System Guide

INSIGNIA® I Ultra

MODELS 1190/1290/1291

Multiprogrammable Pacemakers

RESTRICTED DEVICE: Federal law (USA) restricts the device to sale, distribution, and use by, or on the lawful order of a physician trained or experienced in device implant and follow-up procedures.

GUIDANT

ABOUT THIS MANUAL

This pacemaker system guide can be used with all INSIGNIA I Ultra pacing systems. These pacemakers are used with the Model 2892 CONSULT Software Application and the ZOOM LATITUDE Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM). Refer to the PRM Operator's Manual for full instructions.

Manual Conventions

Throughout this manual, the following text conventions will be used:

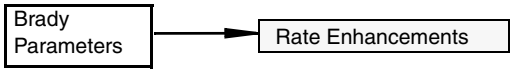
PRM KEYS	The names of the PRM keys will appear in capital letters (e.g., PROGRAM, INTERROGATE).
Screen Text	When text appearing on the PRM screen is referred to in the manual, it will appear with the first letter of each word capitalized.
1., 2., 3.	Numbered lists indicate a series of instructions that should be followed in the order given.
•	Bullets precede items in a list, or a series that is not sequential.
	A pacemaker profile appears in the margin if the feature being discussed applies only to a specific type of pacemaker (e.g., DR). If the feature applies to all models, there will be no profile.

This manual uses two graphic representations to help the reader locate features on the PRM. As each PRM screen is introduced, a graphic of the PRM toolbox button bar indicates the button to be selected. In the following example, the Temporary Parameters button on the toolbox button bar is shaded, indicating the PRM screen being discussed in that section.

Temporary Parameters Screen

In the following example, the graphic shows that the Rate Smoothing parameter is found by accessing the Rate Enhancements submenu from the Brady Parameters screen.

Rate Smoothing



All screen illustrations in this manual show typical screens from an INSIGNIA I Ultra Model 1290 pacemaker. The screens you see when interrogating or programming other pacemaker models will be similar but may not include any dual-chamber fields, depending on the model.

In this manual, “select” means to touch the stylus to the desired item on the screen. Menu buttons and parameter selection buttons will activate when touched; the buttons in the parameter value palettes will activate when the stylus is lifted from the screen.

Other Related Manuals and Information Tools

The ***Physician’s Technical Manual*** is packaged with the pacemaker and provides the information needed to implant the pacemaker at nominal parameter settings. All information in the Physician’s Technical Manual is also included in this manual.

The ***ZOOM Programming System Operator’s Manual*** provides information specific to the PRM, such as setting up the system, maintenance, and handling.

The **Lead Manuals** provide specific information and instructions regarding the implanted lead(s).

Symbols on Packaging

The following symbols may be used on pulse generator packaging and labeling (Table 1):

Table 1. Symbols on packaging

Symbol	Definition
	Opening instructions
	Wand placement indicator

CONTENTS

SENSOR SUBMENU

A-TACHY RESPONSE

RATE ENHANCEMENTS SUBMENU

REFERENCE TABLES

Nominal Mechanical Specifications

Model[a]	Type	Dimensions W x H x D (mm)	Volume (cc)	Mass (g)	Connector
1190	SSIR	42 x 42 x 8	10.0	23.4	IS-1[b] only
1290	DDDR	42 x 44 x 8	10.8	25.4	IS-1 only
1291	DDDR	43 x 49 x 8	12.6	29.6	3.2-mm or IS-1[c]

a. All devices use a size 2 hex wrench.
b. IS-1 refers to the international standard ISO 5841.3:1992.
c. Accepts IS-1 or 3.2-mm unipolar/bipolar leads.

X-ray Identifier

The pacemakers have an identifier located on the header of the device that is visible on x-ray film or under fluoroscopy. This provides noninvasive confirmation of the manufacturer. The identifier for INSIGNIA I devices consists of the letters “GDT” to identify the manufacturer (Guidant). The letters are followed by “003” to identify the Model 2892 software application needed to communicate with the pacemaker.

Refer to the Quick Start section (page 5-5) for information on identifying the device via the programmer.

The model number of the pacemaker is stored in the device's memory and is available on the About screen selectable through the Utilities menu when the pacemaker is interrogated.

Longevity Projections (Years)[a] [b] (Sheet 1 of 2)

Amplitude and Pacing	Models		
	1190	1290	1291
A and V Amplitudes 3.5 V			
100% Paced			
350 Ω	6.8	4.9	7.0
500 Ω	7.3	5.4	7.7
750 Ω	7.8	6.0	8.5
1000 Ω	8.1	6.4	9.0
50% Paced			
350 Ω	7.9	6.2	8.8
500 Ω	8.2	6.6	9.3
750 Ω	8.5	7.0	9.9
1000 Ω	8.7	7.3	10.2
A and V Amplitudes 2.5 V			
100% Paced			
350 Ω	7.4	5.6	7.9
500 Ω	7.8	6.0	8.5
750 Ω	8.2	6.5	9.2
1000 Ω	8.4	6.9	9.7
50% Paced			
350 Ω	8.3	6.7	9.5
500 Ω	8.5	7.0	9.9
750 Ω	8.8	7.3	10.4
1000 Ω	8.9	7.5	10.6

Longevity Projections (Years)[a] [b] (Sheet 2 of 2)

Amplitude and Pacing	Models		
	1190	1290	1291
Automatic Capture On (A= 3.5 V[c], V= 1.0 [assuming a threshold of 0.5])			
100% Paced			
350 Ω	8.9	6.0	8.4
500 Ω	8.9	6.3	9.0
750 Ω	9.0	6.8	9.5
1000 Ω	9.0	7.0	9.9
50% Paced			
350 Ω	9.0	6.9	9.7
500 Ω	9.1	7.2	10.1
750 Ω	9.1	7.4	10.4
1000 Ω	9.1	7.6	10.7
Automatic Capture On (A= 2.5 V[c], V= 1.0 [assuming a threshold of 0.5])			
100% Paced			
350 Ω	8.9	6.4	9.1
500 Ω	8.9	6.7	9.5
750 Ω	9.0	7.1	10.0
1000 Ω	9.0	7.3	10.3
50% Paced			
350 Ω	9.0	7.2	10.2
500 Ω	9.1	7.4	10.4
750 Ω	9.1	7.6	10.7
1000 Ω	9.1	7.7	10.9

a. Amplitudes shown are both atrial and ventricular; pulse width = 0.4 ms, pacing rate = 60 ppm, sensors = On.
b. Table displays typical parameter settings and the corresponding longevities from implant to ERT for all pacemaker models. Longevity can be greatly influenced by parameter settings.
c. This value is not applicable in single-chamber devices.

Magnet Test and Battery Operation

Magnet Rate[a]	Battery Status	Comments
100 ppm	BOL (Beginning of Life)	Perform normally scheduled follow-ups.
90 ppm	ERN (Elective Replacement Near)	Intensify follow-ups.
85 ppm	ERT (Elective Replacement Time)	Schedule replacement. Beat-to-Beat ventricular Automatic Capture is disabled and ventricular output is fixed at twice the last measured threshold but not > 5.0 V and not < 3.5 V. For adaptive-rate modes only: When the pacemaker reaches ERT, the mode will change to nonadaptive rate mode (e.g., DDDR to DDD, VVIR to VVI, etc)
85 ppm or less	EOL (End of Life)	Three months after ERT, the device will reach EOL. When EOL is reached, dual-chamber pacemakers will change modes to single-chamber operation (DDD and VDD revert to VVI) and the LRL will be lowered to 50 ppm. Schedule replacement immediately.

a. To perform a battery test using the magnet, the magnet operation must be programmed to Async. The AV Delay during a magnet test is 100 ms. When Automatic Capture is programmed Off, the third pulse of the magnet test is at 50% of the programmed Pulse Width to allow evaluation of the pacing safety margin.

Features List

Refer to Chapter 6, “Therapy” and Chapter 7, “Diagnostics and Follow-Up” for complete descriptions of the features.

Diagnostic Features

- Autothreshold (Commanded and Ambulatory)
- Interactive P- and R-Wave Amplitude measurements
- Interactive A and V Lead Impedance measurements
- Event Counters
- Sensor trending
- Patient Activity Log
- Rate Histograms
- Real-time intracardiac EGMs
- Annotated Event Markers
- Automatic Stored EGM
- Patient-Triggered Stored EGM

- High-Resolution Rate and Sensitivity trending
- Beat-to-Beat Holter
- Arrhythmia Logbook
- Daily P- and R-Wave Amplitude measurements and trend
- Daily A and V Lead Impedance measurements and trend
- Daily V Automatic Capture threshold measurements and trend
- Quick Check

Therapy Features

- Ventricular Automatic Capture
- AutoLifestyle
- Adaptive-Rate Sensors
  - Accelerometer
  - Minute Ventilation
    - MV Lead selection
    - Blended sensor
- A-Tachy Response
- Auto Sense
- Dynamic AV Delay
- PVARP after PVC/PAC
- PMT Termination
- Rate Smoothing
- Sensed AV Offset
- (Sensor) Rate Hysteresis
- Atrial Flutter Response
- AV Search Hysteresis
- Dynamic PVARP
- Programmed Electrical Stimulation/Burst
- Sudden Brady Response
- Sudden Brady Response with MV Offset
- Ventricular Rate Regulation (VRR)
- Safety Switch

INFORMATION FOR USE

CHAPTER 1

This chapter includes the following information associated with the INSIGNIA I Ultra pacemakers.

- Device Description
- Indications and Usage
- Contraindications
- Warnings and Precautions
- Adverse Events
- Summary of Clinical Studies
- Product Reliability
- Federal Communications Commission (FCC)
- Patient Counseling Information

DEVICE DESCRIPTION

The INSIGNIA I Ultra pacemakers are multiprogrammable. The family consists of both dual-chamber and single-chamber models, offering conventional and adaptive-rate therapy and ventricular Automatic Capture, as well as various levels of therapeutic and diagnostic functionality. The ventricular Automatic Capture feature automatically measures the ventricular pacing threshold and adjusts the pacing output to 0.5 V above this measured threshold. Following each ventricular pacing output, capture is automatically verified by the pacemaker via sensing of the evoked response. The pacemakers feature IS-1[1] as well as 3.2-mm/IS-1 connectors. The 3.2-mm/IS-1 connectors accept both IS-1 and 3.2-mm leads. Refer to page iv in the front of the manual for a list of features.

Two sensors are available with the INSIGNIA I Ultra adaptive-rate models: minute ventilation (MV) and an accelerometer (motion sensor). MV responds to changes in respiration, and the accelerometer responds to patient activity (motion). The INSIGNIA I Ultra models can use either the accelerometer or the MV sensor, or a blend of both accelerometer and MV. Refer to Chapter 3, “Technical Information” for a detailed description of the sensors.

INDICATIONS FOR USE

This pacemaker system is indicated for patients with any of the following conditions:

- Symptomatic paroxysmal or permanent second- or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (e.g., sinus bradycardia, sinus arrest, sinoatrial [SA] block)
- Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias
- Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes

1. IS-1 refers to the international standard ISO 5841.3:1992.

Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity.

The INSIGNIA I Ultra pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony.

Dual-chamber modes are specifically indicated for treatment of the following:

- Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm

CONTRAINDICATIONS

Use of certain pacing modes available in the INSIGNIA I Ultra pacemaker is contraindicated for the following patients under the circumstances listed:

- Patients with unipolar pacing leads or in MV mode with an implanted cardioverter defibrillator because it may cause unwanted delivery or inhibition of ICD therapy
- MV mode in patients with both unipolar atrial and ventricular leads
- Single chamber atrial pacing in patients with impaired AV nodal conduction
- Atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing
- Dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias
- Asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms

WARNINGS AND PRECAUTIONS

MV Sensor Calibration at Implant

WARNING: Inappropriate sustained high-rate pacing occurred in the PULSAR MAX clinical study in 5 out of 130 patients with Minute Ventilation On, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming:

- **a reduced Max Sensor Rate (MSR), or**
- **MV to Passive**

These programming recommendations are intended to assure that MV calibration is evaluated, and, if necessary, recalibrated (4→ On**) when the patient and pacing system have stabilized post-implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred. (See "MV Initialization" on page 1-8 for details of evaluation and correction of inappropriate high-rate pacing.)**

Clinical Considerations

- In devices with the Safety Switch programmed to On, the lead polarity will revert to unipolar in the presence of a lead impedance of < 100 Ω or > 2500 Ω. Unipolar pacing is contraindicated for patients with an ICD.
- STAT PACE will initiate unipolar pacing, which is contraindicated for patients with an ICD.
- Adaptive-rate pacing should be used with care in patients unable to tolerate increased pacing rates.
- Adaptive-rate modes based completely or in part on MV might be inappropriate for patients who can achieve respiratory cycles shorter than 1 second (greater than 60 breaths per minute). Higher respiratory rates attenuate the impedance signal, which diminishes the MV rate response (i.e., the pacing rate will drop toward the programmed Lower Rate Limit).
- Use of AAT or VVT modes outside of a diagnostic setting is not recommended due to the potential for triggered pacing in response to oversensing.

- Slow retrograde conduction combined with a short PVARP might induce pacemaker-mediated tachycardia.

- Automatic Capture is intended for ventricular use only. Do not program Amplitude to Auto for single-chamber devices implanted in the atrium.

- The safety and efficacy of the MV sensor modes have not been clinically established in patients with abdominal implant sites.

- Performance of the MV sensor may be adversely affected under transient conditions such as pneumothorax, pericardial effusion, or pleural effusion. Consider programming the MV sensor Off until these conditions are resolved.

Adaptive-rate modes based completely or in part on MV should not be used for the following patients:

- Those implanted with an ICD

- Those with unipolar leads, because a bipolar lead is required in either the atrium or ventricle for minute ventilation detection

- Those with epicardial ventricular leads, because MV measurement has only been tested with a bipolar transvenous lead

- Those using a mechanical ventilator, because use of the ventilator might result in an inappropriate MV sensor-driven rate

Sterilization, Storage, and Handling

- Storage Temperature and Equilibration. Recommended storage temperatures are 0°C–50°C (32°F–122°F). Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function. **Extremely** low temperatures (below –20°C) could result in permanent memory loss. If this occurs, as indicated by a programmer error message, return the device to Guidant for inspection.

- FOR SINGLE USE ONLY–DO NOT RESTERILIZE DEVICES. Return the unimplanted device to Guidant.

Do not implant a pacemaker if any of the following conditions apply:

- The pacemaker is dropped onto a hard surface. Return the device to Guidant for inspection.

- **Use before date**. Implant the device system before the USE BEFORE date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 1. **If a pacemaker with an expired "USE BEFORE" date is implanted, the pacemaker warranty is void.**

- The storage package has been pierced or altered, because this could have rendered it nonsterile.

Lead Evaluation and Connection

- **Pacing and sensing safety margins.** Consider lead maturation in choice of pacing amplitudes, pacing pulse widths, and sensing levels.

  - Acute pacing thresholds greater than 1.5 V or chronic pacing thresholds greater than 3 V can result in loss of capture because thresholds increase after implantation.

  - R-wave amplitude less than 5 mV or P-wave amplitude less than 2 mV can result in undersensing because sensed amplitude decreases after implantation.

  - Pacing lead impedance should be within the range of 100 Ω and 2500 Ω.

- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment, because leakage current exceeding 10 μA can induce ventricular fibrillation.

- **Setscrew position.** Do not insert a lead into the pacemaker connector without first visually verifying that the setscrews are sufficiently retracted to allow insertion.

- **Pacemaker/lead compatibility.** Prior to implanting this pacemaker, verify lead/pacemaker compatibility with Guidant Technical Services.

- **Proper programming of the lead configuration**. If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.

Implantation

- **Implanting a replacement pacemaker in a subcutaneous pocket that previously housed a larger device** may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Flooding the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.

- **Defibrillation causing a power surge exceeding 360 watt-seconds** can damage the pacemaker system.

Programming and Pacemaker Operation

- **Use a Guidant ZOOM LATITUDE Programming System, which includes the Model 2892 CONSULT Software Application** to communicate with the INSIGNIA I pacemakers.

- **Telemetry communication can be interrupted by electrical noise, thus preventing improper interrogation or programming.** If the message window appears indicating that the wand is out of range or there is telemetry noise, move the PRM and/or the wand away from such electrical devices as electrosurgical and monitoring equipment and ensure that the wand cord and cables are not crossing one another. Telemetry communication will resume when the noise source is removed. The message window also has a Cancel button that, when selected, will stop the interrogation.

- **A pacemaker programmed to STAT pacing, if not reprogrammed, will continue to pace in SSI mode at the high-energy STAT values.** Reprogram the pacemaker to other parameter settings for alternative patient therapies or to extend pacemaker longevity.

- **Adaptive-rate pacing is not limited by refractory periods.** A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods, since the combination can cause a very small sensing window or none at all. Use Dynamic AV Delay or Dynamic PVARP to optimize sensing windows.

- **If the Amplitude is Off during temporary programming, the pacemaker will not pace.** Pacing with the permanently programmed parameters can be

restored by breaking the telemetry link or by selecting the Cancel button on the Temporary Parameters Now in Use dialogue window.

MV Initialization

- In some patients MV Initialization will need to be repeated by performing the 4→ On-A or 4→ On-V initialization procedure. Factors affecting the MV baseline included lead maturation effects, air entrapment in the pocket, pacemaker motion due to inadequate suturing, and other patient complications (e.g., pneumothorax).

- A 4→ On initialization should be performed if the pacemaker is removed from the pocket following implant, such as during a lead repositioning procedure.

- A 4→ On initialization should be performed to establish a new MV baseline if one of the following conditions is noted during MV sensor evaluation:

  - Failure to achieve a significant sensor-indicated response with the MV Response Factor set to level 16

  - Observed maximum or elevated sensor-indicated rates with the MV Response Factor set to level 2

Environmental and Medical Therapy Hazards

Patients should be directed to avoid devices that generate strong electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

Hospital and Medical Environments

Confirm pacemaker operation after any of the following medical procedures.

- **Mechanical ventilators** might result in an inappropriate MV sensor-driven rate when MV is programmed On. Program the MV sensor Off during mechanical ventilation.

- **Electrical signals** introduced into the body by some hospital monitoring and/or diagnostic equipment may result in accelerated pacing, possibly up to the maxi-

mum sensor-driven rate, when MV is programmed On. Examples of this equipment include, but are not limited to, respiratory monitors, diagnostic echo imaging, surface ECG monitors, and hemodynamic monitors. Deactivate the MV sensor when interaction with this equipment is suspected.

- **Electrosurgical cautery** could induce ventricular arrhythmias and/or fibrillation, may cause asynchronous or inhibited pacemaker operation, or may trigger the EOL indicator. If electrocautery cannot be avoided, observe the following precautions to minimize complications:
  - Program the device to the VOO/AOO/DOO mode and avoid direct contact with the pacemaker or leads.
  - Position the ground plate so that the current pathway does not pass through or near the pacemaker system.
  - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
  - Use a bipolar electrocautery system where possible.
  - Have temporary pacing and defibrillation equipment available.
- **Radio-frequency (RF) ablation** may cause asynchronous or inhibited pacemaker operation, and possible reset of the pacemaker. During RF ablation, the current path (electrode tip to ground plate) should be kept as far away from the pacemaker and leads as possible, and the output amplitude of the pacemaker should be programmed to the 5-V setting, or greater. Avoid direct contact between the ablation catheter and the implanted lead and pacemaker.
- **Magnetic resonance imaging** (MRI) for pacemaker patients has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decision to use MRI with pacemaker patients.
  - Magnetic and RF fields produced by MRI may increase ventricular pacing beyond the rate limit, result in total inhibition of pacing output, result in pacing at random rates, or result in asynchronous pacing.
  - Magnetic fields may activate magnet mode operation and cause asynchronous pacing.
  - MRI can irreversibly damage the pacemaker.

  - Pacemaker patients treated with MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI.

- **Lithotripsy** may permanently damage the pacemaker if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, do not focus near the pacemaker site. The lithotriptor is designed to trigger off the R-wave on the ECG resulting in shock waves being delivered during the ventricular refractory period. Program to VVI/VOO mode because atrial pacing pulses can trigger the lithotriptor.

- **Therapeutic ultrasound energy** may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site.

- **Therapeutic diathermy** may cause fibrillation, burning of the myocardium, and irreversible damage to the pacemaker because of induced currents.

- **External defibrillation** may damage the pacemaker. Attempt to minimize the current flowing through the pacemaker and lead system by following these precautions:

  - Position defibrillation paddles as far from the pacemaker as possible and perpendicular to the implanted pacemaker/lead system.

  - Use the lowest clinically appropriate energy output (watt-seconds). Protective thyristors help shield pacemaker circuitry from electrical damage during external defibrillation procedures up to 360 watt-seconds. However, the precautionary measures listed in the “External Defibrillation Protection” section on page 3-6 should be implemented.

- **Transcutaneous electrical nerve stimulation** (TENS) may interfere with pacemaker function. If necessary, the following measures may reduce interference:

  - Place the TENS electrodes as close to each other as possible.

  - Place the TENS electrodes as far from the pacemaker/lead system as possible.

  - Monitor cardiac activity during TENS use.

- **Diagnostic x-ray and fluoroscopic radiation** should not affect the pacemaker. For high radiation sources, see ionizing radiation therapy warning below.

- **Ionizing radiation therapy** may adversely affect device operation. During ionizing radiation therapy (e.g., radioactive cobalt, linear accelerators, and betatrons) the pulse generator must be shielded with a radiation-resistive material, regardless of the distance of the device to the radiation beam. Do not project the radiation port directly at the device. Always evaluate device operation, including interrogation and sensing and pacing threshold testing after each radiation treatment.

Home and Occupational Environments

Patients should be advised of the following potential sources of EMI:

- **High-voltage power transmission lines** might generate enough EMI to interfere with pacemaker operation if approached too closely.

- **Communication equipment** such as microwave transmitters, linear-power amplifiers, or high-powered amateur transmitting systems might generate enough EMI to interfere with pacemaker operation if approached too closely.

- **Commercial electrical equipment** such as arc welders, induction furnaces, or resistance welders might generate enough EMI to interfere with pacemaker operation if approached too closely.

- **Electronic article surveillance (EAS) equipment** such as retail theft prevention systems might interact with pulse generators. Patients should be advised to walk directly through and not to remain near an EAS system longer than is necessary.

- **Home appliances** that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

Cellular Phones

Patients having an implanted pacemaker who operate a cellular phone should observe the following precautions:

- Maintain a minimum separation of 6 inches (15 cm) between a handheld personal cellular phone and the implanted device. Portable and mobile cellular phones generally transmit at higher power levels compared to handheld models.

For phones transmitting above 3 watts, maintain a minimum separation of 12 inches (30 cm) between the antenna and the implanted device.

- 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 6 inches (15 cm) of the implanted device as some phones emit signals when they are turned On but not in use (i.e., in the listen or standby mode). Store the phone in a location opposite the side of the implant site.

Explanted Pacemakers

- Do not incinerate pacemakers, because they can explode if subjected to incineration or cremation temperatures; be sure that the pacemaker is explanted before a deceased patient is cremated.

- Return all explanted pacemakers and leads to Guidant for analysis and disposal. Examination of explanted devices can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

- Do not implant an explanted pacemaker in another patient as sterility, functionality, and reliability cannot be insured.

ADVERSE EVENTS

Observed Adverse Events

All adverse events were classified as observations and complications. All observations and complications are listed by type and category in Table 1-1. There were 93 documented adverse events of Type I-IV in the INSIGNIA I Ultra Clinical. To date, there have been no reported unanticipated adverse events due to the testing and/or implantation of the INSIGNIA I Ultra system.

Table 1-1. Adverse Events Reported

	Total Number Of Events (number of patients)	% Comps (Patient) N=101 Patients	N Comps/ 100 Device Months 443 Months	% Obs (Patient) N=101 Patients	N Obs/ 100 Device Months 443 Months
Total Adverse Events	**93 (55)**	**6.9 (7)**	**1.6 (7)**	**51.5 (52)**	**19.4 (86)**
PG-related Events					
Autothreshold-related problem	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Event marker, noise	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Intrinsic measurement, inaccurate	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Pectoral muscle stimulation	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Rate response insufficient, brady	4 (4)	0.0 (0)	0.0 (0)	4.0 (4)	0.9 (4)
Rate response too aggressive, brady	10 (9)	0.0 (0)	0.0 (0)	8.9 (9)	2.3 (10)
RA Lead-related Events					
Lead dislodgment, right atrium	3 (3)	3.0 (3)	0.7 (3)	0.0 (0)	0.0 (0)
Oversensing, atrium rate, tachy	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)
Oversensing, atrium rate sense, brady	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)
Phrenic Nerve Stimulation	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Threshold difference, pacing, elevated, chronic	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Threshold difference, pacing, elevated, acute	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Threshold difference, pacing, non-specific	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)

Table 1-1. Adverse Events Reported

	Total Number Of Events (number of patients)	% Comps (Patient) N=101 Patients	N Comps/ 100 Device Months 443 Months	% Obs (Patient) N=101 Patients	N Obs/ 100 Device Months 443 Months
Undersensing, atrium rate sense, brady	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
RV Lead-related Events					
Oversensing, ventricle pace sense, brady	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Oversensing, ventricle rate sense, brady	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Threshold Difficulty	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Undersensing, ventricle rate sense, brady	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Subtotal, Device-related Events	**35 (25)**	**3.0 (3)**	**0.7 (3)**	**23.8 (24)**	**7.2 (32)**
Procedure-related Events					
Bleeding/fluid accumulation	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Hematoma	3 (3)	0.0 (0)	0.0 (0)	3.0 (3)	0.7 (3)
Infection, post-operative wound	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Muscle stimulation	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Pericardial effusion	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Pneumothorax	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Subtotal, Procedure-related Events	**8 (8)**	**0.0 (0)**	**0.0 (0)**	**7.9 (8)**	**1.8 (8)**
Cardiovascular-related Events					
Angina	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Arrhythmia	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)
Arrhythmia, SVT	10 (10)	2.0 (2)	0.5 (2)	7.9 (8)	1.8 (8)

Table 1-1. Adverse Events Reported

	Total Number Of Events (number of patients)	% Comps (Patient) N=101 Patients	N Comps/ 100 Device Months 443 Months	% Obs (Patient) N=101 Patients	N Obs/ 100 Device Months 443 Months
Chest pain	3 (3)	0.0 (0)	0.0 (0)	3.0 (3)	0.7 (3)
Congestive heart failure	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Dizziness	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)
Dyspnea (shortness of breath)	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)
Hypertension	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Palpitations	7 (6)	0.0 (0)	0.0 (0)	5.9 (6)	1.6 (7)
Pleural effusion	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Pulmonary edema	2 (2)	0.0 (0)	0.0 (0)	2.0 (2)	0.5 (2)
Respiratory distress	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Syncope	5 (5)	0.0 (0)	0.0 (0)	5.0 (5)	1.1 (5)
High Pacing Rate	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Thrombosis	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Ventricular fibrillation	1 (1)	0.0 (0)	0.0 (0)	1.0 (1)	0.2 (1)
Subtotal Cardiovascular-related Events	**41 (30)**	**2.0 (2)**	**0.5 (2)**	**27.7 (28)**	**8.8 (39)**
Total Non-cardiovascular-related Events	**9 (9)**	**2.0 (2)**	**0.5 (2)**	**6.9 (7)**	**1.6 (7)**

Potential Adverse Events

Historically reported adverse events from implantation of a pacemaker are listed below in alphabetical order:

- Cardiac perforation
- Cardiac tamponade
- Component failure

- Death
- Elevated thresholds
- Erosion through the skin
- Fibrotic tissue formation
- Foreign body rejection phenomena
- Hematoma/seroma
- Infection
- Lead abrasion
- Lead fracture, insulation break
- Local tissue reaction
- Myopotential sensing
- Nerve and muscle stimulation
- Pacemaker mediated tachycardia (PMT)
- Pacemaker migration
- Transvenous lead-related thrombosis

SUMMARY OF CLINICAL STUDIES

Clinical Study, INSIGNIA I Ultra

Study Design

This clinical study was a prospective, multi-center, randomized test order within patient, clinical evaluation to document appropriate system performance of the INSIGNIA I Ultra pacemaker system in humans. Patients implanted with the INSIGNIA I Ultra pacemaker were followed through pre-discharge, 1-month and 3-month follow-ups. The purpose of this clinical study was to support safety and effectiveness of the Guidant INSIGNIA I Ultra pacemaker system.

Patient Demographics

The patients who participated in this study were from each investigator's general patient population which met indications for use (page 1-2) and had no contraindications (page 1-3) of the INSIGNIA I Ultra system. There were 105 patients enrolled in this clinical study; 101 that were implanted with the pacemaker system and followed through three months. Four patients were enrolled but did not undergo an implant procedure (intent). There were no patients attempted but not implanted.

The mean age of patients implanted with an INSIGNIA I Ultra was 69.5 years. The INSIGNIA I Ultra clinical study consisted of 62 males and 39 females. The predominant pacemaker indications were 3rd degree AV block, sinus bradycardia and sinus node dysfunction. These indications are typical of dual chamber pacemaker implants.

Commanded Autothreshold versus Manual Threshold Test

The accuracy of the Autothreshold test performed by the device was evaluated by comparing the threshold test results obtained by using the device commanded Autothreshold feature to those of manual threshold testing in the ventricle of the same patient at the same pulse width (0.4ms). The manual threshold and commanded Autothreshold algorithms decrements by a resolution of 0.2 V. The Autothreshold was evaluated at pre-discharge, one and three month follow-ups in all patients. The order of the threshold tests (commanded/manual or manual/commanded) was randomized at pre-discharge and that order was followed also at the one and three month follow-ups. Refer to Table 1-2 on page 1-17.

Table 1-2. Commanded Autothreshold Performance

Threshold Test	n	mean ± std	Range	p-value
Commanded test	296	0.652 ± 0.335	[0.200–2.100]	
Manual test	300	0.651 ± 0.335	[0.200–2.200]	
Paired Difference	296	-0.001 ± 0.049	[-0.300–0.300]	<0.0001[a]

a. Paired comparison for equivalence. Small p-value supported the alternative hypothesis that the means are equivalent.

Ventricular Lead Mix

The Automatic Capture feature is designed to work with any ventricular lead. The INSIGNIA I Ultra clinical study allowed for any type of leads chosen by physicians without excluding any specific lead.

The following lead manufacturers leads were used: APC, Biotronik, Ela, Guidant, Intermedics, Medtronic, St. Jude, Sorin, Teletronics, and Viatron. There were 31 different types of ventricular leads in the INSIGNIA I Ultra clinical study:

- Polarity: 11% unipolar 89% bipolar

- Fixation: 45% passive 55% active
- Impedance: 17% normal 83% high
- Steroid: 14% non-steroid 86% steroid

The data indicates that the Commanded Autothreshold test accurately determines the ventricular pacing threshold using any ventricular lead.

Complication Free Rate

The complication free rate was observed from all scheduled and unscheduled follow-up visits through the patient's three-month follow-up period. A complication is defined as a clinical event that results in invasive intervention, injury, or death (e.g., surgical evacuation of a hematoma, lead dislodgment requiring invasive lead repositioning, pulse generator replacement). The complication free rate was 93.1%; this met the goal of ≥ 90% (by equivalent test, $p < 0.0001$). There were no complications related to the Automatic Capture and AutoLifestyle features, which were required to be turned "ON" throughout the study.

Delivery of the Backup Pulse

The Automatic Capture feature backup pulse delivery was evaluated at the 3-month visit in 83 patients. These patients had the Automatic Capture feature turned "ON" and were in beat-to-beat capture verification mode. Patients underwent 24-hour Holter monitoring and analysis. During beat-to-beat capture verification mode, the device determines if a pacing pulse captured the heart and, if a loss of capture is determined, delivers a back-up pulse.

Table 1-3. Loss of Capture without Back-up Pulse Events

Number of Patients Evaluated[a]	Number of Events
83	0

a. Eleven patients did not require a Holter, five patients did not have valid Trending Data Exports disk, and one patient did not have a valid Holter.

This data indicates that the Automatic Capture feature during beat-to-beat capture verification mode appropriately determines if the primary pacing pulse captured the ventricle and delivers a back-up pacing pulse when needed.

Evaluation of Ambulatory Autothreshold

The ability of the Ambulatory Autothreshold test to determine the ventricular threshold overall was 97.1% (n=3746 tests). The primary reason for unsuccessful Ambulatory Autothreshold tests was that the pacemaker initiated an ATR mode switch during the ambulatory threshold test.

The data indicates that the Ambulatory Autothreshold test accurately determines the ventricular pacing threshold on any lead.

AutoLifestyle Feature

This endpoint evaluated the ability of the AutoLifestyle feature to increase or decrease the MV max Long Term resulting from daily activities and/or a maximal exercise test. The AutoLifestyle feature was evaluated at the one and three-month follow-up in all patients. At the one-month visit the first 60 patients with a minimum of 15 valid tests from each group (AutoLifestyle "ON"/"4 -minute fast walk within 30 minutes" and AutoLifestyle "ON") participated in a maximal exercise test (Borg Scale value 15-20 on a scale 6-20). All patients were to have the AutoLifestyle feature on throughout the entire evaluation period.

The feature was evaluated by verifying data from the activity log of the device for no inappropriate response. The activity log records the time, date, MV Response Factor and MV max with the change in the MV max Long Term invoked by the AutoLifestyle feature.

All patients were evaluated at the 1-month and 3-month follow-up visits. There was no incidence of inappropriate response per the predefined criteria at either the 1-month or 3-month follow-ups.

Conclusions

The objective of this study was to provide clinical information to support the complication free rate and to assess the effectiveness of the INSIGNIA I Ultra pacemaker system. The following conclusions can be made from this study:

- The data indicates that the Commanded Autothreshold test accurately determines the ventricular pacing threshold on any lead
- This data provides reasonable assurance the INSIGNIA I Ultra pacemaker system is safe

- The Automatic Capture feature during beat-to-beat capture verification mode appropriately determines if the primary pacing pulse captured the ventricle and delivers a back-up pacing pulse when needed

- The data indicates that the Ambulatory Autothreshold test accurately determines the ventricular pacing threshold on any lead

Clinical Studies, Adaptive Rate Therapy PULSAR MAX

The INSIGNIA I systems have the same sensing, therapies, diagnostics, and electrophysiology testing features as the PULSAR MAX system; therefore, the PULSAR MAX study supports the INSIGNIA I system. The PULSAR MAX system is included to augment clinical data from the INSIGNIA I Ultra study as presented above.

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 CAEPs were performed (n = 56 blended, n = 54 MV only), and data were available for 96 of these (Table 1-4 on page 1-21). 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.

Methods

Rate response was evaluated using system diagnostic outputs during predischarge submaximal exercise using a low-intensity treadmill exercise (LITE) protocol for sensor optimization and 24-hour Holter monitoring. Chronotropic Assessment Exercise Protocol (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 1-4 provides a summary of patient characteristics. Table 1-5 lists the patient arrhythmia history.

Table 1-4. 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 1-5. Patient Arrhythmia History

Arrhythmias[a]	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

Table 1-5. Patient Arrhythmia History

Arrhythmias[a]	Model 1270 (N = 130)
Right Bundle Branch Block	11
Arrhythmia Resulting from Ablation	4
Intraventricular Conduction Delay	1
Other	23

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

Table 1-6 summarizes the programmed parameters for patients who performed CAEP exercise testing.

Table 1-6. 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.

Results

Table 1-7 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 1-7. 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 Efficiacy Endpoint.

Figure 1-1 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.

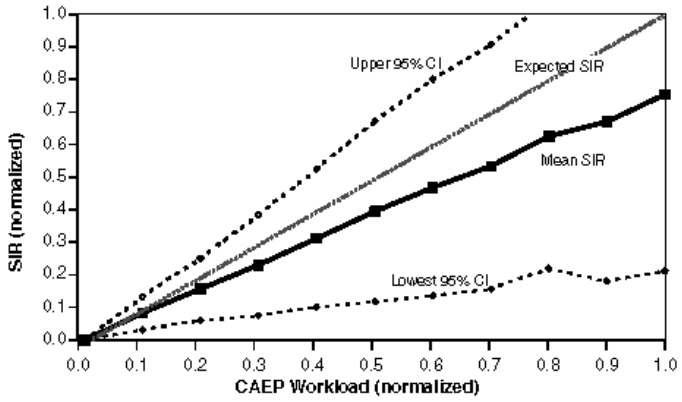


Figure 1-1. Sensor-indicated rate (SIR) vs expected rate during CAEP. All patients completing at least four stages of exercise, blended sensor only. (n = 46, 1 month)

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 1-2 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 (eg., angina, drop in blood pressure) as defined by the American College of Sports Medicine.[1]

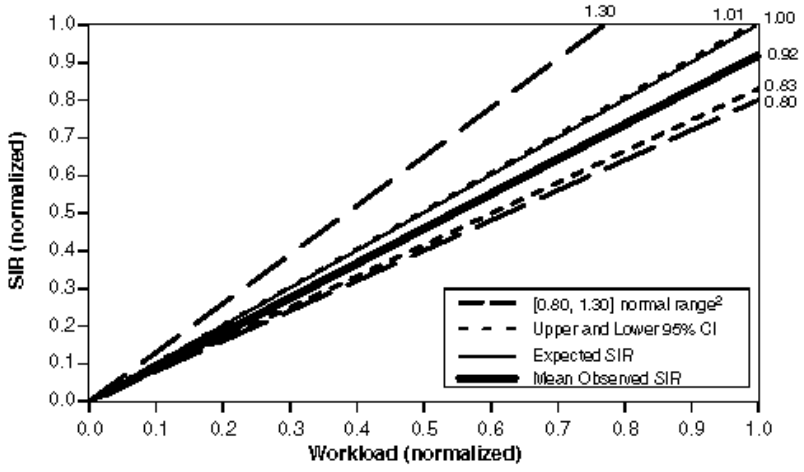


Figure 1-2. Sensor-indicated rate (SIR) vs expected rate during CAEP (1 month). Patients reaching maximal workload, blended sensor mode. Expected rate, mean, and normal range. (n = 31)

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

Table 1-8 shows the summary statistics for exercise testing in blended sensor and MV-only modes.

Table 1-8. 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)[1].

Clinical Study, Auto Sense

The INSIGNIA I systems have the same sensing, therapies, diagnostics, and electrophysiology testing features as the PULSAR MAX II system; therefore, the PULSAR MAX II study supports the INSIGNIA I system. The purpose of the study was to demonstrate the safety and efficacy of the PULSAR MAX II device.

Patient Demographics

The patients (65 M / 38 F) had a mean age of 70 years (range 36 to 94). Most (80 patients) presented with Sinus Bradycardia and Sinus Node Dysfunction.

Methods

The PULSAR MAX II chronic study collected data at implant, pre-discharge, 1-month, 1 month and 1day, 3 months, and 3 months and 1 day. Data collected consisted of Holter data, CAEP testing, pacemaker evaluation and observation/complication recording.

Results

A complication-free rate of 92.2% seen in this investigation met the acceptance criteria of being equivalent to the complication free rate observed in the PULSAR MAX study.

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

The results of the Auto Sense feature performance of PULSAR MAX II demonstrate that Auto Sense and manual programming of sensitivity are equivalent in both the atrium and the ventricle when comparing mal-sensing episodes. This comparison on paired differences was conducted at 1 month (Atrium: p-value <0.0001, ventricle: p-value: <0.0001) and at 3 months (Atrium: p-value <0.0001, ventricle: p-value: <0.0001). Comparisons between the mean differences determined for Auto Sense ON at the one-month and three-month follow-ups were evaluated and no significant differences in the atrium (p-value: 0.1188) or ventricle (p-value: 0.3177) were observed, indicating that the Auto Sense feature's performance does not change over time.

Conclusion

The results of the Auto Sense feature of PULSAR MAX II demonstrate that Auto Sense and manual programming of sensitivity are equivalent.

PRODUCT RELIABILITY

It is Guidant's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. These malfunctions may include the following:

- Premature battery depletion
- Sensing or pacing issues
- Error codes
- Loss of telemetry

Refer to Guidant's CRM Product Performance Report on www.guidant.com for more information about device performance, including the types and rates of malfunctions that these devices have experienced historically. While historical data may not be predictive of future device performance, such data can provide important context for understanding the overall reliability of these types of products.

Sometimes device malfunctions result in the issuance of safety advisories. Guidant determines the need to issue safety advisories based on the estimated malfunction rate and the clinical implication of the malfunction. When Guidant communicates safety advisory information, the decision whether to replace a device should take into account the risks of the malfunction, the risks of the replacement procedure, and the performance to date of the replacement device.

FEDERAL COMMUNICATIONS COMMISSION (FCC)

This device complies with Title 47, Part 15 of the FCC rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation of the device.

CAUTION: Changes or modifications not expressly approved by Guidant could void the user's authority to operate the equipment.

PATIENT COUNSELING INFORMATION

The following are topics that the clinician might want to discuss with the patient prior to discharge:

- Signs and symptoms of infection
- Symptoms that should be reported (e.g., sustained high-rate pacing requiring reprogramming)
- Activity restrictions (if applicable)
- Minimum heart rate (lower rate limit of the pacemaker)
- Frequency of follow-up
- MV sensor adaptation process and symptoms of high-rate pacing
- It is Guidant's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. When Guidant communicates safety advisory information, the decision whether to replace a device should take into account the risks of the malfunction, the risks of the replacement procedure, and the performance to date of the replacement device.

Patient Handbook

A copy of the patient handbook, *Your Pacemaker and You,* is packaged with each device. It contains information for the patient, patient's relatives, and other interested people. Discuss the information in the handbook with concerned individuals both before and after pacemaker implantation so they are fully familiar with operation of the device. For additional copies of the patient handbook, contact the nearest sales representative or contact Guidant at the address on the back cover of this manual.

Patient Identification (ID) Card

A temporary patient identification (ID) card is packaged with each device. A permanent ID card will be sent to the patient 4 to 6 weeks after the implant form is received by Guidant. The patient should be advised to carry the patient ID card at all times.

PRE-IMPLANT AND IMPLANT INFORMATION

CHAPTER 2

This chapter discusses procedures used when implanting the INSIGNIA I Ultra pacemakers. The following topics are discussed:

- Storage
- Opening Instructions
- Items Included
- Sterilization
- Lead Connections
- Pacemaker Insertion

STORAGE

Take the following precautions when storing or handling a pacemaker:

CAUTIONS:

- Never attempt to resterilize a pacemaker or the wrench packaged with it. Instead, return the pacemaker to Guidant.

- **Use before date.** Implant the device system before the USE BEFORE date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 1. **If a pacemaker with an expired "USE BEFORE" date is implanted, the pacemaker warranty is void.**

- Some conditions and exposure to low preimplant temperatures (lower than 0°C) during shipping or storage may cause an electrical reset to occur. In these cases, warm the device to room temperature and, if possible, clear the status with the programmer. If this is not possible, call Guidant Technical Services.

- Storage Temperature and Equilibration. Recommended storage temperatures are 0°C–50°C (32°F–122°F). Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function. **Extremely** low temperatures (below –20°C) could result in permanent memory loss. If this occurs, as indicated by a programmer error message, return the device to Guidant for inspection.

- Do not implant a pacemaker if the storage package has been pierced or altered, because this could have rendered it nonsterile.

- If a pacemaker is dropped onto a hard surface, do not implant it. Return the device to Guidant for inspection.

OPENING INSTRUCTIONS

The outer package and sterile trays should be opened by authorized personnel under clean conditions. To ensure sterility, the sealed inner tray must be opened using accepted aseptic technique by scrubbed, masked, sterile-gowned personnel. The sterile trays are opened by peeling back the covers.

ITEMS INCLUDED

Each pacemaker is packaged with one bidirectional torque wrench and product literature including the *Physician's Technical Manual*, patient handbook, forms, and a limited warranty.

STERILIZATION

The pacemaker blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pacemaker is received, it is sterile, provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Guidant.

CAUTION: FOR SINGLE USE ONLY—DO NOT RESTERILIZE DEVICES. Return the unimplanted device to Guidant.

LEAD CONNECTIONS

INSIGNIA I pacemakers are available with various lead connectors that accept IS-1 and 3.2-mm leads.

Lead selection depends on the needs of each patient. The longevity of this product, as with other pacemakers, may be enhanced by using high-impedance pacing leads. Using a bipolar lead will reduce the chance of myopotential sensing.

NOTE: *A bipolar lead must be used in either the atrium or the ventricle when the pacemaker is programmed to use the MV sensor.*

Refer to the lead's instruction manual for implant information, general warnings and precautions, indications, contraindications, and technical specifications. Read this material carefully for implant procedure instructions specific to the chosen lead configurations.

CAUTIONS:

- Prior to implanting this pacemaker, verify lead/pacemaker compatibility with Guidant Technical Services.

- If using an IS-1 or 3.2-mm unipolar lead not manufactured by Guidant with the INSIGNIA I pacemakers, be sure the lead has an anode terminal protector to permit tightening of the proximal setscrew. All Guidant IS-1 and 3.2-mm leads have this protector.

- The absence of a lead or plug in a lead port may affect device performance. If a lead is not used, be sure to properly insert a plug in the unused port.
- Exercise extreme caution if testing leads using line-powered equipment, because leakage current exceeding 10 μA can induce ventricular fibrillation.
- Consider lead maturation in choice of pacing amplitude and sensitivity, for the following reasons:
  - Acute pacing thresholds greater than 1.5 V or chronic pacing thresholds greater than 3 V can result in loss of capture because thresholds increase after implantation.
  - R-wave amplitude less than 5 mV or P-wave amplitude less than 2 mV can result in undersensing because sensed amplitude decreases after implantation.
  - Pacing lead impedance should be within the range of 100 Ω to 2500 Ω.
- Proper programming of the Lead Configuration is essential. If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.

Lead Adapters

When replacing another pacemaker with an INSIGNIA I pacemaker, you may need to use an adapter that will enable you to connect the new pacemaker to the existing leads. Refer to Table 2-1 to determine the correct model and adapter.

Table 2-1. Lead Adapters[a]

Lead Terminal	IS-1 Only	3.2-mm/IS-1
	Models 1190, 1290	**Model 1291**
Unipolar IS-1	Direct connection	Direct connection
Bipolar IS-1	Direct connection	Direct connection
Unipolar 3.2 mm	Model 6986	Direct connection
Bipolar 3.2 mm	Model 6986	Direct connection
Bipolar 2 x 5 (4.75 mm) Bifurcated	Model 6024	Model 6024
Unipolar 5 (4.75 mm)	Not available	Not available
Unipolar 6 (5.38 mm)	Not available	Not available

a. Guidant leads are recommended for use with these pacemakers.

When using an adapter, follow the connection procedure described in the applicable adapter product data sheet. Always connect the adapter to the lead and repeat threshold and sensing measurements before connecting the adapter to the pacemaker.

Lead-to-Pacemaker Connection

After placing the lead and preparing a subcutaneous pocket, connect the lead to the pacemaker using the following procedure:

1. **Insert the lead terminal into the connector**.

NOTE: *If necessary, lubricate the lead terminal sparingly with sterile water to make insertion easier.*

CAUTIONS:

- Do not insert a lead into the pacemaker connector without first visually verifying that the setscrews are sufficiently retracted to allow insertion.

- Insert the lead connector straight into the lead port. Do not bend the lead near the lead–header interface. Improper insertion (see following notes) can cause insulation damage near the terminal ring that could result in lead damage.

NOTES:

- *For proper connection of an IS-1 lead to the pacemaker, be certain that the connector pin visibly extends through the connector block at least 1 mm (Figure 2-1).*

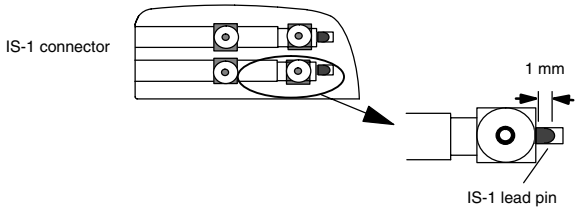


Figure 2-1. The IS-1 connector.

- *For proper connection of a 3.2-mm (i.e., not an IS-1 style lead) to the pacemaker, be certain that the lead connector pin is within 1 mm of the end of the pacemaker lead barrel (Figure 2-2).*

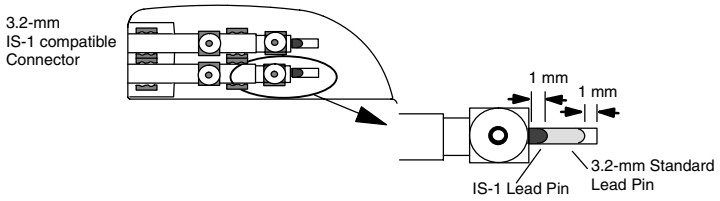


Figure 2-2 The 3.2-mm/IS-1 connector.

