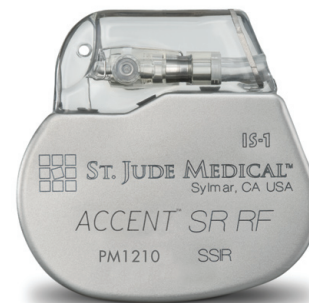


Accent™ SR RF

Single-Chamber Pacemaker

MODEL PM1210



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.
- 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.
- 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.
- 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.
- 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 14 minutes of stored EGMs when encountering one or more programmable trigger options.
 - Preferential EGM storage capability allows prioritization of episode storage.
- Weekly Lead Impedance Trend displays the current measurement, historical test results, pacing polarity and any polarity switches.
- Upon interrogation, the device displays the last automatically measured capture threshold results from the ventricle. In addition, the pacemaker automatically measures intrinsic R-wave activity daily and displays the last test results in combination with a weekly R-wave trend. Results are displayed with follow-up EGMs for quick verification.
- Industry-leading seven-year warranty.¹

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. **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.

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. **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. 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.

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.

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

¹ Terms and conditions apply. Refer to the warranty for details.

PHYSICAL SPECIFICATIONS

Model	PM1210
Telemetry	RF
Dimensions (mm)	52 x 52 x 6
Weight (g)	23
Volume (cc)	12.8 ³
Connector	IS-1

PARAMETER SETTINGS

Rate/Timing

Ventricular Pace/Sense Refractory (Fixed) (ms)	125; 160-400 in steps of 30; 440; 470 ²
Base Rate (bpm)	30-130 in steps of 5; 140-170 in steps of 10
Mode	V00(R); VVI(R); VVT(R); Pacing Off
Hysteresis Rate (bpm)	Off; 30-150 in steps of 5 ³
Search Interval (bpm)	Off; 1; 5; 10; 15; 30
Cycle Count	1-16 by 1
Intervention Rate (bpm)	Off; Same Basic Rate; 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

Output/Sensing

V Pulse Amplitude (V)	0.25-4.0 in steps of 0.25; 4.5-7.5 in steps of 0.5
V Pulse Width (ms)	0.05; 0.1-1.5 in steps of 0.1
V Sensitivity (mV)	0.5-5.0 in steps of 0.5; 6-10 in steps of 1.0; 12.5 ⁴
V Pulse Configuration	Unipolar (tip-case); Bipolar (tip-ring)
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 ⁵
Search Interval (hours)	8; 24
SenseAbility® Technology	Off; On (Automatic Sensitivity Control adjustment for ventricular events)
Max Sensitivity (mV)	0.2-2.0 in steps of 0.1
Threshold Start	(Ventricular Post-Sense) 50; 62.5; 75; 100% (Ventricular Post-Pace) Auto; 0.2-3.0 in steps of 0.1 mV
Decay Delay (ms)	(Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220

Rate-Modulated Parameters

Maximum Sensor Rate (bpm)	80-150 in steps of 5; 160-180 in steps of 10
Rate Responsive VREF	Off; Low; Medium; High
Shortest VREF	125-475 in steps of 25
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

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

Other

Lead Monitoring	Monitor; Auto Polarity Switch
V Low Impedance Limit (Ω)	100-500 in steps of 225
V High Impedance Limit (Ω)	750-2500 in steps of 250; 3000
Magnet Response	Off; Battery Test
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	2-25 in steps of 1
S1; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10 (Fixed or Adaptive)
Diagnostic Trends	Exercise & Activity; Lead Impedance; R Wave; V Threshold

Patient Notifiers

Programmable Notifiers (On; Off)	Device at ERI; Ventricular Lead Impedance Out of Range
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 The highest available setting for hysteresis rate will be 5 min⁴ below the programmed base rate.
 4 Sensitivity is with respect to a 20 ms haversine test signal.
 5 This parameter is not programmable.
 6 S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE, DISTRIBUTION AND USE BY OR ON THE ORDER OF A PHYSICIAN.
Brief Summary: Prior to using these devices, please review the User's Manual for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Unless otherwise noted, ® or TM indicates a registered or unregistered trademark or service mark owned by, or licensed to, St. Jude Medical, Inc. or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies.
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