DESCRIPTION

The Microny™ SR+ Model 2425T is a small, rate-responsive, multi-programmable, multi-mode, single-chamber pulse generator for either ventricular or atrial applications.

The device is equipped with the AutoCapture™ Pacing System in VVI mode. This system automatically sets the ventricular pulse amplitude and regularly adjusts the setting according to the patient's measured capture threshold.

The Microny™ SR+ pulse generator provides rate-responsive pacing through its activity-responsive magnetic-ball sensor. The device is not polarity programmable with fixed bipolar sensing and fixed unipolar pacing, which requires use of a bipolar lead.

The Microny™ SR+ can be programmed with a Pacesetter APS® II programmer with Model 3204a or higher software, the APS®µ hand-held programmer, and Models 3500 and 3510 programmers with Model 3304 software.

INDICATIONS AND USAGE

The Microny™ SR+ is indicated for:

- Accepted Patient Conditions warranting chronic cardiac pacing which include:
  - sick sinus syndrome
  - chronic, symptomatic second- and third-degree AV block
  - recurrent Adams-Stokes syndrome
  - symptomatic bilateral bundle branch block when tachy-arrhythmia and other causes have been ruled out.
- Atrial Pacing in patients with sinus node dysfunction and normal AV and intraventricular conduction systems.
- Ventricular Pacing in patients with significant bradycardia and:
  - normal sinus rhythm with only rare episodes of A-V block or sinus arrest requiring short periods of pacing support
  - chronic atrial fibrillation
  - severe physical disability.
- Rate-Modulated Pacing in patients who would benefit from increased pacing rates concurrent with physical activity.

CONTRAINDICATIONS

The Microny™ SR+ is contraindicated for:

- Single-Chamber Ventricular Demand Pacing in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or who suffer a drop in arterial blood pressure with the onset of ventricular pacing.
- Single-Chamber Atrial Pacing in patients who have demonstrated compromise of AV conduction.
- Rate-Modulated Pacing in patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates.

- Unipolar Pacing in patients with an implanted cardioverter-defibrillator (ICD) since it may inhibit or trigger ICD therapy. The Microny™ SR+ is programmed to unipolar pacing and may be inappropriate for patients with an ICD.

WARNINGS AND PRECAUTIONS

PACEMAKER AND LEAD SELECTION

- Compatible Pacing Leads. Prior to implantation, make sure the pacing lead fits easily and snugly into the pulse generator's header.
- AutoCapture™ Pacing System Lead Compatibility. The AutoCapture™ Pacing System will operate only with a low polarization, bipolar pacing lead. Before implanting a lead, verify compatibility by conducting the E/R Sensitivity Test. For more information on AutoCapture™-compatible leads, contact your St. Jude Medical Cardiac Rhythm Management Division representative or Technical Services (page 39).

PACEMAKER-DEPENDENT PATIENTS

- Emergency VVI. When programming the pulse generator to Emergency VVI settings, press the programmer's Emergency VVI or Programmer Reset button only once. For a complete list of emergency settings, see Table 16 on page 36.
- Pulse Amplitude. If the AutoCapture™ Pacing System is not in use or if the lead is implanted in the atrium, determine the capture threshold before programming the Pulse Amplitude. Program Pulse Amplitude to yield a suitable safety margin for reliable, long-term capture. Reassess capture thresholds periodically.
- Recommended Replacement Time (RRT). At RRT, the nominal life of the pulse generator is three months.

When the pacemaker exhibits signs of RRT, it should be replaced expeditiously. RRT is indicated by:

- Magnet test rate below 81 ppm
- Test rate interval greater than 706 ms
- Cell impedance of 15 kΩ or greater
- battery voltage decrease to 2.65 volts
- the Sensor automatically programmed to Off.

Patient follow-up visits should be scheduled at an appropriate frequency so RRT can be detected well before EOL. See "Battery Status Indicators" on page 35.

MEDICAL THERAPY

- Electrosurgery. Do not use electrosurgical devices in the vicinity of an implanted pulse generator. If electrocautery is necessary, use a bipolar cauterizer or place the indifferent electrode as far from the pulse generator as possible. The axis of the electrocautery should be perpendicular to the electrode axis.
- Lithotripsy. Do not focus a lithotripsy beam within six inches of the pulse generator. Program the pulse generator to Sensor Off prior to lithotripsy to prevent inappropriate

increases in pacing rate. A thorough assessment of pulse generator function should be performed following exposure to lithotripsy.

- Therapeutic Radiation should not be used in the vicinity of an implanted pulse generator. Radiation therapy may damage the microprocessor circuitry of a pulse generator.
- Ultrasound Treatment. To avoid damage to the pulse generator, do not use therapeutic ultrasound within six inches of the pulse generator. Ultrasound energy may cause mechanical damage to the device.

PERFORM A THOROUGH ASSESSMENT OF PULSE GENERATOR FUNCTION FOLLOWING EXPOSURE TO ANY OF THE ABOVE.STORAGE AND RESTERILIZATION

- For single use only.
- Do not implant or resterilize a pulse generator that has been contaminated by contact with body fluids.
- Do not resterilize the pulse generator more than once.
- Do not implant a pulse generator from a damaged package without resterilizing it.
- To sterilize the pulse generator, use ethylene oxide gas at temperatures not exceeding +50 °C (122 °F), according to the sterilizer manufacturer's instructions. Allow proper aeration per local and national ordinances.[1]
- Do not sterilize the pulse generator with an autoclave, steam, gamma radiation, or ultrasonics.
- If you suspect the pulse generator has been damaged, do not implant it; return it to the manufacturer.
- Do not subject the pulse generator to temperatures above +50 °C (122 °F) or below 0 °C (32 °F). Exposure to low temperatures may cause a temporary high battery impedance reading until the device has returned to normal room temperatures.
- Do not incinerate the pulse generator.

PACKAGING

The Microny™ SR+ pulse generator is packaged one per package in a sterile package. Prior to opening the sterile package:

- Verify that the package contains the correct pulse generator.
- Verify that the pulse generator is operating properly by positioning the programmer telemetry head over the package and selecting "interrogate." The unit's Measured Data should indicate normal voltage and battery status, and the programmed parameters should be identical to the Shipped Settings on the package label.
- Verify that the package has not been opened or in any way compromised. If damage is suspected, return it to the manufacturer.
- Do not implant the pulse generator after the "use before" date printed on the label.

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[1] See also ANSI/AAMI ST41:1999 – Ethylene oxide sterilization in health care facilities. Safety and effectiveness.

Observe complete sterile technique when opening the package's inner tray. The package's outer tray may be opened in non-sterile surroundings.

Lead Evaluation and Lead Connection

- Connector compatibility. Do not use any lead with this pacemaker without first verifying connector compatibility.
- Set-Screw. When connecting a lead, exercise caution when turning the set-screw. A set-screw may back out of the terminal block if turned excessively counterclockwise.

Programming and Pacemaker Operation

Pre-Implant Testing. Test the device using a pacing system analyzer (PSA) with recently calibrated sensitivity and output settings. When the probe is attached to the pulse generator's connector, the programmed parameters should be identical to the Shipped Settings listed on the package label. When performing the PSA test a constant voltage setting should be used.

- Capture/Sensing Thresholds. Determine capture and sensing thresholds with a PSA before implanting the pulse generator. When performing the PSA test a constant voltage setting should be used. Connect the negative (black) PSA terminal to the portion of the lead terminal pin corresponding to the tip electrode. The positive (red) terminal should be connected to the ring electrode portion of the lead pin for bipolar leads or to an indifferent electrode. For more information, consult the PSA technical manual and the programmer's Programming Guide.
- The Microny™ SR+ pulse generator limits the time at which the sensor-indicated rate will operate above 140 ppm to 15 minutes. The feature acts as a "watchdog" to prevent potentially dangerous high rates for extended periods of time.
- Programming. The Microny™ SR+ can be programmed with the APS® II, APS®µ, and the Model 3500 and Model 3510 programmers. For more information on programming the Microny™ SR+, refer to the programmer's Programming Guide.
- Unipolar Pulse Configuration. Implant the pulse generator with its uncoated (logo) side up to minimize the potential for pocket stimulation.

Environmental and Medical Therapy Hazards

The Microny™ SR+ is equipped with special shielding and filters to reduce the adverse effects of electromagnetic interference (EMI) on the device.

Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields. If the pacemaker 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 pulse generator, including areas protected by a warning notice preventing entry by pacemaker patients.

Hospital and Medical 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. Certain hospital equipment may prompt the activity sensor to generate strong sensor signals which may cause inappropriately high pacing rates.

- External Defibrillation. Do not place defibrillator paddles directly over the pulse generator or pacing lead Placing the defibrillator paddles too close to the pulse generator and the pacing leads could generate a high current into the leads and the pulse generator damaging the defibrillation protection circuit or other circuitry. 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 pacemaker. The extremely strong magnetic fields generated during MRI may cause the pulse generator to temporarily pace in the asynchronous mode (VOO or AOO) at the magnet test rate and reverts the device to Magnet mode The magnet test rate is between 60 ppm and 100 ppm, depending on remaining battery capacity.
- Ionizing Radiation. Therapeutic ionizing radiation (e.g., used in linear accelerators and cobalt machines) can permanently damage the pulse generator's circuitry. The effect of ionizing radiation is cumulative; the potential for damage to the pulse generator is proportional to the patient's total radiation dosage. If the patient must be exposed to ionizing radiation, protect the pulse generator during the procedure with local radiation shielding. If tissue near the implant site must be irradiated, it may be necessary to move the pulse generator to another area. Before and after exposure to radiation, evaluate the pulse generator operation to identify any adverse consequences.
- Transcutaneous Electrical Nerve Stimulation (TENS). To reduce the possibility of interference with pacemaker function, place the TENS electrodes close to one another and as far from the pulse generator as possible. Monitor the patient's cardiac activity throughout the procedure.
- Therapeutic Diathermy. Avoid using diathermy equipment, including therapeutic ultrasound, in the vicinity of the pacemaker.
- Electrosurgical Cautery can induce ventricular arrhythmias and/or fibrillation or may cause asynchronous or inhibited pulse generator operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the pulse generator and leads as possible. The axis of the electrocautery should be perpendicular to the electrode axis. A bipolar cauterizer may minimize these effects. Following electrocautery, conduct a thorough assessment of the pulse generator.