- *During implant of a pacemaker in unipolar pacing configuration, asynchronous pacing spikes occurring at the programmed rate could be observed on an ECG before placing the pacemaker into the subcutaneous pocket. These subthreshold spikes will not occur when contact between the pacemaker case and subcutaneous tissue completes the normal pacing circuit.*

2. Insert the torque wrench into the center, preslit depression of the seal plug (Figure 2-3) located near the tip of the fully inserted lead connector pin.

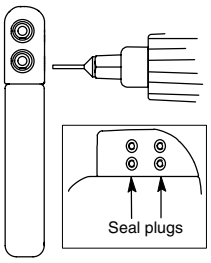


Figure 2-3. Tightening the set-screws.

NOTE: *The pacemaker features captured setscrews that require use of the bidirectional torque wrench included in the package.*

CAUTION: Failure to properly insert the torque wrench into the preslit location of the seal plug could result in damage to the plug and its sealing properties. Failure to use the supplied torque wrench could result in damage to the setscrew or connector threads.

3. **Maintain pressure on the lead to ensure that it remains fully inserted into the lead barrel.**

4. **Tighten the setscrews until the wrench handle ratchets.**

   Additional force is unnecessary as the torque wrench is preset to apply adequate force to the setscrew. Tighten the other setscrew(s) in a similar manner.

NOTE: *Electrical contact between the pacemaker and lead is established as soon as the lead connector is inserted into the lead barrel.*

PACEMAKER INSERTION

Automatic Lead Implant Detection

The pacemaker is shipped in a Ship mode. The Ship parameters are listed in Table 2-2. When the pacemaker is in the Ship mode, the atrial and ventricular lead impedances are measured in Bipolar configuration. Upon insertion and tightening of either an atrial or ventricular Bipolar lead into the header, the impedance measurement circuit will detect an impedance measurement of < 2500 Ω, which indicates that the device is implanted. The pacemaker will automatically switch to the nominal parameters (Table C-1 on page C-1). The pacemaker can also be

programmed out of the Ship mode prior to implant using the PRM and the Model 2892 CONSULT Software Application. Any programming action prior to implant will take the pacemaker out of the Ship mode.

Table 2-2. Ship Parameter Values

Parameter	Ship (DOO or SOO)
Pacing rate (ppm)	30
Pulse Width (ms)	0.4
Amplitude (V)	3.5
Sensitivity (mV)	NA
Refractory (ms)	NA
Lead Configuration	Bipolar
Magnet Response	Off

The following will initialize and start once lead insertion has been detected (lead impedance < 2500 ohms):

- Daily Lead Impedance measurements
- Daily P- and R-wave measurements
- Arrhythmia Logbook (Ventricular Tachy Detection and A-Tachy Response triggers)
- Activity Log

The following will initialize and start when the device exits the Ship mode:

- Rate Trending
- Histograms and Counters

NOTES:

- *If a unipolar pacing configuration is required at implant, program the Lead Configuration to Unipolar before implant.*

- *Arrhythmia Logbook and Stored EGM data will not be stored for the first 2 hours after the lead is inserted into the header during implant.*

Pacemaker Insertion Procedure

1. **Place the pacemaker into the subcutaneous implant pocket.**

   If the pacemaker is coated, the uncoated window must face away from the muscle to reduce the possibility of muscle stimulation. Use caution to prevent damage to the silicone coating during the implant procedure.

CAUTION: If pacing is unipolar, be sure that permanent contact has been established between the pacemaker window and subcutaneous tissue. Otherwise, the pacemaker might not function properly.

2. **Verify pacemaker operation using an ECG.**

   If the patient's intrinsic rhythm is above the programmed rate, use a magnet to temporarily switch the pacemaker to an asynchronous magnet rate at 100 ppm (see "Magnet Test" on page 4-5). If proper pacing and/or sensing are not demonstrated, disconnect the lead from the pacemaker and visually inspect the connector and leads. If necessary, retest the lead. Inadequate signals could indicate possible lead dislodgment, which would necessitate lead repositioning.

3. **Suture the pacemaker in position.**

   Use the suture hole in the pacemaker top to secure the pacemaker in the subcutaneous pocket. This will ensure proper MV sensing

CAUTIONS:

- Implanting a replacement pacemaker in a subcutaneous pocket that previously housed a larger device may result in pocket air entrapment, migration, erosion, or insufficient grounding between the device and tissue. Flooding the pocket with sterile saline solution decreases the possibility of pocket air entrapment and insufficient grounding. Suturing the device in place reduces the possibility of migration and erosion.
- Before closing the subcutaneous pocket, ensure that the setscrews are properly tightened and that the pacemaker functions properly.

TECHNICAL INFORMATION

CHAPTER 3

This chapter includes the following technical information about the INSIGNIA I Ultra pacemakers:

- Adaptive-Rate Sensors
- X-ray Identifier
- Minimizing Pacemaker/ICD Interaction
- External Defibrillation Protection
- Reset
- Output Pulse
- Output Circuit Recharge Cycle
- Runaway Protection

ADAPTIVE-RATE SENSORS

Two sensors are available with the INSIGNIA I Ultra pacemakers: an accelerometer and minute ventilation (MV) detection. The accelerometer responds to patient activity (motion), and MV responds to changes in respiration. The devices can use either the accelerometer or MV sensor, or a blend of both accelerometer and MV.

Accelerometer

The pacemakers sense body motion by means of an integrated circuit accelerometer located on the hybrid circuit board. The accelerometer responds to activity in the frequency range of typical physiologic activity (1–10 Hz). An algorithm translates the measured acceleration in this range into a rate increase above the Lower Rate Limit. Because the accelerometer is not in contact with the pacemaker case, response to pressure applied to the pacemaker is negligible. See the “Sensor Submenu” section on page 6-22 for information on programming the accelerometer parameters.

Minute Ventilation (MV)

Minute ventilation (MV) is the product of respiration frequency (breaths/minute) and tidal volume.

Up to the anaerobic threshold, MV is by approximation linearly related to heart rate. At exercise levels beyond the anaerobic threshold, the relationship is still approximately linear but at a reduced slope (Figure 3-1).

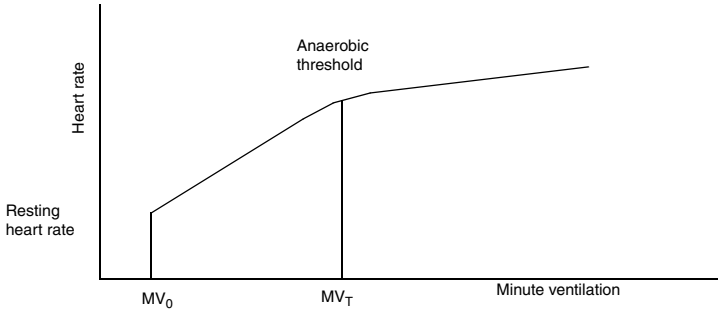


Figure 3-1. Typical relationship between MV and heart rate.

The MV sensor for rate adaptation is derived by means of transthoracic impedance measurement. Approximately every 50 ms (20 Hz), the device will drive a current

excitation waveform between the selected (atrial or ventricular) lead ring electrode and the pacemaker case.[1]

CAUTION: Electrical signals introduced into the body by some hospital monitoring and/or diagnostic equipment may result in accelerated pacing, possibly up to the maximum sensor-driven rate, when MV is programmed On. Examples of this equipment include, but are not limited to, respiratory monitors, diagnostic echo imaging, surface ECG monitors, and hemodynamic monitors. Deactivate the MV sensor when interaction with this equipment is suspected.

The application of the current (i) between the ring electrode and the case will create an electrical field across the thorax (v), modulated by respiration. During inspiration the transthoracic impedance is high, and during expiration it is low. The device will detect the resulting voltage modulations between the lead tip electrode and the indifferent electrode located on the pacemaker header (Figure 3-2).

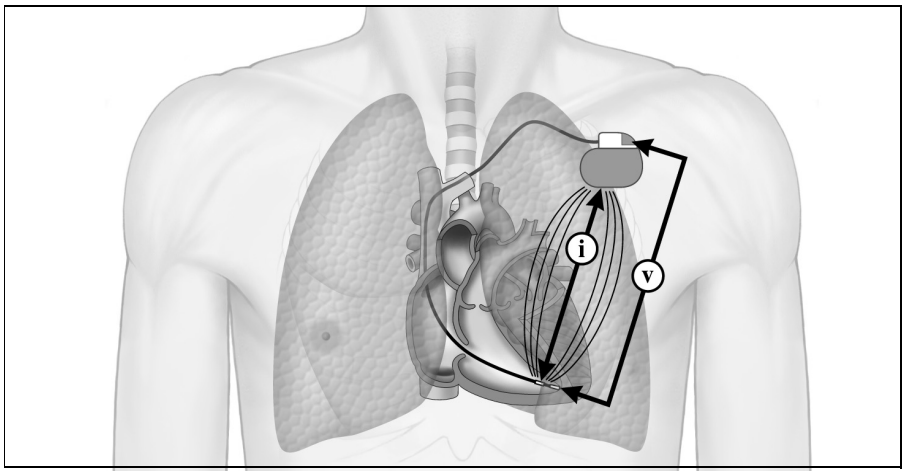


Figure 3-2. Voltage (V) is measured between the tip electrode on the lead and the indifferent electrode on the pacemaker case.

Due to advanced filtering, the algorithm supports breathing rates up to 60 breaths per minute. The filtered waveform is then processed to obtain the total volume measurement.

1. The average excitation current that is delivered to the tissue is approximately 0.5 µA. The excitation waveform is a balanced low amplitude signal that will not distort surface ECG recordings. On some ECG monitoring equipment, the waveforms may be detected and displayed. These waveforms are present only when the MV sensor is used.

The device keeps a 2-hour moving average (baseline) of these measurements as well as a short-term (approximately 30-second) moving average (acute), which is updated every 8.0 seconds. The difference between the baseline and the acute MV measure represents the relative increase or decrease in MV, which is translated by the algorithm into a rate increase over the Lower Rate Limit. (Refer to “Minute Ventilation” on page 6-29, for a complete discussion of the parameters.)

X-RAY IDENTIFIER

The pacemakers have an identifier that is visible on x-ray film or under fluoroscopy. This provides noninvasive confirmation of manufacturer. The identifier for the INSIGNIA I devices consists of the letters “GDT” to identify the manufacturer (Guidant). The letters are followed by 003, identifying the Model 2892 CONSULT Software Application needed to communicate with the pacemaker.

Refer to the Quick Start section (page 5-5) for information on identifying the device via the programmer.

The model number of the pacemaker is stored in the device's memory and is available on the About screen selectable through the Utilities menu when the pacemaker is interrogated.

MINIMIZING PACEMAKER / ICD INTERACTION

The INSIGNIA I Ultra pacemakers employ bipolar pacing and therefore are compatible for use with an implantable cardioverter defibrillator (ICD) when implanted with bipolar leads and programmed to bipolar pacing configuration.

A pacemaker can interact with an ICD in the following ways:

- If during a tachyarrhythmia the pacemaker is not inhibited and the pacing pulses are detected by the rate-sensing circuit of the ICD, the ICD could interpret the pacing pulses as a normal rhythm. The ICD would not detect the arrhythmia and therefore would not deliver therapy.

- Pacemaker failure to sense or to capture could result in two independent signals (intrinsic and pacing pulses) to the ICD. This could cause the ICD’s rate measurement to be faster than the actual heart rate. As a result, the ICD could deliver unnecessary therapy.

- If the ICD counts both the pacing pulses and the resultant ventricular depolarizations, the ICD's rate measurement would be faster than the actual heart rate. This could result in unnecessary ICD therapy.

- An ICD shock could alter the pacemaker's programmed settings or damage the pacemaker.

- An INSIGNIA I pacemaker concomitantly implanted with an ICD could experience a reset following the delivery of a shock from the ICD. Upon reset, the pacemaker will conduct a memory check to determine if the parameters essential for safe operation have been affected. If the parameters were not affected, the pacemaker will continue to operate as programmed. If essential parameters have been affected, the pacemaker will revert to VVI pacing mode, using pacing and sensing configurations as determined by a lead configuration test. The pacemaker can then be reprogrammed to the appropriate parameter settings.

To help minimize device–device interaction of a bipolar pacemaker when an ICD is already implanted, follow these precautionary measures:

- At implantation, place the pacemaker leads as far from the ICD sensing and defibrillating leads as possible. If an endocardial defibrillation lead is positioned in the right ventricle, consider using a positive fixation bipolar lead in the right ventricle and positioning the bipolar lead high on the septal wall or in the right ventricular outflow tract to get maximum distance between the bipolar pacing lead and the distal defibrillation coil. Place the atrial bipolar pacing lead as far as possible from the proximal defibrillation coil using a positive fixation bipolar pacing lead. Use of bipolar pacing leads with close electrode spacing (e.g., 11 mm) is recommended in both chambers.

- Consider programming the pacemaker to (1) the lowest amplitude allowable for safe capture in the chronic state, (2) the maximum sensitivity (the lowest programmable level) while maintaining an adequate safety margin, and (3) the minimum cardiac rate acceptable for the patient.

In addition to the above steps, perform the following testing to assess device–device interaction:

- Use the ICD features, such as markers, real-time electrograms (EGMs), and/or beeping tones, to help evaluate potential for pacemaker interaction due to oversensing by the ICD.

- Ventricular fibrillation and all of the patient's ventricular tachycardias should be induced while the ICD is activated and the pacemaker is programmed to an asynchronous mode at maximum amplitude and pulse width. This should provide the greatest opportunity for inhibition of arrhythmia detection due to detection of pacemaker pacing pulses. The pacemaker leads could have to be repositioned to eliminate detection of the pacing pulses by the ICD.

Temporarily deactivate the patient's ICD when (1) evaluating pacing and sensing thresholds, (2) when using an external temporary pacemaker during implant, and (3) when reprogramming an implanted pacemaker.

Following any ICD discharge, reinterrogate the pacemaker to ensure that the programmed parameters have not been altered or that the ICD shock did not damage the pacemaker or cause a reset.

If implanting an ICD in a patient who has a pacemaker already implanted, refer to the ICD manual for implantation considerations.

WARNINGS:

- Use of the MV sensor is contraindicated for patients with an ICD.
- In devices with the Safety Switch programmed to On, the lead polarity will revert to Unipolar in the presence of a lead impedance of < 100 Ω or > 2500 Ω. Unipolar pacing is contraindicated for patients with an ICD.
- STAT PACE will initiate unipolar pacing, which is contraindicated for patients with an ICD.

EXTERNAL DEFIBRILLATION PROTECTION

Protective thyristors help shield the pacemaker from current surges of up to 360 watt-seconds caused by external defibrillation procedures.

CAUTION: Defibrillation causing a power surge exceeding 360 watt-seconds can damage the pacemaker system.

After external defibrillation procedures, monitor the pacemaker system for proper performance. The pacemaker could experience a reset condition after receiving a defibrillation shock. See "Reset" on page 3-7 for more information. The amount of damage to the cardiac muscle resulting from defibrillation can be increased due to the presence of an implanted pacing system.

The following precautionary measures will help prevent defibrillation damage to the pacemaker and/or stunning of the cardiac tissue at the lead/tissue interface:

1. Position defibrillation paddles as far from the pacemaker as possible. Positioning the defibrillation paddles perpendicular to the implanted pacemaker/lead system can minimize current flow through the pacemaker and leads (Figure 3-3).

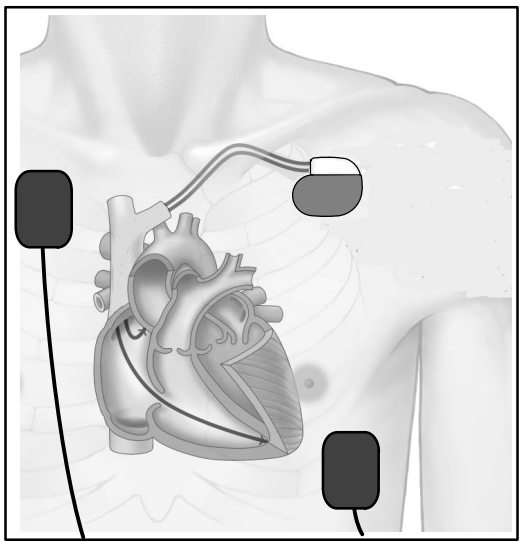


Figure 3-3. Recommended position of external defibrillation paddles.

2. Use the lowest energy output (watt-seconds) of defibrillation equipment that is clinically acceptable.

3. Confirm pacemaker function following any internal or external defibrillation episode.

RESET

Exposure of the pacemaker to certain conditions such as strong electrical interference from electrocautery or a defibrillation shock, or to low temperatures (prior to implantation) could cause a temporary reduction in the battery voltage. The pacemaker might be reset and conduct a memory check to determine if the parameters essential for safe operation have been affected. If the parameters were not affected, the pacemaker will continue to operate as programmed. If essential

parameters have been affected, the pacemaker will revert to Reset mode using pacing and sensing configurations as determined by the Lead Configuration test, which is performed as part of the Reset cycle. After a Reset, diagnostic information will be cleared. Reset parameter values are listed in Table 3-1.

Table 3-1. Reset Parameter Values

Parameter	Reset (VVI/SSI)[a]
Pacing rate (ppm)	65
Pulse Width (ms)	1.0
Amplitude (V)	5.0
Sensitivity (mV)	1.5
Refractory (ms)	320
Lead Configuration	Depends on lead[b]
Magnet Response	Off

a. All other parameters normally available in these modes are disabled.
b. Lead Configuration will be Unipolar if a unipolar lead is implanted, and Bipolar if a bipolar lead is implanted.

PACING OUTPUT

INSIGNIA I pacemakers use a reduced output capacitance to improve the evoked response signal used to confirm pacing capture. The leading edge voltage is 10% higher than the programmed Voltage. This creates an output pulse with an average voltage that is approximately equal to the programmed setting (Figure 3-4).

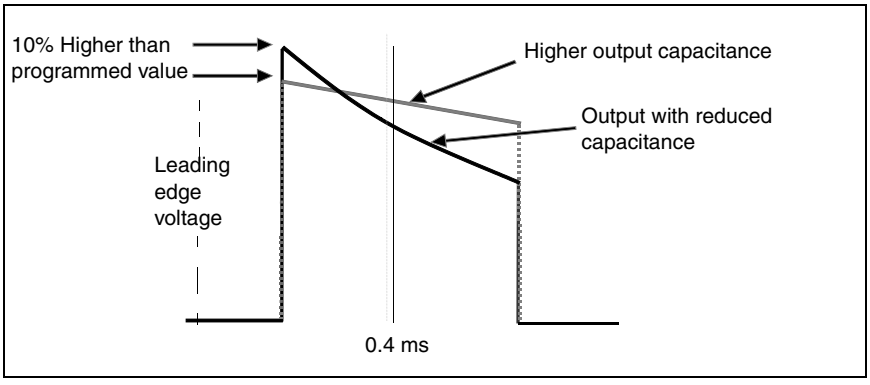


Figure 3-4. The leading edge voltage is 10% higher than the programmed Voltage.

OUTPUT RECHARGE CIRCUIT CYCLE

INSIGNIA I Ultra pacemakers are designed with a fast recharge circuit for discharging the output coupling capacitor following a paced pulse. This circuit ensures proper amplitude pulses at high rates and improves sensing circuit recovery following an output pulse. The recharge appears on the pacing leads as a low amplitude pulse of opposite polarity immediately following the output pulse. This pulse cycle is approximately 8 ms long for outputs of ≤ 3.5 V and pulse width ≤ 0.4 ms. For outputs > 3.5 V or pulse width > 0.4 ms, the pulse cycle is approximately 20 ms long.

RUNAWAY PROTECTION

INSIGNIA I pacemakers have runaway protection circuitry designed to prevent pacing rate acceleration beyond 210 ppm for most single-component failures. This runaway protection circuitry is independent of the pacemaker's basic pacing circuitry.

During PES/Manual Burst pacing and temporary high-rate pacing, runaway protection is disabled to allow high-rate pacing.

POSTIMPLANT INFORMATION

CHAPTER 4

This chapter includes information to be used following the implant of the INSIGNIA I Ultra pacemakers. The following topics are discussed in this chapter:

- Power Source
- Pacemaker Longevity Projections
- Battery Status
- Elective Replacement Time
- Explant Information
- Warranty Information

POWER SOURCE

The INSIGNIA I Ultra pacemakers use a single-cell lithium-iodine battery. The cell slowly decreases in output voltage over its lifetime; Table 4-1 includes information about the output voltage and usable battery capacity.

Table 4-1. Battery Information[a]

Device Model	Battery Model	Usable Battery Capacity (Ah)	BOL Voltage (V)	Battery Capacity at ERT (Ah)
1291	WGL 9841/Litronik 2269	1.53	2.8	0.087
1290	WGL 9840/Litronik 1869	1.04	2.8	0.105
1190	WGL 9840/Litronik 1869	1.04	2.8	0.067

a. The INSIGNIA I Ultra pacemakers use a single-cell lithium-iodine battery. The cell slowly decreases in output voltage over its lifetime.

PACEMAKER LONGEVITY PROJECTIONS

Table 4-2 displays typical parameter settings and the corresponding longevities from implant to Elective Replacement Time (ERT) for all models of the pacemakers. Longevity can be greatly influenced by parameter settings.

Table 4-2. Longevity Projections (Years)[a] [b] (Sheet 1 of 2)

Amplitude and Pacing	Models		
	1190	**1290**	**1291**
Amplitudes 3.5 V			
100% Paced			
350 Ω	6.8	4.9	7.0
500 Ω	7.3	5.4	7.7
750 Ω	7.8	6.0	8.5
1000 Ω	8.1	6.4	9.0
50% Paced			
350 Ω	7.9	6.2	8.8
500 Ω	8.2	6.6	9.3
750 Ω	8.5	7.0	9.9
1000 Ω	8.7	7.3	10.2
Amplitudes 2.5 V			
100% Paced			
350 Ω	7.4	5.6	7.9
500 Ω	7.8	6.0	8.5
750 Ω	8.2	6.5	9.2
1000 Ω	8.4	6.9	9.7
50% Paced			
350 Ω	8.3	6.7	9.5
500 Ω	8.5	7.0	9.9
750 Ω	8.8	7.3	10.4
1000 Ω	8.9	7.5	10.6

Table 4-2. Longevity Projections (Years)[a] [b] (Sheet 2 of 2)

Amplitude and Pacing	Models		
	1190	1290	1291
Automatic Capture On (A = 3.5 V[c], V = 1.0 V [assuming a threshold of 0.5])			
100% Paced			
350 Ω	8.9	6.0	8.4
500 Ω	8.9	6.3	9.0
750 Ω	9.0	6.8	9.5
1000 Ω	9.0	7.0	9.9
50% Paced			
350 Ω	9.0	6.9	9.7
500 Ω	9.1	7.2	10.1
750 Ω	9.1	7.4	10.4
1000 Ω	9.1	7.6	10.7
Automatic Capture On (A = 2.5 V[c], V = 1.0 V [assuming a threshold of 0.5])			
100% Paced			
350 Ω	8.9	6.4	9.1
500 Ω	8.9	6.7	9.5
750 Ω	9.0	7.1	10.0
1000 Ω	9.0	7.3	10.3
50% Paced			
350 Ω	9.0	7.2	10.2
500 Ω	9.1	7.4	10.4
750 Ω	9.1	7.6	10.7
1000 Ω	9.1	7.7	10.9

a. Amplitudes shown are both atrial and ventricular; pulse width = 0.4 ms, pacing rate = 60 ppm, sensors = On.
b. Table displays typical parameter settings and the corresponding longevities from implant to ERT for all models of the pacemakers. Longevity can be greatly influenced by parameter settings.
c. This value not applicable for single-chamber devices.

BATTERY STATUS

Pacemaker battery status can be assessed either through programmer telemetry using the PRM and accessing the Battery Status screen, or by using a manually applied external magnet stronger than 70 gauss. See Chapter 7, “Diagnostics and Follow-up” for more information about the Battery Status test.

Magnet Test

If the Magnet Response on the Battery Status screen is programmed to Async, the magnet actuates a switch within the pacemaker, thereby converting it to an asynchronous mode (DOO or SOO) with a fixed pacing rate (100 ppm at Beginning of Life [BOL]) and a magnet AV Delay of 100 ms).

If Automatic Capture is programmed off, the third pulse during the magnet test will be issued at 50% of the programmed Pulse Width to allow the clinician to evaluate the safety margin.

NOTE: *If the Magnet Response is programmed to Off or EGM, the pacemaker will* ***not*** *revert to asynchronous operation in the presence of a magnet.*

The pacemaker remains in Magnet Response as long as the magnet is positioned over the middle of the pacemaker, **parallel** to the lead connector block (Figure 4-1). When the magnet is removed, the pacemaker automatically resumes pretest operation.

NOTE: *If adaptive-rate pacing or Automatic Capture has been programmed, it is suspended for the duration of magnet application.*

Elective Replacement Near (ERN)

Intensified follow-up is recommended when the Battery Status screen indicates the device has reached ERN (Elective Replacement Near) or when the magnet rate is 90 ppm. **Schedule replacement of the pacemaker when the Battery Status screen indicates the device has reached ERT, or the Magnet Rate is 85 ppm or less.**

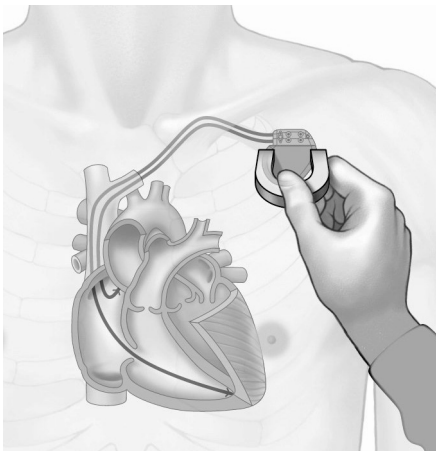


Figure 4-1. Magnet placement.

ELECTIVE REPLACEMENT TIME (ERT) OPERATION

Figure 4-2 illustrates the stages of pacemaker battery life. See Table 4-2 for the projected BOL to ERT time intervals. Under conditions of long-term low energy pacing therapy, device longevity can be enhanced and ERT delayed.

NOTE: *In adaptive-rate modes, when the pacemaker reaches ERT the mode will be changed to a nonadaptive-rate mode (DDDR to DDD, VVIR to VVI, etc.).*

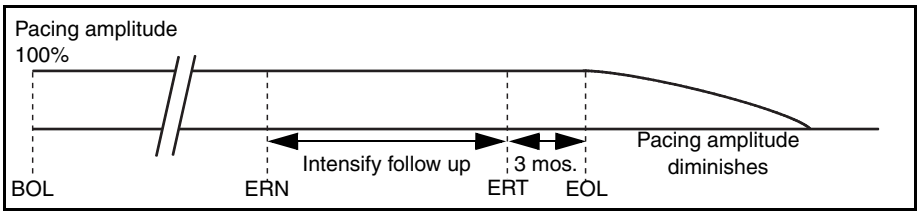


Figure 4-2. Pacemaker battery life stages.

The following features are not available when the pacemaker reaches ERT:

- Sensors
- Beat-to-Beat Automatic Capture–ventricular output is fixed at twice the last measured threshold (but not > 5.0 V and not < 3.5 V)

- Commanded Autothreshold
- Stored EGM
- Sensor Trending
- Real-time EGMs
- Activity Log
- Event Markers
- EP Test
- Rate Trending

If you are reprogramming Rate, Pulse Width, or Amplitude near ERT, make small incremental changes for better patient management and conservation of remaining energy. Care should also be taken near ERT when programming to an adaptive-rate mode or programming other parameter changes that increase the current drain.

End-of-Life (EOL) Operation

Three months after ERT, as the battery continues to deplete, the device will reach End of Life (EOL). When EOL is reached, the dual-chamber pacemakers will change modes to single-chamber operation (DDD and VDD will revert to VVI) and the LRL will be lowered to 50 ppm. As the battery continues to deplete during EOL, the pacemaker will decrease the pacing amplitude. Telemetry is not guaranteed after EOL.

The following features are not available when the pacemaker reaches EOL:

- Dual-chamber (reverts to single-chamber)
- Temporary Parameters
- Safety Switch—the Lead Configuration remains at its pre-EOL value
- Rate Smoothing
- Search Hysteresis

- Arrhythmia Logbook
- Event Counters
- Histograms
- Quick Check
- Lead Impedance measurements—stored and interactive
- P and R-wave measurements—stored and interactive
- Semi-automatic Threshold Tests

EXPLANT INFORMATION

Return all explanted pacemakers and leads to Guidant for analysis and disposal. Examination of explanted devices can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

CAUTIONS:

- Never incinerate a pacemaker because it can explode if subjected to incineration or cremation temperatures; be sure that the pacemaker is explanted before a deceased patient is cremated.
- Do not implant an explanted pacemaker in another patient as sterility, functionality, and reliability cannot be ensured.

WARRANTY INFORMATION

A limited warranty certificate for INSIGNIA I Ultra pacemakers is included with the pacemaker. For additional copies, please contact Guidant at the address and phone number on the back cover of this manual.

USING THE PROGRAMMER / RECORDER / MONITOR (PRM)

CHAPTER 5

This chapter describes how to use the ZOOM LATITUDE Programming System, Model 3120 Programmer/Recorder/Monitor (PRM) and the Model 2892 CONSULT Software Application to communicate with the INSIGNIA I pacemakers. Refer to the PRM Operator's Manual for full instructions. The chapter is divided into three sections:

- Instructions for starting up the PRM and software application, and using the touchscreen and keys
- Introduction to software application terminology and how to move around the software application
- Instructions for communicating with the pacemaker (interrogating, programming, STAT PACE therapy delivery), and quitting a session

The terms used in this chapter will be used throughout the rest of this manual to describe how to change and program specific parameter settings. A clear understanding of interrogating and programming the pacemaker is important, as this information is not routinely repeated throughout the manual when specific functions are discussed.

STARTING UP THE PRM AND SOFTWARE

In this manual, the word “select” means to touch the stylus to the desired item on the screen. Use the stylus to activate the desired menu buttons and parameter selection buttons by touching and releasing the screen target. Touch the screen navigation buttons at the bottom of the screen to move from one screen to another.

NOTE: *Use of the stylus is recommended for accuracy; however, touching the screen with your finger will also activate a selection.*

A communication session may be started between the PRM and the pacemaker by performing the following steps. (The *ZOOM Programming System* Operator’s Manual contains a complete description of the PRM.)

1. Connect the power cord to the PRM system and an outlet. (Refer to the PRM system operator’s manual for a complete description of the programmer.)

2. Raise the screen to a comfortable viewing angle.

3. Press the On/Off button (⏻) on the left side of the PRM.

4. Wait for the Guidant startup screen (Figure 5-1) to appear.

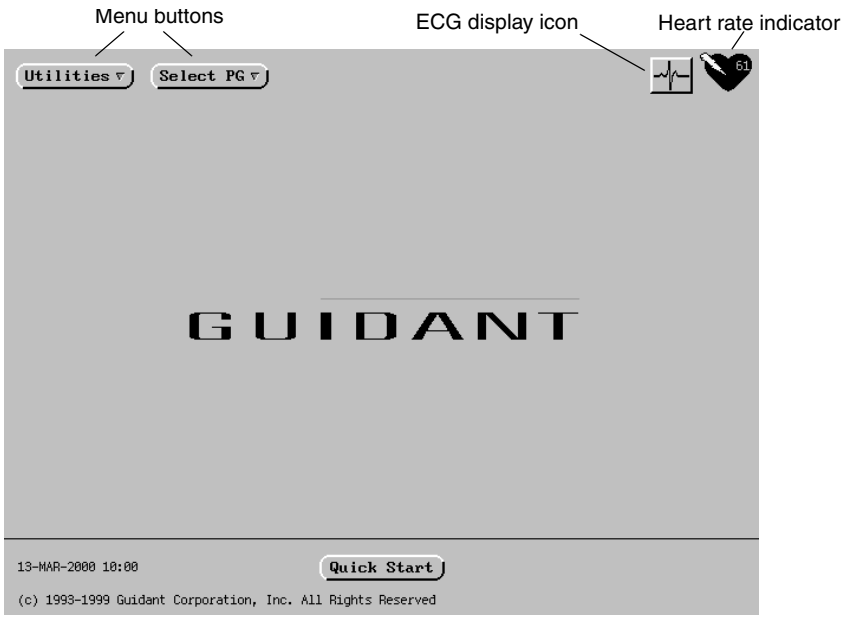


Figure 5-1. The startup screen is displayed when the PRM is powered On.

The startup screen displays the following information:

- The Utilities menu button allows access to PRM information and setup functions prior to accessing the application software.
- The Select PG menu button allows the desired application to be chosen and started.
- The ECG display icon changes the screen display to an ECG display available for patient diagnosis.
- The heart rate indicator logo displays a value corresponding to the intrinsic ventricular rate of the patient.
- The Quick Start button is an automated method for starting the application.
- The bottom left corner of the screen displays the date and time.

ECG Display

To display surface ECG signals on the PRM without device interrogation (Figure 5-2), select the ECG display icon on the startup screen. Refer to Appendix B for instructions on proper patient cable connections. The PRM can display three surface leads using six limb leads and one chest lead. The displayed leads will be shown with the pacing spike marker if that feature is selected. To display the pacing spike markers correctly, the Lead II electrodes must be connected to the patient, regardless of which lead is displayed.

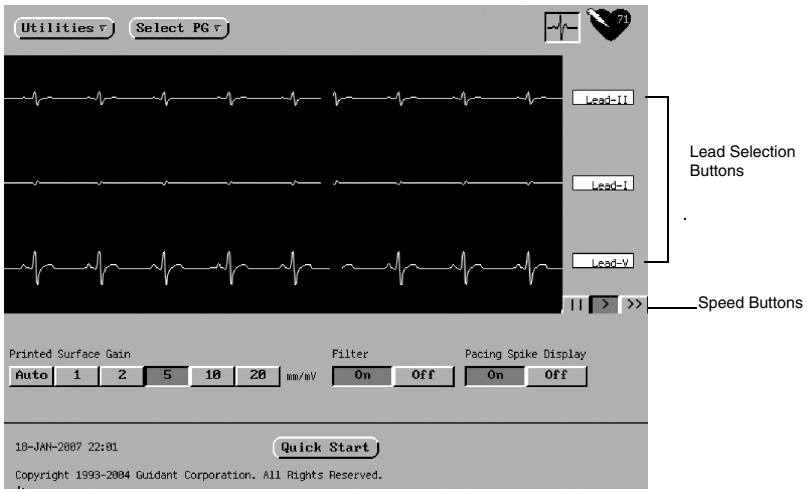


Figure 5-2. The ECG screen as accessed from the startup screen.

The following screen features can be used to change the values and appearance of the traces:

- **Select Leads—**Select each of the lead traces to be displayed.
- **Speed Buttons—**Select the desired speed button on the ECG display; pause (II) to freeze the trace, play (>), or fast-forward (>>).
- **Printed Surface Gain—**Adjust the surface gain of the traces that are captured on printouts by selecting the appropriate value.

- **Surface Filter—**Select the Filter On setting to minimize noise on the surface ECG. The Filter Off setting allows viewing surface ECGs with diagnostic filter settings.

- **Pacing Spike Display—**Program this feature On to show detected pacing spikes, shown by a marker on the top waveform.

To display a calibration pulse on the PRM, press the key labeled ⎍. Press the key labeled ⎽⎽↓⎽⎽ to force the surface trace back to baseline. To print the surface ECG on the PRM printer/recorder, select the desired speed key (10, 25, 50, or 100 mm/sec) on the printer/recorder. To stop the printer/recorder, press the speed key labeled 0 (zero).

Printing to an External Recorder

To view the surface ECG traces on an external recorder, press the desired speed key on the external recorder while the traces are displayed on the PRM screen. See Appendix B for instructions on connecting the PRM to the external recorder. Refer to the manual for the external recorder for instructions specific to its operation.

Quick Start

To automatically identify and interrogate the implanted pacemaker, place the telemetry wand over the pacemaker and select the Quick Start button. A window indicating one of the following conditions will appear, based on the implanted device:

- **Application Startup in Progress—**If the software for the implanted device is installed on the PRM, the PRM will identify the device, open the correct application, and automatically interrogate the pacemaker.

- **Software Not Installed—**If the software application for the implanted device is available for the PRM but not installed on it, a message window will appear identifying the device and stating that the software is not installed on the PRM.

- **Software Not Available on PRM—**If an older model Guidant device is identified, a message window will appear informing the user that he or she must use a Model 2035 or Model 2901 PRM to interrogate and/or program the device.

- **PG Not Identified—**If a non-supported pulse generator is implanted, a message window will appear notifying the user that either the wand is out of range, there is telemetry noise, or the device is not identified.

To access the Demo mode, use the Select PG button at the top of the screen to choose the pacemaker family instead of using the Quick Start button.

The Utilities Menu on the Startup Screen

Before accessing the pacemaker software application, you may select the Utilities menu to access PRM information and clock and disk functions. To view or change the values, select the appropriate function from the Utilities menu.

The About Utility

The About utility screen lists the versions of the system software and the applications available on the PRM, and provides the means to set or change the institution name and print the application revision information. To return to the startup screen, select the Close button.

Select the Set Institution option to update the institution name. If the PRM has been moved to a different institution, the name of the institution as it appears on the About screen can be changed prior to accessing the application software. The institution name also is displayed in the heading of printed reports.

After selecting the Set Institution field, a graphic keyboard (Figure 5-6 on page 5-18) together with the name of the institution will appear. Select the Clear button to remove the institution name from the graphic keyboard. Alternatively, one letter of the name at a time can be deleted by selecting the left arrow key on the graphic keyboard. Each time the left arrow is selected, a character will be deleted in the box. Delete all the undesired characters.

To enter new characters, select the desired characters on the graphic keyboard one at a time. To cancel any deletions or additions just made to the institution name, select the Cancel Changes button.

When all characters are selected, select the Close key on the graphic keyboard. The keyboard will disappear and the new name will appear on the About screen.

The Set Programmer Clock Utility

Select the Set Programmer Clock option to change the PRM date and time (24-hour clock), which is displayed in the lower left corner of the startup screen. The Set Date and Time window (Figure 5-3), which includes a display of real-time seconds, will appear. Change the values by selecting an up or down arrow. When the desired values are displayed, select the Set Programmer Clock button to confirm the new

date and time. (To cancel any changes prior to confirming the new values, select the Cancel button.)

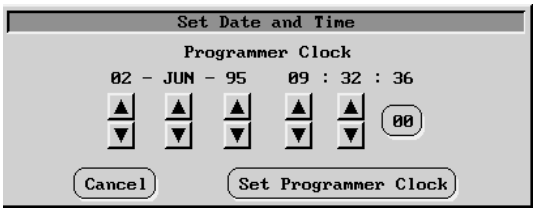


Figure 5-3. The Set Date and Time window.

NOTE: *When the pacemaker is interrogated, the time stamp stored in the pacemaker is used in conjunction with the programmer clock. For this reason, it is important that the programmer clock be properly set before interrogation.*

Copy Disk

This feature is available to make duplicate copies of a Model 6627 Patient Data Disk.

1. Select the Copy Disk option from the Utilities menu. A message will appear instructing the user to insert the source disk.

2. Insert into the disk drive of the PRM the disk that contains the information to be copied (the source disk) and select the Read Disk button. The PRM will read the information from the disk. When completed, a message will appear indicating that a new disk (the destination disk) should be inserted.

3. Insert a new patient data disk and select the Write Disk button. (Do not use a disk that contains other patient data, as the existing data would be lost.) The information will be copied onto the new disk. Write the patient name on the disk label.

CAUTION: Make sure the disk drive light is off before removing the patient data disk from the disk drive. Removing the disk while the drive heads are engaged can damage the disk and/or the drive.

Format Disk

This feature is available for erasing data from and reformatting a patient data disk.

1. Insert a patient data disk into the disk drive of the PRM.

2. Select the Format Disk option from the Utilities menu. Formatting a disk will remove all data from the disk.

3. When formatting is complete, insert another disk and select the Format Another Disk button or select the Cancel button to exit the format feature.

The Select PG Option on the Startup Screen

This option allows the device to be selected manually. Use this method of device selection when using the Demo mode. Otherwise, use the Quick Start feature described earlier in this chapter.

1. To display the desired software application, which allows communication with a pacemaker family, select the Select PG button.

2. The names of the available pulse generator families will appear. Select the applicable family.

3. The sign-on window will appear. Choose Interrogate either by selecting the Interrogate button on the menu or by pressing the INTERROGATE key on the PRM, or select the Demo mode. The Main Application screen will appear, with the System Summary screen displayed (Figure 5-4).

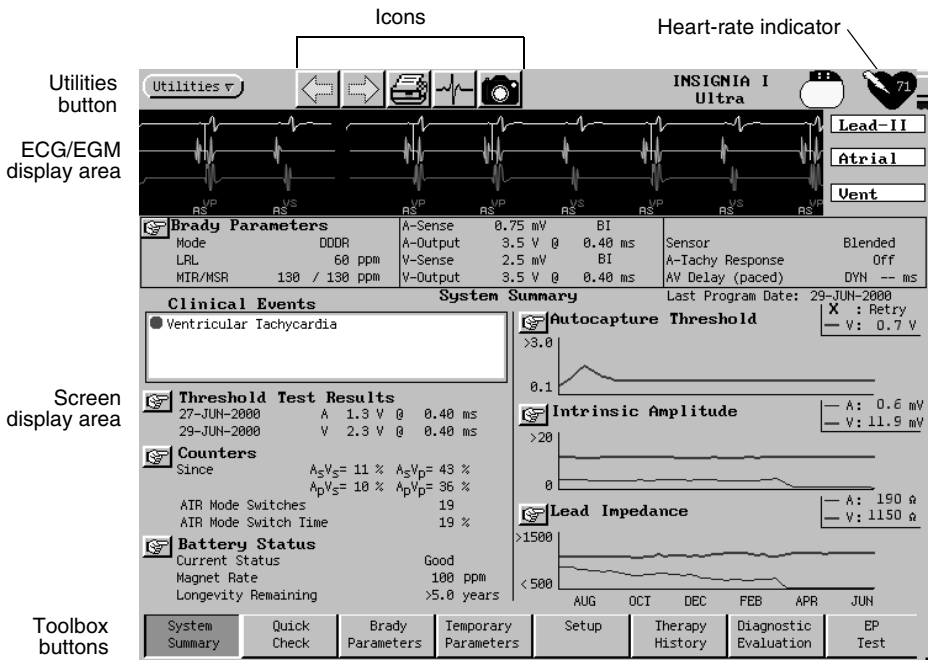


Figure 5-4. The Main Application screen with the System Summary screen displayed.

NOTE: *All screen illustrations in this manual show typical screens from an INSIGNIA I Ultra Model 1290 pacemaker. The screens you see when interrogating or programming other pacemaker models will be similar but may not include any dual-chamber or adaptive-rate fields.*

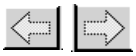
INTRODUCTION TO SOFTWARE TERMINOLOGY AND HOW TO MOVE AROUND

Utilities Button and Screen Icons

The Utilities button and screen icons, when selected, initiate an activity, display a list of options, or change information displayed.

Utilities Button

Selecting the Utilities button on the Main Application screen opens a menu that allows access to most of the same functions as the Utilities menu on the startup screen as well as selections that allow the user to enter Patient Data information, Save All to Disk, select a New Patient, and Quit the application. See the “Utilities Menu on the Startup Screen” section on page 5-6 or the “Utilities Menu on the Main Application Screen” section on page 5-19 for complete information about the menu choices.



Arrows

The arrow icons allow navigation to screens previously viewed. Select the left arrow icon to view the most recent screen viewed. Continue selecting this icon to move through screens in reverse order of viewing. Once you have viewed previous screens, the right arrow will advance back towards the screen viewed most recently.

Printer

The printer icon will navigate directly to the Choose Reports to Print window. The window must be closed before continuing.

ECG

Selecting the ECG icon from the startup screen will navigate to an ECG screen available for patient diagnosis. When in the Model 2892 software application, the ECG icon will navigate directly to the ECG/Trace Selections.

Snapshot

The snapshot icon will activate the snapshot capture feature. The captured activity may then be viewed on the Snapshot Viewer screen, accessed through the Diagnostic Evaluation toolbox button.

Information (Parameter Interaction Warning)

When a new parameter is entered into the Change column of a screen, it is immediately checked for interactions with other parameters. The exclamation point icon indicates that a Parameter Interaction warning is present. Whenever a parameter is changed in such a way that additional information needs to be presented to the clinician, this icon can be selected to view the information. Changes to the affected parameter(s) need not be made to proceed with the patient session; however, physician discretion is advised depending on the type of patient or other circumstances before proceeding. Changes to the affected parameters can be made directly from the Parameter Interaction window.

Stop Sign (Parameter Interaction)

When a new parameter value is entered in the Change column of a screen, it is immediately checked for interactions with other parameters. If the new value violates interactive limits within the application, a stop sign icon will appear at the top of the display, indicating a Parameter Interaction error. Select this icon to access the Parameter Interaction screen to view the error and its suggested resolution. A correction to the affected parameter must be made in order to proceed with programming changes and can be made directly from the Parameter Interaction window. When changing the setting of several parameters, the clinician might not wish to select the Parameter Interaction icon immediately, as subsequent changes could eliminate the interaction.

Stop Sign in the System Summary Screen (Clinical Event)

If an important event has occurred since the last follow-up, a stop sign icon will appear in the System Summary screen. Selecting the stop sign button or its associated text opens a window or navigates to a screen containing information about the event.

Shortcut

In the screen display area, select the shortcut icon to go directly from the parameter, feature, or associated event to the screen that provides detailed information. Use the left arrow button to return to the original screen.

Magnifying Glass

In the screen display area, select the magnifying glass icon to open a window that displays more detailed information about a parameter, feature, or event. The window must be closed before continuing.

Check Box

In the screen display area, a check in a box indicates that the function or activity will be active. Select a box containing a check to clear the check and deactivate the function or activity.

Go

Select a Go icon to initiate any test on the Quick Check screen.

Logos

Demo

This logo is displayed when the application is initially accessed without interrogating a pacemaker or reading a disk. This allows familiarization with the software without having to interact with a pacemaker.

Pacemaker

This logo is displayed when a pacemaker has been interrogated.

Heart Rate Indicator

The heart rate logo displays the heart rate from the ECG.

ECG/EGM Display

This display shows real-time surface ECG traces, intracardiac EGMs, and event markers. See Chapter 8, “Electrograms (EGMs)/Event Markers/Reports” for details.

Toolbox Buttons

The toolbox determines which screen is displayed, depending on the chosen toolbox button. The screens allow interaction with the pacemaker as well as a review of diagnostic data in pacemaker memory. Only one tool can be selected at a time.

General Window Functions

Windows contain information relevant to a particular function and include names of pacemaker parameters and functions, value boxes to accommodate value changes, buttons to open additional windows, and buttons to Cancel Changes or Close the window. To remove the window from the display, select the Close or Cancel button.

How to Move a Window

To accommodate viewing of multiple open windows, the windows can be moved to another location on the screen using the touchscreen stylus.

1. Position the stylus within the title bar at the top of the window.

2. An outline appears around the window to indicate the window can be moved. While touching the stylus to the window outline, drag the window to the desired location.

3. Lift the stylus when the outline is in the desired location. The window will move to and remain in that location until it is moved again, or until the window is closed.

Message Window

Message windows (Figure 5-5) may appear during a communication session. Some require action before continuing the session, while others simply relay information without requiring further action. The messages indicate the required action, if any.

Many message windows have a Cancel or Close button at the bottom of the window. Select this button to cancel the action being performed as explained in the message and/or close the window.

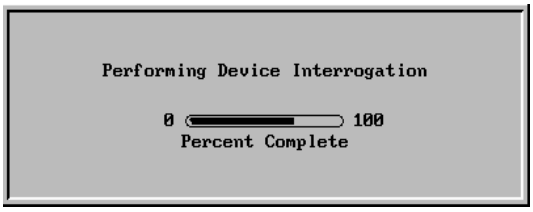


Figure 5-5. A typical message window.

