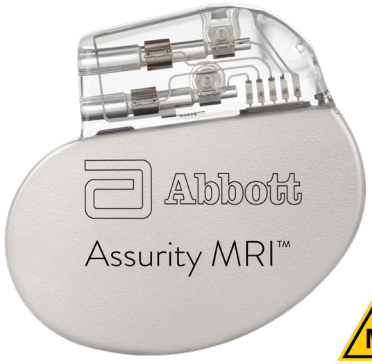
PACEMAKER

Assurity MRI™

Dual Chamber Pacemaker



MR

Merlin@home™ Transmitter Compatible

Product Highlights

- 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.*
- Physician-preferred size and physiologic shape minimize pocket size.[1,2]
- Outstanding longevity provides 9.4 years of service life,[3] which is supported by an eight-year warranty.[4]
- 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.
- 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.[5]
- A suite of state-of-the-art features — complete automaticity (atrial and ventricular), Ventricular Intrinsic Preference (VIP™) technology, AF Suppression™ algorithm and Sense*Ability*™ sensing algorithm technology — are designed to deliver optimal therapy for patients at implant and throughout their lives.
- Six-month ERI-EOL interval.

*MRI Scan Parameters in MRI-Ready Systems manual.

Ordering Information

MRI-Ready Pacing System

MODEL NUMBER	DESCRIPTION	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM2272	Assurity MRI™ Pacemaker	47 × 50 × 6	20	10.4 (± 0.5)	IS-1

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTH (CM)
LPA1231	UltiPace™ Pacing Lead	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 52, 58, 65
2088TC	Tendril™ STS Pacing Lead	Optim™	Ext/Ret helix	6	IS-1 bipolar	46, 52, 58, 65**, 100**

***Not MR Conditional*

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Product Specifications

PHYSICAL SPECIFICATIONS	
Model	PM2272
Telemetry	RF
Dimensions (mm)	47 × 50 × 6
Weight (g)	20
Volume (cc)	10.4[6]
Connector	IS-1
Remote Monitoring	Compatible with Merlin@home™ Transmitter

RATE / TIMING	
Parameter	**Settings**
Atrial Pace Refractory (ms)	190–400 in steps of 30; 440; 470[7]
Atrial Sense Refractory (ms)	93; 125; 157; 190–400 in steps of 30; 440; 470[7]
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Base Rate (bpm)	30–130 in steps of 5; 140–170 in steps of 10
Far-Field Protection Interval (ms)	16[8]
Hysteresis Rate (bpm)	Off; 30[9]–150 in steps of 5
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16 in steps of 1
Intervention Rate (bpm)	Off; Same 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 (bpm)	90–130 in steps of 5; 140–210 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 (bpm)	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[10] (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470; 500[7]

RATE-MODULATED PARAMETERS	
Parameter	**Settings**
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

Product Specifications

OUTPUT/SENSING	
Parameter	**Settings**
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[11]
Ventricul Sensitivity (mV)	0.5–5.0 in steps of 0.5; 6–10 in steps of 1.0; 12.5[11]
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5.0[8]
Search Interval (hours)	8; 24
AutoCapture Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
SenseAbility™ Sensing	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

AF MANAGEMENT	
Parameter	**Settings**
AF Suppression™ Algorithm	Off; On
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
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to VVI(R); VDD(R) to VVI(R)
AMS Base Rate (bpm)	40–170 in steps of 5

Product Specifications

STORED ELECTROGRAMS	
Parameter	**Settings**
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 (bpm)	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
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
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High

MRI SETTINGS	
Parameter	**Settings**
MRI Mode	AOO; VOO; DOO; Pacing Off
MRI Base Rate	85 bpm; 30–120 bpm in steps of 5 bpm
MRI Paced AV Delay	120 ms; 25, 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 PARAMETERS***			
Lead Model	**Magnet (Tesla)**	**RF Transmit Conditions**	**Scan Region**
Tendril™ STS Pacing Lead	1.5 T / 3 T	Normal Operating Mode	Full-body
2088TC (lead lengths: 46, 52, 58 cm)			
UltiPace™ Pacing Lead	1.5 T / 3 T		
LPA1231 (Lead lengths 46, 52, 58, 65 cm)			

***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.

Product Specifications

OTHER	
Parameter	**Settings**
A and V Lead Monitoring	Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	100–500 in steps of 50
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 or Ventricular
Coupling Interval (ms)	100–800 in steps of 10[13]
S1 Count	2–25 in steps of 1
S1[12]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Ventricular Support Rate (bpm)	Off; 30–95 in steps of 5
Sinus Node Recovery Delay (sec)	1; 2; 3; 4; 5
PMT Options	Off; Passive; Atrial Pace[7]
PMT Detection Rate (bpm)	90–180 in steps of 5
PVC Response	Off; Atrial Pace[7]
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

References

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.

End Notes

3. A,V = 2.5 V @ 0.4 ms; 500 ohms; 100% DDD pacing @ 60 bpm; AutoCapture™ Pacing System OFF; SEGMs ON.

4. Terms and conditions apply; refer to the warranty for details.

5. 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.

6. ± 0.5 cc

7. Programming options dependent on pacing mode.

8. This parameter is not programmable.

9. The highest available setting for hysteresis rate will be 5 bpm below the programmed base rate.

10. In dual-chamber modes, the maximum ventricular refractory period is 325 ms.

11. Sensitivity is with respect to a 20 ms haversine test signal.

12. Values 0.1–0.4 not available in a unipolar sense configuration.

13. During atrial NIPS in dual-chamber modes, the shortest coupling interval will be limited by the programmed AV/PV delay.

14. S1 burst cycle is applied at the preprogrammed S1 cycle length.

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.

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 suffera 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: air embolism; body rejection phenomena; cardiac tamponade or perforation; hematoma, bleeding hematoma, seroma; formation of fibrotic tissue, local tissue reaction; inability to interrogate or program due to programmer or device malfunction; infection; erosion; interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic; lead malfunction due to conductor fracture or insulation degradation; loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface; 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; pacemaker migration or pocket erosion; pectoral muscle or diaphragmatic stimulation; phrenic nerve stimulation; pneumothorax/hemothorax; device migration and pocket erosion; endocarditis; excessive bleeding; induced atrial or ventricular arrhythmias; myocardial irritability; pericardial effusion; pericardial rub; pulmonary edema; rise in threshold and exit block; valve damage; death.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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