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Figure 1. Frontier II Model 5596 Cardiac Resynchronization Device

Description

The Frontier™ II Model 5596, and Model 55861 are multi-site, implantable cardiac resynchronization devices with one atrial and two independent ventricular ports for those patients who can benefit from biventricular sensing and pacing.

Through its multi-chamber triggering mode (DDT) and its Negative AV/PV Hysteresis feature, the Frontier II device also enables continual, synchronous, ventricular pacing. In addition, the device is equipped with a number of programmable blanking periods that can exclude extraneous or secondary far-field sensed events from the sensing amplifier.

The Frontier II device contains independent right- and left-ventricular pulse configurations, a number of automatic rate-adjusting algorithms, patient safety features, and an extensive offering of diagnostic tools and tests, including:

- Programmable Interventricular Pace Delay2 and First Chamber Paced2
- AF Suppression™ algorithm, a unique automatically adjusting pacing algorithm intended to suppress atrial arrhythmias, Advanced atrial arrhythmia diagnostics, including AT/AF Burden Trend and Event Counts, AT/AF Episode Histogram and Log, and AF Suppression Histogram
- Stored Electrocardiograms, a record of real-time EGM waveform and Event Marker data of events preceding and following a user-defined trigger
- Rate Responsive Refractory Periods that adjust automatically according to the pacing rate
- An Advanced Hysteresis Response that provides a means to periodically search for intrinsic rate and to respond to a sudden drop in the intrinsic rate with user-programmable Intervention Rate and Duration
- Atrial Protection Interval, designed to minimize atrial competitive pacing
- Far-field Protection Interval, designed to reduce the incidence of far-field signal sensing in the atrium
- The Omnisense™ accelerometer activity sensor which provides rate-modulated pacing.

In addition, with the Frontier II device, the Model 3510 Programming System and Merlin™ Patient Care System also offer:

- On-screen Reference Manual
- Removable media database interface
- Continuous real-time printing of ECG, EGM, and Markers.

A single setscrew for each lead secures the pin within the connector. The device header accepts unipolar or bipolar IS-1 short terminal pin leads.

The Frontier II device can be programmed with the Model 3510 Programming System with Model 3307 software version 4.8 or higher or with the Merlin PCS.

For detailed information on programming, testing, and displaying diagnostic data, refer to the Bradycardia Devices Reference Manual, select the HELP button on the Model 3510 programmer, or select the “?” button on the Merlin PCS.

Indications and Usage

Implantation of the Frontier™ II device is indicated for patients who:

- Would benefit from resynchronization of the right and left ventricles, such as patients with congestive heart failure
- Have one or more conventional indications for the implantation of a pacemaker

Additionally, implantation of the Frontier II device is indicated in the following permanent conditions, when associated with symptoms including, but not limited to:

- Syncope
- Presyncope
- Fatigue

1. When Model 5586 is interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin™ PCS Model 3650 with Model 3330 version 6.1.1 software or higher, parameters, settings and functionality are the same as Model 5596, except as noted.

2. Available in Model 5596 and in Model 5586 when interrogated with the Model 3510 Programming System with Model 3077 version 6.4.1 software or higher, or with the Merlin™ PCS Model 3850 with Model 3330 version 6.1.1 software or higher.
• Disorientation
• Or any combination of those symptoms.

**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.

**AF Suppression Pacing** is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above indication and sinus node dysfunction.

**Atrial Pacing** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems, as well as for patients who would benefit from a high percentage of automatically adjusting, high-rate atrial pacing.

**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

**Rate-Modulated Pacing** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased pacing rates concurrent with physical activity.

**CONTRAINDICATIONS**

Implantation of the Frontier™ II device is contraindicated in patients who:
• Have been implanted with an implantable cardioverter-defibrillator (ICD).
• Have chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate.

**Rate-Modulated Pacing** (Sensor On) 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 pacing rate tolerated by the patient.

**AF Suppression Pacing** is not recommended in patients who cannot tolerate high atrial-rate pacing.

**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.

For specific indications and contraindications associated with individual modes, refer to Operating Modes on page 7.

**Warnings**

To prevent permanent damage to the device and tissue damage at the electrode/tissue interface:
• **Electrosurgery.** Do not use electrosurgical devices in the vicinity of an implanted device. If electrocautery is necessary, use a bipolar cautery or place the indifferent electrode as far from the device as possible.
• **Lithotripsy.** Do not focus a lithotripsy beam within 16 centimeters of the device. Program the device to Sensor Off prior to lithotripsy to prevent inappropriate increases in the pacing rate. A thorough assessment of device’s function with special attention to the sensor should be performed following exposure to lithotripsy.
• **Therapeutic Radiation.** Do not use ionizing radiation in the vicinity of an implanted device. Radiation therapy may damage the electronic circuitry of the device.
• **Ultrasound Treatment.** Do not use therapeutic ultrasound within 16 centimeters of the device.
• **Ventricular Sensing.** Ventricular Sensitivity should be programmed to the highest setting (lowest sensitivity) that will provide ventricular sensing with adequate sensing margin. Left ventricular lead dislodgement, to a position near the atria, can result in atrial oversensing and ventricular inhibition.

Perform a thorough assessment of the device function following exposure to any of the above.

**Backup VVI Operation.** In rare instances, the device may revert to Backup VVI operation at the programmed settings listed in Table 1. These values are not programmable.

---

3. Chronotropic incompetence has not been rigorously defined. A conservative approach, supported by the literature, defines chronotropic incompetence as the failure to achieve an intrinsic heart rate of 75% of the age-predicted maximum heart rate or 120 min⁻¹ during exercise testing, whichever is less, where the age-predicted heart rate is calculated as 197—(0.56 x age). Gwinn N, Leman R, Kratz J, et al. Chronotropic incompetence: A common and progressive finding in pacemaker patients. *American Heart Journal* 1992; 128:1216-19.
When the device has reverted to Backup VVI operation, the programmer will display a pop-up message indicating that the device is operating at the Backup VVI values. Press [Continue] and follow the on-screen instructions.

Under most conditions, the previously programmed settings can be restored. The programmer will execute a short routine (approximately five minutes) to restore the previously programmed settings. When the routine is complete, a Device Status Report will be generated. This report should be returned to the St. Jude Medical location indicated on the report. Normal follow-up testing should be performed and the restored parameter settings should be reviewed.

**Elective Replacement Indicator (ERI).** At ERI, the nominal life of the device is three months. When the device exhibits signs of ERI, described on page 19, it should be replaced expeditiously.

**Patient follow-up visits should be scheduled at an appropriate frequency so that ERI can be detected well before End-of-Life (EOL).**

### Precautions

- For single use only.

### Sterilization

- The package contents have been sterilized with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.

### Storage and Handling

- **Mechanical Shock.** St. Jude Medical™ device are ruggedly constructed. However, if you suspect the device has been damaged, do not implant it; return it to St. Jude Medical.
- **Temperature.** Do not subject the device to temperatures above 50°C (122°F) or below -5°C (23°F). Exposure to temperatures below 0°C may cause false ERI indications. Following exposure to extreme temperatures, warm the device to room temperature. If ERI indications are still present, return the device to St. Jude Medical.
- **Incineration.** Do not incinerate the device.

### Preparation for Implantation

- **Package Label.** Before opening the sterile package, carefully read the label and verify that the package contains the desired device.
- **Verifying Operation.** Before opening the sterile package, verify that the device is operating properly by interrogating it in the package. Remove the magnet and position the Model 3510 programmer or Merlin™ PCS telemetry wand over the package and select “Interrogate.” Then, select the “Meas. Data/Diagnostics” tab. The unit’s Measured Data should indicate normal voltage and battery status, and the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 8 on page 20.

---

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode</td>
<td>VVI</td>
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<tr>
<td>Base Rate</td>
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<tr>
<td>Ventricular Pacing Chamber</td>
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</tr>
<tr>
<td>RV Pacing Configuration</td>
<td>Unchanged</td>
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<tr>
<td>Sense Configuration</td>
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<tr>
<td>Pulse Amplitude</td>
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</tr>
<tr>
<td>Pulse Width</td>
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</tr>
<tr>
<td>Refractory Period</td>
<td>335 ms</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>2.0 mV</td>
</tr>
</tbody>
</table>

**Table 1. Backup VVI Settings**

An RV lead must be used with the Frontier II device. Back-Up VVI pacing is delivered to the right ventricle only.

When the device has reverted to Backup VVI operation, the programmer will display a pop-up message indicating that the device is operating at the Backup VVI values. Press [Continue] and follow the on-screen instructions.

Under most conditions, the previously programmed settings can be restored. The programmer will execute a short routine (approximately five minutes) to restore the previously programmed settings. When the routine is complete, a Device Status Report will be generated. This report should be returned to the St. Jude Medical location indicated on the report. Normal follow-up testing should be performed and the restored parameter settings should be reviewed.

**Elective Replacement Indicator (ERI).** At ERI, the nominal life of the device is three months. When the device exhibits signs of ERI, described on page 19, it should be replaced expeditiously.

**Patient follow-up visits should be scheduled at an appropriate frequency so that ERI can be detected well before End-of-Life (EOL).**

### Precautions

- For single use only.

### Sterilization

- The package contents have been sterilized with ethylene oxide before shipment. This device is for single use only and is not intended to be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.

### Storage and Handling

- **Mechanical Shock.** St. Jude Medical™ device are ruggedly constructed. However, if you suspect the device has been damaged, do not implant it; return it to St. Jude Medical.
- **Temperature.** Do not subject the device to temperatures above 50°C (122°F) or below -5°C (23°F). Exposure to temperatures below 0°C may cause false ERI indications. Following exposure to extreme temperatures, warm the device to room temperature. If ERI indications are still present, return the device to St. Jude Medical.
- **Incineration.** Do not incinerate the device.

### Preparation for Implantation

- **Package Label.** Before opening the sterile package, carefully read the label and verify that the package contains the desired device.
- **Verifying Operation.** Before opening the sterile package, verify that the device is operating properly by interrogating it in the package. Remove the magnet and position the Model 3510 programmer or Merlin™ PCS telemetry wand over the package and select “Interrogate.” Then, select the “Meas. Data/Diagnostics” tab. The unit’s Measured Data should indicate normal voltage and battery status, and the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 8 on page 20.
• **Package Integrity.** Ensure that the package has not been opened or in any way compromised. If damage is suspected, return it to the manufacturer.

• **“Use Before” Date.** Do not implant the device after the “use before” date printed on the label.

• **Ventricular Leads with Polished Platinum Tip Electrodes.** Pairing a ventricular lead with a polished platinum tip electrode with a ventricular lead with a tip electrode of a different material may create a source impedance mismatch that could adversely affect sensing.

• **Opening the Package.** If interrogation of the device in its sterile packaging indicates normal functioning, remove it from the package. The package’s outer tray can be opened in nonsterile surroundings. However, when opening the inner tray, complete sterile technique must be observed (Figure 2).

