Cardiac Rhythm Management
International Product Catalog
January 2012

St. Jude Medical™

More control. Less risk.

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.

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Customer Support: 46-8-474-4756

ST. JUDE MEDICAL

MORE CONTROL. LESS RISK.

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)

Merlin@home™ Transmitter Compatible

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

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 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 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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Unify Quadra™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3251-40**	**CD3251-40Q**
Telemetry	RF	RF
Delivered Energy (J)	40	40
Volume (cc)	40	38
Weight (g)	83	81
Size (mm)	83 x 41 x 14	76 x 41 x 14
Defibrillation Lead Connections	DF1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
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
V. Triggering (BiV™ Trigger Mode)	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay, interventricular pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
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*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mV;
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; 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 zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; 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/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	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can

Bradycardia Pacing	
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); VVI(R); AAI(R); AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
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™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off
Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	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; 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; V Rate During AT/AF; % 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
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; 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

* QHR is a trademark of Greatbatch, LTD.
** LV first with 10ms interventricular delay

Customer Support: 46-8-474-4756

Item GMCRM798EN

GMCRM798EN

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Promote Quadra™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

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, 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Promote Quadra™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3239-40**	**CD3239-40Q**
Telemetry	RF	RF
Delivered Energy (J)	40	40
Volume (cc)	46	44
Weight (g)	88	87
Size (mm)	81x51x14	74x51x14
Defibrillation Lead Connections	DF1	DF4-LLHH
LV Lead Connections	IS4-LLLL	IS4-LLLL
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
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
V. Triggering (BiV™ Trigger Mode)	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay, interventricular pace
V-V Timing	Simultaneous**; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
Ventricular Pacing Chamber	RV only; biventricular
Negative AV Hysteresis/Search (ms)	Off; -10 to -120
Shortest AV Delay (ms)	25-120
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*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
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 zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; 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/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	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can
Bradycardia Pacing	
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); VVI(R); AAI(R); AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}) Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV and LV) (V); Pulse Width (Atrial; RV and LV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
AMS Detection Rate (min^{-1})	110-300
AMS Base Rate	40; 45; ...135
Auto PMT Detection/Termination	A Pace on PMT; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
BiVCap™ Confirm; LVCap™ Confirm; RVCap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed 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; V Rate During AT/AF; % V pacing; CorVue™ Congestion Trigger
Device 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 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

*QHR is a trademark of Greatbatch, LTD.
**LV first with 10 ms interventricular delay.

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.

Item GMCRM766EN

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Unify™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

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, 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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Unify™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3235-40**	**CD3235-40Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	36	36
Weight (g)	78	77
Size (mm)	79 x 40 x 14	73 x 40 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
V. Triggering (BiV™ Trigger Mode)	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay; Interventricular Pace delay
V-V Timing	Simultaneous**; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
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 bipolar; 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*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Sense Filter	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2-3,0 mV;
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; 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 zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; 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/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	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can
Bradycardia Pacing	
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); VVI(R); AAI(R); AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}) Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV and LV) (V); Pulse Width (Atrial; RV and LV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
AMS Detection Rate (min^{-1})	110-300
Atrial Tachycardia Base Rate	40; 45; ... 135
Auto PMT Detection/Termination	A Pace on PMT; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
LV Cap™ Confirm; RV Cap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed 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; V Rate During AT/AF; % 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
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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; unloaded battery voltage; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

*QHR is a trademark of Greatbatch, LTD.
**LV first with 10 ms interventricular delay.

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.

Item GMCRM767EN

GMCRM767EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Promote Accel™

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

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. LVCap™, RVCap™ and ACap™ 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*™ 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, 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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)	43	42
Weight (g)	82	82
Size (mm)	81 x 50 x 14	75 x 50 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
V. Triggering (BiV Trigger Mode)	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay; Interventricular Pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
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 bipolar; 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*Ability*™ 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 zone
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 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	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can

Bradycardia Pacing

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); VVI(R); AAI(R); AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}) Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV and LV) (V); Pulse Width (Atrial; RV and LV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
AMS Detection Rate (min^{-1})	110-300
Atrial Tachycardia Base Rate	40; 45; ...135
Auto PMT Detection/Termination	A Pace on PMT; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
LV Cap™ Confirm, RV Cap™ Confirm	Setup; On; Monitor; Off
ACap™ Confirm	On; Monitor; Off

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

Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed 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	2
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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS
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 et al. ICD waveform optimization: a randomized prospective, pair-sampled multicenter study. PACE 2000; 23 (Part II):1992-1995.

2 Sweeney MO, Natale A, Volosin KJ et al. Prospective randomized comparison of 50%/50% versus 65%/65% tilt biphasic waveform on defibrillation in humans. PACE 2001; 24:60-65.

3 Baker et al. Acute evaluation of programmer-guided AV/PV and VV delay optimization comparing an IEGM method and echocardiogram for cardiac resynchronization therapy in heart failure patients and dual-chamber ICD implants. Journal of Cardiovascular Electrophysiology, Vol. 18 No. 2, Feb. 2007.

4 Chan et al. Tissue Doppler guided optimization of A-V and V-V delay of biventricular pacemaker improves response to cardiac resynchronization therapy in heart failure patients. J Cardiac Failure 2004; 10:4 (supplement): 572 (abstract 199).

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.

Customer Support: 46-8-474-4756

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Item GMCRM917EN

GMCRM917EN

ST. JUDE MEDICAL
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Promote™+

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Merlin@home™ Transmitter Compatible

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 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

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ST. JUDE MEDICAL
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Promote™+

Cardiac Resynchronisation Therapy Defibrillator (CRT-D)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD3211-36**	**CD3211-36Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/42	36/42
Volume (cc)	43	42
Weight (g)	82	82
Size (mm)	81 x 50 x 14	75 x 50 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
Biventricular Pacing	
V. Triggering (BiV™ Trigger Mode)	On; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/paced AV delay; Interventricular Pace delay
V-V Timing	Simultaneous*; RV First; LV First
Interventricular Pace Delay (ms)	RV First 10-80 / LV First 15-80 in increments of 5
Ventricular Sensing	RV only (not programmable)
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 bipolar; 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*Ability*™ 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-Sensed/Post-Paced; Atrial/Ventricular) 0-220; (Post-Paced Ventricular), Auto
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 zone
Burst Cycle Length	Readaptive or Fixed
Min. Burst Cycle Length (ms)	150-400 in increments of 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	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); DOO(R); VOO(R); AOO(R)
Temporary Modes	Off; DDD(R); DDT(R); DDI(R); VVT(R); VVI(R); AAI(R); AAT(R); DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV and LV) (V); Pulse Width (Atrial; RV and LV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Auto Mode Switch (AMS)	Off; DDI(R); DDT(R); VVI(R); VVT(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
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™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)

Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	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; 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; V Rate During AT/AF; 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; 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates During AMS
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.

Customer Support: 46-8-474-4756

Item GMCRM768EN

GMCRM768EN

ST. JUDE MEDICAL
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Anthem™ RF

Cardiac Resynchronisation Therapy Pacemaker

Merlin@home™ Transmitter Compatible

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	13,7[1]	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 III or IV) in those patients who remain 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 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, severe physical disability. ***AF Suppression*** is indicated for suppression of paroxysmal or persistent 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 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. ***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 dislodgement 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 or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/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 cardiac vein thrombosis.

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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Anthem™ RF

Cardiac Resynchronisation Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM3212**
Telemetry	RF
Dimensions (mm)	58 x 52 x 6
Weight (g)	25
Volume (cc)[1]	13,7[1]
Connector	IS-1

PARAMETER	SETTINGS
Resynchronisation Therapy	
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay; Interventricular Paced Delay
RV and LV Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
RV Pulse Configuration	Unipolar; Bipolar
LV Pulse Configuration	Unipolar; Bipolar; LV Tip-RV Ring; LV Ring-RV Ring
Ventricular Sense Configuration	BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; LV Unipolar Tip; LV Bipolar; RV Unipolar Ring; LV Tip-RV Tip
Ventricular Pacing Chamber	BV; RV only; LV only (temporary mode)
First Chamber Paced	Simultaneous[2]; RV; LV
Interventricular Pace Delay (ms)	10–80 in steps of 5
Output/Sensing	
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
Shortest AV/PV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10
Atrial ACap™ Confirm	On; Off; Monitor
Primary Pulse Confirmation	Bipolar
Backup Pulse Confirmation	Bipolar
Backup Pulse Amplitude (V)	5,0
Searchable Intervals (hrs)	8; 24
Atrial Pulse Configuration	Unipolar (tip–case); Bipolar (tip–ring)
Atrial Sense Configuration	Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar Ring (ring–case)
Atrial Sensitivity[3,4] (Fixed) (mV)	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
Atrial Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
Atrial Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ 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
Ventricular Sensitivity (fixed) (mV)	0,5-12,5 in steps of 0,5[3,4]
Rate/Timing	
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); DOO(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off
DDT Trigger[5]	R wave
DDT Timing[5]	DDI
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Hysteresis Rate (min^{-1})	Off; 30-150 in steps of 5[6]
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16
Intervention Rate (min^{-1})	Off; Same Base Rate; 80-120 in steps of 10 (Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30)
Intervention Duration (min^{-1})	1–10
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30-150 in steps of 5
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–180 in steps of 10
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Ventricular Pace/Sense Refractory[7] (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470[8]
Atrial Pace Refractory	190-400 in steps of 30; 440; 470[8]
Atrial Sense Refractory	93; 125; 157; 190-400 in steps of 30; 440; 470[8]
PVARP (ms)	125–500 in steps of 25
Atrial Protection Interval (ms)[5]	125
Far-Field Protection Interval (ms)[5]	16

1 ± 0,5 cc
2 LV first with 10 ms interventricular delay.
3 Sensitivity is with respect to a 20 ms haversine test signal.
4 Values 0,1-0,4 not available 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-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
8 Programming options dependent on pacing mode.
9 During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay.
10 S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Rate-Modulated	
Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF	125–475 in steps of 25
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
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})[5]	10
Upper Rate Overdrive (min^{-1})[5]	5
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12
Auto Mode Switch	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)
AMS Base Rate (min^{-1})	40-170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
Magnet Response	Off; Battery Test
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50–150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
of the Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Post Vent. Atrial Blanking (PVAB) (ms)	60-200 in steps of 10; 225; 250
Ventricular Safety Standby	Off; On
PVC Response	Off; Atrial Pace[8]
PMT Options	Off; Passive; Atrial Pace[8]
PMT Detection Rate (min^{-1})	90–180 in steps of 5
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Atrial; Right Ventricular
Coupling Interval[9] (ms)	200-800 in steps of 10
S1 Count	2-25 in steps of 1
S1[10]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Right Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (s)	1-5 in steps of 1
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold
Patient Notifiers	
Programmable Notifiers (On; Off)	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
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22

Customer Support: 46-8-474-4756

Item GMCRM769EN

GMCRM769EN

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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*™ 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

Ordering Information

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	11,5[1]	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 III or IV) in those patients who remain 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 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, severe physical disability. ***AF Suppression*** is indicated for suppression of paroxysmal or persistent 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 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. ***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 dislodgement 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 or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/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 cardiac vein thrombosis.

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, 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.