Home and Occupational Environments

- High-Voltage transmission lines and equipment, arc or resistance welders, induction furnaces, and similar equipment may generate substantial EMI fields which may interfere with pulse generator operation.
- Communication Equipment such as microwave transmitters,[2] linear power amplifiers, or high-power amateur transmitters may generate sufficient EMI to interfere with pacemaker operation. Advise patients to move away from this equipment to resume normal pacemaker operation.

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[2] Home appliance microwave ovens do not interfere with pulse generator operation.

- Home Appliances which are in good working order and properly grounded do not usually produce enough EMI to interfere with pacemaker operation. Electric vibrators, razors, and handtools held directly over the pacemaker may disturb pacemaker function.
- Patient Activities which involve repetitive impacts or jarring (such as horseback riding, jackhammer use, etc.) may increase the pacing rate when the pulse generator's Sensor is programmed On. Caution patients against such activity and program Sensor parameters with these activities in mind. The sensor is mounted in such a way that the ball moves more freely and generates stronger signals when the patient is in an upright position, generating weaker signals when the patient is supine.
- 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 path of the beam.
- No Pacer Symbol. Caution pacemaker patients to be cognizant of labeling in EMI fields, such as with EAS detection.

Cellular Telephones

Studies indicate there may be a potential interaction between cellular phones and pacemaker operation. When the phone is within six inches of the pulse generator, effects could include inhibition or asynchronous pacing. Any effects resulting from an interaction between cellular phones and implanted pacemakers are temporary. Moving the phone away from the device will return it to its previous state of operation.

Because of the great variety of cellular phones and the wide variance in patient physiology, an absolute recommendation to cover all patients cannot be made. The following is a general guideline for patients with an implanted pulse generator who desire to operate a cellular phone:

- Maintain a minimum separation of six (6) inches between a hand-held cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to hand-held models. For phones transmitting above three watts, a minimum separation of 12 inches between the antenna and the implanted device is advised.
- Patients should hold the phone to the ear opposite the side of the implanted device.
- Patients should not carry the phone in a breast pocket, or on a belt over or within six inches of the implanted device as some phones emit signals only when they are turned on but not in use).
- Storing the phone in a location opposite the side of the implant is recommended.

ADVERSE EVENTS

The clinical study evaluating the Microny™ SR+ and Regency® SR+ pulse generators when used with the Passive Plus® DX (Model 1346T) and Tendril® DX (Model 1388T) steroid-eluting pacing leads involved 324 Regency® SR+ and 178 Microny™ SR+ devices implanted in 502 patients. The study's cumulative implant duration was 11,196 months with a mean implant duration of 678 ± 298 days (range of 0 to 1,093 days). A total of 72 deaths were reported during the course of the study. Investigators judged that none of the deaths were device-related. The Regency® SR+ device will not be marketed in the US. Regency® SR+ operates the same as the Microny™ SR+, except it has a larger capacity battery and therefore the clinical results using the Regency® SR+ can also be applied to the Microny™ SR+.

OBSERVED ADVERSE EVENTS

An Adverse Event was defined as any unfavorable clinical event which impacted or had the potential to impact the health or safety of a Clinical Study participant caused by, or associated with, a study device or intervention. An Adverse Event can occur during exposure to the procedure, exposure to the device, and/or at implant.

All adverse events have been classified as a complication or an observation. A complication was defined as any adverse event resulting in an injury or an invasive intervention (e.g., lead repositioning after lead dislodgment) which would not have occurred in the absence of the implanted device and/or system components. An observation was defined as any adverse event that was not associated with injury to the patient or an invasive intervention (e.g., reprogramming to adapt for an unusually high capture threshold).

Table 1 summarizes the adverse events reported and classified as complications during the study.

*Table 1. Complications**

Type of Complication	# of Patients	% of Patients	# of Events	Events per Device-year*	Events per Patient-Month**
Lead Dislodgement	9	1.8	9	0.00966	0.00080
Lead Replacement	2	0.4	2	0.00215	0.00018
Failure to Capture	2	0.4	2	0.00215	0.00018
Oversensing	1	0.2	1	0.00107	0.00009
High Lead Impedance	1	0.2	1	0.00107	0.00009
Premature Battery Depletion	1	0.2	1	0.00107	0.00009
Repositioning of Implant	1	0.2	1	0.00107	0.00009
Infection	1	0.2	1	0.00107	0.00009
No Venous Access	1	0.2	1	0.00107	0.00009
Pulse Generator Replacement	1	0.2	1	0.00107	0.00009

* All patients implanted (502 pulse generators out of 502 patients). Total 932 patient-years follow-up. Cumulative implant duration = 11,196 device months
† One patient had more than 1 event reported.
‡ This rate is obtained by dividing the number of adverse events by the total device cumulative implant duration in years.
** This rate is obtained by dividing the number of adverse events by the total patient cumulative implant duration in months.

Table 2 on page 8 summarizes the adverse events reported and classified as observations during the study.

*Table 2. Observations**

Type of Observation	# of Patients†	% of Patients	# of Events	Events per Device-Year‡	Events per Patient-Month**
Programmer Software Error	17	3.4	17	0.01824	0.00152
Undersensing	4	0.8	4	0.00429	0.00036
Blunted Sensor Response	3	0.6	3	0.00322	0.00027
Pocket Stimulation	3	0.6	3	0.00322	0.00027
Acute Lead Dislodgement/Instability	3	0.6	3	0.00322	0.00027
Intermittent Capture	3	0.6	3	0.00322	0.00027
High Capture Threshold	2	0.4	2	0.00215	0.00018
Low E/R Signal Amplitude	2	0.4	2	0.00215	0.00018
E/R Undersensing	2	0.4	2	0.00215	0.00018
No E/R Signal	1	0.2	1	0.00107	0.00009
Oversensing	1	0.2	1	0.00107	0.00009
No Sensor Response	1	0.2	1	0.00107	0.00009
Pacemaker Syndrome	1	0.2	1	0.00107	0.00009
High Polarization Value	1	0.2	1	0.00107	0.00009
Failure to Capture	1	0.2	1	0.00107	0.00009
Syncope	1	0.2	1	0.00107	0.00009
Reprogramming	1	0.2	1	0.00107	0.00009
Stripped Set-screw	1	0.2	1	0.00107	0.00009
Hematoma	1	0.2	1	0.00107	0.00009

* All patients implanted (502 pulse generators out of 502 patients). Total 932 patient-years follow-up. Cumulative implant duration = 11,196 device months.

† Four patients had more than 1 event reported.
‡‡ This rate is obtained by dividing the number of adverse events by the total device cumulative implant duration in years.
** This rate is obtained by dividing the number of adverse events by the total patient cumulative implant duration in months.

POTENTIAL ADVERSE EVENTS

Adverse events, including those reported in Table 1 on page 7, associated with the use of any pacing system include:

- Air embolism
- Bleeding/hematoma
- Body rejection phenomena
- Cardiac tamponade or perforation
- Formation of fibrotic tissue; local tissue reaction
- Inability to interrogate or program due to programmer or device malfunction
- Infection/erosion
- Interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic
- Lead malfunction due to conductor fracture or insulation degradation
- Loss of capture or sensing due to lead dislodgment or reaction at the electrode/tissue interface
- 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 device function due to battery failure or component malfunction
- Pacemaker migration, pocket erosion, or hematoma
- Pectoral muscle or diaphragmatic stimulation
- Phrenic nerve stimulation
- Pneumothorax/hemothorax.

CLINICAL STUDIES

The "Microny SR+ and Regency SR+ Clinical Trial" was conducted using the Microny™ SR+ Model 2425T and Regency® SR+ Model 2400L pulse generators along with the Passive Plus® DX model 1346T and Tendril® DX model 1388T. The Regency® SR+ device will not be marketed in the US. Regency® SR+ operates the same as the Microny™ SR+, except it has a larger capacity battery and therefore the clinical results using the Regency® SR+ can also be applied to the Microny™ SR+. The Microny™ and Regency® pacing system was evaluated in a multicenter (37 US centers and 7 Canadian centers) clinical trial involving 502 patients.

The primary objectives of the clinical trial were to: 1) evaluate the safety and efficacy of the ventricular AutoCapture™ Pacing System algorithm, and 2) to evaluate the rate-modulation capability of the device's activity sensor during Chronotropic Assessment Exercise Protocol (CAEP) treadmill test.

The clinical study was conducted in two parts, one for evaluating the AutoCapture™ Pacing System and the other, to evaluate the Casino sensor. Results of these two evaluations are presented separately below under the appropriate headings.

