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CLINICAL SUMMARY

# **PULSAR MAX STUDY**

**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.

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## TABLE OF CONTENTS

<b>CLINICAL STUDY - SUMMARY OF PULSAR MAX</b> .....	<b>1</b>
Summary .....	1
Patient Demographics .....	1
Study Design .....	1
Methods .....	1
Study Results .....	3
Conclusion .....	4
Subanalysis: Population Reaching Maximal Exertion .....	5



## **CLINICAL STUDY - SUMMARY OF PULSAR MAX**

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### **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 pre-discharge 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.

**Table 1. Patient Population Characteristics**

Characteristic	Model 1270 (N = 130)
Age at Implant (years)	
Minimum	18.2
Maximum	92.2
Mean	67.5
Standard Deviation	13.2
Gender (# of patients, %)	
Male	81 (62.3%)
Female	49 (37.7%)

**Table 2. Patient Arrhythmia History**

Arrhythmias <sup>a</sup>	Model 1270 (N = 130)
Sinus Bradycardia	40
Sinus Arrhythmia	1
Paroxysmal Atrial Fibrillation	27
Atrial Fibrillation (AF) (Chronic)	1
Atrial Flutter	4
PSVT	3
PAT	5
Sinus Arrest	6
Sinus Node Dysfunction (Brady-Tachy Synchrony)	21
1st-Degree AV Heart Block	19
2nd-Degree AV Block (Mobitz I)	6
2nd-Degree AV Block (Mobitz II)	18
3rd-Degree AV Block	33
Left Bundle Branch Block	6
Right Bundle Branch Block	11
Arrhythmia Resulting from Ablation	4

**Table 2. Patient Arrhythmia History**

Arrhythmias <sup>a</sup>	Model 1270 (N = 130)
Intraventricular Conduction Delay	1
Other	23

a. Numbers may not be summed as some patients may be reported in more than one category.

Table 3 summarizes the programmed parameters for patients who performed CAEP exercise testing.

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

Brady Parameter	Mean	SD	Minimum	Maximum
Lower Rate Limit	64	6.5	55	80
Maximum Sensor Rate	151	16.0	100	185
MV Rate Response Factor	5	1.7	3	11

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

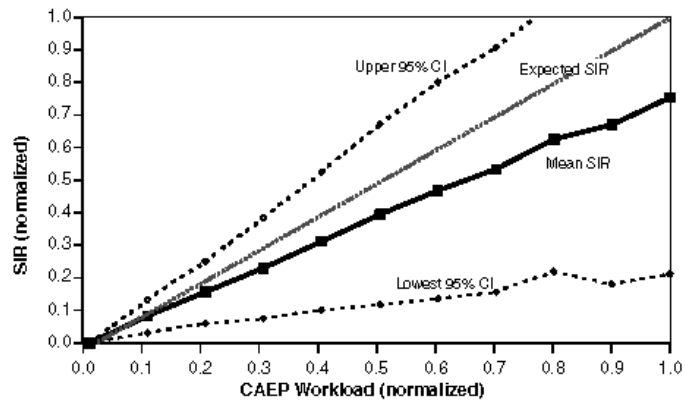
Table 4 shows the summary statistics for exercise testing in blended sensor and MV-only modes. All patients completing exercise testing by mode, number percent and 95% confidence intervals.

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

Population	n (% of pts)	Slope mean (95% CI)
Blended	51 (91%)	0.81 (0.73, 0.89)
MV only	45 (83%)	0.83 (0.74, 0.92)

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.



**Figure -1. Sensor-indicated rate (SIR) vs expected rate during CAEP. All patients completing at least four stages of exercise, blended sensor only. (n = 46, 1 month)**

## Conclusion

The results met the acceptance criteria as defined in the PDP protocol Primary Efficacy Endpoint (95% confidence interval of the slope completely contained within



[0.65, 1.35]). 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.<sup>1</sup>

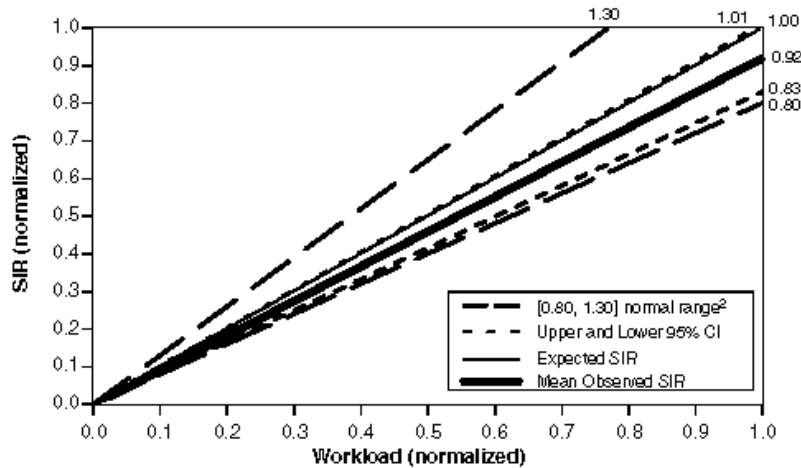


Figure -2. Sensor-indicated rate (SIR) vs expected rate during CAEP (1 month). Patients reaching maximal workload, blended sensor mode. Expected rate, mean, and normal range. (n = 31)

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

1. ACSM Guidelines for Exercise Testing and Prescriptions. 4th ed. Philadelphia: Lea & Febiger; 1991.

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

Population	n (% of pts)	Slope mean (95% CI)
Blended	31 (55%)	0.92 (0.83, 1.01)
MV Only	29 (54%)	0.97 (0.89, 1.05)

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)<sup>1</sup>.

1. Wilkoff, et al. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology. 1989;3:176-180.



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