

Sustain™ XL DC

Dual-Chamber Pacemaker

Product Highlights

- Device features small, physiologic shape and offers superior longevity (9,8 years) without compromising size.¹
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and ventricular threshold tests.
- The Ventricular Intrinsic Preference (VIP™) algorithm automatically searches for intrinsic conduction.
- The AutoCapture™ Pacing System feature offers the maximum in threshold adaptability and patient safety with ventricular Beat-by-Beat™ capture confirmation.
- Stored electrograms (EGMs) record a real-time EGM waveform as well as the associated event markers that precede and follow a specific triggering event.

1. A, V = 2,5 V/0,4 ms, A,V = 500 ohms, 100% DDD pacing @ 60 bpm, SEGMS ON; data on file.



Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM2134	44 x 52 x 6	23,5	11	IS-1

Indications and Usage: Implantation of Sustain pulse generators is indicated in the following permanent conditions, when associated with symptoms including, but not limited to: syncope, presyncope, fatigue, disorientation or any combination of those symptoms. **Dual-Chamber Pacing (Models PM2134 and PM2136 only)** 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™ (Models PM2134 and PM2136 only)** is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications. For specific indications associated with individual modes, refer to the programmer's on-screen help.

Contraindications: **Implanted Cardioverter-Defibrillator (ICD).** Because Sustain pulse generators will be automatically programmed to a unipolar pulse configuration if the device initiates Backup VVI pacing, Sustain devices are contraindicated in patients with an implanted cardioverter-defibrillator. **AF Suppression (Models PM2134 and PM2136 only)** stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. **Dual-Chamber Pacing (Models PM2134 and PM2136 only)** 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.

For specific contraindications associated with individual modes, see the programmer's on-screen help.

Potential Adverse Events: 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 pulse generator because of programmer malfunction, infection, interruption of desired pulse generator 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 pacemaker function due to battery failure or component malfunction, pacemaker migration, pocket erosion, or hematoma, pectoral muscle stimulation, phrenic nerve or diaphragmatic stimulation.

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

Customer Support: 46-8-474-4756

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 registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All rights reserved.

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Product Specifications

PHYSICAL SPECIFICATIONS

Model	PM2134
Dimensions (mm)	44 x 52 x 6
Weight (g)	23,5
Volume (cc)	11 ¹
Connector	IS-1

PARAMETER SETTINGS

Rate/Timing

Atrial Absolute Refractory Period	60; 80; 100 -350 in steps of 25
Atrial Protection Interval (ms)	125 ²
Atrial Refractory (PVARP) (ms)	125-500 in steps of 25; 275
AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350; 200
Base Rate (bpm)	30 ³ ; 40-130 in steps of 5; 140-170 in steps of 10; 60
Far-Field Protection Interval (ms)	16 ²
Hysteresis Rate (min ⁻¹)	Off ; 30-130 in steps of 5; 140; 150 ⁴
Search Interval (min)	Off; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (min ⁻¹)	Off; 60; 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; 130
Mode	A00; AAI; AAT; OAO; VOO; VVI; VVT; VDD; OVO; D00; DVI; DDI; DDD ; ODO
Post Vent. Atrial Blanking (PVAB) (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 150 ; 155; 165; 170; 180; 185; 195; 200
Rate Responsive AV/PV Delay	Off ; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low ; Medium; High
Shortest PVARP/VREF	120-350 in steps of 10; 170
PV Delay (ms)	25; 30-200 in steps of 10; 225-325 in steps of 25; 150
Rest Rate (min ⁻¹)	Off ; 30-130 in steps of 5; 140; 150
Shortest AV/PV Delay (ms)	30-50 in steps of 5; 60-120 in steps of 10; 100
Ventricular Blanking (ms)	12-52 in steps of 4; 12
Ventricular Refractory (ms)	125-500 in steps of 25 ⁵ ; 250

Output/Sensing

A or V Pulse Amplitude (V)	0,0-4,0 in steps of 0,25; 4,5-7,5 in steps of 0,5; 2,5
A or V Pulse Width (ms)	0,05; 0,1-1,5 in steps of 0,1; 0,4
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 in steps of 0,1 ⁶ ; 0,5; 0,75-2,0 in steps of 0,25; 2,0-4,0 in steps of 0,5; 5,0 ⁷
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0 ²
Threshold Search Interval (hours)	8; 24
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5; 2,0 ⁷

AF Management

AF Suppression™ Algorithm	Off ; On
Lower Rate Overdrive (min ⁻¹)	10 ²
Upper Rate Overdrive (min ⁻¹)	5 ²
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12
Maximum AF Suppression Rate (min ⁻¹)	80-150 in steps of 5; 160-180 in steps of 10
Atrial Tachycardia Detection Rate (min ⁻¹)	110-150 in steps of 5; 160-200 in steps of 10; 225-300 in steps of 25; 180
Auto Mode Switch	Off; DDD to DDI; VDD to VVI; DDI
AMS Base Rate (min ⁻¹)	Base Rate +0 to Base Rate +35 in steps of 5; Base Rate +20

Stored Electrograms

Options

Sampling Options	Freeze ; Continuous
No. of Stored EGMs	1; 2; 4; 8; 12
Channel	Atrial; Ventricular; Dual ; Cross-Channel

Triggers

Advanced Hysteresis	On; Off
AMS Entry/AMS Exit	On; Off
AT/AF Detection	On; Off
Magnet Placement	On; Off
High Atrial Rate	Off ; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off ; 125; 150; 175; 200; 225; 250; 275; 300
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	On; Off
PVC Detection	On; Off
No. of Consecutive PVCs	2; 3; 4; 5

Other

A and V Lead Monitoring	Off ; Monitor; Auto Polarity Switch
A and V Low Impedance Limit (Ω)	200 ²
A and V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
Lead Type	Uncoded ; Unipolar; Bipolar Only; Unipolar/Bipolar
Magnet Response	Off ; Battery Test
Negative AV/PV Hysteresis Search (ms)	Off ; -10 to -110 in steps of 10
NIPS Options	
Stimulation Chamber	Atrial; Ventricular
Coupling Interval	100-800 in steps of 10 ⁸
S1 Count	1-25 in steps of 1
S1 ⁹ ; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Ventricular Support Rate (min ⁻¹)	Off; 30; 40; 45; 50; 55; 60; 65; 70; 75; 80; 85; 90; 95
Sinus Node Recovery Delay (sec)	1-5 in steps of 1
PMT Options	Off; 10 Beats > PMT; Auto Detect
PMT Detection Rate (min ⁻¹)	90-150 in steps of 5; 160-180 in steps of 10; Off ; 110
PVC Options	Off; A Pace on PVC ; +PVARP on PVC (VDD mode only)
Signal Amplitude Monitoring	
P-Wave Monitoring	Off; On
R-Wave Monitoring	Off; On
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

1. \pm 0,5 cc

2. This parameter is not programmable.

3. The actual pacing rate for the 30 bpm is 31 bpm.

4. The highest available setting for Hysteresis Rate will be 5 bpm 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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