Figure 2. Opening the Sterile Package

**Pre-Implant Testing**

• **Pacing System Analyzer.** Before implantation, the clinician may wish to test the device using a compatible pacing system analyzer (PSA) with calibrated sensitivity and output settings. When the probe is attached to the device’s connector, the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 8 on page 20.

• **Adaptor Probes.** Use only IS-1 PSA cable adaptor probes when testing the device. Other probes may damage the connector.

• **Compatible Leads.** Use only St. Jude Medical™ leads as the left ventricular lead in the Frontier™ II device. The device header accepts unipolar or bipolar IS-1 short terminal pin leads. Prior to implantation, make sure the leads fit easily and snugly into the device header.

• **Capture/Sensing Thresholds.** Capture and sensing thresholds should be determined with a pacing system analyzer (PSA) before implanting the device. Connect the negative PSA terminal to the portion of the lead terminal pin corresponding to the tip electrode. The positive terminal should be connected to the ring electrode portion of the lead pin for bipolar leads or to an indifferent electrode. For more information on conducting capture and sensing threshold tests, please consult the PSA technical manual.

• **Establishing Baseline Capture/Sensing Thresholds.** After the leads have been implanted and before they are connected to the device, establish and document the baseline morphology for capture and sensing thresholds for each lead using a suitable recording system, such as a 12-lead ECG or Intracardiac Electrogram (IEGM).

**Implantation**

• **Case Markings.** Examine the markings on the device case and verify proper atrial, left and right ventricular connection.

• **Setscrew.** Exercise caution when turning the setscrew, which may be backed out of the connector if turned counter-clockwise for more than two rotations.

• **RV Lead.** An RV lead must be used with the Frontier II device. Back-Up VVI pacing is delivered to the right ventricle only.

**Programming**

• **Programmer.** The Frontier™ II device can be interrogated and programmed with the Model 3510 programmer® with Model 3307 software version 4.8 or higher or with the Merlin™ PCS. For a list of programmable parameters and their programmable values, see Table 9 on page 22.

• **Setting Lead Type.** When the user interrogates the device for the first time, the programmer will prompt the user to set the Lead Type. The right and left ventricular lead types are independently set. Because some parameters are determined by the Lead Type (for example, Pulse Configuration), the user should set this parameter when the device is implanted. See Ventricular Lead Selection on page 15.

• **Lead Impedance Values.** Independent lead impedance values are displayed for the RV and LV leads.

4. The Frontier II device can not be used with the Model 3500 programmer.
• **Ventricular Pulse Amplitudes and Pulse Widths.** The right and left ventricular pulse amplitudes and pulse widths are independently programmable. The pulse amplitude should be evaluated in each chamber accordingly. Typically, capture thresholds are higher in the left ventricle.

• **Follow-up Capture Threshold Measurements.** The RV and LV capture threshold measurements are evaluated independently. During an RV or LV capture test, the clinician may be able to determine when capture is occurring by noting changes in the ECG morphology. Capture tests are not performed in triggered ventricular pacing modes. Upon initiation, the pacing mode is temporarily programmed to the corresponding inhibited mode. See the Bradycardia Devices Reference Manual, select the HELP button on the Model 3510 Programmer for more information, or select the “?” button on the Merlin PCS.

• **Emergency VVI.** When programming the device to Emergency VVI settings, press the programmer’s Emergency VVI button only once. Settings for Emergency VVI can be found in the Bradycardia Devices Reference Manual, by selecting the HELP button on the Model 3510 programmer, or by selecting the “?” button on the Merlin PCS.

• **AOO(R), VOO(R), and DOO(R) Modes** are primarily intended for temporary diagnostic use. Long-term use may result in competitive pacing, inducing potentially dangerous arrhythmias.

• **OVO and OAO Modes** are not recommended for patients who would be adversely affected by even a short cessation of pacing.

• **Noninvasive EP Testing and NIPS.** Atrial or ventricular tachycardia or fibrillation may occur during noninvasive EP testing and Noninvasive Pacing Stimulation (NIPS). Therefore, (1) closely monitor the patient, and (2) have emergency equipment for cardioversion/defibrillation readily available while conducting EP testing or NIPS.

• **High-Output Settings.** Programming high-output settings with a high Base Rate may shorten the time to ERI.

• **Runaway Protection.** Hardware circuitry in the device prevents the device from pacing at rates higher than 190 min⁻¹ (± 10 min⁻¹). When the device is pacing in a biventricular configuration, the device software provides the runaway protection.

• **Sensing Configuration.** Sensing tests should be performed whenever changes are made to the sensing configuration.

• **Sensitivity Settings.** Careful consideration should be given to patient exposure to electromagnetic interference if programming sensitivity greater than 0.3 mV with a bipolar sense configuration setting and 2.0 mV with a unipolar sense configuration setting.

**Environmental and Medical Therapy Hazards**

St. Jude Medical™ devices are equipped with special shielding and filters which significantly reduce the adverse effects of electromagnetic interference (EMI) on the operation of the device.

Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields. If the device inhibits or reverts to asynchronous operation while in the presence of electromagnetic interference (EMI), the patient should move away from the EMI source or turn the source off.

Advise patients to seek medical guidance before entering environments which could adversely affect the operation of the device, including areas protected by a warning notice preventing entry by pacemaker patients.

**Medical Procedures and Environments**

In general, pacemaker patients should not be exposed to hospital equipment that produces high electromagnetic field strength signals, such as diathermy machines and electrosurgical units.

• **External Defibrillation.** The electronic circuitry in the device provides protection from defibrillation discharges. Nevertheless, do not place defibrillator paddles directly over the device or pacing lead. Following defibrillation, ensure that the pacemaker is operating correctly.

• **Magnetic Resonance Imaging (MRI).** Before and after the patient is exposed to MRI, conduct a detailed assessment of the device. The extremely strong magnetic fields generated during MRI may cause the device to temporarily pace in an asynchronous mode (VOO, DOO, or AOO) if the Magnet Response is set to an option other than Off. If a patient must undergo MRI before the procedure, program the device to Sensor Off and Magnet Response Off.

• **Therapeutic Diathermy.** Therapeutic diathermy can induce ventricular arrhythmias and/or fibrillation or may cause asynchronous or inhibited device operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the device and leads as possible. A bipolar cautery may minimize these effects. Following electrocautery, conduct a thorough assessment of the device.

• **Radiofrequency (RF) Ablation.** Radiofrequency (RF) ablation in patients with a device may cause any of the following: asynchronous pacing above or below the programmed rate, reversion to an asynchronous operation, device electrical reset, or premature triggering of the elective replacement indicator. RF ablation risks may be minimized by programming a non-rate responsive, asynchronous pacing mode prior to the RF ablation procedure; avoid direct contact between the ablation catheter and the implanted lead or pulse generator; positioning the ground plate so that the current pathway does not pass through or near the pulse generator system, i.e., place the ground plate under the patient’s buttocks or legs; having a programmer available for temporary pacing; or having external defibrillation equipment available.
Patient Environment

- **High-Voltage** transmission lines and equipment, arc or resistance welders, induction furnaces, and similar equipment may generate substantial EMI fields that may interfere with device operation.
- **Communication Equipment,** such as microwave transmitters, linear power amplifiers, or high-power amateur transmitters may generate sufficient EMI to interfere with the operation of the device. Advise patients to move away from this equipment to resume normal pacemaker operation.
- **Home Appliances** that are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. Electric vibrators, razors, and handtools held directly over the device may disturb its operation.
- **Twiddler’s Syndrome.** Caution patients against manipulating the implanted device since it may result in lead damage or lead displacement.
- **Patient Activities.** Any activities that involve repetitive impacts or jarring (such as horseback riding, jackhammer use, etc.) may increase the pacing rate when the device’s Sensor is programmed On. Caution patients against such activity and program Sensor parameters with these activities in mind.
- **Theft Detection Systems.** Theft detection systems, such as those often located at the entrances and exits of stores and public libraries, may disturb pacemaker function only if the patient pauses in the field path.
- **No Pacer Symbol.** Caution patients implanted with this device to avoid areas marked with the NO PACER symbol.

Figure 3. No Pacer Symbol

- **Cellular Phones.** A St. Jude Medical-designed protective filter in the device prevents cellular phone-generated electromagnetic signals from interfering with the operation of the device. Clinical tests performed by the manufacturer and five independent organizations have documented that devices with this filter are not affected by any known analog cellular phone systems or any of the digital phone technologies listed in Table 2.

<table>
<thead>
<tr>
<th>Type</th>
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<tr>
<td>NADC (TDMA 50)</td>
<td>North American Digital Communications (TDMA 50 Hz)</td>
</tr>
<tr>
<td>US (TDMA 11)</td>
<td>Time Division Multiple Access 11 Hz</td>
</tr>
<tr>
<td>CDMA</td>
<td>Code Division Multiple Access</td>
</tr>
<tr>
<td>PCS (GSM 1.9 GHz)</td>
<td>Personal Communication Systems (GSM 1.9 GHz)</td>
</tr>
</tbody>
</table>

Table 2. Digital Phones Standards Tested

No special precautions are required for patients using the cellular phones listed above. Phone systems not listed in Table 2 have not been tested, and their interaction with the device cannot be guaranteed.

The device has also been tested for compatibility with handheld transmitters in accordance with the requirements of AAMI PC69. This testing covered the operating frequencies (450 MHz - 3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. For more information, you or your patient may wish to contact Technical Support (page 29) to obtain more information on the interaction of certain cellular phones and this device.

Explanation

- **Do not reuse explanted devices and leads.**
- **Clean explanted equipment with +1% sodium hypochlorite, rinse with water, dry.**
- **Return the explanted device to the manufacturer.**
- **Explant the device before cremation of a deceased patient.**
- **Hex wrenches are available for disconnecting a previously implanted device from the indwelling leads. To obtain the wrenches, contact your local St. Jude Medical representative.**

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5. Home appliance microwave ovens do not interfere with device operation.
7. Center for Devices and Radiological Health, FDA, Rockville MD; Medical Devices Bureau of Health, Ottawa, Ontario, Canada; Mount Sinai Medical Center of Greater Miami, Miami Beach FL; Center for Study of Wireless Electromagnetic Compatibility, University of Oklahoma, Norman OK; Qualcomm, Inc., San Diego, CA.
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
- Formation of fibrotic tissue; local tissue reaction
- Inability to interrogate or program a device because of programmer malfunction
- Infection
- Interruption of desired device 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.

Operating Modes

The Frontier™ II device is a biventricular resynchronization device capable of operating in the following therapy modes. All modes can also be programmed to operate with rate-modulation (R). See Rate-Modulated Modes on page 13.

Dual Chamber Modes

DDT

(Dual Chamber Pacing, Sensing, and Triggering)

DDT mode allows pacing in the atrium and both ventricle(s) as well as sensing in both chambers. Intrinsic atrial activity inhibits atrial output and is tracked in the ventricles. In the absence of intrinsic activity, the atrium and ventricle(s) are paced at the programmed Base Rate, AV Delay, and Interventricular Pace Delay.