PRM Keys

STAT PACE

The PRM's STAT PACE key initiates special high-output unipolar SSI/VVI modes of pacemaker operation. Pressing the STAT PACE key twice causes the pacemaker to operate under a predetermined set of STAT high-energy pacing parameters. See Table 5-1 for a list of STAT parameters.

Table 5-1. STAT Parameter Values

Parameter	STAT (VVI/SSI)[a]
Pacing rate	65 ppm
Pulse Width	1.0 ms
Amplitude	5.0 V
Sensitivity	1.5 mV
Refractory	320 ms
Lead Configuration	Unipolar
Magnet Response	As Programmed

a. All other parameters normally available in these modes are disabled.

Press the STAT PACE key twice and position the telemetry wand within telemetry range of the pacemaker to program STAT PACE parameters in the pacemaker.

WARNING: STAT PACE will initiate unipolar pacing, which is contraindicated for patients with an ICD.

CAUTION: If the pacemaker is not reprogrammed, it will continue to pace in SSI mode at the high-energy STAT values. You might wish to reprogram the pacemaker to other parameter settings for alternative patient therapies or to extend pacemaker longevity.

NOTE: *Exit STAT by programming new Brady Parameters.*

PROGRAM and INTERROGATE

These keys are discussed in “Programming and Interrogation” below.

DIVERT THERAPY and STAT SHOCK

The DIVERT THERAPY and STAT SHOCK keys are not applicable within the Model 2892 software application.

PROGRAMMING AND INTERROGATION

The INSIGNIA I pacemakers are programmed through noninvasive RF telemetry using the Guidant Model 3120 PRM equipped with the Model 2892 CONSULT Software Application and a Model 6577 Sterilized Telemetry Wand.

During a programming sequence, the telemetry wand is positioned over the pacemaker. Allow all telemetry sequences to complete before removing the wand. The sequence is complete when the scale in the message window reaches 100% and the message window closes.

Interrogation is accomplished in a similar fashion. If a permanent record of interrogated data is desired, the PRM can provide printed reports that include such information as present parameter values, therapy history data, pacemaker battery status, and programmed patient data that has been entered (e.g., date of implant, lead type, patient indications).

Establishing Telemetry Communication

Telemetry communication is required to direct the INTERROGATE, PROGRAM, and STAT PACE commands on the PRM, which are described in this chapter. Telemetry communication also is required to perform other features such as Lead Impedance and Threshold Tests, described in later chapters.

A communication session with the PRM can be established by performing the following steps:

1. Connect the telemetry wand to the PRM.

2. Position the wand over the pacemaker.

3. Direct a command from the PRM to the pacemaker (e.g., INTERROGATE or PROGRAM). The telemetry indicator light will illuminate when telemetry is occurring or being attempted.

NOTES:

- *Even if the wand is correctly positioned, the telemetry indicator light illuminates only while telemetry communication is occurring with the pacemaker. The light extinguishes as soon as the communication sequence is successfully completed or canceled.*

- *Status windows might appear on the screen during a communication session to indicate that the pacemaker is out of range. Reposition the wand to reestablish communication or try turning the telemetry wand over. (When event markers or intracardiac EGMs are activated, a message will not appear, but the event marker or intracardiac EGMs transmission will be interrupted until telemetry is restored.)*

Interrogating the Pacemaker

Pacemaker interrogation is the first step in any follow-up session. An initial interrogation retrieves the following information from pacemaker memory: parameter settings, patient data, and battery status. When the Quick Start button is selected on the startup window, the PRM will identify the device, open the correct application, and automatically interrogate the pacemaker.

Use the following procedure to interrogate the pacemaker, if the Quick Start feature is not used:

1. To initially interrogate the pacemaker, select the Interrogate button on the sign-on screen (or the INTERROGATE key on the PRM). To perform interrogations during a session, press the INTERROGATE key on the PRM panel while in the Brady Parameters screen. A message window will appear.

2. Position the telemetry wand over the pacemaker. The scale in the message window will indicate the progression of the interrogation.

Maintain the telemetry link until the scale indicates that the interrogation has reached 100% completion and the message window disappears.

Prematurely moving the wand away from the pacemaker during the interrogation sequence causes a message to appear, indicating that there is telemetry noise or that the wand has been moved out of telemetry range. Reestablish telemetry communication to continue the interrogation sequence. If communication cannot be reestablished, select Cancel in the message window to stop the interrogation sequence.

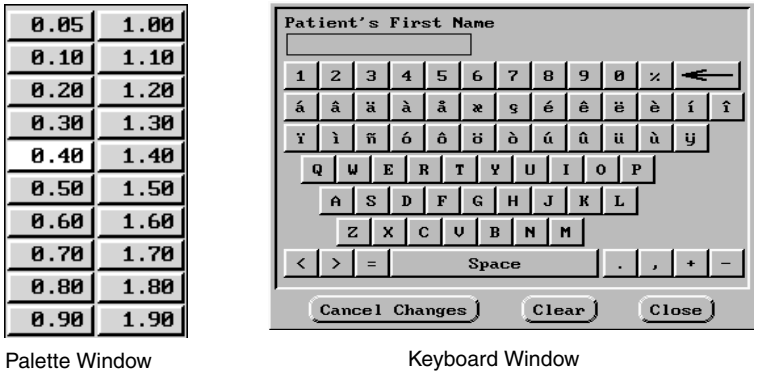
CAUTION: Computerized systems can be subject to electrical interference, or "noise." In the presence of such interference, telemetry communication is interrupted and prevents improper interrogation or programming. If the message window appears indicating that the wand is out of range or there is telemetry noise, move the PRM away from such electrical devices as electrosurgical and monitoring equipment and ensure that the wand cord and cables are not crossing one another. Telemetry communication will resume when the noise source is removed. The message window also has a Cancel button that, when selected, will stop the interrogation.

Changing Parameter Values

The parameter values are changed by touching the stylus to the appropriate parameter box in the Change column and lifting the stylus from the screen. When changes have been made to parameter values, the data appear in the Change box until programmed into the pacemaker. Use one of the following methods to select the desired value, according to the window that appears:

- **Palette Window—**Touch the desired value and lift the stylus; it will be selected and will appear in the Change column parameter box.

- **Keyboard Window—**Touch the first character of the new value; it will appear in the data entry box. Continue until the entire new entry appears. Alternatively, one character can be deleted at a time by selecting the left arrow key on the graphic keyboard. Each time the left arrow is selected, a character will be deleted in the box. Delete all the undesired characters. To cancel any deletions or additions just made, select the Cancel Changes button. When all characters are selected, select the Close button on the graphic keyboard.



Palette Window Keyboard Window

Figure 5-6. Types of windows enabling value changes.

Touching the screen outside the window will close it without a selection. Once a value is selected, sliding the stylus outside the active menu without lifting it closes the menu options and parameter value selection windows without making a selection.

NOTE: If additional parameters require reprogramming, repeat these steps. Multiple parameter changes can be programmed at one time.

Programming the Pacemaker

When changes have been made to parameter values, the data appear in the Change boxes until programmed into the pacemaker. When the PROGRAM function is initiated, all changed data (from all parameters on the Brady Parameters screen and its submenus) will be programmed.

Use the following procedure to program the pacemaker parameters:

1. Select the Brady Parameters button on the toolbox button bar.

2. Make the desired parameter changes.

3. Position the telemetry wand over the pacemaker.

4. Select the PROGRAM key on the PRM panel. A message window will appear and the scale in the message window will indicate the progress of the

programming. If a sensor is being enabled or disabled, a second message window will indicate that Trending Setup is occurring.

5. Maintain the telemetry link until the scale indicates that the programming has reached 100% completion and the message window disappears. Prematurely moving the wand away from the pacemaker during the programming sequence causes a message to appear, indicating that there is telemetry noise, or that the wand has been moved out of telemetry range. Reestablish telemetry communication to continue the programming sequence. If communication cannot be reestablished or if you wish to halt the sequence, select Cancel in the message window to stop the programming sequence. Allow the cancel sequences to complete before removing the telemetry wand. The sequence is complete when the scale in the message window reaches 100% and the message window closes.

CAUTION: Whenever telemetry communication has been canceled during programming, interrogate the pacemaker and review the affected screen(s) to verify that the appropriate values were programmed and are displayed correctly.

THE UTILITIES MENU ON THE MAIN APPLICATION SCREEN

The Utilities menu button at the top of the screen will allow you to access any of the following functions described below. Many of these functions also are available from the Utilities menu on the startup screen, and are described in detail in that section earlier in this chapter.

Patient Data

Important information about the implant and about the patient can be stored in the pacemaker for future reference and viewed on the Patient Data window. The information can be accessed at any time using normal interrogation procedures. Except for the lead type, this information does not affect the operation of the pacemaker. If a unipolar lead type is selected, the pacing and/or sensing configurations cannot be programmed to Bipolar. See “Bipolar Configuration Lock-out” on page 6-62 for more information.

The pacemaker model number and serial number are retrieved directly from the pacemaker and cannot be modified by the clinician.

Use the following procedure to make changes to the patient data stored in the pacemaker:

1. Select Patient Data from the Utilities menu at the top of the screen.

2. Touch the stylus to the parameter that you want to change. Depending on the parameter type, a numeric palette, a menu, or the graphical keyboard will be displayed.

3. Make the necessary modifications to the parameter value.

4. To store the data to the pacemaker, select Store Data. The new information will be stored in the pacemaker's internal memory.

Save All to Disk

When a Model 6627 patient data disk is inserted in the disk drive of the PRM, the following data can be saved:

- Brady Parameters
- Patient Data
- Intrinsic Amplitude test results
- Lead Impedance test results
- Threshold test results
- Battery Status
- Arrhythmia Logbook
- Histograms/Counters

NOTE: *Data stored on this disk cannot be read using the PRM.*

1. Insert a patient data disk into the disk drive of the PRM.

NOTE: *The write-protect tab on the disk should be in the closed position (black tab covering the hole) when saving data to the disk.*

2. Select the Save All To Disk option from the Utilities menu.

3. When the data have been saved on the disk, remove the disk from the drive and write the name of the patient on the disk label. (If multiple disks are used to save all the data for one patient, number the disks sequentially or write the date that the information was saved.)

NOTES:

- *If you insert a patient data disk containing data downloaded using a programmer other than the Model 3120 PRM, a message will appear indicating the disk is unreadable. If you reformat the patient data disk for use on the Model 3120 PRM, any data on the disk will be lost.*

- *Refer to the ZOOM LATITUDE Programming System Operator's Manual for care instructions for data disks.*

Copy Disk
Format Disk
Set Programmer Clock

For information regarding these three options, refer to "Utilities Menu on the Startup Screen" on page 5-6.

About

When this option is selected a window will appear indicating the software model and revision numbers, programmer serial number, institution name, and the model number and type of pacemaker.

Print Memory

This utility allows the PRM to retrieve and print memory data from the current pulse generator. The clinician should only use the Print Memory utility when directed by a Guidant representative. The report will contain specific data that can be interpreted by Guidant Technical Services and is intended for clinical or troubleshooting purposes.

New Patient

The Utilities menu offers a New Patient option that ends a current patient session and allows a different device to be interrogated without having to exit the Model 2892 software application. If a second device is interrogated without ending a previous session, a message will appear indicating that the wrong pacemaker was identified. Use the following steps to start a follow-up procedure for a new patient:

Select the Utilities menu from the Main Application screen.

1. Highlight and select the New Patient option. A message window will appear indicating that selecting Confirm for new patient will restart the Model 2892 application and that all session data will be lost.

NOTE: *If reports are being printed, the Cancel Printing button must be selected before the Confirm button can be selected.*

2. Select the Confirm button. (Selecting the Close button will remove the message window and retain the current patient session.) The current session will end, the sign-on screen will be displayed, and the options to Interrogate, or Quit, or access the Demo mode will be available.

Quit

The Utilities menu offers a Quit option that ends the current session, exits the software application, and returns to the startup screen.

1. Select the Utilities menu from the Main Application window.

2. Highlight and select the Quit option. The message will appear indicating that selecting Quit will exit the application and return to the startup screen.

NOTE: *If reports are being printed, the Cancel Printing button must be selected before the Quit button can be selected.*

3. Select the Quit button to end the session. (Selecting the Close button will remove the message window and retain the current patient session.)

THERAPY

CHAPTER 6

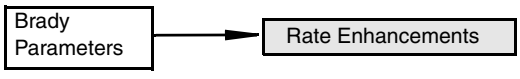
This chapter includes descriptions of the programmable therapy parameters available with the INSIGNIA I Ultra pacemakers.

The following therapy features and their programmable parameters are discussed in this chapter:

All parameters described in this chapter are accessible through the Brady Parameters screen. In this chapter, if a submenu button is used to access a parameter, the appropriate submenu button is graphically illustrated by the subject heading.

For example, the graphic below shows that the Rate Smoothing parameter is found by accessing the Rate Enhancements submenu from the Brady Parameters screen.

Rate Smoothing



BRADY PARAMETERS SCREEN

The Brady Parameters screen (Figure 6-1) is divided into two areas: the basic brady parameters are displayed on the left, and additional parameters are found under the submenus on the right side of the screen. There are two columns on each side of the screen next to the parameter names: the Present column displays the currently programmed value for each parameter, and the Change column allows the clinician to make changes to the parameters. If a particular parameter is not applicable in the current mode, dashes will be displayed in the Present column. If a parameter is not applicable to the mode in the Change column, that parameter's change box is not displayed. If there is a value in the Present column but the Change column is blank, the parameter is modified by using the appropriate submenu.

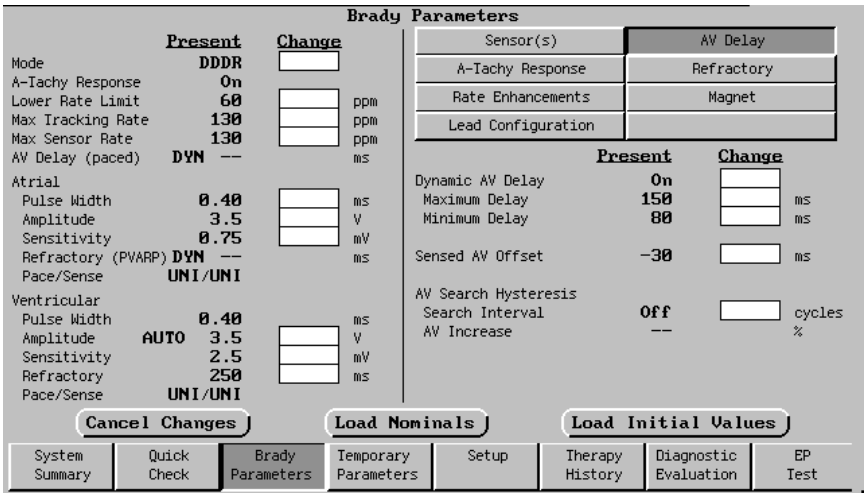


Figure 6-1. The Brady Parameters screen for the dual-chamber adaptive-rate pacemakers.

Brady Parameters Submenus

Additional features are accessed via submenus. These features are displayed on the right side of the Brady Parameters screen below the buttons that provide access to the submenus (Figure 6-1). To display a particular submenu, select the button for that submenu. If parameter settings in that submenu have been changed but not programmed into the pulse generator, slash marks (////) will appear on the submenu button. When the values are programmed, the slash marks will disappear.

As with the basic Brady Parameters, availability of the submenu parameters is dependent on the selected mode. If a particular parameter is not applicable to the mode displayed at the top of the Present column, the parameter line will display dashes. If a parameter is not applicable to the mode in the Change column, that parameter's change box is not displayed.

Modifying Parameter Values

Use the following procedure to make changes to the permanent pacing parameters:

1. Select the Brady Parameters toolbox button.

2. Select the parameter to change by touching the Change box next to the parameter.

3. Select new parameter values by increasing or decreasing values in the Change column. If additional parameters require reprogramming, repeat to achieve the desired values. **Multiple parameter changes can be programmed at one time.**

   After the change(s) has been entered, make sure that the STOP or ⚠ icon is not displayed at the top of the screen. If it is, select that icon to determine how the current changes violate interactive limits. The stop sign indicates an error that must be corrected before programming can occur; warnings, indicated by the exclamation mark, should be carefully considered before continuing.

4. Press the PROGRAM key to program the changes in the pacemaker via telemetry. These parameters now become the permanent pacing parameters and are listed in the Present column.

The Cancel Changes Button

The Cancel Changes button can be selected to delete the values from the Change column before they are programmed.

The Load Nominals Button

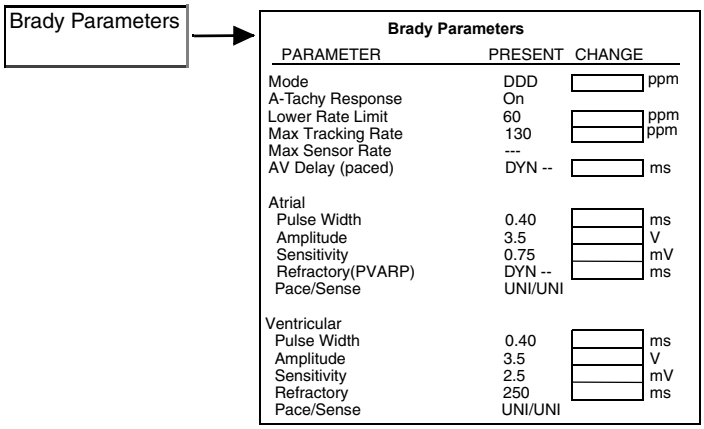
Selecting this button will place the nominal values of the pacemaker, except for nominal Lead Configuration, in the Change column; press the PROGRAM key to program the changes in the pacemaker via telemetry. These parameters now become the permanent pacing parameters and are listed in the Present column. Lead Configuration will remain as originally programmed.

The Load Initial Values Button

At the start of a patient session, when the pacemaker is initially interrogated, the currently programmed values are displayed on the PRM screen and are referred to as the initial values. At any time during the patient session, the initial values can be reloaded by selecting this button if values have been changed. The values will be visible in the Change column; press the PROGRAM key to program the changes in the pacemaker via telemetry. These parameters now become the permanent pacing parameters and are listed in the Present column.

Load Initial Values is particularly helpful when mode changes have been made during a programming session because it ensures that all programmable settings, including lead polarity, are returned to initial values.

BASIC BRADY PARAMETERS



This subchapter discusses the basic parameters appearing on the left half of the PRM Brady Parameters screen. Each parameter is described, and the programmable values are listed.

MODE

Programmable Values: Refer to Table 6-1 for modes available for each model.

The pacemakers can be programmed to the following modes, depending on the model. For a complete discussion of each of these modes, see Appendix A.

Table 6-1. Available Modes By Model

Mode	Models	
	DDDR 1290, 1291	**SSIR 1190**
DDDR	X	
DDIR	X	
DOOR	X	
VDIR	Fallback only	
VVIR	X	
AAIR	X	
SSIR		X
VOOR	X	
AOOR	X	
SOOR		X
DDD	X	
DDI	X	
DOO	X	
VDD	X	
VDI	Fallback only	
VVI	X	
AAI	X	
SSI		X
VOO	X	
AOO	X	
SOO		X
VVT	X	
AAT	X	
SST		X
OSO[a]		X
ODO[a]	X	
OOO[a]	X	X

a. Available only during Temporary programming.

A-TACHY RESPONSE

This field indicates whether A-Tachy Response is programmed On or Off. The On or Off state cannot be changed from this screen; to change the state, select the A-Tachy Response submenu button.

LOWER RATE LIMIT (LRL)

Programmable Values: 30–50 ppm (5-ppm increments), 50–90 ppm (1-ppm increments), 90–150 ppm (5-ppm increments) (Nominal = 60 ppm)

Lower Rate Limit (LRL) is the rate at which the pacemaker paces the atrium and/or ventricle in the absence of sensed intrinsic activity and the absence of sensor-controlled pacing at a higher rate.

As long as the ventricle is being paced, the escape interval is timed from one ventricular event to the next. Whenever an event is sensed in the ventricle (i.e., intrinsic AV conduction occurs before the AV Delay elapses), the timing base switches from ventricular-based timing to atrial-based timing (Figure 6-2). This switching of timing base ensures accurate pacing rates even during intrinsic AV conduction.

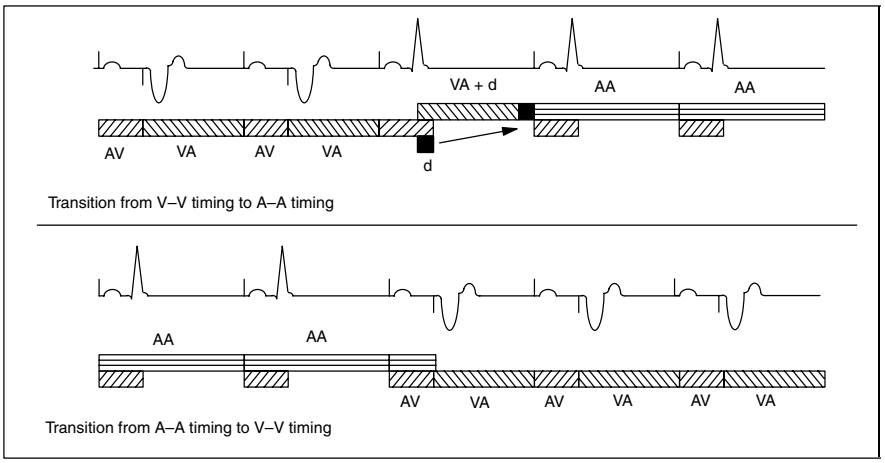


Figure 6-2. Illustration of timing transitions (*d* = the difference between AV Delay and the AV interval in the first cycle during which intrinsic conduction occurs. The value of *d* is applied to the next V–A interval to provide a smooth transition without affecting V–V intervals).

MAX TRACKING RATE (MTR)

Programmable Values: 80–185 ppm (5-ppm increments) (Nominal = 130 ppm)

In the DDD(R) and VDD modes, the Max Tracking Rate (MTR) is the maximum rate at which the paced ventricular depolarization will track 1:1 with nonrefractory sensed atrial events.

In AAT, VVT, and SST modes, the MTR determines the maximum rate at which sensed events (including externally applied stimuli) will trigger pacing.

Conventional DDD Behavior

The following discussion assumes the following parameters are programmed to Off: A-Tachy Response, Rate Smoothing, Dynamic AV Delay, and Dynamic PVARP.

One-to-one atrial-tracked ventricular pacing will occur in the absence of a sensed ventricular event within the programmed AV Delay. When the sensed atrial rate exceeds the MTR, upper rate behavior in the form of pacemaker Wenckebach or 2:1 block may occur. High-rate atrial tracking is limited by the programmed MTR and the total atrial refractory period (AV Delay + postventricular atrial refractory period [PVARP]).

NOTE: *For the purpose of atrial tachycardia detection and histogram updates, atrial events are detected throughout the cardiac cycle (except during atrial blanking) including AV Delay and PVARP.*

As illustrated in Figure 6-3, if the atrial rate exceeds the MTR, the AV Delay will be progressively lengthened (AV′) until an occasional P-wave is not sensed because it falls into the atrial refractory period. This results in occasional loss of 1:1 tracking as the pacemaker synchronizes its paced ventricular rate to the next sensed P-wave (pacemaker Wenckebach).

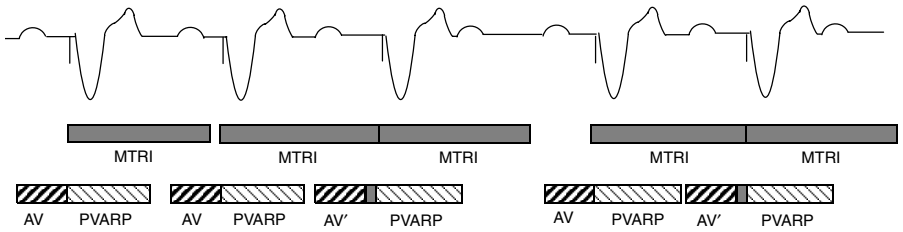


Figure 6-3. Illustration of lengthened Wenckebach behavior at MTR (MTRI = MTR Interval).

Figure 6-4 illustrates another type of pacemaker upper rate behavior (2:1 block) that can occur when tracking high atrial rates. In this type of behavior, every other intrinsic atrial event occurs during PVARP and thus is not sensed, resulting in a 2:1 ratio of atrial-to-ventricular events or a sudden drop in the ventricular paced rate to half of the atrial rate. At faster atrial rates, several atrial events can fall in the AV Delay + PVARP period, resulting in the pacemaker sensing only every third or fourth P-wave. Block then occurs at rates such as 3:1 or 4:1.

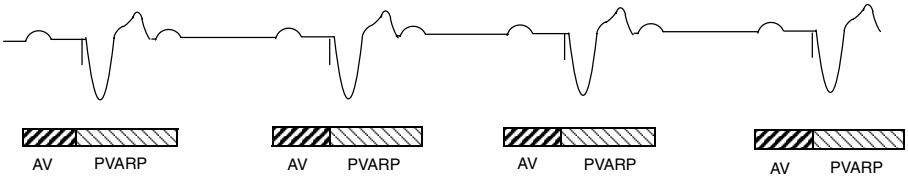


Figure 6-4. Illustration of pacemaker 2:1 block, in which every other P-wave falls inside the PVARP interval.

Either Wenckebach or 2:1 block can occur at atrial rates above the MTR depending upon the programmed MTR, AV Delay, and PVARP.

In order to avoid complete closure of the sensing window at MTR resulting in 2:1 block, the programmer does not allow programming to permanent modes with an MTR interval shorter than the sum of the AV Delay and the PVARP. The sensing window should be maximized by programming the appropriate AV Delay and PVARP. At rates close to the MTR, the sensing window can be maximized by programming Dynamic AV Delay and Dynamic PVARP, and Wenckebach behavior will be minimized.

Programming Rate Smoothing, Atrial Flutter Response, and/or A-Tachy Response to On may reduce or eliminate rapid changes in the paced ventricular rate caused by sensed atrial rates above the MTR.

MAX SENSOR RATE

Programmable Values: 80–185 ppm (5-ppm increments) (Nominal = 130 ppm)

Max Sensor Rate (MSR) is the maximum pacing rate allowed as a result of sensor control (either accelerometer, MV or the blend of both). The MSR parameter is independently programmable at, above, or below the MTR. It is possible to program the MSR greater than, equal to, or less than the ATR Trigger Rate unless the permanent mode is nonrate-adaptive and the ATR Fallback Mode is rate-adaptive, in which case the PRM prevents the user from programming an MSR greater than the ATR Trigger Rate.

- If the MSR setting is higher than the MTR, AV synchronous pacing above the MTR may occur if the sensor rate exceeds the MTR.

- If the MSR setting is lower than the MTR, ventricular pacing above the MSR can occur only in response to intrinsic atrial activity.

CAUTION: Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods, since the combination can cause a very small sensing window or none at all.

Examples:

- An AV Delay setting of 200 ms combined with a PVARP of 300 ms will result in asynchronous atrial pacing at sensor-indicated rates above 120 ppm in dual-chamber adaptive-rate pacemakers.

- A refractory period of 500 ms will result in asynchronous pacing at sensor-indicated rates above 120 ppm in atrial adaptive-rate pacemakers.

AV DELAY (PACED)

Programmable Values: 10–300 ms (10-ms increments) (Nominal = 150 ms)

The AV Delay is the programmable period from the beginning of an atrial event, either intrinsic or paced, to the paced ventricular event. AV Delay is applicable to all dual-chamber modes. In the DDI(R), VDD, and DDD(R) modes, the pacemaker delivers a ventricular pace at the end of the AV Delay unless inhibited by an intrinsic ventricular depolarization or if the MTR would be exceeded. In DOO mode, the device delivers a ventricular pace at the end of the AV Delay regardless of intrinsic ventricular depolarization.

AV Delay can be programmed to a fixed value—AV Delay (paced)—or can be calculated dynamically based on the previous A–A interval (Dynamic AV Delay). Dynamic AV Delay is nominally programmed On. Refer to “Dynamic AV Delay” on page 6-65 for additional information.

If a fixed AV Delay is programmed, the AV Delay will remain unchanged as the rate increases. This can result in a significant reduction in the sensing window at MTR.

The Dynamic AV Delay (on the AV Delay submenu) provides a more physiologic AV coupling across the programmed rate range and maximizes the sensing window at higher rates. This minimizes the occurrence of pacemaker Wenckebach behavior when the atrial rate exceeds the MTR. The applied AV Delay may be programmed from 10 ms to 300 ms.

NOTE: *The Automatic Capture feature may add an additional 64 ms AV Hysteresis in order to accommodate a fusion check for a maximum AV Hysteresis delay of 364 ms.*

Refer to “AV Delay Submenu” on 6-65 for information about Dynamic AV Delay, Sensed AV Offset, and AV Search Hysteresis.

PULSE WIDTH

Programmable Values: 0.05 ms and 0.1–1.0 ms (0.1-ms increments) (Nominal = 0.4 ms)

The Pulse Width, also referred to as pulse duration, determines how long the output pulse will be applied between the pacing electrodes. Atrial and ventricular pulse widths are independently programmable.

The energy delivered to the heart is proportional to the Pulse Width; doubling the Pulse Width doubles the energy delivered. *Therefore, programming to a narrow (lower) Pulse Width while maintaining an adequate safety margin will increase pacemaker longevity.*

AMPLITUDE

Programmable Values:
Atrial: **0.1–3.5 V (0.1-V increments), 4.0–5.0 V (0.5-V increments), 6.5 V (Nominal = 3.5 V)**
Ventricular: **Auto, 0.1–3.5 V (0.1-V increments), 4.0–5.0 V (0.5-V increments), 6.5 V (Nominal = 3.5 V)**

Amplitude is measured at the leading edge of the output pulse, and is measured in volts. Amplitude is independently programmable in the atrium and ventricle. During Temporary programming the mode may be programmed to OSO, ODO, or OOO (in effect, turning the Amplitude off) to monitor the patient's underlying rhythm.

The energy delivered to the heart is proportional to the square of the Amplitude. In other words, doubling the Amplitude quadruples the energy delivered, which will decrease pacemaker longevity (Figure 6-5). *Programming to a lower Amplitude while maintaining an adequate safety margin will increase battery longevity.*

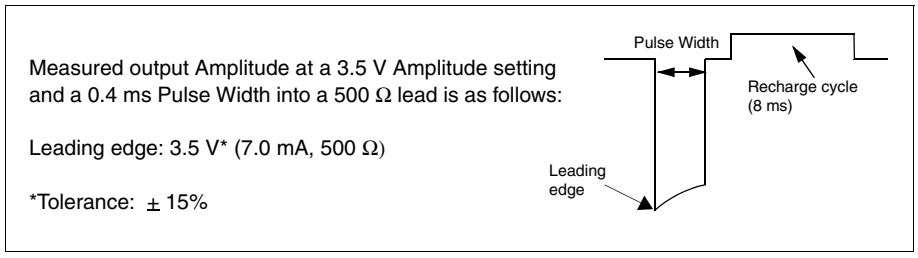


Figure 6-5. Nominal pulse characteristics.

AUTOMATIC CAPTURE

The Automatic Capture feature is designed to dynamically adjust the ventricular pacing output to ensure capture of the ventricle while optimizing the output voltage to 0.5 V above the capture threshold. Automatic Capture maintains this output and confirms capture on a beat-to-beat basis.

The Ventricular Automatic Capture feature can be selected by choosing Auto from the Ventricular Amplitude parameter options. For more programming details, please refer to the section “Amplitude” on page 6-12.

Programming the ventricular output to Auto will automatically adjust the output Pulse Width to 0.4 ms and set the ventricular voltage output to an initial value of 3.5 V. The Automatic Capture algorithm then measures the ventricular pacing threshold and adjusts the voltage output to the threshold + 0.5 V. On a beat-to-beat basis, Automatic Capture confirms that each ventricular pacing output captures the ventricle. This is accomplished by observing the evoked response following each ventricular pacing output and determining if that pacing output captured the ventricle. If the ventricle was not captured, the pacemaker will deliver a back-up pacing output within 100 ms of the primary pulse. The back-up safety pulse amplitude will be at least 1.5 V higher than the measured threshold, with a minimum of 3.5 V and a maximum of 4.5 V. (see Table 6-2).

Table 6-2. Back-up safety pulse values

Measured Threshold (V)	Backup Safety Pulse (V)
1.0	3.5
1.5	3.5
2.0	3.5
3.0	4.5

The Automatic Capture feature has been designed to operate with a large range of pacing leads (high impedance, low impedance, tined or positive fix). Also, Automatic Capture is independent of pacing and sensing lead polarity; the ventricular output and sensing can be programmed to Unipolar or Bipolar.

NOTES:

- *Prior to programming Automatic Capture On, the clinician should consider performing a Commanded Ventricular Automatic Threshold Measurement to verify system compatibility.*

- *Automatic Capture is intended for ventricular use only. Do not program Amplitude to Auto for single-chamber devices implanted in the atrium.*

- *Automatic Capture is available in permanent DDD(R), VVI(R), and VDD mode. Automatic Capture is also available during VDI(R) and DDI(R) fallback modes.*

- *Automatic Capture's fusion management is enhanced with higher Maximum Tracking Rates and shorter AV Delays.*

- *When Automatic Capture is enabled, the minimum effective AV Delay allowed is 40 ms. For example if the AV Delay is 70 ms and the sensed AV offset is -30 ms, the effective AV delay is 40 ms (70 – 30 ms = 40 ms).*

- *If noise (which could potentially be a fusion beat) is detected in the evoked response signal, the AV interval (dual-chamber modes) or V-V interval (single-chamber modes) will be extended by 64 ms on the next cardiac cycle in an attempt to distinguish the fusion beat from a capture of the ventricle.*

- *Automatic Capture is designed to work with typical lead implant criteria including:*
  - *Ventricular threshold between 0.1 V and 3.0 V at 0.4 ms*
  - *Lead impedance between 100 Ω and 2500 Ω*
  - *Ventricular intrinsic amplitude > 5 mV.*

Automatic Capture must first successfully measure the ventricular threshold before it will enter its beat-to-beat capture verification mode. This measurement can be made through commanded test, or it will be performed automatically after the programming session is completed. Both methods are described below.

Commanded Ventricular Automatic Threshold Measurement

An automatic threshold measurement can be commanded via the Threshold Tests screen. If the ventricular auto threshold measurement completes successfully and Automatic Capture is programmed On, Automatic Capture will enter its beat-to-beat capture verification mode. This can be confirmed by observing the output Voltage on the Brady Parameters screen, which will show the actual operating Voltage of the Automatic Capture algorithm (the ventricular threshold + 0.5 V).

NOTE: *In order for the clinician to better recognize appropriate loss of capture, backup pacing is not active during a Commanded Ventricular Automatic Threshold Measurement except when the device confirms loss of capture.*

If an auto threshold measurement is not successfully completed and Automatic Capture is programmed On, the Threshold Tests screen will display the reason the test was not successful[1] and Automatic Capture will enter Retry mode. See “Automatic Capture Retry” on page 6-16.

If an automatic threshold measurement is not commanded by the clinician, the algorithm will automatically try to measure the ventricular threshold within 10 minutes after the programming session is completed. This is referred to as an ambulatory automatic threshold measurement and is described below.

Ambulatory Ventricular Automatic Threshold Measurement

When Automatic Capture is On, ambulatory ventricular automatic threshold measurements are conducted by the pacemaker every 21 hours or when loss of capture is detected. As with the commanded auto threshold measurement, if the pacemaker cannot perform this test, Automatic Capture enters Retry mode. See “Automatic Capture Retry” on page 6-16.

In dual-chamber mode, the automatic threshold measurement adjusts the following parameters to help ensure a measurement:

- AV Delay (paced) changes to 60 ms
- Sensed AV Offset changes to -30 ms
- Starting ventricular pacing output amplitude is 3.5 V.
- Following every primary pacing pulse, a back-up pulse is delivered.

In non-tracking modes VVI(R), VDI(R), and DDI(R), the automatic threshold measurement adjusts the following parameters to help ensure a measurement:

- AV Delay (paced) changes to 60 ms.

1. Reasons for an unsuccessful threshold measurement include: noise detected on the evoked response channel or ventricular sense amplifier, inadequate evoked response signal, threshold not found at the lowest paced amplitude, or threshold > 3.0 V.

- Sensed AV Offset changes to -30 ms.
- Starting ventricular pacing output amplitude is 3.5 V
- Following every primary pacing pulse, a back-up pulse is delivered
- The ventricular rate will be increased by a maximum of 10 ppm above the current rate (paced or intrinsic) and will not exceed the maximum sensor rate or maximum pacing rate.

The pacemaker will apply at least 3 captured paced pulses at each output. With the occurrence of noisy evoked response or loss of capture, additional pace pulses will be issued. If at the beginning of the test, the current pacing rate is more than 50 ppm greater than the LRL, the pacemaker will postpone the test for one hour. The test will also be postponed if the device is being telemetered at the time of the test.

Automatic Capture Retry

Once the Automatic Capture feature is active, it remains active until the ventricular output is programmed to a manual Voltage setting or ERT is reached. If Automatic Capture is active but unable to determine the pacing threshold as described above, it will enter Retry mode. The pacing output will operate at twice the last measured threshold, but not > 5.0 V, and not < 3.5 V (See Table 6-3). Periodically, Automatic Capture will attempt to measure the ventricular threshold. If successful, Automatic Capture will return to the Beat-to-Beat mode.

How often Automatic Capture re-attempts the threshold measurement depends upon the reason the pacemaker entered Retry. For example, if the reason was noise detected on the evoked response channel or on the ventricular sense amplifier, the threshold test is attempted every hour. If the reason was inadequate evoked response signal, threshold not found at lowest pacing amplitude, or threshold > 3.0 V, the threshold test is attempted every 21 hours.

Table 6-3. Pacing output during Automatic Capture retry

Last Measured Threshold (V)	Output During Retry (V)
0.5	3.5
1.0	3.5
2.0	4.0
3.0	5.0

Although Automatic Capture is designed to work with a wide range of pacemaker leads, in some patients the lead signals may hinder successful determination of the ventricular threshold. In these instances, Automatic Capture will continually operate in the Retry mode with a minimum ventricular output of 3.5 V and a maximum of 5.0 V.

Reasons for entering the Retry mode include an evoked response signal amplitude that is too small, a signal-to-artifact ratio that is too low, the device is unable to measure loss of capture, the threshold is >3.0 V, or there are insufficient paced events. For these patients, the clinician may choose to turn Automatic Capture Off by programming the ventricular output to Manual.

SENSITIVITY

Programmable Values:
Atrial: **Auto, 0.15, 0.25, 0.50, 0.75, and 1.0–8.0 mV (0.5-mV increments), 9.0, 10.0 mV (Nominal = 0.75 mV)**
Ventricular/Single: **Auto, 0.25, 0.50, 0.75, 1.0–8.0 mV (0.5-mV increments), 9.0, 10.0 mV (Nominal = 2.5 mV)**

The Sensitivity parameter allows the pacemaker to detect intrinsic cardiac signals that exceed the programmed value.

When Sensitivity is programmed to a very sensitive setting (i.e., a low value), the pacemaker may detect signals unrelated to cardiac depolarization (oversensing, such as sensing of myopotentials). When Sensitivity is programmed to a less sensitive setting (i.e., a higher value), the pacemaker may not detect the cardiac depolarization signal (undersensing). For manual programming, Sensitivity must be programmed to a value that prevents sensing of extraneous signals, but ensures accurate sensing of intrinsic cardiac signals. Intrinsic atrial signals are typically smaller than ventricular signals, so lower Sensitivity settings are typically pro-

grammed for the atrium. When a single-pass VDD lead is used with a dual-chamber device, the atrial electrodes might not be in contact with the atrial wall. In this case, the measured depolarization signal has a relatively low Amplitude and could require a Sensitivity setting as low as 0.15 mV. P-waves that are less than 0.25 mV and R-waves that are less than 1.5 mV will not be sensed when Auto Sense is used.

Auto Sense

Auto Sense is designed to automatically adjust pacemaker sensitivity to cardiac signal changes without clinician intervention. The sensitivity level is updated each cardiac cycle. The Auto Sense sensitivity range for the atrium is 0.25–4.0 mV and for the ventricle is 1.5–6.0 mV. For both Auto Sense and fixed programmed Sensitivity, the minimum recommended P-wave is 2.0 mV and the minimum recommended R-wave is 5.0 mV.

In dual-chamber applications, Auto Sense is a programmable option that can be used independently in each chamber. In single-chamber applications, Auto Sense defaults to the ventricular algorithm; therefore, Auto Sense should be used only in the ventricle for single-chamber uses. Auto Sense uses similar algorithms for atrial and ventricular sensing. When programmed On, the Auto Sense algorithm automatically adjusts the atrial and/or ventricular sensitivity levels based on the Amplitude of previously sensed events, the type of cardiac cycle (paced or sensed), and a measurement of the current myopotential/environmental noise level (see Figure 6-6 and Figure 6-7).

- **Amplitude of Sensed Events**—When Auto Sense is detecting intrinsic events, it will adjust the sensing threshold level based on a smoothed average of the measured intrinsic events.

- **Type of Cardiac Signal (Sensed or Paced)**—When sensing, Auto Sense uses the smoothed average of the measured intrinsic events to determine the sensitivity level. When pacing occurs, Sensitivity is slowly adjusted, becoming more sensitive each cardiac cycle until maximum sensitivity is reached at 0.25 mV in the atrium or 1.5 mV in the ventricle.

- **Myopotential/Environmental Noise Level**—In the ventricle, Auto Sense measures the myopotential/environmental noise level during the last 50 ms of ventricular refractory. In the atrium, Auto Sense determines the myopotential/environmental noise level by evaluating atrial senses during PVARP.

NOTE: *Auto Sense is disabled during PES and Burst pacing and nonpacing Temporary modes such as ODO. The sensing threshold remains at the level previously determined by Auto Sense for the duration of these temporary states.*

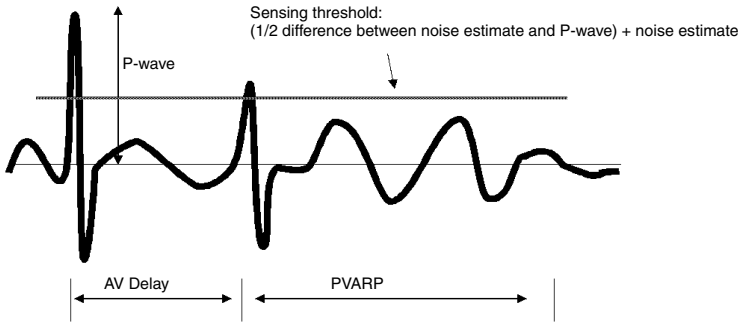


Figure 6-6. In the atrium, Auto Sense adjusts the Sensitivity levels based on the Amplitude of previously sensed P-waves, myopotential/environmental noise detection during PVARP, and the type of cardiac cycle (paced or sensed). In this example, the myopotential/environmental noise level does not cause the Sensitivity level to be adjusted.

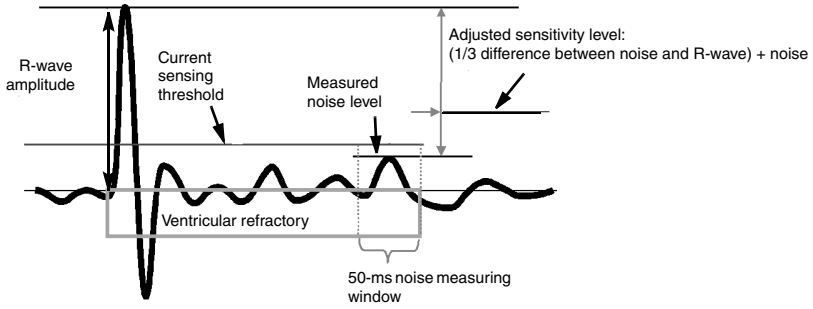


Figure 6-7. In the ventricle, Auto Sense adjusts the Sensitivity levels based on the Amplitude of previously sensed R-waves, the myopotential/environmental noise level measured during the last 50 ms of ventricular refractory, and the type of cardiac cycle (paced or sensed). In this example, the sensing threshold is adjusted based on the measured myopotential noise level.

REFRACTORY PERIODS

The refractory period is the interval following a paced or sensed event during which the pacemaker is not inhibited or triggered by detected electrical activity. Refractory periods avoid triggering or inhibition of pacemaker events due to detection of inappropriate signals such as retrograde P-waves, far-field R-waves, or noise.

Refer to the “Refractory Submenu” on page 6-71 for information about PVARP after PVC/PAC and V-Blanking after A-Pace or A-Blanking after V-Pace.

Atrial Refractory Period

Programmable Values: 150–500 ms (10-ms increments) (Nominal = 300 ms)

In three single-chamber atrial modes (AAT, AAI, AAIR), the Atrial Refractory period is defined as the period after an atrial event, either paced or sensed, when activity in the atrium does not inhibit or trigger an atrial stimulus.

Adaptive-rate pacing is not inhibited during refractory periods. See “Max Sensor Rate” on page 6-10 for further discussion.

Post-Ventricular Atrial Refractory Period (PVARP)

Programmable Values: 150–500 ms (10-ms increments) (Nominal = 250 ms)

The post-ventricular atrial refractory (PVARP) is defined as the period after a ventricular event, either paced or sensed, when activity in the atrium does not inhibit an atrial stimulus nor trigger a ventricular stimulus. It is designed to prevent the atrial channel from sensing the ventricular pacing pulse, the far-field R-waves, or retrograde P-waves.

PVARP should be programmed to a value greater than the patient’s V–A retrograde conduction time to prevent the atrial channel from sensing a retrograde atrial depolarization and possibly initiating pacemaker-mediated tachycardia.

This parameter can be programmed to fixed value (PVARP) or can be calculated dynamically based on the previous cardiac cycles (Dynamic PVARP). Dynamic PVARP is nominally programmed On. See “Dynamic PVARP” on page 6-71.

Using a long PVARP shortens the atrial sensing window. Programming a long PVARP in combination with a long AV Delay can cause 2:1 block to occur abruptly at the programmed MTR. See “Max Tracking Rate” on page 6-8 for further discussion.

Ventricular Refractory Period

Programmable Values: 200–500 ms (10-ms increments) (Nominal = 250 ms)

The ventricular refractory period is defined as the period following a ventricular event, either paced or sensed, when sensed electrical activity in the ventricle does not inhibit the pacemaker. This parameter is available in any mode in which ventricular sensing is enabled.

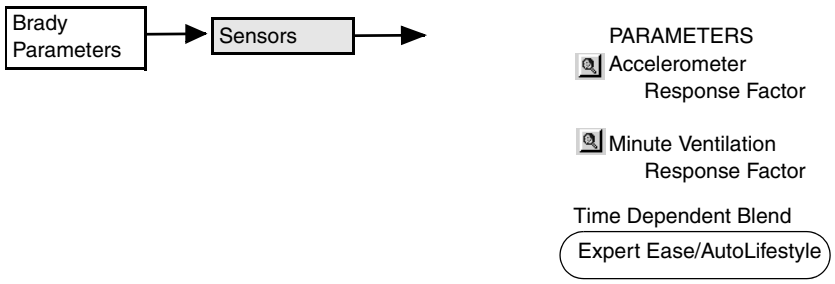
Use of a long Ventricular Refractory period shortens the ventricular sensing window. Programming the Ventricular Refractory period to a value greater than PVARP can lead to competitive pacing. For example, if the Ventricular Refractory is longer than PVARP, an atrial event can be appropriately sensed following PVARP and intrinsic conduction to the ventricle falls into the Ventricular Refractory period. In this case, the pacemaker will not sense the ventricular depolarization and will pace at the end of the AV Delay, resulting in competitive pacing.

Adaptive-rate pacing is not inhibited during Refractory periods.

PACE/SENSE

The Pace/Sense field indicates the programmed lead polarity. The polarity cannot be changed from this screen; to change polarity, select the Lead Configuration submenu button.

SENSOR SUBMENU

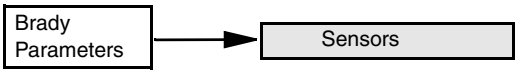


ADAPTIVE-RATE PACING

In the adaptive-rate modes (i.e., any mode ending with R), sensors are used to detect changes in metabolic demand and to increase the pacing rate accordingly. Adaptive-rate pacing is available in the DDDR, DDIR, DOOR, VVIR, AAIR, SSIR, VOOR, AOOR, and SOOR permanent modes as well as the DDIR and VDIR fallback modes. In these modes, the pacemaker will pace at the sensor-indicated rate unless inhibited by sensed events.

