pocket erosion, or hematoma, pectoral muscle or diapragmatic stimulation, phenic nerve stimulation, pocket erosion, or hematoma, pectoral muscle or diapragmatic stimulation, phenic nerve stimulation, previnder aversing a geneviting and advertial pockets to the loar's Maxwell function and experimentary.





Microny[™] II SR+

Single-Chamber Pacemaker

Product Specifications

Model Dimensions (mm) Weight (g) Volume (cc) Connector Battery Data

PHYSICAL SPECIFICATIONS

2525T 33 x 33 x 6 12,8 5,9 IS-1 Bipolar Lithium-iodine cell; 2,80 V/0,35 Ah

SETTINGS

PARAMETER Rate/Timing

Mode Basic Rate (ppm) Hysteresis Rate (ppm) Refractory Period (ms) A00(R); AAI(R); AAT(R); VO0(R); VVI*(R); VVT(R) 45 - 160 in steps of 5; 60* 0; 10; 20; 30 below the basic or sensor-indicated rate; Off* 250; 300*; 350; 400; 450; 500; 550

Output/Sensing

Pulse Amplitude (V) Pulse Width (ms)

P/R Sensitivity (mV) ER Sensitivity (mV) Pulse Polarity Configuration Sense Polarity Configuration $\begin{array}{l} Auto^{**} \ 0.3 - 4,5 \ in \ steps \ of \ 0.3; \ 2,4^{*} \\ 0.03, \ 0.06; \ 0.09; \ 0.12; \ 0,15; \ 0,18; \ 0,21; \ 0,24; \ 0,31^{*}; \ 0,37; \ 0,43; \\ 0.49; \ 0,58; \ 0,70; \ 0.82; \ 1,0 \\ 0.5; \ 0.8; \ 1,2; \ 2,0; \ 3,0^{*}; \ 5,0; \ 7,5; \ 12 \\ 1,6; \ 2,5; \ 4,0^{*}; \ 6,0; \ 10,0; \ 15,0; \ 24,0 \\ Unipolar \\ \end{array}$

Rate-Modulated Parameters

VARIO Ventricular AutoCapture[™] Pacing System Sensor Maximum Sensor Rate (ppm)*** Slope*** Reaction Time*** Recovery Time*** Fast Response***

 Capture
 Pacing System
 On, Off.

 or, Off.
 Passive
 90 - 160 in steps of 10; 130*

 or Rate (ppm)***
 90 - 160 in steps of 1; 10*

 **
 Very Fast; Fast; Medium*; Slow; Very Slow

 **
 Very Fast; Fast; Medium*; Slow; Very Slow

 **
 On; Off*

On; Off* On; Off*

* Standard/Nominal settings. ** Only with AutoCapture ON. *** Inactive. Activate by programming the sensor ON or PASSIVE.



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. 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 one 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.

Item GMCRM818EN



Verity[™] ADx XL VDR Model 5456 Rate-responsive Pacemaker

Product Highlights

- Extended longevity offers the benefit of fewer device replacements, reducing the risk of complications associated with surgery.
- The AutoCapture[™] pacing system offers the maximum in threshold adaptability and patient safety with Beat-by-Beat[™] capture confirmation
- The FastPath[™] Summary Screen displays key parameters and follow-up test results on one screen and provides one-step navigation to all available diagnostic tools.
- The Programmable Back-up Pulse may be programmed to either a bipolar or unipolar configuration
- The Auto Mode Switch algorithm reliably switches to a non atrial-tracking mode in the presence of atrial tachyarrhythmia episodes.
- Automatic P&R Wave Measurements provide the option of measuring hte amplictudes of intrinsic P-waves or R-waves. It then recommends a sensitivity setting based on a recommended safety margin. Automatic P&R Wave Measurements promote accurate sensitivity settings and save valuable clinic time.



Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5456	44 x 52 x 6	23,5	11 (± 0,5)	IS-1

Indications and Usage: Implantation of pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. *Dual-Chamber Pacing (Models 5826, 5820 nhy)* is indicated for patients with chronotropic sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. Atrial Pacing is indicated for patients with significant bradycardia and. Normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. *AF Suppression (Models 5826, 5820 only*) is indicated for supression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. For specific indications associated with individual modes, refer to Operating Modes.

Contraindications: Verity devices are contraindicated in patients with an implanted cardioverter-defibrillator. **Rate-Adaptive Pacing** may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. **AF Suppression** (**Models 5826, 5820 only**) stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Dual-Chamber Pacing (Models 5826, 5820 only) though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated emonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, refer to Operating Modes.

Potential Adverse Events: Adverse events associated with the use of any pacing system include: Air embolism, Bleeding Hematoma, Body rejection phenomena, Cardiac tamponade or perforation, Formation of fibrotic tissue, local tissue reaction, Inability to interrogate or program due to programmer or device malfunction, Infection/recosion, Interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, Lead malfunction due to conductor fracture or insulation degradation, Loss of capture or sensing due to lead dislodgement or reaction at the electrode interface, Loss of desired pacing and/or sensing due to lead dislodgement or reaction at the electrode interface, ender due to the state or damage to insulation). Loss of normal device function due to battery failure or component malfunction, Pacemaker migration, pocket erosion or hematoma, Pectoral muscle or diaphragmatic stimulation, Phrenic nerve stimulation, Pneumothorax/hemothorax.



Verity[™] ADx XL VDR

Model 5456 Rate-responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	5456
Dimensions (mm)	44 x 52 x 6
Weight (g)	23.5
Volume (cc)	111
Connector	IS-1
PARAMETER	SETTINGS
Rate/Timing	
Mode	VOO(R); VVI(R); VVT(R); VDD(R); OVO; OAO; ODO
Base Rate (ppm)	30 ² ; 40–130 in steps of 5; 140–170 in steps of 10; 60
Hysteresis Rate (ppm)	Off; 30–130 in steps of 5; 140; 150 ³
Search Interval (min)	Off; 5; 10; 15; 30
Cycle Count	1-3; 1
Rest Rate (ppm)	Off; 30–130 in steps of 5; 140; 150
Maximum Tracking Rate (ppm)	90–130 in steps of 5; 140–180 in steps of 10; 110
PV Delay (ms)	25; 30-200 in steps of 10; 225–325 in steps of 25; 150
Shortest AV/PV Delay (ms)	30–50 in steps of 5; 60–120 in steps of 10; 70
Ventricular Refractory (ms)	125-500 in steps of 25; 2504
Atrial Refractory (PVARP) (ms)	125–500 in steps of 25; 275
Vent. Blanking (ms)	12-52 in steps of 4; 12
Far Field Protection Interval (ms)	16
Output/Sensing	
Ventricular AutoCapture™ Pacing System	On; Off
Back-up Pulse Configuration	Unipolar; Bipolar
Evoked Response Sensitivity (mV)	Dependent upon the Measured Evoked Response; 49.7
V. Pulse Amplitude (V)	0.0–4.0 in steps of 0.25; 4.5–7.5 in steps of 0.5; 3.5
V. Pulse Width (ms)	0.05; 0.1–1.5 in steps of 0.1; 0.4
V. Sensitivity ⁵ (mV)	0.5–5.0 in steps of 0.5; 6–10 in steps of 1.0; 12.5; 2.0
V. Pulse Configuration	Unipolar (tip–case); Bipolar (tip–ring)
Sense Configuration (A or V)	Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar
A Constituité (mV)	Ring (ring-case)
A. Sensitivity ⁵ (mV)	0.1; 0.2; 0.3; 0.4; 0.5; 0.75; 1.0; 1.25; 1.5; 1.75; 2.0; 2.5; 3.0; 3.5; 4.0; 5.0
Rate-Modulated Parameters	
Auto Mode Switch	Off, DDDR to DDIR; DDD to DDI; VDDR to VVIR; VDD to VVI; DDDR to DDI; DDD to DDIR; VDDR to VVI; VDD to VVIR
AMS Base Rate (ppm)	Base Rate +0 to Base Rate +35 in steps of 5; 60
Sensor	On; Off; Passive
Max Sensor Rate (ppm)	80-150 in steps of 5; 160-180 in steps of 10; 110
Threshold	Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0); Auto
	(+1.5); Auto +(2.0); 1-7 in steps of 0.5
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16; 8
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Other	
Magnet Response	Off; Battery Test
AutoIntrinsic Conduction Search (ms)	Off; +10 to +120 in steps of 10
Negative AV/PV Hysteresis Search (ms)	Off; -10 to -110 in steps of 10
Atrial Tachycardia Detection Rate (ppm)	110–150 in steps of 5; 160–200 in steps of 10;
Post Vent. Atrial Blanking (PVAB) (ms)	225–300 in steps of 25; 225 60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140;
Vant Safaty Standby	150; 155; 165; 170; 180; 185; 195; 200
Vent. Safety Standby	Off; On Off. + BWARB on BVC
PVC Options PMT Options	Off; +PVARP on PVC
PMT Detection Rate (ppm)	Off; 10 Beats > PMT; Auto Detect 90-150 in steps of 5; 160-180 in steps of 10; 110
Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar
2000	encease, empoiar, orporar enty, empoiar orporar

- ± 0.5 cc
 The actual pacing rate for the 30ppm is 31ppm.
 The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.
 In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
- 5. Sensitvity is with respect to a 20 ms haversine test signal.

Customer Support: 46-8-474-4756

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. 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 one 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.



Pacing Leads

St. Jude Medical Pacing Leads

The St. Jude Medical portfolio of highly advanced bradycardia pacing leads has been designed for ease of implant, reliability and performance.

Optim[™] lead insulation used in the newest leads is the first silicone-polyurethane co-polymer insulation designed specifically for cardiac lead use. The innovative insulation material blends the best features of polyurethane and silicone, enabling the durability of polyurethane and the flexibility of silicone.

Options with shorter tip-to-ring spacing allow for more accurate sensing and appropriate diagnostics and therapies. Ventricular straight or atrial J-shape active fixation options and multiple lengths offer the flexibility to address the needs of patients with varying physical statures and vascular anatomies. Three different J-shape stylets and a long tool provide options for atrial lead placement and lead handling preferences.

Steroid elution and titanium nitride fractal coating on electrodes enable low thresholds.