PATIENT POPULATION

The overall study population consisted of 502 enrolled patients. .All patients were evaluated for safety, 137 patients were evaluated for AutoCapture™ effectiveness and 46 patients were evaluated for Sensor performance. Of these patients, 291 (58%) were males and 211 (42%) were females. The mean age at implant was 71 ± 17 years. Indications for pulse generator implantation in the study population are summarized in Table 3. As some patients had more than one indication, the total number of indications exceeds the number of patients in the study.

The mean duration of implant for all patients in the study was 22.3 months, ± 9.8 months (minimum duration: 0 months; maximum duration: 36 months).

Table 3. Indications for Implantation

Indication	Number of Patients
Persistent or Intermittent AV Block	172 (34%)
Bradycardia-Tachycardia Syndrome	122 (24%)
Sick Sinus Syndrome	96 (19%)
Sinus Bradycardia	62 (!2%)
Atrial Fibrillation/Atrial Flutter	37 (7%)
Sinus Node Arrest or Exit Block	9 (2%)
Chronotropic Incompetence	4 (0.8%)
Not Reported	15 (3%)

AUTOCAPTURE™ PACING SYSTEM EVALUATION

The AutoCapture™ Pacing System was evaluated in a multicenter (15 US centers and 7 Canadian centers) clinical trial involving 137 patients implanted with 138 devices.

The purpose of this part of the study was to assess the ability of the AutoCapture™ Pacing System to correctly identify loss of capture and to deliver an appropriate backup safety pulse to ensure 100% pacing as verified by a surface ECG and 24-hour Holter monitoring data.

Table. 4 Indications for Implantation

Indication	Number of Patients
Persistent or Intermittent AV Block	56
Bradycardia-Tachycardia Syndrome	33
Sick Sinus Syndrome	24

Atrial Fibrillation/Flutter	19
Sinus Bradycardia	8
Sinus Node Arrest or Exit Block	5

PATIENT POPULATION

Of the 137 patients enrolled in the study, 80 (58.4%) were males and 57 (41.6%) were females. The age at implant ranged from 22 to 96 years with a mean of 73 (± 13) years.

Indications for implantation in the study population are summarized in Table 4. Because some patients had more than one indication, the total number of indications exceeds the number of patients in the study.

METHODS

The AutoCapture™ Pacing System's stored diagnostic data summarizing the number of capture losses and backup safety pulses were compared to the results of a surface ECG taken at the time of implant, pre-discharge, one-month follow-up, and three-month follow-up.

The AutoCapture™ Pacing System's stored diagnostic data was also compared to the results of a 24-hour Holter monitor conducted on all patients within one month of the device implantation. Patients were also asked to record their activities during the monitoring period in a diary, and the Holter data was checked against the diary entries.

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Table 5. ECG Analysis Results

Analysis Date	Patients (N)	Events Analyzed (N)	Paced Events (N)	Capture Losses (N)	Capture Losses Followed By A Backup Pulse (N)	Capture Losses Followed By A Backup Pulse (%)
Implant	134	4,719	4,472	176	176	100%
Pre-discharge	131	3,915	3,709	168	168	100%
One Month	116	2,832	2,721	232	232	100%
Three Month	60	1,526	1,314	133	133	100%

Table 6. Holter Monitoring Analysis Results

Time Recorded (Hours)	Events Analyzed (N)	Paced Events (N)	Capture Losses (N)	Capture Losses Followed By A Backup Pulse (N)	Capture Losses Followed By A Backup Pulse (%)
1,157	4,949,313	2,031,279	820	820	100%

RESULTS

In Table 5, the number of losses of capture threshold recorded by the ECG is compared to the number of capture losses followed by a backup safety pulse as recorded by the AutoCapture™ Pacing System. The analysis found that every instance of capture loss recorded by the ECG was recognized by the AutoCapture™ Pacing System. In addition, each loss of capture was followed by a backup safety pulse as required by the AutoCapture™ Pacing System.

Table 6 presents the results of the Holter monitoring analysis, taken at one-month follow-up. A total of 820 instances of loss of capture were recorded on Holter monitoring, and the same number (100% consistency) were recorded by the AutoCapture™ Pacing System. In addition, every instance (100%) of loss of capture was appropriately followed by a backup safety pulse.

SUMMARY

These results of ECG and Holter monitoring analyses demonstrate that the AutoCapture™ Pacing System can safely provide a pacing stimulus by accurately detecting loss of capture and delivering a backup pulse for each capture loss.

SENSOR EVALUATION

The objective of this part of the study was to evaluate the rate-modulation capability of the device's activity sensor. This was accomplished by performing both a hall-walk test and a Chronotropic Assessment Exercise Protocol (CAEP) treadmill test in study patients.

The hypothesis was: the activity sensor provides a rate-response (sensor-indicated rate or SIR) which is similar to the predicted heart rate response based on the Wilkoff model.[3]

METHODS

SIR was evaluated using the pacing system's diagnostic data during hall-walk testing and exercise testing to generalized exhaustion using a modified Chronotropic Assessment Exercise Protocol (CAEP).

PATIENT POPULATION

A total of 46 patients were included in this study. Of those patients, 27 (58.7%) were male and 19 (41.3%) were female. The ages of the patient population at the time of implant ranged from 35 to 98 years with a mean of 72.4 ± 14.8 years.

Patient indications for implant were consistent with the overall study patient population and patients who réquire single chamber pacing. The indications are summarized in Table 7. (Patients could have more than one indication.) All implants were pectoral. The mean duration of implant to the date the hall-walk and treadmill test was performed was 21.4 ± 9.6 months, ranging from 0.9 to 33.8 months.

Table 7. Indications for Sensor Evaluation

Indication	Number of Patients
AV Block	21
Bradycardia-Tachycardia Syndrome	16
Sick Sinus Syndrome	3
Atrial Fibrillation/Flutter	5
Sinus Bradycardia	2
Sinus Node Arrest	2

RESULTS

Of the 46 enrolled, 30 patients were used in the final analysis. Sixteen (16) patients were excluded from analysis because they did not complete the required minimum number of stages of CAEP (N=13) or because data was not available (N=3).

Hall-walk Analysis

The hallwalk test is routinely used by the clinician to optimize the sensor to the individual patient's activity level. All patients who underwent CAEP treadmill testing had sensor optimization performed prior to the treadmill test. The hallwalk optimization consisted of invoking the prediction model algorithm and performing a 2-3 minute (approximate) walk at the patient's normal walking speed on a level surface. The data from this hallwalk exercise was retrieved and the sensor output for the activity performed was modeled. The clinician then chose the apropriate sensor response for the level of activity performed.

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[3] Wilkoff B, Corey J, Blackburn G. A Mathematical Model of the Cardiac Chronotropic Response to Exercise. J Electrophysiology. 1989; 3:176—180.

During the hall-walk test, an average SIR of 101 was achieved. The overall SIR/EHR ratio during the hall-walk was 0.93 with a 95% confidence interval of (0.863, 0.999). .This hall-walk activity is considered to be similar to the activity requirements for the activities of daily living.[4]

CAEP ANALYSIS

Figure 1 on page 14 shows the mean SIR vs. Expected (Wilkoff) SIR and the upper bound and the lower bound of the 95% confidence interval of the observed SIR for all 30 patients included in the analysis. The graph is normalized based on the CAEP workload (METs), with the mean of SIR calculated at each stage and its corresponding confidence intervals being plotted.

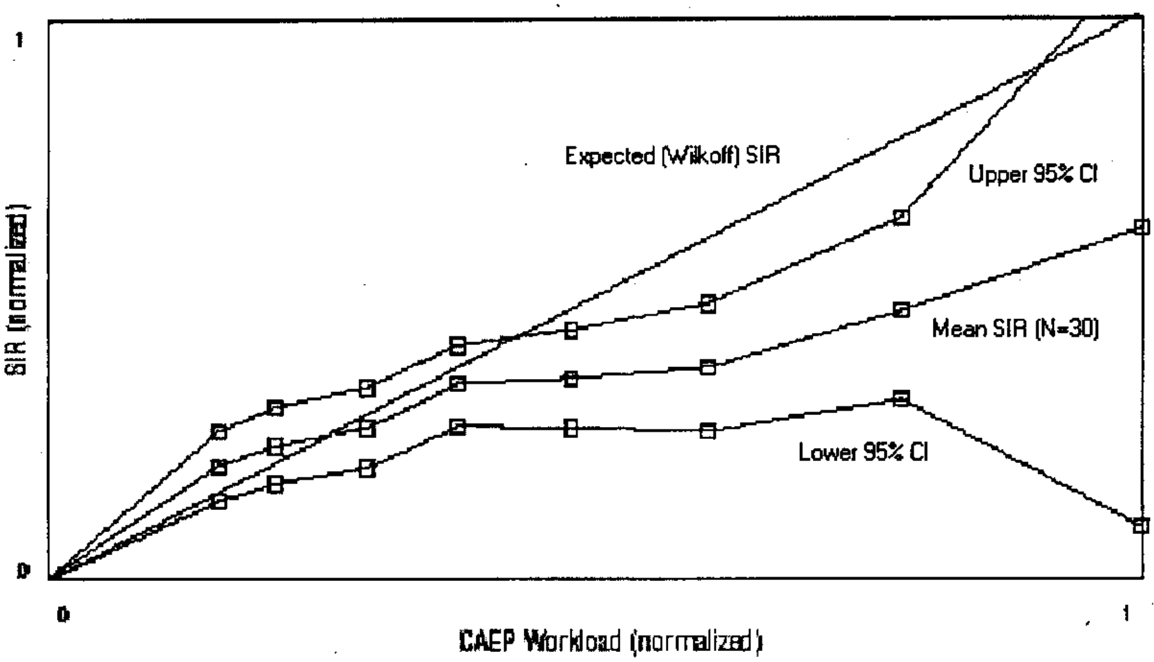

FIGURE 1. Mean Sensor-Indicated Rate (SIR) vs. Expected Sensor-Indicated Rate (SIR) During CAEP

The arithmetic mean of the 30 slopes derived directly from the 30 individual patient linear regression lines of SIR versus EHR is 0.495 with a 95% confidence interval (0.365, 0.625).

