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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ST. JUDE MEDICAL
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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

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Item GMCRM739EN

GMCRM739EN

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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

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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.

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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

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

Item GMCRM740EN

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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.
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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.

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Item GMCRM855EN

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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

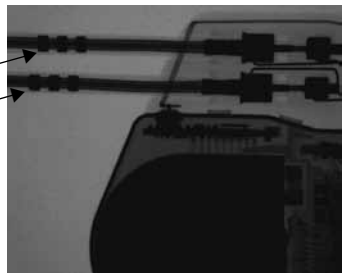
1. See manual for additional details before performing an MRI scan.
2. Bench testing data on file.

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.

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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.

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Item GMCRM741EN

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