The pacemakers can be programmed to use the Accelerometer, or Minute Ventilation, or a blend of both the Accelerometer and Minute Ventilation. The clinical benefit of adaptive-rate pacing using either of these sensors has been shown in previous Guidant clinical studies.

ACCELEROMETER



Programmable Values: Off, On, ATR-only[a] (Nominal = Off)

a. ATR only is not a user selectable setting. It is set when the primary mode is not rate-responsive and a rate-responsive ATR Fallback Mode is selected.

The Accelerometer detects motion associated with physical activity and generates an electronic signal that is proportional to the magnitude of motion resulting from body movement.

Based on the accelerometer input, the pacemaker estimates the patient's energy expenditure as a result of exercise and then translates it into a rate increase. To measure acceleration, both the frequency and the amplitude of the sensor signal are evaluated during signal processing. Signal frequency reflects how often an activity occurs, such as the number of steps per minute taken during a brisk walk. Signal amplitude reflects the force of the motion—for example, the more deliberate steps taken while walking. See Chapter 3 "Technical Information" for further discussion of accelerometer function.

If the pacemaker is permanently programmed to a nonadaptive-rate mode, it is possible to program ATR Fallback Mode to an adaptive-rate mode using the Accelerometer sensor. In this case, on the sensor submenu, the Accelerometer field will display ATR Only.

The following programmable parameters control the pacemaker's response to the sensor values generated by the Accelerometer:

- Response Factor
- Activity Threshold
- Reaction Time
- Recovery Time

Response Factor (Accelerometer)

Programmable Values: Passive, 1–16 (Nominal = 8)

The Accelerometer Response Factor parameter determines the pacing rate that will occur above the LRL at various levels of patient activity. Figure 6-8 shows the relationship of the Response Factor settings.

NOTE: *The AutoLifestyle must be Off or set to Reset before changing the Response Factor setting.*

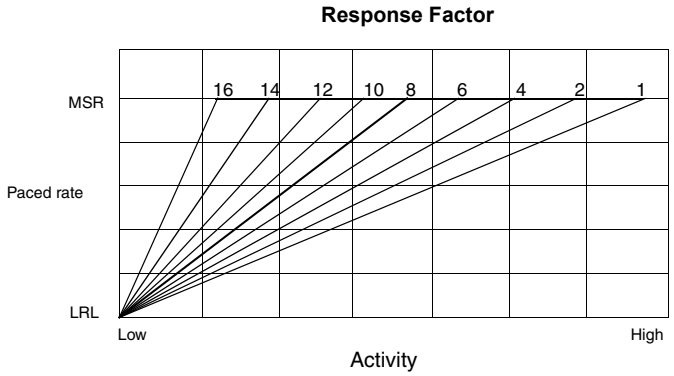


Figure 6-8. The relationship between the programmed Response Factor setting and the rate response.

Setting the Response Factor to a higher value will enable the rate to reach the MSR with a lower level of activity than will a low value. Figure 6-9 illustrates the effect of higher and lower settings during a theoretical two-stage exercise test.

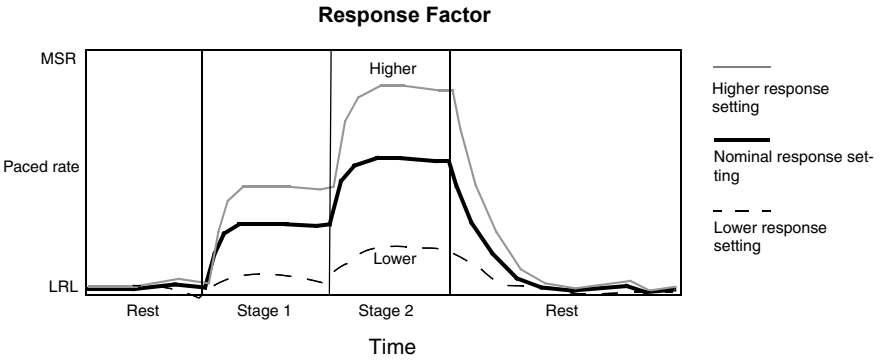


Figure 6-9. Effects of Response Factor settings in a two-stage exercise test.

The pacing rate achieved can be limited either by the detected level of activity or by the programmed MSR. If the detected activity level results in a steady-state rate below the MSR, pacing rate can still increase when the detected activity levels increase.

Programming the LRL up or down will move the entire response up or down without changing its shape. The steady state response is independent of the programmed reaction and recovery times.

The nominal setting has been shown to be appropriate for the majority of the patients in a previous Guidant study, and therefore is recommended for use in monitoring the rate response prior to programming changes.

The Passive setting can be used to allow accelerometer trending without a rate response.

Advanced Accelerometer Parameters

Activity Threshold

Programmable Values: V-Low, Low, Med-Lo, Medium, Med-Hi, High, V-High (Nominal = Medium)

The Activity Threshold prevents the pacemaker from increasing the rate due to low-intensity extraneous motion (e.g., motion caused by respiration, heart beat, or, in some cases, tremor associated with Parkinson's disease). The pacemaker will not increase the paced rate above the LRL until the accelerometer signal has increased above the Activity Threshold. Select an Activity Threshold setting that allows a rate increase with minor activity (such as walking), but high enough so that the pacing rate will not increase inappropriately when the patient is inactive. A lower Activity Threshold setting will be easily exceeded by a minimum of motion, while a higher setting will require a greater amount of motion to result in an increased pacing rate (Figure 6-10). The nominal setting has been shown to be appropriate for the majority of the patients in a previous Guidant study, and therefore is recommended for use in monitoring the rate response prior to programming changes.

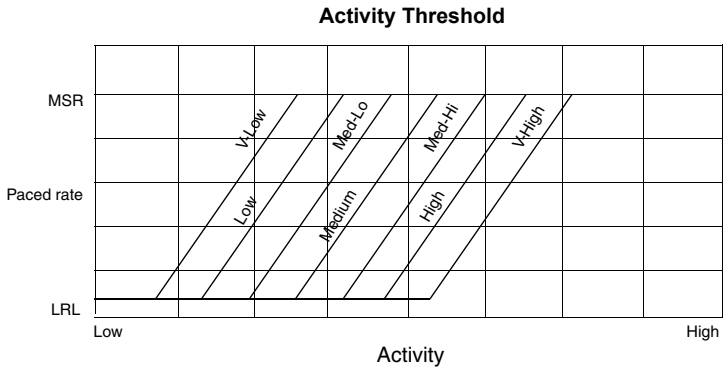


Figure 6-10. Relationship between the programmed Activity Threshold and the rate response.

Increasing the Activity Threshold reduces the response to a theoretical two-stage exercise test as shown in Figure 6-11. Decreasing the Activity Threshold increases the response.

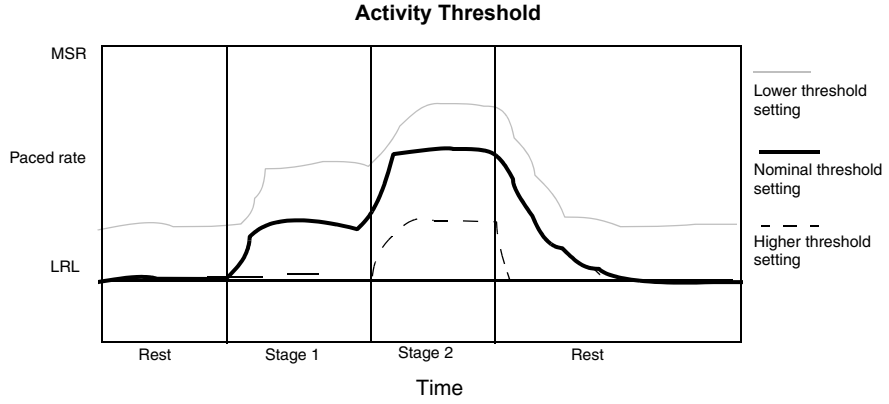


Figure 6-11. Effects of Activity Threshold settings in a two-stage exercise test.

Reaction Time

Programmable Values: 10–50 sec (10-sec increments) (Nominal = 30 sec)

When an increase in the level of activity is detected, the pacing rate will increase. How quickly the pacing rate will rise to the new level is determined by the Reaction Time. The value selected for Reaction Time determines the time required for the

paced rate to reach the MSR for a maximum level of activity. See Figure 6-12 for a graphic representation of the Reaction Time slopes. Reaction Time affects only the time required for a rate increase to occur. A short Reaction Time will allow the pacing rate to increase rapidly in response to patient activity. A long Reaction Time will result in a slower increase in pacing rate (Figure 6-13). The nominal setting has been shown to be appropriate for the majority of the patients in a previous Guidant study, and therefore is recommended for use in monitoring the rate response prior to programming changes.

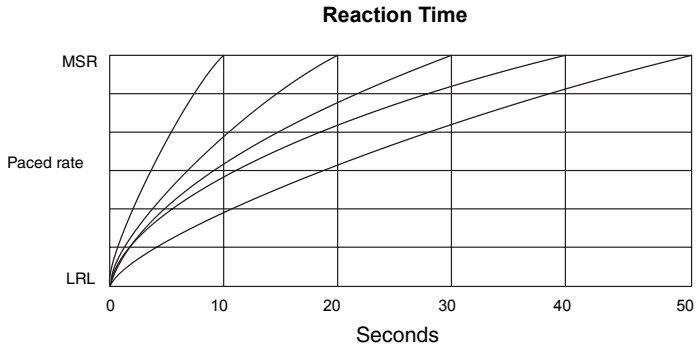


Figure 6-12. The relationship of reaction time and paced rate depending on the programmed Reaction Time setting.

A shorter Reaction Time setting results in a more rapid rate increase during a theoretical two-stage exercise test than will a longer Reaction Time (Figure 6-13).

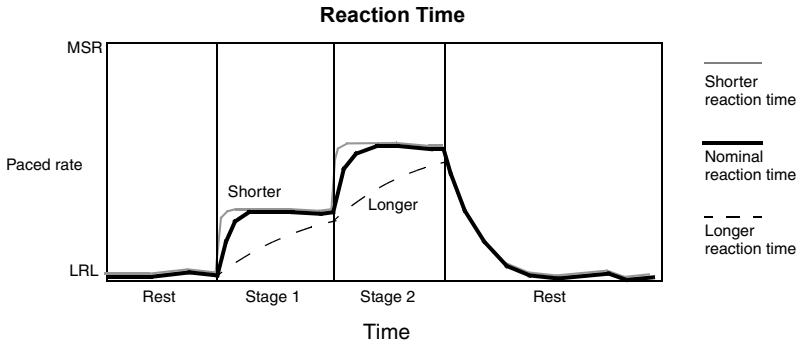


Figure 6-13. Effects of Reaction Time settings in a two-stage exercise test.

Recovery Time

Programmable Values: 2–16 minutes (1-minute increments) (Nominal = 2 minutes)

The Recovery Time parameter determines the time required for the paced rate to decrease from MSR to LRL in the absence of activity. This feature is intended to prevent an abrupt decrease in pacing rate concurrent with the conclusion of patient activity. See Figure 6-14 for a graphic representation of the recovery times.

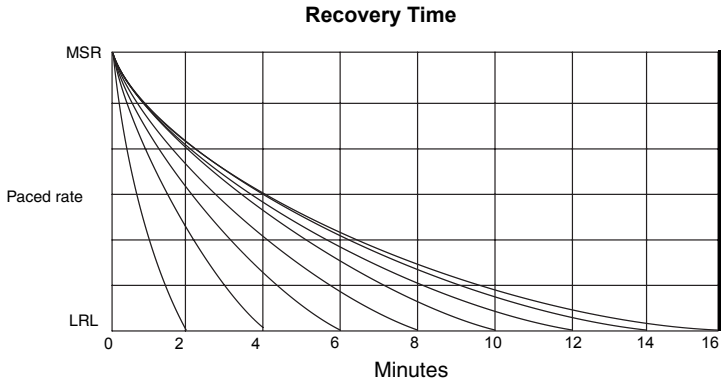


Figure 6-14. The relationship of paced rate to recovery depending on the programmed Recovery Time. Only even-numbered settings are shown. There are 15 settings available.

A shorter Recovery Time will allow the pacing rate to decrease more rapidly after cessation or lowered patient activity. A longer Recovery Time will force a slower decrease in pacing rate. Figure 6-15 illustrates the effect of higher and lower settings during a theoretical two-stage exercise test.

When using dual-sensor blending, program Recovery Time for the Accelerometer to the minimum value of 2 minutes. This allows the physiologic MV signal to control adaptive-rate pacing in the exercise recovery phase.

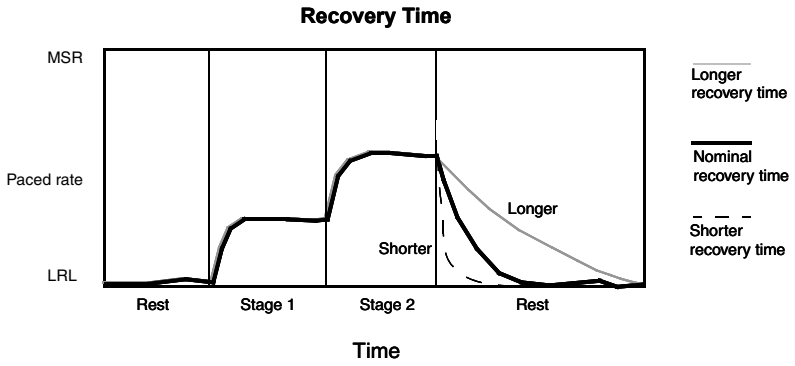
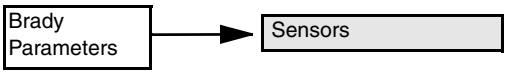


Figure 6-15. Effects of Recovery Time settings in a two-stage exercise test.

Recovery Time affects only rate deceleration and is independent of other parameters.

MINUTE VENTILATION (MV)



Programmable Values:
Dual-chamber devices—Off, On, 4→ **On-A,** 4→ **On-V (Nominal = Off);**
Single-chamber devices—Off, On, 4→ **On (Nominal = Off)**

The INSIGNIA I Ultra adaptive-rate pacemakers use transthoracic impedance to measure minute ventilation (MV), which is the product of respiration rate and tidal volume. Based on the MV measurement, the pacemaker calculates the sensor rate. The minute ventilation signal can be measured through either the atrial or the ventricular lead. The selected MV lead must be bipolar but the Lead Configuration can be programmed Unipolar or Bipolar. See Chapter 3 “Technical Information” for a discussion of MV detection.

CAUTION: Electrical signals introduced into the body by some hospital monitoring and/or diagnostic equipment may result in accelerated pacing, possibly up to the maximum sensor-driven rate, when MV is programmed On. Examples of this equipment include, but are not limited to, respiratory monitors, diagnostic echo imaging, surface ECG monitors, and hemodynamic monitors. Deactivate the MV sensor when interaction with this equipment is suspected.

To obtain a relative MV measure, a long-term (2-hour) average of the measurements (also referred to as the baseline) is compared to a short-term (approximately 30-second) average to determine the change in MV due to increased metabolic demand. If the short-term average increases above the long-term, the difference will be used to increase the sensor rate (Figure 6-16).

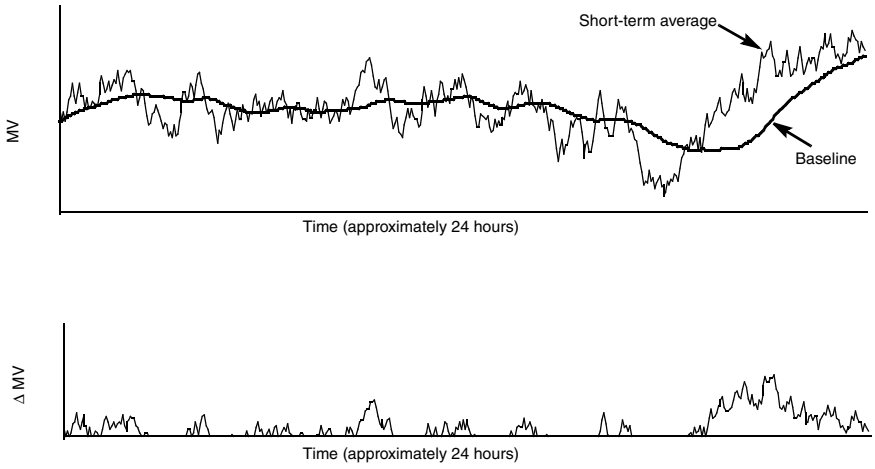


Figure 6-16. TOP: The Baseline (long-term average) follows the drift of the short-term average with a 2-hour time constant. BOTTOM: The difference between the short- and long-term average is used for increasing the pacemaker's rate upon exertion.

To allow active patients who exercise for a long duration (e.g., long-distance runners) to maintain an adequate sensor-driven rate throughout the exercise period, the baseline (long-term average) is fixed for up to 4 hours when the sensor rate is above 50% of the programmed rate range ([LRL + MSR] / 2). For example, if the LRL is 60 ppm and the MSR is 120 ppm, the baseline average will freeze when the heart rate exceeds 90 ppm (180 / 2). After a maximum of 4 hours or when the sensor rate falls below the 50% point, baseline adaptation will be re-enabled. This feature is always active when MV is used.

To activate the Minute Ventilation sensor, the system needs a measure of the baseline or resting MV. In dual-chamber devices, the clinician may collect values through the atrial lead (4→ On-A) or the ventricular lead (4→ On-V). (In single-chamber devices, the selection is 4→ On). Selecting one of the 4→ On options instructs the pacemaker to collect resting MV values for 4 minutes and estimate the MV baseline based on this short measurement before automatically activating the MV sensor. The PRM will display the MV Lead selected.

NOTES:

- *Whenever a magnet is applied and the Magnet Response has been programmed to Async, the pacemaker will pace asynchronously at the magnet rate and will not respond to MV data.*
- *When a 4→ On initialization is selected, AutoLifestyle is automatically enabled.*
- *Maintain the telemetry communication link until the scale indicates that the programming has reached 100% completion and the message window closes.*

CAUTIONS:

- A 4→ On initialization should be performed if the pacemaker is removed from the pocket following implant, such as during a lead repositioning procedure.
- A 4→ On initialization should be performed to establish a new MV baseline if one of the following conditions is noted during MV sensor evaluation:
  - Failure to achieve a significant sensor-indicated response with the MV Response Factor set to level 16
  - Observed maximum or elevated sensor-indicated rates with the MV Response Factor set to level 2

NOTE: *As a diagnostic, the device measures and stores MV baseline on an hourly basis for the last 24 hours. Performing a 4→ On calibration clears all the MV measurements. This action also resets AutoLifestyle.*

Response Factor (Minute Ventilation)

Programmable Values: Passive, 1–16 (Nominal = 3)

An increase in MV over baseline due to an increase in metabolic demand will be detected by the pacemaker and converted by its algorithm into an increased pacing rate. The relationship between the detected increase in MV and the resulting increase in rate is established by the MV Response Factor.

The Response Factor can be automatically optimized to the patient's activity profile using AutoLifestyle™. AutoLifestyle must be programmed Off to program a specific Response Factor for MV. Refer to "AutoLifestyle" on page 6-38 for more information.

The Response Factor parameter determines the pacing rate that will occur above the LRL at various elevated levels of MV. Figure 6-17 shows the relationship of the Response Factor settings. Larger Response Factor values will result in higher sensor rates for a given MV level.

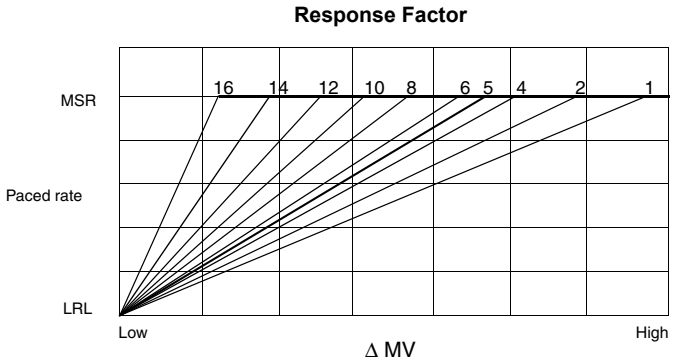


Figure 6-17. Relationship between the programmed Response Factor setting and the rate response.

Figure 6-18 illustrates the effect of higher and lower Response Factor settings during a theoretical two-stage exercise test.

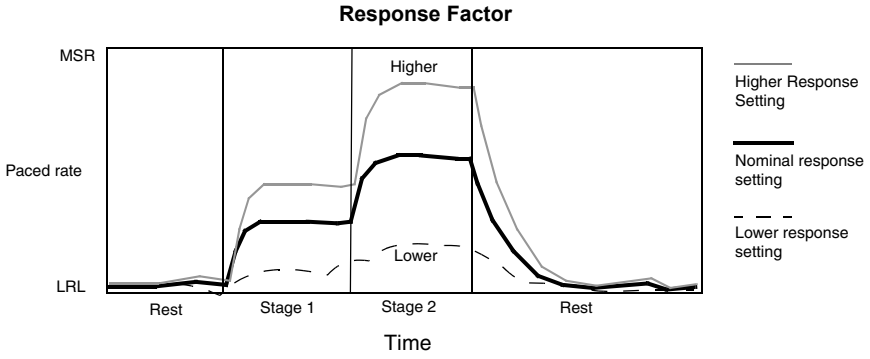
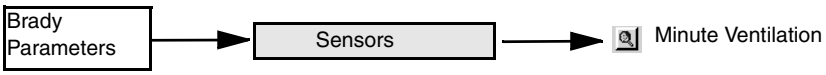


Figure 6-18. Effects of Response Factor settings in a two-stage exercise test.

The MV Response Factor may be programmed to Passive to allow for MV trending without a rate response.

NOTE: *The AutoLifestyle must be Off or set to Reset before changing the Response Factor setting.*

Advanced Minute Ventilation Parameters



High Rate Response Factor

Programmable Values: Off, 55%, 70%, 85% (Nominal = 70%)

The physiologic relationship between MV and rate is approximately bilinear as shown in Figure 6-19. During exercise levels up to the anaerobic threshold, this relationship can be approximated by a linear relationship. At exertion levels above the anaerobic threshold, the slope becomes less pronounced. The relationship between the secondary slope and the primary slope varies from person to person and depends on several factors such as gender, age, and exercise frequency and intensity.

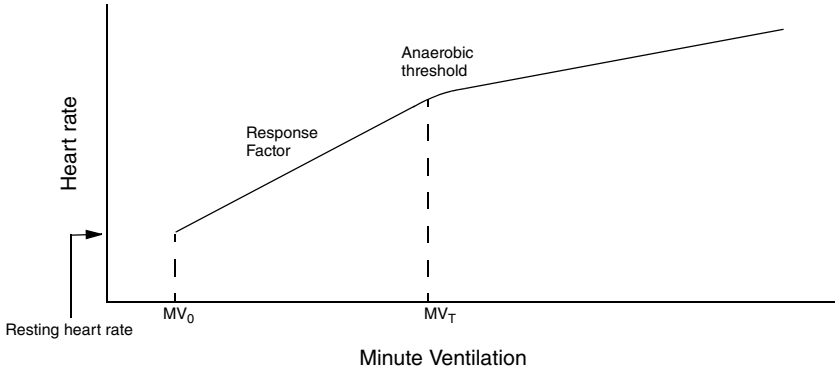


Figure 6-19. Typical physiologic relationship between MV and heart rate. (MV_0 = resting MV; MV_T = MV at the anaerobic threshold.)

The pacemakers allow programming of a secondary, less aggressive slope that mimics the physiologic relationship between MV and heart rate. The High Rate Response Factor is programmed as a percentage of the Response Factor.

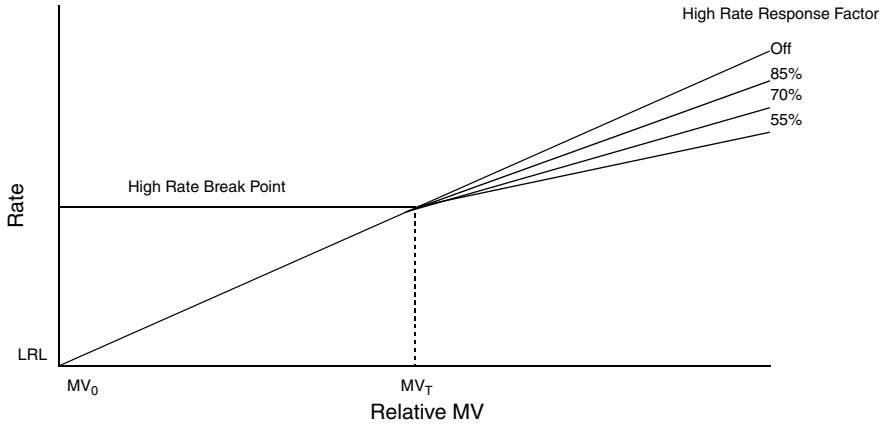


Figure 6-20. The Response Factor is linear from the resting state up to the anaerobic threshold predicted heart rate (High Rate Break Point). (MV_0 = resting MV; MV_T = MV at the anaerobic threshold.)

The High Rate Response Factor is in effect at rates above the High Rate Break Point and will result in a less aggressive response to increased MV at higher rates (Figure 6-20).

High Rate Break Point

Programmable Values: 80–185 ppm (5-ppm increments) (Nominal = 110 ppm)

The Response Factor controls the MV rate response for sensor rates between the LRL and the High Rate Break Point. The High Rate Response Factor controls the MV rate response when the sensor rate is between the High Rate Break Point and the MSR.

As an aid to programming the MV sensor, Expert Ease/AutoLifestyle will provide suggested settings for the High Rate Response Factor and High Rate Break Point based on patient's age. See "Expert Ease/AutoLifestyle" on page 6-38 for further information.

DUAL-SENSOR BLENDING

Whenever both adaptive-rate sensors are selected for adaptive-rate pacing, the INSIGNIA I Ultra pacemakers will blend the two sensor-indicated rates to produce a

rate-dependent weighted average response. As a result, the blended response will always be equal to or between the two individual responses.

Whenever the Accelerometer response is less than the MV response, the sensor blending will be 100% MV-based. If the accelerometer response is greater than the MV response, the blending will range from 80% accelerometer and 20% MV when the blended rate is at LRL, to 40% Accelerometer and 60% MV when the blended rate is at MSR.

The following examples illustrate the blending algorithm operation:

Example 1: The accelerometer detects motion with a simultaneous MV increase (Figure 6-21). Upon exercise the blended response will promptly (within 4 seconds) increase the rate based on the Accelerometer response. As the rate continues to increase, the blended response will be moving towards the MV response, but will always remain between the Accelerometer and MV responses. At higher rates the changes in accelerometer input will have a lesser effect on the blended response (only 40% at MSR), whereas changes in MV will have a more significant effect. At cessation of exercise, the accelerometer rate will decrease as prescribed by the recovery parameter and, in this example, will drop below the MV response. As a result, the algorithm will switch over to a 100% MV blend during the recovery phase for as long as the accelerometer response remains below the MV response.

When using dual-sensor blending, program Recovery Time for the Accelerometer to a minimum value of 2 minutes. This allows the physiologic Minute Ventilation signal to control adaptive-rate pacing in the exercise recovery phase.

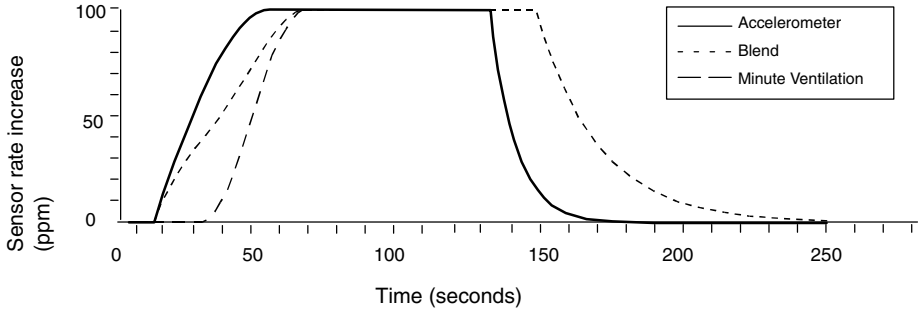


Figure 6-21. Example of blended response using an Accelerometer Reaction Time of 30 seconds (nominal).

The aggressiveness of response at the onset of exercise can be controlled by programming a shorter Accelerometer Reaction Time (Figure 6-22).

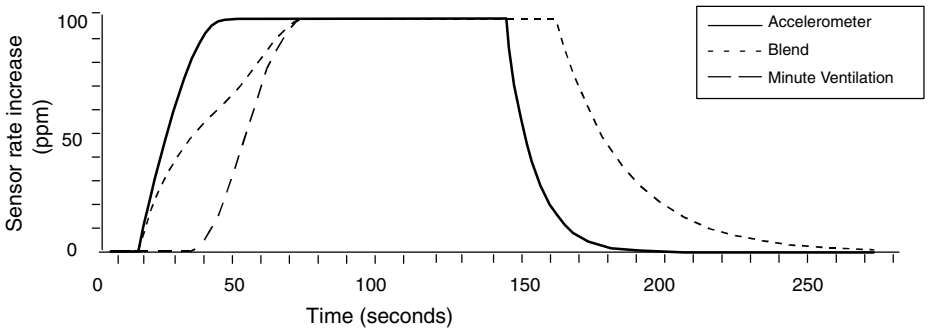


Figure 6-22. Example of blended response using a shorter Accelerometer Reaction Time of 20 seconds. There is a more pronounced rate increase at the onset of exercise.

Example 2: The accelerometer detects motion with little MV increase (Figure 6-23). The response of the blended sensor will be limited to approximately 60% of the accelerometer response. Once the accelerometer response drops below the MV response during recovery, the blended response will be 100% MV-driven.

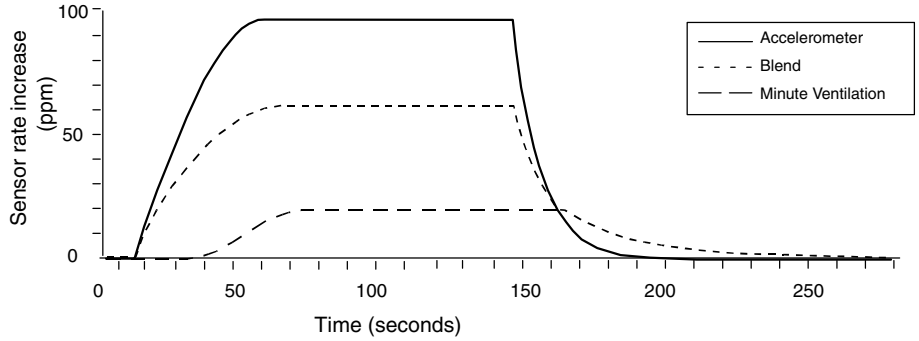


Figure 6-23. The Accelerometer detects motion with little or no increase in Minute Ventilation.

Example 3: MV increases with little accelerometer rate increase (Figure 6-24). The blended response will initially increase with the accelerometer response, but as the MV response increases over the accelerometer response, the blended response will be 100% MV-driven. This provides an adequate response during increases in metabolic demand, with little or no upper body movement.

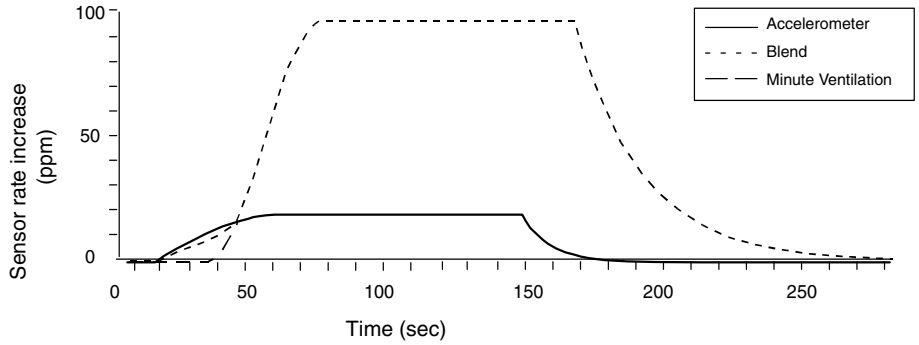


Figure 6-24. Minute Ventilation increases with little or no motion detected.

Time Dependent Blend

Programmable Values: Off, On (Nominal = Off)

The Time Dependent Blend algorithm will reduce the accelerometer-driven sensor response over a period of minutes until either intrinsic activity occurs, LRL/hysteresis limit is reached, or the MV sensor-driven pacing rate is reached (Figure 6-25). This algorithm helps ensure the MV sensor governs the sensor-driven pacing rate during the recovery phase of exercise.

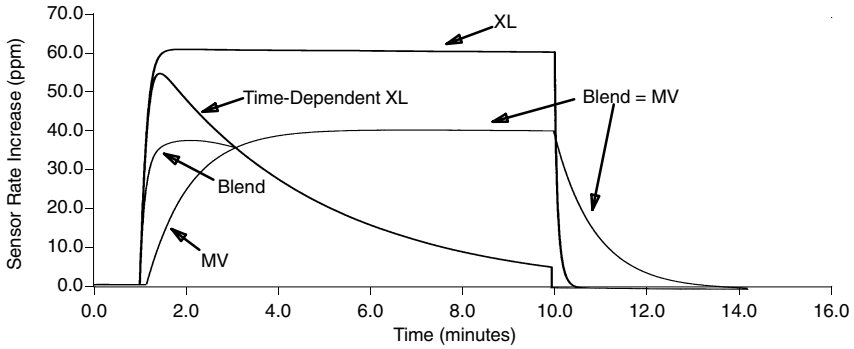


Figure 6-25. Example of time-dependent blend response to exercise with constant motion and minute ventilation. The time-dependent blend algorithm attenuates the detected motion so that MV controls the rate at the end of exercise.

AUTOLIFESTYLE

Programmable Values: Off, On, Reset (Nominal = On)

The AutoLifestyle feature will adjust the MV Response Factor and Accelerometer Response Factor to adapt the sensor-driven pacing rate to correspond with the patient's actual measured activity. The measurement of exercise intensity and frequency is determined by measuring MV and accelerometer values during patient activity.

Automatic Response Factor Adjustment (MV)

MV Response Factor adaptation is based on the pacemaker's continual measurements of the patient's maximum MV (their functional capacity) and their exercise intensity and frequency.

NOTE: *As a diagnostic, the device measures and stores MV baseline on an hourly basis for the last 24 hours. Performing a 4→ On calibration clears all the MV measurements. This action also resets AutoLifestyle.*

The AutoLifestyle feature is designed to adjust MV Response Factor between the 10 nonprogrammable response factor values so that the patient's age-predicted maximum heart rate (220 – patient's age) will be reached when the patient reaches their maximum MV (MV Max). The Max Sensor Rate (MSR) still limits the actual sensor-driven pacing rate, and MSR can be adjusted independently of the patient's age-predicted maximum heart rate. Adjusting the MSR will not affect the AutoLifestyle algorithm. MV must be active in order for AutoLifestyle to operate, although the Accelerometer can be either On or Off. If the Accelerometer is programmed Off, the pacemaker will still use the Accelerometer for exercise measurements, but accelerometer-driven pacing will not occur.

When the algorithm is first activated, it does not have a measured MV Max from the patient. It starts with an MV Max initial value that is typically higher than the patient's true MV Max. This high value will cause the algorithm to under-respond initially. AutoLifestyle continually monitors the patient's MV Max along with the accompanying accelerometer cross-check value. This data is used to update the MV Max Long Term—the MV Max value stored and updated by the device. Whenever this MV Max Long Term is updated, AutoLifestyle recalculates the MV Response Factor so that the age-predicted maximum heart rate will be reached at this new MV Max value. The algorithm determines the patient's true MV Max by increasing or decreasing the MV Max Long Term. See "MV Max Long Term" on page 6-39.

MV Max Long Term

The MV Max Long Term is stored by AutoLifestyle and decreased or increased over time in response to the patient's true MV Max.

Decreasing MV Max Long Term

MV Max Long Term can be decreased based on weekly measurements of MV. The weekly measurements evaluate the greatest measured MV Max during the last seven days and its corresponding accelerometer value. The accelerometer (cross check) value indicates if the MV Max occurred during mild, moderate, or vigorous exercise. Using this information, the patient's true MV Max is estimated by the device. If the estimate is more than 15% lower than the present MV Max Long Term, this value is decreased in 15% increments.

Increasing MV Max Long Term

MV Max Long Term is increased whenever AutoLifestyle measures an MV Max that is 10% or more higher than the present MV Max Long Term. Once MV Max Long Term is increased, the weekly evaluations for decreasing MV Max are discontinued.

By using these measured MV Max values, the AutoLifestyle algorithm is able to approximate the patient's actual MV Max value and adjust the MV response factor based on this information. AutoLifestyle continues to update the MV Max measurement throughout the patient's lifetime by using the maximum MV measurement that occurred. This allows for continual adjustment to the patient's changing functional capacity.

AutoLifestyle also adjusts the Accelerometer and MV Response Factor using a Sensor Rate Target that is established by device measurements of patient activity. See "Sensor Rate Target for AutoLifestyle" on page 6-40.

The AutoLifestyle algorithm maintains its measured settings for a minimum of 24 hours and a maximum of 48 hours after being programmed Off. If the algorithm is programmed back to On within 24 hours, AutoLifestyle will resume its operation using the previously measured values. AutoLifestyle data such as measured MV Max and Accelerometer values are printed out as a part of the Activity Log report.

On with Exercise

Programmable Values: Yes, No (Nominal = Yes)

When the On with Exercise option is programmed to Yes, the AutoLifestyle algorithm can more quickly adjust to the patient's measured MV Max because the algorithm will start with a measured MV Max instead of the initial value. When On with Exercise is used, the patient should exercise within the next 30 minutes. Typically, a fast walk for 4 minutes will be detected as exercise by the accelerometer in the device. The device will record the patient's MV Max and the accelerometer (cross-check) value and will use this data to start the algorithm at an estimated MV Max Long Term. If the device does not detect exercise (i.e., the accelerometer value does not meet the minimum cross-check value), AutoLifestyle will set a high initial MV Max value.

Sensor Rate Target for AutoLifestyle

Throughout AutoLifestyle, the MV and Accelerometer response factors are adjusted using the Sensor Rate Target. The pacemaker automatically determines the Sensor Rate Target by monitoring the exercise intensity measured each day. This information is gathered weekly and the Sensor Rate Target is then adjusted (Figure 6-26).

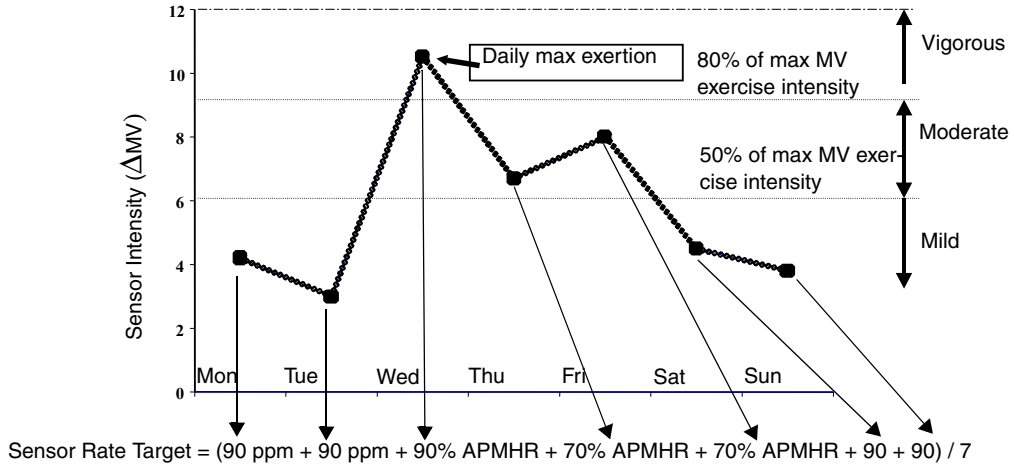


Figure 6-26. Sensor Rate Target weekly calculation (APMHR = Age Predicted Maximum Heart Rate).

Expert Ease/AutoLifestyle

The Expert Ease/AutoLifestyle feature is used to assist the clinician in optimizing the pacemaker's sensor behavior based on the patient's age. Expert Ease/AutoLifestyle will provide suggested values for LRL, MSR, High Rate Response Factor, and High Rate Break Point (Figure 6-27).

Age

Programmable Values: 1–127 (1-year increments) (Nominal = 60 years)

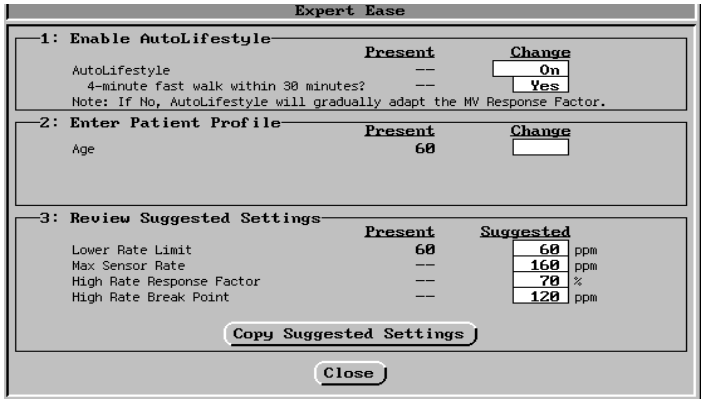
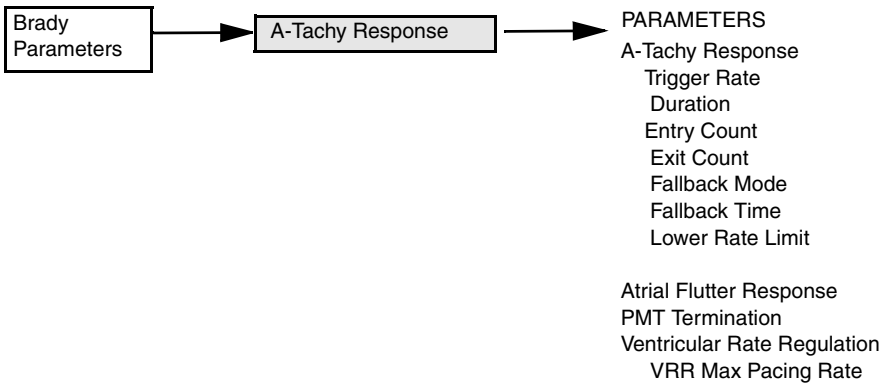


Figure 6-27. The Expert Ease/AutoLifestyle screen.

A-TACHY RESPONSE



A-TACHY RESPONSE (ATR)

DR

Programmable Values: Off, On (Nominal = On)

The A-Tachy Response (ATR) feature provides mode switching from DDD(R) to DDI(R) or VDI(R), and from VDD to VDI(R) in the presence of detected atrial activity that exceeds the ATR Trigger Rate. A-Tachy Response limits the amount of time that the ventricular paced rate is at the MTR or exhibits upper-rate behavior (2:1 block or Wenckebach) in response to a pathological atrial arrhythmia.

Rate Smoothing, Dynamic AV Delay, and Dynamic PVARP can be used in combination with the A-Tachy Response feature. The operation of one feature will not conflict with the operation of the other.

Trigger Rate

Programmable Values: 100–200 ppm (5-ppm increments) (Nominal = 170 ppm)

ATR Trigger Rate is an independently programmable parameter that allows the clinician to determine the rate cutoff at which the pacemaker begins to detect atrial tachycardias (Figure 6-28). The pacemaker monitors atrial events throughout the pacing cycle except during the atrial blanking period and noise interrogation intervals. Events at or above the ATR Trigger Rate will increase the entry counter, and

events below the ATR will decrease the entry counter. When the ATR detection counter reaches the programmable Entry Count, the ATR Duration begins and the Exit Count starts (Figure 6-28 on page 6-44). When the ATR Exit Count reaches zero at any point in time, ATR Duration and/or ATR Fallback will be terminated and the ATR algorithm will be reset. An event marker will be generated whenever the ATR Exit Count or entry counter is incremented or decremented.

Entry Count

Programmable Values: 1–8 cycles (increments of 1) (Nominal = 8 cycles)

The Entry Count is an independently programmable parameter that allows the clinician to determine how quickly an atrial arrhythmia is initially detected. The lower the programmable value, the fewer fast atrial events are required to fulfill initial detection. Once the number of fast atrial events detected equals the programmable Entry Count, ATR Duration begins and the Exit Count is started.

CAUTION: Exercise care when programming the Entry Count to low values in conjunction with a short Duration. This combination allows mode switching with very few fast atrial beats. If the Entry Count were programmed to 2 and the Duration to 0, for example, ATR mode switching could occur on two fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.

Exit Count

Programmable Values: 1–8 cycles (increments of 1) (Nominal = 8 cycles)

The Exit Count is an independently programmable parameter that allows the clinician to determine how quickly the A-Tachy Response algorithm is terminated once the atrial arrhythmia no longer is detected. The lower the programmable value, the more quickly the pacemaker will return to dual-chamber pacing. Once the number of slow atrial events detected equals the programmable Exit Count, ATR Duration and/or ATR Fallback Mode will be terminated and the A-Tachy Response algorithm will be reset. The exit counter is loaded with the programmable value and begins its count once the Entry Count criteria are fulfilled.

CAUTION: Exercise care when programming the Exit Count to low values. If the Exit Count were programmed to 2, for example, a few cycles of atrial undersensing could cause termination of mode switching.

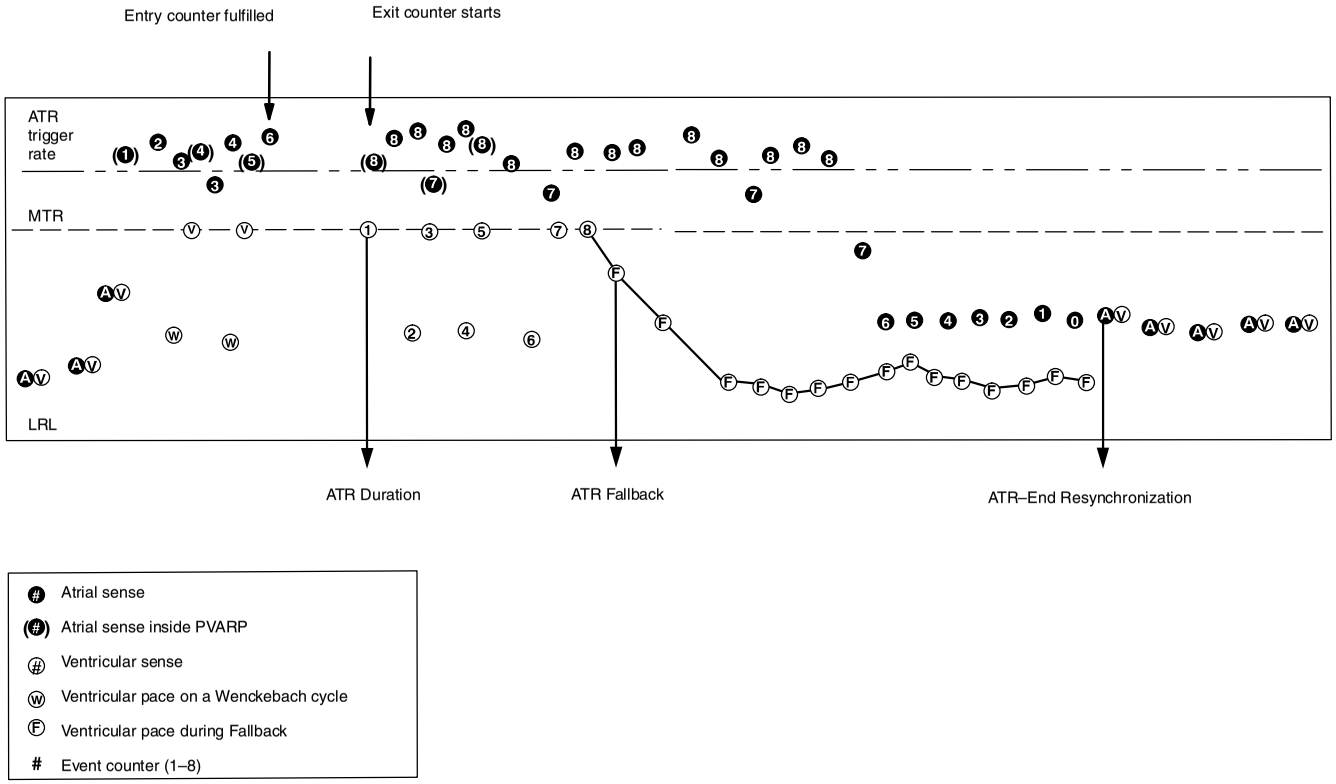


Figure 6-28. Illustration of A-Tachy Response behavior (Fallback Mode = VDI, Duration = 8 cycles, Entry Count = 6 cycles, Exit Count = 8 cycles, Fallback Time = 5 sec).

