

System Guide

VITALITY[®] 2

Implantable

Cardioverter Defibrillator

MODELS T165/T167/T175/T177

RESTRICTED DEVICE:
Federal law (USA) restricts
this device to sale, distribution,
and use by, or on the lawful order
of a physician trained or experi-
enced in device implant and fol-

GUIDANT

ABOUT THIS MANUAL

This ICD System Guide contains information about the VITALITY 2 ICD system used with the Model 2857 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.

The VITALITY 2 family of products include dual-chamber and single-chamber models. This manual is written for full description of dual-chamber devices. For use with single-chamber devices, ignore references to dual-chamber features, such as atrial parameters or dual-chamber modes. When a single-chamber mode is interrogated, the PRM screens will reflect only the features available for single-chamber devices.



All PRM screen illustrations in this manual show typical screens for a VITALITY 2 DR pulse generator. The screens you see when interrogating or programming other pulse generator models will be similar but may not include any dual-chamber or adaptive-rate fields, depending on the model or programmed pacing mode.

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

PRM KEYS	The names of the PRM keys will appear in capital letters (eg, 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.

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Graphical Symbols for Medical Device Labeling

Symbol	Definition
	Opening instructions.
	Wand placement indicator

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INFORMATION FOR USE

CHAPTER 1

This chapter contains the following topics:

- “Device Description” on page 1-1
- “Indications and Usage” on page 1-3
- “Contraindications” on page 1-3
- “Warnings” on page 1-3
- “Precautions” on page 1-4
- “Adverse Events” on page 1-12
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DEVICE DESCRIPTION

The Guidant VITALITY 2 implantable cardioverter defibrillators (ICDs) are designed to detect and terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) and provide bradycardia therapy (atrial and ventricular pacing). Therapies include

both low- and high-energy shocks using either a biphasic or monophasic waveform. The VITALITY 2 models use the Guidant TRIAD electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the Guidant ENDOTAK two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. VITALITY 2 devices also offer a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias.

Bradycardia pacing, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy. The devices denoted with DR offer dual-chamber bradycardia features (atrial and/or ventricular pacing and sensing), and the devices denoted with VR offer single-chamber bradycardia features (ventricular pacing and sensing).

The pulse generator, along with compatible commercially available pace/sense leads and cardioversion/defibrillation leads, constitutes the implantable portion of the ICD systems. The device's small, physiologic shape minimizes pocket size and may minimize device migration. The lead systems for the VITALITY 2 ICD pulse generators are implanted using either transvenous or transthoracic techniques. The external portion of the ICD systems allows interrogation and programming of the pulse generator, as well as access to the device's diagnostic features. The external components consist of an accessory telemetry wand, the Model 2857 Software Application, and the ZOOM LATITUDE Programming System, which includes the Model 3120 Programmer/Recorder/Monitor (PRM). VITALITY 2 systems can be programmed to provide a variety of detection options. They also can provide noninvasive diagnostic testing and therapy history data. In addition, customized follow-up and implant parameters can be programmed and saved.

Related Manuals and Information Tools

The Operator's Manual for the Guidant Programmer/Recorder/Monitor provides information specific to the programmer, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads. The Physician's Technical Manual is packaged with the pulse generator and provides the information needed to implant the device at nominal parameter settings. All information in the Physician's Technical Manual is also included in this manual.

INDICATIONS AND USAGE

Guidant ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias.

CONTRAINDICATIONS

Use of the VITALITY 2 pulse generators are contraindicated in:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning
- Patients who have a unipolar pacemaker

WARNINGS

General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the ICD system. Such damage can result in injury to or death of the patient.
- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or post-mortem procedures to avoid inadvertent high voltage shocks.
- **Backup defibrillation protection.** Always have sterile external and internal defibrillation protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

- **Magnetic resonance imaging (MRI) exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Diathermy.** Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator.

Programming and Device Operation

- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.)

Implant Related

- **Separate pulse generator.** Do not use this pulse generator with another CRM pulse generator. This combination could cause pulse generator interaction resulting in patient injury or a lack of therapy delivery.

PRECAUTIONS

Clinical Considerations

- **Pacemaker-mediated tachycardia (PMT).** Retrograde conduction combined with a short PVARP might induce PMT.

Sterilization, Storage, and Handling

- **For single use only—do not resterilize devices.** Do not resterilize the device or the accessories packaged with it because the effectiveness of resterilization cannot be ensured.
- **If package is damaged.** The pulse generator blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator 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.
- **Storage temperature and equilibration.** Recommended storage temperatures are 0°–50°C (32°–122°F). Allow the device to reach a proper temperature

before programming or implanting the device because temperature extremes may affect initial device function.

- **Device storage.** Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage.
- **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.

Implantation and Device Programming

- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.
- **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- **Telemetry wand.** Make sure the telemetry wand is connected to the PRM system and that it is available throughout the session. Verify that the wand cord is within reach of the pulse generator.
- **Programming for supraventricular tachyarrhythmias (SVTs).** Determine if the device and programmable options are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy.
- **Device communication.** Use only the designated PRM and software application to communicate with the pulse generator.
- **STAT PACE settings.** When a pulse generator is programmed to STAT PACE settings, it will continue to pace at the high-energy STAT PACE values if it is not reprogrammed. The use of STAT PACE parameters will decrease device longevity.
- **Pacing and sensing margins.** Consider lead maturation in your choice of pacing amplitude, pacing pulse width, and sensitivity settings.

- An acute pacing threshold greater than 1.5 V or a chronic pacing threshold greater than 3 V can result in loss of capture because thresholds may increase over time.
- An R-wave amplitude less than 5 mV or a P-wave amplitude less than 2 mV can result in undersensing because the sensed amplitude may decrease after implantation.
- Pacing lead impedance should be within the range of 200 Ω and 2000 Ω .
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10 mA can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.
- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- **Defibrillation power surge.** Defibrillation that causes a power surge exceeding 360 watt-seconds can damage the pulse generator system.
- **Ventricular refractory periods (VRPs) in adaptive-rate pacing.** 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 you are entering a fixed AV delay, consider the sensing outcomes.
- **Do not bend the lead near the lead–header interface.** Improper insertion can cause insulation damage near the terminal end that could result in lead failure.
- **Shock waveform polarity.** Never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched physically.
- **Absence of a lead.** 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.

- **Electrode connections.** Do not insert a lead into the pulse generator connector without first visually verifying that the setscrew is sufficiently retracted to allow insertion. Fully insert each lead into its lead port and then tighten the setscrews onto the electrodes.
- **Tachy Mode to Off.** To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode(s) is programmed to Off when not in use and before handling it. For tachyarrhythmia therapy, verify that the Tachy Mode(s) is programmed to On.
- **Atrial oversensing.** Take care to ensure that artifacts from the ventricles are not present on the atrial channel, or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction. (Applies to dual-chamber devices only.)
- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15 Ω total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20 Ω , reposition the shocking electrodes to allow a greater distance between the shocking electrodes.
- **ATR Entry Count.** Exercise care when programming the Entry Count to low values in conjunction with a short ATR duration. This combination allows mode switching with very few fast atrial beats. For example, if the Entry Count was programmed to 2 and the ATR Duration to 0, ATR mode switching could occur on 2 fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.
- **ATR Exit Count.** Exercise care when programming the Exit Count to low values. For example, if the Exit Count was programmed to 2, a few cycles of atrial undersensing could cause termination of mode switching.
- **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during tachyarrhythmia induction because it may shunt energy. This could result in less energy getting to the patient and damage to the implanted system.
- **Replacement device.** Implanting a replacement device 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. Irrigating 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.

Follow-up Testing

- **Conversion testing.** Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively.
- **Pacing threshold testing.** If the patient's condition or drug regimen has changed or device parameters have been reprogrammed, consider performing a pacing threshold test to confirm adequate margins for pace capture.

Explant and Disposal

- **Incineration.** Be sure the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- **Device handling.** Before explanting, cleaning, or shipping the device, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:
 - Program the pulse generator Tachy and Brady Modes to Off
 - Program the Magnet Response feature to Off
 - Program the Beep When ERI Is Reached feature to Off
- **Explanted devices.** Return all explanted pulse generators and leads to Guidant. Examination of explanted pulse generators can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

Do not implant an explanted pulse generator in another patient as sterility, functionality, and reliability cannot be ensured.

Environmental and Medical Therapy Hazards

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are:
 - electrical power sources, arc welding equipment and robotic jacks
 - electrical smelting furnaces

- large RF transmitters such as RADAR
- radio transmitters including those used to control toys
- electronic surveillance (anti-theft) devices
- an alternator on a car that is running

Hospital and Medical Environments

- **Internal defibrillation.** Do not use internal defibrillation paddles or catheters unless the pulse generator is disconnected from the leads because the leads may shunt energy. This could result in injury to the patient and damage to the implanted system.
- **External defibrillation.** Use of external defibrillation can damage the pulse generator.
- **Transcutaneous electrical nerve stimulation (TENS).** TENS may interfere with pulse generator function. If necessary, the following measures may reduce interference:
 - Place the TENS electrodes as close to each other as possible and as far from the pulse generator and lead system as possible.
 - Monitor cardiac activity during TENS use.

For additional information, contact Technical Services at the number shown on the back cover of this manual.

- **Electrical interference.** Electrical interference or “noise” from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.
- **Electrocautery.** The use of electrocautery could induce ventricular arrhythmias and/or fibrillation, cause asynchronous or inhibited pulse generator operation, or cause the pulse generator to deliver an inappropriate shock. If electrocautery cannot be avoided, observe the following precautions to minimize complications:

- Select Off-Electrocautery Mode, which programs the pacing mode to VOO, AOO, or DOO and turns the Tachy Mode(s) to Off. Avoid direct contact with the pulse generator or leads.
- Monitor the patient and have temporary pacing equipment, external defibrillation equipment, and knowledgeable medical personnel available.
- Position the ground plate so that the current pathway does not pass through or near the pulse generator system.
- Use short, intermittent, and irregular bursts at the lowest feasible energy levels.
- Use a bipolar electrocautery system where possible.

Remember to program the Tachy Mode(s) to On after turning off the electrocautery equipment.

- **Ionizing radiation therapy.** Ionizing radiation therapy may adversely affect device operation. During ionizing radiation therapy (eg, 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. After waiting a minimum of one hour following radiation treatment (to allow for a device memory check to occur), always evaluate device operation including interrogation and sensing and pacing threshold testing. At the completion of the entire course of treatments, perform device interrogation and follow-up, including sensing and pacing threshold testing and capacitor re-formation.
- **Lithotripsy.** Lithotripsy may permanently damage the pulse generator if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, avoid focusing near the pulse generator site.

The lithotripter is designed to trigger off the R-wave on the ECG, resulting in shock waves being delivered during the VRP.

- If the patient does not require pacing, program the pulse generator Brady Mode to Off.
- If the patient requires pacing, program the pulse generator to the VVI mode because atrial pacing pulses can trigger the lithotripter.

- **Ultrasound energy.** Therapeutic ultrasound (e.g. lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g. echocardiography) is not known to be harmful to the pulse generator.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed On during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy, or may cause inhibition of pacing therapy. Minimize risks by following these steps:
 - Program the Tachy Mode to Off or Off-Electrocautery to avoid inadvertent tachycardia detection (sensing) or therapy.
 - Avoid direct contact between the ablation catheter and the implanted leads and pulse generator.
 - Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
 - Have external defibrillation equipment available.
 - Consider the use of external pacing support for pacemaker-dependent patients.

Remember to reactivate the pulse generator after turning off the radio frequency ablation equipment.

Home and Occupational Environments

- **Home appliances.** Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There have been reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.
- **Magnetic fields.** Advise patients to avoid equipment or situations where they would have extended exposure to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could be inhibited. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within

0.5 inches (1.27 cm) of the pulse generator, and magnetic wands such as those used for airport security and in the game “Bingo”.

- **Electronic article surveillance (EAS).** Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries, and to walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.
- **Cellular phones.** Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone that is turned on in a breast pocket or on a belt within 6 inches (15 cm) of the implanted device since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

ADVERSE EVENTS

Potential Adverse Events

Based on the literature and pulse generator implant/explant experience, the following alphabetical list includes possible adverse events associated with implantation and explantation of a pulse generator system:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nerve stimulation)
- Failure to convert an induced arrhythmia
- Foreign body rejection phenomena
- Formation of hematomas or seromas

- Heart failure following chronic RV apical pacing
- Inability to defibrillate or pace
- Inappropriate therapy (e.g., shocks where applicable, ATP, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgement
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Myocardial infarction
- Myocardial necrosis
- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia (Applies to dual-chamber devices only)
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator migration
- Shunting current during defibrillation with internal or external paddles
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)
- Worsening heart failure

Patients may develop psychological intolerance to a pulse generator system that may include the following:

- Dependency
- Depression
- Fear of premature battery depletion
- Fear of shocking while conscious
- Fear that shocking capability may be lost
- Imagined shocking

CLINICAL STUDIES

Clinical Study Populations

Guidant ICDs have been demonstrated to be safe and effective in patient populations including, but not limited to, those with:

- Prior myocardial infarction and an ejection fraction (EF) $\leq 30\%$, based on the Guidant sponsored MADIT II clinical study. (Guidant devices were the only devices studied in the MADIT II clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT II population.)
- Prior myocardial infarction, left ventricular ejection fraction of $\leq 35\%$, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia, based on the Guidant sponsored MADIT clinical study. (Guidant devices were the only devices studied in the MADIT clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT population.)

Chronic Implant Study: VITALITY

The purpose of this study was to evaluate the safety and effectiveness of Guidant VITALITY family devices with Automatic Intrinsic Rhythm ID. This clinical study was a single-arm, prospective, multi-center study. There were a total of 100 patients enrolled at 21 US investigational centers between December 3, 2002, and January 10, 2003.

Patient Population: One hundred patients were enrolled in this study and 96 patients received investigational devices. The mean age of the patients implanted with the VITALITY device was 67.3 ± 10.8 years old. The mean left ventricular ejection fraction was 30.4% (range 11.0% - 71.0%). Seventy-eight (78) patients (81.3%) were male. The primary cardiovascular disease (42.1%) was

coronary artery disease (CAD) and the primary tachyarrhythmia (38.5%) was monomorphic ventricular tachycardia (MVT).

Methods: A prospective, multi-center, nonrandomized clinical study evaluated the safety and effectiveness of the VITALITY device in humans. Ninety-six patients selected from the investigator's general patient population who met the indications for use of the VITALITY device were followed through pre-discharge, 2-week and 1-month follow-ups and continued every 3 months thereafter until study closure.

Results: A total of 100 patients were enrolled in this study. Of these, 96 patients were successfully implanted, with 4 intents. Ninety-three (93) patients finished their 1-month follow-up per the study protocol. All primary and secondary endpoints of this study were met. The results from this study provide evidence of the safety and effectiveness of the VITALITY with Automatic Intrinsic Rhythm ID algorithm. Refer to Table 1-1 for a detail of the VITALITY chronic study results.

Table 1-1. VITALITY Chronic Study Results

Safety Endpoints			
VT/VF Detection Time			3.43 seconds
Primary Endpoints			
Sensitivity			
Induced VT/VF			100%
Spontaneous VT/VF			100%
Specificity–Induced			
Rhythm	Physician/ Annotation	Device Decision– SVT	Specificity
Atrial Fibrillation	71	68	95.8%
Atrial Flutter	94	88	93.6%
Sinus Tachycardia	7	5	71.4%
Total Induced	172	161	93.6%
Specificity–Spontaneous			
Rhythm	Physician/ Annotation	Device Decision– SVT	Specificity

Table 1-1. VITALITY Chronic Study Results

Atrial Fibrillation	65	65	100%
Atrial Flutter	31	28	90.3%
Sinus Tachycardia	37	32	86.5%
Other	7	7	100%
Total Spontaneous	140	132	94.3% ^a
Combined Specificity^b	312	293	93.9%
Secondary Endpoints			
Acute Automatic Rhythm ID Accuracy (2 weeks)			100%
Automatic Rhythm ID Accuracy (1 month)			97.7%
Manual Rhythm ID Accuracy (1 month)			100%

a. GEE adjusted specificity = 93.7%

b. Combined specificity includes both Induced and Spontaneous data.

Acute Study

The VITALITY ICD was compared to a commercially available ICD (VENTAK PRIZM® or VENTAK PRIZM 2 ICD) in an acute (nonimplant) paired study of 50 patients enrolled at nine investigating centers between March 8, 2001 and July 24, 2001. A total of 47 patients were tested with the study device, followed by a control device at the time of a Guidant commercially approved (VENTAK PRIZM, model 1851 or VENTAK PRIZM 2, model 1861) implantation.

The purpose of the acute study was to demonstrate that the addition of an SVT detection enhancement and brady features did not adversely impact normal ICD sensing and detection functionality. A total of 50 patients were tested in nine U.S. centers.

Patients studied: The patients (38 M/9 F) had a mean age of 66 years (range 37 to 90) and a left ventricular ejection fraction of 32% (range 10% to 62%). Most (40%) presented with monomorphic ventricular tachycardia (MVT) and nonsustained VT as their primary arrhythmia. Of the patients studied, 87 percent presented with coronary artery disease or ischemic cardiomyopathy.

Methods and statistics: The acute study was done in the operating room or electrophysiology laboratory without implantation of the study device. The primary end-

point was to determine that VT/VF detection time for induced episodes is within two seconds of the VENTAK PRIZM or VENTAK PRIZM 2 detection time.

Results: A total of 50 patients were enrolled in the acute study. Of those, 47 patients were successfully tested with the system per study protocol; there were two attempted procedures and one intent. There was one clinical complication and two observations reported in the acute study, all of which were non-investigational device related. No patient deaths were reported. The VT/VF detection time of the VITALITY ICD was found to be within two seconds of the VENTAK PRIZM 2 detection time, leading to the conclusion that activating the additional VITALITY features does not have a negative effect on the existing ICD sensing and detection functionality.