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Anthem™

Cardiac Resynchronisation Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM3112**
Telemetry	Inductive
Dimensions (mm)	52 x 52 x 6
Weight (g)	21
Volume (cc)[1]	11,5[1]
Connector	IS-1

PARAMETER	SETTINGS
Resynchronisation Therapy	
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV Delay; Interventricular Paced Delay
RV and LV Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
RV Pulse Configuration	Unipolar; Bipolar
LV Pulse Configuration	Unipolar; Bipolar; LV Tip-RV Ring; LV Ring-RV Ring
Ventricular Sense Configuration	BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; LV Unipolar Tip; LV Bipolar; RV Unipolar Ring; LV Tip-RV Tip
Ventricular Pacing Chamber	BV; RV only; LV only (temporary mode)
First Chamber Paced	Simultaneous[2]; RV; LV
Interventricular Pace Delay (ms)	10–80 in steps of 5
Output/Sensing	
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
Shortest AV/PV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10
Atrial ACap™ Confirm	On; Off; Monitor
Primary Pulse Confirmation	Bipolar
Backup Pulse Confirmation	Bipolar
Backup Pulse Amplitude (V)	5,0
Searchable Intervals (hrs)	8; 24
Atrial Pulse Configuration	Unipolar (tip–case); Bipolar (tip–ring)
Atrial Sense Configuration	Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar Ring (ring–case)
Atrial Sensitivity[3,4] (Fixed) (mV)	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
Atrial Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
Atrial Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ 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
Ventricular Sensitivity (fixed) (mV)	0,5-12,5 in steps of 0,5[3,4]
Rate/Timing	
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); DOO(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off
DDT Trigger[5]	R wave
DDT Timing[5]	DDI
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Hysteresis Rate (min^{-1})	Off; 30-150 in steps of 5[6]
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16
Intervention Rate (min^{-1})	Off; Same Base Rate; 80-120 in steps of 10 (Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30)
Intervention Duration (min^{-1})	1–10
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30-150 in steps of 5
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–180 in steps of 10
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Ventricular Pace/Sense Refractory[7] (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470[8]
Atrial Pace Refractory	190-400 in steps of 30; 440; 470[8]
Atrial Sense Refractory	93; 125; 157; 190-400 in steps of 30; 440; 470[8]
PVARP (ms)	125–500 in steps of 25
Atrial Protection Interval (ms)[5]	125
Far-Field Protection Interval (ms)[5]	16

1 ± 0,5 cc
2 LV first with 10 ms interventricular delay.
3 Sensitivity is with respect to a 20 ms haversine test signal.
4 Values 0,1-0,4 not available 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-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
8 Programming options dependent on pacing mode.
9 During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay.
10 S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Rate-Modulated	
Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF	125–475 in steps of 25
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
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})[5]	10
Upper Rate Overdrive (min^{-1})[5]	5
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12
Auto Mode Switch	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)
AMS Base Rate (min^{-1})	40-170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
Magnet Response	Off; Battery Test
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50–150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
of the Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Post Vent. Atrial Blanking (PVAB) (ms)	60-200 in steps of 10; 225; 250
Ventricular Safety Standby	Off; On
PVC Response	Off; Atrial Pace[8]
PMT Options	Off; Passive; Atrial Pace[8]
PMT Detection Rate (min^{-1})	90–180 in steps of 5
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Atrial; Right Ventricular
Coupling Interval[9] (ms)	200-800 in steps of 10
S1 Count	2-25 in steps of 1
S1[10]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Right Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (s)	1-5 in steps of 1
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold
Patient Notifiers	
Programmable Notifiers (On; Off)	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
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22

Customer Support: 46-8-474-4756

Item GMCRM776EN

GMCRM776EN

ST. JUDE MEDICAL
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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 Suppression™ Algorithm is clinically proven to reduce AF burden[1] 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

1. 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.
2. 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.
3. 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 ≤ 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 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, severe physical disability. ***AF Suppression*** is indicated for suppression of paroxysmal or persistent 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 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. ***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 dislodgement 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 or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/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 cardiac vein thrombosis.

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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Frontier™ II

Cardiac Resynchronisation Therapy Pacemaker

PHYSICAL SPECIFICATIONS	
Model Number	**5596**
Dimensions (mm)	49 x 52 x 6
Weight (g)	25
Volume (cm3)◊◊	11.5
Connector	IS-1

PARAMETER	SETTINGS
Resynchronization Therapy	
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, Interventricular Pace delay
RV and LV Pulse Width (ms)	0,05, 0,1-1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,0-4,0 in steps of 0,25, 4,5-7,5 in steps of 0,5
RV Pulse Configuration	Unipolar, Bipolar
LV Pulse Configuration	Unipolar, Bipolar, LV Tip-RV ring
Ventricular Sense Configuration	BV Unipolar Tip, BV Bipolar, RV Unipolar Tip, RV Bipolar, LV Unipolar Tip, LV Bipolar, RV Unipolar Ring, LV tip-RV tip
Ventricular Pacing Chamber	BV, RV only, LV only
First Chamber Paced	Simultaneous***, RV, LV
Interventricular Pace Delay (ms)	20-80 in steps of 5
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5, 6-10 in steps of 1,0, 12,5
Negative AV/PV Hysteresis Search (ms)	Off, –10 to –110 in steps of 10
Shortest AV/PV Delay (ms)	30–50 in steps of 5, 60–120 in steps of 10
Atrial Output/Sensing	
Atrial Pulse Configuration	Unipolar (tip–case), Bipolar (tip–ring)
Atrial Sense Configuration	Unipolar Tip (tip–case), Bipolar (tip–ring), Unipolar Ring (ring–case)
Atrial Sensitivity‡v (mV)	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
Atrial Amplitude	0,0-4,0 in steps of 0,25, 4,5-7,5 in steps of 0,5
Atrial Pulse Width	0,05, 0,1-1,5 in steps of 0,1
Rate/Timing	
Mode	AOO(R), AAI(R), AAT(R), OAO, VOO(R), VVI(R), VVT(R), OVO, DOO(R), DVI(R), DDI(R), DDT(R), DDD(R), ODO
DDT Trigger$^{\Delta}$	R-wave
DDT Timing$^{\Delta}$	DDD, DDI
Base Rate (min^{-1})	30*, 40–130 in steps of 5, 140–170 in steps of 10
Hysteresis Rate (min^{-1})	Off, 30–130 in steps of 5, 140, 150**
Search Interval (min^{-1})	Off, 5, 10, 15, 30
Cycle Count	1–16
Intervention Rate (min^{-1})	Off, 60, 80-120 in steps of 10 (Intrinsic +0, Intrinsic +10, Intrinsic +20, Intrinsic +30)
Intervention Duration (min^{-1})	1–10
Recovery Time	Fast, Medium, Slow, Very Slow
Rest Rate (min^{-1})	Off, 30–130 in steps of 5, 140, 150
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5, 140–180 in steps of 10
AV Delay (ms)	25, 30–200 in steps of 10, 225–300 in steps of 25, 350
PV Delay (ms)	25, 30-200 in steps of 10, 225–325 in steps of 25
Ventricular Refractory† (ms)	125–500 in steps of 25
Atrial Refractory (PVARP) (ms)	125–500 in steps of 25
Ventricular Absolute Refractory Period (ms)	60-240 in steps of 10
Ventricular Blanking (ms)	12-52 in steps of 4
Atrial Absolute Refractory Period (ms)	60, 80, 100–350 in steps of 25
Atrial Protection Interval (ms)$^{\Delta}$	125
Far Field Protection Interval (ms)$^{\Delta}$	16
AF Management	
AF Suppression™	Off, On
Lower Rate Overdrive (min^{-1})$^{\Delta}$	10
Upper Rate Overdrive (min^{-1})$^{\Delta}$	5
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery$^{\Delta}$ (ms)	8, 12
Auto Mode Switch	Off, DDDR to DDIR, DDD to DDI, DDT (D) to DDT (I), DDT (D) to DDTR (I), DDTR (D) to DDTR (I), DDTR (D) to DDT (I), DDDR to DDI, DDD to DDIR
AMS Base Rate (min^{-1})	Base Rate +0 to Base Rate +35 in steps of 5
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
Slope	Auto (-1), Auto (+0), Auto (+1), Auto (+2), Auto (+3), 1-16
Reaction Time	Very Fast, Fast, Medium, Slow
Recovery Time	Fast, Medium, Slow, Very Slow
Stored Electrograms	
Options	
Sampling Options	Freeze, Continuous
No. of Stored EGMs	1, 2, 4, 8, 12
Channel	Single, Dual
Triggers	
Magnet Placement	On, Off
High Atrial Rate (ms)	Off, 125-300 in steps of 25
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
Post Vent. Atrial Blanking (PVAB) (ms)	60, 70, 80, 85, 95, 100, 110, 115, 125, 130, 140, 150, 155, 165, 170, 180, 185, 195, 200
Ventricular Safety Standby	Off, On
PVC Options	Off, +PVARP on PVC
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	
Stimulation Chamber	Atrial, Right Ventricular
Coupling Interval◊ (ms)	200-800 in steps of 10
S1 Count	1-25 in steps of 1
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 cm^3
* The actual pacing rate for the 30 min^{-1} setting is 31 min^{-1}.
** The highest available setting for Hysteresis Rate is 5 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.
v 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 by the programmed AV/PV Delay.
¥ S1 Burst Cycle is applied at the preprogrammed S1 cycle length.
Δ This parameter is not programmable.

Customer Support: 46-8-474-4756

Item GMCRM889EN

GMCRM889EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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.

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Quartet™

Left-Heart Lead

Product Specifications

PHYSICAL 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.

GMCRM770EN

Customer Support: 46-8-474-4756

Item GMCRM770EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

QuickFlex™

Left-Heart Lead

Product Specifications

PHYSICAL 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.

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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

QuickFlex™ µ

Left-Heart Lead

Product Specifications

PHYSICAL SPECIFICATIONS

MODEL	1258T
Parameter	**Description**
Connector	IS-1 Bipolar
Lead Length	75 cm; 86 cm; 92 cm
Lead Body Size	4,3 F (1,42 mm/0,056")
Tip Electrode Size	4,0 F (1,33 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	5,0 mm^2
Ring Electrode Surface Area	7,4 mm^2
Tip-to-Ring Electrode Spacing	20 mm
Lead Body Insulation	Optim™ insulation
Lead Body Coating	Fast-Pass™ coating
Conductors*	
Distal (coil)	MP35N™
Proximal (cables)	MP35N™
Suture Sleeve	Attached

*MP35N is a trademark of SPS Technologies, Inc.

GMCRM772EN

Customer Support: 46-8-474-4756

Item GMCRM772EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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 Distal 8 cm: silicone rubber	Proximal: polyurethane 55D Distal 7 cm: silicone rubber
Conductors	Two ETFE-insulated low resistance cables, multifilar MP35N™*coil	Two ETFE-insulated low resistance cables, multifilar MP35N™* coil

ACCESSORIES PACKAGED WITH THE QUICKSITE LEAD

Stylets (6)	0,36 mm/0,014″ (diameter) 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)
Guidewire	PTFE-coated, 180 cm long, 0,36 mm/0,014″ (diameter) with 5 cm floppy tip; two torque tools included
Lead Flushing Tools (2)	White ABS coupling with Luer Lock™ connector
Stylet Guide (funnel)	
Vein Pick	

*MP35N is a trademark of SPS Technologies, Inc.

GMCRM773EN

Customer Support: 46-8-474-4756

Item GMCRM773EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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

PHYSICAL SPECIFICATIONS

MODELS	1084T (25 cm)	1084T (35 cm)	1084T (54 cm)
Electrode surface area	10 mm^2 cathode 62 mm^2 anode	10 mm^2 62 mm^2	10 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 38 ohms anode	27 ohms 46 ohms	41 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 Platinum/Iridium Titanium-nitride coated anode plate titanium	Titanium-nitride coated Platinum/Iridium Titanium-nitride coated titanium	Titanium-nitride coated Platinum/Iridium Titanium-nitride coated titanium
Conductor material	MP35N™ (multifilar coil)	MP35N™ (multifilar coil)	MP35N™ (multifilar coil)
Insulation material	Silicone rubber (medical grade)	Silicone rubber (medical grade)	Silicone rubber (medical grade)
Connector pin material	316L stainless steel	316L stainless steel	316L stainless steel
Steroid plug	<1 mg dexamethasone sodium phosphate	<1 mg dexamethasone sodium phosphate	<1 mg dexamethasone 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)

Customer Support: 46-8-474-4756

Item GMCRM918EN

GMCRM918EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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)

Merlin@home™ Transmitter Compatible

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, 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Fortify™ ST DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD2235-40**	**CD2235-40Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	74 x 40 x 14	71 x 40 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETERS	SETTINGS
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15-40 in increments of 5
Maximum AF Suppression Rate	80-150 min^{-1}
Sensing/Detection	
Sense*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
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
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; 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 programmable 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	DDD(R); DDI(R); VVI(R); AAI(R); Pacer Off
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220
Rate and Delay Parameters	Programmable Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV) (V); Pulse Width (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
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
Ventricular Intrinsic Preference (VIP™)	Off; 50-200 (50-150 in increments of 25; 450 to 200 in increments of 10)
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm	On; Monitor; Off

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; or DDD
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 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; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue Congestion Trigger
Device Parameter Reset	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 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS
PMT Data	Information regarding PMT detections
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; ST Episode Log
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

*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 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.

Item GMCRM777EN

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ST. JUDE MEDICAL
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Fortify™ ST VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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, 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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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*Ability*™ Technology	Automatic Sensitivity Control adjustment 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; 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
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150 - 300 bpm
Burst Cycle Length	Adaptive; 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
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; Ventricular) 0-220
Programmable	Off; Base Rate (min^{-1}); Rest Rate (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
Ventricular AutoCapture™ Pacing System	On; Off
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
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 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; 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
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 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; ST Episode Log
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

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Customer Support: 46-8-474-4756

Item GMCRM778EN

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ST. JUDE MEDICAL
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Fortify™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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, 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.

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ST. JUDE MEDICAL
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Fortify™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD2233-40**	**CD2233-40Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	40/45	40/45
Volume (cc)	35	35
Weight (g)	76	75
Size (mm)	74 x 40 x 14	71 x 40 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
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*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
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
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; 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 programmable 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	DDD(R); DDI(R); VVI(R); AAI(R); Pacer Off
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	(Post-Sense/Post-Pace; Atrial/Ventricular) 0-220
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV) (V); Pulse Width (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
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
Ventricular Intrinsic Preference (VIP™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm	On; Monitor; Off

Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed 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; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue Congestion Trigger
Device Parameter Reset	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 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high-voltage lead impedances; unloaded battery voltage; and signal amplitudes
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8-18 days

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Customer Support: 46-8-474-4756

Item GMCRM779EN

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Fortify™ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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

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, 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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

PARAMETERS	SETTINGS
Sensing/Detection	
Sense*Ability*™ 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
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150 - 300 bpm
Burst Cycle Length	Adaptive; 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
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; 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™ Pacing System	On; Off
Post-Therapy Pacing (Independently programmable from Bradycardia and ATP)	
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 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; 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
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 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

*QHR is a trademark of Greatbatch, LTD.