In this AV-sequential pacing mode, the device paces after a sensed R-wave. The device can also be programmed to adjust its timing according to atrial or ventricular activity. In a biventricular configuration, the device delivers a pulse through each ventricular lead whenever an R-wave is sensed.

When the user programs DDT mode, the programmer displays two additional parameters: DDT Timing and DDT Trigger.

DDT Timing gives the user the option of using atrial-based timing (DDD) or ventricular-based timing (DDI).

DDT Trigger is not programmable and the pulse can only be triggered by an R-wave.

A sensed ventricular event during the alert period causes the device to pace in each ventricle after the sensed ventricular activity.

Figure 4 depicts the operation of DDT mode with DDD timing.

---

8. Model 5596 allows biventricular, RV-only, or LV-only pacing. Model 5586 allows biventricular pacing and RV-only pacing when interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin™ PCS Model 3650 with Model 3330 version 6.1.1 software or higher. If Model 5586 is interrogated with earlier versions of programmer software, only biventricular pacing is available.
Operating Modes

Figure 4. DDT Mode, with DDD Timing

**Indications.** DDT operation is intended for patients in whom simultaneous pacing of left and right ventricles may lead to resynchronization of left and right ventricles and improved cardiac hemodynamics.

**Contraindications.** DDT mode with DDD timing is contraindicated in the presence of chronic atrial tachyarrhythmias or silent atria. However, AF Suppression may provide a high degree of atrial pacing and may help reduce atrial tachycardias. Retrograde conduction, though not a contraindication, requires the careful programming of an appropriate Post Ventricular Atrial Refractory Period (PVARP) value. DDT mode with DDI timing is contraindicated in high-grade AV block with normal sinus nodal function, chronic atrial fibrillation or flutter, and silent atria.

DDD

(Dual Chamber Pacing, Sensing, and Inhibition; Atrial Tracking)

DDD mode allows pacing in the atrium and ventricle(s) as well as sensing in both chambers. Intrinsic activity inhibits the output in the respective channel and intrinsic atrial events are tracked in the ventricles. In the absence of intrinsic activity, both chambers are paced at the programmed Base Rate and AV Delay (Figure 5).

**Indications.** DDD operation is indicated in the presence of AV conduction disorders with normal or abnormal sinus node function and if the patient may benefit from a high degree of ventricular pacing.

---

**Note**

In DDDR mode, during activity and at rates below Maximum Tracking Rate (MTR), the device’s A-A interval is adjusted to reflect the sensor-indicated pacing rate determined for each cycle.

---

**Indications.** DDD operation is indicated in the presence of AV conduction disorders with normal or abnormal sinus node function and if the patient may benefit from a high degree of ventricular pacing.

---

**Figure 5. DDD Mode**

DDD operates on atrial based timing. When an intrinsic atrial event is sensed before the completion of A-A interval, the atrial alert interval, the atrial output pulse is inhibited, and the timing cycle for the PV Delay begins. If no intrinsic atrial event is sensed, an atrial pulse is delivered at the end of the A-A interval and the timing cycle for the AV Delay begins.

In the presence of atrial pacing, the pacing rate will not change. Acceleration does not occur if an intrinsic ventricular event is sensed during the AV/PV Delay, although ventricular output is inhibited. If no ventricular event is sensed in AV/PV Delay, the interval times out, a ventricular pulse is delivered in each chamber, and the timing cycle for the atrial escape interval (AEI) restarts.

Intrinsic ventricular activity sensed during the ventricular alert period of the AEI will inhibit both atrial and ventricular output pulses and recycle the timing cycles on both channels to the beginning of the AEI.
Contraindications. DDD operation is contraindicated in the presence of chronic atrial tachyarrhythmias or silent atria. However, the device's combination of AF Suppression and Auto Mode Switch features may provide a high degree of atrial pacing that may help reduce atrial tachycardias. Retrograde conduction, though not a contraindication, requires the careful programming of an appropriate Post-Ventricular Atrial Refractory Period (PVARP) value.

DDI

(Dual Chamber Pacing; Ventricular Sensing and Inhibition; No Atrial Tracking)

In DDI mode, the device paces in the atrium and both ventricle(s) as well as senses in both chambers. Intrinsic atrial activity during the atrial alert period will inhibit the atrial output pulse and prevent competitive atrial pacing. This sensing will not affect the device’s timing and, in the absence of intrinsic ventricular activity, a ventricular output pulse will be provided at the end of the programmed rate (V-V) interval (Figure 6).

Figure 6. DDI Mode

This mode provides AV sequential pacing at the programmed rate in the absence of intrinsic activity. It also provides functional single chamber atrial pacing with backup ventricular support in the presence of intact AV nodal conduction. Additionally, intrinsic ventricular activity occurring during the ventricular alert period of the atrial escape interval or AV Delay will inhibit the device and reset the timing as previously described.

Indications. DDI operation is indicated in situations where dual chamber pacing is required, and there is a specific reason that atrial tracking is not desired.

Contraindications. DDI operation is contraindicated in AV block with normal sinus node function, chronic atrial fibrillation or flutter, and silent atria.

DVI

(Dual Chamber Pacing; Ventricular Sensing, Inhibition)

In DVI mode, the device paces the atrium and both ventricle(s) but senses only in the ventricles. In the absence of intrinsic ventricular activity, all chambers are paced at the programmed Base Rate and AV Delay. When a ventricular event is detected during the AEI, all device output is inhibited and the timing cycle of the AEI is restarted. If no intrinsic ventricular event is sensed, the AEI times out, and an atrial output pulse is delivered (Figure 7).

Figure 7. DVI Mode

A native ventricular event during either the AEI or the AV Delay will inhibit the ventricular output and reset the timing cycle of the AEI. If no sensed ventricular event occurs within the AV Delay, it times out, at which point a ventricular output is delivered.

Indications. DVI operation is indicated in situations where dual channel pacing is required and there is a specific reason that atrial sensing is not desired.

Contraindications. DVI pacing is contraindicated in the presence of competitive intrinsic atrial rhythms or silent atria.
DOO

(Dual Chamber Asynchronous Pacing)

In DOO mode, the device paces the atrium and both ventricle(s) at the programmed Base Rate and AV Delay, regardless of intrinsic activity (Figure 8).

*Indications.* DOO mode is indicated when there is a need for dual chamber pacing along with the likelihood of significant electromagnetic or electromyogenic noise that could inappropriately inhibit or trigger the device.

![Figure 8. DOO Mode](image)

*Contraindications.* DOO mode is contraindicated in the presence of competitive intrinsic cardiac rhythm.

---

**CAUTION**

DOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous tachyarrhythmias.

---

Single Chamber Modes

VVI

(Ventricular Pacing, Sensing, and Inhibition)

In VVI mode, the device paces the ventricle(s) at the programmed rate in the absence of intrinsic activity. Intrinsic activity during the alert period will inhibit the output pulse by resetting the device timing to the beginning of the refractory period (Figure 9).

![Figure 9. VVI Mode](image)

*Indications.* VVI pacing is indicated for symptomatic bradycardia of any etiology. This includes, but is not limited to, AV block or sinus node dysfunction and the various manifestations of sinus node dysfunction, including sinus node arrest, sinus bradycardia, and brady-tachy syndrome.

*Contraindications.* VVI pacing is contraindicated in the presence of pacemaker syndrome.

VVT

(Ventricular Pacing, Sensing, and Triggering)

In VVT mode, the device paces the ventricle(s) at the programmed rate in the absence of intrinsic ventricular activity. Intrinsic ventricular activity during the alert period causes the device to deliver an output pulse synchronously with the detected ventricular event (Figure 10).
VVT Mode

Indications. VVT pacing is intended for temporary diagnostic use in the evaluation and management of arrhythmias performed by triggering the device output through chest wall stimulation.

VVT operation is intended for patients in whom simultaneous pacing of left and right ventricles may lead to resynchronization of left and right ventricles and improved cardiac hemodynamics.

Triggered pacing modes, such as VVT, may be useful in avoiding inappropriate inhibition of the device due to electromagnetic or electromyo-genic interference. A triggered mode will pace on detection of such signals, instead of being inhibited by them.

VVT pacing may also be used to identify the sensing site within a complex and for temporary diagnostic use in the evaluation and management of arrhythmias performed by triggering the device output through chest wall stimulation.

Contraindications. VVT pacing is contraindicated in the presence of pacemaker syndrome.

VOO (Ventricular Asynchronous Pacing)

In VOO mode, the device paces the ventricle(s) at the programmed rate, regardless of the intrinsic rhythm (Figure 11).

Contraindications. VOO pacing is contraindicated in the presence of competitive intrinsic cardiac rhythm and in patients who have or are likely to experience pacemaker syndrome during single chamber ventricular pacing.

CAUTION
VOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous ventricular tachyarrhythmias.

AAI

(Atrial Pacing, Sensing, and Inhibition)

In AAI mode, the device paces the atrium at the programmed rate in the absence of intrinsic atrial activity. Intrinsic atrial activity during the alert period will inhibit the output pulse and reset device timing to the beginning of the refractory period (Figure 12).
# AAI Mode

**Indications.** AAI pacing is indicated for symptomatic bradycardia caused by sinus node dysfunction.

**Contraindications.** AAI pacing is contraindicated in the presence of AV conduction disorders, chronic atrial fibrillation, or atrial flutter.

---

# AAT

(Atrial Pacing, Sensing, and Triggering)

In AAT mode, the device paces the atrium at the programmed rate in the absence of intrinsic atrial activity. Intrinsic atrial activity during the alert period causes the device to deliver an output pulse synchronously with the detected atrial event (Figure 13).

**Indications.** AAT pacing is primarily intended for temporary use in the evaluation of arrhythmias through chest wall stimulation. Triggered pacing modes, such as AAT, may be useful in avoiding inappropriate inhibition of the device due to electromagnetic or electromyogenic interference. A triggered mode will pace on detection of such signals, instead of being inhibited by them. AAT pacing may also be used to identify the sensing site within a complex and for temporary diagnostic use in the evaluation and management of arrhythmias performed by triggering the device output through chest wall stimulation.

**Contraindications.** AAT pacing is contraindicated in the presence of AV conduction disorder, atrial fibrillation, or atrial flutter.

---

# AOO

(Atrial Asynchronous Pacing)

In AOO mode, atrial pacing is provided at the programmed rate regardless of intrinsic rhythm (Figure 14).

**Indications.** AOO is indicated when there is a need for atrial pacing and in the presence of significant electromagnetic or electromyogenic noise that could inappropriately inhibit the device.

**Contraindications.** AOO mode is contraindicated in the presence of competitive intrinsic cardiac rhythm or AV conduction disorders.

---

**CAUTION**

AOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous atrial tachyarrhythmias.
OVO and OAO Modes

In these modes, pacing is turned off while the device continues to sense intrinsic activity and record the events in the device memory. These modes are useful primarily for temporary diagnostic evaluation of underlying rhythm and when a record of the activity is needed. However, when these modes are programmed, the programmer does not display Event Markers or measured heart rate.