Table 1-2. Acute Study Results

Study Endpoint	VITALITY (Mean \pm std) N	VENTAK PRIZM 2 DR (Mean \pm std) N
VT/VF Detection Time (seconds)	3.60 \pm 0.60 N = 47	3.52 \pm .057 N = 47
p-value: <0.001		

Chronic Implant Study: VENTAK AV II DR

Since the VITALITY ICD systems have many of the same therapies, diagnostics, and electrophysiology testing features as the VENTAK® AV III DR system, the VENTAK AV II DR implant study, which was used to support the VENTAK AV III DR system, was used also to support the VITALITY system.

The purpose of the implant study was to confirm that the VENTAK AV II DR could sense, detect, and deliver ventricular tachyarrhythmia therapy. In addition, the adaptive-rate pacing function was evaluated by exercise testing. Fifty-two patients were enrolled and implanted in 18 centers outside the U.S. between June 27 and October 21, 1997. A total of 53 devices were used throughout the duration of the study and consisted of VENTAK AV II DR, models 1821 and 1826. The VENTAK AV II was approved for commercial distribution in the U.S. on March 13, 1998.

This clinical data remains applicable to the VITALITY devices since there are no significant differences between tachyarrhythmia therapy and adaptive-rate pacing capabilities between VENTAK AV II DR and the VITALITY VR/DR/DR+ devices.

Patients Studied: The patients (46 M/ 6 F) had a mean age of 60 years (range 30 to 78) and a left ventricular ejection fraction of 36% (14% to 76%). Most (86%) presented with coronary artery disease or ischemic cardiomyopathy and 53% presented with monomorphic ventricular tachycardia (MVT) as their primary arrhythmia.

Methods: This was an observational study. No control group was used. Patients underwent standard ICD implant procedure and were evaluated at predischarge, 1 month, and 3 months postimplant. At the one-month follow-up, an exercise test consisting of a 6 minute brisk walk or 6 minutes of stair climbing was required for all patients included in the study if the accelerometer sensor was programmed on. The purpose of the exercise test was to verify if there was an adequate rate response of the sensor under exercise conditions. After the test, the device was interrogated to verify if the rate response during activity functioned according to patient need. If the rate response was insufficient, the trending function was used to optimize the sensor settings.

Results: The mean implant duration was 3.03 months (range 0.23 to 3.8) with a cumulative implant duration of 157.4 months. All patients were implanted in a lead alone configuration. Two patients were later revised to add SQ arrays. The mean DFT for 26 patients who were tested under a step down to failure protocol was 10.3 J stored energy. A total of 432 episodes of ventricular arrhythmias (VF/PVT and MVT) were treated including spontaneous (N = 112) and induced (N = 320). Three patients had episodes that were not converted by the device. One patient had 4 VF episodes during DFT testing at implant that were not converted by the device and were converted externally. A second patient had an electrical storm directly postimplant in which two episodes of MVT were converted externally; the device detected all episodes appropriately and used multiple attempts to deliver therapy for all episodes in the storm. A third patient's MVT accelerated to VF and was successfully terminated by the device. All other episodes of ventricular arrhythmias were converted by device therapy. There were two patient deaths: one was classified witnessed, noncardiac, nonsudden, and the other was classified unwitnessed, assumed sudden.

Forty patients had the sensor programmed "ON" and performed an exercise test. The remaining patients were not tested for the following reasons: patient had sinus rhythm and did not require adaptive-rate pacing, patient could not tolerate exercise testing, and patient death. Nominal settings were appropriate for 80% of patients tested; in all cases, the physician was able to program appropriate adaptive-rate settings to accommodate patient need.

Table 1-3. Implant Study Results

Effectiveness Measure	VENTAK AV II DR Mean \pm SD [95% CI] N
Defibrillation threshold (J) stored energy	10.3 \pm 3.7 [8.8, 11.8] N = 26
Safety Measure	Rate (%)
Operative mortality	1/52 (1.9%)
Conversion efficacy for all ventricular arrhythmias	425/432 (98.4%)

DEVICE FEATURES

By programming device parameters, the ICD pulse generator is able, for a given patient, to detect and treat ventricular tachycardia and ventricular fibrillation with a combination of antitachycardia pacing and monophasic or biphasic cardioversion/defibrillation shocks. Detection of the atrial rate is available using an atrial lead. The pulse generator also detects and treats bradycardia conditions with pacing pulses in both the atrium and ventricle. Pulse generator memory provides a record of patient data, therapy delivery counts, and a therapy history consisting of arrhythmia episode data, conversion attempt data, stored electrograms (EGM), and annotated P-P and R-R intervals present during and following a tachyarrhythmic episode. The pulse generator automatically re-forms its capacitors and provides diagnostic data for evaluating battery status, lead integrity, and pacing thresholds.

The total system allows the physician to noninvasively interact with the pulse generator as listed below:

- Interrogate and program the pulse generator's tachycardia and bradycardia detection and therapy parameters
- Deliver a maximum-output STAT SHOCK with the STAT SHOCK command
- Deliver emergency VVI pacing with the STAT PACE command
- Divert therapy delivery
- Access the pulse generator memory to review therapy history and stored electrograms
- View real-time electrograms and event markers
- Induce, monitor, and terminate arrhythmias during electrophysiologic testing

- Program optional features such as magnet use and audible tones
- Review the pulse generator battery status
- Print reports and save patient information on disk
- Program and save customized parameter files and follow-up programmer settings

MECHANICAL SPECIFICATIONS

Table 1-4. Nominal Mechanical Specifications

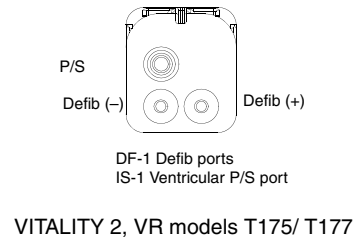
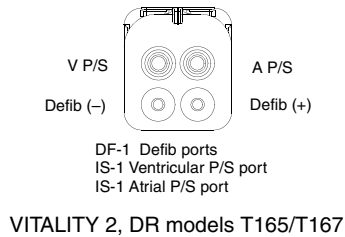
	Dimensions W x H x D (cm)	Volume (cc)	Mass (g)	Connector Size	Case Electrode Surface Area (mm ²)
VITALITY 2, models T165/T175	5.9 x 6.5 x 1.1	30	82	IS-1/DF-1	6084
VITALITY 2, models T167/T177	6.3 x 7.1 x 1.1	35	90	IS-1/DF-1	7059

Table 1-5.

All Models	
Case Material	Hermetically sealed titanium
Header Material	Implantation-grade polymer
Power Supply (WGT)	Lithium-silver vanadium oxide cell

Lead Connections

- All models use the pulse generator case as a defibrillating electrode.
- For lead compatibility information, refer to the lead system precaution on page 1-5.
- DF-1 refers to the international standard ISO 11318:2002. IS-1 refers to the international standard ISO 5841-3:2000.



Factory Nominal Parameter Settings

The pulse generator's parameters are preset at factory nominal values. Refer to the section "Factory Nominal Parameter Settings" on page 9-1. Appendix A provides a complete list of parameters and available programmable values.

MAINTAINING DEVICE EFFECTIVENESS

Perform follow-up testing to maintain continued verification of detection and therapy efficacy. Refer to the section "Follow-up Testing" on page 10-1.

X-RAY IDENTIFIER

The pulse generators have an identifier that is visible on x-ray film or under fluoroscopy. This provides noninvasive confirmation of the device manufacturer. The identifier consists of the letters "GDT" to identify the manufacturer (Guidant), followed by 109, identifying the Model 2857 programmer software application needed to communicate with the pulse generator.

Refer to the Quick Start section (page 2-4) for information on identifying the device via the programmer.

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

PULSE GENERATOR LONGEVITY

Based on simulated studies, it is anticipated that VITALITY 2 pulse generators have average longevity to ERI as indicated below. The longevity expectations, accounting for the energy used during manufacture and storage (approximately six months), apply at the conditions shown below. Values apply whether Electrogram Storage options are programmed On or Off. VITALITY 2, models T167 and T177, are extended longevity devices.

	VVI Mode (Years)	VVIR Mode (Years)	DDD Mode (Years) (Models T165 and T167 only)	DDDR Mode (Years) (Models T165 and T167 only)	
VITALITY 2 models T165, T175	900 Ω pacing impedance				
	0% pacing	6.7	6.6	6.0	5.9
	15% pacing	6.6	6.5	5.9	5.8
	50% pacing	6.5	6.4	5.6	5.6
100% pacing	6.3	6.2	5.3	5.2	
VITALITY 2 models T167, T177					
	0% pacing	9.0	8.9	8.0	7.9
	15% pacing	8.9	8.8	7.9	7.8
	50% pacing	8.7	8.6	7.5	7.4
	100% pacing	8.4	8.3	7.1	7.0
VITALITY 2 models T165, T175	500 Ω pacing impedance				
	0% pacing	6.4	6.4	5.8	5.7
	15% pacing	6.4	6.3	5.6	5.5
	50% pacing	6.0	6.0	5.2	5.1
100% pacing	5.8	5.6	4.7	4.7	
VITALITY 2 models T167, T177					
	0% pacing	8.8	8.6	7.8	7.7
	15% pacing	8.6	8.4	7.6	7.4
	50% pacing	8.2	8.1	6.9	6.9
	100% pacing	7.7	7.6	6.3	6.3

The longevity of the pulse generator decreases with an increase in the pacing rate, pacing pulse amplitude, pacing pulse width, percentage of bradycardia paced to

sensed events, or charging frequency, or with a decrease in pacing impedance. Device longevity in VITALITY 2 systems also is reduced if the Patient Triggered Monitor feature is programmed On (refer to “Patient Triggered Monitor” on page 7-18). A maximum-energy shock is equal to approximately 11 days of monitoring.

The longevity of the device is also affected by:

- Tolerances of electronic components
- Variations in programmed parameters
- Variations in usage as a result of patient condition

As a result, the observed longevity of your ICD may vary considerably from the estimates provided in this manual.

Warranty Information

A limited warranty certificate for the pulse generator accompanies the pulse generator. For additional copies, please contact Guidant Corporation at the address and phone number on the back cover of this manual.

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 topics should be discussed with patients prior to discharge.

- Patients should:

- Contact their physician immediately if they hear tones coming from their pulse generator.
- Contact their physician to have their pulse generator system evaluated if they receive external defibrillation.
- Understand the signs and symptoms of infection.
- Understand the symptoms that should be reported (e.g., sustained high-rate pacing requiring reprogramming).
- Seek medical guidance before entering areas protected by a warning notice that prevents entry by patients who have a pulse generator.
- Understand and avoid potential sources of EMI and magnetic fields in home, work, and medical environments. (See Warnings and Precautions for more detailed information about specific sources.)
- Persons administering CPR may experience the presence of voltage (tingling) on the patient's body surface when the pulse generator delivers a shock.
- 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 Manual

Guidant recommends that the physician discuss the information in the patient manual with concerned individuals both before and after pulse generator implantation, so they are fully familiar with operation of the device. A copy of the patient manual is provided for the patient with the device. For additional copies of the patient manual, contact the nearest Guidant sales representative or contact Guidant at the phone number on the back cover of this manual.

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
- Inability to shock
- 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.

USING THE PROGRAMMER/RECORDER/MONITOR

CHAPTER 2

This chapter describes how to use the ZOOM LATITUDE Programming System, which includes the Model3120 Programmer/Recorder/Monitor (PRM) and the Model 2857 CONSULT Software Application to communicate with the VITALITY 2 pulse generators. Refer to the PRM Operator's Manual for full instructions.

The chapter is divided into the following sections:

1. "Starting Up the Programmer and Software" on page 2-1.
2. "Introduction to CONSULT Software Terminology and Navigation" on page 2-8.
3. "Establishing Telemetry Communication" on page 2-27, which includes instructions for communicating with the pulse generator (interrogating, programming, manual therapy delivery, and therapy divert).

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 pulse generator is important, as this information is not routinely repeated throughout the manual when specific functions are discussed.

STARTING UP THE PROGRAMMER AND SOFTWARE

Perform the following steps to start a communication session:

1. Connect the power cord to the PRM system and an outlet. (Refer to the operator's manual for the PRM System 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 to appear (Figure 2-1). Adjust the screen brightness.

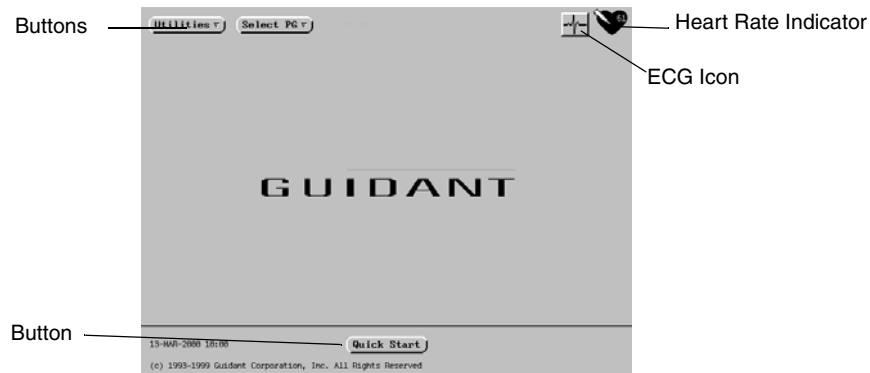


Figure 2-1. The startup screen is displayed when the programmer is powered on.

Startup Screen

The startup screen allows access to the following buttons and icons:

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

NOTE: Only one of the buttons or icons may be selected at a time.

In this manual, the word “select” means to touch the desired item on the screen with the stylus, then lift the stylus from 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.

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

ECG Display from the Startup Screen

The ECG display on the PRM can be used to display a patient's surface ECGs prior to accessing the VITALITY/VITALITY 2 application; select the ECG display icon on the startup screen. Refer to Appendix C for instructions on proper patient connections. 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. Refer to the section "ECG Display on the Main Application Screen" on page 2-14 for more information about traces within the VITALITY/VITALITY 2 application.

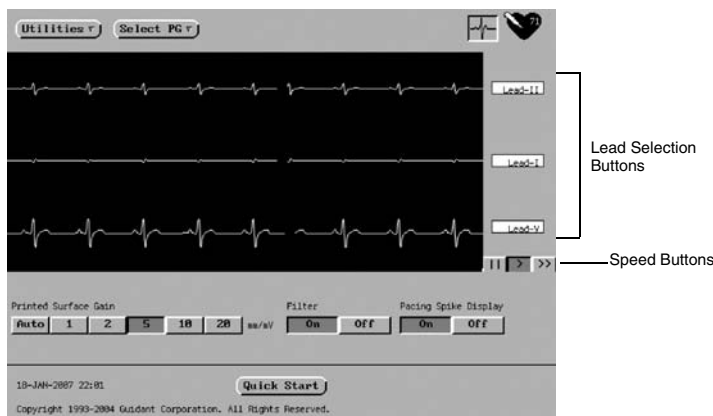




Figure 2-2. The ECG screen is accessed from the startup screen.

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

- **Lead Selection Buttons**—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.

- **Filter**—Select the Filter On setting to minimize noise on the surface ECG.
- **Pacing Spike Display**—Program this feature On to show detected pacing spikes, annotated by a marker on the uppermost waveform.

NOTE: The values as set up on the startup screen will be the defaults used for the VITALITY/VITALITY 2 application traces. The corresponding values can be changed from the Trace Selections screen while in the VITALITY/VITALITY 2 application. Refer to the section “ECG Display on the Main Application Screen” on page 2-14.

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 printer/recorder while the traces are displayed on the PRM screen. See Appendix C 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 a pulse generator, place the telemetry wand over the pulse generator and select the Quick Start button. A window indicating one of the following conditions will appear, based on the device:

- **Application Startup in Progress**—If the software for the device is installed on the PRM, the PRM will identify the device, open the correct application, and interrogate the device.
- **Software not installed**—If the software application for the 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 of Guidant device is identified, a message window will appear informing the user that he or she must use

a Model 2035 or Model 2901 programmer to interrogate and/or program the device.

- **PG not identified**—If a non-Guidant or one of certain older models of Guidant pulse generators 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 demonstration mode or read disk feature, use the Select PG button at the top of the screen to choose the pulse generator application instead of using the Quick Start button. Refer to the section “Select PG Button” on page 2-6.

Utilities Button on the Startup Screen

If desired, before accessing the pulse generator software application, the version numbers of the programmer and software applications can be displayed, the programmer clock can be modified, the institution name can be changed, and data disks can be copied and formatted. To access the startup screen from within a software application, select the Quit option from the Exit button to exit the software application and return to the startup screen.

1. On the startup screen, select the Utilities button.
2. Select the About option to view the version numbers of the system software and application software residing on the programmer.
3. Select the Set Programmer Clock option to change the programmer date and time (24-hour clock), which is displayed in the lower left corner of the startup screen. The Set Date and Time window will appear (Figure 2-3).
 - a. Change the values by selecting an up or down arrow.
 - b. To reset the seconds display to zero, select the box containing two digits (shown as 00 in Figure 2-3).

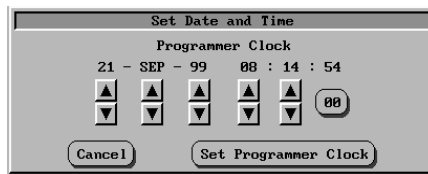


Figure 2-3. The Set Date and Time window.

- c. 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; the window will close without changing the values.)

NOTE: The programmer and pulse generator clocks may be synchronized once the application is accessed. Refer to the section “Set Clock” on page 2-22.

4. Select the Set Institution option to update the institution name. If the programmer has been moved to a different institution, the name of the institution as it appears on the startup screen can be changed. Refer to the section “Changing Parameter Values” on page 2-29 for instructions on entering new data.

NOTE: The institution name also is displayed in the heading of printed reports.