Customer Support: 46-8-474-4756

Item GMCRM780EN

GMCRM780EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current Accel™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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
- AutoCapture™ Pacing System offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation. The AutoCapture™ 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
- ACap™ 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*™ 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
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 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current Accel™ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD2215-36**	**CD2215-36Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/42	36/42
Volume (cc)	42	41
Weight (g)	80	80
Size (mm)	77 x 50 x 14	74 x 50 x 14
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1
High-Voltage Can	Electrically active titanium can	Electrically active titanium can

PARAMETER	SETTINGS
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*Ability*™ 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
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); VOO(R); AAI(R); AOO(R)
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; AAT(R); DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV) (V); Pulse Width (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	DDD(R); DDI(R); DOO(R); VVI(R); VOO(R); AAI(R); AOO(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
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™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)
Ventricular AutoCapture™	
Pacing System	On; Off
ACap™ Confirm	On; Monitor; Off

Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	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; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; 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; 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS
PMT Data	Information regarding PMT detections
Real-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, ™ 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.

Item GMCRM775EN

GMCRM775EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current Accel™ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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
- ACap™ 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*™ 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
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, 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current Accel™ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL 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*Ability*™ 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
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	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
Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
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; 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 Stimulation (NIPS)	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

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.

Item GMCRM774EN

GMCRM774EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current™+ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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

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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current™+ DR

Dual-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD2211-36**	**CD2211-36Q**
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/42	36/42
Volume (cc)	42	41
Weight (g)	80	80
Size (mm)	77 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

PARAMETER	SETTINGS
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*Ability*™ Technology	Automatic Sensitivity Control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
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-Sensed/Post-Paced; Atrial/Ventricular) 0-220; (Post-Paced Ventricular) Auto
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
High-Voltage Therapy	
High-Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can
Bradycardia Pacing	
Permanent Modes	DDD(R); DDI(R); DOO(R); VVI(R); VOO(R); AAI(R); AOO(R)
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; AAT(R); DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay; Pulse Amplitude (Atrial; RV) (V); Pulse Width (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	DDD(R); DDI(R); DOO(R); VVI(R); VOO(R); AAI(R); AOO(R)
Atrial Tachycardia Detection Rate (min^{-1})	110-300
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™)	Off; 50-200 (50-150 in increments of 25; 160-200 in increments of 10)

Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Post-Shock Base Rate (min^{-1})	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)	0,5-5,0
Burst Fibber Cycle Length (ms)	20-100
Noninvasive Programmed Stimulation (NIPS)	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; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; High-Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; 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; 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	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS
PMT Data	Information regarding PMT detections
Real-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, ™ 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.

Item GMCRM781EN

GMCRM781EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current™+ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

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

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, 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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Current™+ VR

Single-Chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS		
Models	**CD1211-36**	**CD1211-36Q**
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*Ability*™ Technology	Automatic Sensitivity Control adjustment 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; Ventricular) 0-220; (Post-Paced Ventricular) Auto
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
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
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	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
Post-Therapy Pacing (independently programmable from Bradycardia and ATP)	
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; 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 Stimulation (NIPS)	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

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.

Item GMCRM782EN

GMCRM782EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Defibrillation Leads

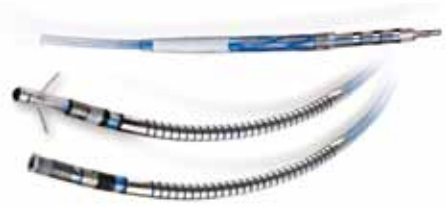
St. Jude Medical Defibrillation Leads

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.

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 – flat-wire 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, 7120Q, 7121, 7121Q, 7122, 7122Q, 7170, 7170Q, 7171, 7171Q and 7172Q 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 7120, 7120Q, 7121, 7121Q, 7122, 7122Q, 7170, 7170Q, 7171, 7171Q and 7172Q leads are contraindicated for extra firm (red color knob) stylets. The lead is not designed, sold, or intended for use other than as indicated.

1. St. Jude Medical DF1 lead connectors conform to the international connector standard ISO 11318/Amd.
2. St. Jude Medical IS-1 lead connectors conform to the international connector standard ISO 5841.
3. 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, myocarditis, post-operative heart failure, chronic mechanical stimulation of the heart, tricuspid valve dysfunction, lead fracture necessitating surgical removal, pneumothorax, hemothorax, infection, tissue necrosis and erosion of the skin. 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.

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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Durata™

Defibrillation Lead

Product Specifications

PHYSICAL SPECIFICATIONS

True Bipolar, Active-Fixation Defibrillation Leads

Models	7120	7120Q	7121	7121Q	7122	7122Q
Fixation	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix	Ext/Ret Helix
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65	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 Defibrillation Leads

Models	7170	7170Q	7171	7171Q	7172Q
Fixation	Tines	Tines	Tines	Tines	Tines
Shock Configuration	Dual-Coil	Dual-Coil	Dual-Coil	Dual-Coil	Single-Coil
Sensing Configuration	True Bipolar	True Bipolar	True Bipolar	True Bipolar	True Bipolar
Min. Size Introducer	7 F	7 F	7 F	7 F	7 F
Lengths (cm)	60; 65; 75	52; 58; 65	60; 65; 75	52; 58; 65	52; 58; 65
Connector	DF1; IS-1	DF4	DF1; IS-1	DF4	DF4
Body Diameter	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
Tip-to-Proximal Coil	17 cm	17 cm	21 cm	21 cm	N/A
Tip Electrode Area	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2	3.5 mm^2
Steroid Plug	Yes	Yes	Yes	Yes	Yes
Distal Shock Coil Area	367 mm^2	367 mm^2	367 mm^2	367 mm^2	367 mm^2
Proximal Shock Coil Area	588 mm^2	588 mm^2	588 mm^2	588 mm^2	N/A

GMCRM783EN

Customer Support: 46-8-474-4756

Item GMCRM783EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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 high-power, 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 safe[2], 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

1. 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

Accent MRI™ DR

Dual-Chamber Pacemaker with Wireless Telemetry

Merlin@home™ Transmitter Compatible

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 Sense*Ability*™ 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 warranty[3]

1. 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
PM2224 (RF)	52 x 53 x 6	24	13,1 (± 0,5)	IS-1

Radiopaque markers

St. Jude Medical identifier — SJM HM MRI — 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 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. 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, severe 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 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 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. 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 battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, and 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, and palpitations with high-rate pacing.

Refer to the User's Manual for more 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, 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.

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Accent MRI™ DR

Dual-Chamber Pacemaker with Wireless Telemetry

Product Specifications

PHYSICAL SPECIFICATIONS

Model	PM2224
Telemetry	RF
Dimensions (mm)	52 x 53 x 6
Weight (g)	24
Volume (cc)	13,1[1]
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)	125[3]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[3]
Hysteresis Rate (min^{-1})	Off; 30[4]-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(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)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	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	AOO; VOO; DOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI Paced AV Delay	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	1,0 ms
MRI RV Pulse Configuration	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)	5,0
Search Interval (hours)	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); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	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™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[3]
Search Interval (hours)	8; 24
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; 12,5[7]
Sense*Ability*™ 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

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
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF (ms)	125-475 in steps of 25
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

AF Management

AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[3]
Upper Rate Overdrive (min^{-1})	5[3]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[3]
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 in steps of 10
Atrial Tachycardia Detection Rate (min^{-1})	110-200 in steps of 10; 225-300 in steps of 25
Auto Mode Switch	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)
AMS Base Rate (min^{-1})	40-170 in steps of 5

Stored Electrograms

Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High

Other

A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100-500 in steps of 25
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[8]
S1 Count	2-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[2]
PMT Detection Rate (min^{-1})	90-180 in steps of 5
PVC Response	Off; Atrial Pace[2]
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec; 1; 3; 5; 10; 30 min
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold

Patient Notifiers

Programmable Notifiers (On; Off)	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)
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

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 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 pre-programmed S1 cycle length.

Customer Support: 46-8-474-4756

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Item GMCRM737EN

GMCRM737EN

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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 Sense*Ability*™ 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 warranty[3]

1. 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 — SJM HM MRI — 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 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. 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, severe 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 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 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. 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 battery failure or component malfunction, device migration, pocket erosion, or hematoma, pectoral muscle stimulation, and 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, and palpitations with high-rate pacing.

Refer to the User's Manual for more 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, 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.

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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)	13,1[1]
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)	125[3]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[3]
Hysteresis Rate (min^{-1})	Off; 30[4]-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(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)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	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	AOO; VOO; DOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI Paced AV Delay	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	1,0 ms
MRI RV Pulse Configuration	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)	5,0
Search Interval (hours)	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); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	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™	
Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[3]
Search Interval (hours)	8; 24
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; 12,5[7]
Sense*Ability*™ 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

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
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF (ms)	125-475 in steps of 25
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

AF Management

AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[3]
Upper Rate Overdrive (min^{-1})	5[3]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[3]
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 in steps of 10
Atrial Tachycardia Detection Rate (min^{-1})	110-200 in steps of 10; 225-300 in steps of 25
Auto Mode Switch	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)
AMS Base Rate (min^{-1})	40-170 in steps of 5

Stored Electrograms

Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High

Other

A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100-500 in steps of 25
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[8]
S1 Count	2-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[2]
PMT Detection Rate (min^{-1})	90-180 in steps of 5
PVC Response	Off; Atrial Pace[2]
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec; 1; 3; 5; 10; 30 min
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold

Patient Notifiers

Programmable Notifiers (On; Off)	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)
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

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 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 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 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.

Item GMCRM739EN

GMCRM739EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Accent MRI™ SR

Single-Chamber Pacemaker with Wireless Telemetry

Merlin@home™ Transmitter Compatible

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 warranty[3]

1. 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 — SJM HM MRI — 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 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 (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, 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.

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, and 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, and palpitations with high-rate pacing.

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Accent MRI™ SR

Single-Chamber Pacemaker with Wireless Telemetry

Product Specifications

PHYSICAL SPECIFICATIONS

Model	PM1224
Telemetry	RF
Dimensions (mm)	52 x 53 x 6
Weight (g)	24
Volume (cc)	13,1[1]
Connector	IS-1

PARAMETER SETTINGS

Rate/Timing

Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470; 500[2]
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Mode	VOO(R); VVI(R); VVT(R); Pacing Off
Hysteresis Rate (min^{-1})	Off; 30[3]-150 in steps of 5
Search Interval (min^{-1})	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 by 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 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 (min^{-1})	Off; 30-150 in steps of 5

MRI Settings

MRI Mode	VOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms

Output/Sensing

V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
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; 12,5[4]
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)	5,0[5]
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	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25
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	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Magnet Response	Off; Low; High
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	Off; Low; High
Noise Reversion	Off; Low; High

Other

Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100-500 in steps of 25
V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	2-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	Exercise; Lead Impedance; R Wave; V Threshold

Patient Notifiers

Programmable Notifiers (On; Off)	Device at ERI; Ventricular Lead Impedance Out of Range
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

1. ± 0,5 cc
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 preprogrammed S1 cycle length.

Item GMCRM738EN

ST. JUDE MEDICAL
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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 Sense*Ability*™ 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 warranty[3]

1. 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 — SJM HM MRI — 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 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 (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, 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.

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, and 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, and palpitations with high-rate pacing.

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Accent MRI™ SR

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS

Model	PM1124
Telemetry	Inductive
Dimensions (mm)	46 x 52 x 6
Weight (g)	22
Volume (cc)	12[1]
Connector	IS-1

PARAMETER SETTINGS

Rate/Timing

Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470; 500[2]
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Mode	VOO(R); VVI(R); VVT(R); Pacing Off
Hysteresis Rate (min^{-1})	Off; 30[3]-150 in steps of 5
Search Interval (min^{-1})	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 by 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 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 (min^{-1})	Off; 30-150 in steps of 5

MRI Settings

MRI Mode	VOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
MRI RV Pulse Configuration	Bipolar
MRI RV Pulse Amplitude	5,0 V; 7,5 V
MRI RV Pulse Width	1,0 ms

Output/Sensing

V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
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; 12,5[4]
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)	5,0[5]
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	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25
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	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Magnet Response	Off; Low; High
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	Off; Low; High
Noise Reversion	Off; Low; High

Other

Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100-500 in steps of 25
V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	2-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	Exercise; Lead Impedance; R Wave; V Threshold

Patient Notifiers

Programmable Notifiers (On; Off)	Device at ERI; Ventricular Lead Impedance Out of Range
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

1. ± 0,5 cc
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 preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Item GMCRM740EN

ST. JUDE MEDICAL
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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 scan[1]
  - Disabled after an MRI scan[1]
  - Verified at any time

Ordering Information

Contents: SJM MRI Activator device

Reorder Number	Description
EX4000	SJM MRI Activator EX4000

Intended Use: The SJM 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 (EMI). EMI could interfere with communication between the activator and the implanted St. Jude Medical ™ 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. Communication equipment such as microwave transmitters or high-power amateur 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. A 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

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.