These modes are not available when Sensor is programmed On or Passive, and the Sensor cannot be programmed On when these modes are programmed.

As with all modes, programming a different mode will clear diagnostic data.

CAUTION

OVO or OAO modes are not recommended for pacemaker-dependent patients or patients who might be affected by even a short cessation of the device’s operation.

Biventricular Pacing

Biventricular pacing always occurs in both the left and right ventricles. Pacing in the ventricle(s) is determined by the Ventricular Pacing Chamber Lead Type, Pulse Amplitude, Pulse Width, and Pulse Configuration are independently programmed for the right and left ventricular pacing outputs. Ventricular sensing is performed with a single ventricular sense amplifier and is configured using V. Sense Configuration.

Interventricular Pace Delay determines the interval between the delivery of the first and second ventricular pulses in the order determined by First Chamber Paced. During the interventricular delay period, no sensing occurs. Timing (A-V, refractory periods, V-A, intervals, etc.) is referenced from the first chamber paced.

Note

In simultaneous biventricular pacing, the pulse is delivered to the left ventricle first with a second pulse delivered 10 ms after the first.

Note

When programmed to a triggered pacing mode, a sensed ventricular event causes a pulse to be delivered to the programmed First Chamber Paced 10 ms following the sense event, and the second pulse is delivered 10 ms after the first.

1. For Model 5596 and Model 5586 interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin™ PCS Model 3650 with Model 3330 version 6.1.1 software or higher, First Chamber Paced is programmable. When Model 5586 is interrogated with earlier versions of programmer software, the left ventricle is always paced first.

Rate-Modulated Modes

The function of rate-modulated modes (Sensor On) is to alter the pacing rate to match activity changes in accordance with programmed parameters. Rate-modulation can be enabled with any mode.

Indications. These are the same as modes without rate-modulation, except that rate-modulated modes are further indicated when an increase in pacing rate with activity is desired.

Contraindications. These are the same as modes without rate-modulation, except that rate-modulated modes are also contraindicated when pacing rates above the programmed Base Rate may not be well tolerated.

9. For Model 5596 and Model 5586 interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin™ PCS Model 3650 with Model 3330 version 6.1.1 software or higher, Pulse Configuration is independently programmable in the right and left ventricles. When Model 5586 is interrogated with earlier versions of programmer software, V. Pulse Configuration programs the right and left ventricles to the same setting.

10. For Model 5596 and Model 5586 interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin PCS Model 3650 with Model 3330 version 6.1.1 software or higher, Interventricular Pace Delay and First Chamber Paced are programmable. When Model 5586 is interrogated with earlier versions of programmer software, Interventricular Pace Delay is not programmable and is set to Simultaneous. In simultaneous biventricular pacing, the pulse is delivered to the left ventricle first with a second pulse delivered 10 ms after the first.
Programming Guidelines

General
The Frontier™ II cardiac resynchronization device can be programmed using the Model 3510 programmer with Model 3307 software version 4.8 or higher or the Merlin™ PCS. For detailed information on the programmer, consult the Bradycardia Devices Reference Manual, select the HELP button on the Model 3510 programmer, or select the “?” button on the Merlin PCS. For a list of all programmable parameters and settings, see Table 9 on page 22.

Magnet Use
To interrogate the device, remove the magnet from the programmer telemetry wand. A magnet will interfere with proper telemetry.

Temporary Programming
The Frontier™ II cardiac resynchronization device features Temporary Programming to aid the clinician in diagnosing and treating the patient. The clinician can temporarily program parameters to assess their effects with the ability to quickly cancel or permanently program the setting. For more information, consult the Bradycardia Devices Reference Manual, select the HELP button on the Model 3510 programmer, or select the “?” button on the Merlin PCS.

Preset Programmed Settings
Shipped Settings
The device’s parameter settings are preset when the device is manufactured. These settings can be found in Table 8 on page 20.

Emergency Settings
The device is equipped with standard, high-output settings that can be quickly programmed using the programmer’s Emergency VVI function. Settings for Emergency VVI can be found in the Bradycardia Devices Reference Manual, by selecting the HELP button on the Model 3510 programmer, or by selecting the “?” button on the Merlin™ PCS.

Diagnostic Data, Tests, and Tools
The Frontier™ II device collects and retains a variety of diagnostic data that can be viewed and printed with the Model 3510 programmer or the Merlin™ PCS. These include:
- AT/AF Burden Trend and Event Counts
- AT/AF Episode Histogram and Log
- Stored EGMs which can be triggered manually or by a number of automatic criteria (for example, auto mode switch entry or high intrinsic rates)
- Auto Mode Switch Histogram (Peak Filtered Rate and Duration) and AMS Log
- Event Histogram
- Heart Rate Histogram
- Sensor-Indicated Rate Histogram
- Measured Data: magnet rate, pulse amplitude, current, energy, and charge, lead impedance, battery voltage, battery current, and battery impedance
- Estimated remaining device longevity
- Previous Follow-up tests
- Event Record
- Date Last Programmed
- Device identification with model name and number, unit serial number, lead information, and battery identification
- A portion of the device memory to store important Patient Information, including Implant Date.

The Frontier II device also offers features to facilitate follow-up, including:
- Automated Follow-up, which allows collection of all important diagnostic and test data with the selection of a single button
- Noninvasive slaved electrophysiologic (EP) lab tests and Noninvasive Pacing Stimulation (NPS)
- Automatic P-wave and R-wave measurements

Note
When Emergency VVI is selected, diagnostic data are cleared from memory without a warning.
• Semiautomatic capture and sensing threshold tests
• Battery Test, which allows assessment of the battery status with application of a magnet
• Simultaneous display of ECGs and Intracardiac Electrograms (IEGM) with annotated Markers and Electronic Calipers
• Simultaneous display of atrial and ventricular markers
• Continuous ECG printing during normal programmer operation
• Extended Markers depicting events within the refractory period
• Temporary programming of all parameters for diagnostic purposes
• Auto-Set and Prediction Model, which facilitate activity sensor programming.

For more information on these features, see the Bradycardia Devices Reference Manual, select the HELP button on the Model 3510 programmer, or select the “?” button on the Merlin PCS.

Implantation and Lead Connection

Package Contents
The Frontier™ II device is shipped in a sterile box containing:
• Frontier II device
• Two IS-1 header plugs for sealing unused ports
• #2 Torque Wrench
• Literature.

Ventricular Lead Selection
The Frontier™ II device will operate with any combination of unipolar or bipolar IS-1 short terminal pin leads. Pairing a ventricular lead with a polished platinum tip electrode with a lead with a tip electrode of a different material may create a source impedance mismatch that could adversely affect sensing.

Note
The clinician should enter the lead types for each ventricular lead in the Patient Information memory, which is accessed by selecting the Patient Data tab on the Programmed Parameters screen.

<table>
<thead>
<tr>
<th>Lead Combination (RV Lead+ LV Lead)</th>
<th>Pulse Configuration Setting</th>
<th>RV Electrode Signal (Cathode — Anode)</th>
<th>LV Electrode Signal (Cathode — Anode)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Model 5586</td>
<td>Model 5596</td>
</tr>
<tr>
<td>Bipolar+ Bipolar</td>
<td>Bipolar</td>
<td>RVtip — RVring</td>
<td>LVtip — LVring</td>
</tr>
<tr>
<td>Unipolar</td>
<td>RVtip — Case</td>
<td>LVtip — Case</td>
<td>LVtip — Case</td>
</tr>
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<td>Bipolar+ Unipolar</td>
<td>Bipolar</td>
<td>RVtip — RVring</td>
<td>LVtip — RVring</td>
</tr>
<tr>
<td>Unipolar</td>
<td>RVtip — Case</td>
<td>LVtip — Case</td>
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</tr>
<tr>
<td>Bipolar+ Bipolar</td>
<td>Bipolar</td>
<td>RVtip — LVring</td>
<td>LVtip — LVring</td>
</tr>
<tr>
<td>Unipolar</td>
<td>RVtip — Case</td>
<td>LVtip — LVring</td>
<td>LVtip — LVring</td>
</tr>
<tr>
<td>Unipolar+ Bipolar</td>
<td>Bipolar</td>
<td>RVtip — Case</td>
<td>LVtip — LVring</td>
</tr>
<tr>
<td>Unipolar+ Unipolar</td>
<td>Unipolar</td>
<td>RVtip — LVring</td>
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</tr>
</tbody>
</table>

Table 3. Pulse Configurations for All Combinations of RV and LV Lead Types
1. For Model 5596 and Model 5586 interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin™ PCS Model 3650 with Model 3330 version 6.1.1 software or higher, RV and LV Pulse Configuration are independently programmable.

12. Right ventricular and left ventricular capture threshold measurements are evaluated independently.
13. Right ventricular, left ventricular, and biventricular markers.
### Lead Connection

**Frontier™ II Models 5596 and 5586**

- Bipolar+ Bipolar
  - **BV Bipolar**
    - **LVtip+RVtip — LVring+RVring**
  - **RV Unipolar Tip**
    - n/a
    - **RVtip — RVtip**
  - **RV Unipolar Ring**
    - n/a
    - **RVtip — RVtip**
  - **LV Unipolar Tip**
    - n/a
    - **LVtip — LVtip**
  - **LV Unipolar Ring**
    - n/a
    - **LVtip — LVtip**
- Bipolar+ Unipolar
  - **BV Bipolar**
    - **RVtip+LVtip — RVtip**
  - **BV Unipolar Tip**
    - **RVtip+LVtip — Case**
  - **RV Bipolar**
    - n/a
    - **RVtip — RVtip**
  - **RV Unipolar Tip**
    - n/a
    - **RVtip — RVtip**
  - **RV Unipolar Ring**
    - n/a
    - **RVtip — Case**
  - **LV Unipolar Tip**
    - n/a
    - **LVtip — LVtip**
  - **LV Unipolar Ring**
    - n/a
    - **LVtip — LVtip**
- Unipolar+ Bipolar
  - **BV Bipolar**
    - **RVtip+LVtip — LVtip**
  - **BV Unipolar Tip**
    - **RVtip+LVtip — Case**
  - **RV Bipolar**
    - n/a
    - **RVtip — RVtip**
  - **RV Unipolar Tip**
    - n/a
    - **RVtip — RVtip**
  - **LV Bipolar**
    - n/a
    - **LVtip — LVtip**
  - **LV Unipolar Tip**
    - n/a
    - **LVtip — LVtip**
  - **LV Unipolar Ring**
    - n/a
    - **LVtip — LVtip**
- Unipolar+ Unipolar
  - **BV Unipolar Tip**
    - **RVtip+LVtip — Case**
  - **RV Unipolar Tip**
    - n/a
    - **RVtip — Case**
  - **LV Unipolar Tip**
    - n/a
    - **LVtip — Case**
  - **LV Unipolar Tip**
    - n/a
    - **LVtip — Case**
  - **LV Unipolar Ring**
    - n/a
    - **LVtip — RVtip**

<table>
<thead>
<tr>
<th>Lead Combination (RV Lead+ LV Lead)</th>
<th>Ventricular Sense Configuration Setting</th>
<th>Signal (Cathode — Anode)</th>
<th>5586</th>
<th>5596</th>
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</thead>
<tbody>
<tr>
<td>Bipolar+ Bipolar</td>
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<td>LVtip+RVtip — LVtip+RVring</td>
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<tr>
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<td>BV Unipolar Tip</td>
<td>RVtip+LVtip — Case</td>
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<td></td>
<td>RV Bipolar</td>
<td>n/a</td>
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<td>RV Unipolar Tip</td>
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<td>LVtip — RVtip</td>
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<td>LVtip — RVtip</td>
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</tbody>
</table>

Table 4. Sense Configurations for All Combinations of Ventricular Lead Types

### Lead Connection

**Frontier™ II Models 5596 and 5586** accept all unipolar or bipolar IS-1 short terminal pin leads.

The device has a single setscrew for each lead. The setscrew makes contact with the lead connector pin (cathode) securing the lead within the pacemaker connector while an annular spring makes contact with the proximal ring (anode).