Duration

Programmable Values: 0, 8–2048 cycles (powers of 2) (Nominal = 8 cycles)

ATR Duration is a programmable parameter that determines the number of ventricular cycles during which the atrial events continue to be evaluated after initial detection. If the atrial tachycardia persists for the programmed duration, mode switching occurs and the ventricular rate begins to decrease to the sensor rate or the ATR Lower Rate Limit (Figure 6-28 on page 6-44). The Duration feature is intended to avoid mode switching due to nonsustained episodes of atrial tachycardia. Whenever the ATR Exit Count reaches 0 during Duration, the A-Tachy Response algorithm will be reset.

Fallback Mode

Programmable Values: VDI(R), DDI(R) (Nominal = VDI)

Once Duration has been fulfilled, the pacemaker will automatically switch to the programmed Fallback Mode. After switching modes, the device gradually decreases the ventricular paced rate to the sensor-indicated rate or the ATR Lower Rate Limit, depending on the programmed Fallback Mode. The decrease in ventricular paced rate is controlled by the Fallback Time parameter.

Fallback Time

Programmable Values: 0–120 sec (5-sec increments) (Nominal = 30 sec)

The Fallback Time determines how quickly the rate in fallback will decrease to the ATR Lower Rate Limit or sensor rate. The Fallback Time parameter controls the decrease in the paced rate.

During fallback, the following features will be disabled:

- Rate Smoothing, until fallback reaches ATR Lower Rate Limit or the sensor-indicated rate
- Rate Hysteresis and Search Hysteresis
- AV Search Hysteresis

All sensor parameters must be programmed when the adaptive-rate Fallback Mode is selected. When the pacemaker is permanently programmed to an adaptive-rate mode with an adaptive-rate ATR Fallback Mode, the pacemaker will use the sensor and sensor parameters already in effect at the time of the switch.

If the pacemaker is permanently programmed to a nonadaptive-rate mode, it is possible to program ATR Fallback Mode to an adaptive-rate ATR Fallback Mode using the accelerometer sensor. In this case, on the Sensors submenu, the Accelerometer field will display “ATR Only."

ATR Lower Rate Limit

Programmable Values: 30–50 ppm (5-ppm increments), 50–90 ppm (1-ppm increments), 90–150 ppm (5-ppm increments) (Nominal = 70 ppm)

The ATR Lower Rate Limit allows an independently programmed LRL during an ATR mode switch. When the ATR Fallback Mode is programmed to a rate-adaptive mode, the response slope is not affected. Consequently, the activity level necessary for rate-adaptive pacing to achieve a specific pacing rate remains the same during ATR Fallback as it does during normal dual-chamber rate-adaptive pacing.

The ATR Lower Rate Limit must be equal to or greater than the permanently programmed brady LRL.

End of ATR Episode

The pacemaker will continue to pace in the Fallback Mode at the sensor-indicated rate or the ATR Lower Rate Limit until the atrial arrhythmia terminates. Upon termination of the arrhythmia, the ATR Exit Count decrements from its programmed value until it reaches 0 (Figure 6-28). The ATR Exit Count is decremented by atrial events slower than the Trigger Rate or paced ventricular events without an intervening atrial event. When the ATR Exit Count reaches 0, the pacing mode automatically resynchronizes to the programmed tracking mode, and P-synchronous pacing is restored.

ATR Diagnostic Data

A-Tachy Response continuously monitors atrial rates. The onset rate is the rate of the last interval when Duration is met. The maximum rate is the rate of the shortest interval after Duration is met. The number of ATR Fallback events is stored for display in the counter function of the device. Event markers are issued whenever the

ATR Count increments or decrements, or whenever the other events outlined in Table 6-4 occur.

Table 6-4. ATR Event Marker Annotations

Event Marker	Explanation
ATR ↑	ATR Count incremented
ATR ↓	ATR Count decremented
ATR–Dur	ATR Duration started
ATR–FB	ATR Fallback started, pacemaker switched to nontracking mode
ATR–End	ATR Fallback ended, resynchronization occurred

VENTRICULAR RATE REGULATION (VRR)

Programmable Values: Off, On
***Dual-chamber modes* (Nominal = On)*, Single-chamber modes* (Nominal = Off)**

Ventricular Rate Regulation (VRR) is designed to reduce V–V cycle length variability during conducted atrial arrhythmias. The VRR algorithm calculates a VRR-indicated pacing interval based on a weighted sum of the current V–V cycle length and the previous VRR-indicated pacing intervals (this is similar to Rate Smoothing, which only uses the most recent V–V interval). Paced intervals have more influence than sensed intervals such that paced events cause a decrease in the VRR-indicated rate. For sensed intervals, the VRR-indicated rate may be increased; however, the influence is tempered by the previous history. This is due to the weighted-sum methodology stated above. The VRR-indicated rate is further bound by the Lower Rate Limit and the VRR Max Pacing Rate.

When programmed On in tracking modes, VRR is active only when an A-Tachy Response mode switch has occurred. Once tracking mode operation resumes at the termination of the atrial arrhythmia, VRR becomes inactive. In tracking modes where both Rate Smoothing and VRR are programmed On, whenever VRR is active the pacemaker will automatically disable Rate Smoothing and reactivate Rate Smoothing once the atrial arrhythmia has terminated.

When programmed On in single-chamber modes, VRR is continually active and updates the smoothed average on each cardiac cycle.

VRR Max Pacing Rate

Programmable Values: 60–150 ppm (5-ppm increments) (Nominal = 110 ppm)

VRR Max Pacing Rate limits the maximum pacing rate the VRR algorithm can reach.

ATRIAL FLUTTER RESPONSE (AFR)

DR

Programmable Values: Off, 130-230 ppm (increments of 10 ppm)
(Nominal = Off for DDD[R] mode, Nominal = 230 ppm for DDI[R] mode)

Atrial Flutter Response (AFR) is designed to prevent pacing into the atrial vulnerable period and to provide immediate fallback for atrial rates higher than the AFR programmable rate. This fallback will be maintained as long as atrial events continually exceed the AFR programmable rate.

When AFR is programmed to 230 ppm, for example, a detected atrial event inside the PVARP or a previously triggered AFR interval will start an AFR window of 260 ms (230 ppm). Atrial detection inside the AFR will be classified as refractory senses and will not be tracked. The sensing window starts only after both the AFR and the PVARP have expired. Paced atrial events scheduled inside an AFR window will be delayed until the AFR window has expired. If there are fewer than 50 ms remaining before a ventricular pace, the atrial pace is inhibited for the cycle. The ventricular pace is not affected by AFR and will take place as scheduled. The wide programmable range for AFR rates allows for appropriate sensing of slow atrial flutters.

High-rate atrial sensing may continuously retrigger the AFR window, effectively resulting in fallback to the VDI(R) mode.

The Atrial Flutter Response feature is available only in DDD(R) and DDI(R) modes. Whenever DDI(R) mode is programmed On, AFR will be set to 230 ppm automatically. The setting should be programmed to Off if the AFR feature is not desired.

When both the Atrial Flutter Response and the A-Tachy Response are active, mode switches may take longer than when Atrial Flutter Response is not active, as described below.

For atrial arrhythmias that meet the programmed AFR rate criteria, using the Atrial Flutter Response feature will result in slower ventricular pacing rates. If the A-Tachy

Response feature is also programmed On and Duration is programmed to a value > 0, the time to an actual mode switch may be longer with AFR active. This is because the ATR Duration feature counts ventricular cycles for meeting duration and the AFR feature slows the ventricular response to fast atrial arrhythmias.

PMT TERMINATION

DR

Programmable Values: Off, On (Nominal = On)

In DDD(R) and VDD pacing modes, any pacemaker may detect retrograde conducted P-waves that fall outside of PVARP, causing triggered ventricular pacing rates as high as the MTR (i.e., pacemaker-mediated tachycardia [PMT]). When the PMT Termination feature is enabled, a PMT condition will be detected by counting 16 successive ventricular paces at the MTR following atrial sensed events.

Also, the V–A interval will be monitored during the 16 intervals to determine if a PMT is occurring or if the intrinsic atrial rate is simply meeting or exceeding the MTR. The V–A intervals will be compared to the first V–A interval measured during the 16 ventricular paced events. If any of the successive intervals is more than 32 ms shorter or longer than this first interval, the rhythm will be declared a Wenckebach event, the Wenckebach counter will increment, and the algorithm will continue to monitor successive ventricular paces for the presence of a PMT. If the V–A intervals are all within this 32-ms criteria, the rhythm will be declared a PMT.

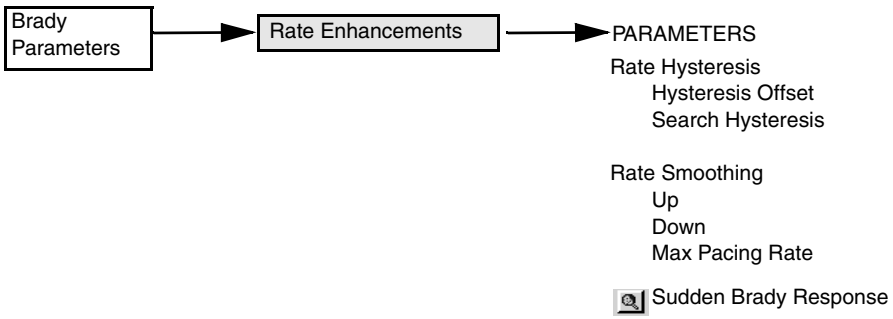
When a PMT condition at the MTR is detected, the pacemaker will set the PVARP setting to a fixed value of 500 ms for one cardiac cycle, attempting to break the PMT.

Programming the PVARP after PVC/PAC option and/or Rate Smoothing can also be useful in controlling the pacemaker's response to retrograde conduction.

The pacemaker can store PMT episodes in the Arrhythmia Logbook if the PMT EGM trigger is enabled.

NOTE: *Some pacemaker Wenckebachs will not fulfill the criteria of 16 successive ventricular paces at the MTR. Consequently, the Wenckebach counter will not show all Wenckebach events.*

RATE ENHANCEMENTS SUBMENU



RATE HYSTERESIS

Hysteresis Offset

Programmable Values: Off, -5 to -80 ppm (5-ppm increments) (Nominal = Off)

Rate Hysteresis can be used in the DDD(R), DDI(R), VVI(R), and AAI(R) modes. When the pacemaker senses intrinsic activity, the escape rate will be lowered by the programmed Hysteresis Offset value, allowing intrinsic contractions below the LRL or sensor-indicated rate.

In nonadaptive-rate modes, the escape rate is lowered by the Hysteresis Offset below the LRL. In adaptive-rate modes, the escape rate is lowered below the sensor-indicated rate. As a result, the patient might benefit from longer periods of sinus rhythm. In addition, due to the reduction of the number of pacing stimuli, Rate Hysteresis can improve pacemaker longevity.

NOTES:

- *When Rate Smoothing Down is enabled, Rate Hysteresis will remain in effect until pacing occurs at the hysteresis rate. This allows Rate Smoothing to control the transition to the hysteresis rate.*

- *During an A-Tachy Response mode switch, Rate Hysteresis is deactivated.*

Rate Hysteresis in Nonadaptive-Rate Modes

When Rate Hysteresis is enabled in DDD or DDI mode or in single-chamber atrial modes, a single nonrefractory sensed atrial event will activate Rate Hysteresis (Figure 6-29). Rate Hysteresis will be deactivated by a single atrial pace at the hysteresis rate. In DDD and DDI mode, Rate Hysteresis will also be deactivated by a single atrial pace during a cardiac cycle when a ventricular pace is scheduled at the hysteresis LRL, or, in DDD mode, whenever the atrial rate rises above the MTR.

In the VVI mode, a single nonrefractory sensed ventricular event will activate Rate Hysteresis. A single ventricular pace at the hysteresis rate will deactivate it.

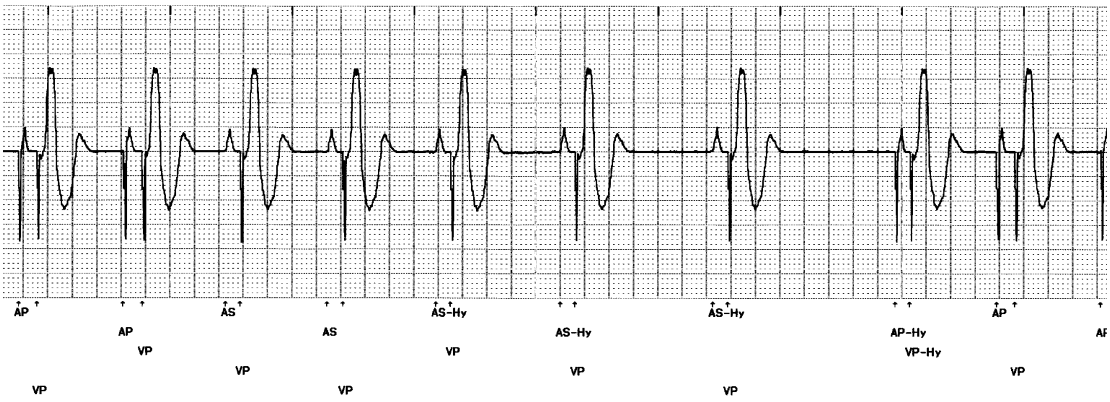


Figure 6-29. Example of Rate Hysteresis in nonadaptive-rate modes.

Rate Hysteresis in Adaptive-Rate Modes

DR

The hysteresis rate in adaptive-rate modes is dynamically calculated by lowering the sensor-indicated rate by the programmed Hysteresis Offset.

When Rate Hysteresis is enabled in an adaptive-rate mode, a single nonrefractory sensed atrial event will activate Rate Hysteresis (Figure 6-30). In single-chamber atrial modes, Rate Hysteresis will be deactivated by a single atrial pace at the sensor hysteresis rate. In DDDR or DDIR mode, Rate Hysteresis will be deactivated by a single atrial pace during a cardiac cycle when a ventricular pace is scheduled at the hysteresis rate, or, in DDDR mode, whenever the atrial rate rises above the MTR.

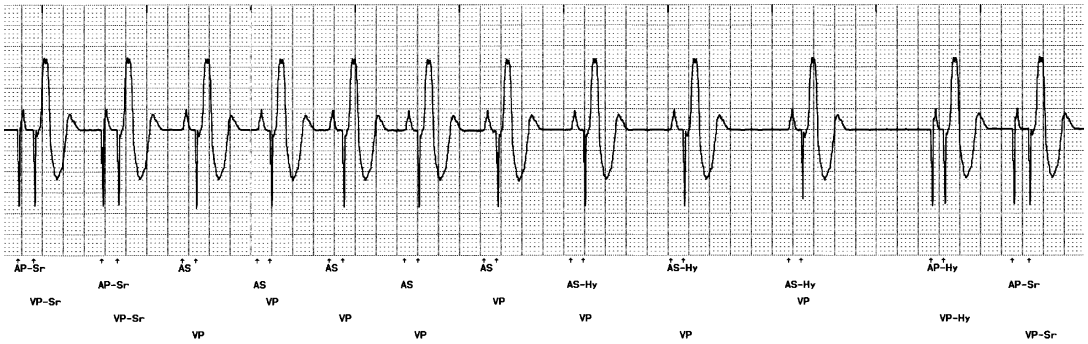


Figure 6-30. Example of Rate Hysteresis in adaptive-rate modes.

In VVI(R) mode, a single nonrefractory sensed ventricular event will activate Rate Hysteresis. A single ventricular pace at the hysteresis rate will deactivate it.

Search Hysteresis

Programmable Values: Off, 256–4096 cycles (powers of two) (Nominal = Off)

When the Search Hysteresis feature is enabled, the pacemaker will periodically lower the escape rate by the programmed Hysteresis Offset in order to reveal potential intrinsic activity below the LRL or sensor rate (Figure 6-31).

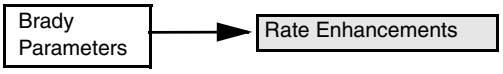
During Search Hysteresis, the pacing rate is lowered by the Hysteresis Offset for up to 8 cardiac cycles. The search will end and hysteresis will remain active when intrinsic activity is sensed during that period. If there is no intrinsic activity during the 8-cycle search, pacing resumes at the LRL or the sensor-indicated rate.

Figure 6-31. Example of Search Hysteresis.

Example: At a rate of 70 ppm and a search interval of 256 cycles, a search for intrinsic activity would occur approximately every 3.7 minutes (256 ÷ 70 = 3.7).

Rate Smoothing is disabled during the search cycles. If there is no detected intrinsic activity during the search, the pacing rate is brought up to the LRL or sensor-indicated rate, and programmed Rate Smoothing Up and Rate Smoothing Down are re-enabled. See “Rate Smoothing Up” on page 6-55 and “Rate Smoothing Down” on page 6-55 for more information.

RATE SMOOTHING



Rate Smoothing is a programmable feature that controls the pacemaker’s response to atrial and/or ventricular rate fluctuations that cause sudden changes in pacing intervals. In a normal conduction system, limited cycle-to-cycle variation in rate occurs. However, in the presence of any of the following, the paced rate can change dramatically from one beat to the next:

- Sinoatrial disease such as sinus pause or arrest, sinoatrial block, brady–tachy syndrome

- Premature atrial and/or ventricular contractions (PAC/PVC)
- Pacemaker Wenckebach
- Intermittent, brief, self-terminating supraventricular tachycardias, atrial flutter/fibrillation
- Retrograde conducted P-waves
- Pacemaker sensing of myopotential signals, electromagnetic interference, crosstalk, etc.

Pacemaker patients who experience large variations in their ventricular paced rate can feel symptomatic during these episodes. Rate Smoothing can prevent these sudden rate changes and their accompanying patient symptoms (such as palpitations, dyspnea, and dizziness).

Rate Smoothing is an important enhancement of the A-Tachy Response (ATR) feature. Rate Smoothing can significantly reduce rate fluctuations associated with the onset and cessation of atrial arrhythmias.

Rate Smoothing operates between the LRL and the MTR or the Max Pacing Rate (SSI and DDI) in nonadaptive-rate modes. When the sensor is enabled and MSR is higher than MTR, the operational range is from the LRL to the MSR. Rate Smoothing is also applicable between the hysteresis rate and LRL when hysteresis is active, except during Search Hysteresis.

When programmed On:

- Programmable Rate Smoothing values are a percentage of the R–R interval (3%–24% in 3% increments) and can be independently programmed for increase or decrease.
- The pacemaker stores in memory the most recent R–R interval. R-waves may be either intrinsic or paced. Based on this R–R interval and the programmed Rate Smoothing value, the pacemaker sets up two synchronization windows for the next cycle–one for the atrium and one for the ventricle.
- Rate Smoothing is functional except:
    - During the 8 cycles of Search Hysteresis

- During ATR Fallback, until fallback reaches ATR Lower Rate Limit or the sensor indicated rate.
- Upon triggering of the PMT Termination algorithm
- Immediately following programmed increases in the LRL
- When VRR is active in the dual chamber mode.

Also, Rate Smoothing cannot be programmed On when Sudden Brady Response is On.

The clinician should ascertain a given patient's physiologic cycle-to-cycle variation and program the Rate Smoothing parameter to a value that protects against pathologic interval changes, yet allows physiologic interval changes in response to increases in activity or exercise.

NOTE: *Without Rate Smoothing, a sudden, large atrial rate increase (e.g., paroxysmal atrial tachycardia) will cause a simultaneous sudden increase in the paced ventricular rate as high as the programmed MTR. With Rate Smoothing, the ventricular paced rate in response to such a change might not reach the programmed MTR.*

Rate Smoothing Up

Programmable Values: Off, 3–24% (3% increments) (Nominal = Off)

The Rate Smoothing Up parameter controls the largest increase allowed in the pacing rate when the intrinsic or sensor rate is increasing.

Rate Smoothing Down

Programmable Values: Off, 3–24% (3% increments) (Nominal = Off)

The Rate Smoothing Down parameter controls the largest decrease allowed in the pacing rate when the intrinsic or sensor rate interval is decreasing.

NOTE: *When Rate Smoothing Down is programmed On and Rate Smoothing Up is programmed Off, the pacemaker will automatically prevent fast intrinsic beats (e.g., PVCs) from resetting the Rate Smoothing Down escape rate any faster than 12% per cycle.*

Max Pacing Rate (DDI and SSI)

Programmable Values: 80–185 ppm (5-ppm increments) (Nominal = 130 ppm)

When Rate Smoothing is programmed On in DDI, VVI, or AAI, the Rate Smoothing Up parameter is used only between the hysteresis rate and the LRL. The Rate Smoothing Down parameter requires the programming of a Max Pacing Rate. The Rate Smoothing Down parameter will then be used only between the Max Pacing Rate and the LRL or the hysteresis rate.

Rate Smoothing Example

The pacemaker stores in memory the most recent R–R interval. R-waves may be either intrinsic or paced. Based on this R–R interval and the programmed Rate Smoothing value, the pacemaker sets up two synchronization windows for the next cycle–one for the atrium and one for the ventricle. This synchronization window is defined as follows:

Ventricular synchronization window = Previous R–R interval ± Rate Smoothing value

Atrial synchronization window = (Previous R–R interval ± Rate Smoothing value) – AV Delay

An example of how these two synchronization windows are calculated is illustrated below and in Figure 6-32:

Previous R–R interval = 800 ms

AV Delay = 150 ms

Rate Smoothing Up = 9% Rate Smoothing Down = 6%

Ventricular synchronization window = 800 – 9% to 800 + 6% = 800 ms – 72 ms to 800 ms + 48 ms = 728 ms to 848 ms

Atrial synchronization window = ventricular synchronization window – AV Delay = 728 ms – 150 ms to 848 ms – 150 ms = 578 ms to 698 ms

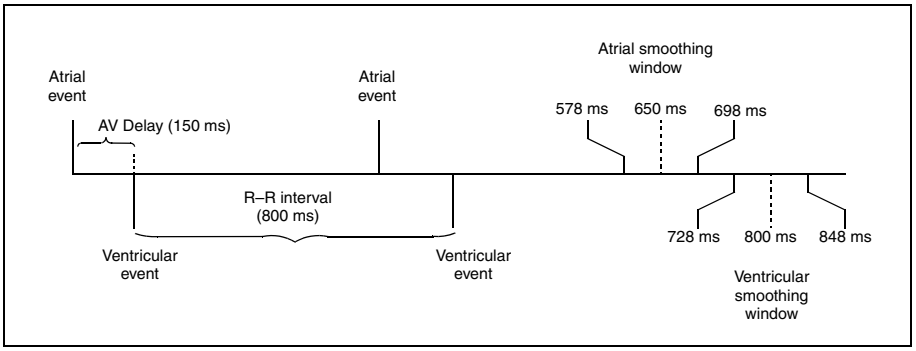


Figure 6-32. An example of the synchronization window.

The timing for both windows is initiated at the end of every ventricular event (R–R interval). Paced activity, if it is to occur, must occur within the appropriate synchronization window.

SUDDEN BRADY RESPONSE (SBR)

DR

Programmable Values: Off, On (Nominal = Off)

Sudden Brady Response (SBR) is designed to respond to sudden decreases in intrinsic atrial rates by applying dual-chamber pacing at an elevated pacing rate. SBR is available in DDD(R) modes. When SBR is enabled, Rate Smoothing Up and Rate Smoothing Down are not available.

SBR is declared when the atrial chamber has been continuously sensed for a programmable time, followed by a sudden decrease in atrial rate such that atrial pacing occurs at the LRL or the sensor-indicated rate for a programmable number of cycles. The decrease in atrial rate preceding the paced events must exceed 10 ppm.

The SBR algorithm continually monitors the average of the atrial rate and this average is updated each cardiac cycle. This average rate is used both to determine if the atrial rate has decreased more than 10 ppm and to determine the rate of SBR therapy.

SBR Detect Time

Programmable Values: 1–15 minutes (increments of 1 minute) (Nominal = 5 minutes)

SBR Detect Time is the programmable time interval during which the atrium must be 100% sensed.

SBR Number of Beats

Programmable Values: 1–8 cycles (increments of 1 cycle) (Nominal = 4 cycles)

The SBR Number of Beats criteria are applied once the decrease in atrial rate has been detected and LRL or sensor-indicated rate pacing has occurred. Atrial pacing must occur for the programmable number of consecutive intervals before the SBR criteria are met, with one exception. A “slow” PVC can count as the first SBR Number of Beats. A “slow” PVC is one that yields a ventricular rate that is ≥ 10 ppm slower than the average atrial rate.

SBR Therapy Rate Offset

Programmable Values: 5–40 ppm (increments of 5-ppm) (Nominal = 5 ppm)

SBR Therapy Rate Offset is calculated by using the patient’s average atrial rate before the bradycardia and adding a programmable positive offset (Figure 6-33). Pacing is applied in the DDD(R) mode at the greater of either (1) the previous average atrial rate plus the SBR Therapy Rate Offset, not to exceed the MTR, or (2) the sensor-indicated rate (DDDR mode only).

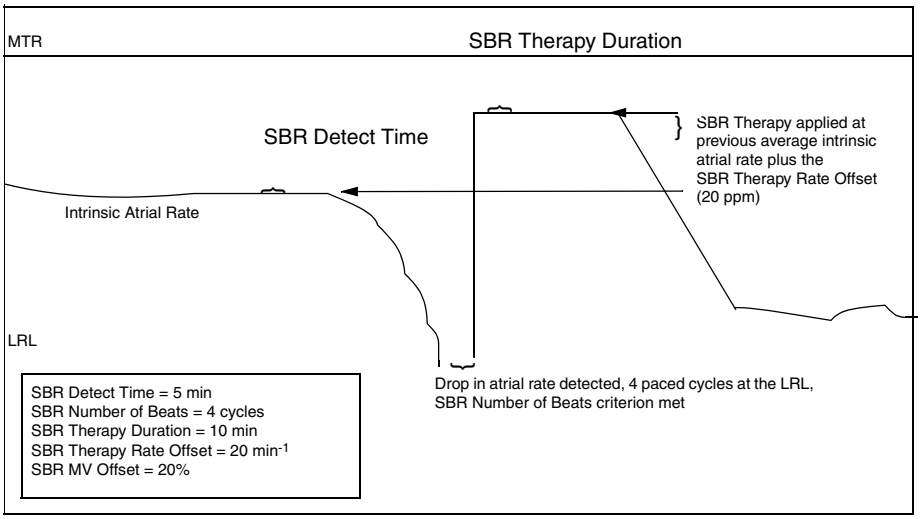


Figure 6-33. Example of a decrease in atrial rate meeting the SBR criteria.

SBR Therapy Duration

Programmable Values: 1–15 minutes (increments of 1 minute) (Nominal = 10 minutes)

SBR Therapy Duration is the programmable time interval during which SBR pacing therapy will be used. Once pacing therapy has been delivered, the atrial pacing rate will be decreased using a 12% Rate Smoothing Down factor until the LRL or sensor-indicated rate is reached.

SBR MV Offset

Programmable Values: Off, 10%–50% (increments of 10%) (Nominal = Off)

SBR MV Offset provides the ability to inhibit SBR therapy when the SBR rate and duration criteria are met but the patient's current MV measurement is lower than a programmed value, the MV comparison value.

The Minute Ventilation sensor must be On for the SBR MV Offset to be used. When MV is activated, the pacemaker records the MV baseline value once every hour. The pacemaker then determines the lowest measured MV baseline value over a 1-week period. The SBR MV Offset is a percentage of this lowest weekly MV baseline and is

added to the lowest weekly MV baseline to determine the MV comparison value. For example, if the SBR MV Offset is programmed to 20%, the lowest weekly value for MV baseline is increased by 20% to get the MV comparison value for the SBR algorithm. Each week, this MV comparison value is updated so that the algorithm adjusts to long-term changes in the patient's MV baseline.

In the event the SBR atrial rate and duration criteria are met, the current MV measurement is compared to the MV comparison value. If the current MV measurement is less than the comparison value, SBR therapy is inhibited (Figure 6-34). If the present MV measurement is more than the comparison value, SBR therapy is initiated (Figure 6-35).

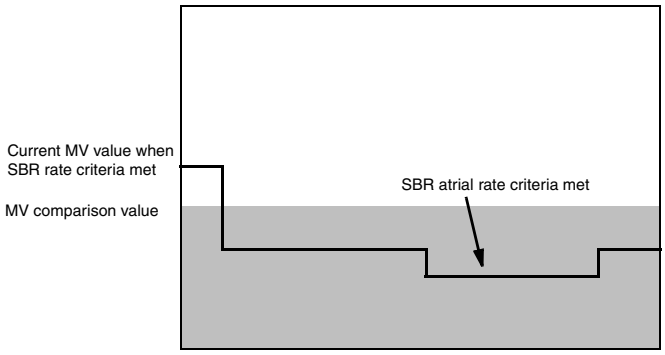


Figure 6-34. In this example, the current MV value is less than the MV comparison value, so when the SBR rate criteria are met, SBR therapy is inhibited.

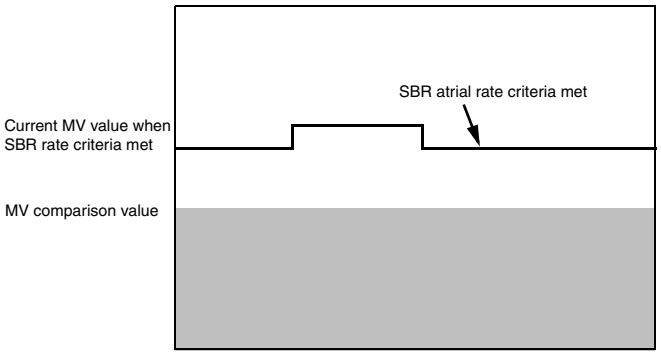
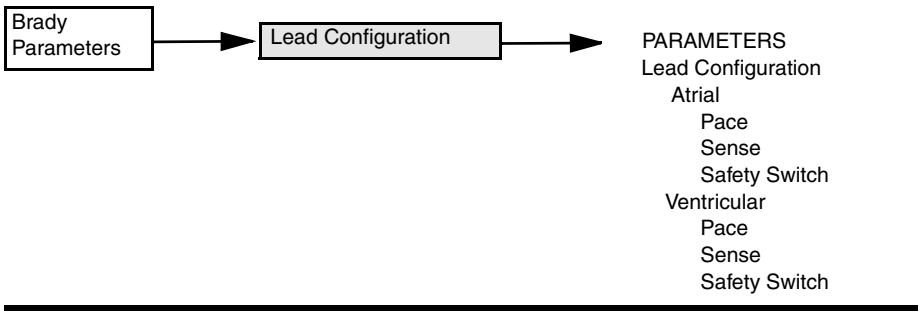


Figure 6-35. In this example, the current MV value is greater than the MV comparison value, so when the SBR rate criteria are met, SBR therapy is delivered.

To assist in programming the SBR MV Offset value, the pacemaker records the patient's MV baseline values hourly for the last 24 hours and makes them available for display on the PRM.

LEAD CONFIGURATION SUBMENU



The INSIGNIA I pacemakers are programmable to either Unipolar or Bipolar sensing and pacing when bipolar leads are used. Pacing and sensing configurations are individually programmable in both the atrium and ventricle.

BIPOLAR CONFIGURATION LOCK-OUT

The bipolar configuration lock-out feature prevents the clinician from inadvertently programming a unipolar lead to bipolar configuration. If the atrial or ventricular lead type is specified as Unipolar on the Patient Data screen, programming to Bipolar configuration for either pacing or sensing is not allowed by the software.

LEAD CONFIGURATION

Programmable Values: Unipolar, Bipolar, Split (Nominal = Bipolar)

In dual-chamber devices, choosing Bipolar or Unipolar will configure both leads to that configuration; if the two leads need to be configured differently or if different configurations are required for both pacing and sensing, choose Split, then set each configuration separately.

CAUTION: Do not attempt to program unipolar leads to a Bipolar configuration; no pacing and erratic sensing will occur.

NOTES:

- *If at implant a unipolar pacing configuration is required, ensure that the configuration is programmed to Unipolar before implant.*

- *Unipolar pacing and sensing do not exclude the use of the Minute Ventilation sensor as long as a bipolar lead is used for the MV lead. MV sensor availability is not dependent on the programmed lead configuration setting.*

- *If the clinician selects Unipolar for the atrial or ventricular lead on the Patient Data screen, the application will not allow that lead configuration to be programmed to Bipolar.*

Pacing Configuration

When the unipolar pacing configuration is programmed, the pacing stimulus will be applied between the lead tip and the pacemaker case. In the bipolar pacing configuration, the stimulus will be applied between the lead tip and the lead ring.

In the unipolar pacing configuration, the pacing artifact should be clearly visible on the surface ECG, which will assist in its interpretation. However, unipolar pacing at high outputs is more likely than bipolar pacing to cause muscle stimulation.

Sensing Configuration

When the unipolar sensing configuration is programmed, the cardiac signals are detected between the lead tip and the pacemaker case. In the unipolar sensing configuration, the pacemaker can generally discern smaller intrinsic cardiac signals than in the bipolar configuration. However, the unipolar configuration is also more sensitive to myopotentials.

In bipolar configurations, because of the relatively short distance between the tip and ring electrodes, sensitivity is highest for signals originating in the proximity of the lead tip and ring. As a result, the pacemaker is less likely to sense myopotentials and other signals unrelated to cardiac depolarization.

SAFETY SWITCH (AUTOMATIC LEAD CONFIGURATION)

Programmable Values: On, Off, Reset (Nominal = Off)

The Safety Switch feature allows the pacemaker to monitor lead integrity and to switch the pacing and sensing configuration from bipolar to unipolar if the impedance criteria indicate unacceptably high or low lead impedances.

The pacemaker monitors lead integrity daily by measuring lead impedance during paced events. When the Safety Switch feature is programmed On in either the

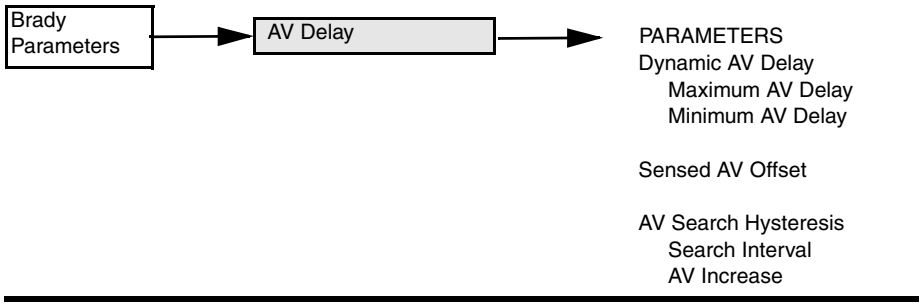
atrium or the ventricle and the measured impedance falls outside the 100–2500 Ω range for any daily measurement, both pacing and sensing configurations will automatically be switched to Unipolar for that chamber. Once the configuration has switched, it will remain Unipolar. Selecting Reset will return the lead configuration to the value programmed prior to the Safety Switch action.

CAUTION: If high-impedance leads with measured values approaching 2500 Ω are used, consider programming the Safety Switch Off.

When the lead configuration switches to Unipolar for the lead that is being used for MV, the Minute Ventilation sensor function is automatically disabled.

WARNING: In devices with the Safety Switch programmed to On, the lead polarity will revert to Unipolar in the presence of a lead impedance of < 100 Ω or > 2500 Ω. Unipolar pacing is contraindicated for patients with an ICD.

AV DELAY SUBMENU



DYNAMIC AV DELAY

DR

Programmable Values: On, Off (Nominal = On)

When Dynamic AV Delay is enabled, the pacemaker automatically calculates the AV Delay based on the duration of the previous A–A interval and the programmed parameters for Minimum AV Delay and Maximum AV Delay. The Dynamic AV Delay is not adjusted during a PVC or when the previous cardiac cycle was limited by the MTR or Rate Smoothing Up.

Dynamic AV Delay mimics normal AV nodal function of progressive P–R shortening in response to an increase in rate. When the atrial rate is between the LRL and the higher of the MTR and the MSR, the pacemaker calculates the Dynamic AV Delay based on the previous A–A interval according to the linear relationship shown in Figure 6-36. This relationship is determined by the programmed values for Minimum AV Delay, Maximum AV Delay, LRL, and the higher of the MTR or MSR. Figure 6-37 illustrates an ECG strip with Dynamic AV Delay.

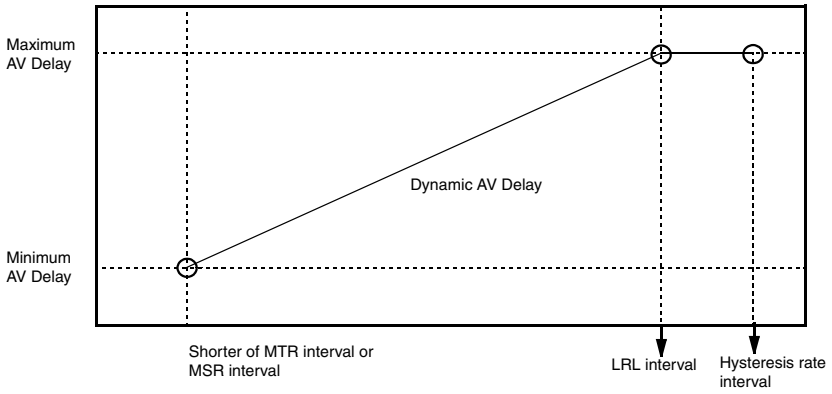


Figure 6-36. Dynamic AV Delay as a function of the escape interval.

Figure 6-37. Example of ECG strip with Dynamic AV Delay.

Maximum AV Delay

Programmable Values: 20–300 ms (10-ms increments) (Nominal = 150 ms)

If the atrial rate is at or below the LRL (i.e., hysteresis), the Maximum AV Delay is used.

Minimum AV Delay

Programmable Values: 10–290 ms (10-ms increments) (Nominal = 80 ms)

If the atrial rate is at or above the higher of the MTR and the MSR, the programmed Minimum AV Delay is used.

SENSED AV OFFSET

Brady Parameters → AV Delay

DR

Programmable Values: Off, –100 to –10 ms (10-ms increments) (Nominal = –30 ms)

When the Sensed AV Offset feature is enabled, the AV Delay will be shortened by the programmed Sensed AV Offset after a sensed atrial event. The decrease in AV Delay is intended to compensate for the time difference between a paced atrial event, where the atrial contraction begins with pacing, and an intrinsic atrial event that is sensed later during the atrial contraction (Figure 6-38).

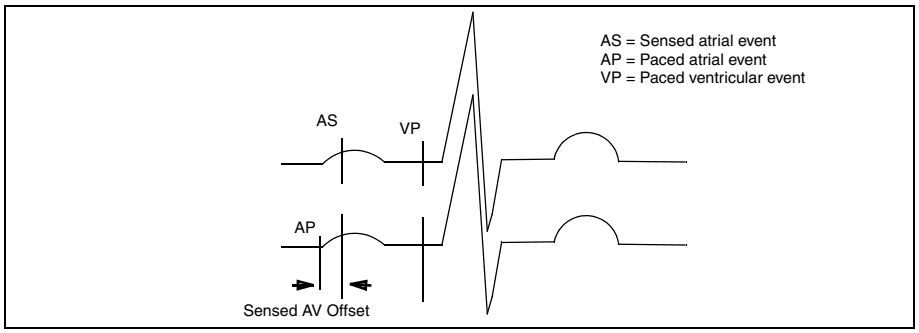


Figure 6-38. The Sensed AV Offset compensates for the difference between the paced atrial event and the sensed atrial event.

The hemodynamic impact of the AV Delay depends on the appropriateness of the timing between the atrial and ventricular contractions. An atrial pace starts the atrial contraction, whereas the atrial sense occurs during the contraction. As a result, when Sensed AV Offset is not programmed On, the hemodynamic AV interval will differ between paced and sensed atrial events.

Sensed AV Offset to Fixed AV Delay

The typical application of Sensed AV Offset is to shorten the AV Delay by 30–60 ms after an atrial sensed event. This offset is applied to the Fixed AV Delay or the AV Search Hysteresis AV Delay, depending on which parameter is operational. When Fixed AV Delay is selected, the Sensed AV Offset also will be fixed at its programmed value.

Sensed AV Offset to Dynamic AV Delay

When Dynamic AV Delay is selected, the pacemaker will calculate the Sensed AV Offset based on the atrial rate. To reflect the narrowing of the P-wave during periods of increased metabolic demand, the Sensed AV Offset will linearly shorten from the programmed value at the LRL to a value determined by the ratio of Minimum AV Delay and Maximum AV Delay at the higher of the MTR or MSR (Figure 6-39).

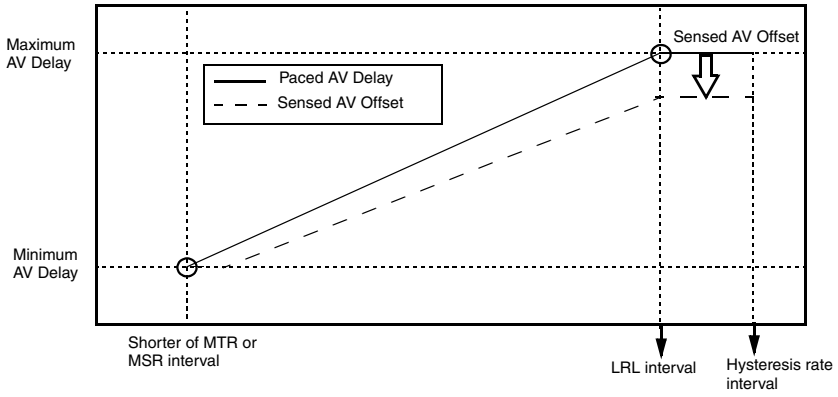
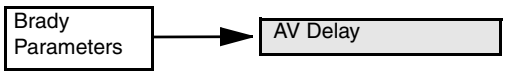


Figure 6-39. Dynamic AV Delay and Sensed AV Offset as a function of the escape interval.

AV SEARCH HYSTERESIS



DR

In patients with exercise-dependent or intermittent AV nodal block, the AV Search Hysteresis allows intrinsic AV conduction beyond the programmed AV Delay during episodes of normal AV nodal function. Allowing intrinsic AV conduction via AV hysteresis can improve hemodynamic performance and increase device longevity due to a reduced number of ventricular paces.

When the AV Search Hysteresis feature is enabled, the AV Delay will be lengthened periodically for up to 8 consecutive cardiac cycles. The hysteresis AV Delay will remain active as long as the intrinsic P–R intervals are shorter than the hysteresis AV Delay. The pacemaker will revert to the programmed AV Delay following the first ventricular pace at the hysteresis AV Delay, or when the 8-cycle search expires without sensing intrinsic ventricular activity.

AV Search Interval

Programmable Values: Off, 32–1024 cycles (powers of 2) (Nominal = Off)

The AV Search Interval controls the frequency of the AV Search Hysteresis (Figure 6-40).

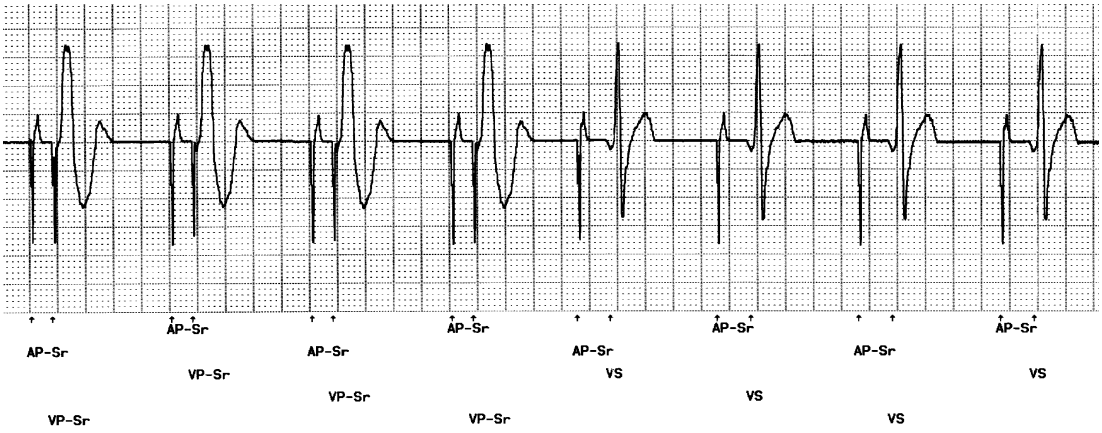


Figure 6-40. Example of ECG strip with a successful AV Search.

AV Increase

Programmable Values: 10–100% (10% increments) (Nominal = 30%)

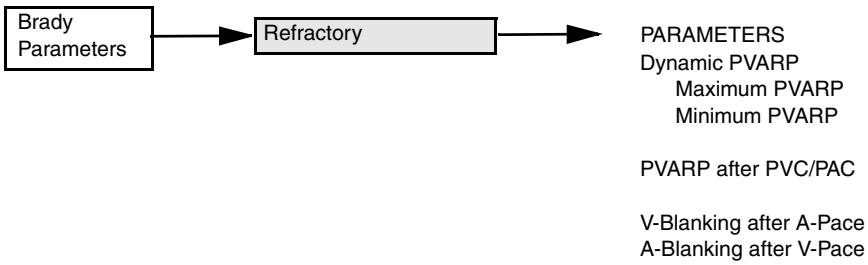
The AV Increase determines how much the AV Delay will lengthen during a search cycle. This percentage is applied to the Fixed AV Delay or the Dynamic AV Delay (depending on which option is programmed) to determine the hysteresis AV Delay. The AV increase from hysteresis AV Delay has a maximum design limit of 300 ms.

NOTES:

- *During AV Search Hysteresis, the Sensed AV Offset lengthening will be limited to prevent the ventricular pacing rate from dropping below the LRL, sensor-indicated rate, or hysteresis rate.*

- *The Automatic Capture feature may add an additional 64 ms AV Hysteresis in order to accommodate a fusion check for a maximum AV Hysteresis delay of 364 ms.*

REFRACTORY SUBMENU



DYNAMIC PVARP

DR

Programmable Values: On, Off (Nominal = On)

Programming of Dynamic PVARP and Dynamic AV Delay increases the sensing window at higher rates, allowing upper rate behavior (e.g., 2:1 block and pacemaker Wenckebach) in DDD(R) and VDD modes to be significantly reduced, even at the higher MTR settings. At the same time, Dynamic PVARP reduces the likelihood of PMTs at the lower rates. Dynamic PVARP will also reduce the likelihood of competitive atrial pacing.

The Dynamic PVARP feature is enabled by programming the Dynamic PVARP parameter to On and selecting the minimum and maximum values for PVARP. The pacemaker then automatically calculates the Dynamic PVARP using a weighted average of the previous cardiac cycles. This will result in a shortening of the PVARP in a linear fashion as the rate increases.

When the average rate is between the LRL and the MTR, the pacemaker calculates the Dynamic PVARP according to the linear relationship shown in Figure 6-41. This relationship is determined by the programmed values for Minimum PVARP, Maximum PVARP, the LRL, and the MTR.

CAUTION: Programming Minimum PVARP less than retrograde V–A conduction may increase the likelihood of a PMT.

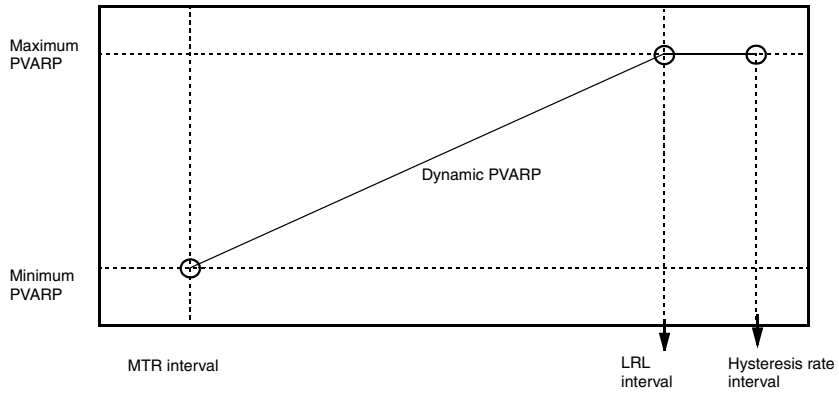


Figure 6-41. Illustration of Dynamic PVARP as a function of the escape interval.