[4] Fox SM, Naughton JP, Gorman PA. Physical Activity and Cardiovascular Health III: The Exercise Prescription: Frequency and Type of Activity. Mod Concepts Cardiovascular Dis, 1972; 41:6.

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INDIVIDUALIZATION OF TREATMENT

The Microny™ SR+ pulse generator contains a number of special features to individualize pacing therapy, automate programming, enhance patient safety, assist diagnosis of the patient's intrinsic rhythm, and assess the pulse generator's operation.[5]

These features include:

- Operating Modes
- Programmable Parameters
- Sensor Functions
- Diagnostic Data

Diagnostic Tests and Tools such as Prediction Model, which helps the clinician optimize Sensor parameter settings

- AutoCapture™ Pacing System.

Each of these features is explained in the sections following.

OPERATING MODES

The Microny™ SR+ pulse generator is a single-chamber device that may be programmed to the following pacing therapy modes, depending upon the chamber to be paced.

MODES WITH THE AUTOCAPTURE™ PACING SYSTEM OFF

AOO

(Atrial Asynchronous Pacing)

In AOO mode, atrial pacing is provided at the programmed rate regardless of intrinsic rhythm (Figure 2).

Figure 2. Atrial Asynchronous Pacing (AOO)

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

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

Caution

AOO(R) mode is intended for temporary use. Long-term use may result in competitive pacing in the atrium.

AAT

[5] For a complete list of possible settings and options, see Table 17 on page 38.

(Atrial Synchronous Pacing)

The AAT mode paces the atrium at the programmed rate in the absence of intrinsic atrial activity. Intrinsic atrial activity during the alert period causes the pacemaker to deliver an output pulse synchronously with the detected atrial event (Figure 3).

Figure 3. Atrial Synchronous Pacing (AAT)

Indications. AAT pacing is primarily intended for temporary use in the evaluation of arrhythmias through chest wall electrical stimulation.

Triggered pacing modes, such as AAT, may be useful in avoiding inappropriate inhibition of the pulse generator due to electromagnetic or electromyogenic interference. A triggered mode will pace on detection of such signals, rather than be inhibited by them.

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

AAI

(Atrial Inhibited Pacing)

The AAI mode 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 pacemaker timing to the beginning of the refractory period (Figure 4).

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.

Figure 4. Atrial Inhibited Pacing (AAI)

VOO

(Ventricular Asynchronous Pacing)

The VOO mode paces the ventricle at the programmed rate, regardless of the intrinsic rhythm (Figure 5).

Figure 5. Ventricular Asynchronous Pacing (VOO)

Indications. VOO pacing may be indicated for patients who need continual ventricular pacing and who are subject to electromagnetic interference or electromyogenic noise which could inappropriately inhibit the pulse generator.

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, inducing potentially dangerous ventricular tachyarrhythmias.

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VVT

(Ventricular Synchronous Pacing)

The VVT mode paces the ventricle at the programmed rate in the absence of intrinsic ventricular activity. Intrinsic ventricular activity during the alert period causes the pacemaker to deliver an output pulse synchronously with the detected ventricular event (Figure 6).

Figure 6. Ventricular Synchronous Pacing (VVT)

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

Triggered pacing modes, such as VVT, may be useful in avoiding inappropriate inhibition of the pulse generator due to electromagnetic or electromyogenic interference. A triggered mode will pace on detection of such signals, rather than be inhibited by them.

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

VVI

(Ventricular Inhibited Pacing)

The VVI mode paces the ventricle at the programmed rate in the absence of intrinsic activity. Intrinsic activity during the alert period will inhibit the output pulse by resetting the pacemaker timing to the beginning of the refractory period (Figure 7).

Figure 7. Ventricular Inhibited Pacing (VVI)

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.

Modes with the AutoCapture™ Pacing System On or Off

VVI

(Ventricular Inhibited Pacing)

The VVI mode is ventricular pacing at the programmed Base Rate in the absence of intrinsic activity. Intrinsic activity occurring outside the refractory period resets pacemaker timing to the beginning of the refractory period and inhibits the output pulse.

Indications

- Sinus node arrest
- Sinus bradycardia
- Brady-tachy syndrome

- Atrioventricular conduction disorders that result in symptomatic bradycardias

Contraindications. The VVI mode may be inappropriate in patients who have experienced, or are expected to experience, pacemaker syndrome during ventricular pacing.

RATE-RESPONSIVE MODES

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

Indications. These are the same as non-rate responsive modes except that rate-responsive modes are further indicated when an increase in pacing rate with activity is desired.

Contraindications. These are the same as non-rate responsive modes, except that rate-responsive modes are also contraindicated when pacing rates above the programmed Base Rate may not be well tolerated.

NONPROGRAMMABLE PARAMETERS

PULSE AND SENSE CONFIGURATION

The pacing and sensing configurations in Microny™ SR+ are nonprogrammable and set at unipolar pacing, bipolar sensing.

Note. *In order for the AutoCapture™ Pacing System to operate, the clinician must implant a low polarization, bipolar lead. See "AutoCapture™ Pacing System Lead Compatibility" on page 30.*

PROGRAMMABLE PARAMETERS

Programmable parameters available with the Microny™ SR+ are accessed through a Pacesetter programmer equipped with appropriate software.

VENTRICULAR (V.) AUTOCAPTURE™

Also available as AutoCapture™ Function (APS II), this parameter activates the AutoCapture™ Pacing System, which is described in detail starting on page 28.

BASE RATE

The Base Rate parameter controls the number of pulses per minute (ppm) emitted by the pulse generator. In atrial modes, the Base Rate interval is measured from an atrial stimulus to the next atrial stimulus without an intervening sensed atrial event. In ventricular modes, the interval is from a ventricular stimulus to the next stimulus without an intervening sensed ventricular event.

When the battery's Recommended Replacement Time (RRT) is reached, the Magnet Test Rate drops to 81 ppm or lower. If RRT is considerably exceeded, a "warning" is given in the form of a 20 ppm drop in the programmed pacing rate. When this happens, the battery has reached end-of-life (EOL), and the pulse generator should be replaced without delay.

Hysteresis Rate

Programming a Hysteresis Rate alerts the Microny™ SR+ to allow more extensive use of the patient's intrinsic rhythm, even if it is lower than the Base Rate. Encouraging intrinsic rhythm in this way can result in improved cardiac hemodynamics, greater patient comfort, and lower power consumption.

When a value is programmed for this parameter, the Microny™ SR+ becomes alert to sensed intrinsic activity. If a sensed event occurs, the pulse generator decreases the Base Rate or the sensor-indicated rate to the Hysteresis Rate (Figure 8).

In atrial modes, a P-wave sensed during the pacing interval will initiate operation at the Hysteresis Rate. In ventricular modes, an R-wave or PVC will initiate Hysteresis Rate operation.A sensed event outside refractory restarts an escape interval.

The pulse generator continues to pace and sense at the programmed Hysteresis Rate interval as long as it senses intrinsic activity. When no intrinsic activity is sensed, the Hysteresis Rate interval times out, and the pulse generator resumes operation at the programmed Base Rate.

Values for Hysteresis Rate are always lower than the Base Rate.

If the pulse generator is programmed to a rate-responsive mode, hysteresis will only be active at the Base Rate. Sensor-driven increases in the paced rate disable Hysteresis Rate.

Figure 8. Hysteresis Rate

Hysteresis Rate is available in inhibited and triggered modes, and with AutoCapture™ On or Off. When V. AutoCapture™ is programmed On, Hysteresis Rate is auto-programmed to 10 ppm below the Base Rate or the sensor-indicated rate.

Refractory

This parameter specifies a time period in which sensing for a particular channel is unresponsive to all electrical stimuli. This helps prevent the pacemaker from responding to known but inappropriate electrical signals, such as T-waves.

In some programming situations, the Refractory Period may be automatically programmed to an appropriate interval, but this setting may be changed by the user.

The Refractory Period begins with a paced or sensed event and is made up of two segments— an absolute refractory period, during which all signals to the pulse generator are blocked, followed by a relative or noise test refractory period of 100 ms. The programmed Refractory includes the noise test period. (For example, a programmed Refractory of 500 ms would comprise 400 ms as an absolute refractory period followed by a 100 ms relative refractory period. See Figure 9). A signal detected during the relative refractory period initiates a new 100 ms noise sampling period.

Figure 9. Refractory Period

If electrical signals continue to be detected during this extension, further extensions will be made in the same way. The result is asynchronous pacing in the presence of continuously detected noise.

During periods of noise detection, the pulse generator stimulates at the programmed Pulse Amplitude and Pulse Width if the AutoCapture™ Pacing System is programmed

Off. If AutoCapture™ is On, the algorithm is interrupted and the output is 4.5V at 0.49 ms to ensure capture.

When noise is no longer detected, the pulse generator reverts to the normal inhibited mode with the same Pulse Amplitude and Pulse Width as before the noise sampling period(s) was initiated.