5. Select the Format Disk option to erase all data from a Model 6627 patient data disk and reformat it so new data can be saved on the disk. Follow the directions displayed in the message windows.
6. Select the Copy Disk option to copy patient data from one disk (the source disk) to another (the destination disk). Do not use a destination disk that contains patient data, as the existing data would be lost. Follow the directions displayed in the message windows. (This function performs in the same manner as the Copy Disk function of the software application; refer to the section “Utilities Button on the Main Application Screen” on page 2-18.)

Select PG Button

This option allows the software application to be selected manually. Use this option to access the demonstration (DEMO) mode or read a patient data disk. A pulse generator can be interrogated via this option as well. Otherwise, use the Quick Start feature described earlier in this chapter.

1. To display the desired software application without using the Quick Start feature, select the Select PG button.
2. The names of the available software applications will appear. Select the VITALITY/VITALITY 2 option. The VITALITY/VITALITY 2 application communicates with all models of the VITALITY 2 adaptive-rate pulse generators.
3. A screen will appear with options to either interrogate the pulse generator, use a demonstration mode, use profiles, or read a patient data disk.
4. To become familiar with this software without interrogating a pulse generator, select the DEMO button; the main application screen will be displayed and the DEMO logo will appear at the top of the screen. The screens displayed during the DEMO mode reflect the DR model features and programmable values. When other models are interrogated, the screen will reflect the respective features and programmable values.
5. To exit the demonstration mode, select the New Patient option from the Exit button. Refer to page 2-23 for more information about these options.
6. Once familiar with the software, to proceed with an interrogation session refer to the section "Interrogating the Pulse Generator" on page 2-28. To read data from a patient data disk, refer to the section "Disk Operations" on page 2-19.

NOTE: *STAT PACE, STAT SHOCK, and DIVERT THERAPY commands are functional in DEMO mode if the telemetry wand is positioned over a pulse generator.*

INTRODUCTION TO CONSULT SOFTWARE TERMINOLOGY AND NAVIGATION

VITALITY 2 MAIN APPLICATION SCREEN

The main application screen will always be displayed while interacting with the software. The sections of the screen are labeled in Figure 2-4 and described below.

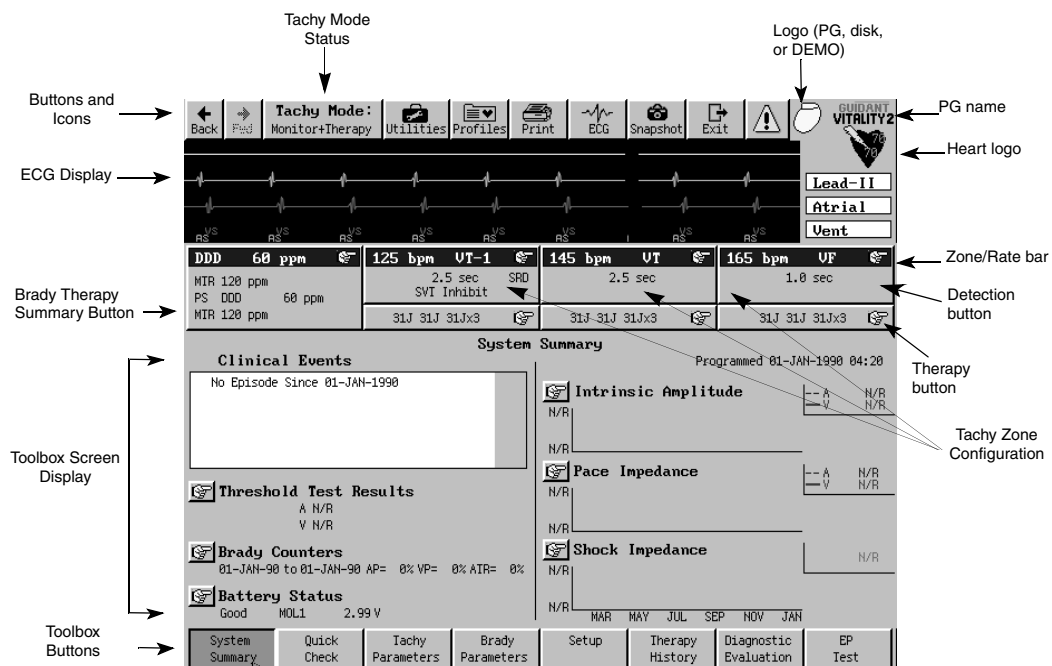


Figure 2-4. The main application screen and its elements, with the System Summary tool visible.

Buttons and Icons

Buttons and icons are graphic elements that, when selected, initiate an activity, display a list of options, or change the information displayed.



Arrows

The arrow icons allow navigation to screens previously viewed. Select the back-arrow 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, select the forward-arrow icon to advance towards the most recent screen viewed. (Note that changing the number of zones will clear the navigation sequence.)



Tachy Mode

Select the Tachy Mode button to display a list of mode options. The text inside the Tachy Mode button indicates the current mode of tachyarrhythmia therapy and is visible at all times. Refer to the section “Accessing the Tachy Mode Parameter” on page 3-3.



Utilities

Select the Utilities button to display a list of options allowing access to functions that are not displayed directly on the main application screen. Refer to the section “Utilities Button on the Main Application Screen” on page 2-18.



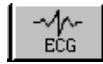
Profiles

Select the Profiles button to access the functions associated with My Patient Profile. This feature permits the user to program and save customized parameter files and follow-up programmer settings. Refer to “My Patient Profile” on page 7-25.



Printer

Select the Printer button to access the print options associated with the currently displayed tool and other reports. Refer to the section “The Print Icon” on page 2-23 for a detail of reports and their associated tools.



ECG

Select the ECG icon to navigate to a screen with ECG and trace selection options, and to view a larger trace area. Exit the screen by selecting any tool button or the back-arrow icon. Refer to the section “Toolbox and Toolbox Buttons” on page 2-13.



Snapshot

Select the snapshot icon to capture a 20-second snapshot from the ECG display. Refer to the section “ECG Display on the Main Application Screen” on page 2-14.



Exit

The Exit icon allows the software application to be exited and returns to the startup screen or a new patient session to be selected. Refer to the section “The Exit Icon” on page 2-25.



Information (Parameter Interaction Warning)

This 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 in order to proceed with the patient session; however, physician discretion is advised depending on the type of patient or other circumstances before proceeding.



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 Parameter Interaction stop sign icon will appear at the top of the display. Select this icon to access the Parameter Interaction screen in order to view the nature of the interaction and its suggested resolution.

Changes to the affected parameters can be made directly from the Parameter Interaction window; changes will take effect when the device is programmed. 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 (Clinical Event) (on the System Summary Screen)

The stop sign icon indicates an important event that has occurred since the last follow-up and appears in the System Summary screen. Selecting the stop sign icon or its associated text opens a window or navigates to a screen containing information about the event.



Shortcut

Select the shortcut icon to go directly from the parameter, feature, or associated event to the screen that provides detailed information. Use the back-arrow icon to return to the previous screen.



Magnifying Glass

Select the magnifying-glass icon to open a window with detailed information about a parameter, feature, or event. The window must be closed before continuing.



Check box

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

Displayed on the Quick Check screen, Go icons will start the respective test.

Logos



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



This logo is displayed when a pulse generator has been interrogated.



This logo is displayed when data have been retrieved only from a patient data disk and not from an interrogation of a pulse generator.



The heart rate logo displays the real-time sensed or paced ventricular and atrial (dual-chamber devices) rates as communicated by the pulse generator. The wand must be positioned over the pulse generator for values to appear.

Tachy Zone Configuration

This area indicates the number of tachyarrhythmia zones programmed in the pulse generator. Each zone is identified by a bar with the name of the zone (VT-1, VT, and VF) and its rate threshold. The brady therapy summary is also visible.

When the Tachy Parameters screen is displayed, the zone configuration area also includes a summary of detection and therapy parameters for each zone (Figure 2-5). Access the detection parameters for a zone by selecting the respective detection button. Access the therapy parameters for a zone by selecting the respective therapy button. Select a zone's rate threshold value box to easily change the rate threshold. The number of tachyarrhythmia zones can be changed by selecting the button with the desired number of zones in the "# Zones" column. If

parameter settings have been changed but not programmed into the pulse generator, hatch marks (////) will appear in the summary area. When the values are programmed, the hatch marks disappear.

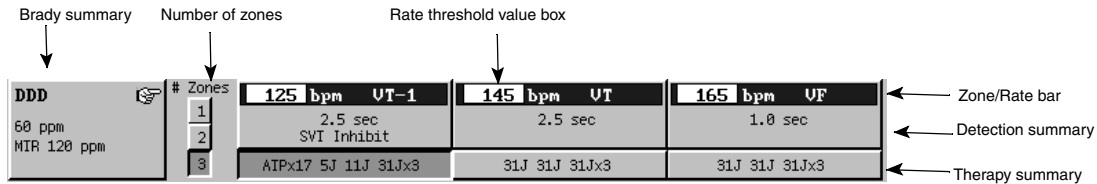


Figure 2-5. The zone configuration area as displayed when the Tachy Parameters screen is visible.

A subset of zone configuration information is displayed when the System Summary and Quick Check screens are visible, which allows a shortcut to the detection and/or therapy parameters screens. (Only presently programmed values are displayed; it does not display changed data that has not yet been programmed into the device nor hatch marks.) Select a shortcut icon to navigate to the Tachy Parameters screen, which will display detailed information. If a shortcut icon appears dim, it indicates that a change to the number of zones has not been programmed; thus, a shortcut is not available to the parameter screens.

Brady Therapy Summary

This area displays the normal and post-shock bradycardia modes and rates. Additional bradycardia parameter settings may be viewed and changed by selecting the brady summary button when a shortcut icon is visible, or the Brady Parameters tool. Depending on which toolbox screen is visible, this summary button may show just the rate/zone bar or may include the additional information as shown in the example in Figure 2-5 on page 2-13.

Toolbox and Toolbox Buttons

System Summary	Quick Check	Tachy Parameters	Brady Parameters	Setup	Therapy History	Diagnostic Evaluation	EP Test
----------------	-------------	------------------	------------------	-------	-----------------	-----------------------	---------

The toolbox displays various features depending on the chosen toolbox button. The features allow interaction with the pulse generator as well as a review of data in pulse generator memory. Only one tool may be selected at a time. (The System Summary tool is selected when the application is initially accessed. However, if an

episode is in progress at initial interrogation, the EP Test screen will be displayed.) Hatch marks will appear on the Tachy Parameters, Brady Parameters, and Setup buttons if respective parameter settings have been changed but not programmed into the pulse generator. When the values are programmed, the hatch marks disappear.

General Window Functions

Windows contain information relevant to a particular function and may include names of pulse generator 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 button that initiates activity or select the Close or Cancel button.

Message Windows

Message windows may appear during a communication session. Some require action as indicated in the window before continuing the session, while others simply relay information without requiring further action or show status of an activity. Many message windows have a Cancel or Close button; select the desired button to cancel the action being performed as explained in the message and/or close the window. Figure 2-6 is an example of message windows.

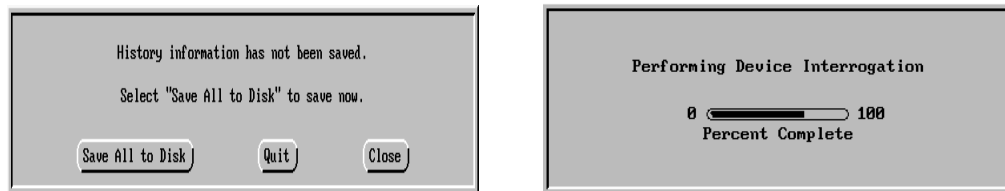


Figure 2-6. Message windows provide information and instructions throughout the session.

ECG Display on the Main Application Screen

When the VITALITY/VITALITY 2 application is accessed, the ECG display shows real-time surface ECG traces, as well as real-time electrograms (EGMs) and annotated event markers which are useful in ascertaining system performance. To view surface ECGs, refer to Appendix C for instructions on proper patient cable connections.

- Real-time electrograms can be transmitted from the pace/sense or shocking electrodes to evaluate lead system integrity such as lead fractures, insulation breaks, or dislodgments.
- Annotated event markers identify certain intrinsic cardiac and device-related events, and provide information such as sensed/paced events, decision of detection criteria, and therapy delivery. The annotated markers are displayed on the PRM printer/recorder and the ECG display (refer to Table 2-1 on page 2-17).

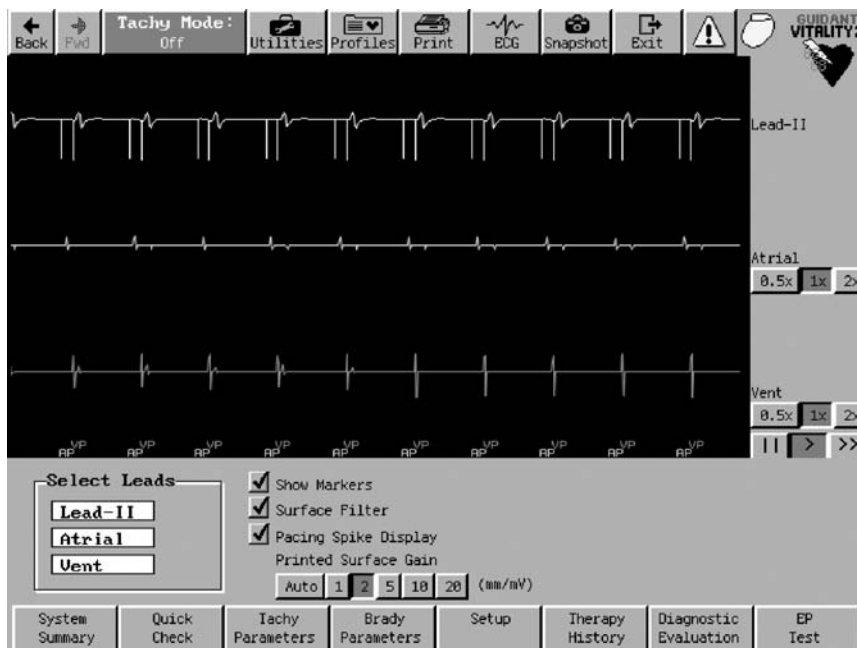




Figure 2-7.

Refer to Figure 2-7 and the following text for an explanation of the display.

1. To enlarge the trace and view optional display settings, select the ECG icon. The display options are described below.
 - Lead selection—Indicates the surface ECG lead trace to be displayed.
 - Trace selection—Allows a choice of 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 (>>).
- Show Markers—Displays annotated markers. Refer to Table 2-1 on page 2-17.
- 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.
- Pacing Spike Display—Displays detected pacing spikes, annotated by a marker on the surface ECG waveform.
- Displayed EGM Gain—Adjusts the gain of the intercardiac electrograms (0.5x, 1x, or 2x).

NOTE: The values displayed for Surface Gain, Surface Filter, and Pacing Spike Display correspond to the same options as selected from the ECG display on the startup screen (refer to section “ECG Display from the Startup Screen” on page 2-3).

2. To view surface ECG traces on the display, refer to Appendix C for instructions on proper patient cable connections.
3. Establish telemetry communication. The traces and event markers will be transmitted as long as telemetry communication is maintained. If telemetry communication is interrupted, reestablish the telemetry link to resume the transmission.
4. To capture and automatically print an ECG trace displaying on the screen, select the  snapshot icon. The printed trace shows 10 seconds before and up to 10 seconds after the moment of capture. (Refer to the section “Snapshot Viewer” on page 7-23 for information about viewing the trace.)
5. To print an electrogram and/or event markers and the surface ECG from the PRM, press the desired speed key on the printer/recorder. The key labeled  on the recorder may be pressed to force the surface trace back to baseline. Electrograms and ECGs also can be transmitted to an external strip chart recorder if connected to the programmer.

NOTES:

- When printing stored shock electrograms from the Episode Detail screen, the EGM Gain setting applies at the time the electrograms were stored. The automatic gain control circuit of the pulse generator causes signal filtering of the rate and shock electrogram; therefore, rate electrograms may appear slightly different from the surface ECG.
- Whenever telemetered EGMs are enabled they will automatically be output to the external analog output jacks (see Appendix C for cable connections). The ECG display or the PRM printer/recorder need not be activated.
- Marker annotation definitions can be printed by selecting the Marker Legend option on the reports window (accessed via the Print option from the Utilities button), or by pressing the \square (calibrate) key on the PRM while traces are active.

Table 2-1. Annotated marker definitions (Sheet 1 of 2)

AS	Atrial Sense - after refractory and AFR window	PVC	PVC After Refractory
AS-Hy	Atrial Sense - in hysteresis offset	VT-1	VT-1 Zone Sense
AS-FI	Atrial Sense - in AFR window	VT	VT Zone Sense
(AS)	Atrial Sense - during TARP ^a	VF	VF Zone Sense
[AS]	Atrial Sense - during blanking	TN	Telemetry Noise
AP	Atrial Pace - lower rate	AN	Atrial Rate Noise
AP↓	Atrial Pace - rate smoothing down	VN	Ventricular Rate Noise
AP↑	Atrial Pace - rate smoothing up	ATR↓	Atrial Tachycardia Sense - count down
AP-FB	Atrial Pace - fallback (in ATR)	ATR↑	Atrial Tachycardia Sense - count up
AP-Hy	Atrial Pace - at hysteresis rate	ATR-Dur	ATR Duration Started
AP-Sr	Atrial Pace - sensor rate	ATR-FB	ATR Fallback Started
AP→	Atrial Pace - inserted after AFR	ATR-End	ATR Fallback Ended
AP- Ns	Atrial Pace - noise (asynchronous pacing)	RID-FB	Intrinsic Rhythm ID Fallback Started ^b
AP-Tr	Atrial Pace - trigger mode	RID-End	Intrinsic Rhythm ID Fallback Ended ^b
AP-PP	Atrial Pace - Atrial Pacing Preference	PVP→	PVARP After PVC

Table 2-1. Annotated marker definitions (Sheet 2 of 2)

VS	Ventricular Sense - after refractory	PMT-B	PMT Termination
VS-Hy	Ventricular Sense - in hysteresis offset	Epsd	Start/End Episode
[VS]	Ventricular Sense - during blanking	Dur	Duration Met
VP	Ventricular Pace - lower rate or atrial tracked	Detct	Detection Met
VP↓	Ventricular Pace - rate smoothing down	SVTinh	SVT Inhibited
VP↑	Ventricular Pace - rate smoothing up	Chrg	Start/End Charge
VP-FB	Ventricular Pace - fallback (in ATR) ^c	Dvrt	Therapy Diverted
VP-Sr	Ventricular Pace - sensor rate	Shock	Shock Delivered
VP-Hy	Ventricular Pace - at hysteresis rate	SRD	Sustained Rate Duration Expired
VP-MT	Ventricular Pace - atrial tracked at MTR	--	Unclassified Event
VP-Ns	Ventricular Pace - noise (asynchronous pacing)	#. #V	Amplitude Threshold Test
VP-Tr	Ventricular Pace - trigger mode	#. ##ms	Pulse Width Threshold Test
VP-VR	Ventricular Pace - Ventricular Rate Regulation	####	Interval (A-A or V-V)

- Total Atrial Refractory Period (TARP) is equal to AV Delay plus PVARP (Post-ventricular Atrial Refractory Period).
- RID-FB and RID-End are stored markers only.
- Marker is both real-time and stored. When real-time, it is the ATR V-Paced fallback marker. When stored, it notes the need for a V-Pace event during Intrinsic Rhythm ID Fallback.

