Anthem™ RF

Cardiac Resynchronization Therapy Pacemaker

MODEL PM3210

SPECIFICATIONS

- InvisiLink® Wireless Telemetry, in conjunction with the Merlin@home® transmitter and Merlin.net® Patient Care Network (PCN), allows for daily 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.
- AT/AF Alerts can be programmed to notify patients and/or 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.
- 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 Burden Trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 52 weeks. This diagnostic view can help identify long-term trends regarding the time or episodes in AF and may facilitate device/drug management according to the patient's response.
- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and to simplify the diagnosis of complex electrocardiogram (ECG) rhythms associated with heart failure patients.
- AT/AF Episodes Log lists up to 32 recorded AT/AF episodes in the order of occurrence with each episode date and time, duration and maximum rate, providing insight into the patient's arrhythmias, as well as showing whether the episodes are occurring more frequently or lasting longer over time.
- Upon interrogation, the device displays the last automatic capture threshold results from the left and right ventricles. 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 electrograms (EGMs) for quick verification.
- Exclusive Sense*Ability*® feature, with Decay Delay and Threshold Start, provides the flexibility to fine-tune sensing to individual patient needs and helps eliminate oversensing of T waves, fractionated QRS complexes, and other extraneous signals.
- A two-tone audible alert allows programming to notify the patient of changes in device performance, or information can be remotely transmitted to the clinician through the Merlin.net PCN without patient interaction.
- Advanced Biventricular Pacing options.
  – Triggered Pacing with BiV Trigger Mode helps maintain a high percentage of BiV pacing by triggering pacing in both the left and right ventricles in response to a sensed ventricular event.
  – VectSelect® programmable LV pulse configuration (LV ring-RV ring, LV tip-RV ring, LV bipolar, LV unipolar tip) may be adjusted noninvasively via the programmer.
  – Negative AV hysteresis with search promotes ventricular pacing by automatically reducing the AV delay when intrinsic activity is present, thereby promoting a high degree of ventricular pacing.
- QuickOpt® Timing Cycle Optimization provides quick and effective optimization for more patients at the push of a button.[2]
  – IEGM-based AV and V-V optimization allows optimized timing without need for echo-guided optimization.
  – V-V timing optimization may help improve patient outcomes. Because not all patients respond to simultaneous biventricular pacing, programmable timing of right- and left-ventricular outputs helps to ensure appropriate therapy and may reduce the number of non-responders.[3]
- Industry-leading five-year warranty.[4]

Indications: Implantation of Anthem and Anthem RF devices is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure, the reduction of the symptoms of moderate to severe heart failure (NYHA Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration, implantation of Accent™, Accent RF, Anthem, and Anthem RF devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, 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*** 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. ***Atrial Fibrillation.*** Anthem devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

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 cauterizer or place the indifferent electrode as far from the device as possible.
- Lithotripsy. Do not focus a lithotripsy beam within 6 inches 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 ionizing 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 6 inches of the device.
- Ventricular Sensing. Ventricular Sensitivity should be programmed to the highest setting (lowest sensitivity) that will provide ventricular sensing with adequate sensing margin. Left ventricular lead dislodgement, to a position near the atria, can result in atrial oversensing and ventricular inhibition.

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: 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, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis.

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 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.
3 Chan et al. Tissue Doppler guided optimization of A-V and V-V delay of biventricular pacemaker improves response to cardiac resynchronization therapy in heart failure patients. J Cardiac Failure 2004; 10:4 (supplement): 572 (abstract 199).
4 Terms and conditions apply. Refer to the warranty for details.

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MORE CONTROL. LESS RISK.

