Sustain™ XL SR

Single-Chamber Rate-Responsive Pacemaker

Product Highlights

- Device features small, physiologic shape and offers superior longevity (12,8 years) without compromising size.[1]
- Instant follow-up with automatic P- or R-wave, lead impedance measurements and ventricular threshold tests.
- 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% VVI 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
PM1136	42 x 52 x 6	23	10,4	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.

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).*** 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.

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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Single-Chamber Rate-Responsive Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM1136**
Dimensions (mm)	42 x 52 x 6
Weight (g)	23
Volume (cc)	10,4[1]
Connector	IS-1

PARAMETER	SETTINGS
Rate/Timing	
A or V Refractory (ms)	125-500 in steps of 25; **325**
Base Rate (bpm)	30[2]; 40-130 in steps of 5; 140-170 in steps of 10
Mode	A00(R); AAI(R); AAT(R); OAO; VOO(R); **VVI**(R); VVT(R); OVO
Hysteresis Rate (bpm)	**Off**; 30-130 in steps of 5; 140; 150[3]
Search Interval (bpm)	Off; 5; 10; 15; 30
Cycle Count	1-16 in steps of 1
Intervention Rate (bpm)	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
Rest Rate (bpm)	**Off**; 30-130 in steps of 5; 140; 150
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 Sensitivity (mV)	0,5-5,0 in steps of 0,5; 6-10 in steps of 1,0; 12,5[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)
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
Rate-Modulated Parameters	
Maximum Sensor Rate (bpm)	80-150 in steps of 5; 160-180 in steps of 10; **130**
Rate Responsive VREF	**Off**; Low; Medium; High
Shortest VREF	120-350 in steps of 10
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	
Sampling Options	**Freeze**; Continuous
No. of Stored EGMs	1; 2; 4; 8; 12
Channel	Atrial or Ventricular
Triggers	
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
Advanced Hysteresis	On; **Off**
Other	
Lead Monitoring	**Off**; Monitor; Auto Polarity Switch
A or V Low Impedance Limit (Ω)	200[5]
A or V High Impedance Limit (Ω)	750; 1000; 1250; 1500; 1750; 2000
A or V Signal Amplitude Monitoring	Off; **On**
Magnet Response	Off; **Battery Test**
Lead Type	**Uncoded**; Unipolar; Bipolar Only; Unipolar/Bipolar
NIPS Options	
Stimulation Chamber	Atrial or Ventricular
Coupling Interval (ms)	100-800 in steps of 10
S1 Count	1-25 in steps of 1
S1[6]; S2; S3 and S4 Cycle (ms)	100-800 in steps of 10
Sinus Node Recovery Delay (sec)	1-5 in steps of 1

1. ± 0,5 cc
2. The actual pacing rate for the 30 ppm is 31 ppm.
3. The highest available setting for Hysteresis Rate will be 5 ppm 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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Item GMCRM875EN

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