Pacing Leads

Tendril MRI™

Pacing Lead

Product Highlights

- The Tendril MRI lead is designed to ensure patient safety while performing an MRI scan¹
 - The Tendril MRI conditional lead must be used in conjunction with an MRI device from St. Jude Medical and with a 1,5 T (Tesla) MRI scanner
- Soft silicone tip offers more compliance at the lead tip-endocardium interface
 - The soft silicone tip on the Tendril MRI LPA1200M lead reduces tip pressure by approximately 50% over 6 F leads without a soft silicone tip² Though the soft silicone increases the surface area of the lead tip to 9 F, the Tendril MRI lead still fits through an 8 F introducer due to the material's soft nature. Four pads on the silicone tip further increase the surface area of the lead tip that is in contact with the tissue
- Optim[™] lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone—provides improved handling and increased durability
- Limited lifetime warranty
 - Terms and conditions apply. Refer to the warranty for details

See manual for additional details before performing an MRI scan.
 Bench testing data on file.

Ordering Information

Contents: Cardiac pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
LPA1200M	Optim	Ext/Ret helix	8	IS-1 bipolar	46, 52 and 58



Indications: The Tendril MRI[™] 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 MRI lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead such as Tendril MRI lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

This is an MR Conditional lead.

MR Conditional Pacing System: The St. Jude Medical MRI conditional lead is part of the St. Jude Medical[™] MRI conditional pacing system. Patients with an implanted St. Jude Medical[™] MRI conditional pacing system can have an MRI scan if the conditions for use, as described in the MRI Procedure Information document, are met.

Customer Support: 46-8-474-4756

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Contraindications: The Tendril MRI[™] lead is contraindicated in the presence of tricuspid atresia, for patients with mechanical tricuspid valves, and 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 MRI leads are the same as with the use of other active fixation leads and include: perforation of the myocardium, cardiac tamponade, phrenic nerve stimulation, dislodgement of the pacing lead, embodism, temporary or permanent loss of stimulation and/or sensing, infection, valve and/or vessel damage, tissue necrosis.



Tendril MRI[™]

Pacing Lead

Product Specifications

Model	LPA1200M
Minimum Introducer Size	8 F
Minimum Introducer Size with Guidewire	10,5 F
Type of Lead	Active-fixation, steroid-eluting, endocardial, straight pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46, 52 and 58 cm
Fixation Mechanism	Extendable/Retractable helix
Typical Number of Rotations	
for Helix Extension	5-10 (straight stylet)
Lead Body Diameter	2,18 mm (max)/6,6 F
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active TiN-coated Pt/Ir helix (1,8 mm extension)
Tip Electrode Surface Area	6,8 mm ²
Ring Electrode (Anode)	TiN-coated Pt/Ir
Ring Electrode Surface Area	16,5 mm ²
Mapping	Capable with TiN-coated Pt/Ir helix
Steroid	Silicone plug with <1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N ^{™*} coil
Inner Insulation	Silicone
Outer Insulation	Optim™ lead insulation

In Pack

Straight stylets 1 x-soft in lead, 1 x-soft, 1 soft J-shaped stylets Helix extension/retraction clip-on tools 2 soft 2 clip-on tools

Accessory Kits Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DSO6002 with appropriate length designation	46, 52 and 58 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 and 58 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 and 58 cm	Disposable implant tool to facilitate precise lead positioning
	1292 with appropriate length designation	46, 52 and 58 cm	and manipulation with one hand

*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

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Tendril[™] STS

Pacing Lead

Product Highlights

- 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 co-polymer 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 pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Lengths (cm)
2088TC	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.

Customer Support: 46-8-474-4756

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Tendril[™] STS

Pacing Lead

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 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 titanium-nitride-coated Pt/Ir helix (2,0 mm extension)
Tip Electrode Surface Area	6,9 mm ²
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm ²
Mapping	Capable with titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
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	DS06002 with appropriate length designation	46; 52; 58 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 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 cm	Disposable implant tool to facilitate precise lead positioning
	1292 with appropriate length designation	46; 52; 58 cm	and manipulation with one hand

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Customer Support: 46-8-474-4756

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. 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.



Pacing Leads

OptiSense[™] Pacing Lead

Product Highlights

- OptiSense[™] lead technology offers optimal tip-to-ring spacing for more precise atrial sensing without inappropriately sensing extra-atrial signals
 - Unique 1,1 mm tip-to-ring spacing enables sensing of even the finest atrial arrhythmia signals (standard atrial leads typically have a tip-to-ring spacing of 10 mm or more)
 - Accurate atrial sensing enables appropriate atrial diagnostics and therapies
- Less far-field R-wave interference with innovative far-field signal reduction technology
- Optim[™] lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Thin lead body diameter of 5,8 F can be inserted using a 7 F introducer
- Steroid elution and titanium nitride fractal coating on electrodes for low thresholds
- Includes three different J-shaped stylets providing options for different patient anatomies and handling preferences

Ordering Information

Contents: Cardiac pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Lengths (cm)
1999	Optim	Ext/Ret helix	7	IS-1 bipolar	40; 46; 52

Indications: The OptiSense[™] lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the OptiSense, may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the OptiSense, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The OptiSense[™] 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.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.

Adverse Events: Potential complications associated with the use of OptiSense[™] 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 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.





OptiSense™ **Pacing Lead**

Product Specifications

PHYSICAL SPECIFICATIONS			
Model	1999		
Minimum Introducer Size	7 F		
Type of Lead	Active-fixation; bipolar; steroid-eluting; endocardial; atrial pacing lead		
Lead Connector	IS-1 bipolar		
Lead Lengths	40; 46; 52 cm		
Fixation Mechanism	Extendable/Retractable helix		
Lead Body Diameter	0,076"/1,9 mm (5,8 F)		
Tip-to-ring Spacing	1,1 mm		
Lead Tip Electrode (Cathode)	Active titanium-nitride-coated Pt/Ir helix (1,8 mm extension)		
Tip Electrode Surface Area	6,4 mm ²		
Ring Electrode (Anode)	Titanium-nitride-coated titanium ring		
Ring Electrode Surface Area	17 mm ²		
Mapping	Capable with titanium-nitride-coated Pt/Ir helix		
Steroid	< 1 mg dexamethasone sodium phosphate		
Inner Conductor/Outer Conductor	MP35N [™] * coil		
Inner Insulation	Silicone rubber		
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 1 standard; 1 wide; 1 narrow Helix Extension/Retraction Clip-on Tools 2 clip-on tools

Accessorv	Kits

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DS06000 with appropriate length designation	40; 46; 52 cm	1 fixation tool; 1 clip-on tool; 1 standard J shape 1 wide J shape; 1 narrow J shape
	DS06001 with appropriate length designation	40; 46; 52 cm	1 clip-on tool; 1 standard J shape 1 wide J shape; 1 narrow J shape
	DS06002 with appropriate	46; 52 cm	1 fixation tool; 1 clip-on tool;
	length designation		1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
	DSO6003 with appropriate length designation	40; 46; 52 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 cm	Disposable implant tool that facilitates precise lead positioning and allows
	1292 with appropriate length designation	46; 52 cm	manipulation with one hand

Limited Lifetime Warranty

Terms and conditions apply; refer to the warranty for details.

 * MP35N is a registered trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

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Pacing Leads

Tendril[™] ST Optim[™]

Pacing Lead

Product Highlights

- Optim[™] lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Thin lead body to provide ease of passage and a small venous space
- Active mapping collar enables threshold measurements prior to extending the helix to save time at implant
- Ventricular straight or atrial J-shaped active-fixation options

Ordering Information

Contents: Cardiac pacing lead



Model	Type of			Min.		
Number	Lead	Insulation	Fixation	Introducer (F)	Connector	Lengths (cm)
1888TC	Straight	Optim	Ext/Ret Helix	6	IS-1 bipolar	46; 52; 58; 65
1882TC	Atrial J	Optim	Ext/Ret Helix	7	IS-1 bipolar	46; 52

Indications: The Tendril[™] ST Optim[™] lead is designed for permanent sensing and pacing in either the atrium or the ventricle, in combination with a compatible pulse generator. An active lead, such as the Tendril[™] ST Optim[™], may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the Tendril SDX, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The Tendril[™] ST Optim[™] lead is contraindicated: In the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients with one expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Customer Support: 46-8-474-4756

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Adverse Events: Potential complications associated with the use of Tendril[™] ST Optim[™] 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 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.



Tendril[™] ST Optim[™]

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	1888TC	1882TC
Minimum Introducer Size	6 F	7 F
Type of Lead	Transvenous, screw-in, bipolar, steroid	Transvenous, screw-in, bipolar, steroid
Shape	Straight	Atrial J
Lead Lengths	46; 52; 58; 65 cm	46; 52 cm
Fixation	Extendable/retractable helix	Extendable/retractable helix
Tip-to-Ring Spacing	10 mm	10 mm
Lead Tip Electrode (Cathode)	Pt/Ir collar + active titanium nitride coated	Pt/Ir collar + active titanium nitride coated
	Pt/Ir helix (2 mm extension)	Pt/Ir helix (2 mm extension)
Tip Electrode Surface Area	8,5 mm ²	8,5 mm ²
Ring Electrode (Anode)	Titanium nitride coated Pt/Ir ring	Titanium nitride coated Pt/Ir ring
Ring Electrode Surface Area	16 mm ²	16 mm ²
Mapping	Available with collar	Available with collar
Steroid Elution	Yes	Yes
Conductor	MP35N™* coil	MP35N™* coil
Insulation	Optim	Optim

Accessory Kits Available Separately

ACCESSORY	MODEL	AVAILABLE LENGTHS	DESCRIPTION
Stylet Kit	DS06002 and DS06003 with appropriate length designation for use with TC model Tendril and Tendril ST leads	46; 52; 58; 65 cm	$4\ \text{straight}\ \text{stylets}\ (1x\ \text{soft};\ 1\ \text{soft};\ 1\ \text{firm};\ 1\ x\ \text{firm});\ 1\ j;\ 1\ \text{universal}\ \text{clip-on}\ \text{tool}$

*MP35N is a trademark of SPS Technologies. Inc.

Customer Support: 46-8-474-4756

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Tendril[™] SDX

Pacing Lead

Product Highlights

- Radiopaque suture sleeve, ultra-thin lead body and Fast-Pass[™] coating for easy implantation
- Steroid elution and titanium nitride fractal coating on electrodes for low thresholds
- Shorter tip-to-ring spacing and silicone insulation for high performance and reliability



Ordering Information

Contents: Cardiac pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
1688TC	Silicone Rubber	Ext/Ret Helix	7	IS-1 bipolar	100

Indications: The Tendril[®] SDX lead is designed for permanent sensing and pacing in either the atrium or the ventricle, in combination with a compatible pulse generator. An active lead, such as the Tendril SDX, may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the Tendril SDX, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The Tendril[™] SDX 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.

