

Frontier™ II

MODEL 5596 Biventricular Cardiac Resynchronisation Device



49 x 52 x 6 mm

SPECIFICATIONS

Advanced Biventricular Pacing

- **Programmable interventricular pace delay (V-V timing)** Independent timing of right and left ventricular outputs helps ensure appropriate therapy. Either ventricle can be paced first and the delay for the second ventricle can be customized in order to achieve optimal patient hemodynamics.
- **Independently programmable RV and LV amplitudes, pulse widths and pulse configurations** Patients often have different energy requirements for each chamber and programming one output to meet the needs of both chambers may be suboptimal. The Frontier II device allows independent programming of RV and LV outputs to maintain capture of both ventricles.
- **Programmable Ventricular Pacing Configuration** Pacing can be delivered RV only, LV only or biventricular therapy.
- **Triggered Modes** DDT mode ensures continuous resynchronisation therapy delivery. Using triggered modes helps ensure a high percentage of pacing and consistent resynchronisation for optimal patient hemodynamics. DDT mode is supported for both DDD and DDI timing. For optimal pacing even during atrial arrhythmias.
- **Negative AV/PV Hysteresis** This dynamic, self regulating algorithm automatically shortens the programmed AV/PV delay when a sensed ventricular event occurs during the AV/PV delay interval. This algorithm ensures a high percentage of ventricular stimulation which is important for the maintenance of resynchronisation.
- **Auto Rest Rate** Automatically adjusts the pacing rate according to periods of patient inactivity, unlike other devices that depend on pre-programmed clock settings. Auto Rest Rate reduces the pacing rate below the Base Rate when the device senses that the patient has been inactive for more than 15-20 minutes. This feature can be used to provide a more comfortable and physiologic stimulation rate during rest or inactivity.

AF Management

The unique AF Suppression™ algorithm dynamically adjusts the pacing rate so the heart is paced slightly above the native intrinsic rate whether the patient is active or at rest. The operation of this algorithm can be assessed by the AF Suppression Histogram, which provides a graph of the rate distribution of atrial paced events associated with the algorithm, as well as the overall percentage of overdrive pacing.

Advanced AT/AF Diagnostics

- **AT/AF Burden Trend** Provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 28 weeks. This diagnostic view can help identify long term trends regarding the time or episodes in AF and may facilitate device/drug management according to the patient's response.

- **AT/AF Episodes Log** The AT/AF episode log lists up to 32 recorded AT/AF episodes in the order of occurrence with each episode date and time, duration and maximum rate. The first 16 episodes are frozen and the last 16 episodes are continuous. Additionally the total number of AT/AF episodes and percent of time in AT/AF are recorded. This specific episode data helps provide insight into the patient's arrhythmias, as well as showing whether the episodes are occurring more frequently or lasting longer over time. This information is useful in determining whether a revision in therapy is warranted or if there may be a change in the pathology responsible for the AF.
- **AMS Episode Log** AMS prevents the pacemaker from tracking atrial tachyarrhythmias which are common in heart failure patients. The AMS log lists up to 32 recorded AMS episodes, (first 16 frozen and the last 16 continuous) recording each episode's date and time, duration, and maximum rate achieved. The AMS log will display an ECG symbol for an episode with a stored EGM.

Ventricular Rate Control During AT/AF Episodes

The programmable Auto Mode Switch Base Rate allows clinicians to program a higher ventricular base rate that will be in effect for the duration of the mode switch episode. When AF patients experience a loss of atrial output, this can result in impaired hemodynamics, which can be detrimental particularly in a heart failure patient who has impaired ventricular function. The elevated base rate can help compensate for the loss of atrial output in addition to preventing an irregular ventricular response that may be uncomfortable for the patient.

Enhanced Atrial Arrhythmia Detection

Far Field Protection and Atrial Absolute Refractory Period are designed to provide for enhanced AT/AF diagnostics and allow for more accurate mode switch events. The Atrial Protection Interval also provides enhanced protection against competitive atrial pacing.

Stored Electrograms

The Frontier II device records up to 120 seconds of electrocardiograms to help identify key intrinsic and pacemaker-related events and to simplify the diagnosis of complex ECG rhythms associated with heart failure patients. Stored Electrograms record real-time EGMs as well as the associated event markers that precede and follow a specific triggered event. EGMs can be stored when the device encounters one or more of the following triggers:

- Magnet Placement
- AMS Entry
- AMS Exit
- AT/AF Detection
- PMT Termination
- High Atrial Rate
- PVC
- High Ventricular Rate

Frontier™ II Biventricular Cardiac Resynchronisation Device



PHYSICAL CHARACTERISTICS

Dimensions (mm)	49 x 52 x 6
Weight (g)	25
Volume (cm ³) [∅]	11,5
Connector	IS-1

RESYNCHRONISATION THERAPY

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** (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	A00(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 ^A	R-wave
DDT Timing ^A	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) ^A	125
Far Field Protection Interval (ms) ^A	16

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

AF Management

AF Suppression™	Off; On
Lower Rate Overdrive (min ⁻¹) ^A	10
Upper Rate Overdrive (min ⁻¹) ^A	5
No. of Overdrive Pacing Cycles	15-40 in steps of 5
Rate Recovery ^A (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

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 ₀ (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 Ventricular 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.
^	This parameter is not programmable.



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Consult the User's Manual for information on indications, contraindications, warnings and precautions. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical, Inc. or one of its subsidiaries.

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