

Accent MRI™ SR

Single-Chamber Pacemaker

Product Highlights

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



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.

DRAFT SPECIFICATIONS; CE MARK PENDING.

Ordering Information

Contents: Cardiac pulse generator

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

Radiopaque markers

St. Jude Medical identifier



Device MRI symbol

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

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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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	V00(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	V00; 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
SenseAbility™ 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 (Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Decay Delay (ms)	

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

- ± 0,5 cc
- Programming options dependent on pacing mode.
- The highest available setting for hysteresis rate will be 5 min⁻¹ below the programmed base rate.
- Sensitivity is with respect to a 20 ms haversine test signal.
- This parameter is not programmable.
- S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All Rights Reserved. Item No: GMC740EN



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