Customer Support: 46-8-474-4756

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Adverse Events: Potential complications associated with the use of Tendril[™] SDX 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 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.



Tendril[™] SDX

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Model Lead Connector Length Minimum Introducer Size Type of Lead Fixation Mechanism External Lead Body Diameter Tip-to-Ring Spacing Lead Tip Electrode (Cathode)

Tip Electrode Surface Area Ring Electrode (Anode) Ring Electrode Surface Area Mapping Steroid Inner Conductor Inner Insulation Outer Conductor Outer Insulation

1688TC IS-1 Bipolar 100 cm 7 F 7 F Transvenous, screw-in, bipolar, steroid Extendable/Retractable helix (3 facet) 0,081"/2,1 mm (6,2 F) 10 mm Pt/Ir collar + active titanium nitride coated Pt/Ir helix (1,8 mm extension) 8 mm² (collar: 2,4 mm²; helix: 5,6 mm²) Titanium nitride coated Pt/Ir ring 16 mm² 16 mm² Available with collar ≤ 1 mg dexamethasone sodium phosphate MP35N[™]* coil Silicone rubber MP35N™* coil Silicone rubber

* MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



Pacing Leads

IsoFlex[™] Optim[™]

Pacing Lead

Product Highlights

- Straight or J-shaped lead is available in multiple lengths to accommodate varying needs and patient anatomies
- OptimTM lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone—provides improved handling and increased durability
- Symmetrical lead body with coaxial multifilar coils for reliability
- Steroid-eluting tip for reduced inflammation at the lead-tissue interface and low pacing thresholds
- Small tip surface area for higher impedance levels and optimal device longevity
- Titanium nitrade (TiN) coated tip and ring electrode for low polarization values and compatibility with the AutoCapture[™] Pacing System algorithm
- Radiopaque suture sleeve for visibility under fluoroscopy to simplify invasive procedures

Ordering Information

Contents: Cardiac pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Lengths (cm)
1944 (J-Shaped)	Optim	Tines	7	IS-1 bipolar	46; 52
1948 (Straight)	Optim	Tines	7	IS-1 bipolar	46; 52; 58

Indications: The IsoFlex[™] lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the IsoFlex[™], may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the IsoFlex[™], may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage. **Contraindications:** The IsoFlex[™] 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 IsoFlex[™] 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 dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, etcosis. 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.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.





IsoFlex[™] Optim[™]

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS		
Model	1944	1948
Vinimum Introducer Size	7 F	7 F
Type of Lead	bipolar, passive fixation lead	bipolar, passive fixation lead
Lead Connector	IS-1 bipolar	IS-1 bipolar
ead Lengths	46; 52 cm	46; 52; 58 cm
ixation Mechanism	tines	tines
lip-to-ring Spacing	10 mm	10 mm
ead Tip Electrode (Cathode)	Semi spherical shape, steroid coating	Semi spherical shape, steroid coating
ip Electrode Surface Area	3,5 mm ²	
Ring Electrode (Anode)	Platinum-iridium, coated with titanium nitrade	3,5 mm ²
Ring Electrode Surface Area	16 mm ²	16 mm ²
Steroid	< 1 mg dexamethasone sodium phosphate in silicone matrix	< 1 mg dexamethasone sodium phosphate in silicone matrix
nner Insulation	Silicone rubber	Silicone rubber
Outer Insulation	Optim [™] lead insulation	Optim [™] lead insulation
Lead Body Coating	Fast-Pass [™] coating	Fast-Pass [™] coating
n Pack		
Straight Stylets	1 x-soft in lead; 1 x-soft; 1 soft	

J-curved Stylets 1 standard; 1 wide; 1 narrow Helix Extension/Retraction Clip-on Tools 2 clip-on tools

Accessory	Kits
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Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	4064	40, 46, 52, 58 and 85 cm	X-Firm Stylets (2)
Stylet Kit	4062	40, 46, 52, 58 and 85 cm	Firm Stylets (2)
Stylet Kit	4060	40, 46, 52, 58 and 85 cm	Soft Stylets (2)

Limited Lifetime Warranty

Terms and conditions apply; refer to the warranty for details.

Customer Support: 46-8-474-4756

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Pacing Leads

AV Plus[™] DX VDD

Pacing Lead

Product Highlights

- Depending on the model, the AV Plus DX lead is available in multiple lengths, affording physicians the flexibility to address the needs of patients with varying physical statures
- Radiopaque Suture Sleeve is designed to be visible on fluoroscopy, helping physicians to locate the suture sleeve during implant
- Fast-Pass[™] coating makes the lead highly lubricious, helping to facilitate lead insertion through the introducer and the veins
- Durable Design utilises a bipolar coaxial multifilar lead body design with silicone insulation construction
- Tip electrode surface area helps to provide higher lead impedance, thereby reducing pacing current drain and enhancing longevity
- Offers a steroid-eluting plug inside the lead's tip electrode that is designed to reduce tissue inflammation at the electrode-tissue interface
- The tip and ring electrodes are coated with titanium nitride (TiN), which is designed to expand the electrode's virtual surface area, thus providing low polarisation values and improved sensing

Ordering Information

Contents: Cardiac pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Lengths (cm)
1368	Silicone	Tines	9	IS-1 bipolar	52; 58; 65

Indications: The AV Plus™ DX VDD lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the AV Plus™ DX VDD, may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the AV Plus™ DX VDD, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The AV PlusTM DX VDD 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.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precations, 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 one 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.



Adverse Events: Potential complications associated with the use of AV PlusTM DX VDD 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 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.



AV Plus[™] DX VDD

Pacing Lead

Product Specifications

Model	1368
Minimum Introducer Size	9 F
Lead Connector	IS-1 Bipolar
Lead Lengths	52; 58; 65 cm
Fixation Mechanism	Tines
Lead Body Diameter	2,0 mm
Tip to Ventricular Ring Spacing	15 mm
Tip to Atrial Ring Spacing	130 mm
Lead Tip Electrode	Semispherical shape, steroid coating
Tip to Electrode Surface Area	5 mm ²
Ring Electrode	Platinum-iridium, coated with microporous titanium nitride
Ring Electrode Surface Area	32 mm ²
Steroid	<1 mg dexamethasone sodium phosphate in silicone matrix
Insulation	Silicone

Accessory Kits ratal ailahla S

Available Separately	Model Number	Accessory Item	Description
Traffic-Light™ Stylet Kit	4060	40, 46, 52, 58 and 85 cm	2 straight, soft stylets – Green (0,014")
Traffic-Light™ Stylet Kit	4062	40, 46, 52, 58 and 85 cm	2 straight, firm stylets – Yellow (0,015")
Traffic-Light™ Stylet Kit	4064	40, 46, 52, 58 and 85 cm	2 straight, x-firm stylets – Red (0,016")
Traffic-Light™ Stylet Kit	S-65-x	65 cm	2 straight, soft, firm of x-firm stylets



Customer Support: 46-8-474-4756

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ACCESSORIES

Universal Stylet Kit

Product Highlights

- Repositioning kit for use with LV and HV leads
- Kit includes 4 straight stylets (X-Soft: Light Green Soft: Green Firm: Yellow X-Firm: Red), 1 soft
 "J-Shape" stylet (Green with White Cap), 1 Implant Tool (DS06002 only) and 1 Universal Clip-On-Tool
- DS06002 Stylets are 8 cm longer for compatibility with Implant Tool

Ordering Information

Model Number	Length (cm)	Implant Tool
DS06002/52	52	1 included
DS06002/58	58	1 included
DS06002/60	60	1 included
DS06002/65	65	1 included
DS06002/75	75	1 included
DS06002/85	85	1 included
DS06003/52	52	-
DS06003/58	58	-
DS06003/65	65	-
DS06003/75	75	-
DS06003/85	85	-
DS06003/100	100	-



Customer Support: 46-8-474-4756

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Traffic[™] Light Stylet

Product Highlights

- Stylets for passive-fixation leads
- Each pack contains 2 straight stylets
- Available in multiple stiffness levels
 (Soft: Green Firm: Yellow X-Firm: Red)

Ordering Information

Model Number	Stiffness	Diameter (in)	Length (cm)
4060/40	Soft	0,014	40
4060/46	Soft	0,014	46
4060/52	Soft	0,014	52
4060/58	Soft	0,014	58
4060/85	Soft	0,014	85
4062/40	Firm	0,015	40
4062/46	Firm	0,015	46
4062/52	Firm	0,015	52
4062/58	Firm	0,015	58
4062/85	Firm	0,015	85
4064/40	X-Firm	0,015	40
4064/46	X-Firm	0,015	46
4064/52	X-Firm	0,015	52
4064/58	X-Firm	0,015	58
4064/85	X-Firm	0,015	85

Customer Support: 46-8-474-4756

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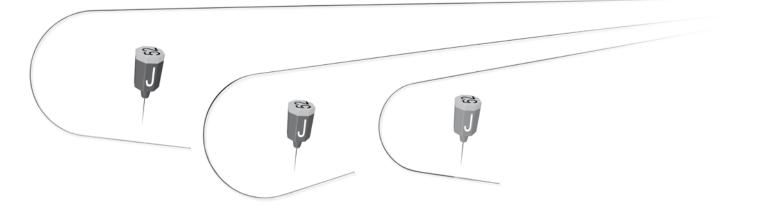
Atrial J Stylet Kit

Product Highlights

- For atrial lead positioning in various patient anatomies
- Stylets Specifications: Ø 0,014" (0,35 mm)
 - Standard is designed for placement in the atrial appendage (Taper Length: 20 mm Curve Ø: 24 mm Curve Angle: 220°)
 - Wide can be used in large atria (Taper Length: 36 mm Curve Ø: 29,5 mm Curve Angle: 180°)
 - Narrow can be used in the high atrial septal position (Taper Length: 10 mm Curve Ø: 20 mm Curve Angle: 170°)
- Kit includes 3 "J-Shape" stylets (Standard: Green Wide: Grey Narrow: Orange)
- 1 Implant Tool (with DS06000 only) and 1 Universal Clip-On-Tool