ST. JUDE MEDICAL
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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)	Type BF
Protection against ingress of liquids	Ordinary equipment
Mode of operation	Non-continuous

1. 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.

Customer Support: 46-8-474-4756

Item GMCRM855EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Accent™ DR RF

Dual-Chamber Pacemaker

Merlin@home™ Transmitter Compatible

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 Sense*Ability*™ 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 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, severe 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 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. ***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, palpitations with high-rate pacing.

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, 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.

ST. JUDE MEDICAL
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Accent™ DR RF

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM2212**
Telemetry	RF
Dimensions (mm)	52 x 52 x 6
Weight (g)	23
Volume (cc)	12,8[1]
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[2]
Atrial Protection Interval (ms)	125[3]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	163
Hysteresis Rate (min^{-1})	Off; 30[4]-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	Off; Same Base Rate; 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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(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)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	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; 500[2]
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0
Search Interval (hours)	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); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	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™	
Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[3]
Search Interval (hours)	8; 24
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; 12,5[7]
Sense*Ability*™ 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	
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
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF (ms)	125-475 in steps of 25
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

AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[3]
Upper Rate Overdrive (min-1)	5[3]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[3]
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 in steps of 10
Atrial Tachycardia Detection Rate (min^{-1})	110-200 in steps of 10; 225-300 in steps of 25
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to VVI(R); VDD(R) to VVI(R)
AMS Base Rate (min^{-1})	40-170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100-500 in steps of 50
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[8]
S1 Count	2-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[2]
PMT Detection Rate (min^{-1})	90-180 in steps of 5
PVC Response	Off; Atrial Pace[2]
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends AT/AF	Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold
Patient Notifiers	
Programmable Notifiers	(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
Device Reset	On
Entry into Backup	VVI Mode On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

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 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 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, 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.

Item GMCRM790EN

GMCRM790EN

ST. JUDE MEDICAL
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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 Sense*Ability*™ 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 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 algorithm is indicated for suppression 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 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.

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, palpitations with high-rate pacing.

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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Accent™ DR

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM2112**
Telemetry	Inductive
Dimensions (mm)	46 x 52 x 6
Weight (g)	19
Volume (cc)	10,5[1]
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[2]
Atrial Protection Interval (ms)	125[3]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[3]
Hysteresis Rate (min^{-1})	Off; 30[4]-150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	Off; Same as Base Rate; 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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DOO(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)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	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]
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0[3]
Search Interval (hours)	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); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	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™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[3]
Search Interval (hours)	8; 24
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; 12,5[7]
Sense*Ability*™ 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	
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
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF (ms)	125-475 in steps of 25
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

AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[3]
Upper Rate Overdrive (min^{-1})	5[3]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[3]
Maximum AF Suppression Rate (min^{-1})	80-200 in steps of 10; 225-300 in steps of 25
Atrial Tachycardia Detection Rate (min^{-1})	110-200 in steps of 10; 225-300 in steps of 25
Auto Mode Switch	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)
AMS Base Rate (min^{-1})	40-170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100-500 in steps of 25
A and V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[8]
S1 Count	2-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (min^{-1})	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[2]
PMT Detection Rate (min^{-1})	90-180 in steps of 5
PVC Response	Off; Atrial Pace[2]
Ventricular Intrinsic Preference, VIP™ (ms)	Off, 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V Threshold
Patient Notifiers	
Programmable Notifiers (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
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

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 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 length.

Customer Support: 46-8-474-4756

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Item GMCRM811EN

GMCRM811EN

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Accent™ SR RF

Single-Chamber Pacemaker

Merlin@home™ Transmitter Compatible

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 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
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 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 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.

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, palpitations with high-rate pacing.

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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Accent™ SR RF

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM1210**
Telemetry	RF
Dimensions (mm)	52 x 52 x 6
Weight (g)	23
Volume (cc)	12,8[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470[2]
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Mode	VOO(R); VVI(R); VVT(R); Pacing Off
Hysteresis Rate (min^{-1})	Off; 30[3]-150 in steps of 5
Search Interval (min^{-1})	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 by 1
Intervention Rate (min^{-1})	Off; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30; Same as Base Rate
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30-150 in steps of 5
Output/Sensing	
V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
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; 12,5[4]
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)	5,0[5]
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	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25
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	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Magnet Response	Off; Low; High
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	Off; Low; High
Noise Reversion	Off; Low; High
Other	
Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100-500 in steps of 225
V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	2-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	Exercise; Lead Impedance; R Wave; V Threshold
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Ventricular Lead Impedance Out of Range
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

1 ± 0,5 cc
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 preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Item GMCRM812EN

GMCRM812EN

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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 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 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.

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, palpitations with high-rate pacing.

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, 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.

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Accent™ SR

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM1110**
Telemetry	Inductive
Dimensions (mm)	42 x 52 x 6
Weight (g)	18
Volume (cc)	9,5[1]
Connector	IS-1

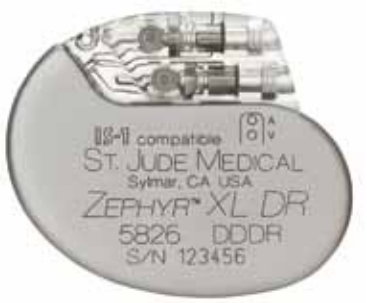
PARAMETER	SETTINGS
Rate/Timing	
Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470[2]
Base Rate (min^{-1})	30-130 in steps of 5; 140-170 in steps of 10
Mode	VOO(R); VVI(R); VVT(R); Pacing Off
Hysteresis Rate (min^{-1})	Off; 30[3]-150 in steps of 5
Search Interval (min^{-1})	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 by 1
Intervention Rate (min^{-1})	Off; 80-120 in steps of 10; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30; Same as Base Rate
Intervention Duration (min)	1-10 in 1 minute intervals
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30-150; in steps of 5
Output/Sensing	
V Pulse Amplitude (V)	0,25-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5
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; 12,5[4]
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)	5,0[5]
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	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25
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	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Magnet Response	Off; Low; High
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125-300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	Off; Low; High
Noise Reversion	Off; Low; High
Other	
Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100-500 in steps of 25
V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	2-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	Off; 100-800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	Exercise; Lead Impedance; R Wave; V Threshold
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Ventricular Lead Impedance Out of Range
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1-16
Time Between Notifications (hours)	10; 22

1 ± 0,5 cc
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 preprogrammed S1 cycle length.

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 5826, 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 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 5826, 5820 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 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.

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 dislodgement 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/hemothorax.

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, 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.

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Zephyr™ XL DR

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**5826**
Dimensions (mm)	44 x 52 x 6
Weight (g)	23,5
Volume (cc)	11[1]
Connector	IS-1 compatible

PARAMETER	SETTINGS
Rate/Timing	
Atrial Absolute Refractory Period	60; 80; 100-350 in steps of 25
Atrial Protection Interval (ms)	125[2]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Base Rate (min^{-1})	30[3]; 40-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[2]
Hysteresis Rate (min^{-1})	Off; 30[3]-130 in steps of 5; 140; 150[4]
Search Interval (min)	Off; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R); DDD(R); ODO
Post Ventricular Atrial Blanking (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 155; 165; 170; 180; 185; 195; 200
PVARP (ms)	125-500 in steps of 25
Sensed AV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	Off; 30-130 in steps of 5; 140; 150
Shortest AV Delay (ms)	30-50 in steps of 5; 60-120 in steps of 10
Ventricular Blanking (ms)	Auto; 12-52 in steps of 4; 12
Ventricular Refractory (ms)	125-500 in steps of 25[5]
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar[2]
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0[2]
Search Interval (hours)	8; 24
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 Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case); Bipolar (tip-ring); Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	0,1-0,4[6]; 0.5 by 0,1, 0,75-2,0 in steps of 0,25; 2,0-4,0 in steps of 0,5; 5,0[7]
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[2]
Search Interval (hours)	8; 24
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; 12,5[7]
Rate-Modulated Parameters	
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
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF	120-350 in steps of 10
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

AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})	10[2]
Upper Rate Overdrive (min^{-1})	5[2]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[2]
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 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
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; DDIR
AMS Base Rate (min^{-1})	Base Rate +0 to Base Rate +35 in steps of 5
Stored Electrograms	
Options	
Sampling Options	Freeze; Continuous
No. of Stored EGMs	1; 2; 4; 8; 12
Channel	Atrial; Ventricular; Dual; Cross-Channel
Triggers	
Advanced Hysteresis	On; Off
AMS Entry/AMS Exit	On; Off
AT/AF Detection	On; Off
Magnet Placement	On; Off
High Atrial Rate	Off; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	On; Off
PVC Detection	On; Off
No. of Consecutive PVCs	2; 3; 4; 5
Other	
A and V Lead Monitoring	Off; Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	200[2]
A and V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -110 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval	100-800 in steps of 10[8]
S1 Count	1-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Ventricular Support Rate (min^{-1})	Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
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
PVC Options	Off; A Pace on PVC; +PVARP on PVC (VDD mode only)
Signal Amplitude Monitoring	
P-Wave Monitoring	Off; On
R-Wave Monitoring	Off; On
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On

1. ± 0,5 cc
2. This parameter is not programmable.
3. The actual pacing rate for the 30 min^{-1} is 31 min^{-1}.
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 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 length.

Customer Support: 46-8-474-4756

Item GMCRM814EN

GMCRM814EN

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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 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 5826, 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 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 5826, 5820 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 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.

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 dislodgement 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/hemothorax.

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, 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.

ST. JUDE MEDICAL
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Zephyr™ DR

Dual-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**5820**
Dimensions (mm)	43 x 44 x 6
Weight (g)	18
Volume (cc)	8,5[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
Atrial Absolute Refractory Period	60; 80; 100-350 in steps of 25
Atrial Protection Interval (ms)	125[2]
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25
Base Rate (min^{-1})	30[3]; 40-130 in steps of 5; 140-170 in steps of 10
Far-Field Protection Interval (ms)	16[2]
Hysteresis Rate (min^{-1})	Off; 30[3]-130 in steps of 5; 140; 150[4]
Search Interval (min)	Off; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10
Mode	AOO(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R); DDD(R); ODO
PVARP (ms)	125-500 in steps of 25
Post Ventricular Atrial Blanking (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 150; 165; 170; 180; 185; 195; 200
Sensed AV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25
Rest Rate (min^{-1})	Off; 30-130 in steps of 5; 140; 150
Shortest AV Delay (ms)	30-50 in steps of 5; 60-120 in steps of 10
Ventricular Blanking (ms)	Auto, 12-52 in steps of 4
Ventricular Refractory (ms)	125-500 in steps of 25[5]
Output/Sensing	
ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar[2]
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5,0[2]
Search Interval (hours)	8; 24
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 Pulse Configuration	Unipolar (tip-case), Bipolar (tip-ring)
A or V Sense Configuration	Unipolar Tip (tip-case), Bipolar (tip-ring), Unipolar Ring (ring-case)
Atrial Sensitivity (mV)	0,1-0,4[6]; 0,5 by 0,1; 0,75-2,0 in steps of 0,25; 2,0-4,0 in steps of 0,5; 5,0[7]
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[2]
Search Interval (hours)	8; 24
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; 12,5[5]; 2,0
Rate-Modulated Parameters	
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
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF	120-350 in steps of 10
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

AF Management	
AF Suppression™ Algorithm	Off, On
Lower Rate Overdrive (min^{-1})	10[2]
Upper Rate Overdrive (min^{-1})	5[2]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12[2]
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 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
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; DDIR
AMS Base Rate (min^{-1})	Base Rate +0 to Base Rate +35 in steps of 5
Stored Electrograms	
Options	
Sampling Options	Freeze, Continuous
No. of Stored EGMs	1; 2; 4; 8; 12
Channel	Atrial; Ventricular; Dual; Cross-Channel
Triggers	
Advanced Hysteresis	On; Off
AMS Entry/AMS Exit	On; Off
AT/AF Detection	On; Off
Magnet Placement	On; Off
High Atrial Rate	Off; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	On; Off
PVC Detection	On; Off
No. of Consecutive PVCs	2; 3; 4; 5
Other	
A and V Lead Monitoring	Off; Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	200[2]
A and V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar
Magnet Response	Off; Battery Test
Negative AV Hysteresis Search (ms)	Off; -10 to -110 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval (ms)	100-800 in steps of 10[8]
S1 Count	1-25 in steps of 1
S1[9], S2, S3 and S4 Cycle (ms)	100-800 in steps of 10
Ventricular Support Rate (min^{-1})	Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
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
PVC Options	Off; A Pace on PVC; +PVARP on PVC (VDD mode only)
Signal Amplitude Monitoring	
P-Wave Monitoring	Off; On
R-Wave Monitoring	Off; On
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	Off; On

1. ± 0,5 cc
2. This parameter is not programmable.
3. The actual pacing rate for the 30 min^{-1} is 31 min^{-1}.
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 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 length.

