

Accent™ DR RF

Dual-Chamber Pacemaker

MODEL PM2212



SPECIFICATIONS

- InvisiLink™ Wireless Telemetry, in conjunction with the Merlin@home™ transmitter and Merlin.net™ Patient Care Network (PCN), allows for seamless remote monitoring and follow-up. InvisiLink RF telemetry uses a dedicated range of frequencies designated for medical devices called the MICS (Medical Implant Communications Service) frequency band, which helps reduce the interference seen on frequencies used by common household electronics.
- Upon interrogation, the device displays the last automatically measured capture threshold results from the atrium and ventricle. In addition, the pacemaker automatically measures intrinsic P- and R-wave activity daily and displays the last test results in combination with a weekly P- or R-wave trend. Results are displayed with follow-up EGMs for quick verification.
- 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.
- ACap™ Confirm pacing system periodically completes a threshold search and automatically adjusts amplitude to address patients' changing atrial thresholds.
- Exclusive SenseAbility™ feature, with Decay Delay and Threshold Start, provides the flexibility to fine-tune sensing to individual patient needs and help eliminate oversensing of T waves, fractionated QRS complexes, and other extraneous signals.
- A two-tone audible alert allows programming for the patient to be alerted to changes in device performance, or information can be sent directly to the clinician through the Merlin.net PCN.
- Exclusive AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
 - Studies show a 25% decrease in symptomatic AF burden.¹
- AT/AF Alerts can be programmed to notify patients and their clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode.
- Clinically proven to reduce unnecessary right ventricular pacing, the Ventricular Intrinsic Preference (VIP™) algorithm allows intrinsic conduction when possible and provides optimised ventricular support when needed.
 - Studies show an 81% decrease in unnecessary RV pacing.²
- QuickOpt™ Timing Cycle Optimisation provides quick and effective optimisation for more patients at the touch of a button.³
 - IEGM-based AV optimisation allows optimised timing without need for echo-guided optimisation.
- Real-time 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 14 minutes of stored EGMs when encountering one or more programmable trigger options.
 - Preferential EGM storage capability allows prioritisation of episode storage.
- Weekly Lead Impedance Trend displays the current measurement, historical test results, pacing polarity and any polarity switches.

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: Implanted Cardioverter-Defibrillator (ICD) Devices 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.

Warnings and Precautions: To prevent permanent damage to the device and tissue damage at the electrode/tissue interface:

- Electrosurgery. Do not use electrosurgical devices in the vicinity of an implanted device. If electrocautery is necessary, use a bipolar cauteriser or place the indifferent electrode as far from the device as possible.
- Lithotripsy. Do not focus a lithotripsy beam within 16 cm of the device. Program the device to Sensor Off prior to lithotripsy to prevent inappropriate increases in pacing rate. A thorough assessment of device function with special attention to the sensor should be performed following exposure to lithotripsy.
- Therapeutic Radiation. Do not use ionising radiation in the vicinity of an implanted device. Radiation therapy may damage the electronic circuitry of the device.
- Ultrasound Treatment. Do not use therapeutic ultrasound within 16 cm of the device.

Perform a thorough assessment of device function following exposure to any of the above.

Device Communication. Communication with the device can be affected by electrical interference and strong magnetic fields. If this is a problem, turn off nearby electrical equipment or move it away from the patient and the programmer. If the problem persists, contact St. Jude Medical.

Suboptimal RF Communication. The Merlin™ Patient Care System (PCS) indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin Antenna.

External Defibrillation. The electronic circuitry in the device provides protection from defibrillation discharges. Nevertheless, do not place defibrillator paddles directly over the device or pacing lead. Following defibrillation, ensure that the device is operating correctly.

Magnetic Resonance Imaging (MRI). MRI for patients with implantable devices has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decisions to use MRI with pacemaker patients.

Additional safety concerns include:

- Magnetic and RF fields produced by MRI may increase pacing rate, inhibit pacing, cause asynchronous pacing or result in pacing at random rates
- MRI may result in changes in capture thresholds due to heating of pacing leads
- MRI may irreversibly damage the device
- Patients should be closely monitored during the MRI
- Assess the device function before and after exposure to MRI.

CT Scans. CT scans, due to their increased power levels and long exposure times, have the remote possibility of interfering with implanted devices. The potential interference is transient and occurs only when the X-ray signal is present. Continuous exposure may cause a temporary sensor rate increase. In addition, there is a remote possibility for a device to intermittently oversense while the CT scanning beam is directly over the implanted device.

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.

1 Carlson MD et al. A new pacemaker algorithm for the treatment of atrial fibrillation: results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). JACC 2003; 42:627-633.

2 Hannah G et al. Reduction of ventricular pacing in pacemaker patients using Ventricular Intrinsic Preference: preliminary results from the VIP trial. Europace Supplement, July 2008.

3 Baker et al. Acute evaluation of programmer-guided AV/PV and VV delay optimization comparing an IEGM method and echocardiogram for cardiac resynchronization therapy in heart failure patients and dual-chamber ICD implants. Journal of Cardiovascular Electrophysiology 2007; 18:185-191.



ST. JUDE MEDICAL™

MORE CONTROL. LESS RISK.

PHYSICAL SPECIFICATIONS

Models	PM2212
Telemetry	RF
Dimensions (mm)	52 x 52 x 6
Weight (g)	23
Volume (cc)	12, 8 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
Atrial Protection Interval (ms)	125 ³
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 ¹ -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 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	AO(R); AA(R); AAT(R); VOO(R); VVI(R); VVT(R); VDD(R); DDO(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
Shortest AV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
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 ²

Output/Sensing

ACap™ Confirm	On; Off; Monitor
Primary Pulse Configuration	Bipolar
Backup Pulse Configuration	Bipolar
Backup Pulse Amplitude (V)	5, 8
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 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 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
Ventricular Sensitivity (mV)	0.5-5.0 in steps of 0.5; 6-10 in steps of 1.0; 12, 5 ⁷
SenseAbility™ Technology	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 (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
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 AV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow
Sensor	On; Off; Passive
Shortest PVARP/VREF (ms)	125-475 in steps of 25
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

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

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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)	80-150 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
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
AI/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 ⁹
S1 Count	2-25 in steps of 1
S1 ² ; 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; Exercise; Lead Impedance; P and R Wave; A and V Threshold

Patient Notifiers

Programmable Notifiers (On; Off)	Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF
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
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.	

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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. ©2009 St. Jude Medical, Inc. All Rights Reserved.
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