Sustain™ XL DR

Dual-Chamber Rate-Responsive 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.
- 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.
- The system also includes the clinically proven Omnisense™ accelerometer sensor, featuring auto rest rate (based on activity rather than on preset clock settings) and auto rate response.

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
PM2136	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 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 (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. ***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 (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. 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.

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.

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Dual-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM2136**
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	AOO(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R); **DDD**(R); 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
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]; **0,5**
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]
Rate-Modulated Parameters	
Maximum Sensor Rate (min^{-1})	80-150 in steps of 5, 160-180 in steps of 10; **130**
Rate Responsive AV/PV 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	120-350 in steps of 10; **170**
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

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; DDDR to DDIR; DDD to DDI; VDDR to VVIR; VDD to VVI; DDDR to DDI; DDD to DDIR; VDDR to VVI; VDD to VVIR; **DDIR**
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. ± 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.

Customer Support: 46-8-474-4756

Item GMCRM874EN

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