Maximum PVARP

Programmable Values: 160–500 ms (10-ms increments) (Nominal = 250 ms)

If the average rate is equal to or lower than the LRL (i.e., hysteresis), the Maximum PVARP is used.

Minimum PVARP

Programmable Values: 150–490 ms (10-ms increments) (Nominal = 240 ms)

If the average rate is equal to or higher than the MTR interval, the programmed Minimum PVARP is used.

PVARP AFTER PVC/PAC

Brady Parameters → Refractory

DR

Programmable Values: Off, 150–500 ms (50-ms increments) (Nominal = 400 ms)

When the pacemaker is programmed to the DDD(R), DDI(R), or VDD mode, the clinician may choose to program the PVARP after PVC/PAC option. This feature is designed to help prevent pacemaker-mediated tachycardia due to loss of A–V syn-

chrony, which may result in retrograde conduction after a premature ventricular contraction (PVC) or a premature atrial contraction (PAC), or atrial oversensing of myopotentials or other EMI which meet the PAC criteria. PVARP is extended for one cycle only and then returns to the originally programmed value. This means that the PVARP will be extended no more frequently than every other cardiac cycle.

The pacemaker automatically extends the PVARP to the programmed value for one cardiac cycle in the following situations:

- Upon detection of a PAC. A PAC is defined as an A–A interval that is equal to or less than 600 ms and more than 25% shorter than the average of the previous four A-A intervals.
- Upon detection of a sensed ventricular event that is preceded by a paced or sensed ventricular event without an intervening atrial event (i.e., a PVC). Atrial senses within PVARP are used.
- If an atrial pace is inhibited due to A-Tachy Response.
- After a ventricular escape pace that is not preceded by an atrial sense in VDD mode.
- When the pacemaker is programmed from a non-atrial tracking mode to an atrial tracking mode.
- When the pacemaker returns from magnet operation to an atrial tracking mode.
- When the pacemaker exits fallback mode after A-Tachy Response.
- When the pacemaker exits from a temporary non-atrial tracking mode to a permanent atrial tracking mode.
- When the pacemaker comes out of noise reversion due to an electromagnetically noisy environment.

BLANKING AND NOISE REJECTION

Blanking is the first part of the refractory period, where sense amplifiers are completely disabled. It is used to prevent cross-chamber sensing and inhibition.

During a blanking interval, the sensing circuit in one chamber ignores sensed electrical activity generated by a pacemaker pulse in the other chamber (cross-talk).

Ventricular pacing, if sensed in the atrium, would initiate an inappropriately high ventricular pacing rate in any pacemaker attempting to maintain AV synchrony. Atrial pacing, if sensed in the ventricle, would inhibit ventricular pulses and thereby cause an inappropriate decrease in paced rate. Therefore, a ventricular pace initiates a programmable atrial blanking interval in DDD(R), DDI(R), and VDD modes, and an atrial pace initiates a programmable ventricular blanking interval in the DDD(R) and DDI(R) modes.

V-Blanking after A-Pace (Ventricular Blanking)

Brady Parameters → Refractory

DR

Programmable Values: 30–200 ms (10-ms increments) (Nominal = 40 ms)

In the ventricle, the atrial pace concurrently starts a retriggerable 60-ms noise rejection interval and a programmable ventricular blanking interval (Figure 6-42). (Whenever a signal is detected during the retriggerable noise rejection interval, the interval will be restarted at the point where a signal is detected.)

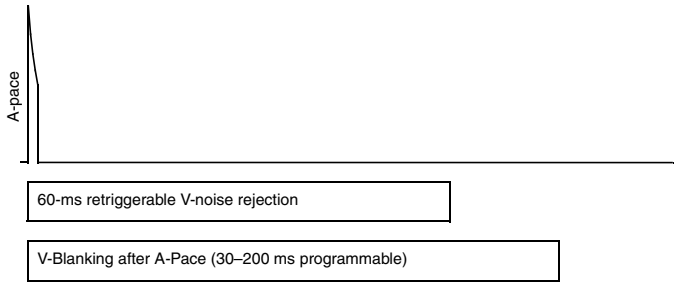
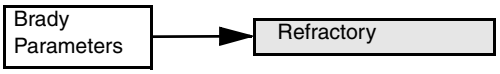


Figure 6-42. Cross-chamber noise rejection after A-Pace and V-Blanking after A-Pace.

A-Blanking after V-Pace (Atrial Blanking)



DR

Programmable Values: 30–200 ms (10-ms increments) (Nominal = 120 ms)

In the atrium, the ventricular pace concurrently starts a 40-ms retriggerable noise rejection interval and a programmable atrial blanking interval (Figure 6-43).

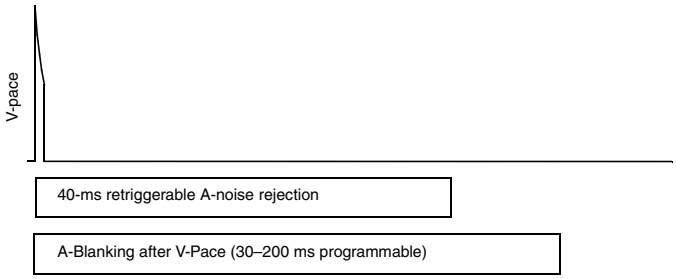


Figure 6-43. Cross-chamber noise rejection after V-Pace and A-Blanking after V-Pace.

Noise Rejection

Atrial or Ventricular Pacing

In both the atrium and the ventricle, a pace concurrently starts a fixed 50-ms noise rejection interval followed by a 40-ms retriggerable atrial noise rejection interval and 60-ms retriggerable ventricular noise rejection interval (Figure 6-44).

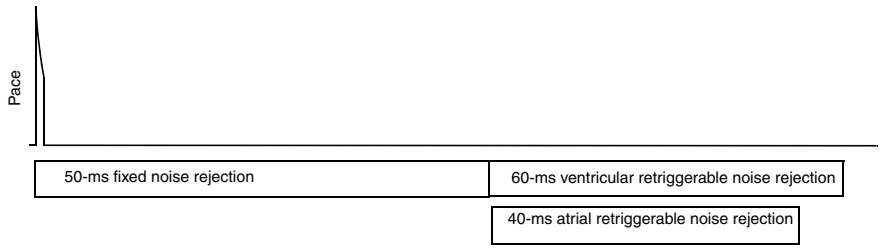


Figure 6-44. Same-chamber noise rejection after pace.

Atrial Depolarization Sensing

When an atrial depolarization is sensed, a 40-ms noise rejection interval is started in the atrium only (Figure 6-45). This interval is retriggered in the continued presence of noise. During noise rejection, intrinsic events will not be detected. Asynchronous operation can result if the noise continues.

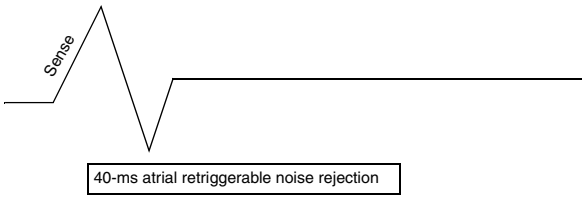


Figure 6-45. Atrial noise rejection after sense

Ventricular Depolarization Sensing

When a ventricular depolarization is sensed, a 60-ms noise rejection interval is started in the ventricle and a 40-ms noise rejection interval is started in the atrium (Figure 6-46). This interval is retriggered in the presence of noise. During noise rejection, intrinsic events will not be detected. Asynchronous operation can result if the noise continues.

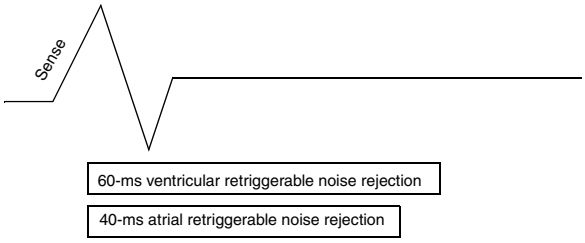
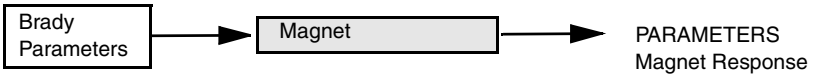


Figure 6-46. Ventricular and atrial noise rejections after ventricular sense.

MAGNET SUBMENU



MAGNET RESPONSE

Programmable Values: Off, Async, EGM (Nominal = Async)

If Magnet Response is programmed to Async, a dual-chamber pacemaker will operate in the mode identified in Table 6-5 when a magnet is applied. A single-chamber or VDD mode will operate in SOO mode when a magnet is applied. The actual pacing rate depends on the battery status (see Table 6-6). If Magnet Response is programmed to Off, the pacemaker will not respond to magnetic fields and/or magnet application.

If Magnet Response is programmed to EGM and the stored EGM diagnostics are enabled, application of the magnet will initiate storage of intracardiac EGMs, and the pacemaker will not perform the normal magnet asynchronous pacing.

Table 6-5. Magnet Modes According to Primary Mode

Primary Modes	Magnet Mode	Magnet Rate/AV Delay (@ BOL)
DDD(R), DDI(R), DOO(R)	DOO	100 ppm/100 ms
VDD, VVI(R), VOO(R), VVT	VOO	100 ppm
AAI(R), AOO(R), AAT	AOO	100 ppm

Table 6-6. Battery Status Indicators and the Respective Magnet Rates

Battery Status Indicator	Magnet Rate
Good	100 ppm
ERN (Elective Replacement Near)[a]	90 ppm
ERT (Elective Replacement Time)	85 ppm
EOL (End of Life)	≤ 85 ppm

a. Intensified follow-up is recommended.

See “Pacemaker Longevity Projections” on page 4-2 for more information.

DIAGNOSTICS AND FOLLOW-UP

CHAPTER 7

This chapter contains information about the INSIGNIA I Ultra diagnostic screens available with the Model 2892 CONSULT Software application.

The screen names appear in the toolbox button bar at the bottom of the PRM screen.

The following is a brief description of each screen described in this chapter:

- **System Summary**—Provides a summary of basic device and lead system information as well as a list of clinical events recorded since the last follow-up.
- **Quick Check**—Provides a method of sequencing through a series of typical follow-up procedures controlled from a single screen.
- **Brady Parameters**—This screen is discussed in detail in Chapter 6.
- **Temporary Parameters**—Allows parameter settings to be tested in a temporary mode while maintaining the “permanent” parameters in the pacemaker’s memory.
- **Setup**—Allows the parameter setup for various features including Magnet, Arrhythmia Logbook, Trending, and Daily Measurement.
- **Therapy History**—Allows viewing of patient therapy including Arrhythmia Logbook, Counters, and Histograms.
- **Diagnostic Evaluation**—Displays data and/or allows testing of Battery Status, Intrinsic Tests, Impedance Tests, Threshold Tests, Activity Log, Daily Measurement, Trending, and Snapshot Viewer.
- **EP Test**—Provides the ability to induce and/or terminate arrhythmias noninvasively.

SYSTEM SUMMARY

The System Summary (Figure 7-1) screen provides a summary of the data retrieved from the device. These data are available in greater detail on other screens. To view those screens, select the shortcut button (☞) next to the feature. Programmable parameters cannot be changed on this screen.

The test values on the System Summary screen will not be updated during a patient session. To view updated test results on the System Summary screen, select New Patient from the Utilities menu and re-interrogate the pacemaker.

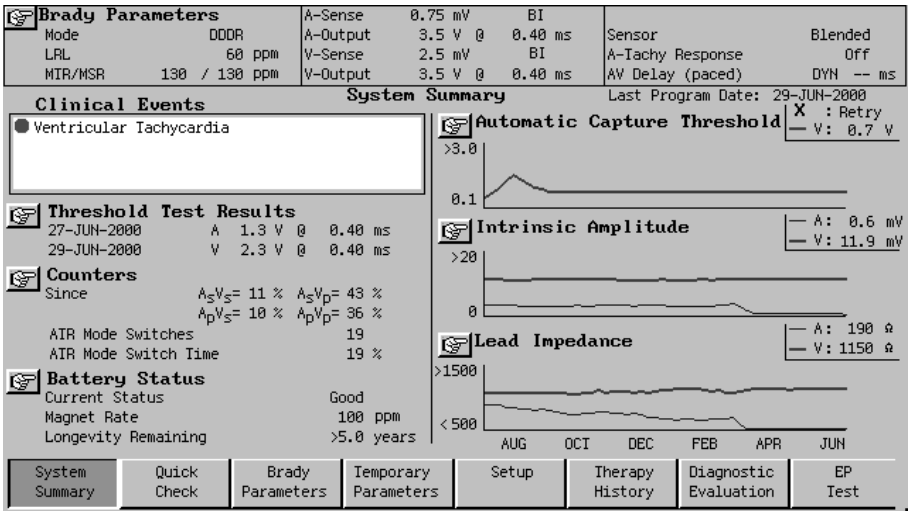


Figure 7-1. A typical System Summary Screen.

The clinical events are considered either informational or important. The important messages will be preceded by a stop sign icon (⬤). The display will show No Events if there are none to report. View detail of the clinical events by selecting the message or the stop sign button next to the event. Clinical events that will be displayed include the following:

- Patient Triggered Event Stored
- Ventricular Tachycardia
- Atrial Tachycardia

- Lead Configuration Switched
- Battery at ERT
- Battery at EOL
- PMT Episode Stored
- Sudden Brady Response
- Patient Activated EGMs On
- Automatic Capture in Retry, Greater than 40%

QUICK CHECK SCREEN

The Quick Check screen (Figure 7-2) provides a method of sequencing through a series of follow-up procedures. The selected tests will be performed in the order they appear on the screen, beginning with the left column when the Start button is depressed. The clinician will be prompted with a dialogue window before each of the following tests: Intrinsic Amplitude Measurement, Lead Impedance Measurement, and Amplitude Threshold Tests. After the Amplitude Threshold Tests, no messages are displayed other than Telemetry in Progress.

Beside each function on the Quick Check screen is a Go button ▶. Individual functions can be activated by depressing the Go button. This allows the user to repeat individual Quick Check functions or perform the tests in any sequence desired. As each test is completed, the results are displayed on the screen.

If a test was unable to complete (e.g., patient was 100% paced during Intrinsic Amplitude Measurement), the results will be reported as NR (no result).

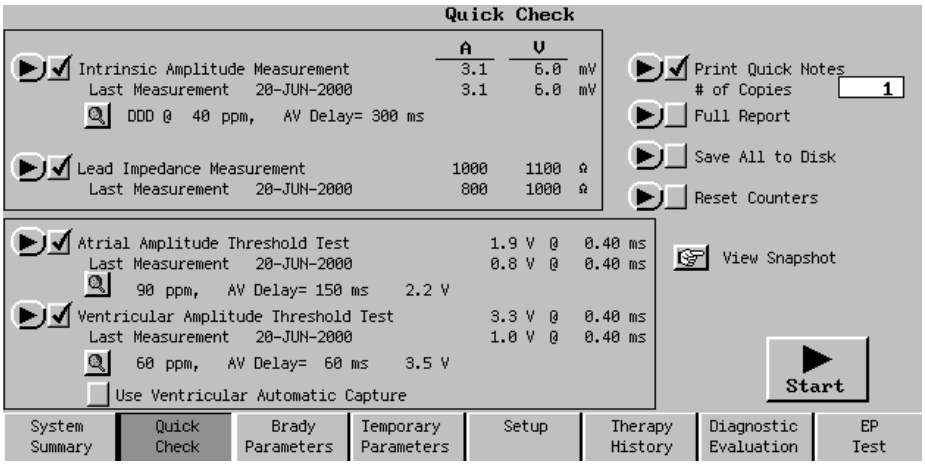


Figure 7-2. The Quick Check screen.

Intrinsic Amplitude Measurement

The Intrinsic Amplitude Measurement test is performed when this function is activated. In dual-chamber modes, both P- and R-waves are measured. In single-chamber modes, only the active chamber is tested. The Mode, LRL, and AV Delay can be changed for this test by clicking the magnifying glass icon to access the popup screen.

The Last Measurement (from the previous session) and the current Intrinsic Amplitude Measurement are both displayed. If multiple measurements are taken during a programming session, the current measurement data will be updated while the Last Measurement will remain the same.

Lead Impedance Measurement

The Lead Impedance Measurement test is performed when this function is activated. In dual-chamber modes, both the atrial and ventricular leads are measured. In single-chamber modes, only the active chamber is tested. If a chamber is not being paced due to the patient's intrinsic rhythm when this test is conducted, the pacemaker will momentarily switch to a triggered mode and pace into the sensed event to ensure a measurement in that chamber. Lead tests may not be conducted in the atrium and/or ventricle if the patient's intrinsic rate is faster than the Maximum Tracking Rate (e.g. devices will not pace beyond this rate). Additionally, lead tests may not be conducted in the atrium for the following reasons:

- In DDD(R) mode, if the pacemaker has ATR mode switched to a non-atrial pacing mode (e.g. VDI) due to an atrial arrhythmia, pacing will not be delivered.

- If the Atrial Flutter Response feature is programmed ON and is active during an atrial flutter.

The Last Measurement (from the previous session) and the current Lead Impedance Measurement are both displayed. If multiple measurements are taken during a programming session, the current measurement data will be updated while the Last Measurement will remain the same.

If you are unable to obtain a successful lead impedance measurement, consider the following temporary programming options as appropriate for each patient:

- Increase the Lower Rate Limit above the patient's intrinsic rhythm,

- Decrease the AV Delay to increase the chance that a ventricular pace occurs prior to an intrinsic/conducted ventricular contraction,

- Program the device to an asynchronous mode (e.g. DOO, AOO or VOO), or

- Program the device to a single-chamber mode (e.g. AAI or VVI) or triggered mode (e.g. AAT or VVT).

Atrial and Ventricular Amplitude Threshold Test

The Ventricular Amplitude Threshold Test can be performed automatically or manually by selecting or deselecting the Use Ventricular Automatic Capture checkbox on the Quick Check screen. The Atrial Amplitude Threshold Test is performed manually.

The Last Measurement (from the previous session) and the current Intrinsic Amplitude Measurement are both displayed. If multiple measurements are taken, the current measurement data will be updated while the Last Measurement will remain the same. The threshold measurement displayed is the voltage step value that is one higher than when the threshold test was terminated.

NOTE: *The Ventricular Amplitude Threshold Test begins immediately after the completion of the Atrial Amplitude Threshold Test.*

Manual Threshold Tests

The Atrial Amplitude Threshold Test and the Ventricular Amplitude Threshold Test use the Smart Start amplitude value, which is three voltage steps above the previously measured threshold. If there has not been a previous threshold, the test will start at the programmed voltage. The LRL, AV Delay, and starting voltage amplitude can be changed for this test by accessing the popup screen with the magnifying glass icon. The surface ECG is automatically set to 2X for the duration of the Atrial Amplitude Threshold Test to help the user distinguish the P-wave. The clinician is prompted to remove the telemetry wand or select Stop at loss of capture. Only the threshold tests require intervention. When the user stops the test because the threshold has been lost, the Snapshot Viewer will automatically be activated and the 10 seconds before loss of capture will be recorded. This information, as well as the Amplitude and Pulse Width settings, can be viewed and printed from the Snapshot Viewer screen.

Automatic Threshold Tests

The automatic Ventricular Amplitude Threshold Test starts at 3.5 V or the threshold plus 0.5 V if Automatic Capture is active and operating in the beat-to-beat mode. The output voltage will automatically be decremented during the test until the ventricular pacing output no longer captures.

Once two non-captured beats occur, the test automatically stops and displays the ventricular threshold. A backup safety pulse is not delivered on the non-captured beat to allow confirmation of the loss of capture. At the end of the test the previously programmed permanent values are immediately restored.

If ventricular Automatic Capture is not presently operating in the beat-to-beat mode when an automatic threshold test is initiated, the first 12–15 paced beats will be used by the device to perform evoked response measurements and then the output reductions will start.

If the measurement was unsuccessful, one of the following reasons will be displayed:

Noise	Noise detected
V-ER?	Inadequate evoked response signal
LOC?	Loss of capture not detected
> 3.0	Threshold is greater than 3.0 V

Noise	Noise detected
Sense	Insufficient paced events

Print Quick Notes

Quick Notes provides a summary of the Quick Check test results. One to five copies can be printed.

Full Report

A summary that includes Quick Check test results, Brady Parameters, Battery Status, Histograms, Counters, Daily Measurement, and Arrhythmia Logbook may be printed using the Full Report function.

Save All to Disk

Patient and device data can be saved to a data disk. The data from only one patient's device can be stored on a single disk; information from multiple devices cannot be stored on the same data disk.

Reset Counters

The event counters can be reset via telemetry by selecting the Reset Counters button. Use caution when performing this operation. Once telemetry is established, some or all of the data will be cleared even if you choose the Cancel button during the operation. Pacing mode changes do not reset the event counters.

BRADY PARAMETERS SCREEN

The Brady Parameters screen and the submenus accessible through it are discussed on page 6-5.

TEMPORARY PARAMETERS SCREEN

The pacemaker can be programmed with temporary parameter values that differ from the programmed "permanent" values. This allows the clinician to examine alternate pacing therapies while maintaining the previously programmed permanent

parameters in the pacemaker memory. Once initiated, temporary programming remains in effect as long as telemetry is maintained between the programmer and the pacemaker. The Temporary Parameters are deactivated and the permanent parameters are restored when the telemetry link is broken or when the Cancel button is selected on the Temporary Parameters Now in Use window.

NOTES:

- *When the pacemaker is transmitting real-time EGMs or is in Temporary Parameters mode, some diagnostic functions are suspended. This includes Trending, Counters, and Histograms. When the pacemaker is in magnet mode, sensor and rate trending are suspended.*

- *If the Minute Ventilation sensor is programmed On in permanent mode, the LRL cannot be programmed < 50 ppm. To program rates lower than 50 ppm in Temporary mode, temporarily program the Minute Ventilation sensor to Off at the same time. Once the Temporary mode is deactivated, the MV sensor response will resume.*

Parameters and range values that are available during permanent programming are also available during Temporary programming with the exception of the following features:

- Magnet
- AutoLifestyle
- Auto Sense
- Automatic Capture
- Lead Safety Switch
- 4→ On MV Initialization

In addition, Temporary programming offers nonpacing modes and values that are not available in permanent programming (see Appendix C for listing). Unlike the permanent parameters, Temporary programming permits Amplitude to be turned Off. This allows examination of underlying cardiac rhythms.

CAUTION: If the Amplitude is Off during Temporary programming, the pacemaker will not pace. Pacing with the permanently programmed parameters can be

restored by breaking the telemetry link or by selecting the Cancel button on the Temporary Parameters Now in Use window.

Implementing Temporary Values

Use the following procedure to program the pacemaker for temporary pacing:

1. Select the Temporary Parameters button on the tool bar.

NOTE: *If a report is desired listing the Temporary Parameters, select the Printer icon and make sure that Print after Modification is set to Enable. The report will print after the Temporary programming session has ended.*

2. Select the parameter to change by clicking on the Temporary box next to the parameter.

3. Select new parameter values. If additional parameters require modification, repeat to achieve the desired values. **Multiple parameter changes can be made at one time.**

   After entering the change(s), make sure that the Parameter Interaction button is not displayed. If it is, select that button to determine how the current changes violate interactive limits. Any interactive limit errors ( ) must be corrected before Temporary programming can occur. Interactive limit warnings ( ) should be taken into careful consideration before continuing, but will not prohibit programming.

4. Press the Start button to send the changes to the pacemaker via telemetry. The PRM will display a window indicating that Temporary programming is in effect. As long as the telemetry link is maintained, the pacemaker will function according to the Temporary values. No changes can be made to permanent parameters while in a Temporary programming mode.

5. To end Temporary programming, press the Cancel button on the Temporary programming window or break the telemetry link. The pacemaker will then return to using the permanent pacing parameters.

After a Temporary programming session, you can perform any of the following actions:

- Make additional changes to the Temporary Parameters for further examination.

- Copy the Temporary parameter values to the Change column on the Brady Parameters screen.
- Choose Cancel Changes. This will clear the Temporary values from the Temporary column.

SETUP

The Setup screen allows access to the setup and/or reset parameters for the following features:

- Magnet
- Arrhythmia Logbook
- Trending
- Daily Measurement

Magnet

Select the Magnet button from the Setup tool kit screen to access the Magnet Setup. This screen allows the Magnet Response to be changed. The programmable values are Off, Async, and EGM.

NOTE: *After changing the Magnet Response value, the Initiate Magnet button must be selected to enable the change.*

Arrhythmia Logbook

Select the Arrhythmia Logbook button from the Setup tool kit to access the Arrhythmia Logbook Setup screen. The Arrhythmia Logbook Setup screen allows the clinician to enable EGM storage and to choose which events will trigger the EGMs.

Stored electrograms (EGMs) must be enabled by the clinician and can be disabled if desired. When enabled, each triggering event will cause an EGM to be stored in the pacemaker. An EGM is stored for each chamber for which sensing is enabled. The

posttrigger portion of the EGM will be stored once the triggering event has occurred. The onset portion of the EGM, which occurred before the event, will also be stored. If all the available storage has been used, the new event will overwrite the oldest event in the pacemaker storage.

NOTE: *Arrhythmia Logbook and Stored EGM data will not be stored for the first two hours after the lead is inserted into the header during implant.*

Recording of arrhythmias can be triggered by up to seven selectable events:

- **Atrial Tachy Detection**—This event is recorded when the pacemaker is operating in an atrial sensing mode and the atrial rate meets or exceeds a programmable Atrial Tachy Detection rate maintained for a programmable Atrial Tachy Detection duration. The Atrial Tachy Detection algorithm does not use any data from the ventricular channel.

  Sensed events falling both outside and inside the atrial refractory period are used to determine the atrial rate.

  The Atrial Tachy Detection trigger is designed to be used when the A-Tachy Response trigger is Off. The PRM will prevent both triggers from being turned on simultaneously.

- **A-Tachy Response**—This event is recorded when A-Tachy Response mode switching fallback is triggered. The ATR mode switching feature on the Brady Parameters screen (A-Tachy Response submenu) must be programmed On for ATR detection to trigger EGM Storage.

  The A-Tachy Response trigger is designed to be used when the Atrial Tachy Detection trigger is Off. The PRM will prevent both triggers from being turned on simultaneously.

- **Ventricular Tachy Detection**—This event is recorded when the pacemaker is operating in a ventricular sensing mode and the ventricular rate meets or exceeds a programmable Ventricular Tachy Detection rate maintained for a programmable Ventricular Tachy Detection duration. The Ventricular Tachy Detection algorithm does not use any data from the atrial channel.

  Sensed events falling both outside and inside the ventricular refractory period are used to determine the ventricular rate.

- **Magnet (Patient Triggered)**—When the pacemaker detects the presence of a magnet, one recording will be triggered. The pacemaker must not have a magnet present for at least one full cardiac cycle following the EGM recording cycle before another magnet-triggered EGM can be recorded. The Magnet Response parameter on the Brady Parameters screen (Magnet submenu) must be programmed to EGM for magnet detection to trigger EGM Storage. This trigger will not be activated if an EGM is being recorded when the magnet is detected.

NOTE: *If patient magnet activation is selected, you may wish to have the patient initiate a stored EGM at the time of feature programming. This may assist with patient education and feature validation.*

- **Nonsustained Ventricular Tachycardia (NSVT)**—This event is recorded when a device is operating in a dual-chamber mode and a run of three or more pacemaker-defined PVCs is detected. The pacemaker definition for a PVC is a sensed ventricular event that is preceded by another sensed or paced ventricular event without an intervening atrial event. Atrial senses within PVARP are used.

- **Sudden Brady Response**—This event is recorded when Sudden Brady Response is triggered. The SBR feature on the Brady Parameters screen (Rate Enhancements submenu) must be programmed On for SBR detection to trigger EGM Storage.

- **Pacemaker Mediated Tachycardia (PMT)**—This event is recorded when the PMT Termination feature is triggered. The PMT Termination feature on the Brady Parameters screen (A-Tachy Response submenu) must be programmed on for a PMT detection to trigger EGM Storage.

When EGM Storage is enabled, the clinician must specify the EGM Storage method. This will determine how many events can be stored in the pacemaker memory.

To select the Trigger Sources, change the selection to On. For the atrial and ventricular detection rates, enter the rate and duration to the right of the parameter name.

For the ventricular and atrial Trigger Sources, sensed events falling both outside and inside the refractory period will be used to determine the rate.

Changes made to the settings on this screen will not be stored automatically. You must select the Initiate Arrhythmia Logbook button before the changes will take

effect. If the EGM Storage Method has been changed, selecting the Initiate Arrhythmia Logbook button will initiate the changes and erase existing EGMs. Changing EGM triggers does not erase data. Navigating to other screens without selecting the Initiate Arrhythmia Logbook button will not delete the changes. If changes to the setup have not been confirmed via the Initiate Arrhythmia Logbook button, they are not used and the pacemaker continues operation using the previous setup information.

EGM Selections

All EGM selections include event markers and an onset portion that occurs before the EGM trigger is satisfied. Using the EGM feature with its onset EGM increases device current drain by less than 0.5%. Stored EGM and Trending can be active at the same time.

The EGM selections with their Event Markers are as follows:

- Off
- 31 episodes (2 seconds pretrigger and 2 seconds posttrigger)
- 15 episodes (4 seconds pretrigger and 4 seconds posttrigger)
- 7 episodes (7 seconds pretrigger and 7 seconds posttrigger)
- 3 episodes (7 seconds pretrigger and 28 seconds posttrigger)
- 2 episodes (28 seconds pretrigger and 14 seconds posttrigger)

Clearing Stored EGMs

EGMs are cleared by changing EGM Storage Method.

Trending

This function allows the clinician to specify which types of data will be collected by the pacemaker and the resolution at which to store the acquired data. Trending and Stored EGM can be activated at the same time.

Use the following procedure to set up the Trending data storage:

1. Select the Trending button from the Setup tool kit.

2. Choose the Source to be used.

   Rate—Rate and sensor data will be recorded

   Sensitivity—Signal amplitude and Auto Sense sensitivity data will be recorded. Auto Sense must be On in at least one chamber to allow Sensitivity to be trended.

3. Choose the Recording Method to be used.

   High Resolution method—The pacemaker averages and records the actual rate and sensor values of the permanently programmed sensors over 16 seconds. Using the High Resolution method in dual-chamber mode, rate, MV, and accelerometer data will be recorded for 6 hours.

   Long Duration method—The pacemaker averages and records the actual rate and sensor values of the permanently programmed sensors over 60 seconds. Using the long duration method in dual-chamber mode, rate, MV, and accelerometer data will be recorded for 23 hours.

   Beat-to-Beat method—The pacemaker records intervals and event markers or sensitivity on a cycle-to-cycle basis. No sensor information will be stored using this recording method. Using Beat-to-Beat in dual-chamber mode at 60 ppm, data will be recorded for 0.6 hours.

   5-Minute method—This method is available only with sensitivity trending. Samples are taken at 5-minute intervals and provide more than 2.5 days of data. No sensor information will be stored using this recording method.

4. Choose how the data should be stored by selecting the Setup Method. There are three ways to save the data:

   Fixed storage starts when the setup is confirmed and continues until the memory buffer is filled, allowing the clinician to view data from initial setup for a specific amount of time.

   Continuous storage has the most recent data available. It starts upon confirmation of the setup and continuously overwrites the oldest data until the information is retrieved. It allows the clinician to view the data for the recording duration immediately previous to the current time.

Timer (fixed) storage allows the clinician to specify the time and date when the pacemaker should begin storing data. The data will then be stored for the recording duration until the memory buffer is filled.

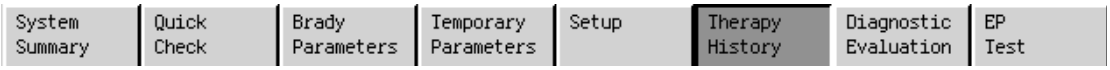
5. When all of the parameters on the Trending Setup screen are as desired, select the Initiate Trend button. The pacemaker will immediately begin storing the data as specified.

   The Selected Duration depends on the number of programmed sensors and recording method and is displayed on the Trending Setup window.

Daily Measurement

The Daily Measurement Setup screen allows the erasure of all Daily Measurement data stored in the pacemaker, up to one year of data.

THERAPY HISTORY



The Therapy History screen allows access to the following patient data:

- Arrhythmia Logbook
- Counters
- Histograms

Arrhythmia Logbook

Recording of arrhythmias can be triggered by up to seven selectable events:

- Atrial Tachy Detection
- A-Tachy Response
- Ventricular Tachy Detection
- Magnet Activation

- Nonsustained ventricular tachycardia (NSVT)
- Sudden Brady Response
- Pacemaker Mediated Tachycardia (PMT)

The Arrhythmia Logbook can store up to 40 separate events. As new events are recorded, the oldest events are overwritten. If EGM Storage has been selected, the most recent events also will have EGMs while older episodes would not.

The Arrhythmia Logbook is continuously updated based on the triggers that have been selected and have detected arrhythmias, but the Arrhythmia Logbook cannot be cleared.

The Arrhythmia Logbook stores the information about detected arrhythmias, as described in the table below. All detected arrhythmias also will include date and time.

Table 7-1. Summary of Information Stored in the Arrhythmia Logbook

Trigger	Onset (ppm)	Max (ppm)	Duration
Atrial Tachy Detection	Last measured interval when the detection criteria are first met	Fastest measured interval during the arrhythmia, after criteria are met	Not applicable
Ventricular Tachy Detection	Last measured interval when the detection criteria are first met	Fastest measured interval during the arrhythmia, after criteria are met	Not applicable
Magnet Activated	Not applicable	Not applicable	Duration is equal to the length of EGM stored
Nonsustained Ventricular Tachycardia (NSVT)	Last measured interval when the detection criteria are first met	Fastest measured interval during the arrhythmia, after criteria are met	Not applicable
A-Tachy Response	Last measured interval when the detection and duration criteria are first met prior to mode switch	Fastest measured interval during fallback	Duration of mode switch[a]
Sudden Brady Response	Average atrial rate measured before the rate decrease to the LRL or sensor-indicated rate	Not applicable	Duration of therapy[a]
Pacemaker Mediated Tachycardia	Not applicable	Not applicable	Not applicable

a. The minimum Duration value is equal to the length of the EGM stored.

When you access the Arrhythmia Logbook screen (Figure 7-3), the arrhythmia data interrogated from the pacemaker at initial interrogation are displayed.

Use the following procedure to retrieve the Arrhythmia Logbook data that have been stored since initial interrogation:

1. The data will be displayed in chronological order. Use the scroll bar to view more episodes.

2. To print out the Arrhythmia Logbook, select the Print Log button.

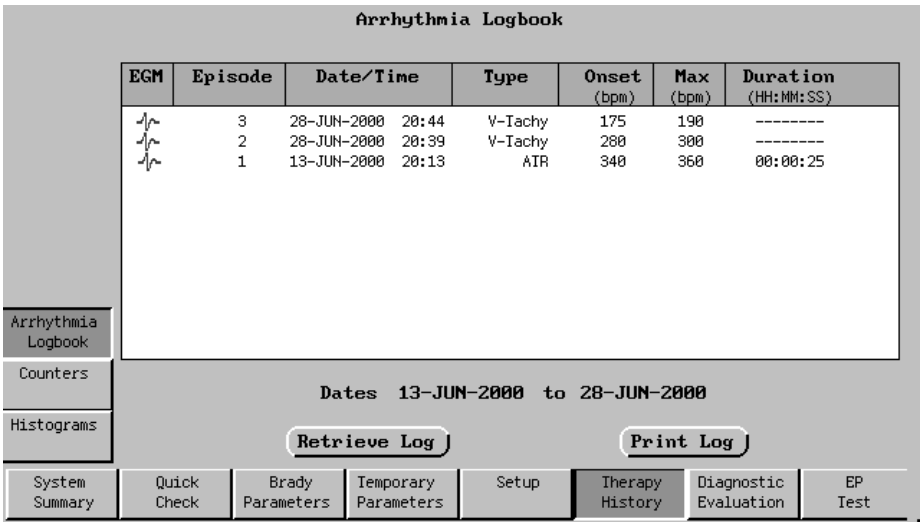


Figure 7-3. The Arrhythmia Logbook screen.

Stored Electrograms (EGMs)

The features on the Stored EGM window (Figure 7-4) allow the clinician to zoom in and out, to scroll the trace left or right, and to drop electronic calipers to make measurements on the screen. The calipers provide the interval in milliseconds between the calipers, and the voltage difference between caliper positions for both the atrial and the ventricular EGMs (if applicable).

Use the following procedure to view a stored EGM:

1. Select the EGM icon on the logbook window next to the entry to be viewed. If the stored arrhythmia does not include a stored EGM, there will be no icon next to that event.

2. Select the sweep speed (mm/s) using the buttons in the middle of the screen.

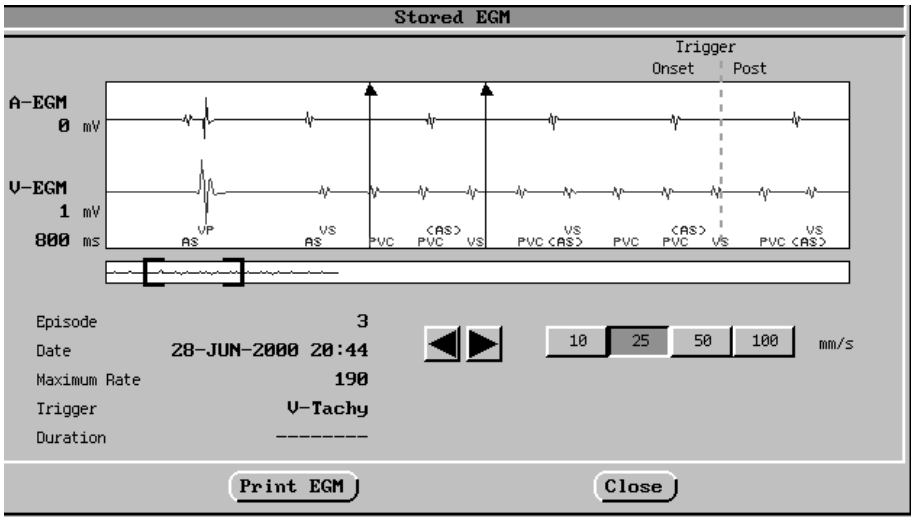


Figure 7-4. The Stored EGM screen.

3. Use the arrow buttons on the screen to scroll the currently displayed view left or right along the trace. Below the trace is a full view bar. The current view is represented by the portion of the full view between the brackets. To select a different section of the recorded trace, touch and hold the desired section with the stylus.

4. To use the electronic calipers, drag the caliper to its new position then lift the stylus. The interval and the amplitude difference for the atrial and ventricular EGMs between the two calipers will be displayed.

5. To print a displayed EGM trace, select the Print EGM button on the screen. The EGM with annotated Event Markers will be printed at the selected sweep speed.

NOTE: *The Stored EGM amplitudes are similar to the real-time EGMs. Changing the programmed Sensitivity will affect the appearance of future stored EGMs, but will not affect EGMs stored previously.*

Counters

Event Counters record the number of intrinsic and pacemaker-mediated events that occur during an event recording period. This period begins with the last time the Counters were reset by the clinician and ends when the data are retrieved from the

pacemaker via telemetry. Neither data retrieval nor changing the programmed parameters resets the Counters.

The following events are counted and recorded when relevant to the currently programmed permanent pacing mode:

- Paced and Sensed Events
- A-Tachy Response Mode Switch Data
    - Total ATR Mode Switches
    - Total ATR Mode Switch Time
    - Maximum Mode Switch Time
    - Average Mode Switch Time
- Ectopic Beats
    - PACs
    - Single or Double PVCs
    - Three or More PVCs
    - Atrial Tachy Detection
    - Ventricular Tachy Detection
- Ventricular Interval Variation
    - V–V Variation 0% ≤ 10%
    - V–V Variation 10% ≤ 20%
    - V–V Variation 20% ≤ 30%
    - V–V Variation > 30%
- Rate Hysteresis searches—total number and number of successful searches

- AV Search Hysteresis—total number and number of successful searches
- Wenckebach Events (PMT Termination algorithm must be active for this counter)
- Minute Ventilation baseline values—hourly for the last 24 hours (MV must be active for this data)

The event counters can be reset via telemetry by selecting the Reset Histograms/ Counters button on the Counters screen (Figure 7-5). Use caution when performing this operation. Once telemetry is established, some or all of the data will be cleared even if you choose the Cancel button during the operation. Pacing mode changes do not reset the event counters. Event counters may also be reset from the Quick Check screen.

NOTE: *When the pacemaker is transmitting real-time EGMs or is in Temporary mode, some diagnostic functions are suspended. This includes Trending, Counters, and Histograms. When the pacemaker is in Magnet Mode, Sensors and Rate Trending are suspended.*

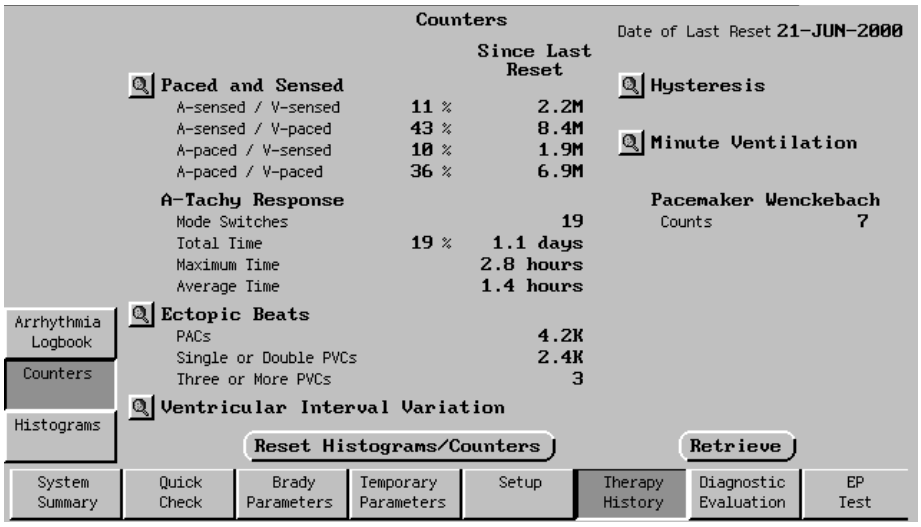


Figure 7-5. The Counters screen.

Histograms

Rate Histograms allow the clinician to graphically display atrial and ventricular paced and sensed events collected during the recording period (Figure 7-6). This period begins with the last time that Histograms were reset by the clinician and ends when the data are retrieved from the pacemaker via telemetry. Select the Retrieve button to retrieve the data.

Two histogram selections are possible: AV and Pace/Sense. The AV histograms show A-sensed events followed by V-sensed and V-paced events, and A-paced events followed by V-sensed and V-paced events. These events are sorted into rate bins. The Pace/Sense histograms show atrial paced and sensed events and ventricular paced and sensed events, also sorted into bins. The histogram bins are large enough to count events for more than 10 years at 60 ppm without reaching their maximum capacity.

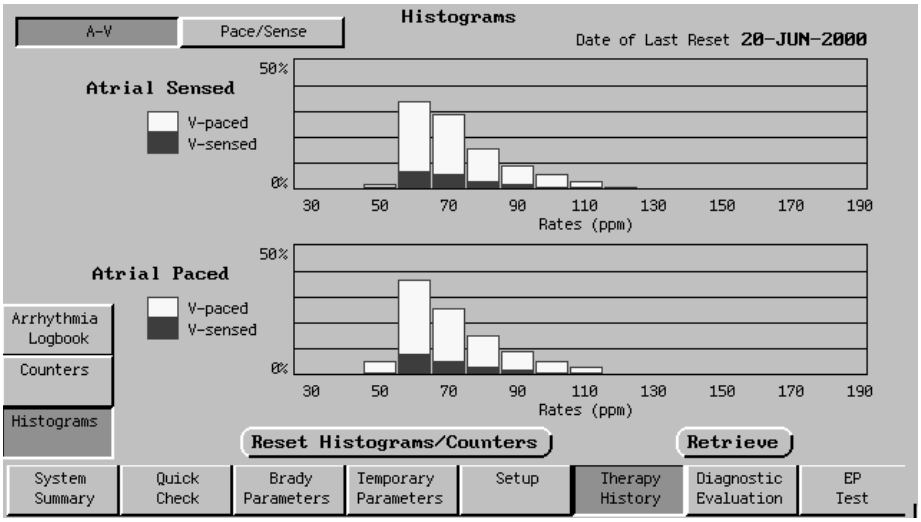


Figure 7-6. The Histograms screen.

The rate distributions are sorted into 10-ppm wide bins for rates between 30 ppm and 180 ppm, and into a single bin for rates above 180 ppm.

Rate histograms must be reset using the Reset button on either the Histograms or Counters window. Parameter changes and mode changes do not reset them. All rate bins and counters are reset simultaneously. Event counters may also be reset from the Quick Check screen.

NOTES:

- *When the pacemaker is transmitting real-time EGMs or is in Temporary mode, some diagnostic functions are suspended. This includes Trending, Counters, and Histograms. When the pacemaker is in Magnet, Sensors and Rate Trending are suspended.*
- *It is possible to see V or A rates below LRL because of Hysteresis or A rates below LRL following a cardiac cycle with no atrial activity (e.g., a PVC).*

DIAGNOSTIC EVALUATION

System Summary	Quick Check	Brady Parameters	Temporary Parameters	Setup	Therapy History	Diagnostic Evaluation	EP Test

The Diagnostic Evaluation screen allows access to the following tests and patient data:

- Battery Status
- Intrinsic Amplitude Test
- Lead Impedance
- Threshold Tests
- Activity Log
- Daily Measurement
- Trending
- Snapshot Viewer

Battery Status

The Battery Status screen (Figure 7-7) displays the date of the last battery test, the previous and present battery status indicators, the current and previous magnet rates of the pacemaker, and the estimated longevity remaining. Battery status will show 100% until the first 11-hour measurement after lead attachment. After implant battery measurements are performed by the pacemaker every 11 hours and cannot be initiated using the PRM. The screen also provides a graphical representation of Battery Status.

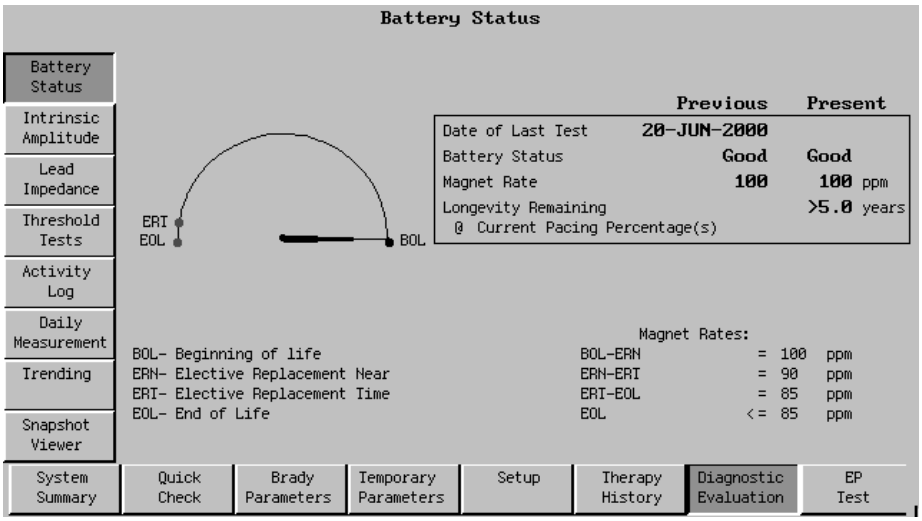


Figure 7-7. The Battery Status screen.

On initial interrogation, the PRM retrieves the most recent battery status data and the previous session's stored data from the pacemaker. Figure 7-7 shows the battery status indicators and their respective magnet rates.

The Longevity Remaining estimate is based on measurements indicating the remaining charge in the battery. The time remaining is calculated by using the percentage pacing that occurred in the last 30 days at the programmed device settings and the measured lead impedance. Before implant the Longevity Remaining calculation assumes a lead impedance of 500 Ω. Time remaining is displayed from > 5.0 years to < 0.5 years in 0.5-year increments. If the pacing percentage increases, the time remaining may be less than the number displayed. If the pacing percentage decreases the time remaining may be more.