### Note

- An RV lead must be used with the Frontier II device. Back-Up VVI pacing is delivered to the right ventricle only.

### CAUTION

- After all leads have been implanted and before they are connected to the device, establish and document the baseline morphology for capture and sensing thresholds for each lead using a suitable recording system, such as a 12-lead ECG or Intracardiac Electrogram (IEGM).
To connect the device to the leads:

1. Remove blood and body fluids from the terminal pins of the implanted leads.
2. Check the markings on the device case and verify proper atrial and ventricular connections.

3. Use the white-handle #2 torque wrench packaged with the device to retract the setscrews in the device connector so that the pacing lead terminal pins can be fully inserted.
4. Insert a lead firmly into the connector until the lead pin is immobile and visible in the viewport at the opposite end of the connector.
5. Insert the white-handle #2 torque wrench through the aperture on the header and into the setscrew on the side of the connector.
6. Turn the wrench clockwise until it clicks. The wrench is torque-limited and will not allow excessive tightening.
7. Repeat Steps 4 through 6 for additional lead(s).
8. Tug gently on the leads to ensure they are secured in the connector.

In order to minimize device migration, secure the device to the subcutaneous pocket via the suture hole in the device header.

After the device has been implanted and the pocket is closed, interrogate the device and set the Lead Type to the correct setting. Lead Type settings are described in the Bradycardia Devices Reference Manual and the On-Screen Help.

- **Note**
  
  For proper sensing and pacing, it is important to ensure that left and right ventricular signals are correctly detected and that pacing pulses are delivered in the desired chamber.

- **Note**
  
  The right and left ventricular pulse amplitudes and pulse widths are independently programmable. The pulse amplitude and pulse width should be evaluated in each chamber accordingly.

- **Note**
  
  Careful consideration should be given to patient exposure to electromagnetic interference if programming sensitivity greater than 0.3 mV with a bipolar sense configuration setting and 2.0 mV with a unipolar sense configuration setting.

- **Note**
  
  Independent lead impedance values are displayed for the RV and LV leads.

### Device Registration

An Implantable Device Registration Form is enclosed with each device to serve as a permanent record of information pertaining to the implanted device. The completed original should be returned to the manufacturer in the postage-paid, addressed envelope provided. Copies of the registration form are provided for the hospital and the physician.

### X-Ray Identification

The device has a radiopaque identifier visible on conventional X-ray film, which consists of the St. Jude Medical™ logo and a two-letter model code (Figure 15).

The code for all Frontier™ II devices is:

- **Note**
  
  The model number of each device is stored in the device’s memory and is automatically displayed on the programmer screen when the device is interrogated.
Device Longevity

Many individual factors affect device service life, such as programmed parameters, percentage of time paced, internal impedance, lead impedance, etc. The projected longevity data in Tables 5 and 6 are based on accelerated battery test data under certain conditions and do not account for such factors as sensor-driven pacing rate changes, effects of rate-limiting algorithms, the patient's medical condition, or effects of a specific prescription. Furthermore, these data are based on battery life projections, which are approximations.

ERI precedes EOL by a wide margin of safety, not less than three months under normal circumstances.

The test data were calculated with Sensor set to Passive\textsuperscript{14}, Pulse Width set to 0.4 ms, AF Suppression set to Off, and all Stored EGM Triggers set to Off.

The ventricular impedance values reported here are the for independent right and left ventricular leads.

<table>
<thead>
<tr>
<th>Pacing at:</th>
<th>Implant to ERI in Years</th>
<th>ERI to EOL in Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV 2.5 V; LV 3.5 V; 500 Ω</td>
<td>9.2</td>
<td>4.9</td>
</tr>
<tr>
<td>RV 2.5 V; LV 3.5 V; 750 Ω</td>
<td>10.9</td>
<td>4.9</td>
</tr>
<tr>
<td>RV 2.5 V; LV 3.5 V; 1000 Ω</td>
<td>12.0</td>
<td>5.2</td>
</tr>
<tr>
<td>RV 3.5 V; LV 5.0 V; 500 Ω</td>
<td>6.5</td>
<td>4.8</td>
</tr>
<tr>
<td>RV 3.5 V; LV 5.0 V; 750 Ω</td>
<td>8.1</td>
<td>4.9</td>
</tr>
<tr>
<td>RV 3.5 V; LV 5.0 V; 1000 Ω</td>
<td>9.3</td>
<td>4.9</td>
</tr>
</tbody>
</table>

Table 5. Projected Time from Implant to EOL (60 min\textsuperscript{−1}, 100% Multi-Chamber VVI Mode Pacing)

<table>
<thead>
<tr>
<th>Pacing at:</th>
<th>Implant to ERI in Years</th>
<th>ERI to EOL in Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>A 2.5 V; RV 2.5 V; LV 3.5 V; 500 Ω</td>
<td>7.6</td>
<td>4.8</td>
</tr>
<tr>
<td>A 2.5 V; RV 2.5 V; LV 3.5 V; 750 Ω</td>
<td>9.1</td>
<td>4.9</td>
</tr>
<tr>
<td>A 2.5 V; RV 2.5 V; LV 3.5 V; 1000 Ω</td>
<td>10.1</td>
<td>4.9</td>
</tr>
<tr>
<td>A 3.5 V; RV 3.5 V; LV 5.0 V; 500 Ω</td>
<td>4.9</td>
<td>4.9</td>
</tr>
<tr>
<td>A 3.5 V; RV 3.5 V; LV 5.0 V; 750 Ω</td>
<td>6.2</td>
<td>4.8</td>
</tr>
<tr>
<td>A 3.5 V; RV 3.5 V; LV 5.0 V; 1000 Ω</td>
<td>7.3</td>
<td>4.8</td>
</tr>
</tbody>
</table>

Table 6. Projected Time from Implant to EOL (60 min\textsuperscript{−1}, 100% Multi-Chamber DDD Mode Pacing)

\textsuperscript{14}. There is no difference in current drain between Sensor On and Sensor Passive with inactivity.
Elective Replacement Indicator

ERI (or Recommended Replacement Time) is the point at which battery voltage has dropped to the lowest capacity that will maintain adequate device operation for a nominal period of three months before EOL.

When the device reaches ERI, a number of indicators alert the clinician to this condition:

- Pacing intervals increase by 100 ms over the Base Rate to reduce current drain (Table 7 shows the difference between the programmed Base Rate and actual pacing rates at ERI).
- The programmer displays a message that the device has detected ERI and prompts the user to clear ERI or continue (see Clearing ERI on page 19).
- The Magnet Response is automatically programmed to Battery Test, and the Magnet Rate will be 86.3 min$^{-1}$ or less.
- Battery voltage drops to 2.5 V or less.
- Sensor and AF Suppression are programmed Off.
- Shortest AV/PV Delay is programmed to 70 ms.
- The following features no longer operate at ERI:
  - Rest Rate
  - All diagnostic data collection
  - NIPS.

For more information, consult the Bradycardia Devices Reference Manual or select the HELP button on the Model 3510 programmer.

**CAUTION**

- Programming to high output settings with a high Base Rate for extended periods of time may shorten the time to ERI. Programming to lower rates and outputs may restore normal battery status.
- If the programmer displays an ERI warning message, the clinician should fully evaluate the device.

<table>
<thead>
<tr>
<th>Programmed Rate</th>
<th>Actual Rate at ERI</th>
<th>Programmed Rate</th>
<th>Actual Rate at ERI</th>
<th>Programmed Rate</th>
<th>Actual Rate at ERI</th>
</tr>
</thead>
<tbody>
<tr>
<td>45</td>
<td>41.9</td>
<td>85</td>
<td>74.4</td>
<td>125</td>
<td>103.4</td>
</tr>
<tr>
<td>50</td>
<td>46.2</td>
<td>90</td>
<td>78.3</td>
<td>130</td>
<td>106.8</td>
</tr>
<tr>
<td>55</td>
<td>50.4</td>
<td>95</td>
<td>82.0</td>
<td>135</td>
<td>110.2</td>
</tr>
<tr>
<td>60</td>
<td>54.5</td>
<td>100</td>
<td>85.7</td>
<td>145</td>
<td>116.8</td>
</tr>
<tr>
<td>65</td>
<td>58.6</td>
<td>105</td>
<td>89.4</td>
<td>150</td>
<td>120.0</td>
</tr>
<tr>
<td>70</td>
<td>62.7</td>
<td>110</td>
<td>93.0</td>
<td>155</td>
<td>123.2</td>
</tr>
<tr>
<td>75</td>
<td>66.7</td>
<td>115</td>
<td>96.5</td>
<td>160</td>
<td>126.3</td>
</tr>
<tr>
<td>80</td>
<td>70.6</td>
<td>120</td>
<td>100.0</td>
<td>165</td>
<td>129.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>170</td>
</tr>
</tbody>
</table>

**Table 7. Programmed Pacing Rate (min$^{-1}$) versus Actual Pacing Rate (min$^{-1}$) at ERI**

1. There is no change to the actual rate at ERI when Base Rate is set to 30 min$^{-1}$.

**WARNING**

At ERI, the nominal life of the device is seldom less than three months. The device should be replaced immediately.

Clearing ERI

When the programmer displays a message that the device has reached ERI, the user is presented with two options: [Continue] or [Clear ERI].

Continue. When this option is selected, the device will continue to operate in ERI state with limited functions. The device should be replaced as soon as possible.

15. Unless Magnet Response is Off, then it is not changed at ERI.
16. With the exception of average measured battery voltage and current.
Clear ERI. This option should be used if the user suspects that ERI is premature. ERI may be artificially reported under such conditions as extreme cold temperatures, abnormally high output and high rate settings, or exposure to EMI sources such as electrocautery and defibrillation. Pressing [Clear ERI] removes the ERI indicator in the device’s processor.

