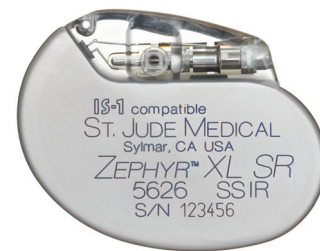


ZEPHYR™ XL SR

MODEL 5626

Single-Chamber Rate-Responsive
Pacemaker



42 x 52 x 6 mm

SPECIFICATIONS

Superior Longevity

The Zephyr™ XL SR pacemaker, model 5626, has superior longevity when compared volume-for-volume with any other pacemaker on the market. Extended longevity offers the benefit of fewer device replacements and reduced risk of complications associated with replacement surgery.

Save Valuable Clinic Time

The Merlin™ Patient Care System software summary screen allows clinical flexibility with multiple follow-up options. Upon interrogation, the Zephyr™ device displays the last measured sense and capture threshold results obtained automatically within the last 24 hours. The results are displayed with follow-up EGMs for quick verification of the test measurements. If the clinician chooses to perform the tests during an in-clinic visit, preset test values will facilitate prompt testing.

Maximize Patient Safety

Only the 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 backup safety pulse when noncapture is detected. This backup safety pulse is 5.0 V and may be programmed to either a bipolar or unipolar configuration. The Zephyr™ device also has a programmable polarity switch. When programmed On, the polarity switch is designed to automatically change the pacing and sensing polarity to unipolar for patient safety if the device detects an out-of-range measurement.

Optimize Therapy by Evaluating Key Events

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 device can be programmed to automatically record up to 12 separate stored EGMs when the device encounters one or more programmable triggers.

A Suite of Powerful Tools

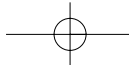
Once a day the pacemaker automatically measures the intrinsic P or R waves and displays the last test results in combination with a Weekly P- or R-Wave Trend. The device automatically measures the lead impedance in the chamber where pacing is programmed to occur. Upon interrogation the clinician will be alerted of any polarity switches. The Zephyr™ device displays a Weekly Lead Impedance Trend showing the current measurement, historical test results, pacing polarity and any polarity switches.

Increase Patient Comfort with a Physiologic-Based Rest Rate

Rest rate is designed to provide a more comfortable stimulation rate during sleep. The algorithm is physiologically based and is activated by patient inactivity. St. Jude Medical's device rest rate is not subject to changes in time zone, daylight savings time, or the patient's schedule.

Address Abrupt Rate Drops with Flexible Programming

Advanced Hysteresis includes a programmable search function with Search Interval and Cycle Count options that maximize opportunities for the patient's own rhythm to prevail, which provides optimal patient comfort and cardiac hemodynamics. Advanced Hysteresis Response also offers an intervention function designed to address abrupt drops in the patient's rhythm by providing short-term pacing at a rate higher than the programmed Base Rate.



ZEPHYR™ XL SR Model 5626

PHYSICAL CHARACTERISTICS

Dimensions (mm)	42 x 52 x 6
Weight (g)	23
Volume (cc)	10,4*
Connector	3,2mm (IS-1 or VS•1)

PARAMETERS

Rate/Timing

A or V Refractory (ms)	125-500 in steps of 25; 325
Base Rate (min ⁻¹)	30**; 40-130 in steps of 5; 140-170 in steps of 10; 60
Mode	A00(R); AA1(R); AAT(R); OAO; V00(R); V11(R) ; VVT(R)
Hysteresis Rate (min ⁻¹)	Off ; 30-130 in steps of 5; 140; 150***
Search Interval (min ⁻¹)	Off ; 5; 10; 15; 30
Cycle Count	1-16 by 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 by 1
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min ⁻¹)	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; 2,5
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
Back-up Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5,0 ^Δ
Search Interval (hours)	8; 24

Rate-Modulated

Maximum Sensor Rate (min ⁻¹)	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; 170
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 ^Δ
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	100-800 in steps of 10
S1 Count	1-25 in steps of 1
S1*, S2, S3 and S4 Cycle (ms)	100-800 in steps of 10
Sinus Node Recovery Delay (sec)	1-5 in steps of 1

Options

* ± 0,5 cc

** The actual pacing rate for the 30 ppm is 31 ppm.

*** The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.

‡ Sensitivity is with respect to a 20 ms haversine test signal.

