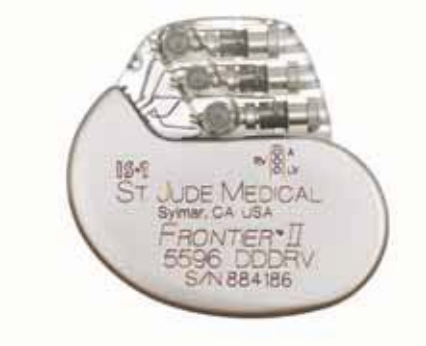
Frontier™ II

Cardiac Resynchronisation Therapy Pacemaker



Product Highlights

- QuickOpt™ Timing Cycle Optimisation provides quick and effective AF optimization at the touch of a button
- Continuous Biventricular Pacing
  - AF Suppression™ algorithm helps control atrial rhythm and maintains AV synchrony
  - Negative AV/PV Hysteresis is designed to ensure biventricular pacing by temporarily shortening the AV/PV delay upon sensing ventricular activity
  - DDT Biventricular Trigger Mode provides triggered pacing in the presence of intrinsic R-waves or PVCs to help promote biventricular pacing
  - Mode Switch Base Rate helps manage ventricular activity during AF episodes
- Exclusive AF Suppression™ Algorithm is clinically proven to reduce AF burden[1] and improve quality of life[2,3]
- AT/AF Burden Trend provides weekly count of the percent of time in AF and identifies long-term trends for device or drug management

1. Carlson M et al. A new pacemaker algorithm for the treatment of atrial fibrillation, results of the Atrial Dynamic Overdrive Pacing Trial (ADOPT). *JACC* 2003; 42:627-33.
2. Attuel P et al and the INOVA Study Group. Quality of life in permanently paced AF patients. The INOVA Study. *Europace* 2003; Abstract A42-6.
3. Davy et al and the INOVA Study Group. Permanent atrial overdrive tolerance in patients with symptomatic paroxysmal AF. The INOVA Study *Europace* 2003; Abstract A42-3.

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
5596	49 x 52 x 6	25	11,5(±0,5)	IS-1

Indications: Implantation of Frontier II device is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure, the reduction of the symptoms of moderate to severe heart failure (NYHA Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration, implantation of Accent™, Accent RF, Anthem, and Anthem RF devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, 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*** 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 patients 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.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface, 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, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax, endocarditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis.

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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Cardiac Resynchronisation Therapy Pacemaker

PHYSICAL SPECIFICATIONS	
Model Number	**5596**
Dimensions (mm)	49 x 52 x 6
Weight (g)	25
Volume (cm3)◊◊	11.5
Connector	IS-1

PARAMETER	SETTINGS
Resynchronization Therapy	
QuickOpt™ Timing Cycle Optimization	Sensed/paced AV delay, Interventricular Pace delay
RV and LV Pulse Width (ms)	0,05, 0,1-1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,0-4,0 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
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***, RV, LV
Interventricular Pace Delay (ms)	20-80 in steps of 5
Ventricular Sensitivity (mV)	0,5-5,0 in steps of 0,5, 6-10 in steps of 1,0, 12,5
Negative AV/PV Hysteresis Search (ms)	Off, –10 to –110 in steps of 10
Shortest AV/PV Delay (ms)	30–50 in steps of 5, 60–120 in steps of 10
Atrial Output/Sensing	
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‡v (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
Rate/Timing	
Mode	AOO(R), AAI(R), AAT(R), OAO, VOO(R), VVI(R), VVT(R), OVO, DOO(R), DVI(R), DDI(R), DDT(R), DDD(R), ODO
DDT Trigger$^{\Delta}$	R-wave
DDT Timing$^{\Delta}$	DDD, DDI
Base Rate (min^{-1})	30*, 40–130 in steps of 5, 140–170 in steps of 10
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
Intervention Rate (min^{-1})	Off, 60, 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, 30–130 in steps of 5, 140, 150
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5, 140–180 in steps of 10
AV Delay (ms)	25, 30–200 in steps of 10, 225–300 in steps of 25, 350
PV Delay (ms)	25, 30-200 in steps of 10, 225–325 in steps of 25
Ventricular Refractory† (ms)	125–500 in steps of 25
Atrial Refractory (PVARP) (ms)	125–500 in steps of 25
Ventricular Absolute Refractory Period (ms)	60-240 in steps of 10
Ventricular Blanking (ms)	12-52 in steps of 4
Atrial Absolute Refractory Period (ms)	60, 80, 100–350 in steps of 25
Atrial Protection Interval (ms)$^{\Delta}$	125
Far Field Protection Interval (ms)$^{\Delta}$	16
AF Management	
AF Suppression™	Off, On
Lower Rate Overdrive (min^{-1})$^{\Delta}$	10
Upper Rate Overdrive (min^{-1})$^{\Delta}$	5
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery$^{\Delta}$ (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})	Base Rate +0 to Base Rate +35 in steps of 5
Rate-Modulated	
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
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
Stored Electrograms	
Options	
Sampling Options	Freeze, Continuous
No. of Stored EGMs	1, 2, 4, 8, 12
Channel	Single, Dual
Triggers	
Magnet Placement	On, Off
High Atrial Rate (ms)	Off, 125-300 in steps of 25
No. of Consecutive Cycles	2, 3, 4, 5, 10, 15, 20
AMS Entry/Exit	On, Off
High Ventricular Rate (ms)	Off, 125-300 in steps of 25
PVC	On, Off
No. of Consecutive PVCs	2, 3, 4, 5
PMT Detection	On, Off
AT/AF Detection	On, Off
Advanced Hysteresis	On, Off
Other	
Magnet Response	Off, Battery Test
AutoIntrinsic Conduction Search (ms)	Off, +10 to +120 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
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
Ventricular Safety Standby	Off, On
PVC Options	Off, +PVARP on PVC
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
Lead Type	Uncoded, Unipolar, Unipolar/Bipolar
NIPS Options	
Stimulation Chamber	Atrial, Right Ventricular
Coupling Interval◊ (ms)	200-800 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
Right Venticular Support Rate (min^{-1})	Off, 30, 40-95 in steps of 5
Sinus Node Recovery Delay (s)	1-5 in steps of 1

◊◊ ± 0,5 cm^3
* The actual pacing rate for the 30 min^{-1} setting is 31 min^{-1}.
** The highest available setting for Hysteresis Rate is 5 min^{-1} below the programmed Base Rate.
*** LV first with 10 ms interventricular delay.
† 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 AV/PV Delay.
¥ S1 Burst Cycle is applied at the preprogrammed S1 cycle length.
Δ This parameter is not programmable.

Customer Support: 46-8-474-4756

Item GMCRM889EN

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