### Note
The programmed parameters that were autoprogrammed at ERI will not be restored to their initial settings when [Clear ERI] is selected. The clinician should interrogate the device and reprogram it.

### End-of-Life
When the output pulse amplitude drops to 50 percent of its programmed value, the device has reached EOL. Typically, this occurs when the battery voltage has fallen to approximately < 2.2 V.

At EOL, the Magnet Response/Battery Test will reveal a Magnet Rate of 68 min\(^{-1}\) or less.

### Technical Data

#### Shipped and Standard Settings

A dash (—) indicates that the parameter is not available in the current configuration. A standard or nominal setting is the value that will be instituted when the parameter is first programmed or autoprogrammed.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Shipped Settings</th>
<th>Standard/Nominal(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Model 5586</td>
<td>Model 5596</td>
</tr>
<tr>
<td>Mode</td>
<td>DDD</td>
<td>DDD</td>
</tr>
<tr>
<td>DDT Timing</td>
<td>—</td>
<td>DDD</td>
</tr>
<tr>
<td>DDT Trigger</td>
<td>—</td>
<td>R-wave</td>
</tr>
<tr>
<td>Base Rate</td>
<td>60 min(^{-1})</td>
<td>60 min(^{-1})</td>
</tr>
<tr>
<td>Hysteresis Rate</td>
<td>Off</td>
<td>Off</td>
</tr>
<tr>
<td>Search Interval</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cycle Count</td>
<td>—</td>
<td>1</td>
</tr>
<tr>
<td>Intervention Rate</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Intervention Duration</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Rest Rate</td>
<td>Off</td>
<td>Off</td>
</tr>
<tr>
<td>Maximum Tracking Rate</td>
<td>110 min(^{-1})</td>
<td>110 min(^{-1})</td>
</tr>
<tr>
<td>AV Delay</td>
<td>170 ms</td>
<td>170 ms</td>
</tr>
<tr>
<td>PV Delay</td>
<td>150 ms</td>
<td>150 ms</td>
</tr>
<tr>
<td>Rate Responsive AV/PV Delay</td>
<td>Off</td>
<td>Off</td>
</tr>
<tr>
<td>Shortest AV/PV Delay</td>
<td>70 ms</td>
<td>70 ms</td>
</tr>
<tr>
<td>V. Refractory</td>
<td>250 ms</td>
<td>250 ms</td>
</tr>
<tr>
<td>V. Absolute Refractory Period</td>
<td>70 ms</td>
<td>70 ms</td>
</tr>
<tr>
<td>A. Refractory (PVARP)</td>
<td>275 ms</td>
<td>275 ms</td>
</tr>
<tr>
<td>A. Absolute Refractory Period</td>
<td>60 ms</td>
<td>60 ms</td>
</tr>
<tr>
<td>Rate Responsive PVARP/REF</td>
<td>n/a</td>
<td>Off</td>
</tr>
<tr>
<td>Shortest PVARP/REF</td>
<td>n/a</td>
<td>—</td>
</tr>
</tbody>
</table>

Table 8. Shipped and Standard Settings for Frontier II Model 5586 and Model 5596 Devices (Footnotes appear on page 22)
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Shipped Settings</th>
<th>Standard/Nominal¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Model 5586</td>
<td>Model 5596</td>
</tr>
<tr>
<td>V. Pacing Chamber</td>
<td>Biventricular</td>
<td>Biventricular</td>
</tr>
<tr>
<td>First Chamber Paced</td>
<td>n/a</td>
<td>Simultaneous</td>
</tr>
<tr>
<td>Interventricular Pace Delay</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>V. Sensitivity</td>
<td>2.0 mV</td>
<td>2.0 mV</td>
</tr>
<tr>
<td>V. Pulse Configuration</td>
<td>See Package Label</td>
<td>n/a</td>
</tr>
<tr>
<td>V. Sense Configuration</td>
<td>See Package Label</td>
<td></td>
</tr>
<tr>
<td>RV Pulse Amplitude</td>
<td>3.5 V</td>
<td>3.5 V</td>
</tr>
<tr>
<td>RV Pulse Width</td>
<td>0.4 ms</td>
<td>0.4 ms</td>
</tr>
<tr>
<td>RV Pulse Configuration</td>
<td>n/a</td>
<td>See Package Label</td>
</tr>
<tr>
<td>LV Pulse Amplitude</td>
<td>5.0 V</td>
<td>5.0 V</td>
</tr>
<tr>
<td>LV Pulse Width</td>
<td>0.4 ms</td>
<td>0.4 ms</td>
</tr>
<tr>
<td>LV Pulse Configuration</td>
<td>n/a</td>
<td>See Package Label</td>
</tr>
<tr>
<td>A. Pulse Amplitude</td>
<td>3.5 V</td>
<td>3.5 V</td>
</tr>
<tr>
<td>A. Pulse Width</td>
<td>0.4 ms</td>
<td>0.4 ms</td>
</tr>
<tr>
<td>A. Sensitivity</td>
<td>0.5 mV</td>
<td>0.5 mV</td>
</tr>
<tr>
<td>A. Pulse Configuration</td>
<td>See Package Label</td>
<td></td>
</tr>
<tr>
<td>A. Sense Configuration</td>
<td>See Package Label</td>
<td></td>
</tr>
<tr>
<td>Magnet Response</td>
<td>Battery Test</td>
<td></td>
</tr>
<tr>
<td>AutoIntrinsic Conduction Search³</td>
<td>n/a</td>
<td>Off</td>
</tr>
<tr>
<td>Negative AV/PV Hysteresis w/Search</td>
<td>Off</td>
<td></td>
</tr>
<tr>
<td>Auto Mode Switch</td>
<td>Off</td>
<td></td>
</tr>
<tr>
<td>AMS Base Rate</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>A. Tachycardia Detection Rate</td>
<td>225 min⁻¹</td>
<td></td>
</tr>
<tr>
<td>AF Suppression</td>
<td>n/a</td>
<td>Off</td>
</tr>
<tr>
<td>No. of Overdrive Pacing Cycles</td>
<td>n/a</td>
<td>—</td>
</tr>
<tr>
<td>Post Ventricular Atrial Blanking (PVAB)</td>
<td>100 ms</td>
<td></td>
</tr>
<tr>
<td>V. Safety Standby</td>
<td>On</td>
<td></td>
</tr>
<tr>
<td>V. Blanking</td>
<td>12 ms</td>
<td>12 ms</td>
</tr>
<tr>
<td>PVC Options</td>
<td>Off</td>
<td></td>
</tr>
<tr>
<td>PMT Options</td>
<td>Off</td>
<td></td>
</tr>
<tr>
<td>PMT Detection Rate</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Sensor</td>
<td>Off</td>
<td></td>
</tr>
<tr>
<td>Maximum Sensor Rate</td>
<td>110 min⁻¹</td>
<td></td>
</tr>
<tr>
<td>Threshold</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Slope</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Reaction Time</td>
<td>—</td>
<td></td>
</tr>
</tbody>
</table>

Table 8. Shipped and Standard Settings for Frontier II Model 5586 and Model 5596 Devices (Footnotes appear on page 22)
Recovery Time — Medium

RV Lead Type Uncoded No Change
LV Lead Type Uncoded No Change
A. Lead Type Uncoded No Change

1. If parameters have not been programmed previously or are not autoprogrammed, the device will institute standard/nominal settings.
2. When Intervention Duration is programmed On, Search Interval is autoprogrammed to a standard setting of 5 min.
3. Not available in biventricular operation.
4. Unless AMS Base Rate is programmed to a specific setting, it is autoprogrammed to equal the permanently programmed Base Rate setting.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Model 5586 Shipped</th>
<th>Standard/Nominal1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery Time</td>
<td>—</td>
<td>Medium</td>
</tr>
<tr>
<td>RV Lead Type</td>
<td>Uncoded</td>
<td>No Change</td>
</tr>
<tr>
<td>LV Lead Type</td>
<td>Uncoded</td>
<td>No Change</td>
</tr>
<tr>
<td>A. Lead Type</td>
<td>Uncoded</td>
<td>No Change</td>
</tr>
</tbody>
</table>

Table 8. Shipped and Standard Settings for Frontier II Model 5586 and Model 5596 Devices (Footnotes appear on page 22)

1. If parameters have not been programmed previously or are not autoprogrammed, the device will institute standard/nominal settings.
2. When Intervention Duration is programmed On, Search Interval is autoprogrammed to a standard setting of 5 min.
3. Not available in biventricular operation.
4. Unless AMS Base Rate is programmed to a specific setting, it is autoprogrammed to equal the permanently programmed Base Rate setting.

Programmable Parameters, Settings, and Tolerances

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Model 5586 Settings</th>
<th>Model 5596 Settings</th>
<th>Units</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode</td>
<td>AOO(R); AAI(R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); OVO; DOO(R); DVI(R); DDD(R); DDT(R)</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>DDT Timing</td>
<td>DDD; DDI</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>DDT Trigger1</td>
<td>R-wave</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Base Rate</td>
<td>30; 40 – 130 in steps of 5; 140 – 170 in steps of 10</td>
<td>min-1</td>
<td>± 30/- 8 ms</td>
<td></td>
</tr>
<tr>
<td>Hysteresis Rate2</td>
<td>Off; 30 – 130 in steps of 5; 140; 150</td>
<td>min-1</td>
<td>± 25/- 8 ms</td>
<td></td>
</tr>
<tr>
<td>Search Interval</td>
<td>Off; 5</td>
<td>Off; 5; 10; 15; 30</td>
<td>min</td>
<td>± 4 ms</td>
</tr>
<tr>
<td>Cycle Count</td>
<td>1</td>
<td>1 – 16</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Intervention Rate</td>
<td>n/a</td>
<td>Off; 60 – 120 in steps of 10; Base Rate; Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30</td>
<td>min-1</td>
<td>± 16 ms (fixed), ± 5 min-1 (intrinsic)</td>
</tr>
<tr>
<td>Intervention Duration</td>
<td>n/a</td>
<td>1 – 10</td>
<td>min</td>
<td>± 4 s</td>
</tr>
<tr>
<td>Rest Rate</td>
<td>Off; 30 – 130 in steps of 5; 140; 150</td>
<td>min-1</td>
<td>± 16 ms</td>
<td></td>
</tr>
<tr>
<td>Maximum Tracking Rate</td>
<td>90 – 130 in steps of 5; 140 – 180 in steps of 10</td>
<td>min-1</td>
<td>± 16 ms</td>
<td></td>
</tr>
<tr>
<td>AV Delay</td>
<td>25; 30 – 200 in steps of 10; 225 – 300 in steps of 25; 350</td>
<td>ms</td>
<td>± 16</td>
<td></td>
</tr>
<tr>
<td>PV Delay</td>
<td>25; 30 – 200 in steps of 10; 225 – 325 in steps of 25</td>
<td>ms</td>
<td>± 25/- 8</td>
<td></td>
</tr>
<tr>
<td>Rate Responsive AV/PV Delay</td>
<td>Off; Low (1); Medium (2); High (3)</td>
<td>ms/ min-1</td>
<td>± 16 ms</td>
<td></td>
</tr>
<tr>
<td>Shortest AV/PV Delay</td>
<td>30 – 50 in steps of 5; 60 – 120 in steps of 10</td>
<td>ms</td>
<td>± 16</td>
<td></td>
</tr>
<tr>
<td>V. Refractory</td>
<td>125 – 500 in steps of 25</td>
<td>ms</td>
<td>± 16</td>
<td></td>
</tr>
<tr>
<td>V. Absolute Refractory Period</td>
<td>70 — 240 in steps of 10</td>
<td>ms</td>
<td>± 8</td>
<td></td>
</tr>
<tr>
<td>A. Refractory</td>
<td>125 – 500 in steps of 25</td>
<td>ms</td>
<td>± 16</td>
<td></td>
</tr>
<tr>
<td>A. Absolute Refractory Period</td>
<td>60; 80; 100 – 350 in steps of 25</td>
<td>ms</td>
<td>± 16</td>
<td></td>
</tr>
<tr>
<td>Rate Responsive PVARP/REF</td>
<td>n/a</td>
<td>Off; Low; Medium; High</td>
<td>n/a</td>
<td>± 16</td>
</tr>
<tr>
<td>Shortest PVARP/REF</td>
<td>n/a</td>
<td>120 – 250 in steps of 10</td>
<td>ms</td>
<td>± 16</td>
</tr>
</tbody>
</table>