Customer Support: 46-8-474-4756

Item GMCRM816EN

GMCRM816EN

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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 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, 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, severe physical disability. ***AF Suppression (Models 5826, 5820 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 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, 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.

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 dislodgement 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/hemothorax.

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

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Zephyr™ XL SR

Single-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**5626**
Dimensions (mm)	42 x 52 x 6
Weight (g)	23,5
Volume (cc)	10,4
Connector	IS-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/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; 12,5[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[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	
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

Other	
Lead Monitoring	Off; Monitor; Auto Polarity Switch
A or V Low Impedance Limit (Ω)	200[5]
A or V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
A or V Signal Amplitude Monitoring	Off; On
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	1-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Sinus Node Recovery Delay (sec)	1-5 in steps of 1

1. ± 0,5 cc
2. The actual pacing rate for the 30 ppm is 31 ppm.
3. The highest available setting for Hysteresis Rate will be 5 ppm 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 preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Item GMCRM815EN

GMCRM815EN

ST. JUDE MEDICAL
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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 5826, 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 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 5826, 5820 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 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, 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.

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 dislodgement 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/hemothorax.

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

ST. JUDE MEDICAL
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Zephyr™ SR

Single-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**5620**
Dimensions (mm)	41 x 44 x 6
Weight (g)	17
Volume (cc)	8[1]
Connector	IS-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/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; 12,5[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[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	
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

Other	
Lead Monitoring	Off; Monitor; Auto Polarity Switch
A or V Low Impedance Limit (Ω)	200[5]
A or V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
A or V Signal Amplitude Monitoring	Off; On
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	1-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Sinus Node Recovery Delay (sec)	1-5 in steps of 1

1. ± 0,5 cc
2. The actual pacing rate for the 30 ppm is 31 ppm.
3. The highest available setting for Hysteresis Rate will be 5 ppm 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 preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Item GMCRM817EN

GMCRM817EN

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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 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 PM2134 and PM2136 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 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. ***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 PM2134 and PM2136 only)*** stimulation 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 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, 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, 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 or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

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, 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.

ST. JUDE MEDICAL
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Sustain™ XL DR

Dual-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM2136**
Dimensions (mm)	44 x 52 x 6
Weight (g)	23,5
Volume (cc)	11[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
Atrial Absolute Refractory Period	60; 80; **100**-350 in steps of 25
Atrial Protection Interval (ms)	125[2]
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; **200**
Base Rate (bpm)	30[3]; 40-130 in steps of 5; 140-170 in steps of 10; **60**
Far-Field Protection Interval (ms)	16[2]
Hysteresis Rate (min^{-1})	**Off**; 30-130 in steps of 5; 140; 150[4]
Search Interval (min)	Off; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10; **130**
Mode	AOO(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R); **DDD**(R); ODO
Post Vent. Atrial Blanking (PVAB) (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; **150**; 155; 165; 170; 180; 185; 195; 200
PV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25; **150**
Rest Rate (min^{-1})	**Off**; 30-130 in steps of 5; 140; 150
Shortest AV/PV Delay (ms)	30-50 in steps of 5; 60-120 in steps of 10; **100**
Ventricular Blanking (ms)	12-52 in steps of 4; **12**
Ventricular Refractory (ms)	125-500 in steps of 25[5]; **250**
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; **2,5**
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1; **0,4**
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)
Atrial Sensitivity (mV)	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[7]; **0,5**
Ventricular AutoCapture™ Pacing System	On; **Off**
Primary Pulse Configuration	Unipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[2]
Threshold Search Interval (hours)	8; 24
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5; **2,0**[7]
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80-150 in steps of 5, 160-180 in steps of 10; **130**
Rate Responsive AV/PV Delay	**Off**; Low; Medium; High
Rate Responsive PVARP/VREF	Off; **Low**; Medium; High
Reaction Time	Very Fast; **Fast**; Medium; Slow
Recovery Time	Fast; **Medium**; Slow; Very Slow
Sensor	On; Off; **Passive**
Shortest PVARP/VREF	120-350 in steps of 10; **170**
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

AF Management	
AF Suppression™ Algorithm	**Off**; On
Lower Rate Overdrive (min^{-1})	10[2]
Upper Rate Overdrive (min^{-1})	5[2]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 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; **180**
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; **DDIR**
AMS Base Rate (min^{-1})	Base Rate +0 to Base Rate +35 in steps of 5; **Base Rate +20**
Stored Electrograms	
Options	
Sampling Options	**Freeze**; Continuous
No. of Stored EGMs	1; 2; **4**; 8; 12
Channel	Atrial; Ventricular; **Dual**; Cross-Channel
Triggers	
Advanced Hysteresis	On; **Off**
AMS Entry/AMS Exit	On; **Off**
AT/AF Detection	On; **Off**
Magnet Placement	On; **Off**
High Atrial Rate	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	On; **Off**
PVC Detection	On; **Off**
No. of Consecutive PVCs	2; 3; 4; 5
Other	
A and V Lead Monitoring	**Off**; Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	200[2]
A and V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
Lead Type	**Uncoded**; Unipolar; Bipolar Only; Unipolar/Bipolar
Magnet Response	Off; **Battery Test**
Negative AV/PV Hysteresis Search (ms)	**Off**; -10 to -110 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval	100-800 in steps of 10[8]
S1 Count	1-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Ventricular Support Rate (min^{-1})	Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95
Sinus Node Recovery Delay (sec)	1-5 in steps of 1
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; Off; **110**
PVC Options	Off; **A Pace on PVC**; +PVARP on PVC (VDD mode only)
Signal Amplitude Monitoring	
P-Wave Monitoring	Off; **On**
R-Wave Monitoring	Off; **On**
Ventricular Intrinsic Preference (VIP™) (ms)	**Off**; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	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 highest 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 length.

Customer Support: 46-8-474-4756

Item GMCRM874EN

GMCRM874EN

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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-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% 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.

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 or to the detection of signals other than patient activity, loss of activity-response due to sensor failure, palpitations with high-rate pacing.

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, 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.

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Sustain™ XL SR

Single-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM1136**
Dimensions (mm)	42 x 52 x 6
Weight (g)	23
Volume (cc)	10,4[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
A or V Refractory (ms)	125-500 in steps of 25; **325**
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); OVO
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 in steps of 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/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; **2,5**
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1; **0,4**
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[5]
Search Interval (hours)	8; 24
Rate-Modulated Parameters	
Maximum Sensor Rate (bpm)	80-150 in steps of 5; 160-180 in steps of 10; **130**
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	
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	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	On; **Off**
Other	
Lead Monitoring	**Off**; Monitor; Auto Polarity Switch
A or V Low Impedance Limit (Ω)	200[5]
A or V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
A or V Signal Amplitude Monitoring	Off; **On**
Magnet Response	Off; **Battery Test**
Lead Type	**Uncoded**; Unipolar; Bipolar Only; Unipolar/Bipolar
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	1-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Sinus Node Recovery Delay (sec)	1-5 in steps of 1

1. ± 0,5 cc
2. The actual pacing rate for the 30 ppm is 31 ppm.
3. The highest available setting for Hysteresis Rate will be 5 ppm 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 preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Item GMCRM875EN

GMCRM875EN

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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 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 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 PM2134 and PM2136 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 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 only)*** stimulation 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 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, 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, 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.

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, 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.

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Sustain™ XL DC

Dual-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM2134**
Dimensions (mm)	44 x 52 x 6
Weight (g)	23,5
Volume (cc)	11[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
Atrial Absolute Refractory Period	60; 80; **100**-350 in steps of 25
Atrial Protection Interval (ms)	125[2]
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; **200**
Base Rate (bpm)	30[3]; 40-130 in steps of 5; 140-170 in steps of 10; **60**
Far-Field Protection Interval (ms)	16[2]
Hysteresis Rate (min^{-1})	**Off**; 30-130 in steps of 5; 140; 150[4]
Search Interval (min)	Off; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min^{-1})	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
Maximum Tracking Rate (min^{-1})	90-130 in steps of 5; 140-180 in steps of 10; **130**
Mode	AOO; AAI; AAT; OAO; VOO; VVI; VVT; VDD; OVO; DOO; DVI; DDI; **DDD**; ODO
Post Vent. Atrial Blanking (PVAB) (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; **150**; 155; 165; 170; 180; 185; 195; 200
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; **170**
PV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25; **150**
Rest Rate (min^{-1})	**Off**; 30-130 in steps of 5; 140; 150
Shortest AV/PV Delay (ms)	30-50 in steps of 5; 60-120 in steps of 10; **100**
Ventricular Blanking (ms)	12-52 in steps of 4; **12**
Ventricular Refractory (ms)	125-500 in steps of 25[5]; **250**
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; **2,5**
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1; **0,4**
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)
Atrial Sensitivity (mV)	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[7]
Ventricular AutoCapture™ Pacing System	On; **Off**
Primary Pulse Configuration	Unipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0[2]
Threshold Search Interval (hours)	8; 24
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5; **2,0**[7]
AF Management	
AF Suppression™ Algorithm	**Off**; On
Lower Rate Overdrive (min^{-1})	10[2]
Upper Rate Overdrive (min^{-1})	5[2]
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12
Maximum AF Suppression Rate (min^{-1})	80-150 in steps of 5; 160-180 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; **180**
Auto Mode Switch	Off; DDD to DDI; VDD to VVI; **DDI**
AMS Base Rate (min^{-1})	Base Rate +0 to Base Rate +35 in steps of 5; **Base Rate +20**

Stored Electrograms	
Options	
Sampling Options	**Freeze**; Continuous
No. of Stored EGMs	1; 2; **4**; 8; 12
Channel	Atrial; Ventricular; **Dual**; Cross-Channel
Triggers	
Advanced Hysteresis	On; **Off**
AMS Entry/AMS Exit	On; **Off**
AT/AF Detection	On; **Off**
Magnet Placement	On; **Off**
High Atrial Rate	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	On; **Off**
PVC Detection	On; **Off**
No. of Consecutive PVCs	2; 3; 4; 5

Other	
A and V Lead Monitoring	**Off**; Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	200[2]
A and V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
Lead Type	**Uncoded**; Unipolar; Bipolar Only; Unipolar/Bipolar
Magnet Response	Off; **Battery Test**
Negative AV/PV Hysteresis Search (ms)	**Off**; -10 to -110 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval	100-800 in steps of 10[8]
S1 Count	1-25 in steps of 1
S1[9]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Ventricular Support Rate (min^{-1})	Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95
Sinus Node Recovery Delay (sec)	1-5 in steps of 1
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; Off; **110**
PVC Options	Off; **A Pace on PVC**; +PVARP on PVC (VDD mode only)
Signal Amplitude Monitoring	
P-Wave Monitoring	Off; **On**
R-Wave Monitoring	Off; **On**
Ventricular Intrinsic Preference (VIP™) (ms)	**Off**; 50-150 in steps of 25; 160-200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Ventricular Safety Standby	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 highest 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 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, 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.

Item GMCRM876EN

GMCRM876EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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 arrhythmia/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.

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.

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, 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.

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Sustain™ XL SC

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM1134**
Dimensions (mm)	42 x 52 x 6
Weight (g)	23
Volume (cc)	10,4[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
A or V Refractory (ms)	125-500 in steps of 25; **325**
Base Rate (bpm)	30[2]; 40-130 in steps of 5; 140-170 in steps of 10
Mode	A00; AAI; AAT; OAO; VOO; **VVI**; VVT; OVO
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 in steps of 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
Rate Responsive VREF	**Off**; Low; Medium; High
Rest Rate (bpm)	**Off**; 30-130 in steps of 5; 140; 150
Shortest VREF	120-350 in steps of 10
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; **2,5**
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1; **0,4**
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[5]
Search Interval (hours)	8; 24

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	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	**Off**; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
Advanced Hysteresis	On; **Off**

Other

Lead Monitoring	**Off**; Monitor; Auto Polarity Switch
A or V Low Impedance Limit (Ω)	200[5]
A or V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
A or V Signal Amplitude Monitoring	Off; **On**
Magnet Response	Off; **Battery Test**
Lead Type	**Uncoded**; Unipolar; Bipolar Only; Unipolar/Bipolar
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	1-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Sinus Node Recovery Delay (sec)	1-5 in steps of 1

1. ± 0,5 cc
2. The actual pacing rate for the 30 ppm is 31 ppm.
3. The highest available setting for Hysteresis Rate will be 5 ppm 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 preprogrammed S1 cycle length.