¥ S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

Δ This parameter is not programmable.

§ Accepts all IS-1, VS•1, and 3,2 mm leads.



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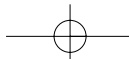
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Consult the User's Manual and the latest Reference Manual for information on indications, contraindications, specifications, warnings and precautions.

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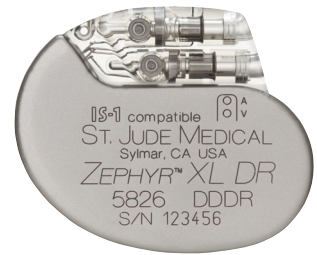
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ZEPHYR™ XL DR

MODEL 5826

Dual-Chamber Rate-Responsive Pacemaker



44 x 52 x 6 mm

SPECIFICATIONS

Optimize AV Delays with the Touch of a Button

Clinically proven to correlate with echo optimization and available on dual-chamber Zephyr™ devices, the QuickOpt™ feature optimizes paced and sensed AV delays.¹ In about a minute, QuickOpt Timing Cycle Optimization electrically characterizes the conduction properties of the heart and uses an exclusive formula to calculate optimal timing cycles. This efficient and effective approach allows for regular timing cycle optimization and improved therapy for more patients.

Save Valuable Clinic Time with a Suite of Powerful Tools

The Zephyr™ pacemaker and Merlin™ Patient Care System summary screen allow clinical flexibility with multiple follow-up options:

Automatic Daily Measurements, Follow-Up EGM and Trends

Upon interrogation, the Zephyr™ device displays the last automatically measured capture threshold results from the atrium and ventricle. In addition, the pacemaker automatically measures intrinsic P-wave 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 of the test results.

Optimized in Clinical Testing

If the clinician chooses to perform tests during an in-clinic visit, preset test values will facilitate prompt testing.

Lead Impedance Trend and Polarity Switch

The Zephyr™ device features a Weekly Lead Impedance Trend that displays the current measurement, historical test results, pacing polarity and any polarity switches.

Maximize Patient Safety

Only the 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 back-up safety pulse when noncapture is detected. This backup safety pulse is 5.0 V and may be programmed to either a bipolar or unipolar configuration. The ACap™ Confirm feature periodically completes a threshold search and adjusts the pulse amplitude accordingly in the atrium. ACap™ Confirm/AutoCapture™ Pacing System technology provides the clinician with a separate Weekly Threshold Trend to monitor atrial and ventricular thresholds. The Zephyr™ device also has a programmable polarity switch.

When programmed On, the polarity switch is designed to automatically change the pacing and sensing polarity to unipolar for patient safety if the device detects an out-of-range lead impedance measurement.

Reduce Ventricular Pacing

In order to reduce ventricular pacing, the Ventricular Intrinsic Preference (VIP™) feature gives clinicians the ability to program not only the value to increase the sensed and paced AV delay, but also the search interval and the number of cycles to maintain the extended AV delay prior to returning to the programmed AV delay. Consecutive spontaneous conduction can also activate the VIP feature. This flexibility allows the patient's intrinsic activity to be sensed the majority of time, and is designed to reduce potential adverse effects on the heart.

Optimize Therapy by Evaluating Key Events

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 device can be programmed to automatically record up to 12 separate stored EGMs when the device encounters one or more of the nine programmable trigger options.

Maximize Flexibility in Managing AF

Flexible approaches to a very difficult-to-manage disease can be the key to patient success. The Zephyr™ device offers multiple algorithms and diagnostics to assist physicians in therapy decisions:

AF Suppression™ Algorithm, Histogram and Events Counter

The AF Suppression™ algorithm is clinically proven to suppress symptomatic episodes of paroxysmal and persistent AF by promoting atrial-based pacing at patient-tailored rates. The AF Suppression™ histogram provides a graphical representation of the rate distribution of all atrial paced and sensed events that occur while the AF Suppression™ algorithm is programmed On.

AT/AF Diagnostic Suite

Designed to give detailed historical data, the AT/AF diagnostic suite allows the physician to identify and evaluate therapy for improved patient management. The burden trend, stored EGMs, histogram and episode log combine to offer a comprehensive diagnostic suite.