Table 9. Programmable Parameters, Settings, and Tolerances for Frontier II Model 5586 and Model 5596 Devices (Footnotes appear on page 24)
### Table 9. Programmable Parameters, Settings, and Tolerances for Frontier II Model 5586 and Model 5596 Devices (Footnotes appear on page 24) (continued)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Settings</th>
<th>Units</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>V. Pacing Chamber</td>
<td>Biventricular&lt;sup&gt;6&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>RV Only; LV Only&lt;sup&gt;7&lt;/sup&gt;; Biventricular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Chamber Paced&lt;sup&gt;8&lt;/sup&gt;</td>
<td>n/a</td>
<td>RV, LV; Simultaneous</td>
<td></td>
</tr>
<tr>
<td>Interventricular Pace Delay</td>
<td>n/a</td>
<td>20 – 80 in steps of 5 ms</td>
<td>± 3</td>
</tr>
<tr>
<td>V. Sensitivity&lt;sup&gt;9&lt;/sup&gt;</td>
<td>0.5 – 5.0 in steps of 0.5; 6.0 – 10.0 in steps of 1.0; 12.5 mV</td>
<td></td>
<td>± 30%&lt;sup&gt;10&lt;/sup&gt;</td>
</tr>
<tr>
<td>V. Pulse Configuration</td>
<td>Unipolar; Bipolar</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>V. Sense Configuration</td>
<td>BV Unipolar Tip; BV Bipolar</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>BV Unipolar Tip (RVtip+LVtip — Case); BV Bipolar (RVtip+LVtip — RVring+LVring); RV Unipolar Tip (RVtip — Case); RV Bipolar (RVtip — RVring); LV Unipolar Tip (LVtip — Case); LV Bipolar (LVtip — LVring); RV Unipolar Ring (RVring — Case); LVtip — RVtip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RV Lead Type</td>
<td>Uncoded; Unipolar; Unipolar/Bipolar</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>RV Pulse Amplitude</td>
<td>0.0 – 4.0 in steps of 0.25; 4.5 – 7.5 in steps of 0.5 V</td>
<td></td>
<td>± 30%&lt;sup&gt;11&lt;/sup&gt; &lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td>RV Pulse Width</td>
<td>0.05; 0.1 – 1.5 in steps of 0.1 ms</td>
<td></td>
<td>= 0.04</td>
</tr>
<tr>
<td>RV Pulse Configuration</td>
<td>n/a</td>
<td>Unipolar; Bipolar</td>
<td>n/a</td>
</tr>
<tr>
<td>LV Lead Type</td>
<td>Uncoded; Unipolar; Unipolar/Bipolar</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>LV Pulse Amplitude</td>
<td>0.0 – 4.0 in steps of 0.25; 4.5 – 7.5 in steps of 0.5 V</td>
<td></td>
<td>± 30%&lt;sup&gt;11&lt;/sup&gt; &lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td>LV Pulse Width</td>
<td>0.05; 0.1 – 1.5 in steps of 0.1 ms</td>
<td></td>
<td>± 0.04</td>
</tr>
<tr>
<td>LV Pulse Configuration</td>
<td>n/a</td>
<td>Unipolar; Bipolar; UVtip — RVtip</td>
<td>n/a</td>
</tr>
<tr>
<td>A. Lead Type</td>
<td>Uncoded; Unipolar; Unipolar/Bipolar</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>A. Pulse Amplitude</td>
<td>0.0 – 4.0 in steps of 0.25; 4.5 – 7.5 in steps of 0.5 V</td>
<td></td>
<td>± 30%&lt;sup&gt;11&lt;/sup&gt; &lt;sup&gt;12&lt;/sup&gt;</td>
</tr>
<tr>
<td>A. Pulse Width</td>
<td>0.05; 0.1 – 1.5 in steps of 0.1 ms</td>
<td></td>
<td>± 0.04</td>
</tr>
<tr>
<td>A. Sensitivity&lt;sup&gt;9&lt;/sup&gt;</td>
<td>0.1; 0.2; 0.3; 0.4; 0.5; 0.75; 1.0; 1.25; 1.5; 1.75; 2.0; 2.5; 3.0; 3.5; 4.0; 5.0&lt;sup&gt;13&lt;/sup&gt;</td>
<td>mV</td>
<td>± 30%&lt;sup&gt;14&lt;/sup&gt;</td>
</tr>
<tr>
<td>A. Pulse Configuration</td>
<td>Unipolar (Atip — Case); Bipolar (Atip — Aring)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>A. Sense Configuration</td>
<td>Unipolar Tip (Atip — Case); Unipolar Ring (Aring — Case)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Magnet Response</td>
<td>Off; Battery Test</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>AutoIntrinsic Conduction Search</td>
<td>n/a</td>
<td>Off, +10 to +120 in steps of 10 ms</td>
<td>± 8</td>
</tr>
<tr>
<td>Negative AV/PV Hysteresis vsSearch</td>
<td>Off, -10 to -110 in steps of 10 ms</td>
<td></td>
<td>± 8</td>
</tr>
<tr>
<td>Auto Mode Switch</td>
<td>Off, DDD to DDI; DDD to DDR; DDT(D) to DOT(D); DOT(D) to DOT(D); DDDR to DDI; DDDR to DDR; DTR(D) to DOT(D); DOT(D) to DDDR(1); DDDR to DDR; DTR(D) to DOT(D); DTR(D) to DDDR(1)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

<sup>6</sup> Biventricular: Two chambers pacing simultaneously.

<sup>7</sup> RV Only: Right ventricular pacing only.

<sup>8</sup> LV Only: Left ventricular pacing only.

<sup>9</sup> V. Sensitivity: Voltage level of the sensed signal.

<sup>10</sup> ± 30%: Tolerance for sensitivity levels.

<sup>11</sup> ± 30%: Tolerance for pulse amplitude.

<sup>12</sup> ± 30%: Tolerance for pulse width.

<sup>13</sup> ± 30%: Tolerance for sensitivity levels.

<sup>14</sup> ± 30%: Tolerance for pulse amplitude.
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Settings</th>
<th>Units</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMS Base Rate</td>
<td>n/a</td>
<td>min⁻¹</td>
<td>± 16</td>
</tr>
<tr>
<td></td>
<td>Base Rate +0 to Base Rate +35 in steps of 5 (Absolute Range 70 – 105 in steps of 5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A. Tachycardia Detection Rate</td>
<td>110 – 150 in steps of 5; 160 – 200 in steps of 10; 225 – 300 in steps of 25</td>
<td>ms</td>
<td>± 16</td>
</tr>
<tr>
<td>AF Suppression</td>
<td>n/a</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Off, On</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower Rate Overdrive¹</td>
<td>n/a</td>
<td>min⁻¹</td>
<td>± 4 ms</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Rate Overdrive¹</td>
<td>n/a</td>
<td>min⁻¹</td>
<td>± 4 ms</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of Overdrive Pacing Cycles</td>
<td>n/a</td>
<td>cycles</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15 — 40 in steps of 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rate Recovery¹</td>
<td>n/a</td>
<td>ms</td>
<td>± 10</td>
</tr>
<tr>
<td>Post Ventricular Atrial Blanking (PVAB)</td>
<td>60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 150; 155; 165; 170; 180; 185; 195; 200; 210; 220; 225; 235; 240</td>
<td>ms</td>
<td>± 16</td>
</tr>
<tr>
<td>V. Safety Standby</td>
<td>Off; On</td>
<td></td>
<td></td>
</tr>
<tr>
<td>V. Blanking</td>
<td>12 – 52 in steps of 4</td>
<td>ms</td>
<td>± 8</td>
</tr>
<tr>
<td>PVC Options</td>
<td>Off; +PVARP on PVC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PMT Options</td>
<td>Off; 10 Beats &gt; PMT; Auto Detect</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PMT Detection Rate</td>
<td>90 – 150 in steps of 5; 160 – 180 in steps of 10</td>
<td>min⁻¹</td>
<td>± 16 ms</td>
</tr>
<tr>
<td>Sensor</td>
<td>On; Off; Passive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum Sensor Rate</td>
<td>80 – 150 in steps of 5; 160 – 180 in steps of 10</td>
<td>min⁻¹</td>
<td>± 16 ms</td>
</tr>
<tr>
<td>Threshold</td>
<td>1 – 7 in steps of 0.5; Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0); Auto (+1.5); Auto (+2.0)</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Slope</td>
<td>1 – 16; Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3)</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Reaction Time</td>
<td>Very Fast; Fast; Medium; Slow</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Recovery Time</td>
<td>Fast; Medium; Slow; Very Slow</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

Table 9. Programmable Parameters, Settings, and Tolerances for Frontier II Model 5586 and Model 5596 Devices (Footnotes appear on page 24) (continued)

1. This parameter is not programmable.
2. The actual pacing rate for the 30 min⁻¹ setting is 31 min⁻¹.
3. The highest available setting for Hysteresis Rate will be 5 min⁻¹ below the programmed Base Rate.
4. Although 30 ms can be programmed, actual PV Delays will not be lower than 40 ms. Actual AV Delays can reach 30 ms.
5. In dual-chamber modes, the maximum setting for Ventricular Refractory Period is 325 ms.
6. Model 5586 allows biventricular pacing and RV-only pacing when interrogated with the Model 3510 Programming System with Model 3307 version 6.4.1 software or higher, or with the Merlin PCS Model 3650 with Model 3330 version 6.1.1 software or higher. If Model 5586 is interrogated with earlier versions of programmer software, only biventricular pacing is available.
7. Available only in Model 5596.
8. In simultaneous biventricular pacing, the pulse is delivered to the left ventricle first with a second pulse delivered 10 ms after the first.
9. Sensitivity is with respect to a 20 ms haversine test signal.
10. For < 1.0 mV setting, tolerance is ± 50%.
11. Tolerances are measured against impedances of 500 Ω and above.
12. For the 0.0 V setting, the tolerance is 0 – 75 mV.
13. Values 0.1 – 0.4 not available in a Unipolar Sense Configuration.
14. For settings of 0.75 mV and below, tolerance is ± 50%.
Physical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Model 5586</th>
<th>Model 5596</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Material</td>
<td>Titanium</td>
<td></td>
</tr>
<tr>
<td>Connector Material</td>
<td>Epoxy</td>
<td></td>
</tr>
<tr>
<td>Dimensions (mm)(^1)</td>
<td>49(h) x 52(l) x 6(t)</td>
<td></td>
</tr>
<tr>
<td>Weight (g)(^1)</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Volume (cm(^3))(^1)</td>
<td>11.5</td>
<td></td>
</tr>
<tr>
<td>Lead Connector</td>
<td>IS-1(^2)</td>
<td></td>
</tr>
</tbody>
</table>

Table 10. Physical Specifications
1. These values are nominal.
2. Accepts IS-1 short terminal pin leads.