PULSE AMPLITUDE

Pulse Amplitude, measured in volts, determines how much electrical potential is applied to the myocardium during the pacing stimulus (Figure 10).

Figure 10. Pulse Amplitude and Width

For a chronic, stable lead system, a 2:1 margin between the measured capture threshold and the Pulse Amplitude setting is commonly advised for pacemaker-dependent patients. Periodically assess capture thresholds to maintain an appropriate margin.

When V. AutoCapture™ is programmed On, Pulse Amplitude is automatically set.

As the battery voltage decreases, actual pulse amplitude (displayed on the Measured Data screen) will decrease from the programmed value. At EOL, pulse amplitude is approximately 50% of the programmed value. As the device nears RRT, carefully observe measured data values to ensure proper pacing.

Note. *Use the capture threshold as a guideline for programming the pacemaker output to yield a suitable safety margin for reliable, long-term capture. Capture thresholds should be assessed periodically.*

PULSE WIDTH

Pulse Width (pulse duration) determines how long the pulse amplitude will be applied to the myocardium.

Note. *A pulse width of 0.2 ms or less is best used for test purposes rather than as a permanent selection.*

P/R SENSITIVITY

P/R Sensitivity is the setting which determines how sensitive the pulse generator will be when it detects P- or R-waves.

The pacemaker detects any signal equal to or greater than the programmed sensitivity mV value. A lower mV value increases sensitivity; a higher mV setting decreases sensitivity.

To avoid potential complications associated with undersensing, maintain a sensing margin of two to four times the intrinsic cardiac amplitude (e.g., for an intrinsic signal of 4 mV, program the sensitivity to 1 or 2 mV).

Low amplitude P- or R-waves may require a high sensitivity setting (low mV value) to ensure that all valid signals are sensed. If the pulse generator responds to extraneous signals or interference, a lower sensitivity (higher mV value) may help filter out those unwanted signals.

The P/R Sensitivity Test (page 28) may be used to automatically measure intrinsic R-wave Amplitude and propose a P/R Sensitivity setting.

E/R Sensitivity

ER (Evoked Response) Sensitivity determines the sensitivity of the pulse generator to evoked response signals used to determine capture when V. AutoCapture™ is programmed On. For a complete discussion, see page 31.

Vario

When this parameter is programmed On, the pulse generator will perform a Vario Threshold Test (page 27) when a magnet is held over the pulse generator or when Magnet is programmed On.

The Vario Test causes the pulse generator to automatically step through all possible Pulse Amplitude settings so the clinician can determine at which settings capture and loss of capture take place. The test can be run with or without a programmer.

Magnet

When this parameter is set to On, the pulse generator operates as if a magnet were held over the device, i.e., the pulse generator paces asynchronously at the Magnet Test Rate (See page 27). If Vario is programmed On, the pulse generator will pace at the Test Rate for 16 cycles and then begin the Vario Threshold Test (page 27). If the AutoCapture™ Pacing System is On, setting Magnet On will suspend operation of the AutoCapture™ Pacing System and cause the device to pace in High Output Mode (See page 31). Setting Magnet to Off restores the programmed pacing or sensor-driven rate and initiates a Threshold Search if V. AutoCapture™ is On.

This parameter is found on the ECG/IEGM display of the APS II programmer and the Parameters display of the APSµ.

SENSOR PARAMETERS

Sensor

This parameter activates rate-responsive pacing through the use of the activity sensor. This consists of a magnetic ball inside a plastic, ellipsoidal housing, surrounded by a thin copper-wire coil. Body movements make the ball roll inside the housing, inducing voltage in the coil. The amplified and filtered signals are then used to regulate the pulse generator's pacing rate.

The Microny™ SR+ has three settings for Sensor, regardless of the programmed mode: On, Off, or Passive.

When Sensor is programmed On, the pulse generator increases or decreases the pacing rate in response to patient activity detected by the sensor, up to the programmed Maximum Sensor Rate.

When Sensor is programmed Off or Passive, the pulse generator does not respond to signals from the activity sensor.

When Sensor is set to Passive, the pulse generator does not respond to sensor signals. However, it records sensor data for the Sensor-Indicated Rate over Time Graph and the Sensor Rate Spread.

When the battery's recommended replacement time (RRT) is reached, the Sensor is automatically programmed Off.

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MAXIMUM SENSOR RATE (MSR)

The Maximum Sensor Rate (MSR) is the highest pacing rate allowed by rate-responsive pacing. It is also the highest sensor-indicated rate that can be recorded in the Passive Sensor setting.

The pulse generator can increase the sensor-indicated rate up to the MSR independently of the programmed refractory period. However, when the sensor-indicated rate interval is shorter than the Refractory Period, the pulse generator will operate asynchronously and may compete with intrinsic cardiac rhythms.

Maximum Time at Maximum Sensor Rate

The Microny™ SR+ pulse generator limits the time at which the sensor-indicated rate will operate above 140 ppm to 15 minutes. The feature acts as a "watchdog" to prevent potentially dangerous high rates for extended periods of time.

If the pulse generator operates at a MSR of 140 ppm or greater for more than 15 minutes, the pacing rate is automatically reduced to the Base Rate at a speed determined by the programmed Recovery Time. Pacing remains at the Base Rate until the sensor-indicated rate has fallen below the Base Rate plus 20 ppm.

SLOPE

This parameter sets the extent to which the pulse generator will adjust its sensor-driven pacing rate. While some patients may need to increase their pacing rate to a very high rate in response to increased activity (such as exercise or exertion), other patients may need only a limited response to sensed activity (e.g., patients in whom high pacing rates may induce angina).

A low Slope setting will result in smaller increases in pacing rate in response to the same patient activity, while a high setting results in greater increases in pacing rate. Low Slope settings (< 8) also limit the maximum amount of rate increase a patient can achieve in response to patient activity.

For example, a Slope setting of 1 limits the pacing rate increase to 20 ppm over the programmed Base Rate. On the other hand, a Slope setting of 16 will allow the pacing rate to increase to the Maximum Sensor Rate for the highest activity level.[6]

Slope can be set manually by selecting the parameter from the Sensor Parameters display. In addition, the user may use the Prediction Model, described on page 28, to set Slope.

REACTION TIME

This parameter controls how quickly a sensor-drive increase in the pacing rate occurs. Fast and Very Fast settings allow more rapid increases in rate during increased levels of physical activity, while Slow and Very Slow settings allow longer time periods for the sensor-indicated rate to increase.

This parameter is controlled by a timer which delays each increase in the sensor-indicated rate until the appropriate time interval has elapsed. Table 8 lists the time of increases in sensor-driven rates for a number of pacing conditions.

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[6] Theoretically, this could be as high as 142.5 ppm above the Base Rate, but MSR limits the highest sensor-driven rate.

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*Table 8. Minimum Time to Increase Rate for Various Reaction Time Settings**

Programmed Reaction Time	Rate Increase 5 ppm	Rate Increase from 60 to 100 ppm	Rate Increase from 60 to 150 ppm
Very Fast	1.0 s	12 s	24 s
Fast	1.5 s	15 s	32 s
Medium	2.0 s	19 s	41 s
Slow	2.5 s	23 s	50 s
Very Slow	3.5 s	31 s	68 s

*The actual time required for an increase in the sensor-driven pacing rate depends on programmed *Base Rate, Maximum Sensor Rate, Slope*, and how rapidly the patient's activity level fluctuates.

FAST RESPONSE

When this parameter is programmed On, the sensor-indicated rate increases by 5 ppm per stimulation interval until it reaches the Base Rate plus 20 ppm. Thereafter, it is increased according to the programmed Reaction Time. This feature is programmable On or Off and functions independently of Reaction Time. Continued exercise may provide further increases in the sensor-indicated rate at the programmed Reaction Time.

RECOVERY TIME

This parameter controls how quickly a sensor-driven decrease in the pacing rate occurs. A slow Recovery Time will result in a slow decrease in pacing rate when the patient's activity level decreases. A faster Recovery Time will allow the pacing rate to decrease more rapidly.

As with Reaction Time, Recovery Time is controlled by a timer which delays each decrease in the sensor-indicated rate until the appropriate time interval has elapsed. Table 9 lists the time of decreases in sensor-driven rates for a number of pacing conditions.

*Table 9. Minimum Time to Decrease Rate for Various Recovery Time Settings**

Programmed Reaction Time	Rate Increase 5 ppm	Rate Increase from 60 to 100 ppm	Rate Increase from 60 to 150 ppm
Very Fast	1.0 s	12 s	24 s
Fast	1.5 s	15 s	32 s
Medium	2.0 s	19 s	41 s
Slow	2.5 s	23 s	50 s
Very Slow	3.5 s	31 s	68 s

*The actual time required for a decrease in the sensor-driven pacing rate depends on programmed *Base Rate, Maximum Sensor Rate, Slope*, and how rapidly the patient's activity level fluctuates.

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DIAGNOSTIC DATA

The Microny™ SR+ can store diagnostic data from one of three different Sampling Sources:

- Sensor Rate - a record of the sensor-driven rate over time
- Rate Spread - the highest, average, and lowest sensor-driven rate[7]
- Threshold - the voltage of sampled stimulation threshold measurements over time (available only if the AutoCapture™ Pacing System is enabled[8]).

The device can only record from a single Sampling Source. This parameter is accessed from the Clear Diagnostic Data screen on the programmer.

A maximum of 256 samples can be stored in the pulse generator memory. The user can select how the pulse generator will handle samples exceeding this number by programming the Sampling Mode to one of two settings:

- Freeze. The pulse generator stops collecting data after the memory is full
- Continuous. The latest sample overwrites the first sample record; i.e., the most recent data is always presented.