Customer Support: 46-8-474-4756

Item GMCRM877EN

GMCRM877EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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 Atrial Pacing in patients who have demonstrated compromise of AV conduction, rate-Modulated Pacing in patients who experience angina or 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.

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 dislodgment 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/hemothorax.

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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ST. JUDE MEDICAL
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Microny™ II SR+

Single-Chamber Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**2525T**
Dimensions (mm)	33 x 33 x 6
Weight (g)	12,8
Volume (cc)	5,9
Connector	IS-1 Bipolar
Battery Data	Lithium-iodine cell; 2,80 V/0,35 Ah

PARAMETER	SETTINGS
Rate/Timing	
Mode	AOO(R); AAI(R); AAT(R); VOO(R); VVI*(R); VVT(R)
Basic Rate (ppm)	45 - 160 in steps of 5; 60*
Hysteresis Rate (ppm)	0; 10; 20; 30 below the basic or sensor-indicated rate; Off*
Refractory Period (ms)	250; 300*; 350; 400; 450; 500; 550
Output/Sensing	
Pulse Amplitude (V)	Auto** 0,3 - 4,5 in steps of 0,3; 2,4*
Pulse Width (ms)	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
P/R Sensitivity (mV)	0,5; 0,8; 1,2; 2,0; 3,0*; 5,0; 7,5; 12
ER Sensitivity (mV)	1,6; 2,5; 4,0*; 6,0; 10,0; 15,0; 24,0
Pulse Polarity Configuration	Unipolar
Sense Polarity Configuration	Bipolar
Rate-Modulated Parameters	
VARIO	On; Off*
Ventricular AutoCapture™ Pacing System	On; Off*
Sensor	On; Off; Passive
Maximum Sensor Rate (ppm)***	90 - 160 in steps of 10; 130*
Slope***	1 - 16 in steps of 1; 10*
Reaction Time***	Very Fast; Fast; Medium*; Slow; Very Slow
Recovery Time***	Very Fast; Fast; Medium*; Slow; Very Slow
Fast Response***	On; Off*

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

Customer Support: 46-8-474-4756

Item GMCRM818EN

GMCRM818EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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 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 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 5826, 5820 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: 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.

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 dislodgement 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/hemothorax.

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, 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.

ST. JUDE MEDICAL
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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)	11[1]
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; 250[4]
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 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; 225–300 in steps of 25; 225
Post Vent. Atrial Blanking (PVAB) (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 150; 155; 165; 170; 180; 185; 195; 200
Vent. Safety Standby	Off; On
PVC Options	Off; +PVARP on PVC
PMT Options	Off; 10 Beats > PMT; Auto Detect
PMT Detection Rate (ppm)	90-150 in steps of 5; 160-180 in steps of 10; 110
Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar

1. ± 0.5 cc
2. The actual pacing rate for the 30ppm is 31ppm.
3. The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.
4. 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

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Item GMCRM941EN

GMCRM941EN

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

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.

Tendril MRI™

Pacing Lead

Product Highlights

- The Tendril MRI lead is designed to ensure patient safety while performing an MRI scan[1]
  - 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 tip[2] 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

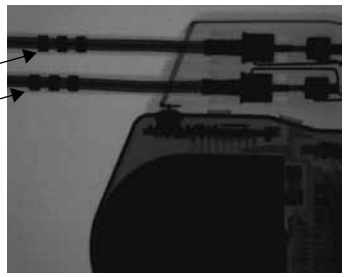
1. See manual for additional details before performing an MRI scan.
2. Bench testing data on file.

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

Easily identifiable unique radiopaque markers



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.

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, embolism, temporary or permanent loss of stimulation and/or sensing, infection, valve and/or vessel damage, tissue necrosis.

Refer to the User's Manual for more 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, 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.

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Tendril MRI™

Pacing Lead

Product Specifications

PHYSICAL 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	2 soft
Helix extension/retraction clip-on tools	2 clip-on tools

Accessory Kits Available Separately

Model Number	Compatible Lengths	Description
Stylet Kit	DSO6002 with appropriate length designation	46, 52 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 and manipulation with one hand
	1292 with appropriate length designation	46, 52 and 58 cm	

*MP35N is a trademark of SPS Technologies, Inc.

Customer Support: 46-8-474-4756

Item GMCRM741EN

GMCRM741EN

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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

ST. JUDE MEDICAL
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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	DSO6002 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 and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58 cm	

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Customer Support: 46-8-474-4756

Item GMCRM822EN

GMCRM822EN

ST. JUDE MEDICAL
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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.

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.

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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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

Accessory 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 length designation	46; 52 cm	1 fixation tool; 1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
	DS06003 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 manipulation with one hand
	1292 with appropriate length designation	46; 52 cm	

Limited Lifetime Warranty

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

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Customer Support: 46-8-474-4756

Item GMCRM824EN

GMCRM824EN

ST. JUDE MEDICAL
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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 Number	Type of Lead	Insulation	Fixation	Min. 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 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™ 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.

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, 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.

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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 helix (2 mm extension)	Pt/Ir collar + active titanium nitride coated 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 straight stylets (1x soft; 1 soft; 1 firm; 1 x firm); 1 j; 1 universal clip-on tool

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GMCRM821EN

Customer Support: 46-8-474-4756

Item GMCRM821EN

ST. JUDE MEDICAL
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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.

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.

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

Customer Support: 46-8-474-4756

ST. JUDE MEDICAL
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Tendril™ SDX

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**1688TC**
Lead Connector	IS-1 Bipolar
Length	100 cm
Minimum Introducer Size	7 F
Type of Lead	Transvenous, screw-in, bipolar, steroid
Fixation Mechanism	Extendable/Retractable helix (3 facet)
External Lead Body Diameter	0,081"/2,1 mm (6,2 F)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Pt/Ir collar + active titanium nitride coated Pt/Ir helix (1,8 mm extension)
Tip Electrode Surface Area	8 mm^2 (collar: 2,4 mm^2; helix: 5,6 mm^2)
Ring Electrode (Anode)	Titanium nitride coated Pt/Ir ring
Ring Electrode Surface Area	16 mm^2
Mapping	Available with collar
Steroid	≤ 1 mg dexamethasone sodium phosphate
Inner Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
Outer Conductor	MP35N™* coil
Outer Insulation	Silicone rubber

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Customer Support: 46-8-474-4756

Item GMCRM823EN

GMCRM823EN

ST. JUDE MEDICAL
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IsoFlex™ Optim™

Pacing Lead

Product Highlights

- Straight or J-shaped lead is available in multiple lengths to accommodate varying needs and patient anatomies
- Optim™ 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, 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

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.

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IsoFlex™ Optim™

Pacing Lead

Product Specifications

PHYSICAL SPECIFICATIONS

Model	1944	1948
Minimum 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
Lead Lengths	46; 52 cm	46; 52; 58 cm
Fixation Mechanism	tines	tines
Tip-to-ring Spacing	10 mm	10 mm
Lead Tip Electrode (Cathode)	Semi spherical shape, steroid coating	Semi spherical shape, steroid coating
Tip 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
Inner Insulation	Silicone rubber	Silicone rubber
Outer Insulation	Optim™ lead insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ 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

Accessory Kits

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.

GMCRM915EN

Customer Support: 46-8-474-4756

Item GMCRM915EN

ST. JUDE MEDICAL
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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 Plus™ 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.

Adverse Events: Potential complications associated with the use of AV Plus™ 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.

Customer Support: 46-8-474-4756

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AV Plus™ DX VDD

Pacing Lead

Product Specifications

PHYSICAL 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

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

Item GMCRM916EN

GMCRM916EN

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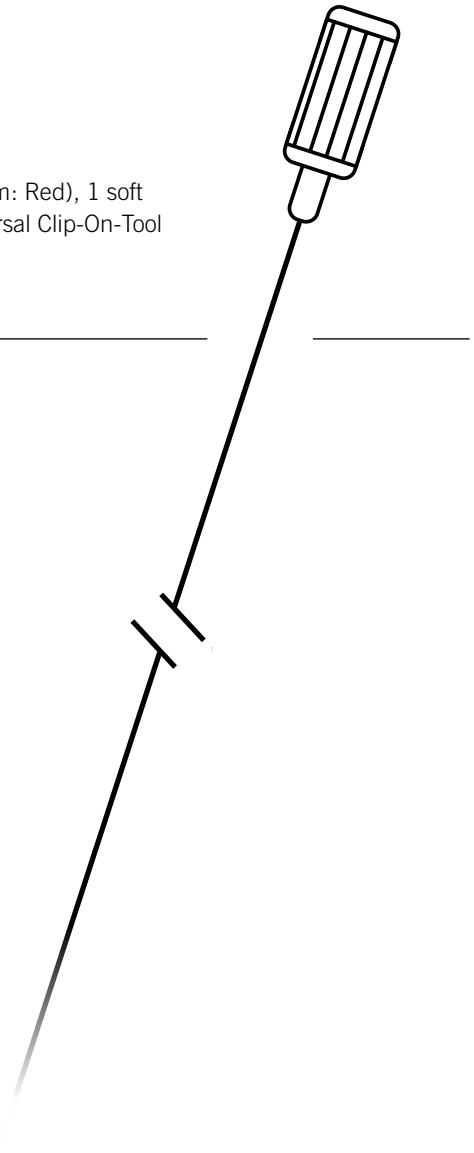
Accessories

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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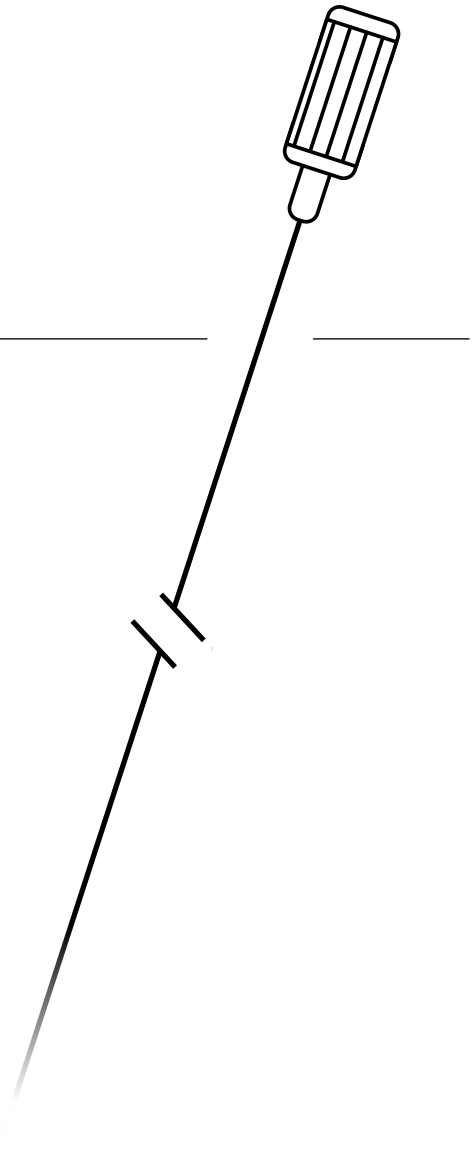
Traffic™ Light Stylet



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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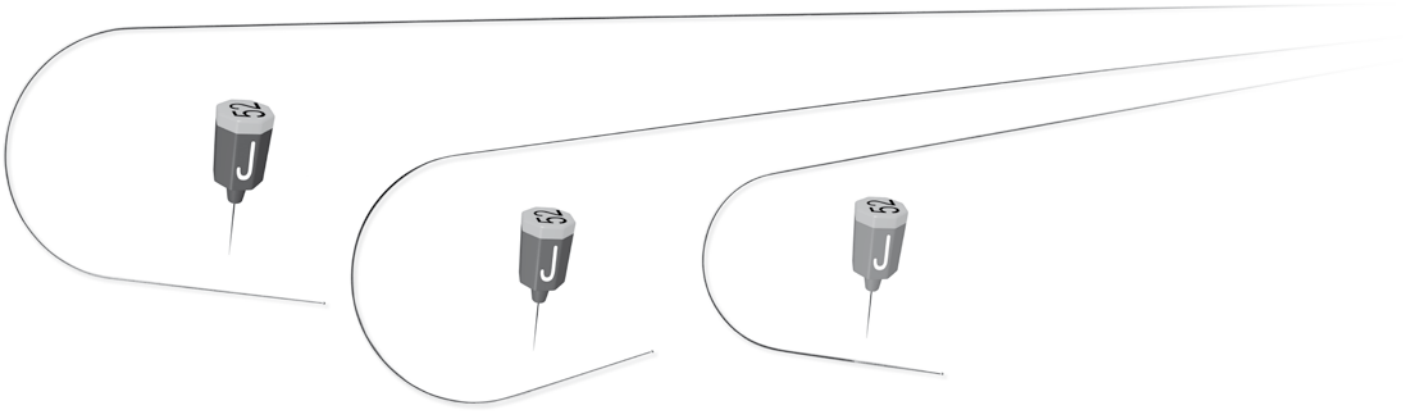
Atrial J Stylet Kit