Utilities Button on the Main Application Screen

The Utilities button allows access to the following functions: Patient Data, Disk Operations, Set Clock, Load Initial Values, and About. Many of these functions also are available from the Utilities button on the startup screen and function in the same manner.

Patient Data

Information about the patient can be stored in pulse generator memory. This information includes patient and physician names, pulse generator serial number, implant date, and lead configurations and implant test measurements. The information can be retrieved anytime by interrogating the pulse generator, and viewed on the PRM screen or printed as a report.

- Select the Utilities icon from the main application screen.
- Select the Patient Data option.

NOTE: If data had previously been entered and saved in the pulse generator, and if the pulse generator has been interrogated, upon accessing the Patient Data screen

the data will appear in the screen. If an interrogation has not been performed (ie, DEMO operation), the data boxes will be blank. Establish telemetry communication and press the PRM INTERROGATE key; the data will appear in the screen.

3. To add patient-specific data to the Patient Data screen, select the desired value box; either a graphic keyboard or a list of options will appear depending on the value box selected.
4. Change the values as described in the section “Changing Parameter Values” on page 2-29.
5. To enter new data in a value box already containing data, select the value box, and then select the Clear button to delete all the characters. Enter new data.
6. To enter the data into pulse generator memory, establish telemetry communication and press the PROGRAM key on the PRM system.
7. Select another toolbox button or an arrow icon on the main application screen to remove the Patient Data screen from the display.

Disk Operations

Functions that involve data disks can be accessed by selecting the Disk Operations button from within the Utilities button. Data disks can contain either patient data or follow-up and implant profiles (refer to page 7-25 for information on patient profiles).

Read Disk

Data on a patient data disk can be retrieved and displayed in the Therapy History tool kit prior to or after a pulse generator interrogation.

NOTE: *The Read Disk, Save All to Disk, and Copy Disk functions are operational for disks containing patient data. To perform similar functions for profile disks, refer to the section “My Patient Profile” on page 7-25.*

1. Insert into the disk drive of the PRM a patient data disk that contains information about the present interrogated pulse generator.
2. Prior to interrogating the pulse generator, select the VITALITY/VITALITY 2 software from the Select PG button. Next, select the Read Disk button. The data will be retrieved from the disk and held in programmer memory. The parameter settings that were last saved to disk will appear in the zone configuration area of

the main application screen. A logo shaped like a data disk will appear on the main application screen to indicate that the data in Therapy History is from a disk.

- If disk data has been retrieved and then an interrogation command is initiated, the programmer compares the model and serial numbers of the disk and pulse generator to ensure that they match. If the data match, the pulse generator is interrogated, and a pulse generator icon will appear on the main application screen. If the data does not match, the interrogation will not be performed.
3. After interrogating a pulse generator and with the main application screen visible, select the Utilities button. Select the Read Disk option from the Disk Operations button within the Utilities menu. If a disk is not inserted, a message will appear indicating that a disk should be inserted and the Read Disk option tried again.
- If a pulse generator interrogation has been done prior to the Read Disk selection, the programmer will compare the model and serial number data on the disk and in the pulse generator. If the numbers do not match, a message will appear indicating that the data will not be retrieved from the disk due to mismatched numbers. If the numbers are the same, the disk data will be retrieved. A disk logo will not replace the pulse generator logo in this case, as the displayed parameter values will continue to be those stored in the pulse generator (not the last values saved to disk).

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 unreadable patient data disk for use on the Model 3120 PRM, any data on the disk will be lost.*
- *Multiple disks for the same patient may be read sequentially. If a Read Disk command is initiated when a disk for a different patient is inserted in the disk drive, a message will indicate that it is an incorrect disk.*
- *When a disk has been read, the STAT SHOCK, STAT PACE, and DIVERT THERAPY commands are functional if the telemetry wand is positioned over the pulse generator.*

4. Select the Therapy History toolbox button to display the information that has been retrieved. Refer to "Therapy History" on page 7-1 for history details.

NOTE: *After disk data have been retrieved prior to an interrogation, screens and toolbox features can be accessed. However, any changes made to parameters cannot be programmed until the proper pulse generator has been interrogated.*

Save All To Disk

When a patient data disk is inserted in the disk drive of the PRM, the following data can be saved: therapy history, programmed parameter values, trending values, and histogram paced/sensed counters.

1. Insert a patient data disk into the disk drive of the PRM; use a new data disk or one that has existing data saved for the same patient (that is, the same pulse generator model and serial number). If a disk for a different patient/pulse generator is inserted, a message will appear indicating that the data will not be saved. If a non-Guidant disk is inserted a message will appear indicating that the correct disk must be inserted.

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 Disk Operations option within the Utilities button. The PRM determines which episode data have already been saved to disk from previous sessions, and will add only the new episode data to the disk. To make duplicates of this saved data, if desired, perform a Copy Disk procedure. **Do not** use the Save All To Disk option to do so, as the therapy history already saved will not be available for saving again.

If a disk is too full, a message will appear indicating such. Insert a new patient data disk and try again to save the data. A disk may hold up to 250 episodes.

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.

When viewing the Arrhythmia Logbook, an asterisk will be displayed in the Saved column for each episode saved to disk.

NOTE: *Refer to the PRM operator's manual for care instructions for data disks.*

Copy Disk

This feature is available to make duplicate copies of a patient data disk.

1. Select the Copy Disk option from the Disk Operations button. A message window will appear.
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 programmer 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 or profile disk.

1. Insert a patient data disk into the disk drive of the PRM.
2. Select the Format Disk option from the Disk Operations button. 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.

Set Clock

Clocks in the programmer and pulse generator can be set so that the proper time appears on printed reports and PRM strip chart recordings.

1. Select the Set Clock option from the Utilities button. A Set Date and Time window will appear.

2. Select a box with an arrow to change each displayed number for the programmer date and time. To reset the seconds display to zero, select the button containing two digits (shown as 00).
3. To synchronize the programmer and pulse generator clock, establish telemetry communication, and select the Synchronize button. The dates and times for both the pulse generator and programmer clocks will be set and the window will be closed.
4. To set the programmer clock only, select the Set Clock button. The window will be closed.

Load Initial Parameter Values

Refer to page 2-28 for a description of this feature.

About

When this option is selected a window will display the programmer model, serial, and software revision numbers being used for the current session, and the institution name.

The Print Icon

The following reports can be printed from either the PRM printer/recorder or external printer so that permanent records may be retained in the patient's file. Each report heading includes patient name (if data entered in Patient Data screen), institution name, dates and time of report printing, model and serial numbers of the pulse generator and programmer, the report name, and an indication of where the data were obtained if other than the pulse generator (ie, patient disk data or demonstration [DEMO] mode).

Report	Associated Tool
Quick Notes	System Summary, Quick Check
Parameters	Tachy Parameters, Brady Parameters and Setup
Conversion Summary	Conversion Summary
Arrhythmia Logbook	Arrhythmia Logbook
Episode Detail	Episode Detail
Intervals	Episode Intervals
Stored EGM	Episode EGM Viewer

Report	Associated Tool
Counters	Counters
Histograms	Histograms
Measured Data	Battery Status, Intrinsic Amplitude, Lead Impedance, Pace Threshold, Intrinsic Rhythm ID Updates
Daily Measurement	Daily Measurement
Trending	Trending
Snapshot	Snapshot Viewer
Patient Data	Patient Data

- **Quick Notes**—prints data from the tests performed during a Quick Check session, as well as therapy history summary, histogram data, device parameters summary, daily measurements, and ICD and lead system data.
- **Parameters**—lists all the programmed tachyarrhythmia detection and therapy parameter values by zone, bradycardia parameters, and Setup settings for magnet, beeper, Episodes/EGMs, and Patient Triggered Monitor functions. It contains the initial parameter values and the changed, reprogrammed present values. If data had been read from a disk, the initial and present values reflect those at the time data were saved to disk.
- **Patient Data**—includes all the data from the Patient Data screen.
- **Measured Data**—prints data from the Battery Status and Diagnostic Evaluation tool kits including last capacitor re-form, last delivered charge, battery status, intrinsic amplitude, lead threshold, Intrinsic Rhythm ID updates, and pace and shock impedance measurement data.
- **Daily Measurement**—prints the values from the daily impedance and amplitude measurements in graphical and tabular format.
- **Marker Legend**—prints definitions of the annotated event markers.
- **Conversion Summary**—prints the number and types of tachyarrhythmia episodes and number of atrial episodes.
- **Arrhythmia Logbook**—prints out the data from the Arrhythmia Logbook screen.
- **Tachy and Brady Counters**—prints all the data as shown on the Counters screen (see “Counters” on page 7-13).

- Histograms Report—prints tachy and brady counter data for Device Totals and Since Last Reset in graphical format.
- Episode Detail—includes episode attempts (newest to oldest). If enabled from Episodes/EGMs setup, it also prints ventricular (and atrial for dual-chamber devices) intervals and stored electrograms with annotated markers.

Printing Reports

1. Select the Print icon. The Choose Reports To Print window will appear. To print the report associated with the displayed screen, select the Print Current Report button at the top of the window.
2. Select the box adjacent to the desired report(s); more than one type of report at the top of the window may be selected, but only one range of Episode reports may be selected at a time. A check mark (✓) will appear in the box. Up to five copies of each selected report can be printed by changing the value in the Number of Copies value box.
3. Select either the External or Internal button. If an external printer is connected to the PRM, the printer default setting will be External. (Refer to Appendix C for printer connection information.) If the Internal button is selected, the reports will be printed on the PRM printer, whether or not an external printer is connected.
4. Select the Print button at the bottom of the window. When printing to the PRM internal printer/recorder, if event markers or electrograms are currently being printed, the printing of them will be stopped. To restart the printing of event markers or electrograms after the report is printed, press a speed key on the PRM printer panel.
5. To stop printing at any time, select the Cancel Printing button; or press the zero key (0 mm/s) on the PRM.

The Exit Icon

The Exit option allows the software application to be exited and returns to the startup screen, or a new patient session to be selected, which ends the current session.

Quit

The Quit option ends the current session, exits the software application, and returns to the startup screen.

1. Select the Exit icon from the top of the screen.
2. Select the Quit option. A message will appear that indicates the application will exit, and the startup screen will be displayed. (Selecting the Close button will remove the message window and retain the current patient session.)
3. Select the Quit button to end the session and return to the startup screen. (Selecting the Close button will not end the session.)

NOTE: See the notes in the New Patient section for further information.

New Patient

The New Patient option, located by selecting the Exit button, ends a current patient session and allows a different VITALITY 2 device to be interrogated or a different VITALITY 2 patient's data disk to be read without having to exit the VITALITY/VITALITY 2 software application.

1. Select the Exit button from the main application screen.
2. Select the New Patient option. A message window will appear.

NOTES:

- If a second device is interrogated or a disk read without ending a previous session, a message will appear indicating that the current session first needs to be terminated. A New Patient button is available on the message window.
- If therapy history data have not been saved to a disk, a message will appear indicating that a patient data disk should be inserted in the disk drive and the data saved. Refer to the section "Save All To Disk" on page 2-21.
- If reports are being printed on the programmer printer, a message will appear allowing the printing to be canceled.
- A warning message will appear if the Tachy Mode of the current session is not programmed to Monitor + Therapy.

3. Select the New Patient button. (Selecting the Close button will remove the message window and retain the current patient session.) The current session will end, a new main application screen will be displayed, and the options to select an Interrogate, use Demo mode, use Profiles, Quit, or Read Disk button will be available.

ESTABLISHING TELEMETRY COMMUNICATION

Telemetry communication is required to direct commands from the PRM system, such as INTERROGATE, PROGRAM, STAT SHOCK, STAT PACE, and DIVERT THERAPY. This chapter describes such commands. Telemetry communication also is required to perform other features such as EP testing, pacing impedance and threshold tests, and manual capacitor re-form. These latter features are described in later chapters.

NOTE: *STAT PACE, STAT SHOCK, and DIVERT THERAPY commands are functional during DEMO mode.*

Follow these steps to establish communication:

1. Connect the telemetry wand to the PRM system.
2. Position the wand over the pulse generator at a distance not greater than 6 cm (2.4 inches).
3. Direct a command from the PRM system to the pulse generator (eg, INTERROGATE or PROGRAM). The telemetry indicator light on the PRM panel will illuminate when the wand is properly positioned and communication is occurring.

NOTES:

- *Even if the wand is correctly positioned, the telemetry indicator light illuminates only while telemetry communication is occurring with the pulse generator. The light extinguishes as soon as the communication sequence is successfully completed.*
- *Status windows may appear during a communication session to indicate that the pulse generator is out of range. Reposition the wand to re-establish communication. (When event markers and/or EGMs are activated and if the pulse generator is out of range, a message will not appear, but rather the event marker*

transmission will be interrupted.) During EP testing the out of range message is located in the status message section of the EP Test screen.

Interrogating the Pulse Generator

Pulse generator interrogation is the first step in any programming session. An interrogation retrieves the following information from pulse generator memory: tachy detection and therapy parameter settings, brady parameter settings, diagnostic tests data, therapy history and counters, and patient data.

Use the following procedure to interrogate the pulse generator, if not already interrogated using the Quick Start feature.

1. To initially interrogate the pulse generator immediately after selecting the Select PG button, select the INTERROGATE button on the message window (or the INTERROGATE key).

To perform interrogations during a session, press the INTERROGATE key on the PRM panel. A message window will appear indicating the status of the interrogation.

2. Position the telemetry wand within telemetry range of the pulse generator ensuring that the telemetry indicator light illuminates. The scale in the message window will indicate the progression of the interrogation.
3. Maintain the telemetry link until the scale indicates that the interrogation has reached 100% completion and the message window disappears. A pulse generator icon will appear at the top of the main application screen and will remain there until the session is ended.

CAUTION: Electrical interference or “noise” from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.

Load Initial Parameter Values

At the start of a patient session, when the pulse generator is initially interrogated, the currently programmed values are displayed on the PRM screen and are referred to as the initial values. Anytime during the patient session, the initial values can be

easily reloaded if values have been changed. Bradycardia parameters, tachycardia detection and therapy parameters (including number of zones), and setup parameters are affected. The Tachy Mode, Patient Triggered Monitor, Trending, and Patient Data settings are not affected.

1. Select the Load Initial Parameter Values option from the Utilities button. A window appears with the options to load Brady Parameters, Tachy Parameters, and Setup parameters.
2. Select the check boxes adjacent to the desired parameters.
3. Select the Continue button to load the initial values of the checked options. The reloaded values appear in the Change column of the affected parameter screens, and hatch marks appear in the zone configuration area of the main application screen indicating the changes have not been programmed.
4. The Cancel button can be selected from the Load Initial Parameter Values window to close the window if Continue has not been selected. (To revert to the currently programmed values, select the Cancel Changes button from the Tachy Parameters, Brady Parameters, or Setup tools. The initial values that were just loaded will be deleted from the Change column.)
5. To program the values in the pulse generator, establish telemetry and press the PROGRAM key on the PRM.

Changing Parameter Values

The screens for many of the features contain parameter information, including parameter names, values for the present parameter settings, value boxes to accommodate value changes, and buttons to cancel changes. In many screens there are two columns displayed next to the parameter names: the Present column displays the currently programmed value for each parameter, and the Change column contains value boxes allowing 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 value box is not displayed.

To change parameter values, select the appropriate value box in the Change column and select a value from the palette window (touch the desired value and lift the stylus). Touching the screen outside a window will close it without a selection. Once a value is selected, sliding the stylus outside the active window without lifting the stylus closes with window without making a selection. When changes have been

made to parameter values, the data appear in the Change box until programmed into the pulse generator.

In some screens (eg, Patient Data screen), data are not displayed in Present and Change columns, but rather have value boxes that require unique data to be entered. Typically the data are entered from a keyboard window. The values entered will remain in the value boxes when programmed; they will not move from a Change column to a Present column.

- **Keyboard Window**—Touch the first character of the new value; it will appear in the data entry box in the graphic keyboard. Continue until the entire new entry appears in the box. To delete one character at a time, starting with the last character, select the left arrow key on the graphic keyboard. 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. If the graphic keyboard initially appears and contains data in the value box, the Clear button will allow deletion of all the characters in the value box.

0.05	1.00
0.10	1.10
0.20	1.20
0.30	1.30
0.40	1.40
0.50	1.50
0.60	1.60
0.70	1.70
0.80	1.80
0.90	1.90

Palette Window

Patient's First Name

1	2	3	4	5	6	7	8	9	0	%	←
Q	W	E	R	T	Y	U	I	O	P		
A	S	D	F	G	H	J	K	L			
Z	X	C	V	B	N	M					
<	>	=	Space					.	,	+	-

Cancel Changes
Clear
Close

Keyboard Window

Figure 2-8. Types of windows enabling value changes.

