CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.
Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.
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CLINICAL STUDY - SUMMARY OF PULSAR MAX

SUMMARY

The exercise rate response of the PULSAR Max pacemaker was evaluated in a multi-center (13 US and 15 European centers) prospective study of the Minute Ventilation-only and blended sensor modes (accelerometer + minute ventilation) for the first month post-implant.

Patient Demographics

A total of 130 patients were implanted with the dual-chamber (DR) PULSAR Max pacemaker in a controlled, prospective study. In these patients, 110 Chronotropic Assessment Exercise Protocols (CAEPs) were performed (n = 56 blended, n = 54 MV only), and data were available for 96 of these (Table 1). The average implant duration was 5.8 months with a maximum implant duration of 7.2 months and a total cumulative implant experience of 754 device-months. The mean age of patients implanted with this device was 67.5 years, with a standard deviation of 13.2 years.

STUDY DESIGN

Methods

Rate response was evaluated using system diagnostic outputs during predischarge submaximal exercise using a low-intensity treadmill exercise (LITE) protocol for sensor optimization and 24-hour Holter monitoring. CAEP treadmill data were used to assess sensor-indicated rates at each exercise stage of the CAEP protocol using repeated treadmill tests (MV-only and blended sensor mode) at the one-month follow-up.

Table 1 provides a summary of patient characteristics. Table 2 lists the patient arrhythmia history.
# CLINICAL STUDY - SUMMARY OF PULSAR MAX

## STUDY DESIGN

### Table 1. Patient Population Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Model 1270 (N = 130)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Implant (years)</td>
<td></td>
</tr>
<tr>
<td>Minimum</td>
<td>18.2</td>
</tr>
<tr>
<td>Maximum</td>
<td>92.2</td>
</tr>
<tr>
<td>Mean</td>
<td>67.5</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>13.2</td>
</tr>
<tr>
<td>Gender (# of patients, %)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>81 (62.3%)</td>
</tr>
<tr>
<td>Female</td>
<td>49 (37.7%)</td>
</tr>
</tbody>
</table>

### Table 2. Patient Arrhythmia History

<table>
<thead>
<tr>
<th>Arrhythmias</th>
<th>Model 1270 (N = 130)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus Bradycardia</td>
<td>40</td>
</tr>
<tr>
<td>Sinus Arrhythmia</td>
<td>1</td>
</tr>
<tr>
<td>Paroxysmal Atrial Fibrillation</td>
<td>27</td>
</tr>
<tr>
<td>Atrial Fibrillation (AF) (Chronic)</td>
<td>1</td>
</tr>
<tr>
<td>Atrial Flutter</td>
<td>4</td>
</tr>
<tr>
<td>PSVT</td>
<td>3</td>
</tr>
<tr>
<td>PAT</td>
<td>5</td>
</tr>
<tr>
<td>Sinus Arrest</td>
<td>6</td>
</tr>
<tr>
<td>Sinus Node Dysfunction (Brady-Tachy Synchrony)</td>
<td>21</td>
</tr>
<tr>
<td>1st-Degree AV Heart Block</td>
<td>19</td>
</tr>
<tr>
<td>2nd-Degree AV Block (Mobitz I)</td>
<td>6</td>
</tr>
<tr>
<td>2nd-Degree AV Block (Mobitz II)</td>
<td>18</td>
</tr>
<tr>
<td>3rd-Degree AV Block</td>
<td>33</td>
</tr>
<tr>
<td>Left Bundle Branch Block</td>
<td>6</td>
</tr>
<tr>
<td>Right Bundle Branch Block</td>
<td>11</td>
</tr>
<tr>
<td>Arrhythmia Resulting from Ablation</td>
<td>4</td>
</tr>
</tbody>
</table>
Table 3 summarizes the programmed parameters for patients who performed CAEP exercise testing.

Table 3. Programmed Parameters During CAEP Testing (n = 55 patients)

<table>
<thead>
<tr>
<th>Brady Parameter</th>
<th>Mean</th>
<th>SD</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower Rate Limit</td>
<td>64</td>
<td>6.5</td>
<td>55</td>
<td>80</td>
</tr>
<tr>
<td>Maximum Sensor Rate</td>
<td>151</td>
<td>16.0</td>
<td>100</td>
<td>185</td>
</tr>
<tr>
<td>MV Rate Response Factor</td>
<td>5</td>
<td>1.7</td>
<td>3</td>
<td>11</td>
</tr>
</tbody>
</table>

The Expected Heart Rate (EHR) and the Sensor-Indicated Rate (SIR) at each stage of exercise were used to generate a slope of response to graded exercise testing (CAEP), using the Wilkoff model. Sensor-indicated rates of MV and blended sensor were measured in repeated (two) identical CAEP treadmill tests with MV or Blended sensor turned on. The EHR slope and the observed SIR slope responses were then compared. A slope of 1.0 was the expected response. Overall device safety and appropriate performance of the enhancement features were evaluated when the device was assigned to either the MV-only or blended sensor mode during the follow-up period.

STUDY RESULTS

Table 4 shows the summary statistics for exercise testing in blended sensor and MV-only modes. All patients completing exercise testing by mode, number percent and 95% confidence intervals.
The data for the MV Only and Blended Sensor CAEP tests demonstrate that the results met the acceptance criteria as defined in the PDP protocol Primary Efficacy Endpoint.

Figure 1 shows the relationship between expected heart rates and the observed sensor-indicated rates for all patients undergoing exercise testing in blended sensor mode. The analysis was based on a normalized interval average with the corresponding 95% confidence intervals, for all patients completing at least four stages of exercise.

### Table 4. Results of Exercise Testing – Total Clinical Population

<table>
<thead>
<tr>
<th>Population</th>
<th>n (% of pts)</th>
<th>Slope mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blended</td>
<td>51 (91%)</td>
<td>0.81 (0.73, 0.89)</td>
</tr>
<tr>
<td>MV only</td>
<td>45 (83%)</td>
<td>0.83 (0.74, 0.92)</td>
</tr>
</tbody>
</table>

The results met the acceptance criteria as defined in the PDP protocol Primary Efficacy Endpoint (95% confidence interval of the slope completely contained within...
These results demonstrate that the sensor-indicated rates in the overall population are proportional to increasing workload in a linear fashion as seen in the normal heart-rate-to-workload relationship.

**Subanalysis: Population Reaching Maximal Exertion**

Figure 2 summarizes the results from a subgroup of patients who reached maximal exertion at their final stage of CAEP exercise. This subgroup includes those subjects who did not terminate exercise testing prematurely due to an abnormal response (e.g., angina, drop in blood pressure) as defined by the American College of Sports Medicine.¹

Table 5 shows the summary statistics for exercise testing in blended sensor and MV-only modes.

The subset of the patients who exercised to their age-predicted maximal heart rate demonstrated a 95% confidence interval of the mean slope that falls within the normal range as defined by Wilkoff (0.80, 1.30). The results of exercise testing-population reaching maximal exertion are shown in Table 5.

Table 5. Results of Exercise Testing-Population Reaching Maximal Exertion

<table>
<thead>
<tr>
<th>Population</th>
<th>n (% of pts)</th>
<th>Slope mean (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blended</td>
<td>31 (55%)</td>
<td>0.92 (0.83, 1.01)</td>
</tr>
<tr>
<td>MV Only</td>
<td>29 (54%)</td>
<td>0.97 (0.89, 1.05)</td>
</tr>
</tbody>
</table>