PHYSICAL SPECIFICATIONS

Model	PM3210
Telemetry	RF
Dimensions (mm)	58 x 52 x 6
Weight (g)	25
Volume (cc)	13.7[1]
Connector	IS-1

PARAMETER SETTINGS

Resynchronization Therapy

QuickOpt® Timing Cycle Optimization	Sensed/Paced AV Delay; Interventricular Paced Delay
RV and LV Pulse Width (ms)	0.05; 0.1-1.5 in steps of 0.1
RV and LV Pulse Amplitude (V)	0.25-4.0 in steps of 0.25; 4.5-7.5 in steps of 0.5
RV Pulse Configuration	Unipolar; Bipolar
LV Pulse Configuration	Unipolar; Bipolar; LV Tip-RV Ring; LV Ring-RV Ring
Ventricular Sense Configuration	BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; LV Unipolar Tip; LV Bipolar; RV Unipolar Ring; LV Tip-RV Tip
Ventricular Pacing Chamber	BV; RV only; LV only (temporary mode)
First Chamber Paced	Simultaneous[2]; RV; LV
Interventricular Pace Delay (ms)	10-80 in steps of 5

Output/Sensing

Negative AV Hysteresis Search (ms)	Off; -10 to -120 in steps of 10
Shortest AV/PV Delay (ms)	25-50 in steps of 5; 60-120 in steps of 10
Sense*Ability*® 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
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
Ventricular Sensitivity (fixed) (mV)	0.5-5.0 in steps of 0.5; 6-10 in steps of 1.0; 12.5[3]

Rate/Timing

Mode	A00(R); AAI(R); AAT(R); V00(R); VVI(R); VVT(R); D00(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off
DDT Trigger[4]	R wave
DDT Timing[4]	DDI
Base Rate (bpm)	30-130 in steps of 5; 140-170 in steps of 10
Hysteresis Rate (bpm)	Off; 30-150 in steps of 5[5]
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16
Intervention Rate (bpm)	Off; Same Base Rate; 80-120 in steps of 10 (Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30)
Intervention Duration (bpm)	1-10
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (bpm)	Off; 30-150 in steps of 5
Maximum Tracking Rate (bpm)	90-130 in steps of 5; 140-180 in steps of 10
Sensed AV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350
Ventricular Pace/Sense Refractory[6] (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470[7]
Atrial Pace Refractory	190-400 in steps of 30; 440; 470[7]
Atrial Sense Refractory	93; 125; 157; 190-400 in steps of 30; 440; 470[7]
PVARP (ms)	125-500 in steps of 25
Atrial Protection Interval (ms)[4]	125
Far-Field Protection Interval (ms)[4]	16

Rate-Modulated

Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF	125-475 in steps of 25
Sensor	On; Off; Passive
Max Sensor Rate (bpm)	80-150 in steps of 5; 160-180 in steps of 10
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
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1-16
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow

AF Management

AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (bpm)[4]	10
Upper Rate Overdrive (bpm)[4]	5
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12
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 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 (bpm)	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 (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

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
Magnet Response	Off; Battery Test
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
Post-Ventricular Atrial Blanking (PVAB) (ms)	60-200 in steps of 10; 225; 250
Ventricular Safety Standby	Off; On
PVC Response	Off; Atrial Pace[7]
PMT Options	Off; Passive; Atrial Pace[7]
PMT Detection Rate *(bpm)*	90-180 in steps of 5
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Atrial; Right Ventricular
Coupling Interval[8] *(ms)*	100-800 in steps of 10
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)
Right Venticular Support Rate (bpm)	Off; 30-95 in steps of 5
Sinus Node Recovery Delay (s)	1; 2; 3; 4; 5
Diagnostic Trends	AT/AF Burden; Exercise & Activity; 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; LV 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 LV first with 10 ms interventricular delay.
3 Sensitivity is with respect to a 20 ms haversine test signal.
4 This parameter is not programmable.
5 The highest available setting for hysteresis rate is 5 min[-1] below the programmed base rate.
6 In dual-chamber modes, the Maximum Ventricular Refractory Period is 325 ms.
7 Programming options dependent on pacing mode.
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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