Copy button: There is a simple way to duplicate parameter values from one screen to another on those screens that contain a Copy button.

1. Select the Copy button. A window will appear with a Copy From and a Copy To column with buttons.
2. Select the desired buttons in both columns and then select the Copy button.

Programming the Pulse Generator

When changes have been made to parameter values, the data appear in the value box until programmed into the pulse generator. When the PROGRAM function is initiated, **all changed data (from all screens) will be programmed.**

NOTE: *When the Tachy Mode is changed, the mode is immediately programmed. The PROGRAM key need not be pressed. Refer to the section "Accessing the Tachy Mode Parameter" on page 3-3.*

Use the following procedure to program the pulse generator:

1. Press the PROGRAM key on the PRM panel. A message window will appear indicating that parameters are being programmed.
2. Position the telemetry wand within telemetry range of the pulse generator ensuring that the telemetry indicator light illuminates. The scale in the message window will indicate the progression of the programming.
3. 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 pulse generator during the programming sequence causes the telemetry indicator light to extinguish and a message window to display Device Out Of Range. Reestablish telemetry communication to continue the programming sequence. If communication cannot be reestablished, press the Cancel Telemetry in the message window to stop the programming sequence.

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

DIVERT THERAPY

When the pulse generator is charging to deliver a shock, the shock delivery may be diverted from the patient. If diverted, the shock does not count as one of the total number of shocks that may be delivered during an episode. If redetection occurs and more shock therapy is required, and if more shocks are available in the therapy prescription, the pulse generator will charge again to deliver subsequent shocks.

Also, the DIVERT THERAPY key can be pressed to divert ATP therapy in midburst or between bursts. If redetection occurs, the ATP scheme will not be used again and the next programmed therapy in the sequence will be initiated.

1. Position the telemetry wand within range of the pulse generator.
2. Press the DIVERT THERAPY key. A message window will appear indicating that a divert attempt is being made.

NOTE: *There is a period of time (500 ms delay) between the end of charging and shock delivery designed to provide a minimum period for the DIVERT THERAPY command. After this time, pressing DIVERT THERAPY will not divert the shock.*

3. Maintain the wand position until the message window disappears indicating the shock has been diverted. Prematurely removing the wand (breaking the telemetry link) may allow the pulse generator to continue charging and to deliver the shock.

STAT SHOCK

A nonprogrammable maximum-output STAT SHOCK can be delivered to the patient at any time during a communication session. The STAT SHOCK can be delivered when the pulse generator's Tachy Mode is programmed to any mode, including the power-saving Storage mode (although the mode is automatically changed from Storage to Off once a STAT SHOCK is commanded). This function does not affect the programmed shock sequences (lower-energy shocks can be delivered following a STAT SHOCK) and does not count as one of the total number of shocks in a therapy sequence for a given episode. The output of the STAT SHOCK is at the maximum-output energy and at the programmed polarity and waveform; STAT SHOCK is always committed regardless of programmed parameters.

1. Position the wand within range of the pulse generator.
2. Press the STAT SHOCK key. A message window will appear with instructions to initiate the shock.
3. To initiate the shock, press the STAT SHOCK key again. A different message window will appear indicating that STAT SHOCK is in process. When the shock has been delivered, the message window will disappear.

NOTE: The STAT SHOCK may be diverted. See the section “DIVERT THERAPY” on page 2-31.

4. Subsequent high-energy STAT SHOCKS may be delivered by repeating steps 1-3.

NOTE: Following STAT SHOCK delivery, if the Tachy Mode is Monitor Only or Monitor + Therapy, post-shock redetection is initiated (initial detection criteria and enhancements are not used). If Tachy Mode is Monitor + Therapy and if redetection determines that further therapy is required, the programmed sequence of therapy will be resumed or initiated, including ATP and/or low-energy shocks. (Refer to the section “Redetection” on page 3-20 for information about tachyarrhythmia detection.)

STAT PACE

Emergency bradycardia pacing using a STAT PACE command function sets the bradycardia operation to parameters intended to ensure capture and keep the patient stable.

Table 2-2. Emergency Normal and Post-shock Bradycardia Pacing Parameter Settings (STAT PACE)^a

Brady Mode	VVI
Brady Rate	60 ppm
Amplitude	7.5 V
Pulse Width	1 ms
Paced Refractory	320 ms
Noise Response	Inhibit
Hysteresis	Off

a. Post-shock Pacing Delay and Post-shock Pacing Period are not reprogrammed during STAT PACE delivery. They remain the same as programmed prior to the STAT PACE.

1. Position the telemetry wand within range of the pulse generator.
2. Press the STAT PACE key on the PRM panel. A message window appears indicating the STAT PACE values.
3. Press the STAT PACE key a second time. The message Performing STAT PACE is displayed, followed by a message that states the STAT PACE values are

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ESTABLISHING TELEMETRY COMMUNICATION

displayed in the Present column of the Brady Parameters screen, which is also visible.

4. Select the Close button on the message window.
5. To stop STAT PACE, press the PROGRAM key. This returns the pulse generator to the previous settings (which are displayed in the Change column during STAT PACE delivery).

CAUTION: Do not leave the device programmed in STAT PACE settings; these settings may significantly reduce the lifetime of the device due to the high output.

TACHYARRHYTHMIA DETECTION

CHAPTER 3

The pulse generator employs programmable detection parameters that, when programmed appropriately, may distinguish ventricular tachyarrhythmias of different rates from bradycardia, sinus rhythm, or atrial arrhythmias. To select an appropriate therapy to deliver, the pulse generator employs initial detection criteria. Following initial therapy, the device evaluates the post-therapy rhythm using redetection criteria, and delivers subsequent therapy if necessary. This chapter discusses initial tachyarrhythmia detection and redetection, followed by a discussion of tachyarrhythmia therapy in Chapter 4. Bradyarrhythmia detection and therapy are discussed in Chapter 5.

This chapter includes the topics:

- “Tachy Mode Parameter” on page 3-1
- “Rate Sensing” on page 3-3
- “Initial Detection” on page 3-5
- “Reconfirmation/Committed Shock” on page 3-10
- “Episodes” on page 3-11
- “Detection Enhancements” on page 3-14
- “Redetection” on page 3-20

TACHY MODE PARAMETER

The Tachy Mode parameter allows the device to be programmed to one of the following modes: Off, Monitor Only, Monitor + Therapy, or Off-Electrocautery. Refer to Table 3-1 on page 3-2 for a list of features available in the different modes. The different mode options allow the user to program the device to fit the type of therapy and detection desired:

- Off—no tachyarrhythmia detection or therapy delivery. This mode is useful when connecting the leads to the pulse generator during the implant procedure.

- **Monitor Only**—detects and records tachyarrhythmia history **but does not automatically deliver therapy to the patient.** This mode is useful in controlled environments, such as during EP testing, exercise testing, and immediately postoperatively, where alternate therapy (eg, external defibrillator) is available.
- **Monitor + Therapy**—allows the full range of detection and therapy options.
- **Off-Electrocautery**—allows the tachyarrhythmia detection and therapy features of the device to be inhibited (deactivated) during use of electrocautery equipment. Bradycardia pacing is still functional; however, the Brady Mode switches to an XOO mode (where X is determined by the programmed Brady Mode setting). (Other bradycardia pacing parameters remain at the programmed settings.)

CAUTION: It is important to program the pulse generator out of Off-Electrocautery mode when any electrosurgical cautery is complete, otherwise the pulse generator will not detect nor deliver therapy for tachyarrhythmias. Verify the programmed parameter settings following any electrosurgical cautery.

Table 3-1. Device Performance in the Tachy Mode Settings

Device Features	Tachy Mode (programmable)				
	Off	Monitor Only	Monitor + Therapy	Off-Electrocautery	Storage ^a
Rate sensing	X ^b	X	X		
Bradycardia pacing	X	X	X	X ^c	
Tachyarrhythmia detection		X	X		
Tachyarrhythmia therapy			X		
Detection/therapy history		X	X		
Stored EGMs	X ^d	X	X		
EP test ^e		X	X		
STAT SHOCK ^f	X	X	X	X ^g	X
STAT PACE	X	X	X	X ^g	X
Real-time annotated EGMs	X	X	X	X	

- a. While the pulse generator is in power-saving mode, the Tachy Mode displays as Storage. These commands will change the Tachy Mode to Off. Once the pulse generator has been taken out of Storage mode, the programmer cannot return it to that mode. Refer to the section "Factory Nominal Parameter Settings" on page 9-1.
- b. In order to enable ventricular sensing when the Tachy Mode is Off, the Brady Mode must be programmed to sense in the ventricle.
- c. The Brady Mode switches to XOO mode.
- d. ATR episodes will store EGMs in Off mode and if brady pacing and ATR are programmed on.
- e. Not all forms of EP tests are available in every mode. Refer to "EP Test Features" on page 8-1.
- f. The STAT SHOCK is delivered asynchronously if Tachy Mode is Off and the Brady Mode is Off or AAI (no sensing in the ventricle).
- g. This command will change the Tachy Mode and Brady Mode to the modes that were programmed immediately prior to entering the Off-Electrocautery mode.

Accessing the Tachy Mode Parameter

1. Select the Tachy Mode menu button from the main application screen to display the parameter options.
2. Select the desired option. The new value will be immediately programmed if the telemetry wand is positioned over the pulse generator. The new programmed value will appear on the Tachy Mode button and will be visible at all times.

NOTE: When Off-Electrocautery mode is selected, a window appears and remains visible while in that mode. To exit the Off-Electrocautery mode, select the Close button on the window.

For another method of changing the Tachy Mode, refer to the section "Performing Commanded ATP" on page 8-14.

RATE SENSING

All detection decisions are based on cardiac cycle length. The pulse generator uses bipolar electrodes and an automatic gain-controlled sensing circuit to determine cardiac cycle lengths. This circuit ensures proper rate sensing by compensating for changing and deteriorating signal amplitudes associated with ventricular tachycardias. The sensing circuit dynamically adjusts the amplifier gain according to the amplitude of the atrial and ventricular signals.

NOTE: In dual chamber models, if any of the following features are programmed, the pulse generator will respond to atrial sensing whether an atrial lead is implanted or not: Rhythm ID programmed On, Brady Mode programmed to DDD(R), DDI(R), DVI(R), VDD(R), or AAI(R) (refer to page 5-9), Electrogram Storage Enabled for the atrial electrode (refer to page 7-12), and Atrial Rate EGM trace selected (refer to page 7-12). If an atrial lead is not implanted, atrial data will be erroneous.

Calculating Rates and Refractory Periods

The pulse generator evaluates rate on an interval-by-interval basis. Following a sensed depolarization, a cycle length is measured and compared to the detection parameters programmed by the user.

The pulse generator employs refractory periods following certain events; sensed events that fall within these periods are ignored for detection purposes. The refractory periods, together with noise windows, may prevent unwanted therapy that could be delivered if nonphysiologic signals are sensed. The nonprogrammable refractory periods are as follows:

- 85 ms atrial refractory following an atrial sensed event (dual-chamber devices)
- 135 ms ventricular refractory following a ventricular sensed event or a capacitor charge
- 250 ms refractory following shock delivery (sensing is ignored in both chambers)

For an illustration of the refractory period following a capacitor charge, refer to the section “Committed Shock/Reconfirmation of the Arrhythmia” on page 4-20. For an explanation of the programmable paced refractory period and noise windows, refer to the bradycardia pacing Refractory submenu on page 5-35 and Noise Window submenu on page 5-41.

Rate Thresholds and Zones

Programmable Values: 90–250 bpm

A zone is a range of heart rates defined by a lower rate threshold. The value programmed for the Rate parameter determines the zone’s rate threshold and is the value to which the pulse generator compares each sensed ventricular cardiac cycle length. Typically, a zone is established for each tachyarrhythmia that can be treated by a separate therapy prescription. From one to three tachyarrhythmia zones may be programmed. Table 3-2 illustrates the various configurations and respective nomenclature for the zones.

Table 3-2. Rate threshold configurations

Configuration	VT-1 Zone	VT Zone	VF Zone
1 Zone			165 bpm
2 Zones		145 bpm	165 bpm
3 Zones	125 bpm	145 bpm	165 bpm

Adjacent zone's rate thresholds must differ by at least 20 bpm. The lowest Tachy Rate Threshold must be ≥ 5 bpm higher than both the Maximum Tracking Rate and Maximum Sensor Rate; and the lowest Tachy Rate Threshold must ≥ 10 bpm higher than the Lower Rate Limit. Refer to "Description of Bradycardia Pacing Therapy" on page 5-2 for brady information.

INITIAL DETECTION

Initial detection criteria consist of the programmable parameters Rate and Duration. The rhythm discrimination enhancement, Rhythm ID, may be used during initial detection to add specificity beyond Rate and Duration. The pulse generator initiates therapy when it determines that detection is met. Detection is met when: a) a zone's **detection window** becomes and remains satisfied throughout Duration, b) the zone's Duration expires, c) detection enhancements indicate therapy (if programmed) and d) the **last detected interval** is in the zone. If the last detected interval is not in the zone, therapy is not initiated and the pulse generator continues to evaluate intervals. The detection criteria are explained more thoroughly in the following pages.

Detection Windows

Appropriate therapy delivery is dependent upon accurately classifying a patient's rhythm. To ensure that appropriate therapy is delivered, the pulse generator employs detection windows to differentiate tachycardias.

Each zone has a detection window that consists of the 10 most recent R-R intervals measured by the pulse generator. As each new interval is measured, it is compared to each zone's programmed rate threshold and classified as either fast or slow (ie, above or below the rate threshold) in each detection window (Figure 3-1).

When 8 of 10 intervals in a zone's detection window have been classified as fast, the window is considered satisfied. The detection window will remain satisfied as long

as 6 of 10 intervals remain classified as fast. If the number of fast intervals falls below 6, the zone's detection window is no longer satisfied. The zone's detection window will only become resatisfied when 8 of 10 intervals are again classified as fast.

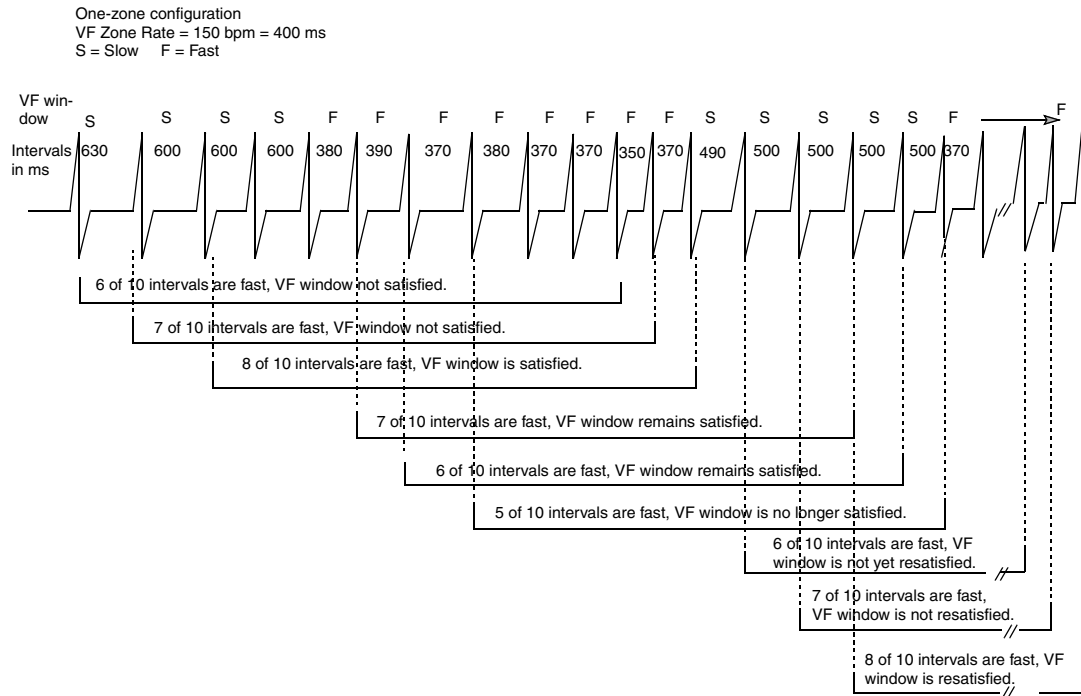


Figure 3-1. A detection window becomes satisfied when 8 out of the most recent 10 intervals are classified as fast. The detection window remains satisfied as long as 6 of 10 intervals are classified as fast.

Because the higher zones' Rate must be programmed at a value greater than the lower zones' Rate, an interval classified as fast in a higher window would also be classified as fast in any lower windows (Figure 3-2).

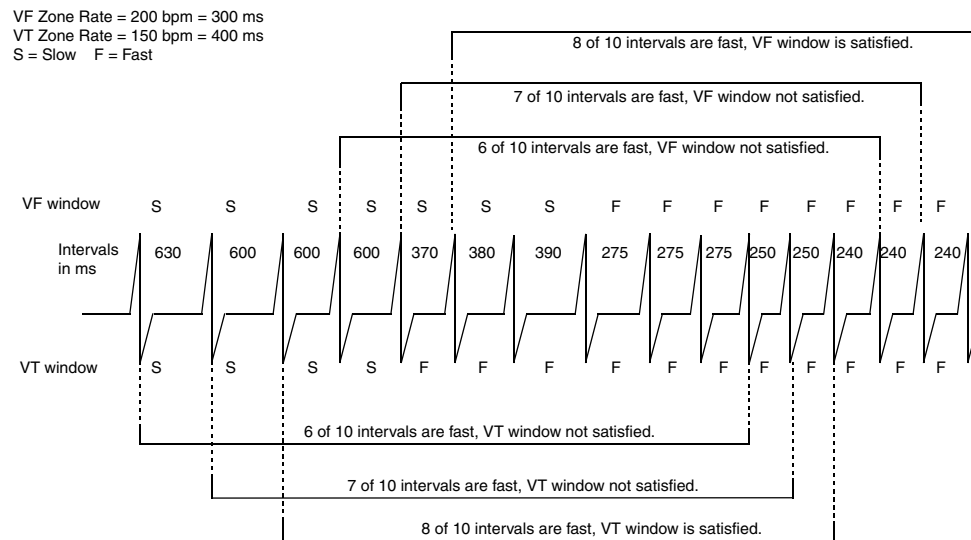


Figure 3-2. Interaction of detection windows in a 2-zone configuration. Each interval is compared to both the VT zone and VF zone rate thresholds to determine whether it is fast or slow in each zone's detection window.

