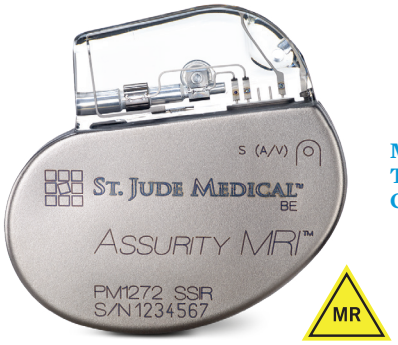
Assurity MRI™

Single-chamber Pacemaker



Merlin@home™ Transmitter Compatible

Product Highlights — Pacemaker

- MRI Ready device tested in combination with MR Conditional leads for full-body scans using a 1.5T and 3T (Tesla) field strength MRI Scanner.*
- An optional, easy-to-use handheld device (SJM MRI Activator™ device) can be used to program the pacemaker to MRI Settings pre- and post-MRI scan, decreasing the number of workflow steps and increasing clinic efficiency.
- Physician-preferred size and physiologic shape minimize pocket size.[1,2]
- InvisiLink™ wireless telemetry system, in conjunction with the Merlin@home™ transmitter and Merlin.net™ Patient Care Network (PCN), allows for daily remote monitoring and follow-up.
- A suite of state-of-the-art features — such as automaticity, Ventricular AutoCapture™ pacing system for ventricular implants, ACap™ Confirm Feature, AF Suppression™ algorithm and AT/AF diagnostics for atrial implants, and Sense*Ability*™ sensing algorithm technology** — are designed to deliver optimal therapy for patients at implant and throughout their lives.
- Outstanding longevity provides 13.9 years of service life,[3] which is supported by a 10-year warranty.[4]
- Six-month ERI-EOL interval.

*MRI Scan Parameters in MRI-Ready Systems manual

**based upon the lead chamber selected

Ordering Information — MRI-Ready Pacing System

MODEL NUMBER	DESCRIPTION	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM1272	Assurity MRI™ Pacemaker	47 × 50 × 6	20	10.4 (± 0.5)	IS-1

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTH (CM)
LPA1200M***	Tendril MRI™ Lead	Optim™	Ext/Ret helix	8	IS-1 bipolar	46, 52, 58
2088TC***	Tendril™ STS Pacing Lead	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 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. **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.

Assurity MRI™

Single-chamber Pacemaker

PHYSICAL SPECIFICATIONS

Model	**PM1272**
Telemetry	RF
Dimensions (mm)	47 × 50 × 6
Weight (g)	20
Volume (cc)	10.4
Connector	IS-1

Remote Monitoring

Compatible with Merlin@home™ Transmitter

PARAMETER SETTINGS

Rate/Timing

Atrial or Ventricular Pace/ Sense Refractory (ms)	125; 160–400 in steps of 30; 440; 470[6]
Base Rate (bpm)	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 (bpm)	Off; 30[7]–150 in steps of 5
Search Interval (bpm)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16 by 1
Intervention Rate (bpm)	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 (bpm)	Off; 30–150 in steps of 5
Rate Responsive VREF	Off; Low; Medium; High
Shortest VREF	125–475 in steps of 25

Output/Sensing

ACap™ Confirm Feature[8]	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[9] 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[10]
V Sensitivity (mV)	0.5–5.0 in steps of 0.5; 6–10 in steps of 1.0; 12.5[10]
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5.0[11]
Search Interval (hours)	8; 24
Sense*Ability*™ Sensing Algorithm Technology	Off; On (Automatic sensitivity control adjustment for atrial or 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

Sensor	On; Off; Passive
Maximum Sensor Rate (bpm)	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
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

MRI Settings

MRI Mode	VOO or AOO (as applicable); Pacing Off
MRI Base Rate	85 bpm; 30–120 bpm in steps of 5 bpm
MRI Pulse Configuration	Bipolar
MRI Pulse Amplitude	5.0 V; 7.5 V
MRI Pulse Width	1.0 ms

MRI Scan Parameters***

LEAD MODEL	MAGNET (TESLA)	RF TRANSMIT CONDITIONS	SCAN REGION
Tendril MRI™ Lead LPA1200M (46, 52, 58 cm)	1.5T	Normal Operating Mode	Full-body
Tendril™ STS Pacing Lead 2088TC (46, 52, 58 cm)	1.5T 3T		

***For additional information about MR Conditional pacemakers and leads, including warnings, precautions, adverse conditions to MRI scanning and potential adverse events, please refer to the MRI-Ready Systems Manual at medical.abbott/manuals or check our MRI Ready resources at cardiovascular.abbott/mriready.

AF Management

AF Suppression™ Algorithm	Off; On (Atrial implants only)
Lower Rate Overdrive (bpm)	10[11]
Upper Rate Overdrive (bpm)	5[11]
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12[11]
Maximum AF Suppression Rate (bpm)	80–150 in steps of 5; 160–180 in steps of 10
Atrial Tachycardia Detection Rate (bpm)	110–200 in steps of 10; 225–300 in steps of 25

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 (bpm)	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[12]; S2; S3 and S4 Cycle (ms)	100–800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	AT/AF Activity[8]; Exercise; Lead Impedance; R (or P) Wave; V (or A) Threshold

1. Abbott. Data on file. Report 60048640. Market Research Report: Pacemaker Size and Shape.
2. Rajappan K. Permanent pacemaker implantation technique: Part I. *Heart*. 2009;95(3):259-264.

Endnotes:

3. A,V = 2.5 V @ 0.4 ms; 500 ohms; 100% VVI pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.
4. Terms and conditions apply; refer to the warranty for details.
5. ± 0.5 cc
6. Programming options dependent on pacing mode.
7. The highest available setting for hysteresis rate will be 5 bpm below the programmed base rate.
8. Atrial implants only.
9. Values 0.1–0.4 not available in unipolar sense configuration.
10. Sensitivity is with respect to a 20 ms haversine test signal.
11. This parameter is not programmable.
12. S1 burst cycle is applied at the preprogrammed S1 cycle length.

Technical Support: 1-800-722-3774

Abbott
One St. Jude Medical Dr.
St. Paul, MN 55117 USA
Tel: 1 651 756 2000
Abbott.com

Rx Only

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.

MAT-2100149 v2.0 | Item approved for U.S. use only.

Abbott