Auto Mode Switch Algorithm and Diagnostic Suite

The Zephyr™ device offers a separate Ventricular Rate Histogram during AMS, which is compiled only from ventricular events that occurred while the device was in mode switch. Auto Mode Switch log, histogram, stored EGMs and programmable base rate during AMS offer a multi-layer approach to atrial arrhythmia management.

¹Porterfield, et al. "Device based intracardiac delay optimization vs. echo in ICD patients (Acute IEGM AV/PV and VV Study)" Europace Vol 8 Supp 1 July 2006 [abstract #6178].

PHYSICAL CHARACTERISTICS

Dimensions (mm)	44 x 52 x 6
Weight (g)	23.5
Volume (cc)	11*
Connector	IS-1 compatible [§]

PARAMETERS

Rate/Timing

Atrial Absolute Refractory Period	60; 80; 100-350 in steps of 25; 100
Atrial Protection Interval (ms)	125 ^Δ
Paced AV Delay (ms)	25; 30-200 in steps of 10; 225-300 in steps of 25; 350; 200
Base Rate (min ⁻¹)	30**; 40-130 in steps of 5; 140-170 in steps of 10; 60
Far-Field Protection Interval (ms)	16 ^Δ
Hysteresis Rate (min ⁻¹)	Off ; 30**-130 in steps of 5; 140; 150***
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 Ventricular Atrial Blanking (ms)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 155; 165; 170; 180; 185; 195; 200; 150
PVARP (ms)	125-500 in steps of 25; 275
Sensed AV 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 Delay (ms)	30-50 in steps of 5; 60-120 in steps of 10; 100
Ventricular Blanking (ms)	Auto, 12-52 in steps of 4; 12
Ventricular Refractory (ms)	125-500 in steps of 25; 200

Output/Sensing

ACap™ Confirm	On; Off ; Monitor
Primary Pulse Configuration	Bipolar ^Δ
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5.0 ^Δ
Search Interval (hours)	8, 24
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; 0.5 by 0.1; 0.75-2.0 in steps of 0.25; 2.0-4.0 ; 0.5 in steps of 0.5; 5.0 ^Δ
Ventricular AutoCapture™ Pacing System	On; Off
Primary Pulse Configuration	Unipolar; Bipolar
Backup Pulse Configuration	Unipolar; Bipolar
Backup Pulse Amplitude (V)	5.0 ^Δ
Search Interval (hours)	8, 24
AutoCapture Paced/Sensed AV Delay (ms)	50/25; 100/70; 120/100
Ventricular Sensitivity (mV)	0.5-5.0 in steps of 0.5; 6-10 in steps of 1.0; 12.5; 2.0

Rate-Modulated Parameters

Maximum Sensor Rate (min ⁻¹)	80-150 in steps of 5; 160-180 in steps of 10; 130
Rate Responsive AV 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 ^Δ
Upper Rate Overdrive (min ⁻¹)	5 ^Δ
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery (ms)	8; 12 ^Δ
Maximum AF Suppression Rate (min ⁻¹)	80-150 in steps of 5, 160-180 in steps of 10; 180
Atrial Tachycardia Detection Rate (min ⁻¹)	110-150 in steps of 5; 160-200 in steps of 10; 225-300 in steps of 25
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; 80

Stored Electrograms

Options	
Sampling Options	Freeze ; Continuous
No. of Stored EGMs	1; 2; 8; 12; 4
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 ^Δ
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 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 [§]
S1 Count	1-25 in steps of 1
S1*, 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; 2; 3; 4; 5
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; 110 min
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

* = 0.5 cc
 ** The actual pacing rate for the 30 ppm is 31 ppm.
 *** The highest available setting for Hysteresis Rate will be 5 ppm below the programmed Base Rate.
 † In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
 ‡ Sensitivity is with respect to a 20 ms haversine test signal.
 v Values 0.1-0.4 not available in a Unipolar Sense Configuration.
 ◇ During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AWPV delay.
 ¥ S1 Burst Cycle is applied at the preprogrammed S1 cycle length.
 Δ This parameter is not programmable.
 § Accepts all IS-1, V5*1, and 3,2 mm leads.



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