Duration Parameter

Programmable Values: 1–60 seconds

Each zone has an associated Duration timer (length of time) to ensure an arrhythmia is sustained before initiating treatment. A Duration timer begins when its respective zone's detection window is satisfied. The programmed Duration time is checked following every cardiac cycle to determine if it has expired. As long as the zone's detection window remains satisfied, the duration timer continues to elapse. When a zone's Duration time expires and if the last detected interval is in that zone, detection is considered met and therapy is initiated (assuming no programmed detection enhancements inhibit therapy delivery) (Figure 3-3). If the last detected interval is not in the zone, therapy is not initiated. Each subsequent interval will be checked until an interval is in the original zone, or the window is no longer satisfied (Figure 3-4). If at any point during Duration, a zone's detection window detects fewer than 6 of 10 fast intervals, Duration is reset to zero (Figure 3-5). It will start again only if the detection window becomes resatisfied.

3-8 | TACHYARRHYTHMIA DETECTION INITIAL DETECTION

NOTE: Since the Duration timer is examined synchronously with a cardiac cycle, the programmed Duration may be exceeded by up to one full cardiac cycle time interval.

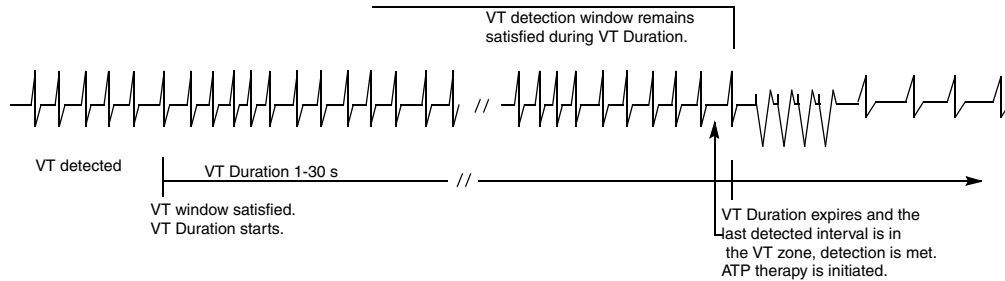


Figure 3-3. Duration starts when a window becomes satisfied and continues to elapse as long as the detection window remains satisfied. Detection is met when Duration expires and the last detected interval is in the same zone.

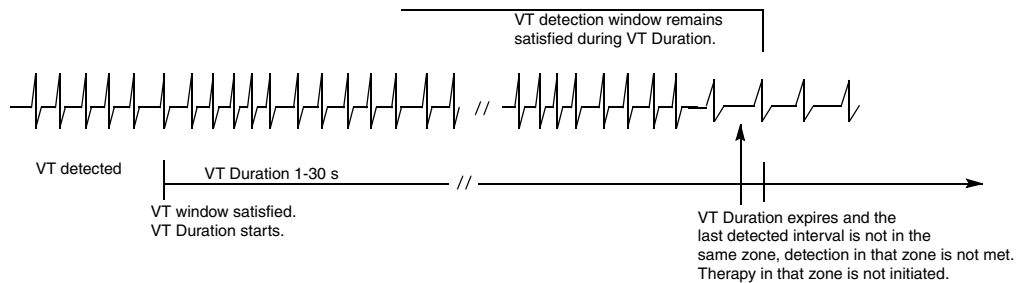


Figure 3-4. The last detected interval is in a different zone so detection in that zone is not satisfied. Therapy for that zone is not initiated.

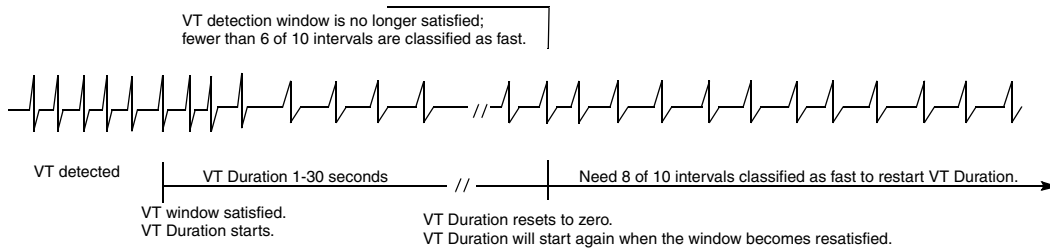


Figure 3-5. Duration resets when during the Duration period the window is no longer satisfied.

A Duration is programmed for each zone. Different values are available, depending on the configuration programmed. Table 3-3 below indicates the programmable options by zone and configuration. The Duration programmed in lower rate zones must be equal to or greater than higher zones. Longer durations may be used to prevent the device from initiating treatment of nonsustained arrhythmias.

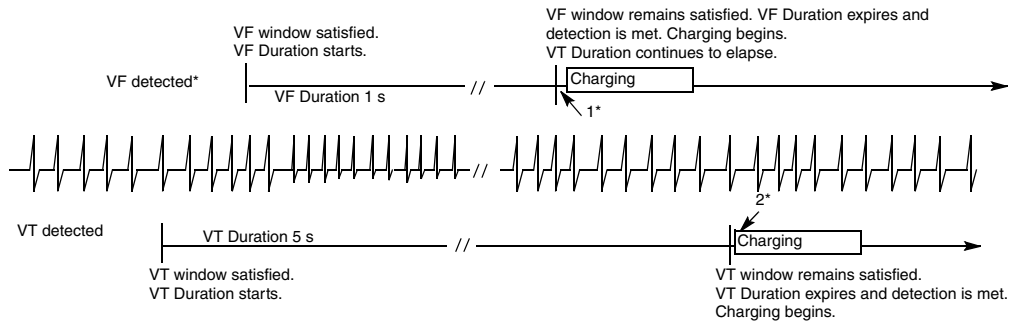
Table 3-3. Duration programmable ranges by zone and configuration

Configuration	VT-1 Zone	VT Zone	VF Zone
1 Zone			1–15 seconds
2 Zones		1–30 seconds	1–15 seconds
3 Zones	1–60 seconds	1–30 seconds	1–15 seconds

Duration in a Multizone Configuration

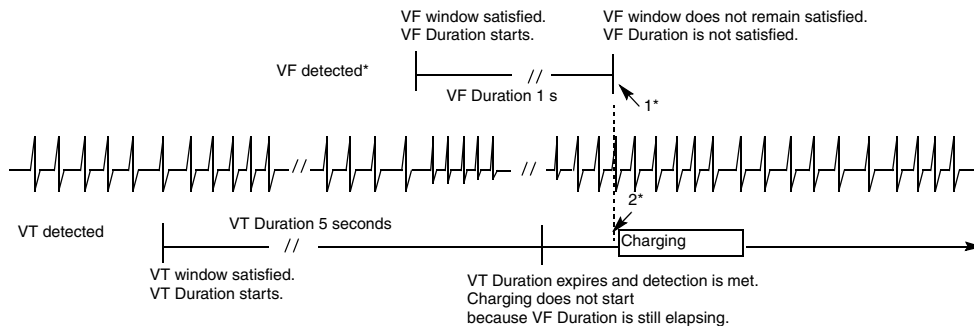
Duration timers run independent of each other within their respective zones. If the arrhythmia is detected in the highest zone, that zone's Duration timer takes precedence over the lower zones' timers; the lower zones' Duration timers continue to elapse but are ignored while the higher zone's Duration timer runs. If the higher zone's duration expires and detection is met, therapy for that zone will be initiated whether the lower zones' duration timers have expired or not. If the higher zone's detection window does not remain satisfied, then the Duration timers for the lower zones' are no longer ignored. Programmed therapy for lower zones will be initiated when a lower zone's detection is met and no higher zone's window is satisfied. Figure 3-6 and Figure 3-7 illustrate how the duration timers for the VT and VF detection windows interact. Both examples are for a two-zone configuration in which only shock therapy is programmed for simplicity of illustration.

3-10 | TACHYARRHYTHMIA DETECTION RECONFIRMATION/COMMITTED SHOCK



* While VT Duration is elapsing, the VF window becomes satisfied and VF Duration starts. The VT Duration continues to elapse, but is ignored. When VF Detection is met, charging begins at point 1. If the VF window's rate falls below the VF threshold before VF Duration expires, the VT Duration is no longer ignored as it continues to elapse. When VT Detection is met, charging would begin at point 2 (charging would not occur at point 1).

Figure 3-6. Interaction of Duration parameters in a two-zone configuration. Charging would occur either at 1 or at 2 (not both).



* While VT Duration is elapsing, the VF window becomes satisfied and VF Duration starts. The VT Duration continues to elapse, but is ignored. When the VT Detection is satisfied, charging does not start because the VF Duration (which has precedence over the VT Duration) is still elapsing. At point 1, the VF window's rate falls below the VF threshold before the VF Duration expires. As long as the VT window remains satisfied and last interval is in the VT zone, charging begins at the corresponding point 2 to deliver the VT therapy. If the VT window does not remain satisfied or the last interval is not in the VT zone, charging would not start.

Figure 3-7. Interaction of Duration parameters in a two-zone configuration when charging is delayed after the VT zone's Duration timer expired. Charging would occur either at 1 or 2 (not both).

RECONFIRMATION/COMMITTED SHOCK

Reconfirmation refers to the monitoring performed by the device during and immediately following capacitor charging for a cardioversion/defibrillation shock.

When the Committed Shock parameter is programmed to No, the device is allowed to reconfirm that a shock should be delivered. Refer to the section “Committed Shock/Reconfirmation of the Arrhythmia” on page 4-20 for details about the Committed Shock parameter and Diverted-Reconfirm.

EPISODES

When any zone’s detection window becomes satisfied, the start of an episode is declared. At the start of an episode, three things happen: 1) Duration timers begin in those zones whose detection windows are satisfied, 2) the pulse generator processes available rate information, and 3) the episode number is incremented and memory is allocated for history data and electrogram storage. When all detection windows are no longer satisfied and remain unsatisfied for a specified time, the episode is declared complete.

NOTE: Refer to the section “Stored Electrograms” on page 7-8 for details about electrogram storage and therapy history data.

Episodes can be classified as treated or nontreated (see Figure 3-8 on page 3-12 through Figure 3-12 on page 3-14).

- A treated episode is one in which therapy is delivered.
- A nontreated episode is one in which no therapy is delivered. (Nontreated episodes are described in more detail in the “Conversion Summary” and “Counters” sections of Chapter 7–“Patient Diagnostics”.)

For a treated episode, an end-of-episode timer starts at the point that therapy is delivered. For a nontreated episode, an end-of-episode timer starts at the point that the pulse generator recognizes that all detection windows are no longer satisfied, or reconfirmation indicates a tachyarrhythmia is no longer present. The end-of-episode time interval is intended to allow the patient to stabilize before initial detection and initial therapy is used again. The episode will be declared complete if no detection window becomes satisfied for a specified time following the last delivered therapy (see Table 3-4). If any window becomes resatisfied prior to the episode time-out being reached, the end-of-episode timer is reset to zero. It will start again when either therapy is delivered or all windows are not satisfied (see Figure 3-12 on page 3-14).

Once an episode has been declared complete, the pulse generator will apply initial detection and therapy to subsequent tachyarrhythmias.

Table 3-4. End-of-Episode Timer

Episode Classification	End-of-Episode Timer (elapsed time required to declare episode over)
Nontreated (no therapy delivered)	10 seconds
Treated (only ATP therapy delivered)	10 seconds
Treated (any shock therapy delivered)	30 seconds

NOTE: If, during an episode, the physician reprograms the Tachy Mode to Off, or if an induction method is attempted before the end-of-episode time-out, the episode is terminated immediately.

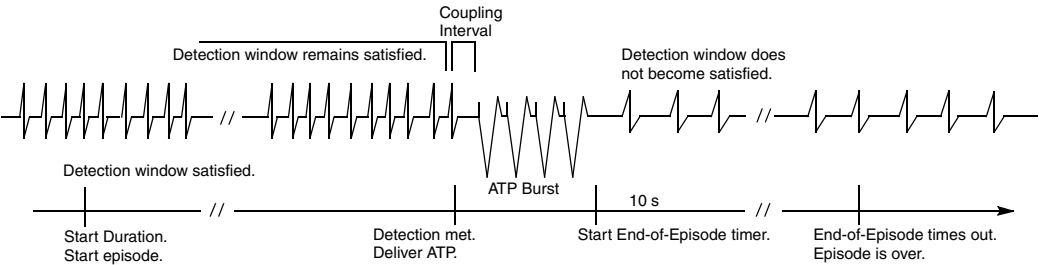


Figure 3-8. Treated episode when Tachy Mode is Monitor + Therapy and ATP therapy is delivered.

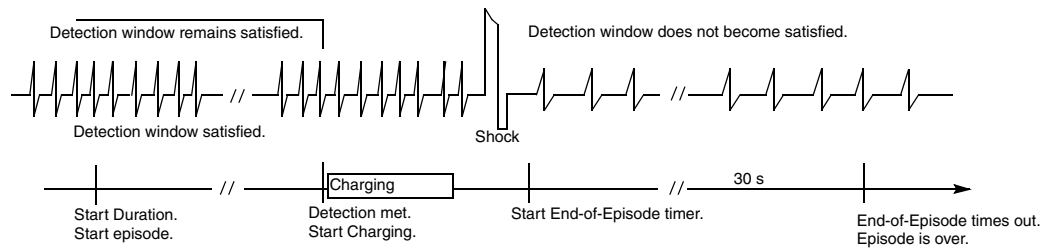


Figure 3-9. Treated episode when Tachy Mode is Monitor + Therapy and shock therapy is delivered.

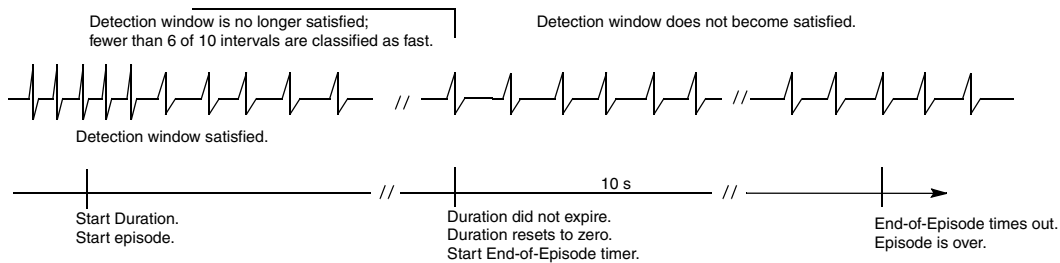


Figure 3-10. Nontreated episode when Tachy Mode is Monitor + Therapy or Monitor Only and Duration did not expire.

3-14 | TACHYARRHYTHMIA DETECTION DETECTION ENHANCEMENTS

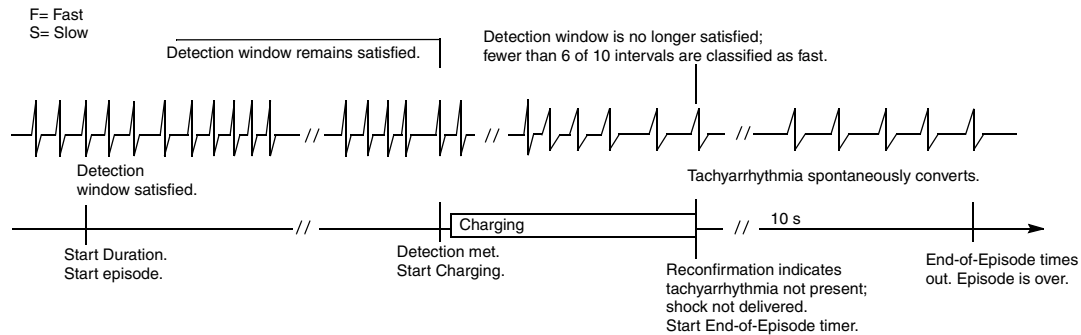


Figure 3-11. Nontreated episode when Tachy Mode is Monitor + Therapy and charging is stopped (prior to shock therapy delivery). This example assumes Committed Shock is programmed to No.

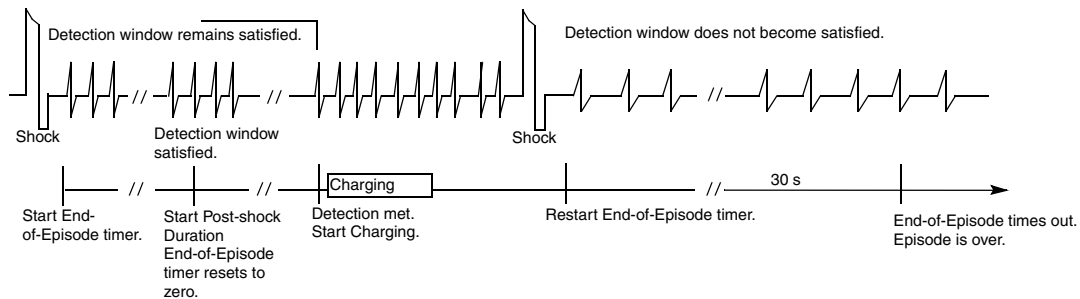


Figure 3-12. Treated episode when Tachy Mode is Monitor + Therapy and the End-of-Episode timer is reset to zero when a detection window becomes satisfied after therapy delivery prior to the episode time-out being reached. In this example, two shocks were delivered in the episode.