The total time sampled for each data set depends on the programmed Sampling Rate, which is shown in Table 10.

Other diagnostic data include:

- Date and time the data were last cleared
- Number of threshold searches (if V. AutoCapture™ is enabled[8]).

Table 10 Total Data Collection Time

Sampling Interval	Sampling Source		
	Stimulation Threshold	Sensor-Indicated Rate	Rate Spread
2 seconds	17 minutes	17 minutes	—
15 seconds	2 hours	2 hours	—
1 minute	8.5 hours	8.5 hours	2 hours
7.5 minutes	64 hours	64 hours	16 hours
30 minutes	10 days	10 days	64 hours
1 hour	20 days	20 days	—
6 hours	18 weeks	18 weeks	—
12 hours	36 weeks	36 weeks	—
24 hours	72 weeks	72 weeks	—

[7] Sensor Rate and Rate Spread are available at any *Sensor* Setting.
[8] *Sampling Source* is autoprogrammed to Threshold when V. AutoCapture is programmed On.

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MEASURED DATA

The programmer's Measured Data screen displays the current status of the pulse generator and the battery, including:

Measured rate

Test rate (See page 27)

Sensor-indicated rate[9]

Pulse amplitude

Pulse current

Pulse energy

Pulse charge

Lead impedance

Battery type and capacity

Battery voltage

Battery current

Battery impedance.

MONITORING LEAD IMPEDANCE AND SENSOR RATE

Both the current lead impedance and the sensor-driven rate can be monitored from the programmer's Measured Data display by selecting Monitor Lead Impedance or Monitor Sensor Rate.[10]

DIAGNOSTIC TESTS AND TOOLS

These tests and tools are conducted with the programmer. For more information on each feature, and how it is accessed with the programmer, consult the appropriate Programming Guide.

AUTOCAPTURE™ TEST

This test (available with the APS II and APSµ) uses the AutoCapture™ Pacing System "Threshold Search" function to automatically search for a capture (stimulation) threshold in the ventricle. For more information, see the discussion on page 29.

CUSTOM REPORT/AUTOMATED FOLLOW UP

Pacesetter programmers can generate a user-definable report on the status of the patient and the pulse generator.

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[9] Not available on the APSµ programmer.
[10] Monitor Sensor Rate is not available on the APSµ programmer.

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EMERGENCY VVI OR PROGRAMMER RESET

Pacesetter programmers are equipped with a red Emergency VVI or Programmer Reset button. Pressing this button at any time during the programming session resets the programmer, and programs the Microny™ SR+ to predefined high-output parameters, as shown in Table 16, on page 36.

Emergency values provide maximum output settings (Pulse Width of 1.0 ms, Pulse Amplitude of 4.5 V). If any difficulties are encountered during a programming session, the clinician can simply select the Emergency VVI or Programmer Reset and the pulse generator will be reset to the emergency high-output parameters.

Caution

The red Emergency VVI or Programmer Reset button should only be pressed or selected ONCE to program emergency values. Repeated pressing prolongs the time before these emergency high-output values can be implemented.

E/R SENSITIVITY TEST

The E/R Sensitivity Test calculates and proposes an appropriate E/R Sensitivity setting. For more information, see the discussion on page 32.

EVENT MARKERS

On the programmer's ECG/EGM display, the user can select Markers to identify all paced and sensed events.

When the lead chamber is programmed to the atrium, the markers are:

A – paced atrial event

P – sensed atrial event

When the lead chamber is programmed to the ventricle, the markers are:

V – paced ventricular event

R – sensed ventricular event.

The atrial or ventricular Refractory Periods are also indicated on annotated ECGs as horizontal lines starting at the letter markers and extending for a length corresponding to the duration of the intervals (Figure 11).

Figure 11. Event Markers

MAGNET MODE

When a magnet is held over the pulse generator or the programmer is set to Magnet On, the device enters the "Magnet Mode," and begins the Battery Test and/or the Vario Test (explained below).

If Vario is programmed On, the device will begin Battery Test for 16 cycles, then switch to the Vario Test, repeating both tests until the magnet is removed or Magnet is turned Off.

If Vario is programmed "Off," the device will only run the Battery Test.

Battery Test

When the device enters magnet mode, the pacing rate changes from the programmed Base Rate or sensor-driven rate to a Magnet Test Rate. This Test Rate corresponds to the battery's voltage and its remaining service life.

As battery power is depleted, the Magnet Test Rate gradually declines from Beginning of Life (BOL) at 99.7 ppm to 80.8 ppm, which indicates Recommended Replacement Time (RRT). Magnet rates at or below 60 ppm indicate End-of-Life (EOL). The Test Rate is displayed on the programmer's Measured Data screen.

Table 11. Magnet Test Rate and Corresponding Battery Conditions

Condition	Magnet Test Rate (ppm)
BOL	99.7
RRT	80.8
EOL	60.0

When the magnet is removed, the pacing rate returns to the programmed Base Rate or sensor-indicated rate. If the AutoCapture™ Pacing System is programmed On, the device will also begin a Threshold Search (page 29).

Note. *If the Pulse Amplitude is programmed to 4.5 V, the Vario test cannot be performed, and the battery test pulses are delivered at 4.5 V and 0.49 ms pulse width.*

Vario Threshold Test

The magnet-generated Vario Threshold Test helps the clinician measure the current capture or stimulation threshold by lowering the Pulse Amplitude to a new setting at each cycle, providing the clinician the opportunity to observe loss of capture on the ECG or the programmer IEGM display.

If the Vario parameter is set to On, the test will run following the Battery Test in Magnet Mode. The Vario Test can also be conducted using the programmer.

When a magnet is applied over the device, the Battery Test will operate for 16 cycles. At the seventeenth cycle, the programmer will command the device to reduce its current Pulse Amplitude by one setting for each cycle.

When the ECG/IEGM indicates loss of capture, the user should remove the magnet or turn the magnet Off and note the setting for the loss of capture. When using the programmer to perform the test, the programmer will indicate capture or capture loss for each Pulse Amplitude setting.

Caution

During this threshold measurement evaluation, the patient could be deprived of capturing stimuli for up to seven seconds, corresponding to 14 impulses. The test can be interrupted at any time by pressing STOP TEST on the programmer or by removing the magnet.

PATIENT DATA

The Microny™ SR+ has reserved a portion of memory for storage of Patient Data. The user can store the following information:

- Patient ID
- Implant Date
- Lead Type
- Lead Chamber.

When the user selects Patient ID from the programmer's Patient Data display, the screen will display a character set. The user can type in up to 12 characters for storage in the device memory.

Note. *Lead Type for the Microny™ SR+ is pre-set to Bipolar.*

Prediction Model

This diagnostic tool displays a graphic model of pulse generator behavior to help the clinician optimize Sensor parameter settings. Using Prediction Model, the clinician can set different Sensor parameter settings and view the predicted response to these settings without permanently programming them. After deciding on optimal settings, the clinician can then permanently program the settings using this feature.

P/R Sensitivity Test

This test automatically measures the amplitude of the intrinsic rhythm of the heart and proposes a setting for the P/R Sensitivity parameter (page 20) which determines how the pulse generator senses P and R waves.

Return to Standard (RTS)

As a safety measure, some Pacesetter programmers are equipped with a Return-to-Standard (RTS) function. Pressing the RTS button resets the Microny™ SR+ pulse generator to a set of predefined standard parameter values, as shown in Table 16 on page 36.

Temp 30 Pacing

This programmer feature temporarily programs the pulse generator to a Base Rate of 30 ppm under direct programmer control.

Temp 30 Pacing is toggled On or Off from the programmer. Temp 30 pacing can be stopped by removing the telemetry head from the pulse generator.

AUTOCAPTURE™ PACING SYSTEM

The AutoCapture™ Pacing System enables the Microny™ SR+ to automatically regulate ventricular pulse amplitude.

When V. AutoCapture™ or AutoCapture™ Function is programmed On, the Microny™ SR+:

- measures the ventricular capture threshold and programs a ventricular automatic pulse amplitude to a setting 0.3 V above the measured threshold
- verifies that capture has occurred on a Beat-by-Beat basis by measuring the evoked response signal in the ventricle after each pacing pulse
- responds within 62 ms to loss of capture with a 4.5 V backup safety pulse

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- recovers capture after loss of capture
- continuously readjusts automatic pulse amplitude when the patient's capture threshold changes.

AutoCapture™ Pacing System Operation

The AutoCapture™ Pacing System performs these functions through the operation of three algorithms:

Capture Verification measures the evoked response signal and delivers a backup safety pulse if capture is lost

Loss of Capture Recovery recovers capture by increasing ventricular pulse amplitude until capture is confirmed

Threshold Search searches for a lower amplitude capture threshold once every eight hours and after each Loss of Capture Recovery operation.

Capture Verification

After each pacing pulse, the device becomes alert to evoked response signals in the myocardium which indicate that capture has occurred. An initial waiting period of approximately 15 ms is followed by an Evoked Response Detection Window approximately 47.5 ms in length.

If the device senses an evoked response in this window, capture is confirmed. The timing cycle is reset, and pacing is resumed at the Automatic Pulse Amplitude and the programmed V. Pulse Width (Figure 12).

Figure 12. Automatic Capture Confirmation

If no evoked response signal is detected, then capture is lost; the device delivers a backup safety pulse of 4.5 V at 0.49 ms duration within 62 ms of the initial pulse to ensure capture (Figure 13).