Table 7-2. Battery Status Indicators and the Respective Magnet Rates

Battery Status Indicator	Magnet Rate
Good	100 ppm
ERN (Elective Replacement Near)	90 ppm
ERT (Elective Replacement Time)	85 ppm
EOL (End of Life)	≤ 85 ppm

Intrinsic Amplitude Test

The Intrinsic Amplitude Test measures and displays the intrinsic amplitude for the atrium and/or ventricle. Intrinsic measurement will be available for a given cardiac chamber only if sensing is enabled for that chamber in the current pacing mode.

For intrinsic measurements in single-chamber modes, the clinician can temporarily program a lower LRL value to bring out the patient's underlying rhythm. This parameter change is in effect only during the test.

If the Intrinsic Amplitude Test is desired for both chambers, the atrial and the ventricular measurements must be conducted individually. In this case, the clinician can program the pacemaker to temporarily change the LRL and AV Delay for the duration of the test. The results for each chamber will be gathered in separate but adjacent search periods.

The Intrinsic Amplitude Test is based on the measurement of one complex per chamber. The test is complete and all effects of the parameters programmed for the test are terminated within 10 seconds for each chamber measured, or when either of the following occur:

- The test is terminated via a command from the PRM (e.g., selecting Cancel or pressing the STAT PACE key)
- The pacemaker exits the temporary state when the telemetry link is broken

The pacemaker stores the results of the last test so that the data from the previous session and the results of the current test can be viewed simultaneously.

Follow these steps to perform an Intrinsic Amplitude Test:

1. Select the Intrinsic Amplitude button on the Diagnostic Evaluation screen.
2. Select the LRL and AV Delay values that will allow the intrinsic rhythms to be seen.
3. Place the wand over the pacemaker, then select the Start button on the screen. The measurement requires a maximum of 10 seconds of telemetry time per chamber, depending on the presence of intrinsic activity. When the tests are completed, the data will be displayed in the Present column.

4. If the tests were unsuccessful because the programmed LRL and/or AV Delay did not allow intrinsic rhythms to be seen (i.e., the Measured Amplitude field reports Paced), repeat steps 2 and 3. If the tests are unsuccessful, an NR message on a popup window will indicate that the measurements could not be completed.

NOTE: *Parameters changed on the Intrinsic Tests screen also will be in effect during Quick Check.*

A report of the displayed test results can be printed as directed in “Obtaining a Printed Report” on page 8-9.

Lead Impedance Test

The Lead Impedance Test will report the lead Impedance, pacing Amplitude, Pulse Width, Current, and Energy at permanently programmed output settings for the leads in the pacemaker system. These energy calculations reflect energy used at programmed settings. To facilitate the measurement, the Amplitude and Pulse Width parameters are temporarily changed to predetermined values based on permanently programmed settings, and the pacemaker switches to a triggered mode. Once the measurements are completed or the measurement period has expired, the permanently programmed pacing parameters are restored.

If the currently programmed pacing Amplitude is 3.5 V or less for the duration of the test, the Amplitude will be set at 3.5 V. If the Amplitude is 4.0, 4.5, or 5.0 V, the Amplitude will be set at 5.0 V. If the Amplitude is 6.5 V, the amplitude will remain at 6.5 V.

If the currently programmed Pulse Width is less than 0.4 ms, the Pulse Width will be set to 0.4 ms; otherwise, the Pulse Width for the test will be set to the currently programmed Pulse Width.

The impedances for the test are based on the measurement of one event and will be reported as <100 Ω, 100 Ω to 2500 Ω in increments of 10 Ω, and >2500 Ω.

If an interactive lead impedance measurement is conducted in DDD mode, the lead impedance for each chamber will be measured separately but in adjacent search periods.

The Lead Impedance Test is complete and the original parameters are restored within 10 seconds for each chamber measured, or sooner if the test is terminated via the Cancel button, or by breaking the telemetry link.

The pacemaker stores the results of the previous Lead Impedance Test so that the data from the previous session and the results of the current test can be viewed simultaneously. The value may differ from a pacing system analyzer measurement due to the method of calculation. The pacing Lead Impedance Test can be used as a relative measure of lead integrity over time. In addition, lead integrity can be ascertained with pacing measurements.

Energy is calculated using programmed outputs and measured lead impedances.

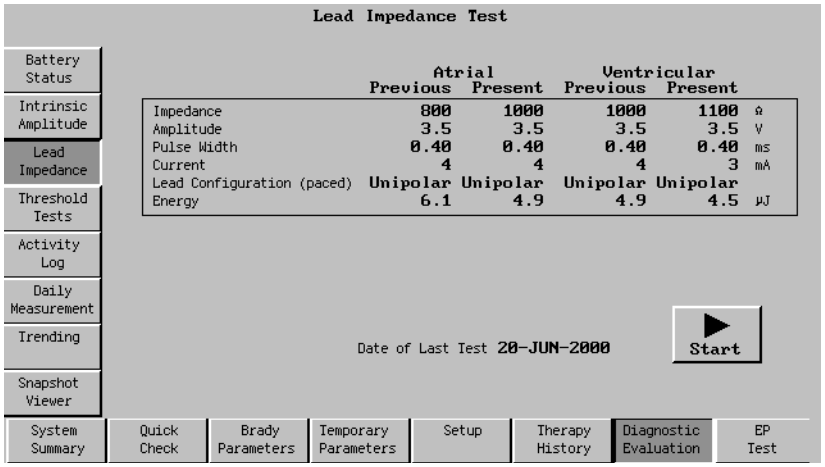


Figure 7-8. A typical Lead Impedance Test screen.

Follow these steps to perform a Lead Impedance Test:

1. Select the Lead Impedance button on the Diagnostic Evaluation screen (Figure 7-8).

2. Place the wand over the pacemaker, then select the Start button on the screen. When the test is completed, the lead Impedance will be displayed in the Present column.

If you are unable to obtain a successful lead impedance measurement, consider the following *temporary* programming options as appropriate for each patient:

- Increase the Lower Rate Limit above the patient's intrinsic rhythm,

- Decrease the AV Delay to increase the chance that a ventricular pace occurs prior to an intrinsic/conducted ventricular contraction,

- Program the device to an asynchronous mode (e.g. DOO, AOO or VOO), or
- Program the device to a single-chamber mode (e.g. AAI or VVI) or triggered mode (e.g. AAT or VVT).

A report of the displayed test results can be printed as directed in “Obtaining a Printed Report” on page 8-9.

Threshold Tests

Threshold testing enables the clinician to determine the minimum energy needed for capture. Identifying and then programming a shorter Pulse Width or lower Amplitude will increase battery longevity.

The Ventricular Amplitude Threshold Test can be performed automatically or manually by selecting Auto or Manual. Pulse Width Threshold Tests and Atrial Amplitude Threshold Tests are performed manually.

Once the threshold test (Auto or Manual) is started, the pacemaker enters a temporary state using the parameters specified in the Start column. The pacemaker then decrements the selected parameter (Pulse Width or Amplitude) until the test is complete. Real-time EGMs and annotated event markers continue to be available during threshold testing.

During the Threshold Tests, the PRM displays the test parameters in a window while the test is in progress. The manual test can be momentarily paused by selecting the Hold button on the window. To continue the test, select the Continue button.

When the threshold has been lost, as determined by the device during automatic testing or as indicated by the user stopping the test or breaking telemetry during manual testing, the snapshot feature will automatically be activated and the 10 seconds before loss of capture will be recorded. This information, as well as the Amplitude and Pulse Width settings, can be viewed and printed from the Snapshot Viewer.

After the test, the permanently programmed Amplitude and Pulse Width settings are automatically restored and the test results are displayed in the Threshold Tests table. Up to six tests can be displayed for each chamber; if more than six tests are performed, the six most recent tests are displayed.

The Threshold Tests are complete and all effects of the parameters programmed for the test are terminated when any of the following occur:

- The lowest available setting for Pulse Width or Amplitude is reached
- The tests are terminated via a command from the PRM (e.g., selecting the End Test button or pressing the STAT PACE key)
- The pacemaker exits the temporary state when the wand is removed
- The device determines threshold is lost (Automatic Ventricular Amplitude Threshold Test only)

Automatic Ventricular Amplitude Threshold Test

The automatic Ventricular Amplitude Threshold Test will start at 3.5 V or the threshold plus 0.5 V if Automatic Capture is active and operating in the Beat-to-Beat mode. The output voltage will automatically be decremented during the test until the ventricular pacing output no longer captures. Once two non-captured beats occur, the test automatically stops and displays the ventricular threshold. A back-up safety pulse is not delivered on the first non-captured beat to allow confirmation of the loss of capture. The test results, as well as the Amplitude and Pulse Width settings, can be viewed and printed from the Snapshot Viewer screen.

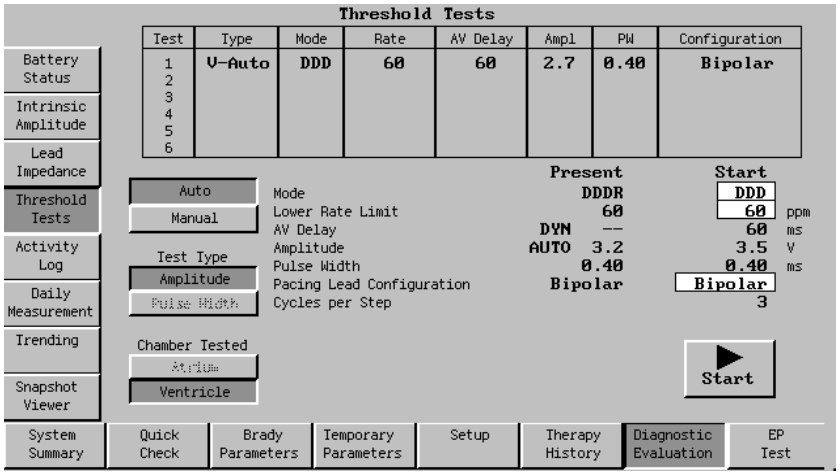


Figure 7-9. The automatic Ventricular Amplitude Threshold Test screen.

Manual Threshold Tests

The Manual Amplitude Threshold Tests use the Smart Start amplitude value, which is three voltage steps above the previously measured threshold. If there has not been a previous threshold, the test will start at the programmed voltage and incrementally step that value down as the test progresses. The clinician can also program the starting Amplitude value. The starting value for Pulse Width and the number of cardiac cycles between step changes is programmable by the clinician. The Mode, LRL, AV Delay, and Pacing Lead Configuration to be used during the Threshold Tests are also programmable (Figure 7-9). These parameters are in effect only during the tests. Testing for a chamber is allowed only when pacing is active for that chamber in the mode specified at the top of the Start column.

Using the Manual Threshold Testing Functions

Follow these steps to perform Threshold Tests:

1. Select the Threshold Tests button on the Diagnostic Evaluation screen.

2. Select the Manual button.

3. Select the type of test to be performed. Two options are available:

   - Choose Amplitude to decrement the pulse amplitude during the test or

   - Choose Pulse Width to decrement the pulse width during the test

4. For dual-chamber modes, select Atrium to test the atrial thresholds or Ventricle to test the ventricular thresholds.

5. Enter the starting values for each applicable parameter in the Start column. Parameter applicability is dependent on the Mode selected.

6. Select the Start button on the screen to begin the threshold test. After the programmed number of cycles, the pacemaker automatically decrements the Amplitude or Pulse Width. This will continue until the telemetry link is broken, End Test or STAT PACE is selected, or until the lowest value has been tested.

7. Watch the ECG monitor and break telemetry by removing the wand or selecting the End Test button when loss of capture is observed. The measurement displayed is one step higher than the step at which the test was terminated. If the measurement was unsuccessful, NR will be displayed.

At the end of the test, the previously programmed permanent values are immediately restored.

8. To perform another threshold test, make changes to the test parameter values in the Change column if desired, then begin again with step 6. Results of the tests will be displayed on the screen table. If more than six tests are performed, the last six tests are displayed by chamber tested, with the most recent test at the top.

NOTE: *Parameters changed on the Threshold Tests screen also will be in effect during Quick Check.*

A report of the displayed test results can be printed as directed in “Obtaining a Printed Report” on page 8-9.

Using the Automatic Ventricular Threshold Test Functions

Follow these steps to perform an Automatic Threshold Test (Figure 7-10):

1. Select the Threshold Tests button on the Diagnostic Evaluation screen.

2. Select the Auto button.

3. Select the Start button. The test will automatically start at 3.5 V or the threshold plus 0.5 V if Automatic Capture is active and operating in the beat-to-beat mode. The output voltage will automatically be decremented during the test until the ventricular pacing output no longer captures.

4. Once two non-captured beats occur, the test automatically stops and displays the ventricular threshold. A back-up safety pulse is not delivered on the first non-captured beat to allow confirmation of the loss of capture. If the measurement was unsuccessful, one of the following reasons will be displayed:

Noise	Noise detected
V-ER?	Inadequate evoked response signal
LOC?	Loss of capture not detected
>3.0	Threshold is greater than 3.0 V
Sense	Insufficient paced events

At the end of the test, the previously programmed permanent values are immediately restored.

5. To perform another ventricular amplitude threshold test, select the Start button. Results of the test will be displayed on the screen table. If more than six tests are performed, the last six tests are displayed with the most recent on top.

NOTES:

- *The pacemaker must stay in telemetry contact with the PRM throughout the duration of the test to obtain a threshold value. Do not remove the wand or cancel the test when loss of capture occurs.*

- *If the lead polarity is changed for the threshold test, the Automatic Capture algorithm must use the first 12–15 paced beats to make evoked response measurements and then the output reductions will start.*

- *To view the Evoked Response EGM during the test, select the V-ER option from the lead selection boxes to the right of the EGM display (Figure 7-10).*

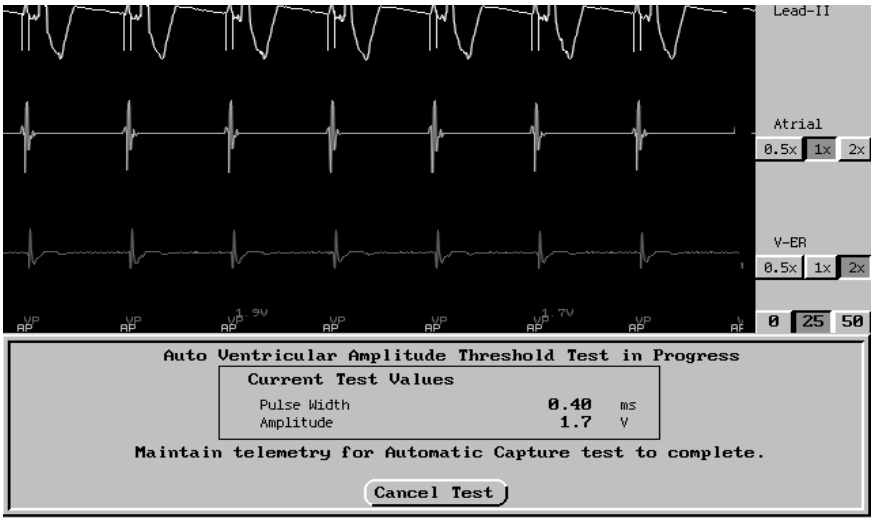


Figure 7-10. The Auto Ventricular Amplitude Threshold Test in Progress.

Activity Log

The Activity Log is a measure of the patient's activity, both intensity, time and frequency, automatically gathered by the pacemaker by using the measured accelerometer data. The accelerometer does not need to be activated by the clinician for this feature to be active.

Every day, the accelerometer is monitored to determine the general activity level of the patient (Percent of Day Active) and the actual exercise performance of the patient. Display Percent of Day Active by selecting % Active. Display Intensity, Frequency, and Time by selecting Exercise.

Percent of Day Active

The Percent of Day Active is determined by measuring what percent of the day the patient's accelerometer-indicated motion is above a fixed minimal threshold. This measurement is completely independent of the accelerometer programmed values, such as Accelerometer Activity Threshold.

The patient's exercise is measured by monitoring both the time the average accelerometer-indicated motion is above a fixed value and the peak average accelerometer-indicated motion. The average accelerometer-indicated motion must be maintained above the fixed value for two minutes before it will be recorded as an exercise event. The peak accelerometer-indicated motion reached for that day is monitored during each exercise event and the maximum for the day is recorded. Intensity level is approximately equal to metabolic equivalents based on patient treadmill testing of accelerometer measurements[1]. For each day, the following exercise information is then stored by the pacemaker:

- Intensity (daily peak average accelerometer-indicated motion)
- Frequency (number of Exercise Events that are two minutes or longer for that day)
- Time (average time of these Exercise Events)

At the end of each week, these daily values are used to determine weekly measurements. For each week, the following exercise information is then stored by the pacemaker:

1. Sun W, Hopper DL, Stahl WK, et al. Estimate of Metabolic Equivalent by Accelerometer or Minute Ventilation Sensors in Implanted Devices: Initial Observations. JACC. 2000;35(2):174A.

- Intensity (greatest daily peak average accelerometer-indicated motion for that week)
- Frequency (average number of Exercise Events that are two minutes or longer occurring on a daily basis)
- Time (average time of these Exercise Events occurring on a daily basis)

The Activity Log (Figure 7-11) will store the last seven days of data and the last 52 weeks of data. By evaluating the trend of the data, both patient activity and exercise patterns can be determined.

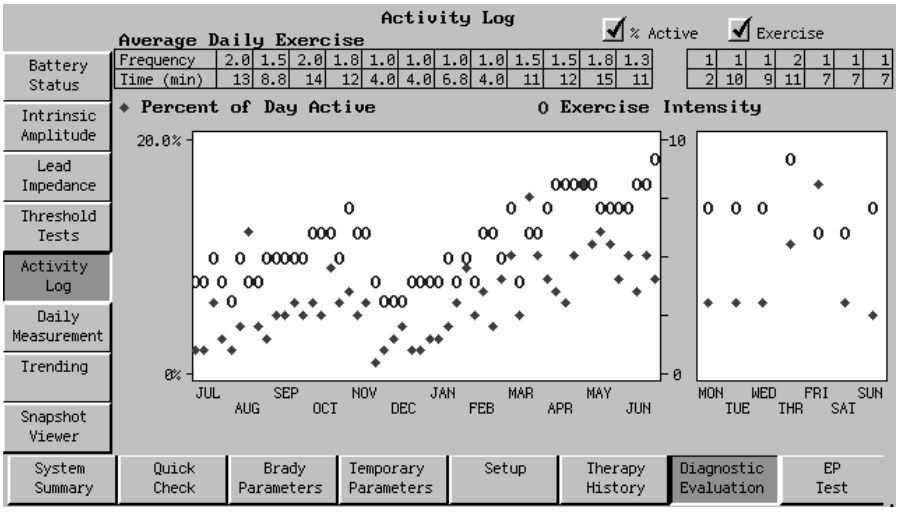


Figure 7-11. The Activity Log screen.

Daily Measurement

Intrinsic Amplitude Measurement

Once each day, based on a 21-hour clock the pacemaker will automatically attempt to measure intrinsic P- and R-wave amplitudes for each cardiac chamber in which sensing is enabled. This measurement will not affect normal pacemaker therapy. The measurement will be taken during a 256-cardiac cycle period. When the pacemaker is operating in a dual-chamber mode, the atrial and the ventricular measurements will be conducted individually. The Intrinsic Amplitude Measurement for each chamber will be gathered in separate but adjacent search periods.

Daily amplitude measurements will be stored for seven days. After seven days, the pacemaker calculates and stores a weekly minimum measurement. These measurements are stored for 52 weeks. At a given time, you can access the daily measurements for the last seven days, and the weekly measurements for the last 52 weeks.

The daily amplitude measurement cannot be taken if events during the test period were all paced. If the measurement is unsuccessful and the measurement period has not expired, the pacemaker will attempt the measurement again. If the test period expires before the measurement can be completed, no data will be stored for that day. Data for other days are not affected.

Lead Impedance Measurement

Once each day, based on a 21-hour clock, the pacemaker will automatically attempt to measure the pacemaker system Lead Impedance for each cardiac chamber in which pacing is enabled. To facilitate the measurement, the Amplitude and Pulse Width parameters are temporarily changed to predetermined values. Once the measurement is completed, the permanently programmed pacing parameters are restored.

If the currently programmed Pulse Width is less than 0.4 ms, the Pulse Width will be set to 0.4 ms; otherwise, the Pulse Width for the test will be set to the currently programmed Pulse Width.

If the currently programmed pacing Amplitude is 3.5 V or less, the Amplitude will be set at 3.5 V. If the pacing Amplitude is 4.0, 4.5, or 5.0 V, the Amplitude is set to 5.0 V. If the Amplitude is set to 6.5 V, it remains at 6.5 V.

Once the measurement is initiated, the pacemaker will allow the system to reach the voltage described above. Once this voltage is reached, the measurement will be taken. If the chamber being tested is having sensed events, the pacing output will be delivered by triggered mode. Triggered pacing will not be delivered during a PVC, refractory event or when the patient's intrinsic rhythm is faster than the Maximum Tracking Rate. When the pacemaker is operating in a dual-chamber mode, the atrial and the ventricular measurements will be conducted individually. The Lead Impedance for each chamber will be gathered in separate but adjacent search periods.

Daily impedance measurements will be stored for seven days. After seven days, the pacemaker calculates and stores a weekly average measurement. These measurements are stored for 52 weeks. At a given time, you can access the daily

measurements for the last seven days, and the weekly average measurements for the last 52 weeks.

Lead tests may not be conducted in the atrium and/or ventricle if the patient's intrinsic rate is faster than the Maximum Tracking Rate (e.g. devices will not pace beyond this rate). Additionally, lead tests may not be conducted in the atrium for the following reasons:

- In DDD(R) mode, if the pacemaker has ATR mode switched to a non-atrial pacing mode (e.g. VDI) due to an atrial arrhythmia, pacing will not be delivered.
- If the Atrial Flutter Response feature is programmed ON and is active during an atrial flutter.

Automatic Capture Threshold Measurement

If ventricular Automatic Capture is active, every day, based on a 21-hour clock, the pacemaker will automatically attempt to measure the ventricular pacing threshold.

Daily threshold measurements will be stored for seven days. After seven days, the pacemaker calculates and stores a weekly maximum measurement. These measurements can be stored for 52 weeks. At any given time you can access the daily measurements for the last seven days, and the weekly measurements for the last 52 weeks.

If Automatic Capture was operating in the Retry[2] mode for more than two days in any given week, that week's threshold will be displayed as 3.5 V, the maximum voltage threshold that can be displayed, and will appear on the graph as Xs. If the measurement is unsuccessful, no data will be stored for that day.

Displaying Daily Measurement Data

The Daily Measurement screens allow the clinician to display the daily measurement data stored in the pacemaker in a tabular or a graphical format.

2. The pacemaker operates in the Retry mode for various reasons, including inadequate evoked response signal or threshold not found at lowest pacing amplitude. The daily measurements display an X for only those instances when the pacemaker was operating in the Retry mode due to inadequate signal measurements. In other instances no data will display (i.e., blanks).

The graphical screen (Figure 7-12) displays the stored data in two views: a point-plot graph showing the weekly measurements and a point-plot graph showing the daily measurements for the last seven days.

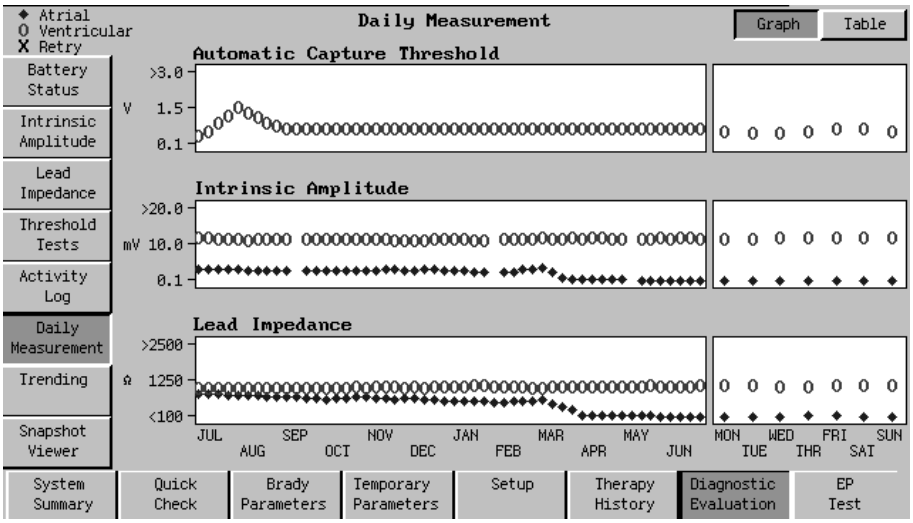
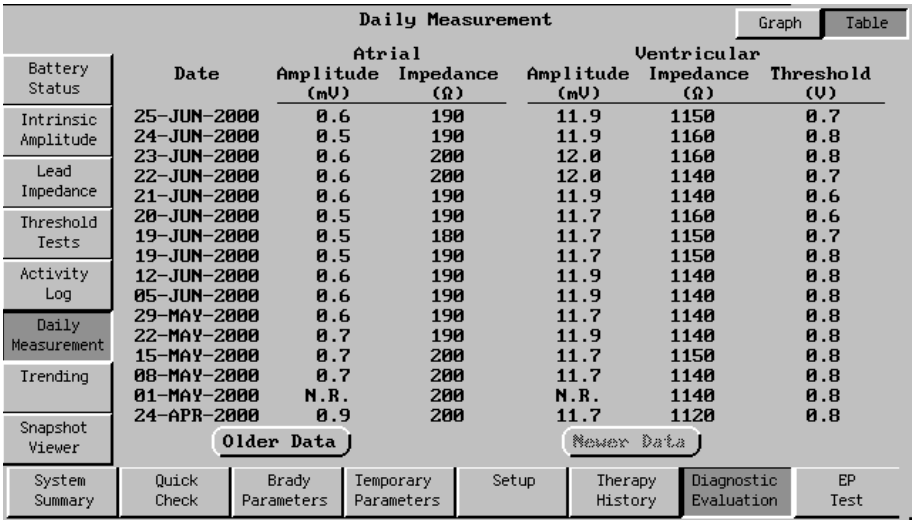


Figure 7-12. The Daily Measurement graphical screen.

To view the data in a tabular format, select the Table button. The tabular screen (Figure 7-13) displays up to 16 measurements at a time. The measurements are displayed in reverse chronological order. The seven daily measurements appear first, and then the weekly values are listed. To view data farther down on the table, select the Older Data button. To view data farther up on the table, select the Newer Data button. If no further data are available in the desired direction, the button will appear gray and cannot be selected. To switch back to the graphical view, select the Graph button.

To clear all Daily Measurement data from the pacemaker, go to Setup →Daily Measurement and select Reset. This will instruct the PRM to establish telemetry with the pacemaker and clear the data storage. Use caution when performing this operation. Once telemetry is established, some or all of the data will be cleared even if you select the Cancel button during the operation.



Date	Atrial Amplitude (mV)	Atrial Impedance (Ω)	Ventricular Amplitude (mV)	Ventricular Impedance (Ω)	Ventricular Threshold (V)
25-JUN-2000	0.6	190	11.9	1150	0.7
24-JUN-2000	0.5	190	11.9	1160	0.8
23-JUN-2000	0.6	200	12.0	1160	0.8
22-JUN-2000	0.6	200	12.0	1140	0.7
21-JUN-2000	0.6	190	11.9	1140	0.6
20-JUN-2000	0.5	190	11.7	1160	0.6
19-JUN-2000	0.5	180	11.7	1150	0.7
19-JUN-2000	0.5	190	11.7	1150	0.8
12-JUN-2000	0.6	190	11.9	1140	0.8
05-JUN-2000	0.6	190	11.9	1140	0.8
29-MAY-2000	0.6	190	11.7	1140	0.8
22-MAY-2000	0.7	190	11.9	1140	0.8
15-MAY-2000	0.7	200	11.7	1150	0.8
08-MAY-2000	0.7	200	11.7	1140	0.8
01-MAY-2000	N.R.	200	N.R.	1140	0.8
24-APR-2000	0.9	200	11.7	1120	0.8

Figure 7-13. The Daily Measurement tabular screen.

Trending

The Trending screen allows the clinician to graphically display rate and sensor information or measured intrinsic events and sensitivity levels stored in the pacemaker (Figure 7-14).

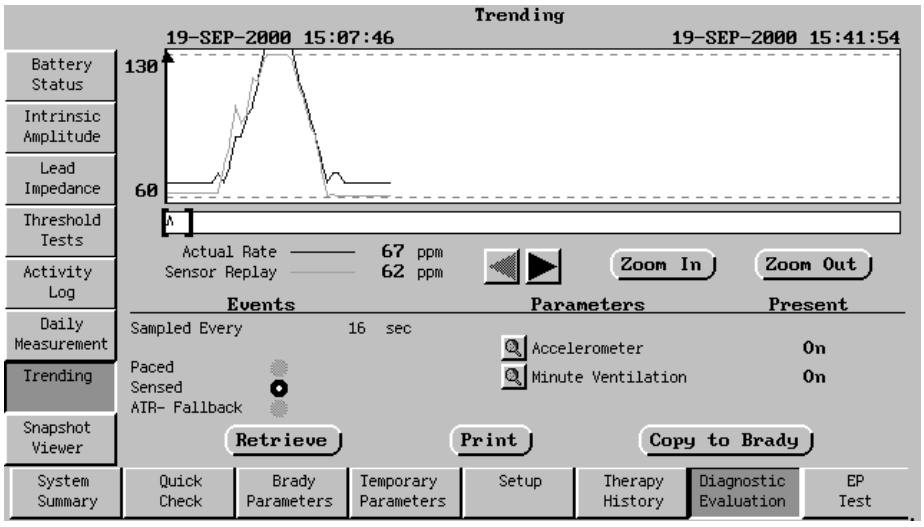


Figure 7-14. A typical rate/sensor Trending screen.

NOTE: *When the pacemaker is transmitting real-time EGMs or is in Temporary mode, some diagnostic functions are suspended. This includes Trending, Event Counters, and Histograms. When the pacemaker is in Magnet Mode, Sensors and rate Trending are suspended.*

Retrieving Trending Data

The Retrieve function allows the clinician to retrieve stored Trending data from the pacemaker. The data are not automatically retrieved from the pacemaker at initial interrogation due to the possibly large volume of data and consequent long transfer time; however, the storage setup information is retrieved.

After establishing telemetry, use the following procedure to retrieve Trending data from the pacemaker:

1. Select the Retrieve button on the screen.

2. While retrieving the data, the PRM will display the Telemetry in Progress window. This window will indicate how much information has been retrieved thus far. The PRM will retrieve the most recent information first. If the interrogation is interrupted, the information already retrieved will be available for analysis.

Working with Rate/Sensor Trending Data

The PRM displays a graphical representation of the retrieved data. Replay allows the clinician to see how changes in the pacing parameters will affect the sensor response. Replay parameters cannot be modified until the trending data have been retrieved from the pacemaker. Parameter availability is dependent on the mode and the permanently programmed sensor.

Follow these steps to use the Trending Replay Parameters function:

1. Retrieve the trending data from the pacemaker using the procedure above. The PRM displays a graphical representation of the patient's rate (black) and sensor response (orange) during the recording.

2. Select the magnifying glass icon next to the sensor (Accelerometer or MV) button, then make changes to the Trending Replay Parameters to optimize the sensor response.

   As the Trending Replay Parameters are modified, the application will modify the sensor graph to illustrate the effects that would result from the changes.

3. If the replayed parameters result in the optimal response, copy the changes to the Brady Parameters screen by selecting the Copy to Brady button.

NOTE: *The Trending function records actual MV and/or Accelerometer outputs during the sampling period. However, as these samples occur less frequently than in the actual device, some differences may be observed in the patient's rate and the sensor response.*

Working with Beat-to-Beat Rate Data

Retrieve the Beat-to-Beat data from the pacemaker using the procedure above.

Upon retrieval, the PRM will display the ventricular rate trend for the duration of the Beat-to-Beat recording. Sensor replay is not available.

By zooming into the level of greatest resolution, you can position the caliper on an individual cycle by dragging it with the stylus or selecting the arrow buttons. The following information is then displayed for that cycle:

- V–V interval

- A–V interval
- V–A interval

Annotated Event Markers will also be displayed on the screen.

Working with Sensitivity Trending Data

Retrieve the trending data from the pacemaker using the procedure above.

Upon retrieval, the PRM will display a graphical representation of the patient's atrial and ventricular intrinsic amplitudes and sensitivity thresholds. By zooming to the level of greatest resolution, you can position the caliper in an individual cycle by dragging it with the stylus or selecting the arrow buttons. The following information is then displayed for that cycle:

- V–V interval
- A–V interval
- V–A interval
- Rate

Annotated Event Markers will also be displayed on the screen.

Snapshot Viewer

The Snapshot Viewer screen (Figure 7-15) allows the clinician to display and analyze previously recorded traces. A snapshot of the trace screen can be made from any screen when the snapshot icon is selected. Surface ECG, A and V EGMs (if applicable), and Ventricular Evoked Response (V-ER), and annotated Event Markers will be captured for the 10 seconds before the button was selected and the 10 seconds after the button was selected. This information is captured by the PRM and does not require any programming or interrogation. If a snapshot was automatically acquired during a pacing threshold test, the snapshot will be 10 seconds long, ending with the termination of the test.

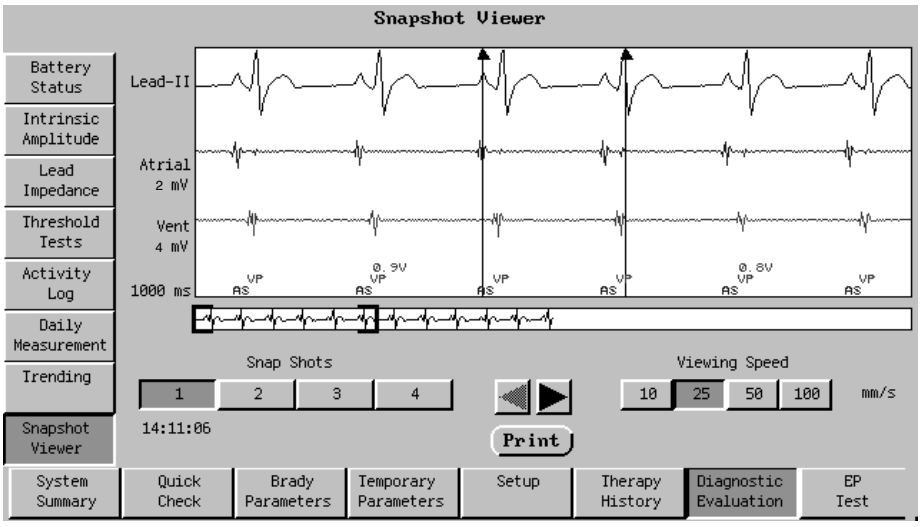


Figure 7-15. The Snapshot Viewer screen.

After the snapshots have been captured, they can be viewed on the Snapshot Viewer screen. Up to four time-stamped snapshots will be retained in the PRM's memory for the current session only; once the session has been terminated by exiting the Model 2892 software application or by interrogating a new patient, the data will be lost.

The features on the screen allow the clinician to zoom in and out, to scroll the trace left or right, and to make interval and amplitude measurements on the screen using electronic calipers. The interval and the amplitude difference between the two calipers will be displayed.

NOTE: *At the 10-mm/sec speed, the annotated Event Markers will not be displayed.*

Use the following procedure to view and analyze a previously recorded snapshot:

1. Select the Snapshot Viewer toolbox button on the screen.

2. Select one of the four time-stamped buttons in the lower left of the Snapshot Viewer screen that identifies the snapshot you want to view.

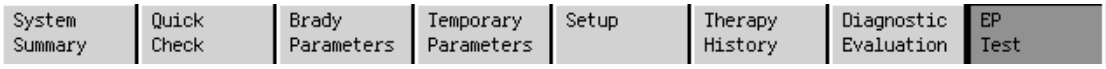
3. Select the sweep speed using the buttons to the right of the snapshot selection buttons to change the view of the snapshot display.

4. Use the arrow buttons on the screen to scroll the currently displayed view left or right. Below the trace is a full view window of the 20-second snapshot. The brackets on the full-view window indicate which portion of the snapshot is shown in detail. To select a different section of the detailed recorded trace, touch and hold the desired section with the stylus.

5. To use the electronic calipers, drag the caliper to its new position, then lift the stylus. The interval and the amplitude difference for the atrial and ventricular EGMs between the two calipers will be displayed.

To print a displayed snapshot, select the Print button on the screen. The currently viewed snapshot and measurements will be printed.

EP TEST



The EP Test (Figure 7-16) enables the clinician to induce and/or terminate tachyarrhythmias noninvasively. These tests can be performed while running the real-time intracardiac ECG traces and markers.

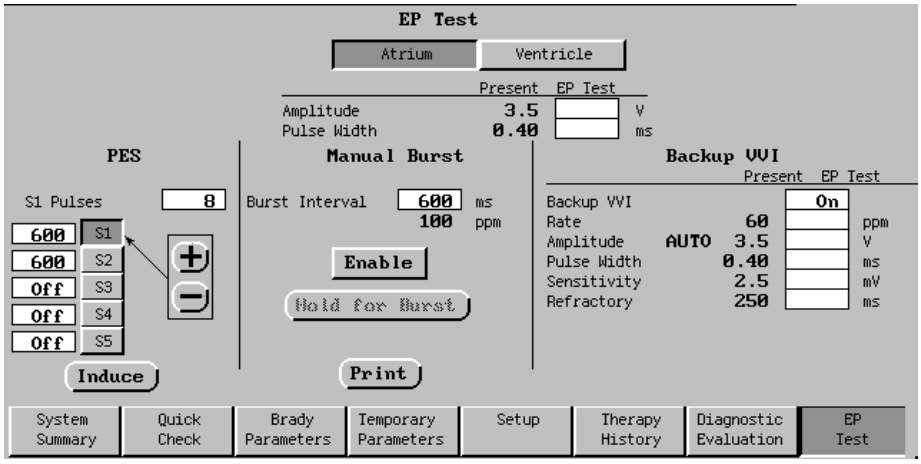


Figure 7-16. The EP Test screen.

The following features allow noninvasive EP testing of arrhythmias:

- Programmed electrical stimulation (PES) allows the pacemaker to deliver a series of timed pacing pulses (S1) that are followed by premature pulses (S2–S5). The pulses can be delivered either to the atrium or the ventricle. The PRM allows flexible setup and control of each PES attempt.

- Manual Burst pacing can be delivered for as long as desired to either the atrium or the ventricle.

Atrial Stimulation and Backup VVI Pacing During EP Testing

During EP testing, atrial stimulation is available for PES and Manual Burst testing. Two buttons are available on the EP Test screen for selecting the cardiac chamber to be stimulated.

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

During atrial stimulation, backup pacing is available in VVI mode if ventricular pacing is enabled in the permanently programmed normal brady mode. The Backup VVI pacing parameters are independently programmable from the permanent pacing parameters. Backup VVI pacing can be programmed off by selecting Off in the Backup VVI parameter box.

Pacing pulses during induction are delivered at the programmed EP Test Pulse Width and EP Test Amplitude.

Programmed Electrical Stimulation (PES)

Programmed electrical stimulation (PES) induction allows the pacemaker to deliver up to 30 equally timed pacing pulses (S1) followed by up to four premature stimuli (S2–S5) to induce or terminate arrhythmias. Drive pulses, or S1 pulses, are intended to capture and drive the heart at a rate faster than the intrinsic rate. This ensures that the timing of the premature extra stimuli will be accurately coupled with the cardiac cycle. The initial S1 pulse is coupled to the last sensed or paced beat at the S1–S1 interval. All pulses are delivered in VOO or AOO mode (depending on the chamber selected) at the programmed PES Pulse Width and PES Amplitude. Figure 7-17 illustrates a PES induction drive train.

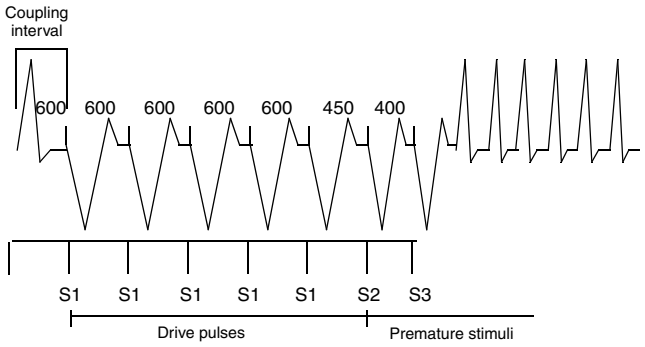


Figure 7-17. PES induction drive train.

Performing PES Induction

1. Choose the cardiac chamber to be paced; select either Atrium or Ventricle.

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

2. To change the number of S1 pulses, select the box next to the words S1 Pulses, and select the desired value.

   Two methods are available to change the cycle length of each pulse (programmed in a range from 120–750 ms or Off):

   a. Select a value box to the left of an S button to display a palette window, and select the desired value.

   b. Select an S button to shift the arrow to that location, then select either the (+) or (–) buttons to increase or decrease the cycle length in 10-ms steps in the value box.

3. Select (do **not** hold) the Induce button to begin delivery of the drive train. The pointer will automatically move to the (–) button so the value can be decreased quickly, if desired, after the test is completed. When the programmed number of S1 pulses is delivered, the pacemaker will then deliver the programmed S2–S5 pulses. The pulses are delivered in sequence until a pulse is encountered that is

set to Off (e.g., if S4 is Off and S5 is set to 200 ms, the S5 pulse will not be delivered).

Once induction is initiated, breaking the telemetry link will stop the PES delivery. If the Induce button is selected again while the S1 pulses are still being delivered, the count of S1 pulses is restarted at the original number and the drive train is effectively extended.

4. PES induction is complete when the drive train and premature stimuli are delivered.

NOTE: *Intracardiac EGMs and annotated Event Markers will continue to be displayed during the entire test sequence.*

Manual Burst Pacing

Manual Burst pacing pulses are delivered in VOO or AOO mode at the programmed EP Test Pulse Width and EP Test Amplitude.

Performing Manual Burst Pacing

1. Choose the cardiac chamber to be paced; select either Atrium or Ventricle.

WARNING: For dual-chamber devices, the cardiac chamber selection is nominally set to Atrium. Life-threatening ventricular arrhythmias can be induced when the selection is set to Ventricle. Ensure that an external cardiac defibrillator is easily accessible.

2. Select the desired value for the Burst Interval; this indicates the cycle length of the intervals in the drive train and is programmable from 100–1000 ms.

3. Select the Enable button. The text on the Hold for Burst button will become selectable.

4. To deliver the burst, touch and hold the stylus on the Hold for Burst button. The Manual Burst will be delivered as long as the stylus is held on the button. Pulses will be at a constant rate.

NOTE: *Intracardiac EGMs and annotated Event Markers will continue to be displayed during the entire Manual Burst pacing.*

5. To stop the burst delivery, lift the stylus from the screen. The text on the Hold for Burst button will become deselectable (gray) again.

6. To deliver additional Manual Burst pacing, repeat steps 3–5.

ELECTROGRAMS (EGMS) / EVENT MARKERS / REPORTS

CHAPTER 8

This chapter includes information about obtaining intracardiac electrograms (EGMs) and real-time annotated event markers, as well as printing reports of parameter settings, session activity, and diagnostics. The following procedures are described in this chapter:

- Displaying surface ECGs and EGMs on the PRM screen or an external recorder
- Displaying annotated Event Markers on the PRM screen
- Printing surface ECGs and EGMs from the PRM
- Printing surface ECGs and EGMs to an external recorder
- Obtaining printed reports of selected data from the programming session on either the internal or external printer

Refer to Appendix B, “External Cable Connections” for instructions on connecting the PRM and patient cables to an external recorder and connecting the PRM to an external printer.

VIEWING AND PRINTING REAL-TIME TRACES AND MARKERS

In addition to displaying surface ECGs, the INSIGNIA I Ultra systems can provide intracardiac EGMs and real-time annotated event markers that identify key intrinsic and pacemaker-related events. The annotated event markers can help you verify the effectiveness of selected parameter settings or simplify diagnosis of complex ECG rhythms.

- High-fidelity real-time atrial and ventricular EGMs and the ventricular evoked response EGM can be transmitted from the pacemaker to evaluate intracardiac signal morphology and rhythm and conduction disorders; they also facilitate the diagnosis of possible lead system issues such as lead fractures, insulation breaks, or dislodgments.

- Event markers can identify intrinsic cardiac and device-related events as interpreted by the pacemaker, and provide information such as sensed/paced events and therapy delivery. The event markers appear as abbreviated annotations on the PRM screen, and as full-disclosure annotations on the internal PRM printout.

- If Intervals are selected on the ECG menu, the key timing intervals will be displayed on the internal PRM printout, but not on the PRM screen. The following intervals will be printed:

  - AS (A–A Interval)
  - AP (A–A Interval)
  - VS (V–V Interval)
  - VP (V–V Interval)
  - VA (V–A Interval)
  - AV (A–V Interval)
  - REFR (PVARP)

NOTE: *The full set of annotated event markers is not available when real-time EGMs are selected, but intervals or a subset of the markers are available. To use the full set of event markers, real-time EGMs must be deactivated. See Table 8-1 and Table 8-2 for a list of the event markers.*

Displaying Surface ECGs, EGMs, and Event Markers

The PRM can display three surface traces using six limb leads and one chest lead. The top displayed lead will be annotated with the pacing spike marker if that feature is selected. To display the pacing spike markers correctly, the Lead II electrodes must be connected to the patient, regardless of which lead is displayed. After selecting the ECG icon on the PRM screen, use the following options to choose the display (Figure 8-1):

- **Select Leads** —Use these value boxes to select whether surface trace, atrial EGMs, ventricular EGMs, or evoked response EGMs (V-ER) should be displayed. The top value selection can only be a surface trace. These options are also available from any PRM screen.

- **Speed buttons**—Select the desired speed button on the ECG display: pause (II) to freeze the trace, play (>), or fast-forward (>>).

- **Show Markers**—Select this check box to display markers.

- **Printed Surface Gain**—Adjust the surface gain of the traces that are captured on printouts by selecting the appropriate value.

- **EGM Gain**—Adjust the gain of the EGM trace by selecting the appropriate value (0.5x, 1x, or 2x).

- **Surface Filter**—Select the Filter On setting to minimize noise on the surface ECG. The Filter Off setting allows viewing surface ECGs with diagnostic filter settings.

- **Pacing Spike Display**—Program this feature On to show detected pacing spikes, annotated by a marker on the uppermost waveform.

- **Printed Event Marker Annotation**—Select Show Markers and Annotation to show the marker annotations (Table 8-1 and Table 8-2) on the printout. Select Show Markers and Intervals to show the intervals and a limited set of annotations.

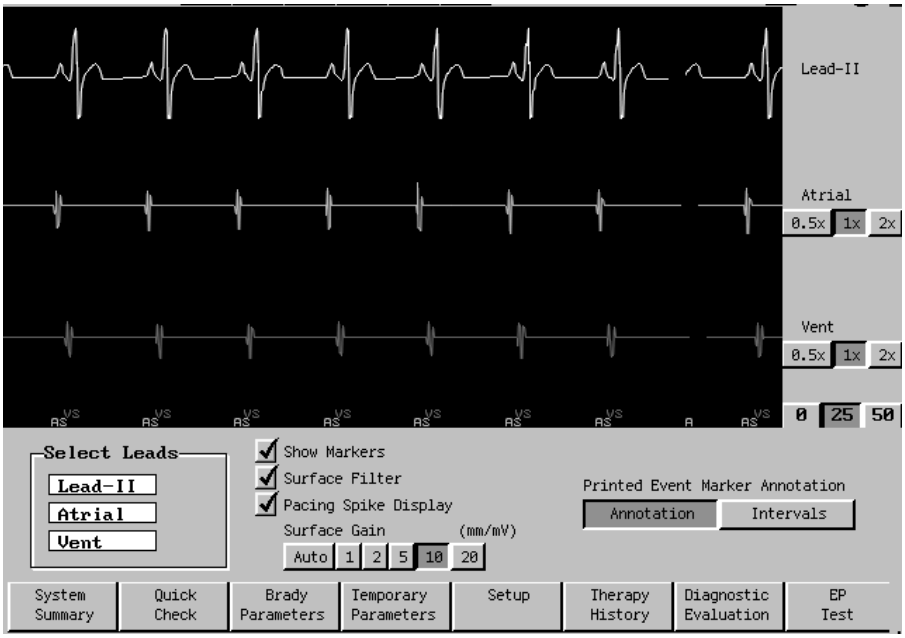


Figure 8-1. The ECG display shows surface ECG traces.