DETECTION ENHANCEMENTS

Detection enhancements may be programmed On to add specificity to the Rate and Duration detection criteria. Enhancements may be programmed to delay or inhibit therapy delivery if certain criteria are not satisfied at the end of Duration. Table 3-5 on page 3-15 illustrates in which zones the enhancements can be programmed.

- Rhythm ID (SVT Inhibit parameter) is used to inhibit therapy delivery in the presence of SVT (refer to the section “Rhythm ID” on page 3-15).
- SRD (Sustained Rate Duration) is used to override the Rhythm ID decision to inhibit therapy if the high rate continues beyond the programmed time period.

Table 3-5. Detection Enhancements Available in Multizone Configurations

	VT-1 Zone	VT Zone	VF Zone
1-zone Configuration			None
2-zone Configuration		Rhythm ID SRD	None
3-zone Configuration	Rhythm ID SRD	Rhythm ID SRD	None

Rhythm ID

Programmable Values: On, Off

The Rhythm ID feature is designed to add specificity to the Rate and Duration detection criteria. The Rhythm ID feature employs an algorithm that performs a vector/timing and correlation analysis. The pulse generator automatically and periodically saves a reference vector (normal conduction) of the patient's sinus rhythm using the shock and rate EGM. When a tachyarrhythmia is detected, Rhythm ID analysis compares the detected arrhythmia conduction vector to the reference vector and determines if a rhythm is SVT (normal conduction vector) or VT (abnormal conduction vector).

NOTE: Refer to the section “Manual Intrinsic Rhythm ID” on page 3-18 for information about obtaining a reference vector by performing a manual Intrinsic Rhythm ID.

The Rhythm ID enhancement parameter, SVT Inhibit, can be programmed On to inhibit therapy in the presence of SVT. SVT Inhibit is separately programmable for initial detection and postshock redetection. It is not available in the VF zone.

In dual-chamber models, during Rhythm ID analysis, the pulse generator first determines if the ventricular rate is greater than the atrial rate. Therapy will be initiated anytime the ventricular rate is greater than the atrial rate. This V Rate > A Rate analysis is made by comparing the average rate of the last 10 ventricular

intervals and 10 atrial intervals prior to the end of duration. If the average ventricular rate is greater than the average atrial rate by at least 10 bpm, the ventricular rate is declared to be faster than the atrial rate and therapy will be initiated. If the ventricular rate is not greater than the atrial rate, the Rhythm ID detection enhancement evaluates the following criteria to determine if therapy should be inhibited or initiated:

- Vector/timing and correlation analysis is performed to determine if the rhythm is SVT. If so, therapy is inhibited.
- The stability of the arrhythmia is evaluated by calculating R-R interval differences. This enables distinction between unstable (irregular) ventricular rhythms from stable (regular) ventricular rhythms. If the average difference is greater than 20 ms and the atrial rate is greater than 200 bpm, the rhythm is declared SVT and therapy is inhibited.

NOTE: *The Rhythm ID analysis does not consider atrial detection criteria (V Rate > A Rate, or A > 200 ppm) in single-chamber models or in dual-chamber models if the Detection Enhancement Mode is programmed to VR. In addition, Stability is not evaluated.*

If therapy is inhibited, the analysis continues until either the ventricular rate is greater than the atrial rate (V Rate > A Rate) or Rhythm ID analysis determines that a normal conduction vector (SVT) is no longer present or SRD expires (if SRD is programmed On), at which time therapy will be initiated.

Rhythm ID Detection Enhancement Mode

In dual-chamber models, Rhythm ID can function in either a VR or DR Detection Enhancement Mode. When the Detection Enhancement Mode is programmed to VR, the Rhythm ID analysis does not consider atrial detection criteria (V Rate > A Rate, or 200 bpm). In addition, Stability is not evaluated. Because the VR detection mode does not consider atrial detection criteria, it is useful in instances where atrial lead problems have occurred. Access the Rhythm ID Detection Enhancement Mode by selecting the Setup tool kit and then selecting the Therapy Features button.

Automatic Intrinsic Rhythm ID

Programmable Values: Automatic Intrinsic Rhythm ID: Off, On; Nominal: On.
Fallback: Off, On; Nominal: On

An automatic method of obtaining the patient's intrinsic rhythm is available. Automatic Intrinsic Rhythm ID Update may be programmed On to enable a periodic update. An Automatic Intrinsic Rhythm ID Fallback Lower Rate Limit (LRL) should be selected to elicit sinus rhythm or atrial pacing with normal AV conduction.

NOTE: *Programming Fallback to Off may prevent obtaining the patient's intrinsic rhythm automatically.*

To select the Automatic Intrinsic Rhythm ID Update feature, select the Therapy Features button from the Setup tool kit.

The device will attempt to collect the Automatic Intrinsic Rhythm ID reference vector every 2.3 hours. If seven days have passed since the last successful collection of a reference vector, then every 27 hours the Automatic Intrinsic Rhythm ID Fallback programming will:

1. Verify that the patient is at rest (as measured by the accelerometer input).
2. Enable a controlled rate decrease to the programmed Rhythm ID Fallback LRL. During this fallback period, the device extends AV Delay up to 400 ms and switches to a non-rate responsive, non-tracking Brady mode. All Rate Smoothing, ATR, hysteresis, and dynamic programming (excluding Dynamic VRP) is suspended.
3. After the Fallback interval, pacing parameters are restored to normal Brady programmed parameters (Figure 3-13). Fallback periods occur no more than

once per day and will typically last one minute.

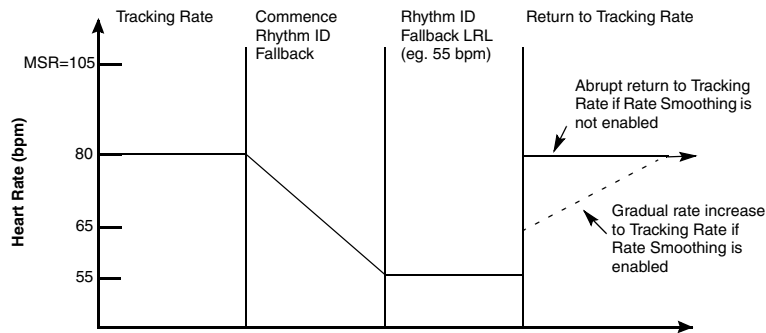


Figure 3-13. Schematic of the Intrinsic Rhythm ID Update.

The Automatic Intrinsic Rhythm ID Update may be programmed Off to disable update attempts. However, if the Detection Enhancements are enabled and the Automatic Intrinsic Rhythm ID Update is Off, use the Manual Intrinsic Rhythm ID method to ensure an appropriate reference vector is stored in the pulse generator memory for use in Rhythm ID analysis.

The times and dates of the last successful completion and the last update attempt using the programmed settings are displayed on the Manual Intrinsic Rhythm ID screen and printed in the Measured Data Report.

NOTE: *Intrinsic Rhythm ID Update LRL settings should be selected such that normal sinus rhythms are promoted (eg. normal AV node conduction). Care must be used when selecting LRL <50 bpm (rates that approach the patient's idioventricular rates). Idioventricular rhythms during manual or automatic Rhythm ID updates may result in inappropriate therapy decisions.*

Manual Intrinsic Rhythm ID

A manual method of obtaining the patient's intrinsic rhythm is available by temporarily programming the Brady Mode and Lower Rate Limit to values that promote either sinus rhythm or atrial pacing with normal AV conduction.

1. Access the Diagnostic Evaluation tool kit and select the Intrinsic Rhythm ID button. Notice that the date and time of the last successful Intrinsic Rhythm ID completion and the date and time of the last attempt using the programmed Fallback Pacing parameters are displayed.

2. If required, reprogram the parameter values to elicit sinus rhythm or atrial pacing with normal AV conduction and select Start to perform the analysis. The device automatically extends AV Delay up to 400 ms. The resulting reference vector will be stored in the pulse generator memory for use in Rhythm ID analysis.

During a Manual Intrinsic Rhythm ID update, the device will:

1. Enable a controlled rate decrease to the programmed Rhythm ID Fallback LRL. During this fallback period, the device extends AV Delay up to 400 ms and switches to a non-rate responsive, non-tracking Brady mode. All Rate Smoothing, ATR, hysteresis, and dynamic programming (excluding Dynamic VRP) is suspended.
2. After the Fallback interval, pacing parameters are restored to normal Brady programmed parameters (Figure 3-13). This process will typically last one minute.

NOTE: *Intrinsic Rhythm ID Update LRL settings should be selected such that normal sinus rhythms are promoted (eg. normal AV node conduction). Care must be used when selecting LRL <50 bpm (eg. rates that approach the patient's idioventricular rates). Idioventricular rhythms during manual or automatic Rhythm ID updates may result in inappropriate therapy decisions.*

Sustained Rate Duration (SRD)

Programmable Values: Off, 10 seconds to 60 minutes

Sustained Rate Duration allows the programmed therapy to be delivered when a tachycardia is sustained for a programmed period of time beyond Duration, but SVT Inhibit indicates to withhold therapy.

SRD is used only when SVT Inhibit is programmed On; but SRD can be programmed separately in the VT-1 and VT zones. The value programmed for the VT-1 zone must be greater than or equal to the value programmed for the VT zone. If SVT Inhibit is withholding therapy delivery and the Rate criterion in the VT-1 zone is maintained, the SRD timer, when programmed on, begins at the end of Duration. (The SRD timer in the VT zone starts concurrently with the VT-1 zone timer.) If the detection window in the VT-1 zone is maintained for the programmed SRD period, the programmed therapy will be delivered at the end of the SRD period.

If the rate accelerates from the VT-1 zone to the VT zone and the Duration for the VT zone expires and SVT Inhibit is programmed Off in the VT zone, then therapy is initiated in the VT zone without waiting for SRD to time out. If the VT zone has SVT Inhibit programmed On, SRD will continue until it reaches the smaller of the programmed SRD values in the VT-1 and VT zone.

NOTE: When reprogramming the pulse generator zone configuration (number of zones), the nominal values of the detection enhancements are adjusted in the zones. Review the values in the Change and Present columns when changing number of zones.

(An independent post-shock SRD value may be programmed; refer to the “Redetection” section below.)

REDETECTION

Redetection is the detection process that occurs following any therapy delivery, diverted therapy due to reconfirmation analysis (diverted-reconfirm), or manually diverted therapy. Redetection uses the same detection window process (8 of 10 fast intervals) and programmed tachycardia rate thresholds as initial detection to confirm or deny the presence of a tachyarrhythmia. The primary difference between initial detection and redetection are the duration parameters used following therapy. The type of therapy last delivered in the current episode determines which of the two duration parameters are used: Redetection Duration or Post-shock Duration. Following therapy, the pulse generator requires 8 of 10 fast intervals to satisfy a detection window and to start the appropriate duration timer (refer to Figure 3-14 on page 3-21 and Figure 3-15 on page 3-21). Whichever duration is determined to be appropriate, that type of duration (Redetection or Post-shock) will be in effect in all zones at each zone’s programmed duration value.

Redetection Duration and Post-shock Duration

Programmable Values: 1–15 seconds. Nonprogrammable in VF zone: 1 second

During the redetection process (looking for 8 of 10 fast intervals), Redetection Duration is applied following delivery of ATP therapy, a diverted-reconfirm, or manually diverted therapy. Post-shock Duration is applied following shock therapy delivery. Redetection Duration is programmable as independent values in the lower zones of a multizone configuration, and is nonprogrammable in the VF zone. Post-shock Duration can be programmed in the same manner. The values programmed in the lower rate zones must be equal to or greater than higher zones.

To help minimize total arrhythmia time, it is recommended that Redetection Duration in the VT-1 and VT zones of multizone configurations be programmed at less than or equal to 5 seconds.

It is recommended that Post-shock Duration in the VT-1 and VT zones of multizone configurations be programmed at less than or equal to 5 seconds. However, programming longer durations may be useful if shock-induced nonsustained high rate rhythms such as accelerated idioventricular rhythm (AIVR) or atrial fibrillation are evident. The longer durations may allow the rhythm to return to a lower rate before redetection is met.

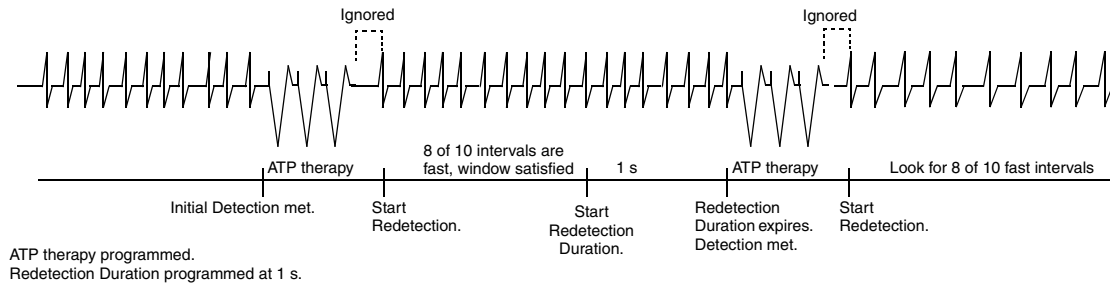


Figure 3-14. Illustration of redetection following ATP therapy delivery.

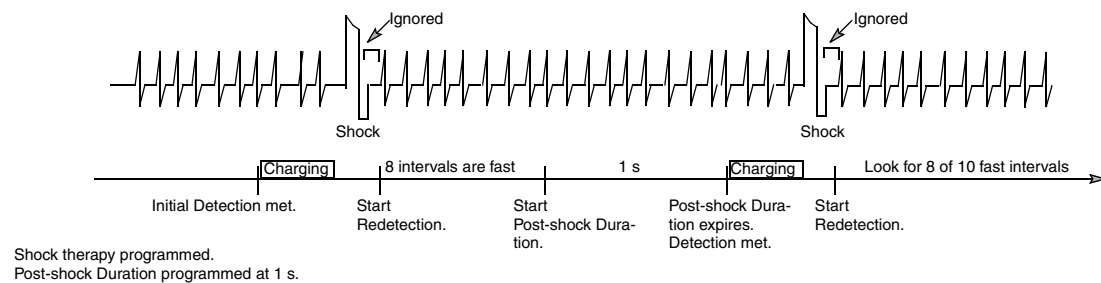


Figure 3-15. Illustration of redetection following shock therapy delivery.

Post-shock Rhythm ID

Programmable Values: On, Off

The Post-shock Rhythm ID enhancement, SVT Inhibit, can be programmed On separately from initial detection. To determine if therapy should be inhibited or initiated, the pulse generator evaluates the following criteria; it does not use the vector/timing and correlation analysis as described for initial Rhythm ID.

- The atrial rate is compared to the ventricular rate (V Rate > A Rate) as described in the initial Rhythm ID section (page 3-15). If the ventricular rate is greater than the atrial rate, therapy will be initiated.
- The stability of the arrhythmia is evaluated by calculating R-R interval differences. If the average difference is greater than 20 ms (30 ms for VR models) the rhythm is declared unstable. Additionally, the atrial rate is compared to a predetermined atrial fibrillation rate threshold of 200 bpm. If the atrial rate is greater than 200 bpm and the rhythm is declared unstable, therapy will be inhibited.

NOTE: *If the Detection Enhancement Mode is programmed to VR, atrial rate evaluation will not be performed and the stability of the arrhythmia is compared to a 30 ms value.*

Post-shock SRD

Post-shock SRD analysis is performed the same as during initial detection. Refer to “Sustained Rate Duration (SRD)” on page 3-19 for a description of SRD analysis.

PROGRAMMING ZONE CONFIGURATIONS AND DETECTION PARAMETERS

The number of zones, the zones’ rate thresholds, and values for detection, redetection, and detection enhancement parameters can be programmed from the zone configuration display in the Tachy Parameters tool kit. Refer to section “Tachy Zone Configuration” on page 2-12.

1. Select the Tachy Parameters button from the tool box to display the zone configuration area and the selected zone’s parameters.
2. Change the number of zones by selecting the desired number (1, 2, or 3) from the #Zones column. The zone configuration will display the selected number of zones with hatch marks overlaying the new zones, which have not been programmed into the device yet.

3. To change the rate threshold, select the value box from the zone/rate bar. Alternatively, to change a zone's rate and view its detection parameter settings, select the zone's detection button.
4. Change any of the desired initial or redetection parameters. Hatch marks will overlay the zone's detection button until the changed parameters have been programmed into the pulse generator.
5. Select the magnifying-glass icon to view the detection enhancement window. Parameter values can be adjusted from this window.

NOTES:

- *If the patient has a slow VT rate, program the lowest tachy zone threshold lower than the patient's slow VT rate.*
- *As parameter values are changed, the information icon and/or stop sign icon may appear at the top of the main application screen to inform of potential parameter interactions. Refer to section "Buttons and Icons" on page 2-8 for a description of the icons.*

TACHYARRHYTHMIA THERAPY

CHAPTER 4

The pulse generator is capable of delivering two types of therapy to terminate ventricular tachycardia or fibrillation: antitachycardia pacing (ATP) and cardioversion/defibrillation shocks. Antitachycardia pacing schemes consist of bursts of pacing pulses that are delivered between the ventricular pace/sense electrodes. Shocks are high-voltage truncated exponential pulses (monophasic or biphasic) delivered through the shocking electrodes synchronously with detected heart activity.

This chapter describes therapy prescription and therapy selection (how the pulse generator determines which therapy to deliver), and the programmable ATP and shock parameters:

- “Therapy Prescription” on page 4-1
- “Antitachycardia Pacing Therapies and Parameters” on page 4-8
- “Shock Therapy and Parameters” on page 4-17
- “Committed Shock/Reconfirmation of the Arrhythmia” on page 4-20
- “Accessing Therapy Parameters” on page 4-22

THERAPY PRESCRIPTION

A therapy prescription determines the type of therapy to be delivered in a particular rate zone, and can consist of a combination of antitachycardia pacing and shocks as indicated in Figure 4-1. Each zone may be programmed with independent therapy prescriptions. ATP therapy is not available in the VF zone of any configuration. Throughout this manual, shock values indicate stored energy; refer to Table 4-1 on page 4-18 for the respective delivered energy values.