Ordering Information

Model Number	Length (cm)	Implant Tool
DS06000/40	40	1 included
DS06000/46	46	1 included
DS06000/52	52	1 included
DS06001/40	40	-
DS06001/46	46	-
DS06001/52	52	-



Customer Support: 46-8-474-4756

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Mond[™] RVOT Stylet

Product Highlights

- Innovative 3D design for precise lead placement in the Right Ventricular Outflow Track (RVOT)
- High tensile stainless steel construction to reduce the likelihood of kinking
- Kit includes 2 stylets (Soft: Green, Ø 0,014" Firm: Yellow, Ø 0,015") 1 Implant Tool (with 4140 and 4150 only) and 1 Universal Clip-On-Tool
- Available in 2 curvatures (Medium and Wide) to accommodate normal and large heart sizes

Ordering Information

Model Number	Primary Curvature	Length (cm)	Implant Tool
4140/52	Medium	52	1 included
4140/58	Medium	58	1 included
4141/52	Medium	52	-
4141/58	Medium	58	-
4141/60	Medium	60	-
4141/65	Medium	65	-
4150/52	Wide	52	1 included
4150/58	Wide	58	1 included
4151/52	Wide	52	-
4151/58	Wide	58	-
4151/60	Wide	60	-
4151/65	Wide	65	-

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High Voltage Leads Stylets

Product Highlights

- For Riata[™] and Durata[™] family of leads
- Available in multiple stiffness levels and taper lengths
- X-Firm stylet is not recommended for Riata[™] ST leads

Ordering Information

S-65-XS for 65 cr S-65-S for 65 cr S-75-S for 75 cr S-60-F for 60 cr	tion S	Stiffness	Diameter (in)	Taper Length (cm)
S-75-S for 75 cr	m leads X	C-Soft	0,014"	4
	m leads S	Soft	0,014"	2
S-60-F for 60 cr	m leads S	Soft	0,014"	2
	m leads F	īrm	0,015"	2
S-65-F for 65 cr	m leads F	īrm	0,015"	2
S-75-F for 75 cr	m leads F	īrm	0,015"	2
S-65-X for 65 cr	m leads X	-Firm	0,016"	2
S-75-X for 75 cr	n leads X	-Firm	0,016"	2

CRT Leads Stylets

Product Highlights

■ For QuickSite[™] leads repositioning

Kit includes: 3 Soft Stylets (Green), 2 Firm Stylets (Yellow), 1 X-Firm Stylet (Red)

Ordering Information

	Lead Length (cm)	Taper Length (cm)
4078S/75/15	75	15
4078S/86/15	86	15
4078S/75/5	75	5
4078S/86/5	86	5

Customer Support: 46-8-474-4756

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Peel-Away Introducer 14 cm Sheath Introducer Kit **7 F-16 F**

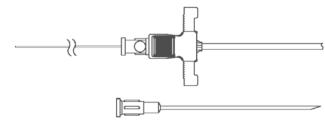
Product Highlights

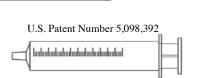
- Proprietary materials improve insertion characteristics and reduce vessel trauma
- Close tolerance extrusion and proprietary tipping process improves tracking on a guidewire
- Reliable peeling characteristics
- Sheath can be totally occluded without kinking to prevent air inspiration
- Di-Lock[™] feature secures dilator in sheath during insertion

Ordering Information

Contents: Peel-Away Sheath, Di-Lock™ Dilator, 12 cc syringe, 18 ga. XTW Needle, and 50 cm Guidewire with 3 mm "J"

Model Number	Size (F)	Maximum Guidewire Diameter (in)	Sheath Usable Length (cm)	Units per Box
405154	7 F-TW	,038	14	1
405145	8 F-TW	,038	14	1
405146	8 F	,038	14	1
405147	9 F	,038	14	1
405149	10 F	,038	14	1
405104	6 F	,038	14	5
405108	7 F	,038	14	5
405112	8 F	,038	14	5
405129	8 F-TW	,038	14	5
405116	9 F	,038	14	5
405118	9,5 F	,038	14	5
405120	10 F	,038	14	5
405122	10,5 F	,038	14	5
405124	11 F	,038	14	5
405128	12 F	,038	14	5
405132	13 F	,038	14	5
405144	16 F	,038	14	5





Customer Support: 46-8-474-4756

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Peel-Away Introducer 23 cm Sheath Introducer Kit 7 F-14 F

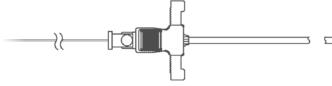
Product Highlights

- Proprietary materials improve insertion characteristics and reduce vessel trauma
- Close tolerance extrusion and proprietary tipping process improves tracking on a guidewire
- Reliable peeling characteristics
- Sheath can be totally occluded without kinking to prevent air inspiration
- Di-Lock[™] feature secures dilator in sheath during insertion

Ordering Information

Contents: Peel-Away Sheath, Di-Lock™ Dilator, and 80 cm Guidewire with 3 mm "J" (10 units per box)

Model Number	Size (F)	Maximum Guidewire Diameter (in)	Sheath Usable Length (cm)
405269	7	,038	23
405270	8	,038	23
405254	9	,038	23
405256	10	,038	23
405258	11	,038	23
405259	12	,038	23
405261	14	,038	23





U.S. Patent Number 5,098,392

Customer Support: 46-8-474-4756

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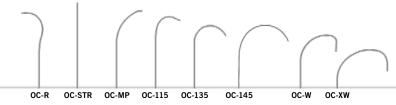
Product Highlights

- Unique SiteMark[™] tungsten marker stripes provide superior fluoroscopic visibility to verify torque transfer
- Compatible with CPS Aim[™] inner catheter and CPS Luminary[™] bideflectable catheter with lumen to modify shape and extend reach if necessary
- EvenPeel[™] stripes provide more smooth and reliable peeling for worry-free sheath removal

Ordering Information

Included: sheath with hemostasis valve attached, dilator and 2 valve bypass tools

Model Number	Curve Shape	Available Length (cm)	Overall Length (cm)	Inner Diameter (F/mm)	Outer Diameter (F/mm)
410210	Straight (OC-STR)	47	50,7	7/2,44	9/3,00
410211	Multipurpose (OC-MP)	47	50,7	7/2,44	9/3,00
410212	115° (OC-115)	47	50,7	7/2,44	9/3,00
410213	135° (OC-135)	47	50,7	7/2,44	9/3,00
410214	Wide (OC-W)	47	50,7	7/2,44	9/3,00
410215	Extra Wide (OC-XW)	47	50,7	7/2,44	9/3,00
410216	Right Sided (OC-R)	47	50,7	7/2,44	9/3,00
410224	145° (OC-145)	47	50,7	7/2,44	9/3,00
410217	Straight (OC-STR)	54	57,7	7/2,44	9/3,00
410218	Multipurpose (OC-MP)	54	57,7	7/2,44	9/3,00
410219	115° (OC-115)	54	57,7	7/2,44	9/3,00
410220	135° (OC-135)	54	57,7	7/2,44	9/3,00
410221	Wide (OC-W)	54	57,7	7/2,44	9/3,00
410222	Extra Wide (OC-XW)	54	57,7	7/2,44	9/3,00
410223	Right Sided (OC-R)	54	57,7	7/2,44	9/3,00
410225	145° (OC-145)	54	57,7	7/2,44	9/3,00



Separately Available Accessories

Model Number	Name	Туре
410194	CPS Direct [™] PL Valve Bypass Tool (Pack of 2)	Valve bypass tool
410195	CPS Direct [™] PL Inner Catheter SafeSheath [™] Sealing Adapter	Self-sealing valve
410190	CPS [™] Implant Kit (Includes Needle, Syringe and 0,035" Guidewire)	Implant Kit

Customer Support: 46-8-474-4756

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CPS Direct[™] SL II Slittable Outer Guide Catheter

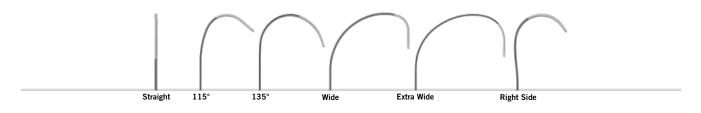
Product Highlights

- Integrated hub and hemostasis valve
- Increased curve retention and optimized catheter body structure for improved kink resistance
- Soft tip to lessen risk of traumatic insertion

Ordering Information

Included: dilator and 2 valve bypass tools

Model Number	Curve Shape	Available Length (cm)	Overall Length (cm)	Inner Diameter (F/mm)	Outer Diameter (F/mm)
DS2C001	Straight	47	50,7	7/2,44	9/3,00
DS2C002	115°	47	50,7	7/2,44	9/3,00
DS2C003	135°	47	50,7	7/2,44	9/3,00
DS2C004	Wide	47	50,7	7/2,44	9/3,00
DS2C005	X-Wide	47	50,7	7/2,44	9/3,00
DS2C006	Right Side	47	50,7	7/2,44	9/3,00
DS2C011	Straight	54	57,7	7/2,44	9/3,00
DS2C012	115°	54	57,7	7/2,44	9/3,00
DS2C013	135°	54	57,7	7/2,44	9/3,00
DS2C014	Wide	54	57,7	7/2,44	9/3,00
DS2C015	X-Wide	54	57,7	7/2,44	9/3,00



Separately Available Accessories

Model Number	Name	Туре
DS2A003	CPS™ Universal Slitter	Slitter
DS2A004	CPS Direct [™] SL Valve Bypass Tool	Valve bypass tool

Customer Support: 46-8-474-4756

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. 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 one 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.