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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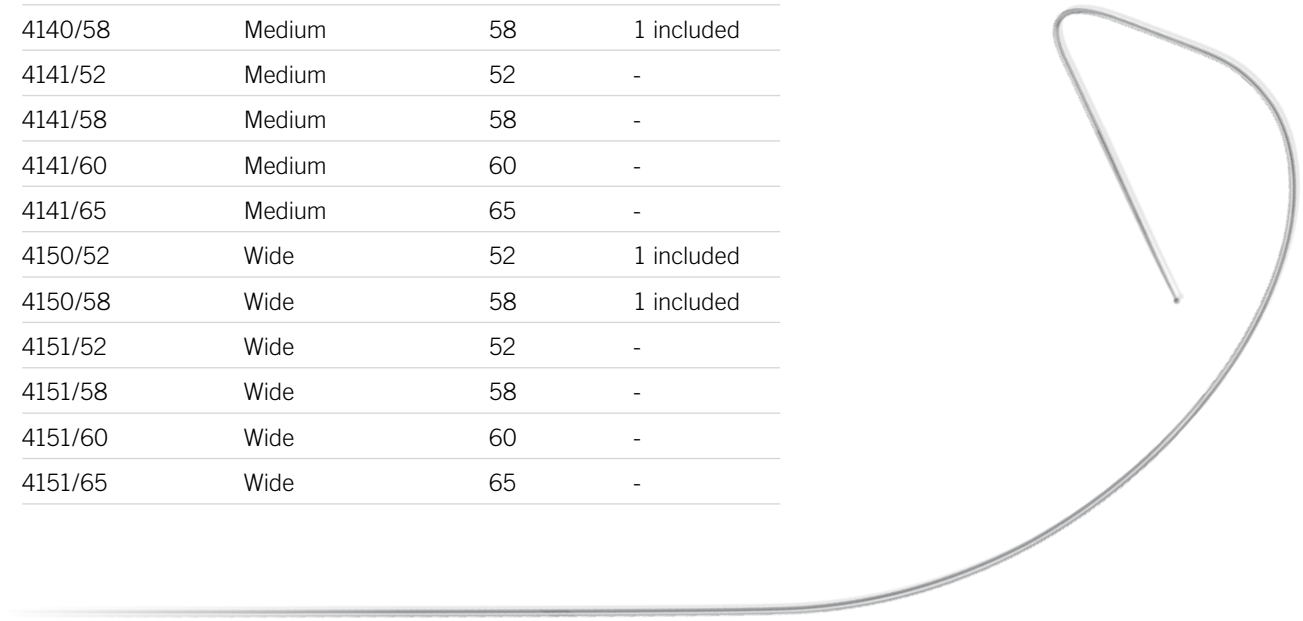
Mond™ RVOT Stylet

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	-



Customer Support: 46-8-474-4756

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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

Model Number	Description	Stiffness	Diameter (in)	Taper Length (cm)
S-65-XS	for 65 cm leads	X-Soft	0,014”	4
S-65-S	for 65 cm leads	Soft	0,014”	2
S-75-S	for 75 cm leads	Soft	0,014”	2
S-60-F	for 60 cm leads	Firm	0,015”	2
S-65-F	for 65 cm leads	Firm	0,015”	2
S-75-F	for 75 cm leads	Firm	0,015”	2
S-65-X	for 65 cm leads	X-Firm	0,016”	2
S-75-X	for 75 cm 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

Model Number	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

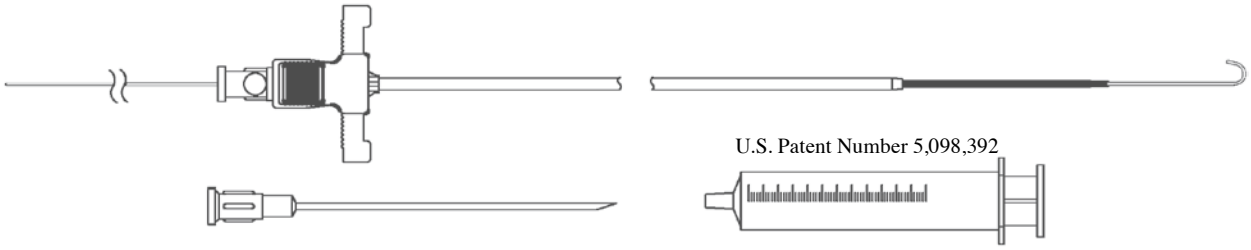
Product Highlights

- 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



U.S. Patent Number 5,098,392

Customer Support: 46-8-474-4756

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Peel-Away Introducer
23 cm Sheath
Introducer Kit

7 F – 14 F

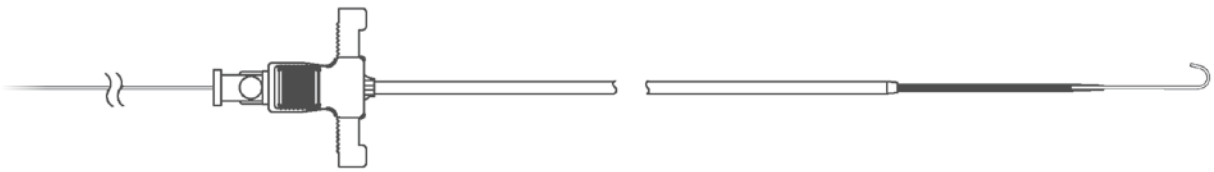
Product Highlights

- 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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CPS Direct™ PL

Peelable Outer Guide Catheter

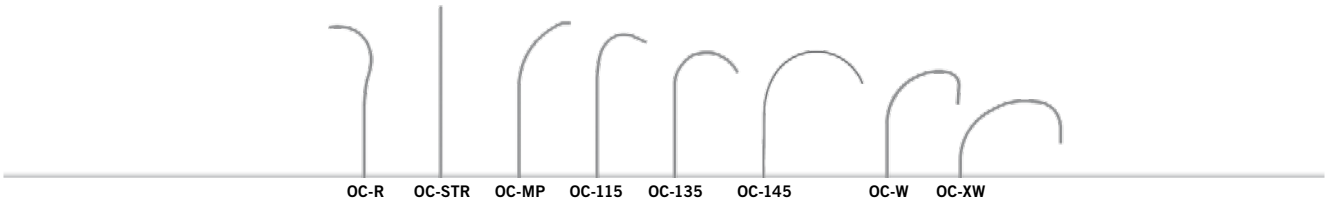
Product Highlights

- 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	Type
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

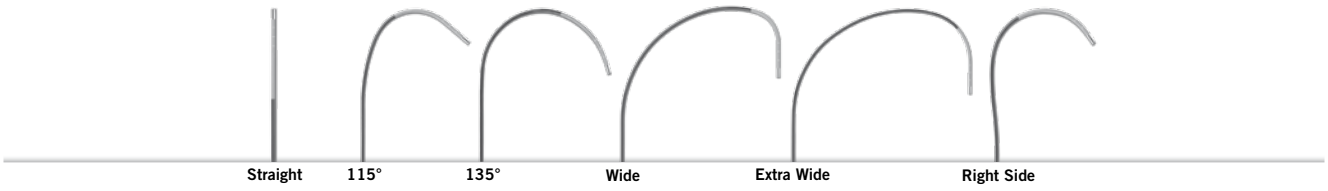
Product Highlights

- 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	Type
DS2A003	CPS™ Universal Slitter	Slitter
DS2A004	CPS Direct™ SL Valve Bypass Tool	Valve bypass tool

Customer Support: 46-8-474-4756

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CPS Aim™ SL

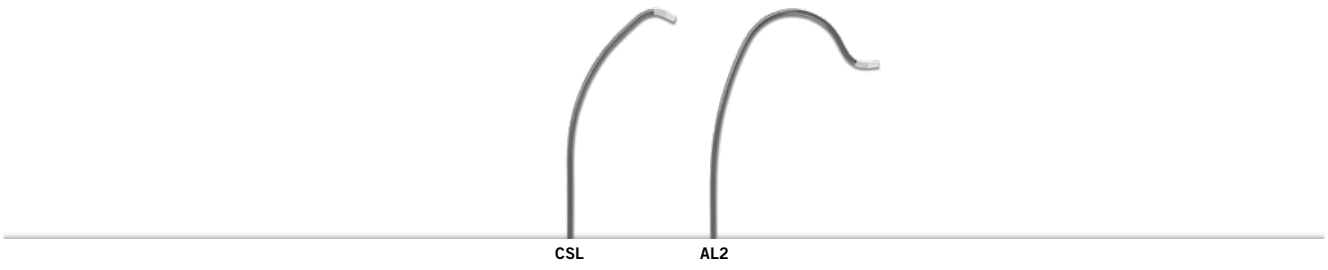
Slittable Inner Catheter Cannulator with Integrated Valve

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	Type
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

Customer Support: 46-8-474-4756

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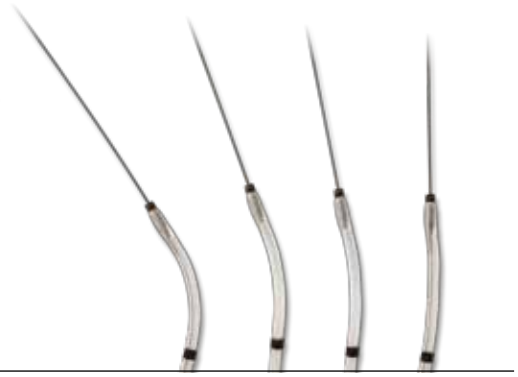
CPS Courier™

Guidewires



Product Highlights

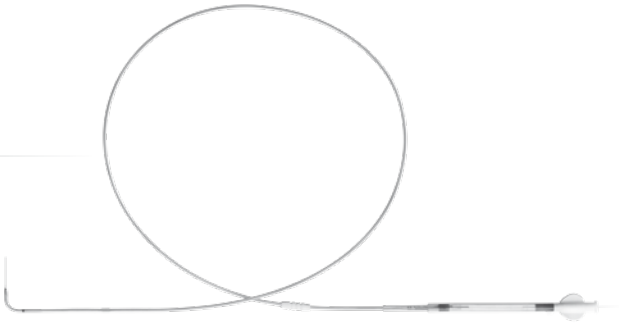
- Helps physicians more easily subselect the target coronary branch vein and deliver the LV lead to its preferred destination

Ordering Information

Model Number	Distal Support	Length (cm)	Units per box	Diameter (in)
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	Type	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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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

Large deflection for CS Cannulation

Small deflection 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

Customer Support: 46-8-474-4756

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CPS Venture™

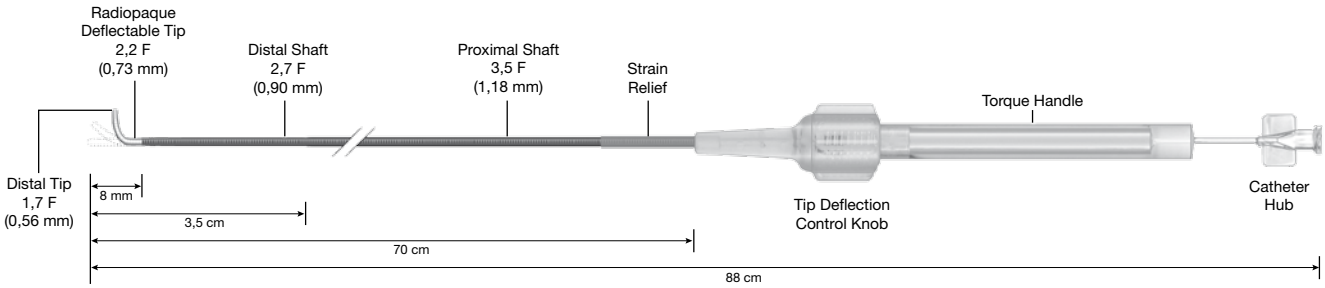
Wire Control Catheter

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



Customer Support: 46-8-474-4756

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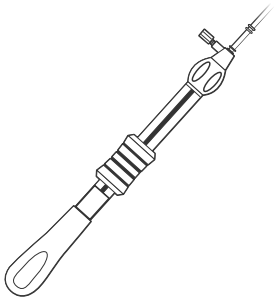
Locator™ Plus

Implant Tools



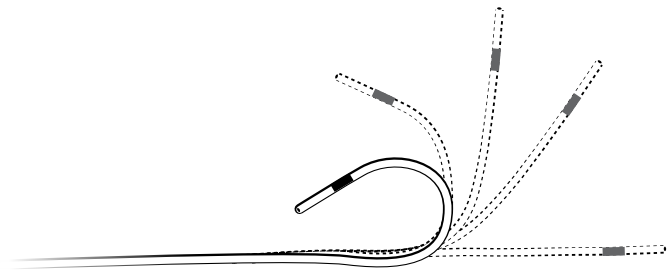
Product Highlights

- 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



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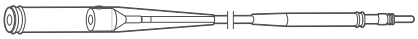
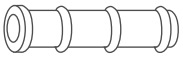
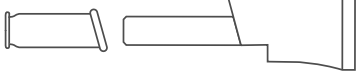
Model Number	Receptacle (for adapting from)	Header Cavity (to device)	
501203	5 mm unipolar (unipolar pacing only)	IS-1 unipolar	
501204	6 mm unipolar	IS-1 unipolar	
501205	5 mm bifurcated (bipolar)	IS-1 bipolar (both unipolar and bipolar pacing compatibility)	
501206	3.2 mm Medtronic™ (CPI™, Telectronic 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 adhesive to cover set screw holes must be ordered separately.

