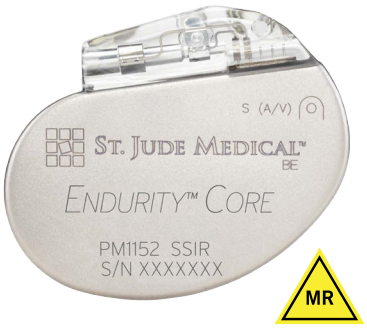
Endurity™ Core

Single-Chamber Pacemaker



Product Highlights - Pacemaker

The Endurity™ Core pacemaker allows patients to undergo MRI scans:

- In patients who have the Tendril™ 2088TC or IsoFlex™ Optim™ 1944/1948 leads, the MRI-ready device:
  - Allows MRI scans*
  - Permits a maximum whole body averaged specific absorption rate (SAR) of 2 Watts per kilogram (W/kg)
- Physician preferred size and physiologic shape minimize pocket size
- Outstanding longevity provides 14,4 years of service life,[7] which is supported by a 5-year warranty[8]
- 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
- 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 2 minutes of stored EGMs when encountering one or more programmable trigger options
- 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
- 6-month ERI-EOL interval

* See MRI Conditional Parameters

Ordering Information - MRI-Ready Pacing System

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1152	Endurity™ Core Pacemaker	41 x 50 x 6	19	9.7 (± 0,5)	IS-1

Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
2088TC	Tendril™ STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 52, 58
1944 (J-shaped)	IsoFlex™ Optim™ Pacing Leads	Optim™	Tines	7	IS-1 bipolar	46,52
1948 (Straight)	IsoFlex Optim Pacing Leads	Optim™	Tines	7	IS-1 bipolar	52, 58

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.

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Endurity™ Core

Single-Chamber Pacemaker

Product Specifications - Pacemaker

PHYSICAL SPECIFICATIONS

Model	PM1152
Telemetry	Inductive
Dimensions (mm)	41 x 50 x 6
Weight (g)	19
Volume (cc)	9.7
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 AOO(R); AAI(R); AAT(R)
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 in steps of 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
Rate Responsive VREF	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25
Output/Sensing	
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[10] 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[4]
V Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5[4]
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
MRI Settings	
MRI Mode	AOO; VOO; Pacing Off
MRI Base Rate	30-120 bpm in steps of 5 bpm
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

MRI Scan Exclusions

Lead	Lead Lengths	Scan Exclusion Zone
Tendril 2088TC Lead	46, 52, 58 cm	Isocenter must be inferior to L4 or 10 cm superior to C1
IsoFlex 1944 Lead	46, 52 cm	Isocenter must be inferior to L4 or superior to C1
IsoFlex 1948 Lead	52, 58 cm	Isocenter must be inferior to L4 or superior to C1

MRI Scan Parameters

Lead	Lead Lengths	Magnet	Full-Body SAR
Tendril 2088TC Lead	46, 52, 58 cm	1.5T	≤ 2 W/kg
IsoFlex 1944 Lead	46, 52 cm	1.5T	≤ 2 W/kg
IsoFlex 1948 Lead	52, 58 cm	1.5T	≤ 2 W/kg

MR 1.5T SAR 2

AF Management[9]	
AF Suppression™ Algorithm	Off; On (Atrial implants only)
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
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80-150 in steps of 5; 160-180 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	
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

High Ventricular Rate can alternately be High Atrial Rate; they use the same sub-parameters.

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

Atrial limits apply when implanted in the atrium.

Lead Type	Uncoded; Unipolar; Bipolar
Magnet Response	Off; Battery Test
NIPS Options	
Stimulation Chamber	Atrial or 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	AT/AF Activity;[9] Lead Impedance; R (or P) Wave; V Threshold

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.
7. A,V = 2,5 V @ 0,4 ms; 500 ohms; 100% VVI pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON
8. Terms and conditions apply; refer to the warranty for details
9. Atrial Implants Only
10. Values 0,1-0,4 not available in a unipolar sense configuration.

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.

SJM-END-1214-0009 I This document is approved for international use only.

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