Accessories

CRT Leads Delivery Tools

CPS Aim[™] SL

Slittable Inner Catheter Cannulator with Integrated Valve

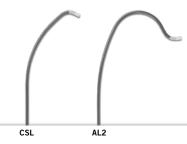
Product Highlights

- Integrated hemostasis valve in slittable catheter design
- Hydrophilic coating on outer catheter surface to enable smooth passage
- New catheter shaft/braid pattern for a kink-resistant and torqueable cannulator



Ordering Information

Model Number	Curve Shape	Available Length (cm)	Overall Length (cm)	Inner Diameter (F/mm)	Outer Diameter (F/mm)
DS2N024	CSL	65	68	5/1,83	7/2,29
DS2N025	AL2	65	68	5/1,83	7/2,29



Separately Available Accessories

Model Number	Name	Туре
DS2A001	CPS Aim [™] SL Inner Catheter SafeSheath [™] Sealing Adapter	Self-sealing valve
DS2A002	CPS Aim [™] SL Valve Bypass Tool	Valve bypass tool
DS2A003	CPS [™] Universal Slitter	Slitter

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CPS Courier™

Guidewires

Product Highlights

Helps physicians more easily subselect the target coronary branch vein and deliver the LV lead to its preferred destination

CRT Leads Delivery Tools

Ordering Information

Model Number	Distal Support	Longth (om)	Units	Diameter (in)
Number	Support	Length (cm)	per box	Diameter (III)
DS2G001	Soft	195	5	0,014
DS2G002	Medium	195	5	0,014
DS2G003	Firm	195	5	0,014
DS2G004	Extra Firm	195	5	0,014

CPS Duo[™] Stylet Guidewire System

Product Highlights

Enables optimal subselection of the branch vein and offers greater maneuverability and control of the LV lead

Ordering Information

Model Number	Туре	Lengths (cm)	Diameter	
DS2M001	CPS Duo [™] Stylet	75; 86	OD: 0,014" LV lead lumen compatible	
			ID: 0,012" compatible	
DS2M006	CPS Duo [™] Guidewire	195	0,012"	

Customer Support: 46-8-474-4756

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Accessories

CRT Leads Delivery Tools

CPS Luminary[™]

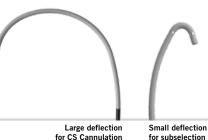
Bideflectable Catheter with Lumen

Product Highlights

- Two deflectable curves a large deflection to facilitate coronary sinus cannulation and a small deflection for target vein subselection
- Soft, atraumatic tip features bipolar mapping electrodes to confirm CS entry
- CPS Direct[™] SL outer guide catheters can be tracked over CPS Luminary[™] catheter into the target vein

Ordering Information

Model Number	Description	Working Size (cm)	Overall Length (cm)	Size (F)	Inner Lumen Diameter
402856	Large Curl (LC)	80	110	7	Up to 0,035" guidewire
402857	Extra Large Curl (XLC)	80	110	7	Up to 0,035" guidewire



for subselection of target branch vein

Separately Available Accessories

Model Number	Name	Pin Design	Working Length (cm)
402854	Bipolar Extension Cable	Shrouded 2 mm length pin	210
402855	Bipolar Extension Cable	Unshrouded 2 mm length pin	210



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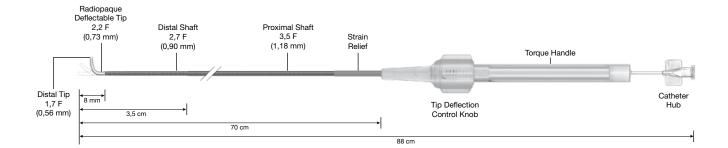
Wire Control Catheter

Product Highlights

- Tip deflects up to 90° to steer any 0,014" guidewire through the most challenging venous anatomies
- Over-the-Wire design permits easy wire exchanges, if necessary

Ordering Information

Model	Working	Overall	Guidewire	Guide Catheter
Number	Length (cm)	Length (cm)	Compatibility (in)	Compatibility (F)
1135-001	70	88	0,014	6



Customer Support: 46-8-474-4756

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Locator[™] Plus

Implant Tools

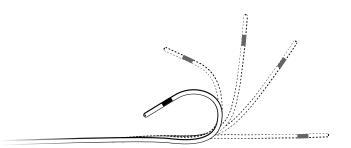
Product Highlights

- Enables fast, accurate endocardial lead positioning
- Facilitates lead maneuverability through tortuous venous pathways
- Eliminates the need for manual shaping, re-shaping, re-inserting and swapping multiple stylets

Ordering Information

0.016", X-Firm

Model Number	Description	Radius (mm)	Reach Length (mm)	Length (cm)
1281/46	Locator Plus, recommended for Atrial Use	14	40	46
1281/52	Locator Plus, recommended for Atrial Use	14	40	52
1281/58	Locator Plus, recommended for Atrial Use	14	40	58
1292/46	Locator Plus, recommended for Ventricular Use	16	55	46
1292/52	Locator Plus, recommended for Ventricular Use	16	55	52
1292/58	Locator Plus, recommended for Ventricular Use	16	55	58



Customer Support: 46-8-474-4756

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Accessor	Accessories Adapter			
Model Number	Receptacle (for adapting from)	Header Cavity (to device)		
501203	5 mm unipolar (unipolar pacing only)	IS-1 unipolar		
501204	6 mm unipolar	IS-1 unipolar		
501205	5 mm bifurcated (bipolar)	IS-1 bipolar (both unipolar and bipolar pacing compatibility)		
501206	3.2 mm Medtronic [™] (CPI [™] , Telectronic Style or IS-1 bipolar)	IS-1 bipolar 47 cm		
501207	Cap and Sleeve Kit Medtronic™ (CPI™, Telectronic Style)	St. Jude Medical [™] (M/S header or 6 mm unipolar)	Includes: 5 mm cap 6 mm cap pin extender Adapter Sleeve (2 sizes) 3,2-5 mm; 5-6 mm	
4023	Sleeve Kit, Medtronic™ (CPI™, Telectronic Style, 3,2 mm, IS-1 or 5 mm, 5-6 mm white tool)	St. Jude Medical [™] (M/S header or 6 mm unipolar; unipolar pacing only; 3,2-6 mm grey tool)	Adapter Sleeve (2 sizes) Tool (2 sizes)	
53424	2 IS-1 bipolar	IS-1 bipolar 17 cm		
53421	IS-1 bipolar	IS-1 bipolar 40 cm		
BLV/BIS-10	LV-1 bipolar	IS-1 bipolar		
Note: Medical ad	hesive to cover set screw holes must be ordered se	eparately.		
LV-1 is a unique E	Boston Scientific (formerly Guidant) connector/tern demark of Medtronic, Inc.			

CPI is a trademark of Cardiac Pacemakers, Inc.

Customer Support: 46-8-474-4756

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Accessories

Model Number	Device	
AC-0160	Test Magnet 90 gauss at 1"	
405	Test Magnet 90 gauss at 1"	
60007717-001	Vein Pick	······
442-2	Torque Wrench (#2)	
437-246	Set of "L" Hex Wrenches (#2, #4, #6)	
4033A	DF4/IS-1/DF-1 Lead Terminal Cap	
6201	FasTac [™] Flex Epicardial Lead Implant Tool	
4080	Lead Removal Tool	
DS0A001	Suture Sleeve (radiopaque 7.0 F)	
SS-1056	Suture Sleeve (radiopaque 6.0 F for QuickSite™ Leads)	
TV-0800	Suture Sleeve (radiopaque 8.0 F)	
AC-0130	Silicone Oil	
424	Medical Adhesive	
FL-1056	Lead Flushing Tool	
AC-TD	Torque Driver (#2 wrench)	
4071	Torque Tool and Tip Introducer	
AC-IP-2	IS-1 Port Plug	
AC-DP-3	DF-1 Port Plug	
AC-IS4PP	IS4/DF4 Port Plug	
4078G	Custom Floppy Firm Guidewire, Straight, 5 cm Floppy Tip, 180 cm, 0.014", PTFE Coa	ted
EX3151	IS4/DF4 Connector Sleeve	

Customer Support: 46-8-474-4756

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Implantable Cardiac Monitors

SJM Confirm[™]

Implantable Cardiac Monitor – Model DM2100

Product Highlights

- Implantable, patient-activated and automatically activated monitoring system that records subcutaneous ECGs and is indicated in the following cases:
 - Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
 - Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- Offers simple-to-configure data storage options to enable physicians to prioritise data based on individual patient conditions, ensuring capture of significant events and to reduce the risk that unexpected events are missed
- Comprehensive diagnostic data reports provide a quick and accurate summary of heart rate, assisting physicians in their diagnosis and treatment of the patient's condition
- The small 6.5 cc size of the SJM Confirm ICM DM2100 is designed to reduce the risk of infection during the implant procedure by requiring a smaller incision and a smaller subcutaneous pocket. A small device footprint may also reduce implant time and means less change in body image for patients
- The proven St. Jude Medical Sense*Ability*TM feature is designed to allow accurate sensing over a wide range of signals, specifically offering more sensitive QRS detection

Ordering Information

Contents: Implantable Cardiac Monitor

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)
DM2100	56,3 x 18,5 x 8	12	6,5 (± 0,5)

Separately Available Accessories

Contents: SJM Confirm External Patient Activator device

Model Number	Description
DM2100A	External Patient Activator Model DM2100A

Indications: The SJM Confirm™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias.

Contraindications: There are no known contraindications for the implantation of the SJM Confirm™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated. Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include, but are not limited to the following: Altergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.



SJM Confirm[™]

Implantable Cardiac Monitor – Model DM2100

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	DM2100
Sampling Rate (Hz)	128
Dimensions (mm)	56,3 x 18,5 x 8
Volume (cc)	6,5
Weight (g)	12
Electrode Spacing (mm)	39
Electrode Minimum Surface Area (mm ²)	30
PARAMETER	SETTINGS
Features	
Longevity	3 years
Patient Trigger	Yes
Auto Activation Trigger	Yes
Tachycardia Trigger	Yes
Tachycardia Cycle Count	Yes
Bradycardia Trigger	Yes
Asystole (duration) Trigger	Yes
EGM Storage	48 minutes
Patient Trigger	Yes, Programmable
Auto Activation	Yes, Programmable
Activity Response	Inhibit, Monitor, Off
Noise Response	Inhibit
Diagnostics	
Episodal Diagnostics	Yes
Heart Rate Histogram	Yes
Mean Heart Rate	No
Remote Monitoring	Transtelephonic monitoring (TTM)*
Patient Activator (PA)	Battery-powered PA (Model DM2100A)

* Connectivity depends upon country and use of a compatible receiver unit. Please contact your St. Jude Medical sales representative for more details.

Customer Support: 46-8-474-4756

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. 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, "M indicates that the name is a trademark of, or licensed to, St. Jude Medical or one 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.