LV-1 is a unique Boston Scientific (formerly Guidant) connector/terminal
Medtronic is a trademark of Medtronic, Inc.
CPI is a trademark of Cardiac Pacemakers, Inc.

Customer Support: 46-8-474-4756

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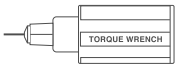
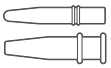
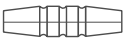
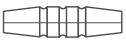
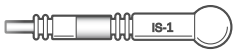
Model Number	Device
AC-0160	Test Magnet 90 gauss at 1"
405	Test Magnet 90 gauss at 1"
60007717-001	Vein Pick 
442-2	Torque Wrench (#2) 
437-246	Set of “L” Hex Wrenches (#2, #4, #6) 
4033A	DF4/IS-1/DF-1 Lead Terminal Cap 
6201	FasTac™ Flex Epicardial Lead Implant Tool
4080	Lead Removal Tool
DS0A001	Suture 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 Coated
EX3151	IS4/DF4 Connector Sleeve

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.

ST. JUDE MEDICAL
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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*™ 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: 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.

Customer Support: 46-8-474-4756

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.*

GMCRM897EN

Customer Support: 46-8-474-4756

Item GMCRM897EN

ST. JUDE MEDICAL
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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*™ 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 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. 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.

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: 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.

Customer Support: 46-8-474-4756

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
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.*

GMCRM898EN

Customer Support: 46-8-474-4756

Item GMCRM898EN

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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 SJM 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 high-power amateur 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. A 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

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.

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SJM Confirm™

External Patient Activator

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)	Type BF
Protection against ingress of liquids	Ordinary equipment
Mode of operation	Non-continuous

Customer Support: 46-8-474-4756

Item GMCRM913EN

GMCRM913EN

ST. JUDE MEDICAL
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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.

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 always-connected 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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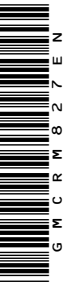

Customer Support: 46-8-474-4756

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.

Item GMCRM827EN

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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

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.

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Customer Support: 46-8-474-4756

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Item GMCRM826EN

ST. JUDE MEDICAL™
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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

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.

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

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

External Pulse Generator

Dual-Chamber (DDD)

Model 3085

Product Specifications

PHYSICAL SPECIFICATIONS

Model	3085
Battery	Standard 9 V, alkaline or lithium
Battery Life Alkaline	Minimal 10 days (VVI, standard parameters), Minimal 8 days (DDD, standard parameters) Plus 1 day reserve after the first appearance of the battery change message
Battery Life Lithium	Minimal 19 days (VVI, standard parameters) Minimal 15 days (DDD, standard parameters) Plus 1 day reserve after the first appearance of the battery change message
Weight (g)	Approximately 490 (including battery)
Size (cm)	20 x 9,6 x 3,8 (7,75 in. x 4 in. x 1,5 in.)

PARAMETER SETTINGS

Technology	
Modes	DDD, DDD + AT, DOO, DAT, DVI, DAI, VVI, VOO, VAT, AAI, AOO, AAT, VDD
Base Pacing Rates (ppm)	30-220
Upper Pacing Rates (MTR) (ppm)	80-230
Rapid Atrial Pacing Rates (ppm)	70-1000
AV Delay (ms)	5-400 (minimum 30 ms when atrial Auto Sense is activated)
PV Delay (ms)	AV delay-30 (minimum 5 ms when atrial Auto Sense is not activated, minimum 30 when atrial Auto Sense is activated)
Pulse Duration (ms)	0,05-1,50
Pulse Amplitude (V)	0,1-18
Atrial Sensitivity (mV)	0,2-20
Ventricular Sensitivity (mV)	1,0-20
Blanking Period (ms)	85 (atrial & ventricular), 55 (ventricular after atrial pacing)
Atrial Refractory Period (ms)	250 … 400 ms ± 5% (AAI, AAT), A-V interval plus PVARP (DDD, VDD, DAI, VAT, DAT)
PVARP (ms)	100-500 (absolute: 90 ms, relative: 90 ms)
Ventricular Refractory Period (ms)	250
Extended PVARP (After PVC) (ms)	500
Crosstalk Detection Window (ms)	40
Emergency Mode	V00 (A00), 80 ppm, 12 V or set value when higher, 0,75 ms (1,00 ms) or set value when longer
Runaway Protection (ppm)	235

Customer Support: 46-8-474-4756

Item GMCRM914EN

GMCRM914EN

ST. JUDE MEDICAL
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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)
- 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

Contraindications: The 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.

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.

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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 V)
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
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

GMCRM921EN

Customer Support: 46-8-474-4756

Item GMCRM921EN

ST. JUDE MEDICAL
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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.

ISO 27001
IS 541672

Merlin@home™ Transmitter Compatible

Customer Support: 46-8-474-4756

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Merlin.net™ Patient Care Network (PCN)

Version 5.0

Product Specifications

Merlin.net PCN Specifications

Connectivity

Direct data export to EHR	EHRDirect Export enables direct export to EHR via IHE or HL7 (2.x and 3.0) format without the need of an intermediary system
Compatible EHR/data management systems	All HL7-compliant EHR systems are compatible. Currently available with: GEMMS™ ONE EHR; Allscripts™ Professional EHR; NextGen™ Ambulatory EHR; EpicCare™ Ambulatory EHR; and GE Centricity™ EHR. Plus compatible with device management solutions such as Paceart™ and ScottCare™ OneView. Ongoing work to integrate with other leading EHR systems.
IHE compatible	YES
Supports HL7	YES
ISO 27001 certified	YES

Scheduling

Online scheduling	Authorized users may schedule patient follow-ups. Automated (SmartSchedule™ Calendar) and manual scheduling options available.
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.

Alerts and Notifications

Daily alert surveillance	DirectAlerts™ Notification available with Merlin@home™ transmitter for all supported devices. Event-based or full disclosure uploads as needed.
Programmable alerts	Physician/clinician option to select only the alerts they want to receive
Diagnostic alert triggers*	Congestion Duration Exceeded Programmed Threshold ST Episode Detected **AT/AF Episode Duration > Threshold **AT/AF Burden > Threshold **Avg. V Rate During AT/AF > Threshold Percent RV Pacing > Threshold Percent BiV Pacing < Threshold
Therapy alert triggers*	High Ventricular Rate Episodes Recorded High Voltage Therapy Delivered Successful ATP Pacing Delivered
Device alert triggers*	Therapy Accelerated Rhythm Longevity Analysis (requires Tech Services support) Tachy Therapy Disabled Charge Time Limit Reached Possible HV Circuit Damage Device Reset 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 Back Up VVI Possible High Voltage Lead Issue LV Pacing Lead Impedance Out of Range (CRT Devices) RV Pacing Lead Impedance Out of Range High Voltage Lead Impedance < Lower Limit High Voltage Lead Impedance > Upper Limit Device Parameter Reset
Alert notification options	E-mail, fax, SMS, website, voice message or smartphone
Alert reports	Alert Summary Report AT/AF alert report accompanies AT/AF alert

Transmitters

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 Transmitter can be issued to patient and paired with his/her device before discharge for remote monitoring from day one

† Available in select markets only

*Different devices support different alerts. Check User's Manual for full list of available alerts.

** If programmed 'On' in patient's device

*** In version 5.0, the inductive Merlin@home™ transmitter unit can support interrogation of legacy devices, including newer Epic ICDs and Atlas ICDs

Website Efficiency

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
Consolidated data	Remote transmissions and in-clinic data available online
Data storage capabilities	All patient transmissions and reports available for immediate access for a minimum of seven years
Data transfers	Patient data follows patient when changing clinics or when patient receives new device
Languages	English, Spanish, French, German, Italian, Japanese

User Interface

Design principles	Similar to Merlin™ Patient Care System (PCS) programmer in colors and design; easy to learn for new users
Report format	Similar to Merlin PCS reports for easy orientation.
Tracking of reviewed transmissions	Viewed field on recent transmissions allows quick indication of which reports have already been viewed; printing reports option to mark as viewed as well
Transmission status, reason for transmission displayed	Scheduled, alert-initiated, patient-initiated
Next transmission column	Date and intervals of next scheduled transmission
Number of days between transmissions	Shown on recent transmissions, patient list, view schedule and manual schedule pages
Identify previous user	Placing mouse over transmission time shows previous user
Rapid alert viewing	Mouse-over alerts shows list of alert types and alert episodes
Clinical comments	Free form, clinic defined or both
Arrhythmia and device management box	Tally of recent transmissions by type
Highlight transmissions with alerts	Customisable by administrator
Inbox/outbox	Recent transmissions/patient list segments files into new and old
Weekly glance	Convenient overview of upcoming transmissions

Education

Interactive practice site	Available

Patient Communication

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
Multiple language support	DirectCall Message tool available in over 20 languages, including English, Spanish, French, Italian, Japanese, German, Dutch, Portuguese, Finnish, Swedish, Danish, Norwegian, Czech, Hungarian, Castilian Spanish, Polish, Turkish, Slovak, Catalonian Spanish, UK English

Patient

Start-up guide	Transmitter Quick Start Guide (QSG) w/step-by-step setup options

Support Materials for Patient and Clinic

Various support materials available. Please meet with sales representative for full complement of training and support materials.

Merlin@home RF Transmitter Specifications

Transmitter model number	EX 1150
Physical components	Single plastic enclosure with external transformer power supply
Weight (w/o power supply)	Less than 2,3 kilograms
Dimensions	Width: 9,18" Height: 6,33" Depth: 5,06"
Wand cable length	NA
Power cord length	Minimum 1,5 meters
Modem	V.92 (56K) – Custom Design
Power source	AC
Line voltage	100-240V
Line frequency	50-60 Hz

Devices Supported by Merlin@home RF Transmitter*** & Merlin.net PCN

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 Fortify™ 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

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)

Customer Support: 46-8-474-4756

Item GMCRM910EN

GMCRM910EN

ST. JUDE MEDICAL
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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

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.

ST. JUDE MEDICAL
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USB Cellular Adaptor

For use with the Merlin@home™ Transmitter

Model EX1151

Product Specifications

PHYSICAL SPECIFICATIONS

Models	EX1151
Dimensions (mm)	65 x 25 x 13,5
Volume (cc)	19,5
Weight (g)	30

TECHNICAL SPECIFICATIONS

Technology

USB Modem	(USB Port)
MSM 7201A	
UMTS with HSDPA Category 8	(7,2 Mbps downlink)
HSUPA Category 5	(2,0 Mbps uplink)
EDGE/GPRS MS Class 12	
WCDMA advanced receiver on UMTS	800/850, 1900, 2100 MHz bands

Bands

800/850, 1900, 2100 MHz WCDMA	Power class 3 (+24dBm)
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

Antenna Diversity Support

800/850, 1900, 2100 MHz

Environmental

Operating Temperature:	0 to 45° Celsius
Storage Temperature:	-40 to 85° Celsius
RoHs Compliant	

Standards/Approvals

CE
FCC
PTCRB
A-tick
GCF
Industry Canada

Package Contents

USB Modem
Clip
USB Extension Cable

CELLULAR TELECOMMUNICATION MODE GENERATION

Generation	Acronym	Title
U1G	AMPS Radiocom 2000 NMT	Advanced Mobile Phone System Radiocom 2000 France Telecom Nordic Mobile Telephone
2G	**GSM**	**Global System for Mobile Communication**
2,5G	**GPRS**	**General Packet Radio Service**
2,75G	**EDGE**	**Enhanced Data Rate for GSM Evolution**
3G	**UMTS**	**Universal Mobile Telecommunications System**
3G+/3,5G	**HSDPA** **HSUPA**	**High Speed Downlink Packet Access** **High Speed Uplink Packet Access**
3,75G	HSOPA	High Speed OFDM Packet Access
4G	LTE Wimax (IT network project)	Long Term Evolution Worldwide Interoperability for Microwave Access

Bold items are supported by the St. Jude Medical USB Cellular Adapter

GMCRM919EN

Customer Support: 46-8-474-4756

Item GMCRM919EN

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Item GMCRM966EN

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