Figure 13. Automatic Backup Safety Pulse

Loss of Capture Recovery

If Capture Verification confirms two consecutive capture losses, the device starts this algorithm (Figure 13). As the device delivers a backup safety pulse, it increases the Automatic Pulse Amplitude by 0.3 V and looks for capture. If no capture is confirmed, the device increases the pulse amplitude by 0.3 V and looks for capture. When two consecutive captures are confirmed, the device begins a Threshold Search (described below).

If capture is not confirmed by the time the device has automatically increased pulse amplitude to 3.9 V, the device switches to "High Output Mode." In this mode, the Automatic Pulse Amplitude is set to 4.5 V and the Pulse Width to 0.49 ms.

Threshold Search

This algorithm acts like the Loss of Capture Recovery in reverse. When initiated, the device decreases the Automatic Pulse Amplitude by 0.3 V until two consecutive losses of capture have occurred. After delivering a backup safety pulse, the Automatic Pulse Amplitude is increased by 0.3 V until two consecutive captures are confirmed. The

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device then sets the Automatic Pulse Amplitude at the measured capture threshold plus a 0.3 V margin.

If the decreasing search fails to find capture loss at the lowest pulse amplitude setting of 0 V, the device switches to High Output Mode.

The Threshold Search algorithm can be initiated

- every eight hours by the internal timer; if the device is in High Output Mode, the search begins at 3.9 V
- by a Loss of Capture Recovery operation
- by removal of a magnet from the pulse generator (except when the device is in High Output Mode)
- by the AutoCapture™ Test conducted with the programmer.
- by programming Ventricular AutoCapture™ On.

AUTOCAPTURE™ PACING SYSTEM EXAMPLE

The example in Figure 14 shows how the pulse generator responds to a sudden threshold increase to 2.1 V. As usual, all non-captured events are followed by backup pulses which reset the Base Rate timer. In this example, the current pulse amplitude is 1.5 V. The last Threshold Search revealed a threshold of 2.1V, and a margin of 0.3 V was added.

Figure 14. Pulse Generator Response to Sudden Threshold Increase

The numbers in Figure 14 Figure indicate the following:

1. No capture at 1.5 V
2. Second pulse not captured at 1.5 V, confirming no capture
3. Amplitude increased to 1.8 V; capture requires a further increase in amplitude
4. Amplitude increased to 2.1 V, with capture
5. Capture confirmed at 2.1 V
6. Threshold Search starts with an amplitude decrease to 1.8 V to confirm the new threshold
7. No capture at 1.8 V, requiring an increase of amplitude
8. Amplitude increased to 2.1 V, resulting in capture
9. Capture at 2.1 V, confirming this threshold setting
10. Pacing continues with 2.4 V amplitude, 0.3 V above the determined threshold.

AUTOCAPTURE™ PACING SYSTEM LEAD COMPATIBILITY

The AutoCapture™ Pacing System requires the use of a bipolar, low polarization ventricular pacing lead. Before activating Ventricular AutoCapture™, the clinician should perform the E/R Sensitivity Test (page 32) to confirm that the AutoCapture™ Pacing System will operate with the implanted lead.

The Microny™ SR+ has a fixed Bipolar Lead Type.

For more information on compatible leads, contact your Pacesetter representative or Technical Services (page 39).

If the lead is implanted in necrotic tissue or if the myocardium does not emit a satisfactory evoked response to the pacing pulse, the AutoCapture™ Pacing System may not operate, even if a compatible pacing lead is used. Use the E/R Sensitivity Test to verify proper AutoCapture™ Pacing System operation.

AUTOCAPTURE™ PACING SYSTEM PARAMETERS

Two programmable parameters control the operation of the AutoCapture™ Pacing System: V. AutoCapture™ and E/R Sensitivity.

AutoCapture™ Function

Setting V. AutoCapture™ to On results in a number of programming changes:

- the programmer will prompt the user to perform the E/R Sensitivity Test (page 32)
- the programmer displays "Auto" for the Pulse Amplitude setting
- the Diagnostic Sampling Source is autoprogrammed to Threshold
- Hysteresis Rate is autoprogrammed to 10 ppm
- If E/R Sensitivity is set to Off, it is autoprogrammed to 4.0 mV

The Pulse Width setting is not changed.

When the Ventricular AutoCapture™ is turned Off:

- Pulse Amplitude is set to twice the value of the last automatic pulse amplitude setting, with a minimum setting of 2.4 V.

E/R Sensitivity

This parameter determines how sensitive (in mV) the pulse generator channel will be to an evoked response cardiac signal during Capture Verification (page 29). This parameter may be set by the user, but the E/R Sensitivity Test (page 32) will propose and program an appropriate setting.

Interactions with Other Pacing Functions

AutoCapture™ Pacing System operation may be suspended under certain conditions. When the condition ends, the device will perform a Threshold Search and resume normal operation.

- Background Noise. Extension of the refractory period from noise will suspend AutoCapture™ Pacing System operation. The device enters High Output Mode until the noise ends.
- Magnet. Placing a magnet over the pulse generator or setting the Magnet parameter to On places the device in High Output Mode; removing the magnet (or setting Magnet to Off) initiates a Threshold Search (page 29) and restores programmed parameters.

AUTOCAPTURE™ PACING SYSTEM DIAGNOSTICS

Threshold

This is a record of capture (stimulation) threshold measurements (in volts) displayed over time.

When Ventricular AutoCapture™ is programmed On, the pulse generator is autoprogrammed to record Threshold measurements at the current Sampling Rate. These rates range from every two seconds to once every 24 hours. The pulse generator can store a maximum of 256 threshold samples, and the time capacity for each Sampling Rate can be found in Table 10, on page 24. The data are displayed by accessing the programmer's Diagnostic Data screen.

On reaching capacity, the pulse generator can either stop recording additional data (by programming Sampling Mode to Freeze) or can overwrite the oldest data (Sampling Mode = Continuous).

Threshold also records:

- date last cleared
- the number of threshold searches initiated by a loss of capture (capacity of 4095 counts[11]).

For more information, see "Diagnostic Data" on page 24 and the programmer's Programming Guide.

AUTOCAPTURE™ PACING SYSTEM TESTS

These diagnostic tests must be performed with the programmer. See the Programming Guide for detailed instructions.

E/R Sensitivity Test

The programmer prompts the user to perform this test when programming AutoCapture™.

The test:

- measures both the evoked response and lead polarization signals and determines if the AutoCapture™ Pacing System will perform successfully
- suggests and programs an E/R Sensitivity setting.

Caution

The ER Test requires VVI(R) mode.

AutoCapture™ Test

This test invokes a Threshold Search (page 29) and sets an appropriate pulse amplitude.

PATIENT COUNSELING INFORMATION

The physician should consider the following points in counseling the patient about this device:

- Registration Card. Counsel the patient that his permanent pacemaker ID card will be issued by the manufacturer, and that the patient should carry it at all times.

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[11] The threshold counter does not record threshold searches initiated by time-driven tests, programmer-initiated searches, or magnet-initiated searches.

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- Electromagnetic Fields. Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields (See page 4.).
- Health Care Providers. Patients should notify health care providers of the presence of this device and of its type.
- Pacemaker Syndrome. Single-chamber mode pacing can cause pacemaker syndrome, which induces symptoms ranging from minor to severe or may simply limit the patient's ability to achieve optimal functional status. Counsel patients to notify their physician of any symptoms immediately.
- Twiddler's Syndrome. Caution patients against manipulating the implanted pulse generator since it may result in lead damage or lead displacement.

CONFORMANCE TO STANDARDS

This device was developed in conformance with all or parts of the following standards:

- ISO 5841-3; 1992, Cardiac Pacemakers, Part 3: Low Profile Connector (IS-1) for Implantable Pacemakers
- EN50061: 1998, Safety of Implantable Cardiac Pacemakers
- PAC49-131 Pacemaker Emergency Intervention System.

CLINICIAN USE INFORMATION

PHYSICIAN TRAINING

Physicians should be familiar with sterile pacemaker implant procedure and familiar with follow-up evaluation and management of patients with a pacemaker (or provide a referral to such a physician).

DIRECTIONS FOR USE

Note. *The pulse generator should be implanted as vertically as possible for optimal rate response function. Device implant orientation approaching 45 degrees or more (compared to vertical) reduces the sensor sensitivity significantly.*

LEAD CONNECTION

The pulse generator has a connector which is compatible with the IS-1 standard. Use only bipolar pacing leads which meet VS-1 or IS-1 standards with the Microny™ SR+.

Caution

The AutoCapture™ Pacing System will only operate with a low polarization, bipolar pacing lead. Before selecting and implanting a lead, ensure that it is compatible by conducting the E/R Sensitivity Test. For more information on AutoCapture™-compatible leads, contact your Pacesetter representative or Technical Services (page 39).

To connect the lead to the pulse generator, first remove blood and body fluids from the end of the implanted pacing lead. Check that the set-screw is retracted so that the pacing lead terminal pin can be fully inserted.

Caution

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Exercise caution when turning the set-screw. A set-screw may back out of the terminal block if turned excessively counterclockwise.

Insert the pacing lead firmly into the pulse generator terminal block until the lead connector pin is immobile and visible in the viewport at the opposite end of the pulse generator connector.

A torque-limiting #2 wrench is provided with the pulse generator. Hold the wrench vertical to the connector head and place the tip of the wrench through the self-sealing aperture (Figure 15). Engage the Set-screw and turn the wrench clockwise until it clicks. A gentle tug will verify that the set-screw is tight.