SJM Confirm[™] Implantable Cardiac Monitor – Model DM2102

Product Highlights

- Accurately detects atrial fibrillation (AF) and rhythm disturbances
- Implantable, patient-activated and automatically activated monitoring system that records subcutaneous ECGs and is indicated in the following cases:
 - Patients who have been previously diagnosed with AF or who are susceptible to developing AF
 - Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
 - Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- Offers simple-to-configure data storage options to enable physicians to prioritise data based on individual patient conditions, ensuring capture of significant events and to reduce the risk that unexpected events are missed
- Comprehensive diagnostic data reports from the provide a quick and accurate summary of heart rate, assisting physicians in their diagnosis and treatment of the patient's condition
- The small 6.5 cc size of the SJM Confirm ICM DM2102 is designed to reduce the risk of infection during the implant procedure by requiring a smaller incision and a smaller subcutaneous pocket. A small device footprint may also reduce implant time and means less change in body image for patients
- The proven St. Jude Medical Sense*Ability*TM feature is designed to allow accurate sensing over a wide range of signals, specifically offering more sensitive QRS detection

Ordering Information

Contents: Implantable Cardiac Monitor

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)
DM2102	56,3 x 18,5 x 8	12	6,5 (± 0,5)

Separately Available Accessories

Contents: SJM Confirm External Patient Activator device

Model Number	Description
DM2100A	External Patient Activator Model DM2100A

Indications: The SJM ConfirmTM ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias. The SJM Confirm ICM, Model DM2102, is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

EUSTRY INFRESEWORTS: THERE 378 nd/kfbwn contraindications for the implantation of the SJM Confirm™ ICM. However, the patient's patient's patient's patient's patient on the subcutaneous, chronically implanted device can be tolerated. Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include, but are not limited to the following: Allergic reaction, Bleeding, Chronic nerve damage, Erosion, Excessive fibrotic tissue growth, Extrusion, Formation of hematomas or cysts, Infection, Keloid formation

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





SJM Confirm[™]

Implantable Cardiac Monitor – Model DM2102

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	DM2102
Sampling Rate (Hz)	128
Dimensions (mm)	56,3 x 18,5 x 8
Volume (cc)	6,5
Weight (g)	12
Electrode Spacing (mm)	39
Electrode Minimum Surface Area (mm ²)	30
PARAMETER	SETTINGS
	SETTINGS
Features	
Longevity	3 years
Patient Trigger	Yes
Auto Activation Trigger	Yes
Atrial Fibrillation Trigger	Yes
Programmable AF episode duration	>30 sec, >1 min, 2 min, >5 min, >10 min
Tachycardia Trigger	Yes
Tachycardia Cycle Count	Yes
Bradycardia Trigger	Yes
Asystole (duration) Trigger	Yes
EGM Storage	48 minutes
Patient Trigger	Yes, Programmable
Auto Activation	Yes, Programmable
Activity Response	Inhibit, Monitor, Off
Noise Response	Inhibit
Diagnostics	
Episodal Diagnostics	Yes
Heart Rate Histogram	Yes
Mean Heart Rate	No
Remote Monitoring	Transtelephonic monitoring (TTM)*
Patient Activator (PA)	Battery-powered PA (Model DM2100A)

* Connectivity depends upon country and use of a compatible receiver unit. Please contact your St. Jude Medical sales representative for more details.

Customer Support: 46-8-474-4756

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ICM External Patient Activator

SJM Confirm[™]

External Patient Activator

Product Highlights

- The SJM Confirm external patient activator uses radio waves to communicate with the Confirm Implantable Cardiac Monitor (ICM)
- Initiates recording of the heart's electrical activity, reads stored data and sends stored data to Merlin[™] Patient Care System



Ordering Information

Contents: SJM Confirm External Patient Activator device

Model Number	Description
DM2100A	External Patient Activator Model DM2100A

Intended Use: The activator is intended for use with SJM Confirm Internal Cardiac Monitor.

Contraindications: There are no contraindications.

Warnings and Precautions: Electromagnetic interference. The activator is not magnetic and has no moving parts. However, you should avoid equipment which generates a strong electromagnetic interference (EMI). EMI could interfere with communication between the activator and the implanted SIM Confirm ICM. Moving away from the source of EMI or turning it off will usually allow the activator to return to its normal mode of operation. Communication equipment. Communication equipment such as microwave transmitters or highpower anateur transmitters may generate enough EMI to interfere with the performance of the activator if you are too close to the source of EMI. Wireless communication devices. Wireless communication devices such as computers that operate on a wireless network, handheld personal computers (PDA), cellular phones, and even cordless telephones may generate enough EMI to interfere with the performance of the activator if it is used too close to the source of EMI. Hospital and Medical equipment. A variety of standard hospital and medical equipment may generate enough EMI to interfere with the performance of the activator. These include, but are not limited to: blood pressure monitors, ECG equipment, external defibrillation equipment, x-ray machines. Office equipment, variety of standard office equipment may generate enough EMI to interfere with the performance of the activator. These include, but are not limited to: desktop or laptop computers, fax machines, phone systems. Industrial equipment. A variety of industrial equipment may generate enough EMI to interfere with the performance of your activator. These include, but are not limited to: arc welders; induction furnaces, very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

Customer Support: 46-8-474-4756

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SJM Confirm[™]

Mode of operation

External Patient Activator

Product Specifications

PHYSICAL SPECIFICATIONS Model EX4000 Dimensions (cm) 7,1 x 5,6 x 1,8 High-impact plastic 1 cell; 3,6 V (nominal); Chemistry: Case material Power source Lithium Thionyl Chloride Battery longevity 3 years from manufacturing date Audible output level 60 dB (minimum) at 10,0 cm Classification with respect to electric shock Internally powered Protection from electric shock (IEC 60601-1) Type BF Protection against ingress of liquids

Ordinary equipment Non-continuous



Customer Support: 46-8-474-4756

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CONNECTIVITY AND REMOTE CARE

Connectivity and Remote Care

The intersection of the internet and mobile technologies with innovative medical device therapies has created the ability to advance patient care through remote monitoring and data management.

Many components are involved in device connectivity: the Merlin[™] programmer used in the physician's office to establish and optimise the device settings; the Merlin.net[™] patient care network that stores device information and makes it accessible via the Internet or transfers the information to an electronic health record; the implantable device itself that transmits data remotely using radiofrequency; and the Merlin@home[™] unit that allows patients to transmit data at home from their device to their physician.

St. Jude Medical offers a completely integrated system designed to provide increased confidence and control, greater insight and improved efficiency from implant to follow-up.



Connectivity

Merlin[™] Patient Care System (PCS)

Product Highlights

- 15" touch screen clearly displays programming and diagnostic screens
- New user interface allows for faster patient management
- Continuous, simultaneous display of surface ECGs, intracardiac electrograms (EGMs) and annotated event markers allow quick interpretation
- Built-in top-load/top-exit printer quickly and quietly prints full-page (8-inch) reports for patient charts
- Integrated cable storage speeds setup and saves space with alwaysconnected cables and ample storage space



Ordering Information

Model Number	Part Number	Description
3650		Merlin Patient Care System (PCS)
Merlin PCS accessories		
Model Number	Part Number	Description
3001		3-Lead ECG Patient Cable
3626		5-Lead ECG Patient Cable
3134	60000909-001	VGA Cable and Adapter (female to male) (25' length)
3615	60004294-001	Adapter for 3150 PSA Wand (required for use of
		PSA Wand Model 3150 with the Merlin Patient Care System)
3616	60005260-001	Wand Extension Cable (4' length)
3617	60005251-001	External ECG Input Cable (25' length)
3620	60005254-001	External Floppy Disk Drive
EX3621-2GB	100006806	Flash Drive (2 GB)
3622	60005256-001	Shoulder Strap
3623	60005257-001	USB to RS232 Serial Adapter (for direct Paceart [™] connection)
3630	60002876-001	Merlin Patient Care System Telemetry Wand (with Magnet)
3630M	60002876-097	Magnet
3638	50019403-001	Antenna (required to enable radio frequency [RF] communication between Merlin PCS and St. Jude Medical [™] implantable devices with RF communication capability)
3643	60003605-001	Thermal Paper

Customer Support: 46-8-474-4756

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Customer Support: 46-8-474-4756

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Item GMCRM827EN



Merlin[™] Pacing System Analyzer (PSA)

Product Highlights

- Provides confidence and control at implant by quickly delivering accurate measurements for optimal lead positioning and a streamlined implant
- Connects directly to the Merlin[™] Patient Care System, delivering a seamless, intuitive interface
- Fast parameter programming and switching speed
- Able to display on external monitors
- Independent atrial, right ventricular and left ventricular channels
- Continuously displayed measurements on a beat-by-beat basis
- Dedicated current of injury display

Ordering Information

Model Number	Part Number	Description
EX3100	100002300	Merlin Pacing System Analyzer (PSA)

Merlin PSA accessories

Model Number	Part Number	Description
EX3160	100031916	Merlin storable pouch
EX3170	100015290	For use with Medtronic-style disposable cables (Models 4051 and 4061)
EX3180	100015301	For use with Medtronic 2292 re-sterilisable cable
EX3190	100019848	USB to RF antenna
4051	1020752-001	Disposable Threshold Cable (Medtronic connector)
4053A	5070142-101	Non-Disposable Adapter (to threshold cable Medtronic connector)
4160	60010198-001	Disposable Threshold cable for DF4 leads (Biotronik connector)
4161	60010086-001	Disposable Threshold cable for DF4 leads (Medtronic connector)
PK-67-S	5030162-001	Non-Disposable Adapter (to threshold cable Biotronik connector)

Intended Use: The Merlin™ PSA is intended to assess the pacing and sensing performance of the lead system prior to pulse generator implantation, or during invasive lead system troubleshooting.

Only use the Merlin PSA with the Merlin PCS.

Contraindications: There are no known contraindications to the use of a lead-analysis device. The patient's age and medical condition, however, may dictate the pacing modes and lead assessment activities appropriate for the patient.

The Merlin PSA is not intended for use as a temporary pacemaker or for life sustaining pacing support. The Merlin PSA is not intended for diagnostic purposes. **Caution**: Federal law (USA) restricts this device to sale by or on the order of a physician.