Temperature Effects

<table>
<thead>
<tr>
<th>Parameter</th>
<th>at 20°C</th>
<th>at 43°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Rate</td>
<td>± 1%</td>
<td>± 1%</td>
</tr>
<tr>
<td>Test Rate</td>
<td>± 1%</td>
<td>± 1%</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>± 1%</td>
<td>± 1%</td>
</tr>
<tr>
<td>Pulse Amplitude</td>
<td>± 1%</td>
<td>± 1%</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>± 5%</td>
<td>± 1%</td>
</tr>
</tbody>
</table>

Table 11. Maximum Temperature Effect on Different Parameters\(^1\)
1. Parameter value deviation from 37°C.

Tolerances for Measured Telemetry Data

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial Pulse Amplitude (V)</td>
<td>± 10%</td>
</tr>
<tr>
<td>RV/LV Pulse Amplitude (V)</td>
<td>± 10% or 0.1 V, whichever is greater</td>
</tr>
<tr>
<td>Pulse Current (mA)</td>
<td>± 15%</td>
</tr>
<tr>
<td>Lead Impedance (Ω)</td>
<td>± 15%(^1)</td>
</tr>
<tr>
<td>Battery Current (µA)</td>
<td>± 15%</td>
</tr>
<tr>
<td>Battery Voltage (V)</td>
<td>± 5%</td>
</tr>
<tr>
<td>Battery Impedance (kΩ)</td>
<td>± (0.2 + 10%)</td>
</tr>
</tbody>
</table>

Table 12. Tolerances for Measured Telemetry Data
1. For Lead Impedance, the tolerance is ± 15% from 200 — 1999 Ω and ± 20% from 2000 — 2500 Ω.
Test Pulse Description

Figure 16. Test Pulse Description

Test Pulse Sensitivity

<table>
<thead>
<tr>
<th>Programmed Nominal</th>
<th>Min</th>
<th>Typical</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Signals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.5</td>
<td>0.55</td>
<td>0.57</td>
<td>0.60</td>
</tr>
<tr>
<td>1.0</td>
<td>1.05</td>
<td>1.11</td>
<td>1.20</td>
</tr>
<tr>
<td>5.0</td>
<td>5.05</td>
<td>5.36</td>
<td>5.75</td>
</tr>
<tr>
<td>10.0</td>
<td>10.25</td>
<td>10.81</td>
<td>11.50</td>
</tr>
<tr>
<td>Negative Signal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.5</td>
<td>– 0.70</td>
<td>– 0.64</td>
<td>– 0.60</td>
</tr>
<tr>
<td>1.0</td>
<td>– 1.30</td>
<td>– 1.24</td>
<td>– 1.20</td>
</tr>
<tr>
<td>5.0</td>
<td>– 6.30</td>
<td>– 5.86</td>
<td>– 5.55</td>
</tr>
<tr>
<td>10.0</td>
<td>– 12.70</td>
<td>– 11.78</td>
<td>– 11.10</td>
</tr>
</tbody>
</table>

Table 13. Test Pulse Sensitivity (mV) – Positive and Negative Signals, Ventricular Channel, 37°C

1. Sensitivity measured using the test pulse shown in Figure 16.

Battery Information

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power source</td>
<td>1 Lithium iodine cell</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Wilson Greatbatch Ltd. USA</td>
</tr>
<tr>
<td>Model</td>
<td>9438</td>
</tr>
<tr>
<td>Voltage at BOL</td>
<td>2.8 V</td>
</tr>
<tr>
<td>Voltage at ERI</td>
<td>2.5 V</td>
</tr>
<tr>
<td>Voltage at EOL</td>
<td>&lt; 2.2 V</td>
</tr>
<tr>
<td>Capacity between BOL and ERI</td>
<td>0.95 Ah</td>
</tr>
<tr>
<td>Capacity between ERI and EOL</td>
<td>0.05 Ah</td>
</tr>
</tbody>
</table>

Table 14. Battery Information
Current Drain

<table>
<thead>
<tr>
<th>Conditions</th>
<th>60 min</th>
</tr>
</thead>
<tbody>
<tr>
<td>VVI 100% Pacing²</td>
<td>12.8</td>
</tr>
<tr>
<td>VVI Inhibited²</td>
<td>9.0</td>
</tr>
<tr>
<td>DDD 100% Pacing³</td>
<td>22.6</td>
</tr>
<tr>
<td>DDD Inhibited³</td>
<td>11.4</td>
</tr>
</tbody>
</table>

Table 15. Current Drain (µA)
1. There is no difference in current drain when the Sensor is set to On or Off.
2. At 37°C, 3.5 V pulse amplitude, 0.4 ms pulse width, 500 Ω ventricular load, BOL.
3. At 37°C, 3.5 V pulse amplitude, 0.4 ms pulse width, 500 Ω atrial load, BOL.

Input Impedance

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input Impedance</td>
<td>30 - 75 kΩ</td>
</tr>
</tbody>
</table>

Table 16. Input Impedance

Output Pulse Characteristics

![Output Pulse Characteristics](image)

Figure 17. Output Pulse Characteristics¹⁷

¹⁷ The pulse amplitude is measured at 60 μs from leading edge of pulse. The pulse width is measured at 50% points on leading and trailing edges. The definition of pulse amplitude in this manual does not conform to EN50061.
Battery Discharge Curve

![Battery Discharge Curve](image)

**Figure 18. Battery Discharge Curve**

**Base Rate Escape Intervals**

<table>
<thead>
<tr>
<th>Base Rate Setting (min⁻¹)</th>
<th>Actual Base Rate (min⁻¹)</th>
<th>Tolerance (min⁻¹)</th>
<th>Interval (ms)</th>
<th>Tolerance (ms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>31.0</td>
<td>± 1</td>
<td>1938</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>40</td>
<td>40.0</td>
<td>± 1</td>
<td>1500</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>45</td>
<td>44.9</td>
<td>± 1</td>
<td>1336</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>50</td>
<td>49.9</td>
<td>± 1</td>
<td>1203</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>55</td>
<td>54.9</td>
<td>± 1</td>
<td>1094</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>60</td>
<td>60.0</td>
<td>± 1</td>
<td>1000</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>65</td>
<td>65.1</td>
<td>± 1</td>
<td>922</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>70</td>
<td>69.8</td>
<td>± 1</td>
<td>859</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>75</td>
<td>75.3</td>
<td>± 1</td>
<td>797</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>80</td>
<td>80.0</td>
<td>± 1</td>
<td>750</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>85</td>
<td>85.4</td>
<td>± 1</td>
<td>703</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>90</td>
<td>90.4</td>
<td>± 1</td>
<td>664</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>95</td>
<td>94.8</td>
<td>± 1</td>
<td>633</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>100</td>
<td>99.8</td>
<td>± 1</td>
<td>602</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>105</td>
<td>105.2</td>
<td>± 1</td>
<td>570</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>110</td>
<td>109.7</td>
<td>± 1</td>
<td>547</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>115</td>
<td>114.7</td>
<td>± 1</td>
<td>523</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>120</td>
<td>120.0</td>
<td>± 1</td>
<td>500</td>
<td>+ 30/- 8</td>
</tr>
<tr>
<td>125</td>
<td>125.9</td>
<td>± 1</td>
<td>477</td>
<td>+ 30/- 8</td>
</tr>
</tbody>
</table>

**Table 17. Base Rate Escape Intervals**

18. Predicted 140 kΩ constant resistance discharge.
Technical Support

You can speak directly to a Technical Support Representative 24 hours of every day for questions on any aspect of the device.

- Outside North America, call:
  +46 8 474 4147
  FAX: +46 8 760 5126 (during business hours only)
- In North America, call:
  +1 818 362 6822
  or (toll-free) +1 800 722 3774
  FAX number: +1 818 362 7182.

Your local St. Jude Medical representative can also provide customer assistance.

Symbols

The following symbols are used on St. Jude Medical™ devices.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDRV</td>
<td>NBG - atrial and ventricular pacing, atrial and ventricular sensing, inhibited response, rate-modulated, biventricular sensing and pacing</td>
</tr>
<tr>
<td>IS-1</td>
<td>Lead connector accepts unipolar or bipolar IS-1 (International Standard-1) short terminal pin leads.</td>
</tr>
<tr>
<td>AFsuppression</td>
<td>Equipped with AF Suppression™ algorithm.</td>
</tr>
<tr>
<td>STERILE EO</td>
<td>Contents are sterile; sterilized with ethylene oxide</td>
</tr>
<tr>
<td>BE MY US</td>
<td>Country of manufacture; BE- Belgium, MY- Malaysia, US- United States</td>
</tr>
<tr>
<td>Ce 0123</td>
<td>Affixed to this device in accordance with European Council Directive 90/385/EEC and 1999/5/EC. Hereby, St. Jude Medical declares that the pacemaker model is in compliance with the essential requirements and other relevant provisions of these Directives.</td>
</tr>
<tr>
<td>01</td>
<td>Affixed to this device in accordance with European Council Directive 1999/5/EC.</td>
</tr>
</tbody>
</table>

Table 17. Base Rate Escape Intervals

<table>
<thead>
<tr>
<th>Base Rate Setting (min⁻¹)</th>
<th>Actual Base Rate (min⁻¹)</th>
<th>Tolerance (min⁻¹)</th>
<th>Interval (ms)</th>
<th>Tolerance (ms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>130</td>
<td>130.2±1</td>
<td>± 1</td>
<td>461</td>
<td>± 30/-8</td>
</tr>
<tr>
<td>140</td>
<td>139.7±1</td>
<td>± 1</td>
<td>430</td>
<td>± 30/-8</td>
</tr>
<tr>
<td>150</td>
<td>150.6±2</td>
<td>± 2</td>
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