



SPECIFICATIONS

- 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.
- LV, RV, and Atrial Capture Confirmation features ensure capture of the myocardium in response to pacing stimuli in the left ventricle, right ventricle and right atrium. LVCap™, RVCap™ and ACap™ Confirm help ensure patient safety and therapy delivery by automatically monitoring and adjusting capture thresholds according to changing patient needs.
- 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™ Patient Care Network (PCN).
- 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.¹
- 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 or LV bipolar and 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 Optimisation provides quick and effective optimisation for more patients at the push of a button.²
 - IEGM-based AV and V-V optimisation allows optimised timing without need for echo-guided optimisation.
 - V-V timing optimisation 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
- Exclusive AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF.
 - Studies show a 25% decrease in symptomatic AF burden.⁴
- 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.
- 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.
- 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.
- Far-Field Protection is designed to provide for enhanced AT/AF diagnostics and allow for more accurate mode switch events. The Atrial Protection Interval also provides enhanced protection against competitive atrial pacing.

- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and to simplify the diagnosis of complex ECG rhythms associated with heart failure patients.

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. Implantation is indicated for patients who would benefit from resynchronisation of the right and left ventricles, or have one or more conventional indications for the implantation of a pacemaker. **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 patient's 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 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.
- 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.

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

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 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.



PHYSICAL SPECIFICATIONS

| | |
|--------------------------|---------------|
| Model | PM3112 |
| Telemetry | Inductive |
| Dimensions (mm) | 52 x 52 x 6 |
| Weight (g) | 21 |
| Volume (cc) ¹ | 11,5 |
| Connector | IS-1 |

PARAMETER SETTINGS

Resynchronisation Therapy

| | |
|-------------------------------------|--|
| QuickOpt™ Timing Cycle Optimisation | Sensed/Paced AV Delay; Interventricular Paced Delay |
| RV and LV Pulse Width (ms) | 0,25; 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 |
| First Chamber Paced | Simultaneous ² ; RV; LV |
| Interventricular Pace Delay (ms) | 15–80 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 |
| Atrial ACap™ Confirm | On; Off; Monitor |
| Primary Pulse Confirmation | Bipolar |
| Backup Pulse Confirmation | Bipolar |
| Backup Pulse Amplitude (V) | 5,0 |
| Searchable Intervals (hrs) | 8; 24 |
| Atrial Pulse Configuration | Unipolar (tip–case); Bipolar (tip–ring) |
| Atrial Sense Configuration | Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar Ring (ring–case) |
| Atrial Sensitivity ^{3,4} (Fixed) (mV) | 0,1–0,5 in steps of 0,1; 0,75–2,0 in steps of 0,25; 2,5–5,0 in steps of 0,5 |
| Atrial Amplitude | 0,0–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5 |
| Atrial Pulse Width | 0,05; 0,1–1,5 in steps of 0,1 |
| RVCap™ Confirm | On; Off; Monitor |
| Searchable Interval (hrs) | 8; 24 |
| LVCap™ Confirm | On; Off; Monitor |
| Searchable Interval (hrs) | 8; 24 |
| SenseAbility™ Technology | Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events) |
| A or V Max Sensitivity (mV) Threshold Start | 0,2–2,0 in steps of 0,1 (Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial and Ventricular Post-Pace) 0,2–3,0 in steps of 0,1 ms (Atrial and Ventricular Post-Sense/Post-Pace) 0–220 ms in steps of 30 |
| Decay Delay | |