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

Customer Support: 46-8-474-4756

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Item GMCRM826EN



Connectivity

External Pulse Generator

Dual-Chamber (DDD) Model 3085

Product Highlights

- Designed for safe and reliable temporary stimulation of the heart in cases of rhythm disturbances and conduction defects, and/or perioperative temporary heart stimulation.
- An extensive dual-chamber feature set including:
 - A full array of mode choices, including a special DDD + AT mode specifically available for bi-atrial stimulation to help avoid atrial fibrillation
 - Atrial auto-sensing for automatic adjustment of sensitivity
 - Completely adjustable stimulation parameters (voltage and pulse width)
 - A wide base rate range of 30-220 ppm for appropriate pacing support for all therapy needs, including those of pediatric patients
 - A max tracking rate of 80-230 ppm for maintaining AV synchrony
 - A PV delay offset for supporting maximum cardiac output
 - Extended PVARP for prevention of retrograde tachycardia
 - Crosstalk protection to aid in preventing far-field sensing, which can result in asystole
- Continuous, independent atrial and ventricular lead surveillance and an audible warning in the event of lead malfunction
- Rapid atrial pacing rates (up to 1000 ppm) are available for pace-termination of atrial tachycardia

Ordering Information

Contents: External pulse generator

Model Number	Dimensions (H x W x T, cm)	Weight (g)	Battery
3085	20 x 9,6 x 3,8	490 (includes battery)	Battery 9 V, alkaline or lithium

Indications for Use: The Model 3085 external pulse generator/temporary pacemaker is designed to be used with cardiac stimulation lead systems for temporary atrial, ventricular or A V sequential stimulation. The Model 3085 has applications where such stimulation modes are indicated for therapeutic, rophylactic, or diagnostic purposes. Specific indications include, but are not limited to, the following:

Sick sinus syndrome, Bradycardia with congestive heart failure; Complete heart block; Acute myocardial infarction complicated with heart block; Sinus bradycardia; Cardiac arrest with ventricular systole; Atrial and/or ventricular ectopic arrhythmia; Postoperatively after cardiac surgery; Temporary application during implantation or exchange of a permanent pacemaker. Indication for atrial overdrive stimulation: Supraventricular tachycardia.

Customer Support: 46-8-474-4756

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Contraindications: There are no contraindications with regards to the use of the Model 3085 for temporary cardiac stimulation for therapy and prevention of arrhythmia. The state of health of the patient, however, can restrict the choice of operational mode and stimulation parameters. For example, a mode of operation with atrial sensing is not suitable or appropriate when atrial fibrillation occurs. This is due to excessive and chaotic frequency of detected fibrillation waves. Overdrive-stimulation therapy must only be used in the atrium. Overdrive-stimulation in the ventricle could cause life threatening ventricular fibrillation



External Pulse Generator

3085

Standard 9 V. alkaline or lithium

battery change message

battery change message Approximately 490 (including battery)

Minimal 10 days (VVI, standard parameters), Minimal 8 days (DDD, standard parameters) Plus 1 day reserve after the first appearance of the

Minimal 19 days (VVI, standard parameters) Minimal 15 days (DDD, standard parameters) Plus 1 day reserve after the first appearance of the

20 x 9,6 x 3,8 (7,75 in. x 4 in. x 1,5 in.)

Dual-Chamber (DDD)

Model 3085

PHYSICAL SPECIFICATIONS

Product Specifications

Model Batterv

Battery Life Alkaline

Battery Life Lithium

Weight (g) Size (cm)

PARAMETER SETTINGS

Modes

Base Pacing Rates (ppm) Upper Pacing Rates (MTR) (ppm) Rapid Atrial Pacing Rates (ppm) AV Delay (ms) PV Delay (ms)

Pulse Duration (ms) Pulse Amplitude (V) Atrial Sensitivity (mV) Ventricular Sensitivity (mV) Blanking Period (ms) Atrial Refractory Period (ms)

PVARP (ms) Ventricular Refractory Period (ms) Extended PVARP (After PVC) (ms) Crosstalk Detection Window (ms) Emergency Mode

Runaway Protection (ppm)

DDD, DDD + AT, DOO, DAT, DVI, DAI, VVI, VOO, VAT, AAI, AOO, AAT, VDD 30-220 80-230 70-1000 5-400 (minimum 30 ms when atrial Auto Sense is activated) AV delay-30 (minimum 5 ms when atrial Auto Sense is not activated. minimum 30 when atrial Auto Sense is activated) 0,05-1,50 0,1-18 0,2-20 1,0-20 85 (atrial & ventricular), 55 (ventricular after atrial pacing) $250 \dots 400 \text{ ms} \pm 5\%$ (AAI, AAT), A-V interval plus PVARP (DDD, VDD, DAI, VAT, DAT) 100-500 (absolute: 90 ms, relative: 90 ms) 250 500 40

V00 (A00), 80 ppm, 12 V or set value when higher, 0,75 ms (1,00 ms) or set value when longer 235



Customer Support: 46-8-474-4756

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Connectivity

External Pulse Generator

Single-Chamber

Model 3077

Product Highlights

- Designed for safe and reliable temporary stimulation of the heart in cases of rhythm disturbances and conduction defects
- An extensive single-chamber feature set, including mode choices, a wide base rate range, adjustable amplitude and sensitivity parameters, and two modes of high-rate pacing
- Up to 12 volts of output available per channel make the Model 3077 temporary pacemaker one of the highest-output devices of its kind available
- Designed for ease of use:
 - Standard 9 volt lithium or alkaline batteries are used, and the device features both visual and audible battery life indicators
 - Large, simple dial
- Small size and lightweight design
- Runaway protection limits the device to a maximum rate of 200 ppm in the unlikely event of circuit malfunction

Ordering Information

Contents: External pulse generator

Model Number	Dimensions (H x W x T, cm)	Weight (g)	Battery
3077	6 x 11,5 x 2,2	185 (includes battery)	9 V, alkaline or lithium

Indications for Use: When combined with a stimulation lead system, the Model 3077 SSI temporary pulsegenerator can be used whenever temporary atrial or ventricular stimulation is indicated. The device can beemployed for therapeutic as well as diagnostic purposes or be used prophylactically.

Some specific indications for temporary stimulation are:

- Complete (third-degree) or intermittent heart block
- Symptomatic sinus bradycardia
- Atrial or ventricular ectopic arrhythmia
- Sick sinus syndrome (SSS)

Customer Supports 46-8-474-4756

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- Acute myocardial infarction induced heart block

- Stimulation during a ventricular asystole

- Usage during the replacement of an implantable pacemaker
- Stimulation and monitoring before the implantation of a cardiac pacemaker

- Stimulation and monitoring following heart surgery $% \label{eq:constraint}$

 $\textbf{Contraindications:} The \ \textsf{Model 3077 SSI temporary pulse generator is contraindicated:}$

 In the treatment of ventricular tachycardia- When overall physiological condition of the patient limits the selection of the stimulation mode and thestimulation parameters.





External Pulse Generator Single-Chamber

Model 3077

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	3085
Battery	Alkaline-38 days (72 ppm, 8,0 V), Lithium-53 days (72 ppm, 8,0 \
Weight (g)	Approximately 185 (including battery)
Size (cm)	6,0 x 11,5 x 2,2 (2.25 in. x 4,5 in. x 0,85 in.)
PARAMETER SETTINGS	
Technology	
Modes	VVI, VOO, AAI, AOO
Base Pacing Rates (ppm)	30-180

Dase i deing Nates (ppin)	30-100
High Pacing Rates (ppm)	360-720
Pulse Width (ms)	0,75
Pulse Amplitude (V)	0,3-12
Sensitivity (mV)	1,0-20
Refractory Period (ms)	250
Runaway Protection (ppm)	200



Customer Support: 46-8-474-4756

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Merlin.net[™] Patient Care Network (PCN) Version 5.0

Product Highlights

- Merlin.net PCN version 5.0 from St. Jude Medical allows more efficient remote management of patients with implanted cardiac devices, including pacemakers, implantable cardioverter defibrillators and cardiac resynchronization therapy devices.
- One-screen Follow-up allows clinicians to view, print, schedule, export and archive from the Recent Transmissions page. This feature also saves time and simplifies follow-ups by allowing clinicians to take action on up to 50 patient files at once.
- DirectAlerts[™] Notification is a physician notification system that provides physician-designated patient alerts between follow-ups.
- Mobile DirectAlerts[™] Notification allows alert-triggered EGMs and reports to be viewed directly on a smartphone; notifications are sent with a doctor's individualised security stamp.
- Patients now have a new way to connect from home for remote follow-ups and monitoring with Merlin.net PCN Wi-Fi Connectivity.[†]



- Alerts generated from the device-based CorVue[™] Congestion Monitoring feature, which measures intrathoracic impedance in multiple vectors for improved accuracy, are displayed; options for both patient and physician alerts are provided.
- EHRDirect[™] Export allows automatic export of transmission data from Merlin.net PCN to a clinic's EHR system. This allows seamless integration of data so care teams can make informed clinical decisions more quickly, without the need for expensive intermediary systems. This feature meets the Integrating the Healthcare Enterprise (IHE[™]) guidelines, supporting Health Level-7 (HL7) standards.
- Inductive Merlin@home[™] transmitters[†] can now be used with newer Epic[™] family devices and Atlas[™] family devices as well as other newer devices. Going forward, inductive Merlin@home transmitters[†] will be issued to patients with newer Epic ICD or Atlas ICD implants. However, Housecall[™] Plus transmitters will still be available[†] for patients with older Epic ICDs and Atlas ICDs.
- Merlin.net PCN now features device support for the Unify Quadra[™] CRT-D and the Accent[™] MRI RF Pacemaker.
- SmartSchedule[™] is an 18-month, rotating perpetual calendar that creates an automatic follow-up transmission schedule. Clinicians can specify length of time, including 91-day and 182-day periods, between transmissions to coordinate follow-ups with the clinic's reimbursement calendar.
- DirectCall[™] Message is an integrated and automated patient communication system designed to save clinic time by reducing routine calls otherwise performed by medical office staff.
- DirectTrend[™] Viewer provides dynamic views of device and clinical trends for comprehensive patient management.
- Merlin.net PCN was the first medical device network to be awarded ISO 27001 certification, a stringent worldwide information security standard.



