The AutoCapture™ (AC) Pacing System truly represents the next generation in pacemaker automaticity and simplicity. Evoked response signal detection and low polarization lead technology make beat-to-beat capture verification feasible. Low outputs reduce energy consumption while the high output back-up pulse eliminates the need to arbitrarily program the device with high outputs to maintain a 2:1 safety margin, the standard for non AutoCapture devices.

Clinical Benefits of the AutoCapture™ Algorithm

- Patient safety and physician peace of mind (Beat-by-Beat® capture)
- Maximum patient comfort with programmable polarity (unipolar or bipolar) for the back-up pulse
- Output automatically adjusts beat-by-beat to patient’s changing threshold needs
- Automatic threshold search will save the clinician time during routine follow-up visits
- No need to measure, calculate, and program ventricular pacing threshold safety margins
- Efficient control of output resulting in an increase in device longevity

Clinical Results

St. Jude Medical conducted a study consisting of 137 patients where implantation data was reviewed for all patients. Of these patients, 80 (58%) were male and 57 (42%) were female. The primary indication for implant was persistent intermittent AV block. The AutoCapture pacing system feature demonstrates 96.6% compatibility with the Passive Plus® DX and Tendril® DX steroid-eluting pacing leads at the three-month follow-up interval.

Based on the success of the AutoCapture pacing system as documented by surface ECGs, a lower 95% confidence bound was obtained, which indicated that the AutoCapture pacing system will be successful at least 99% of the time.

Table 1: ECG Analysis Results

<table>
<thead>
<tr>
<th>Follow-up Evaluation</th>
<th>Implant</th>
<th>Predischarge</th>
<th>1 Month</th>
<th>3 Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>134</td>
<td>131</td>
<td>116</td>
<td>60</td>
</tr>
<tr>
<td>Paced Events</td>
<td>4472</td>
<td>3709</td>
<td>2721</td>
<td>1314</td>
</tr>
<tr>
<td>Losses of Capture*</td>
<td>176</td>
<td>168</td>
<td>232</td>
<td>133</td>
</tr>
<tr>
<td>Losses of Capture Followed by a Back-up Pulse</td>
<td>176</td>
<td>168</td>
<td>232</td>
<td>133</td>
</tr>
<tr>
<td>Percentage Loss of Capture with a Back-up Pulse</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

* Loss of capture from primary pacing pulse

The investigators concluded that use of the AutoCapture pacing system feature increased over time (from implant to 3 months) to 96.6%.

Figure 1: Percent of ER tests which recommended use of AC pacing system

The AutoCapture pacing system algorithm delivered a back-up safety pulse in 100% of the instances of loss of capture. This study confirms the safety and efficacy of the AutoCapture pacing system algorithm when used with Passive Plus DX and Tendril DX steroid-eluting pacing leads. ¹

Sermasi and colleagues report their experience with 54 patients (mean age 76) who received a Microny® SR+ model 2425T pulse generator for management of chronic atrial fibrillation with high grade AV block. The automatic capture threshold was shown to function properly with a good correlation between the Vario threshold measurement. In addition, there were NO episodes in which the system reported capture being present when there was actually loss of capture. The investigators conclude that AutoCapture provided absolute safety for the patient, while keeping the output as low as possible to maximize pulse generator longevity.²

Guerola and colleagues conducted a multicenter clinical study that involved 113 units implanted (57 males and 56 females). In the majority of patients the indication was atrial fibrillation with slow ventricular response. Analysis of 3.7 million beats from the Holter recordings verified that every single event of loss of capture was followed by a successful back-up pulse. The investigators concluded that AutoCapture pacing system monitors and regulates the stimulation outputs safely and reliably in all patients. Without compromising any safety margins, the algorithm reduces energy consumption and increases the output in case of unexpected threshold rises.³

"AutoCapture is an ingenious, yet simple invention—the greatest advance in pacing since the lithium battery."

- Dr. Malcom Clarke, FRCP, FACC

"AutoCapture monitors and regulates the stimulation output safely and reliably in all patients. Without compromising any safety margins, the algorithm reduces energy consumption and increases the output in case of an unexpected threshold rise."

- Dr. Modesto Gurola

The investigators concluded that use of the AutoCapture pacing system feature increased over time (from implant to 3 months) to 96.6%.
The AutoCapture™ algorithm

- Is designed to provide optimum patient safety, peace of mind, and extended device longevity.
- Provides the tools needed to manage changing patient thresholds by confirming capture on a beat-by-beat basis, providing a back-up safety pulse, and adjusting ventricular output accordingly.

How the algorithm works

The AutoCapture pacing system is an algorithm designed to confirm a response (capture) to each pacemaker stimulation and to automatically adjust the energy output of the primary pacing pulse to changes in the patient’s capture threshold. This principle is based on the ability of the pacemaker to recognize the evoked response without being misled by the residual polarization at the electrode-tissue interface. To make this assessment, a quick automatic Evoked Response Sensitivity Test is conducted. Once the sensitivity is programmed, the AutoCapture pacing system monitors every beat for the presence of an evoked response signal and assures capture through four basic steps: 1) Capture confirmation, 2) Loss of capture recovery, 3) Threshold search and 4) Automatic output regulation.

Changes in patient threshold may actually exceed traditional fixed output settings of 2X to 3X measured threshold resulting in loss of capture.

Why is St. Jude Medical better?

St. Jude Medical’s Ventricular AutoCapture Algorithm verifies capture on a beat-by-beat basis to ensure the highest patient safety available. It combines several years of clinical experience and ease of use to become the premier algorithm of choice. Increased longevity and smaller size results in fewer device replacements and a higher quality of life for the patient.

1 This report is based on PMA data corresponding to the FDA report dated December 23, 1996, and summarizes the results of the Microny SR+, Model 2425T and Regency SR+ Model 2400L clinical investigation conducted in North America.


