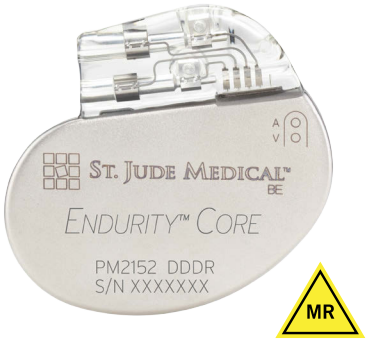
Endurity™ Core

Dual-Chamber Pacemaker



Product Highlights - Pacemaker

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

- When combined with 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 9,7 years of service life,[10] which is supported by an 5-year warranty[11]
- 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
- State-of-the-art features – Ventricular Intrinsic Preference (VIP™) technology, and the AF Suppression™ algorithm, are designed to deliver optimal therapy for patients at implant and throughout their lives
- The only pacemaker with programmable AT/AF alerts specifically indicated for detecting atrial tachyarrhythmias, which have been found to be associated with an increased risk of stroke in elderly, hypertensive, pacemaker patients without prior history of AF[12]
- 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
PM2152	Endurity™ Core Pacemaker	46 x 50 x 6	19	10,4 (± 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

DRAFT SPECIFICATIONS; CE MARK PENDING

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.

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Endurity™ Core

Dual-Chamber Pacemaker

Product Specifications - Pacemaker

PHYSICAL SPECIFICATIONS

Model	PM2152
Telemetry	Inductive
Dimensions (mm)	46 x 50 x 6
Weight (g)	19
Volume (cc)	10,4[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]
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
Rate Responsive AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest AV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
Shortest PVARP/VREF (ms)	125-475 in steps of 25
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; 500 [2]
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)
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
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 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
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
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; Lead Impedance; P and R Wave; V Threshold

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; 30-120 ms in steps of 10 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

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

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.
10. A.V = 2,5 V @ 0,4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON
11. Terms and conditions apply; refer to the warranty for details.
12. Healey JS, Connolly SJ, Gold MR, et al. on behalf of the ASSERT investigators. Sub-clinical atrial fibrillation and the risk of stroke: ASymptomatic atrial fibrillation and Stroke Evaluation in pacemaker patients and the AF Reduction atrial pacing Trial (ASSERT). N Engl J Med 2012; 366:120 –129.

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.

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