Note. *The wrench is limited at a much higher torque in the loosening (counter-clockwise) direction.*

<u>Figure 15. Lead Connection</u>

Caution

The set-screw may be backed out of the connector block if turned too far in a counterclockwise direction. Do not attempt to remove the sealing plug in the self-sealing aperture. This will cause irreversible damage to the pulse generator.

A suture hole in the connector block enables the pulse generator to be secured in a subcutaneous pocket and minimizes possible migration.

X-RAY IDENTIFICATION

The Microny™ SR+ 2425T pulse generator has an identification code which is visible on X-ray film (Figure 16). The code consists of:

S – Manufacturer, Pacesetter AB, Sweden

4 – Year of manufacture (1994)

25 – Model designation (2425T)

<u>Figure 16. X-ray Identification</u>

REGISTRATION CARD

A registration card is enclosed with each pulse generator. When completed, it serves as a permanent record of information pertaining to the implanted device. The manufacturer's copy of the registration card should be returned to St. Jude Medical immediately after implantation to fulfill the warranty conditions.

TECHNICAL DATA

BATTERY

1 lithium-iodine cell

Type WG 9107

Manufacturer: Wilson Greatbatch Ltd. USA

Capacity

0.37 Ah deliverable capacity

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0.35 Ah between beginning of life (BOL) and Recommended Replacement Time (RRT)
0.02 Ah between RRT and end of life (EOL)

Battery Status Indicators

BOL:

Magnet test rate: 99.7 ppm

Test rate interval: 602 ms

Cell impedance: 1 kΩ

RRT:

Magnet test rate: 80.8 ppm ; Sensor Off

Test rate interval: greater than 706 ms

Cell impedance: 15 kΩ

Note. *Replace the pulse generator within three months after RRT. The time between RRT and EOL depends on operating current drain, but is seldom less than three months under normal circumstances.*

EOL:

Magnet test rate: 60 ppm

Cell impedance: 27 kΩ

Drop in programmed pacing rate by 20 ppm

Longevity

Longevity data are based on accelerated battery test data. Consequently, these approximations of service life do not account for many individual factors which affect pulse generator service life – programming, percentage of time paced, internal impedance, etc.

Tables 12 through 14 were calculated using the following conditions: Pulse Width = 0.31 ms, 100% pacing. In the BOL to RRT calculations, "on the shelf" capacity loss has been factored in.

Table 12. Projected Longevity at 90 ppm: BOL to RRT (years)

Amplitude	Load (tip case)	Typical Sensor Off/On	Worst Case Sensor Off/On
1.5 V	500 Ω	7.5/6.5	5.6/4.8
2.4 V	500 Ω	6.5/5.7	4.8/4.2
4.5 V	500 Ω	4.7/4.5	3.5/3.4
1.5 V	300 Ω	6.5/5.7	4.7/4.2
2.4 V	300 Ω	5.4/4.8	3.9/3.5
4.5 V	300 Ω	2.5/2.3	1.8/1.7

Table 13. Projected Longevity at 90 ppm: RRT to EOL (months)

Amplitue	Load (tip case)	Typical Sensor Off	Worst Case Sensor Off
1.5 V	500 Ω	4.3	4.2

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2.4 V	500 Ω	3.7	3.6
4.5 V	500 Ω	1.9	1.9
1.5 V	300 Ω	3.7	3.5
2.4 V	300 Ω	3.0	2.9
4.5 V	300 Ω	1.4	1.3

Table 14. Projected Longevity at 60 ppm: BOL to RRT (years)

Amplitude	Load (tip case)	Typical Sensor Off/ON	Worst Case Sensor Off/On
1.5 V	500 Ω	8.3/7.1	6.2/5.2
2.4 V	500 Ω	7.5/6.4	5.6/4.8
4.5 V	500 Ω	4.4/4.0	3.3/3.0
1.5 V	300 Ω	7.4/6.4	5.5/4.7
2.4 V	300 Ω	6.4/5.6	4.7/4.2
4.5 V	300 Ω	3.3/3.1	2.5/2.3

Table 15. Projected Longevity at 60 ppm: RRT to EOL (months)

Amplitue	Load (tip case)	Typical Sensor Off	Worst Case Sensor Off
1.5 V	500 Ω	4.8	4.6
2.4 V	500 Ω	4.3	4.2
4.5 V	500 Ω	2.5	2.4
1.5 V	300 Ω	4.2	4.1
2.4 V	300 Ω	3.6	3.5
4.5 V	300 Ω	1.9	1.8

Shipped, Return to Standard (RTS), and Emergency VVI Settings

Table 16. Shipped, Return to Standard, and Emergency VVI Settings

Parameters	Shipped	Return to Standard		Emergency VVI
		Ventricular	Atrial	
Mode	VVI	VVI	AAI	VVI — AAI
Base Rate, ppm	60	70	70	70
Amplitude, V	2.4	3.9	3.9	4.5
Pulse Width, ms	0.31	0.37	0.37	1.0
P/R Sensitivity, mV	3.0	2.0	2.0	3.0
Refractory Period, ms	300	300	300	300
Hysteresis Rate	Off	Off	Off	Off
Vario	Off	Off	Off	Off
AutoCapture™ Pacing System	Off	Off	N/a	N/a (AAI) Off (VVI)

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E/R Sensitivity, mV	4.0	N/c	N/a	N/a (AAI) N/c (VVI)
Sensor	Off	Passive	Passive	Off
Maximum Sensor Rate, ppm	130*	N/c	N/c	N/c
Slope	10*	N/c	N/c	N/c
Reaction Time	Medium*	N/c	N/c	N/c
Fast Response	Off*	N/c	N/c	N/c
Recovery Time	Medium*	N/c	N/c	N/c

*Inactive. Activated by programming Sensor On or Passive.
N/a = Not applicable
N/c = No change

PROGRAMMABLE PARAMETERS, SETTINGS, AND TOLERANCES

Table 17. Programmable Parameters and Values

Parameter	Settings	Units	Tolerance
Mode (AutoCapture™ Off)	AAI (R), AAT(R) AOO (R), VVI (R), VVT (R), VOO (R)	N/a	N/a
Mode (AutoCapture™ On)	VVI(R)	N/a	N/a
V. AutoCapture™	On, Off	N/a	N/a
Base Rate	Temp 30, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100, 105, 110, 115, 120	ppm	± 2 ppm
Hysteresis Rate	0, 10, 20, 30 ppm less than Base Rate or sensor-indicated rate	ppm	± 2 ppm
Refractory	250, 300, 350, 400, 450, 500, 550	ms	± 10 ms
Pulse Width	0.03, 0.06, 0.09, 0.12, 0.15, 0.18, 0.21, 0.24, 0.31, 0.37, 0.43, 0.49, 0.58, 0.70, 0.82, 1.0	ms	-0.01/+0.03 ms
Pulse Amplitude	AUTO*, 0.3†, 0.6, 0.9, 1.2, 1.5 1.8, 2.1, 2.4, 2.7, 3.0, 3.3, 3.6, 3.9, 4.2, 4.5	V	-0.1/+0.2 V -0.1/+0.15 V ± 0.15 V
P/R Sensitivity	0.5, 0.8, 1.2, 2.0, 3.0, 5.0, 7.5, 12	mV	±30% or 0.3 mV*
E/R Sensitivity	1.6, 2.5, 4.0, 6.0, 10.0, 15.0, 24.0	mV	±30% or 0.3 mV*
Vario	On, Off	N/a	N/a
Sensor	On, Passive, Off	N/a	N/a

* Only with V. AutoCapture On
† Only with V. AutoCapture Off
* Whichever is greater

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Maximum Sensor Rate	90, 100, 110, 120, 130, 140, 150, 160	ppm	± 2 ppm
Slope	1–16 in steps of 1	N/a	N/a
Reaction Time	Very Fast, Fast, Medium, Slow, Very Slow	N/a	N/a
Fast Response	On, Off	N/a	N/a
Recovery Time	Very Fast, Fast, Medium, Slow, Very Slow	N/a	N/a
Sense Configuration	Bipolar††	N/a	N/a
Pulse Configuration	Unipolar††	N/a	N/a

†† Nonprogrammable parameter

Measured Data Tolerances

Table 18. Measured Data Tolerances

Measured Data	Tolerance
Rate	± 2 ppm
Pulse Amplitude	± (0.1 V + 5%)
Pulse Current	± (0.2 mA + 20%)
Pulse Energy	± (0.4 µJ + 20%)
Pulse Charge	± (0.2 µC + 20%)
Lead Impedance 150 Ω – 1 kΩ 1 kΩ – 2kΩ	 ± (20 Ω ± 10%) ± (50 Ω ± 15%)
Battery Voltage	± 0.1 V
Battery Current	+ 20% / -10%
Battery Impedance	± (0.6 kΩ + 4%)

Additional Information

Runaway Protection Rate

175 ±15 ppm

Physical Specifications

Dimensions: 6 x 33 x 33 mm

Volume: 5.9 cm3

Density: 2.2 g/cm3

Mass: 12.8 g

Encapsulation: Titanium

Connector casting: Epoxy

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Coating: Parylene

Material of integral electrode: Titanium

Lead connector size: 3.2 mm IS-1 BI

TECHNICAL SERVICE

You can speak directly to a Technical Service Representative 24 hours of every day for questions on any aspect of the pacing system by contacting St. Jude Medical.

In North America, call:

- (toll free) 1-800-722-3774
- 1-818-362-6822
- FAX: 1-818-362-7182.

You local sales representative can also provide assistance.

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