NOTE: *Whenever telemetered atrial and ventricular EGMs are enabled, they will automatically be output to the external analog output jacks (see Appendix B, "External Cable Connections." The ECG display or the PRM printer need not be activated.*

To display a calibration pulse on the PRM (Figure 8-2), press the key labeled ⎍. Press the key labeled ⎽↓⎽ to force the surface trace back to baseline. To print the surface ECG on the PRM printer/recorder, select the desired speed key (10, 25, 50, or 100 mm/sec) on the printer/recorder. To stop the printer/recorder, press the speed key labeled 0 (zero).

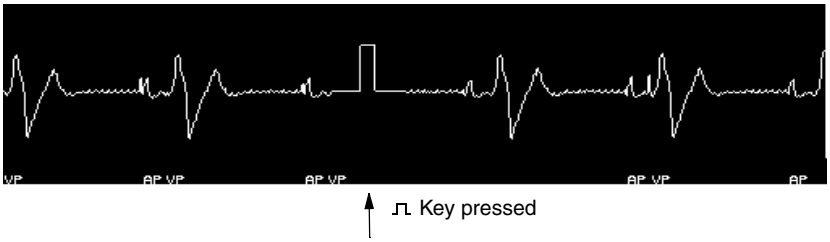


Figure 8-2. A 1-mV calibration pulse for surface ECGs appears on the internal PRM's printout when the ⎍ key is pressed. If Event Markers are active, when the ⎍ key is pressed, a marker legend also will be printed on the PRM printer strip.

Printing to the Internal PRM Printer/Recorder

To print EGMs, the full set of annotated event markers, intervals, and the surface ECG on the PRM printer/recorder, select the desired speed key (10, 25, 50, or 100 mm/sec) on the printer/recorder while the traces are being displayed on the PRM screen.

NOTE: *Event marker annotation definitions (Table 8-1 and Table 8-2) can also be printed by selecting the Marker Legend option on the Choose Reports to Print window. Select the printer icon to open this window.*

Press the ⎍ key (calibrate) to print a list of the event marker annotations, if they are active (Figure 8-2).

To stop the printer/recorder, press the speed key labeled 0 (zero) on the printer/recorder.

Table 8-1. Event Markers for DDD(R) Models (1290, 1291). The markers in bold are included in the subset available when real-time EGMs are selected. (Sheet 1 of 2)

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory/atrial flutter protection	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial sense–in atrial flutter response	AS-FL	AS
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–inserted after atrial flutter protection	AP→	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–atrial pacing preference	AP-PP	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS

Table 8-1. Event Markers for DDD(R) Models (1290, 1291). The markers in bold are included in the subset available when real-time EGMs are selected. (Sheet 2 of 2)

Marker Description	Annotations	
	Printed	Screen
Ventricular sense–AV hysteresis active	VS-Hy	VS
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–ventricular rate regulation	VP-VR	VP
Ventricular pace–sudden brady response	VP-SBR	VP
Ventricular pace–after A-pace during atrial pacing preference	VP-PP	VP

Table 8-2. Event Markers for SSI(R) Model 1190. The markers in bold are included in the subset available when real-time EGMs are selected.

Marker Description	Annotations	
	Printed	**Screen**
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P
Pace–ventricular rate regulation	P-R	P

Printing to an External Printer

The Model 3120 PRM with the Model 2892 CONSULT Software Application also supports printing reports on an external printer using 8.5 x 11-inch/A4 paper. Real-time ECGs and telemetered EGMs are not available on the external printer.

At the end of the initial device interrogation, the printer selection will default to External if the external printer is connected and powered up. If the external printer was not connected or powered up at initial device interrogation but the clinician now wishes to use the external printer, perform the following steps:

1. Connect the external printer as shown in Appendix B, “External Cable Connections.”

2. Power up the printer.

3. Select the External printer on the Choose Reports to Print window. Select the printer icon to open this window. The clinician may use the external printer to print reports while simultaneously using the internal printer to print real-time ECGs and EGMs.

Printing to an External Recorder

To view intracardiac EGMs and the surface ECG on an external recorder, press the desired speed key on the external recorder while the traces are displayed on the PRM screen. See Appendix B, “External Cable Connections” for instructions on connecting the PRM to the external recorder. Refer to the manual for the external recorder for instructions specific to its operation.

OBTAINING A PRINTED REPORT

The Print function can be initiated at any time during a follow-up session. Use the following procedure to print reports:

1. Select the printer icon at the top of the screen to open the Choose Reports to Print window and display available report options (Figure 8-3).

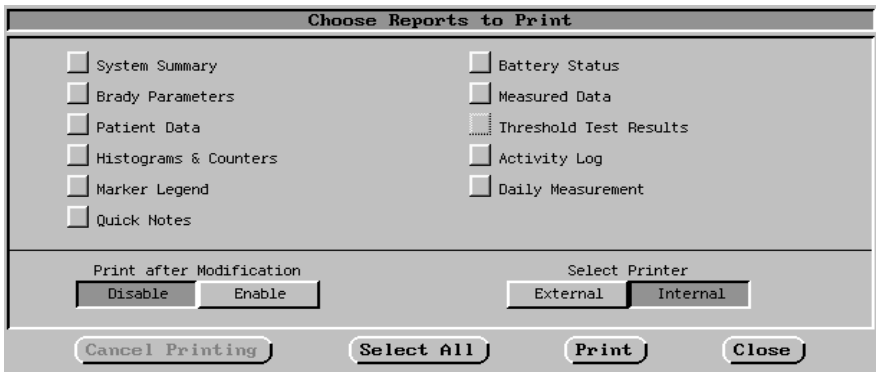


Figure 8-3. The Choose Reports to Print window.

2. Select the desired reports. Choose Select All to print all reports listed.

3. Select the desired printer (External or Internal).

4. Select Print. All selected reports will print.

Other buttons available on the Choose Reports to Print window are described below.

- Select the Close button to close the window without printing.
- Select the Cancel Printing button to stop reports that are in the process of printing.
- Select the Enable button under Print after Modification to trigger the printing of permanent and/or temporary parameter changes as soon as they are programmed.

NOTE: *Be sure to print desired reports prior to selecting Quit or New Patient, since data are erased from the PRM's memory when these actions are performed.*

Printed reports, which are intended to be filed as part of the patient's medical record, also identify the manufacturer, the institution name, the programming device, and the pacemaker name, model number, and serial number.

PACEMAKER MODES OF OPERATION

APPENDIX A

This appendix includes information about the programmable modes available with INSIGNIA I pacemakers. For an explanation of the codes used in pacing, see Table A-1.

PACEMAKER IDENTIFICATION CODES

The identification code of the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG) is based on the following categories:

Table A-1. NASPE/BPEG Generic (NBG) Pacemaker Code[a]

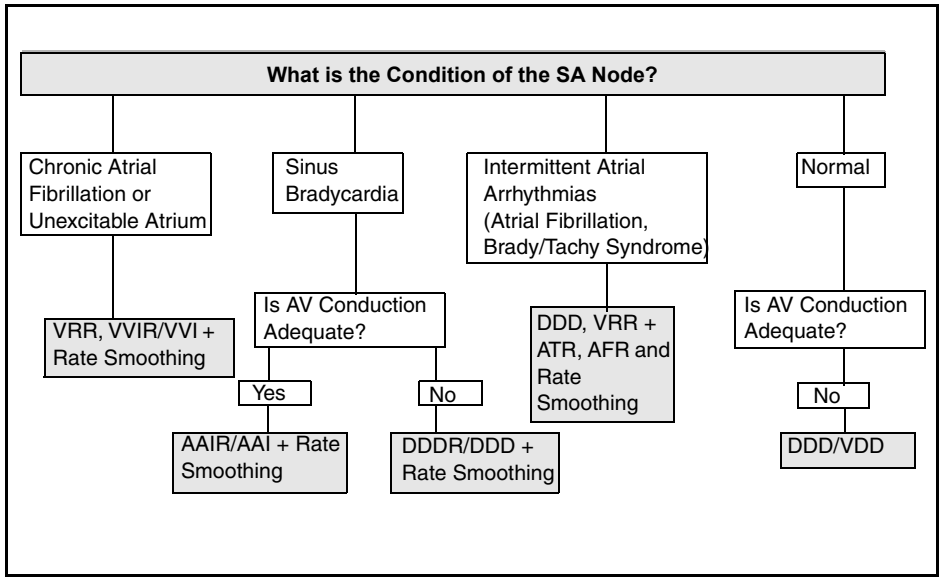
Position	I	II	III	IV	V
Category	**Chambers Paced**	**Chambers Sensed**	**Response to Sensing**	**Programmability, Rate Modulation**	**Antitachyarrhythmia Functions**
Letters	O–None A–Atrium V–Ventricle D–Dual (A&V)	O–None A–Atrium V–Ventricle D–Dual (A&V)	O–None T–Triggered I–Inhibited D–Dual (T&I)	O–None P–Simple Programmable M–Multi-Programmable C–Communicating R–Rate Modulation	O–None P–Pacing (Antitachyarrhythmia) S–Shock D–Dual (P&S)
Mfgrs Designation Only	S–Single (A or V)	S–Single (A or V)			

a. Bernstein A, Camm AJ, Fletcher RD, et al: The NASPE/BPEG generic pacemaker code for anti-bradyarrhythmia and adaptive-rate pacing and antitachyarrhythmia devices. *PACE* 1987;10 (July):795.

Positions I, II, and III identify the chamber paced, chamber sensed, and mode of response to conventional (P- and/or R-wave) sensing, respectively. The fourth position indicates rate modulation (adaptive-rate pacing). For an explanation of the other NASPE/BPEG codes, consult the article footnoted in Table A-1.

OPTIMAL PACING MODE DECISION TREE

The following graphic may be used to assist the clinician in prescribing the most appropriate mode for a specific patient.



AVAILABLE MODES

The INSIGNIA I pacemakers can be programmed to any of the following modes, depending on the model:

DDDR, DDIR, DOOR modes combine adaptive-rate pacing with conventional dual-chamber operation.

VVIR, AAIR, SSIR, VOOR, AOOR, SOOR modes combine adaptive-rate pacing with single-chamber demand pacing.

The other available pacing modes are DDD, DDI, DOO, VDD, VVI, AAI, SSI, VOO, AOO, SOO, VVT, AAT, and SST.

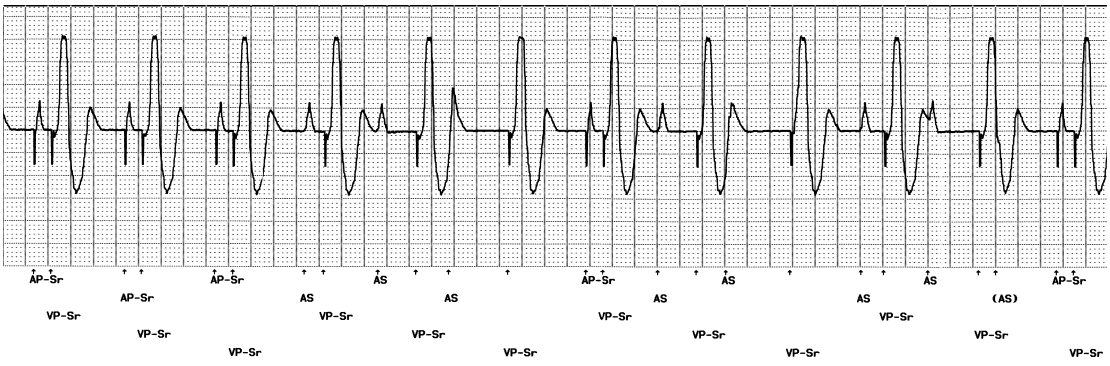
The remainder of this appendix describes each of the modes listed above. ODO, OSO, OOO modes are available only in temporary operation and are used for diagnostic purposes.

DDD(R) Mode

In the absence of sensed P- and R-waves, pacing pulses will be delivered to the atrium and the ventricle at the lower rate limit (DDD) or the sensor-indicated rate (DDDR), separated by the programmed AV delay. A sensed P-wave will inhibit an atrial pace and start the AV delay. At the end of the AV delay, a ventricular pace will be delivered unless inhibited by a sensed R-wave.

DDI(R) Mode

In the absence of sensed P- and R-waves, pacing pulses will be delivered to the atrium and the ventricle at the lower rate limit (DDI) or the sensor-indicated rate (DDIR), separated by the AV delay. A sensed P-wave will inhibit the atrial pace but will not start the AV delay.

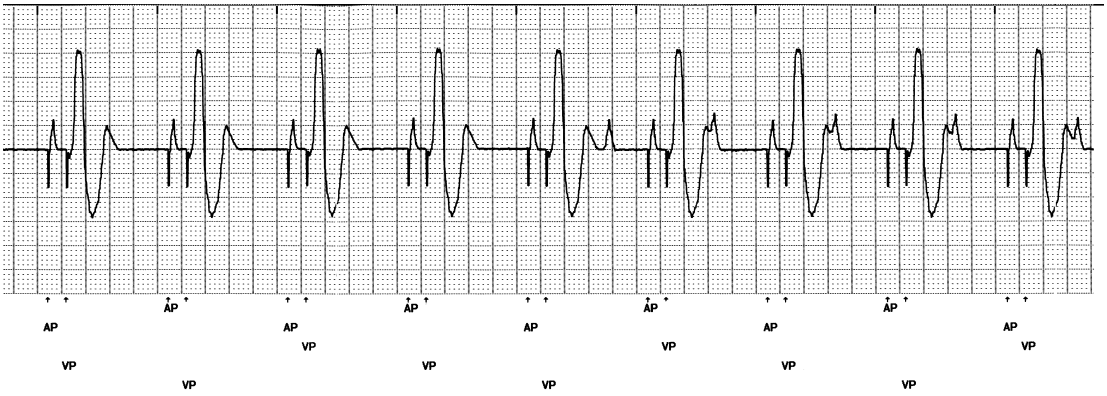


DOO(R) Mode

Pacing pulses will be delivered asynchronously to the atrium and the ventricle at the lower rate limit (DOO) or the sensor-indicated rate (DOOR), separated by the programmed AV delay. Intrinsic events will not inhibit nor trigger pacing in either chamber.

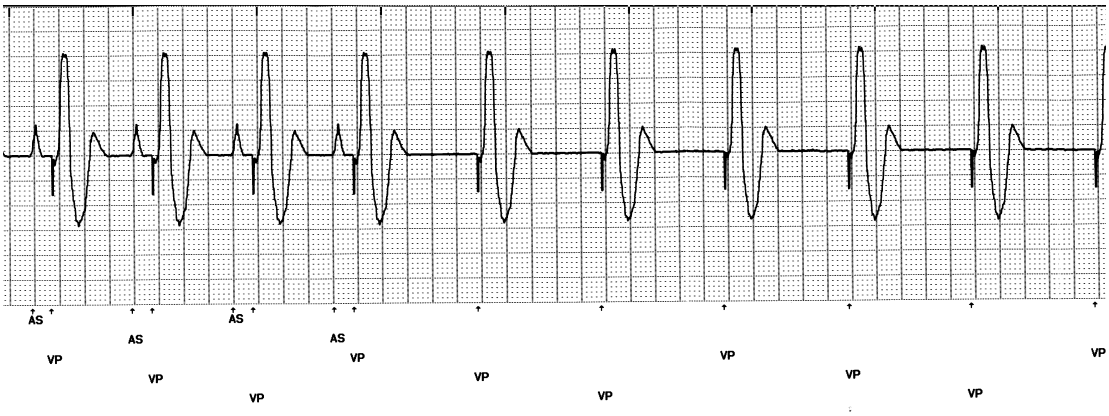
Besides being directly programmable, the DOO mode is also the magnet mode of the corresponding dual-chamber modes, except for VOO, which is the magnet mode for VDD mode.

The DOO mode may be used intraoperatively to reduce the likelihood of inhibition during electrocautery.



VDD Mode

In the absence of sensed P- or R-waves, pacing pulses will be delivered to the ventricle at the programmed lower rate limit. A sensed P-wave will start the AV delay. At the end of the AV delay, a ventricular pace will be delivered unless inhibited by a sensed R-wave. A sensed R-wave or a paced ventricular event will reset the pacemaker's escape interval.

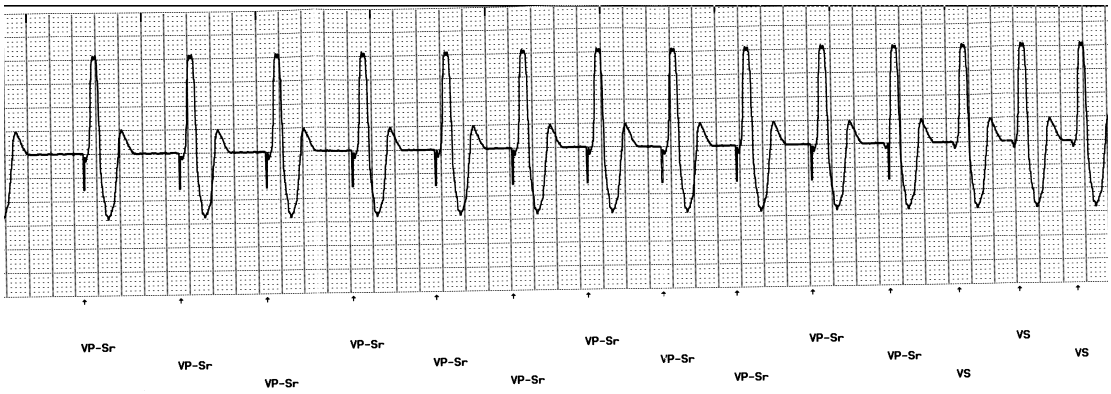


AAI(R) Mode

In AAI(R) mode, sensing and pacing occur only in the atrium. In the absence of sensed events, pacing pulses will be delivered to the atrium at the lower rate limit (AAI) or the sensor-indicated rate (AAIR). A sensed P-wave or a paced atrial event will reset the pacemaker's escape interval.

VVI(R) Mode

In VVI(R) mode, sensing and pacing occur only in the ventricle. In the absence of sensed events, pacing pulses will be delivered to the ventricle at the lower rate limit (VVI) or the sensor-indicated rate (VVIR). A sensed R-wave or a paced ventricular event will reset the pacemaker's escape interval.



AOO(R) Mode

Pacing pulses will be delivered asynchronously to the atrium at the lower rate limit (AOO) or the sensor-indicated rate (AOOR). Intrinsic events will not inhibit or trigger pacing in the atrium.

Besides being directly programmable, AOO is the magnet mode of the AAI(R), AOO(R), and AAT modes.

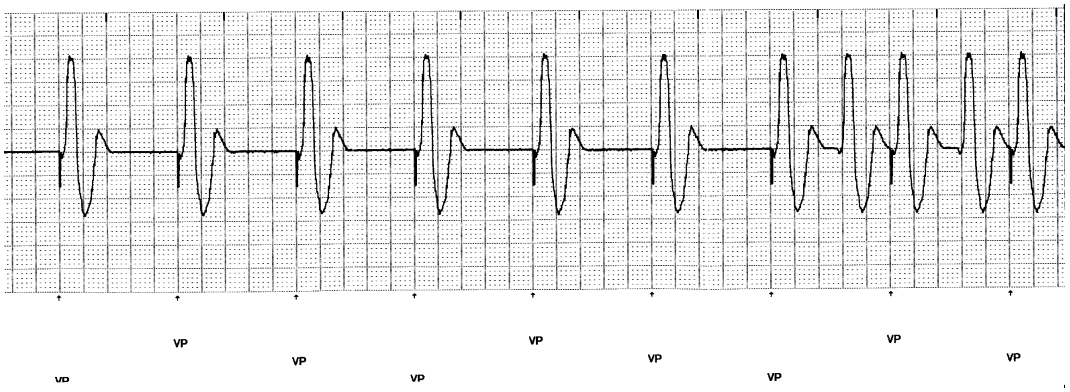
The asynchronous AOO mode may be used intraoperatively to reduce the likelihood of inhibition during electrocautery.

VOO(R) Mode

Pacing pulses will be delivered asynchronously to the ventricle at the lower rate limit (VOO) or the sensor-indicated rate (VOOR). Intrinsic events will not inhibit or trigger pacing in the ventricle.

Besides being directly programmable, VOO mode is the magnet mode of the VVI(R), VOO(R), and VVT modes.

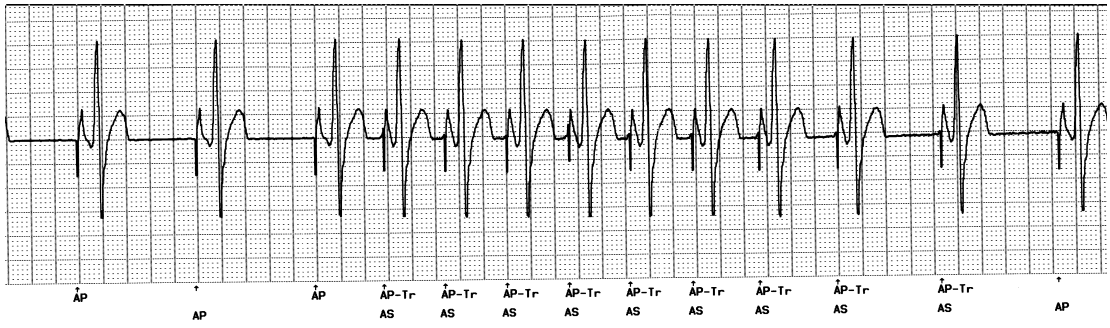
The asynchronous VOO mode may be used intraoperatively to reduce the likelihood of inhibition during electrocautery.



AAT Mode

In the absence of sensed events, pacing pulses will be delivered to the atrium at the lower rate limit. Sensed events will trigger an atrial pulse and reset the escape interval of the pacemaker.

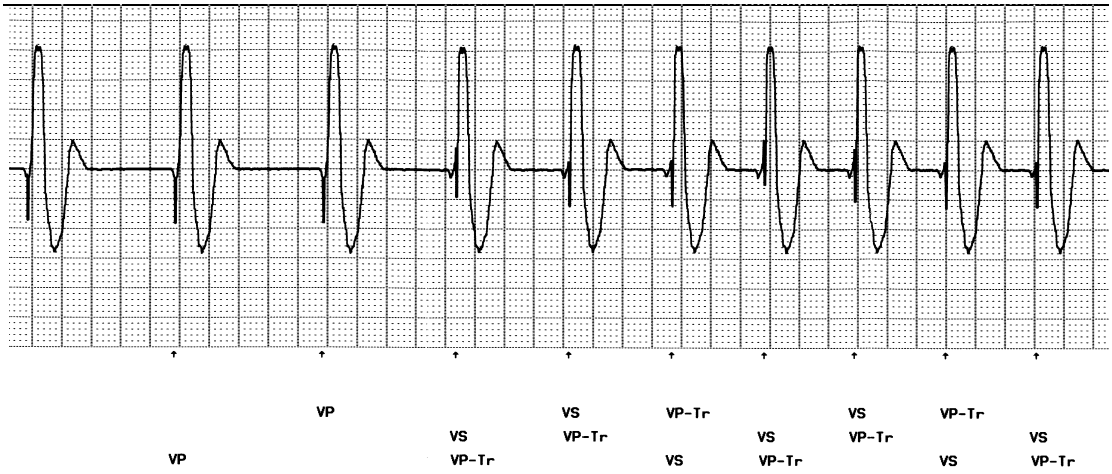
Using the AAT mode outside of a diagnostic setting is not recommended due to the potential for triggered pacing in response to oversensing.



VVT Mode

In the absence of sensed events, pacing pulses will be delivered to the ventricle at the lower rate limit. Sensed events will trigger a ventricular pulse and reset the escape interval of the pacemaker.

Using the VVT mode outside of a diagnostic setting is not recommended due to the potential for triggered pacing in response to oversensing.



EXTERNAL CABLE CONNECTIONS

APPENDIX B

The following cables are required for use with the Model 3120 Programmer/ Recorder/Monitor when using the configurations described in this appendix.

- External Recorder Cable: a six-channel DIN – 6 BNC cables (color-coded and numbered) for connection of the PRM analog output signals to another strip chart recorder or monitor.
- Patient ECG Cable: a six-pin amphenol ECG cable for connecting the patient directly to the PRM.
- ECG-BNC Slave Cable used for input of patient ECG signals to the PRM from an external monitor or recorder.
- Sterilizable Telemetry Wand.

NOTE: *Refer to the ZOOM LATITUDE System Operator's Manual for instructions on connecting an external monitor.*

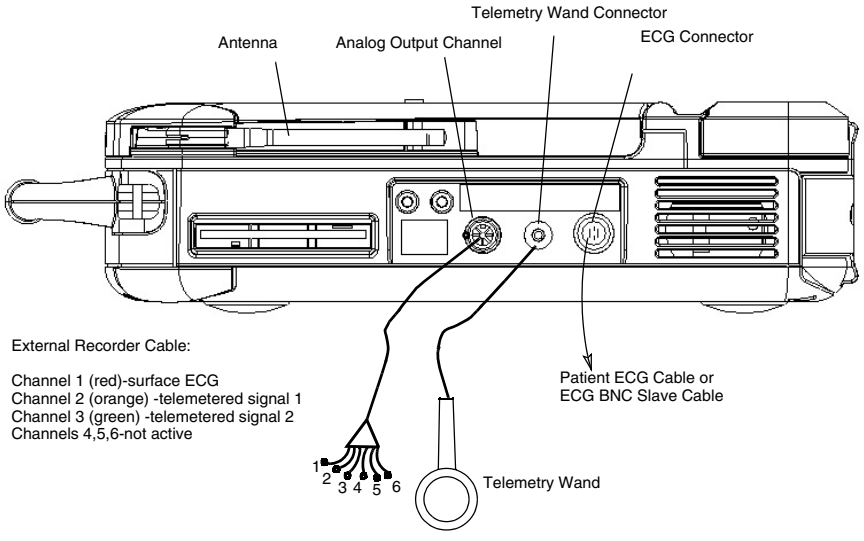


Figure B-1. Cable connections for the Model 3120 PRM.

The PRM also has two adapter kits that adapt cables with BNC connectors to fit other sockets:

- Model 6930: BNC–dual banana plug, BNC–pin tip, BNC–alligator clip adapters
- Model 6934: BNC-phono adapter

Refer to Figure B-1 for cable connections.

Surface ECG Connections

The cable–electrode configurations frequently used to generate surface ECG include the following:

- Patient to external recorder to PRM (Figure B-2 on page B-3)
- Patient to PRM to external recorder (Figure B-3 on page B-4)
- Simultaneous connections from patient to PRM and patient to external recorder (Figure B-4 on page B-5)

NOTE: *Annotated event markers cannot be sent to an external recorder.*

Patient-Recorder-PRM Connection

To display a tracing on an external recorder and the PRM without using the patient ECG cable, set up equipment as shown in Figure B-2.

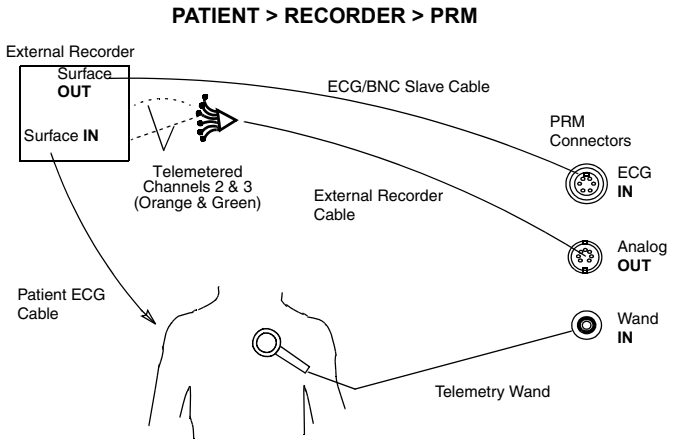


Figure B-2. External recorder gets surface signal and sends it to the PRM. PRM sends electrograms to the external recorder.

1. Connect the external recorder's patient ECG leads to the appropriate electrodes.

2. Route the surface ECG channel to the PRM using the slaved ECG-BNC cable. (Use the Model 6930 or 6934 adapter cables, if necessary.)

3. Connect the orange and green connectors of the external recorder cable to the external recorder for telemetered signals.

4. Adjust gain and filters on the external recorder.

5. Connect the telemetry wand and verify proper position. Make sure the wand cord does not cross other cables.

6. Setup is now complete. Refer to "Displaying Surface ECGs, EGMs, and Event Markers" on page 8-3.

Patient-PRM-Recorder Connection

To display a tracing on the PRM and an external strip chart recorder using the patient ECG cables, set up equipment as shown in Figure B-3.

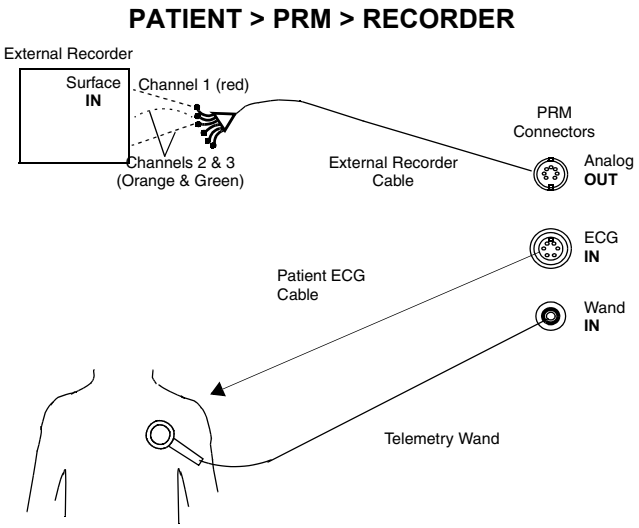


Figure B-3. PRM receives surface signal via the patient cable and then sends surface and telemetered channels to the external strip chart recorder.

1. Connect the external recorder cable from the PRM to the external recorder input ports.

   - Channel 1 (red) for a surface trace
   - Channel 2 (orange) for telemetered signal 1
   - Channel 3 (green) for telemetered signal 2

2. Connect the patient ECG cable to the patient electrodes.

3. Verify proper telemetry wand position.

4. Setup is now complete. Refer to “Displaying Surface ECGs, EGMs, and Event Markers” on page 8-3.

Parallel Connection

To display traces on both PRM and ECG recorders using two different patient ECG leads, set up the equipment as shown in Figure B-4.

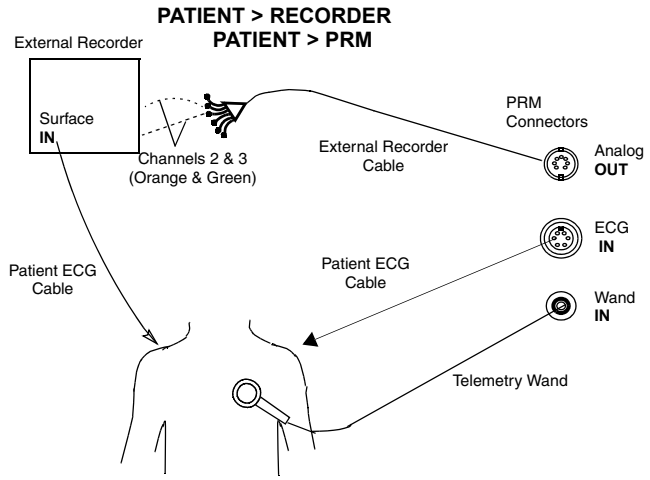


Figure B-4. Parallel connection of PRM surface ECG leads to the appropriate limb electrodes.

1. Connect the external recorder patient ECG leads to the appropriate limb electrodes.

2. Connect the patient ECG cable to patient electrode.

3. Connect the external recorder cable from the PRM to the external recorder.

NOTE: *This configuration will add the most noise to the tracings of the two PRM-recorder configurations.*

4. Adjust gain and filters on the external recorder.

5. Setup is now complete. Refer to “Displaying Surface ECGs, EGMs, and Event Markers” on page 8-3

NOTE: *The right leg electrode on the patient ECG cable is a driven ground. When connecting the PRM and an external ECG monitor in parallel, the driven grounds for the two instruments must be connected to the same patient limb (e.g., right leg); otherwise noise problems will occur.*

Troubleshooting

No Tracing on PRM

If the hookups described above do not yield a tracing on the PRM, check the following PRM functions:

1. Make sure the appropriate sweep speed on the ECG window is selected.

2. Ensure the traces selection is made (surface ECGs, telemetered EGMs, and/or markers).

3. Recheck cable connections as shown in figures above.

If the hook-ups do not yield a satisfactory tracing, contact Guidant Technical Services for assistance.

Noisy Tracing

If the hookups yield a recording with background noise, check the following:

1. Check the cable connections.

2. Check the electrode and skin conditions and electrode placement.

3. Route the ECG cable directly from the PRM to the patient and away from power cords, the telemetry wand cord, and other room equipment.

Optimizing the Quality of ECG Tracings

To improve the clarity of the ECG tracings and optimize the signals, try one or more of the following procedures:

- Change the surface ECG amplitude to 2x gain.

- Route the ECG cables away from other equipment. Unwrap the cables from the power cord or telemetry wand cable if they are intertwined.

- Ensure that there is good contact between the skin and the electrodes. Prepping the skin with ethanol and using electrode gel can make a significant difference in ECG signal quality.

PROGRAMMABLE PACING PARAMETERS AND SPECIFICATIONS

APPENDIX C

Table C-1. Programmable Pacing Parameters (Sheet 3 of 4)

Parameter	Options, Increments, Ranges	Nominals[a]	
		DR Models 1290, 1291	SR Model 1190
Mode–dual chamber	DDD(R), DDI(R), DOO(R), VDD, VVT, VVI(R), VOO(R), AAT, AAI(R), AOO(R), ODO, OOO (Modes beginning with O available in temporary mode only)	DDD	
Mode–single chamber[b]	SSI(R), SOO(R), SST, OSO, OOO (Modes beginning with O available in temporary mode only)		SSI
Lower Rate Limit[c, d] (ppm)	30, 35, ..., 50, 51, ..., 90, 95, ..., 150 (155, 160, ..., 180, 190..., 300, 320, ..., 380 in temporary mode only, and only in SSI, SOO, VVI, VOO, AAI, AOO modes)	60 (1000 ms)	
Max Tracking Rate[c] (ppm)	80, 85, ..., 185	130 (462 ms)	130 (462 ms) SST only
Max Sensor Rate[c j] (ppm)	80, 85, ..., 185	130 (462 ms)	
A or V Pulse Width[e] (ms)	0.05, 0.1, 0.2, ..., 1.0	0.4 NOTE: When Automatic Capture is active, the pulse width is fixed at 0.4 ms.	
A or V Amplitude (V)	Atrial–0.1, 0.2, ..., 3.5, 4.0, 4.5, 5.0, 6.5 Ventricle–Auto, 0.1, 0.2, ..., 3.5, 4.0, 4.5, 5.0, 6.5	3.5	
A or V Sensitivity[f] (mV)	Atrial–Auto, 0.15, 0.25, 0.5, 0.75, 1.0, 1.5, ..., 8.0, 9.0, 10.0 Ventricular/Single–Auto, 0.25, 0.5, 0.75, 1.0, 1.5, ..., 8.0, 9.0, 10.0	A–0.75, V–2.5	2.5
Hysteresis Offset (ppm)	Off, -5, -10, ..., -80	Off	
Search Hysteresis	Off, 256–4096 cycles in powers of 2	Off	
Rate Smoothing (%)	Off, 3%, 6%, ..., 24% Separately programmable for increase and decrease	Off	

Table C-1. Programmable Pacing Parameters (Sheet 3 of 4)

Parameter	Options, Increments, Ranges	Nominals[a]	
		DR Models 1290, 1291	SR Model 1190
Max Pacing Rate[c] (ppm)	80, 85, ..., 185	130 (462 ms)	
A or V Lead Configuration	Unipolar, Bipolar, Split	Bipolar	
Safety Switch	On, Off, Reset	Off	
Magnet Response	Off, Async, EGM	Async	
AV Delay[g]			
AV Delay (paced)[c] (ms)	10, 20, ..., 300[h]	150	
Dynamic AV Delay	On, Off	On	
Maximum AV Delay[c] (ms)	20, 30, ..., 300	150	
Minimum AV Delay[c] (ms)	10, 20, ..., 290	80	
Sensed AV Offset[c] (ms)	Off, -100, -90, ..., -10	-30	
AV Search Interval	Off, 32–1024 cycles in powers of 2	Off	
AV Delay Increase (%)	10, 20, ..., 100	30	
Refractory Periods[i]			
PVARP (fixed)[g] (ms)	150, 160, ..., 500	250	
A Refractory Period (ms)	150, 160, ..., 500	300	
V Refractory Period (ms)	200, 210, ..., 500	250	
Dynamic PVARP[g]	On, Off	On	
Maximum PVARP[g] (ms)	160, 170, ..., 500	250	
Minimum PVARP[g] (ms)	150, 160, ..., 490	240	
PVARP after PVC/PAC[g] (ms)	Off, 150, 200, ..., 500	400	
A-Blanking after V-Pace (ms)	30, 40, ..., 200	120	
V-Blanking after A-Pace (ms)	30, 40, ..., 200	40	
Sensors[i]			
Accelerometer	On, Off, ATR-Only[k]	Off	

Table C-1. Programmable Pacing Parameters (Sheet 3 of 4)

Parameter	Options, Increments, Ranges	Nominals[a]	
		DR Models 1290, 1291	SR Model 1190
Response Factor	Passive, 1, 2, ..., 16	8	
Activity Threshold	V-Low, Low, Med-Lo, Medium, Med-Hi, High, V-High	Medium	
Reaction Time (sec)	10, 20, ..., 50	30	
Recovery Time (min)	2, 3, ..., 16	2	
Minute Ventilation	Off, On, 4→ On-A, 4→ On-V (4→ On for single-chamber devices)	Off	
Response Factor	Passive, 1, 2, ..., 16	3	
High Rate Response Factor (%)	Off, 55, 70, 85	70	
High Rate Break Point (ppm)	80, 85, ..., 185,	110	
Time Dependent Blended Sensor	On, Off	Off	
AutoLifestyle	On, Off, Reset	On	
4-Minute Fast Walk Within 30 Minutes	Yes, No	Yes	
A-Tachy Response (ATR)[g]			
ATR	On, Off	On	
Trigger Rate (ppm)	100, 105, ..., 200	170	
Fallback Mode	VDI(R), DDI(R)	VDI	
Duration (cycles)	0, 8-2048 in powers of 2	8	
Fallback Time (sec)	0, 5, ..., 120	30	
ATR Entry Count (cycles)	1, 2, ..., 8	8	
ATR Exit Count (cycles)	1, 2, ..., 8	8	
ATR Lower Rate Limit (ppm)	30, 35, ..., 50, 51, ..., 90, 95, ..., 150 ATR Lower Rate Limit must be equal to or greater than the permanent Lower Rate Limit.	70	
Atrial Flutter Response[g] (ppm)	Off, 130, 140, ..., 230	Off (except DDI(R)–230)	
PMT Termination[g]	On, Off	On	

Table C-1. Programmable Pacing Parameters (Sheet 3 of 4)

Parameter	Options, Increments, Ranges	Nominals[a]	
		DR Models 1290, 1291	SR Model 1190
Ventricular Rate Regulation (VRR)			
VRR	On, Off	On	Off
VRR Max Pacing Rate (ppm)	60, 65, ..., 150	110	
Sudden Brady Response (SBR)			
SBR	On, Off	Off	
SBR Detect Time (min)	1, 2, ..., 15	5	
SBR Number of Beats (cycles)	1, 2, ..., 8	4	
SBR Therapy Duration (min)	1, 2, ..., 15	10	
SBR Therapy Rate Offset (ppm)	5, 10, ..., 40	5	
SBR MV Offset (%)	Off, 10, 20, ..., 50	Off	

a. Nominal values are for all applicable modes unless otherwise stated.
b. S refers to a single chamber, either atrium or ventricle. For example, SSI indicates programmability to AAI or VVI. Refer to Appendix A for complete explanation of pacemaker identification codes.
c. Tolerance is ± 5 ms of programmed interval, independent of load (100–2500 Ω) temperature (20–43°C), and battery voltage (BOL–EOL).
d. The lower rate limit is the same as basic rate, interference pulse rate, and escape interval.
e. Tolerance is ± 0.02 ms, independent of load (100–2500 Ω), temperature (20–43°C), and battery voltage (BOL–EOL).
f. Programming sensitivity to a less sensitive setting (i.e., a higher value) always results in the pacemaker becoming less sensitive to intrinsic signals, and conversely, programming to a more sensitive setting always results in the pacemaker becoming more sensitive. Tolerance with a 25-Hz haversine test signal is ± 40% (0.15 mV is ± 50%). Levels using the CENELEC test signal are higher by a factor of 1.2 with the same tolerance. (e.g., the 1.5 mV setting will test at 1.2 mV–1.8 mV using a haversine, and 1.44 mV–2.16 mV using the CENELEC test signal. Input impedance is >90 KΩ.)
g. Dual-chamber modes only.
h. The Automatic Capture feature may add an additional 64 ms AV Hysteresis in order to accommodate a fusion check for a maximum AV Hysteresis delay of 364 ms.
i. Tolerance is ± 3 ms of programmed interval, independent of load (100–2500 Ω), temperature (20–43°C), and battery voltage (BOL–EOL).
j. Adaptive-rate modes only.
k. ATR Only is not a user selectable setting. It is set when the primary mode is not rate-responsive and a rate-responsive ATR Fallback Mode is selected.

Table C-2. Mechanical Characteristics

All Models	
Shape of can	Modified elliptical
Envelope	Hermetically sealed titanium
Lead barrel	IS-1[a] and 3.2 mm[b]
Header material	Polyurethane
Indifferent electrode material	Titanium
Shape of indifferent electrode	Triangular
Surface area of indifferent electrode	74 mm^2 (DR, IS-1 models); 61 mm^2 (DR, 3.2-mm models), 54 mm^2 (SR, IS-1 models)
Shape of uncoated window[c]	Modified elliptical
Surface area of uncoated window[c]	1290 –611 mm2
Power supply	2.8-V solid-state lithium-iodine battery
Setscrew style	Pre-inserted captive setscrews and seal plugs[d]

a. Accepts IS-1 unipolar/bipolar leads. (IS-1 refers to the international standard ISO 5841.3:1992.)
b. Accepts IS-1 or 3.2-mm unipolar/bipolar leads.
c. Applies only to models available in coated configuration.
d. All devices use a size 2 hex wrench.

Table C-3. STAT, Reset, and Ship Parameter Values

Parameter	STAT (VVI/SSI)[a]	Reset (VVI/SSI)[a]	Ship (DOO or SOO)
Pacing rate (ppm)	65	65	30
Pulse Width (ms)	1.0	1.0	0.4
Amplitude (V)	5.0	5.0	3.5
Sensitivity (mV)	1.5	1.5	NA
Refractory (ms)	320	320	NA
Lead Configuration	Unipolar	Depends on lead[b]	Bipolar
Magnet Response	As Programmed	Off	Off

a. All other parameters normally available in these modes are disabled.
b. Lead Configuration will be Unipolar if a unipolar lead is implanted, and Bipolar if a bipolar lead is implanted.

Table C-4. Battery Information[a]

Device Model	Battery Model	Usable Battery Capacity (Ah)	BOL Voltage (V)	Battery Capacity at ERT (Ah)
1291	WGL 9841/Litronik 2269	1.53	2.8	0.087
1290	WGL 9840/Litronik 1869	1.04	2.8	0.105
1190	WGL 9840/Litronik 1869	1.04	2.8	0.067

a. The INSIGNIA I Ultra pacemakers use a single-cell lithium-iodine battery. The cell slowly decreases in output voltage over its lifetime.

Table C-5. Lead Adapters[a]

Lead Terminal	IS-1 Only	IS-1/3.2 mm
	Models 1190, 1290	**Model 1291**
Unipolar IS-1	Direct connection	Direct connection
Bipolar IS-1	Direct connection	Direct connection
Unipolar 3.2 mm	Model 6986	Direct connection
Bipolar 3.2 mm	Model 6986	Direct connection
Bipolar 2 x 5 (4.75 mm) Bifurcated	Model 6024	Model 6024
Unipolar 5 (4.75 mm)	Not available	Not available
Unipolar 6 (5.38 mm)	Not available	Not available

a. Guidant leads are recommended for use with these pacemakers.

Table C-6. Telemetry Data Tolerances

Lead impedance repeatability	± 20%, amplitude ≤ 5.0 V, ± 40%, amplitude > 5.0 V
P- and R-wave amplitude (V)	
Atrial	0.15 ± 60%, 0.25-10.0 = ± 50%
Ventricular	0.25-10.0 = ± 50%

Table C-7. Parameter Values During Magnet Test

Magnet Response	Async
BOL rate	100 ppm
ERN rate	90 ppm
ERT rate	85 ppm
EOL rate	≤ 85 ppm
Mode	DOO or SOO
AV Delay	100 ms
Amplitude	Value programmed
Pulse width	Value programmed[a]
Sensitivity	NA
Refractory	NA
Sensor parameters	NA
Lead configuration	Value programmed

a. When Automatic Capture is programmed Off, the third pulse (and only the third pulse) issued during the magnet test is reduced by 50%.

Table C-8. Event Markers for DDDR Models 1290 and 1291. The markers in bold are included in the subset available when real-time EGMs are selected. (Sheet 1 of 2)

Marker Description	Annotations	
	Printed	Screen
PVARP extension end	PVP→	None
Atrial tachy fallback end	ATR-End	None
PMT detection and PVARP extension	PMT-B	None
Atrial tachycardia sense–count up	ATR↑	AS
Atrial tachycardia sense–count down	ATR↓	AS
Atrial tachy response–duration started	ATR-Dur	None
Atrial tachy response–fallback started	ATR-FB	None
Atrial sense–after refractory/atrial flutter protection	AS	AS
Atrial sense–rate hysteresis active	AS-Hy	AS
Atrial sense–during PVARP	(AS)	None
Atrial sense–in atrial flutter response	AS-FL	AS
Atrial pace–rate hysteresis active	AP-Hy	AP
Atrial pace–lower rate	AP	AP
Atrial pace–down rate smoothing	AP↓	AP
Atrial pace–up rate smoothing	AP↑	AP
Atrial pace–trigger mode	AP-Tr	AP
Atrial pace–sensor	AP-Sr	AP
Atrial pace–inserted after atrial flutter protection	AP→	AP
Atrial pace–sense amp noise	AP-Ns	AP
Atrial pace–fallback	AP-FB	AP
Atrial pace–atrial pacing preference	AP-PP	AP
Atrial pace–sudden brady response	AP-SBR	AP
Ventricular sense–after refractory	VS	VS
Ventricular sense–AV hysteresis active	VS-Hy	VS

Table C-8. Event Markers for DDDR Models 1290 and 1291. The markers in bold are included in the subset available when real-time EGMs are selected. (Sheet 1 of 2)

Marker Description	Annotations	
	Printed	Screen
Ventricular sense–rate hysteresis active	VS-Hy	VS
PVC after refractory	PVC	VS
Ventricular sense–during refractory	(VS)	None
Ventricular pace–at hysteresis rate	VP-Hy	VP
Ventricular pace–lower rate	VP	VP
Ventricular pace–down rate smoothing	VP↓	VP
Ventricular pace–up rate smoothing	VP↑	VP
Ventricular pace–trigger mode	VP-Tr	VP
Ventricular pace–in atrial tachy response	VP-FB	VP
Ventricular pace–sensor	VP-Sr	VP
Ventricular pace–atrial tracked	VP	VP
Ventricular pace–atrial tracked, MTR	VP-MT	VP
Ventricular pace–sense amp noise	VP-Ns	VP
Ventricular pace–ventricular rate regulation	VP-VR	VP
Ventricular pace–sudden brady response	VP-SBR	VP
Ventricular pace–after A-pace during atrial pacing preference	VP-PP	VP

Table C-9. Event Markers for SSIR Model 1190. The markers in bold are included in the subset available when real-time EGMs are selected.

Marker Description	Annotations	
	Printed	Screen
Sense–after refractory	S	S
Sense–rate hysteresis active	S-Hy	S
Sense–during refractory	(S)	None
Pace–at hysteresis rate	P-Hy	P
Pace–lower rate	P	P
Pace–down rate smoothing	P↓	P
Pace–up rate smoothing	P↑	P
Pace–trigger mode	P-Tr	P
Pace–sensor	P-Sr	P
Pace–sense amp noise	P-Ns	P
Pace–ventricular rate regulation	P-R	P

Numerics

A

B

C

D

E

N

O

P

Q

R

S

T

U

V

W

X

Xray identifier 3-4

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