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 ⁵ | R wave |
| DDT Timing ⁵ | DDD, DDI |
| Base Rate (min ⁻¹) | 30 ⁶ ; 35; 40–130 in steps of 5; 140–170 in steps of 10 |
| Hysteresis Rate (min ⁻¹) | Off; 30–130 in steps of 5; 140; 145; 150 ⁷ |
| Search Interval (min ⁻¹) | Off; 1; 5; 10; 15; 30 |
| Cycle Count | 1–16 |
| 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) | 1–10 |
| Recovery Time | Fast; Medium; Slow; Very Slow |
| Rest Rate (min ⁻¹) | Off; 30–135 in steps of 5; 140; 150 |
| Maximum Tracking Rate (min ⁻¹) | 90–130 in steps of 5; 140–180 in steps of 10 |
| Sensed AV Delay (ms) | 25; 30–200 in steps of 10; 225–300 in steps of 25; 350 |
| Paced AV Delay (ms) | 25; 30–200 in steps of 10; 225–325 in steps of 25 |
| Ventricular Pace/Sense Refractory ⁸ (Fixed) (ms) | 125–500 in steps of 30 ⁹ |
| Atrial Pace Refractory | 190; 220; 400; 440; 470 ⁹ |
| Atrial Sense Refractory | 93; 125; 157; 190 ⁹ |
| PVARP (ms) | 125–500 in steps of 25 |
| Atrial Protection Interval (ms) ⁵ | 125 |
| Far-Field Protection Interval (ms) ⁵ | 16 |

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 Values 0,1–0,4 not available in a Unipolar Sense Configuration.
 5 This parameter is not programmable.
 6 The actual pacing rate for the 30 min⁻¹ setting is 31 min⁻¹.
 7 The highest available setting for hysteresis rate is 5 min⁻¹ below the programmed base rate.
 8 In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
 9 Programming options dependent on pacing mode.
 10 During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay.
 11 S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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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 (min ⁻¹) | 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 (min ⁻¹) ⁵ | 10 |
| Upper Rate Overdrive (min ⁻¹) ⁵ | 5 |
| No. of Overdrive Pacing Cycles | 15–40 in steps of 5 |
| Rate Recovery (ms) | 8; 12 |
| Auto Mode Switch | Off; DDDR to DDIR; DDD to DDI; DDT (D) to DDT (I); DDT (D) to DDTR (I); DDTR (D) to DDTR (I); DDTR (D) to DDT (I); DDDR to DDI; DDD to DDIR |
| AMS Base Rate (min ⁻¹) | 40–170 in steps of 5 |

Stored Electrograms

| | |
|--|------------------------|
| Options | |
| Priority Options | Off; Low; High |
| No. of Stored EGMs | 1; 2; 4; 8; 12 |
| 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 (min ⁻¹) | Off; Low; High |
| Rate | 175–300 in steps of 25 |
| No. of Consecutive Cycles | 2; 3; 4; 5; 10; 15; 20 |
| High Ventricular Rate (min ⁻¹) | Off; Low; High |
| Rate | 175–300 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

| | |
|--|--|
| Magnet Response | Off; Battery Test |
| Ventricular Intrinsic Preference (VIP™) | Off; 50–150 in steps of 25 |
| Atrial Tachycardia Detection Rate (min ⁻¹) | 110–200 in steps of 10; 225–300 in steps of 25; 225–300 in steps of 25 |
| Post Vent. Atrial Blanking (PVAB) (ms) | 60–200 in steps of 10; 225; 250 |
| Ventricular Safety Standby PVC Response | Off; On |
| PMT Options | Off; Atrial Pace; Extend PVARP (VDD mode only) |
| PMT Detection Rate (min ⁻¹) | Off; 10 Beats > PMT; Auto Detect |
| Lead Type | 90–180 in steps of 5; Passive; Atrial Pace |
| NIPS Options | Uncoded; Unipolar; Unipolar/Bipolar |
| Stimulation Chamber | Atrial; Right Ventricular |
| Coupling Interval ¹⁰ (ms) | 200–800 in steps of 10 |
| 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) |
| Right Ventricular Support Rate (min ⁻¹) | Off; 30; 35; 40–95 in steps of 5 |
| Sinus Node Recovery Delay (s) | 1–5 in steps of 1 |
| Diagnostic Trends | AT/AF Activity; Exercise; Lead Impedance; P and R Wave |

Patient Notifiers

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|------------------------------------|--|
| 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, 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 |

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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. Item MCRM458