Customer Support: 46-8-474-4756

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Merlin.net[™] Patient Care Network (PCN)

Version 5.0

Product Specifications

Merlin.net PCN Specifications			
Connectivity		Website Efficiency	
Direct data export to EHR Compatible EHR/data management systems	EHRDirect Export enables direct export to EHR via IHE or HL7 (2.x and 3.0) format without the need of an intermediary system All HL7-compliant EHR systems are compatible. Currently	Batch operation	Automatic export to EHR is supported by version 5.0 through EHRDirect [™] Export to increase clinic efficiency; print, archive, export to EHR, export to PC database up to 50 records at a time
	available with: GEMMS [™] ONE EHR; Allscripts [™] Professional EHR; NextGen [™] Ambulatory EHR; EpicCare [™] Ambulatory EHR; and GE Centricity [™] EHR. Plus compatible with device management	Consolidated data Data storage capabilities	Remote transmissions and in-clinic data available online All patient transmissions and reports available for immediate access for a minimum of seven years
	solutions such as Paceart [™] and ScottCare [™] OneView. Ongoing work to integrate with other leading EHR systems.	Data transfers	Patient data follows patient when changing clinics or when patient receives new device
IHE compatible Supports HL7	YES YES	Languages	English, Spanish, French, German, Italian, Japanese
ISO 27001 certified	YES	User Interface	
Scheduling		Design principles	Similar to Merlin™ Patient Care System (PCS) programmer in colors and design; easy to learn for new users
Online scheduling	Authorized users may schedule patient follow-ups. Automated (SmartSchedule [™] Calendar) and manual scheduling options available.	Report format Tracking of reviewed transmissions	Similar to Merlin PCS reports for easy orientation. Viewed field on recent transmissions allows quick indication of which reports have already been viewed; printing reports option to mark as
Unscheduled transmissions/ Patient-initiated transmissions	Able to transmit outside of fixed appointment time as needed with physician approval. Able to lock out patients from sending unscheduled transmissions.	Transmission status, reason for transmission displayed Next transmission column	viewed as well Scheduled, alert-initiated, patient-initiated Date and intervals of next scheduled transmission
Alerts and Notifications		Number of days between transmissions	Shown on recent transmissions, patient list, view schedule and manual schedule pages
Daily alert surveillance	DirectAlerts [™] Notification available with Merlin@home [™] transmitter for all supported devices. Event-based or full disclosure uploads as needed.	Identify previous user Rapid alert viewing Clinical comments	Placing mouse over transmission time shows previous user Mouse-over alerts shows list of alert types and alert episodes Free form, clinic defined or both
Programmable alerts Diagnostic alert triggers*	Physician/clinician option to select only the alerts they want to receive Congestion Duration Exceeded Programmed Threshold ST Episode Detected **ATIAF Episode Duration > Threshold	Arrhythmia and device management box Highlight transmissions with alerts Inbox/outbox	Tally of recent transmissions by type Customisable by administrator Recent transmissions/patient list segments files into new and old
	**AT/AF Burden > Threshold **Avg. V Rate During AT/AF > Threshold	Weekly glance Education	Convenient overview of upcoming transmissions
Therapy alert triggers*	Percent RV Pacing > Threshold Percent BiV Pacing < Threshold High Ventricular Rate Episodes Recorded	Interactive practice site	Available
	High Voltage Therapy Delivered	Patient Communication	
Device alert triggers*	Successful ATP Pacing Delivered Therapy Accelerated Rhythm Longerity Analysis (requires Tech Services support) Tachy Therapy Disabled Charge Time Limit Reached Possible HV Circuit Damage Device Reset	Outbound automatic communication tool	Clinic-enabled DirectCall [™] Message options: Missed appointment call – triggered by clinic Normal results call – triggered by clinic Call clinic message – triggered by clinic Remote follow-up reminder call – sent automatically Remote follow-up missed call – sent automatically Emergency contact, if enabled – sent automatically
	Device at ERI Device in MRI Settings HV Lead Impedance Out of Range Atrial Pacing Lead Impedance Out of Range (Dual Chamber and CRT Devices) Device Programmed to Emergency Pacing Values	Multiple language support Patient	Einer Grahl Message tool available in over 20 languages, including English, Spanish, French, Italian, Japanese, German, Dutch, Portugues Finnish, Swedish, Danish, Norwegian, Czech, Hungarian, Castilian Spanish, Polish, Turkish, Slovak, Catalonian Spanish, UK English
	Back Up WI Possible High Voltage Lead Issue	Start-up guide	Transmitter Quick Start Guide (QSG) w/step-by-step setup options
	LV Pacing Lead Impedance Out of Range (CRT Devices) RV Pacing Lead Impedance Out of Range	Support Materials for Patient and	Clinic
	High Voltage Lead Impedance < Lower Limit High Voltage Lead Impedance > Upper Limit Device Parameter Reset	Various support materials available. Please materials.	meet with sales representative for full complement of training and suppo
Alert notification options Alert reports	E-mail, fax, SMS, website, voice message or smartphone Alert Summary Report AT/AF alert report accompanies AT/AF alert	Merlin@home RF Transmitter Specification	S
Transmitters	Al/Ar alert report accompanies Al/Ar alert	Transmitter model number	EX 1150
Merlin@home RF (radio frequency)	For use with compatible RF devices Transmitter stays with the patient when changing clinics or when patient receives new device from the same family Ability to link/re-link transmitter to a patient's device remotely	Physical components Weight (w/o power supply) Dimensions	Single plastic enclosure with external transformer power supply Less than 2,3 kilograms Width: 9,18" Height: 6,33"
	Transmitter can be issued to patient and paired with his/her device before discharge for remote monitoring from day one	Wand cable length Power cord length Modem Power course	Depth: 5,06" NA Minimum 1,5 meters VS2 (56K) — Custom Design
† Available in select markets only *Different devices support different alerts. Check l	User's Manual for full list of available alerts.	Power source Line voltage Line frequency	AC 100-240V 50-60 Hz
** If programmed 'On' in patient's device *** In version 5.0, the inductive Merlin@home™ tr including newer Epic ICDs and Atlas ICDs	ransmitter unit can support interrogation of legacy devices,	Devices Supported by Merlin@home RF Tra	

In version 5.0, the inductive Merlin@home™ transmitter unit can support interrogation of legacy devices, including newer Epic ICDs and Atlas ICDs

Customer Support: 46-8-474-4756

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RF models of the Unify™ Family of CRT-Ds, the Promote™ Family of CRT-Ds, the Current™ Family of ICDs, the AnalyST™ Family of ICDs, the Anthem™ Family of CRT-Ps, the Accent™ Family of Pacemakers and the Nuance™ Family of Pacemakers (Japan)

The Unify™ Family of CRT-Ds, the Promote™ Family of CRT-Ds, the Atlas™ Family of CRT-Ds, the Current™ Family of ICDs, the AnalyST™ Family of ICDs, the Fortify™ Family of ICDs, the Epic™ Family of ICDs, the Convert™ Family of ICDs, the Anthem™ Family of CRT-Ps, the Accent™ Family of Pacemakers and the Nuance™ Family of Pacemakers (Japan)

Devices Supported by Merlin.net PCN through USB Upload from Merlin PCS

Remote Care

USB Cellular Adaptor For use with the Merlin@home[™] Transmitter Model EX1151



Product Highlights

- The USB Cellular Adapter attaches to any Merlin@home transmitter, enabling timely access to comprehensive data of the patient's current disease state and implanted device status through the Merlin.net[™] Patient Care Network.
 - Automatically searches for and connects to the cellular network for use in areas where a landline is neither available nor convenient
 - Does not require any additional hardware and operates on the power supply of the Merlin@home transmitter
 - Transmission of data occurs on the 3G and GSM bands of the cellular network
- The USB Cellular Adaptor is simple to install and use on any new or existing Merlin@home transmitter while maintaining the current user interface
- The USB Cellular Adaptor provide a reliable transmission option that allows patient and clinicians to experience the value of connectivity through the Merlin.net Patient Care Network

Ordering Information

Contents: USB Cellular Adaptor

Model Number	Dimensions (H x W x T, mm)	Volume (cc)	Weight (g)
EX1151	65 x 25 x 13,5	19,5	30

Indications: The USB Cellular Adapter for use with the Merlin@home™ transmitter is indicated for use by patients with supported St. Jude Medical implanted devices.

Contraindications: The USB Cellular Adapter for use with the Merlin@home™ transmitter is contraindicated for use with any implanted medical device other than supported St. Jude Medical implanted devices.

Customer Support: 46-8-474-4756

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USB Cellular Adaptor

For use with the Merlin@home[™] Transmitter Model EX1151

Product Specifications

PHYSICAL SPECIFICATIONS		CELLULAR TE	LECOMMUNICATION MODE GENE	ERATION
Models Dimensions (mm)	EX1151 65 x 25 x 13.5	Generation	Acronym	Title
Volume (cc)	19,5	U1G	AMPS	Advanced Mobile Phone System
Weight (g)	30		Radiocom 2000	Radiocom 2000 France Telecom
			NMT	Nordic Mobile Telephone
TECHNICAL SPECIFICATIONS		26	GSM	Global System for Mobile Communication
Technology				,
USB Modem	(USB Port)	2,5G	GPRS	General Packet Radio Service
MSM 7201A	(7.0 Mhas downlink)	2.75G	EDGE	Enhanced Data Rate for GSM Evolution
UMTS with HSDPA Category 8 HSUPA Category 5	(7,2 Mbps downlink) (2,0 Mbps uplink)		-	
EDGE/GPRS MS Class 12		3G	UMTS	Universal Mobile Telecommunications System
WCDMA advanced receiver on UMTS	800/850, 1900, 2100 MHz bands			
	,,	3G+/3,5G	HSDPA	High Speed Downlink Packet Access
Bands			HSUPA	High Speed Uplink Packet Access
800/850, 1900, 2100 MHz WCDMA	Power class 3 (+24dBm)	3,75G	HSOPA	High Speed OFDM Packet Access
800/850, 900 MHz GSM/GPRS/EDGE	GSM Power class 4/EDGE E2			
1800, 1900 MHz GSM/GPRS/EDGE	GSM Power class 1/EDGE E2	4G	LTE	Long Term Evolution
Antenna Diversity Support			Wimax (IT network project)	Worldwide Interoperability for Microwave Access
800/850, 1900, 2100 MHz		Bold items	are supported by the St. J	ude Medical USB Cellular Adapter
Environmental				
Operating Temperature:	0 to 45° Celsius			
Storage Temperature:	-40 to 85° Celsius			

Standards/Approvals

RoHs Compliant

CE FCC PTCRB A-tick GCF Industry Canada

Package Contents

USB Modem Clip USB Extension Cable

Customer Support: 46-8-474-4756

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ATRIAL FIBRILLATION

CARDIAC RHYTHM MANAGEMENT

CARDIOVASCULAR

NEUROMODULATION

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Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, 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 one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All Rights Reserved.