Within each zone, therapy strength must be in ascending order

Lowest strength → Highest strength

Between zones, therapy strengths are not restricted.

Zone	ATP1**	ATP2**	Shock 1	Shock 2	Shocks 3-5 (Maximum shocks)	Additional Shocks
VF	Not available		0.1-max J	0.1-max J	max J	max J
VT	All ATP types available	All ATP types available	0.1-max J	0.1-max J	max J	Not available
VT-1*	All ATP types available	All ATP types available	0.1-max J*	0.1-max J*	max J*	Not available

* In a VT-1 zone of a 3-zone configuration, some or all of the shocks may be programmed Off, starting with the maximum shocks first. If the maximum shocks are programmed Off, then Shock 2 can be programmed Off, and if Shock 2 is programmed Off, then Shock 1 can be programmed Off. If the arrhythmia persists in the VT-1 zone when some or all of the shocks are programmed Off, no further therapy will be delivered unless the arrhythmia accelerates to a higher zone. A Disable Therapy button is available on the VT-1 therapy window in order to quickly disable all ATP and Shock therapy in that zone.

** ATP therapy can be programmed as Off, Burst, Ramp, Scan, or Ramp/Scan in VT-1 and VT zones.

Figure 4-1. Therapy prescription in a 3-zone configuration.

When programming therapies, the therapies within a zone must be ordered in ascending therapy strengths. All ATP therapies are considered to be of equal strength, but are of lower strength than any shock therapy. The strength of the shock therapies is determined from the programmed energy. In a multizone configuration, therapies in a higher zone may be of lesser strength or equal to those in a lower zone; however, within each zone the therapies must be programmed in equal or increasing energy output.

Therapy Selection

The pulse generator determines which therapy to deliver based on these basic rules:

- Each successive therapy delivery must be greater than or equal to the strength of the previous therapy. Whenever a shock therapy has been delivered, no further ATP therapy is allowed in that episode, since ATP therapy is of lower strength than shock therapy.

- Each ATP scheme (which may consist of multiple bursts) can only be delivered once during an episode.
- Up to 8 shocks may be delivered in an episode: a) the first 2 shocks are programmable, b) the next 3 available shocks are nonprogrammable at the maximum-energy, and c) can be followed by up to 3 additional maximum-energy shocks if the arrhythmia is present in the VF zone (see below).

Additional Shocks

Up to 3 additional maximum-energy shocks per episode may be programmed in the VF zone of a 1-, 2-, or 3-zone configuration. These additional shocks will be delivered during an episode when the first 5 shocks have been delivered and the arrhythmia is present in the VF zone. The arrhythmia may either start in a lower zone and accelerate to the VF zone, or the arrhythmia may start in the VF zone. In either scenario, after the first 5 shocks have been delivered the additional shocks will be delivered as long as the arrhythmia is present in the VF zone. If the arrhythmia decelerates to a lower zone, the remaining additional shocks will not be delivered unless the arrhythmia accelerates back to the VF zone. Refer to section “Shock Energy” on page 4-17 for information about programming the shock energies.

NOTE: *In the event a shock is diverted with the DIVERT THERAPY programmer command, by magnet application, or due to a Diverted-Reconfirm, the diverted shock is not counted as one of the available shocks for that tachyarrhythmia episode. Also, commanded therapies and STAT SHOCK are not counted as one of the available shocks for an episode and do not affect subsequent therapy selection.*

Based on initial detection criteria, the pulse generator selects the first prescribed therapy in the zone in which the tachyarrhythmia is detected. After delivering the selected therapy, the pulse generator begins redetection to determine whether the arrhythmia has been converted.

- If the arrhythmia is converted to a rate below the lowest programmed threshold, the pulse generator continues monitoring until the end of the episode is declared. When the episode ends, the pulse generator will again use initial detection criteria for a new episode. When a new episode is declared, the first prescribed therapy will be delivered again.
- If the arrhythmia is not converted and an arrhythmia is redetected in the same zone, the next programmed therapy in that zone is selected and delivered (as

indicated in Figure 4-2), followed again by redetection. If the arrhythmia persists in the same zone the therapy will progress in that zone.

- If an arrhythmia crosses zones (accelerates or decelerates) following therapy delivery and is redetected in a higher or lower zone, a therapy of equal or greater strength than the previously delivered therapy is selected from the detected zone and delivered. Refer to Figure 4-2a through Figure 4-2e. For shock therapy, the pulse generator determines which shock to deliver prior to capacitor charging, based on the detected rate threshold. If during capacitor charging, the tachyarrhythmia accelerates or decelerates from the initially detected rate, the predetermined energy will be delivered.

Redetection is performed after each therapy delivery to determine if further therapy is required.

Zone	ATP1	ATP2	Shock 1	Shock 2	Remaining Shocks			Additional Shocks
VF			5 J	11 J	max	max	max	max+
VT	Burst	Scan	3 J	9 J	max	max	max	
VT-1	① Burst	② Ramp	③ 0.1 J	④ 2 J	⑤ max	⑥ max	⑦ max	

Figure 4-2. If the arrhythmia remains in the same zone in which it was initially detected, therapy delivery progresses in that zone in the direction indicated by the circled numbers, from the lower strength therapy in the ATP1 column and the highest strength therapy in the right column.

In Figure 4-2a to Figure 4-2e, after each redetection cycle, therapy delivery progresses in the direction indicated by the circled numbers. Upward sloping lines indicate acceleration of the arrhythmia to a higher zone and downward sloping lines indicate deceleration into a lower zone. The lowest strength therapy is in the ATP columns and the therapy strengths increase as you move to the right in the table.

NOTE: In the VT-1 zone of a three-zone configuration, one or two ATP schemes may be programmed as the only therapy, with all shocks programmed off. **If those pacing schemes do not terminate an arrhythmia detected in the VT-1 zone, no further therapy will be delivered in the episode unless the rate is redetected in a higher zone.**

Zone	ATP1	ATP2	Shock 1	Shock 2	Shocks 3–5	Additional Shocks
VF			2 J	⑤ 11 J	max max max	max+
VT	③ Burst	Off	④ 3 J	⑤ 9 J	⑥ max ⑦ max ⑧ max	
VT-1	① Burst	② Ramp	0.1 J	2 J	max max max	

ATP1 in the VT zone is delivered because it is considered of equal strength to VT-1 ATP2 therapy.

When the rhythm accelerates to the VF zone, Shock 2 in the VF zone is delivered since Shock 1 is a lower energy level than Shock 1 in the VT zone.

Figure 4-2a

Zone	ATP1	ATP2	Shock 1	Shock 2	Shocks 3–5	Additional Shocks
VF			11 J	17 J	max ⑦ max max	max+
VT	① Burst	③ Scan	④ 5 J	9 J	⑥ max max ⑧ max	
VT-1	② Burst	Ramp	3 J	⑤ 5 J	max max max	

When the rhythm accelerates back to the VT zone, ATP2 therapy is delivered because ATP1 has already been used during the episode.

Figure 4-2b

Zone	ATP1	ATP2	Shock 1	Shock 2	Shocks 3–5	Additional Shocks
VF			5 J	11 J	⑥ max max max	max+
VT	② Burst	③ Scan	④ 1.1 J	9 J	max ⑦ max ⑧ max	
VT-1	① Burst	Ramp	⑤ 3 J	5 J	max max max	

When the rhythm decelerates to the VT-1 zone, ATP2 of the VT-1 zone is not delivered since a shock had already been delivered in the VT zone. So the next higher strength therapy (Shock 1 of the VT-1 zone) is delivered.

This is the third shock, since two programmable shocks have been delivered.

Figure 4-2c

Zone	ATP1	ATP2	Shock 1	Shock 2	Shocks 3–5			Additional Shocks
VF			2 J	11 J	max	max	max	max+
VT	Burst	Scan	3 J	9 J	max	max	max	
VT-1	① Burst	② Ramp	③ 0.1 J	④ 2 J	Off	Off	Off	

If the arrhythmia persists in the VT-1 zone after the second shock delivery, no further shock therapy will be delivered unless the arrhythmia accelerates to a higher zone since Shocks 3–5 are programmed Off in the VT-1 zone.

Figure 4-2d

Zone	ATP1	ATP2	Shock 1	Shock 2	Shocks 3–5			Additional Shocks
VF			2 J	11 J	max	max	⑦ max	⑧ max ⑩ max+ ⑪
VT	Burst	Off	3 J	9 J	⑤ max	⑥ max	max	⑨
VT-1	① Burst	② Ramp	③ 0.1 J	④ 2 J	max	max	max	

A sixth shock (the first of the Additional Shocks) is delivered since the arrhythmia is in the VF zone.

The arrhythmia decelerated to a lower zone, an additional shock would not be delivered until the arrhythmia accelerated back to the VF zone.

The arrhythmia accelerated back to the VF zone, the second additional shock is delivered. The arrhythmia persists in the VF zone so the third (last) additional shock is delivered.

Figure 4-2e

Redetection After Therapy Delivery

After therapy delivery, the pulse generator employs redetection criteria to evaluate the rhythm and determine whether more therapy is appropriate. When redetection criteria are satisfied, the rules for therapy selection then determine the type of therapy to deliver.

Redetection After ATP Therapy

If an ATP scheme is being delivered, the pulse generator monitors the cardiac rate after each burst and employs detection windows (looking for 8 of 10 fast intervals) and the Redetection Duration to determine if the arrhythmia has terminated. The

ATP scheme will continue with the next bursts in the sequence until any one of the following conditions is satisfied:

- Redetection has declared that therapy is successful (end-of-episode)
- The specified number of ATP bursts in the scheme has been delivered
- The ATP Time-out for the zone has expired
- The detected arrhythmia rate changes to a different rate zone, whereby a different therapy is selected
- A DIVERT THERAPY command is received from the programmer during delivery of a burst or between bursts of a scheme
- A magnet abort occurs during delivery of a scheme

NOTE: *Aborting an ATP burst, either during or between bursts, will terminate the affected ATP scheme; if further therapy is required, the next programmed therapy (either ATP or shocks) in the prescription will be initiated.*

Redetection After Shock Therapy

If shock therapy is being delivered, the pulse generator monitors the cardiac rate after each shock and employs detection windows (looking for 8 of 10 fast intervals) and the Post-shock Duration, and post-shock detection enhancements if applicable, to determine if the arrhythmia has terminated. Shock therapy will continue until one of the following conditions is satisfied:

- Redetection has declared that therapy is successful (end-of-episode)
- All available shocks have been delivered for an episode
- The rhythm is redetected in the VT-1 zone and the available programmed shock(s) (0, 1, 2, or 5) has been delivered and the arrhythmia stays in the VT-1 zone

If all available shocks have been delivered for an episode, no further therapy is available until the pulse generator monitors a rate below the lowest rate threshold for 30 seconds and end-of-episode is declared.

ANTITACHYCARDIA PACING THERAPIES AND PARAMETERS

ATP therapy involves delivering a series of critically timed pacing pulses in an attempt to interrupt reentrant monomorphic ventricular tachycardia. Delivery of ATP therapy is coupled to the last sensed event that fulfills the detection criteria. Figure 4-3 illustrates the basic components of ATP therapy. Within an ATP scheme, the user may define the following components: 1) the number of bursts delivered, 2) the number of pulses within each burst, 3) the Coupling Interval and its characteristics, 4) the Burst Cycle Length and its characteristics, and 5) a minimum pacing interval. The components can be used to produce four types of ATP therapy schemes: burst, ramp, scan, and ramp/scan. The ATP amplitude and pulse width are common to all schemes and are independently programmable from the bradycardia pacing and post-shock brady pacing settings.

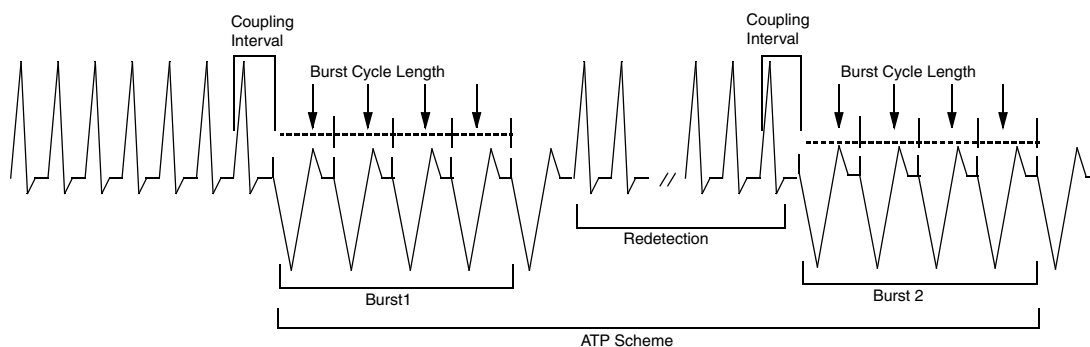


Figure 4-3. The basic components of ATP therapy: Coupling Interval, Burst, and Burst Cycle Length.

Burst Parameters

Programmable Values: Number Of Bursts 1–30 bursts, Off; Initial Pulse Count 1–30 pulses; Pulse Increment 0–5 pulses; Maximum Number of Pulses 1–30 pulses

All ATP schemes have several parameters in common. In addition to programming the type of scheme (burst, ramp, scan, ramp/scan) the following parameters are programmed to optimize ATP therapy:

- The Number Of Bursts parameter determines the number of bursts used in an ATP scheme and may be programmed independently for each ATP scheme. Programming the parameter Off will deactivate the ATP scheme.

- The Initial Pulse Count parameter determines the number of pulses delivered in the first burst of a scheme.
- The Pulse Increment parameter allows the number of pulses per burst to be increased for each successive burst in the scheme.
- The Maximum Number of Pulses parameter determines the greatest number of pulses used in an ATP burst and may be programmed independently for each ATP scheme. After the maximum number of pulses is reached in a burst, each additional burst remaining in the scheme contains the programmed Maximum Number of Pulses. The programmed parameter is effective only if the Pulse Increment is greater than zero.

Figure 4-4 illustrates the interaction of these parameters in a simple burst scheme. Figure 4-10 on page 4-15 illustrates the interaction of these parameters in a ramp/scan scheme.

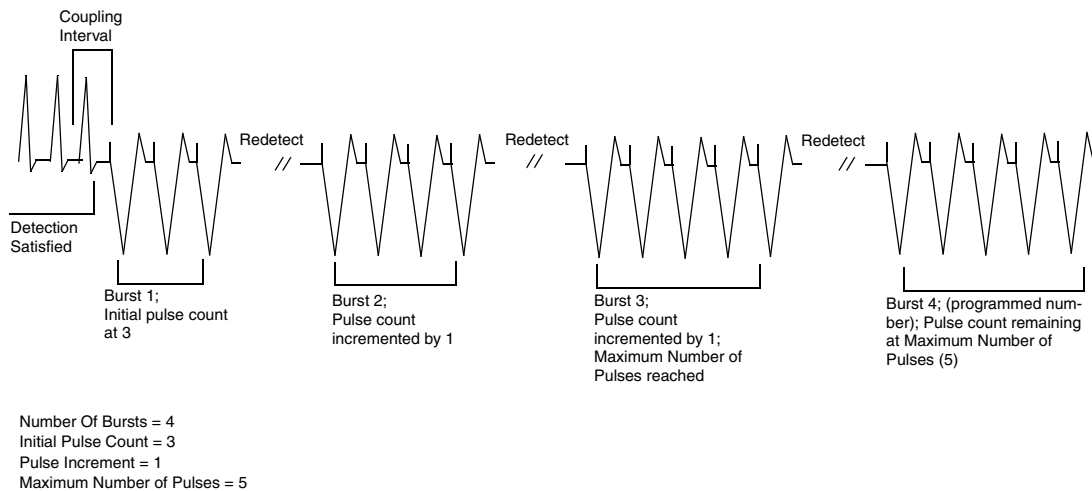


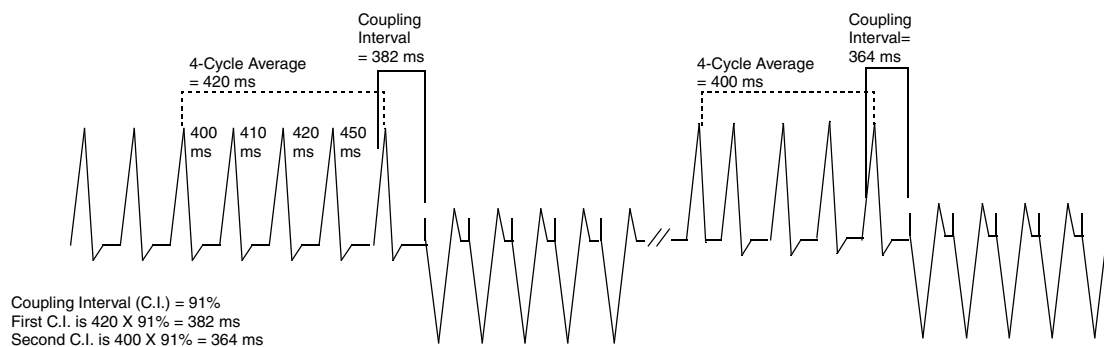
Figure 4-4. In this example, the programmed Maximum Number of Pulses (5) was reached before the Number Of Bursts (4) was reached, so the third and fourth bursts each contained 5 pulses.

Coupling Interval (C.I.) and Coupling Interval Decrement

Programmable Values: Coupling Interval 50–97% or 120–750 ms; Coupling Interval Decrement 0–30 ms

The Coupling Interval controls the timing of the first pulse in a burst. It defines the time between the last sensed event that fulfills the detection criteria and delivery of the first paced pulse in a burst. The Coupling Interval is programmed independent from the Burst Cycle Length. This allows aggressive ramps and scans to be used without compromising capture of the first pacing pulse in a burst. The Coupling Interval can be programmed as 1) adaptive, with timing specified as percentages of the computed average heart rate, or 2) as a fixed interval, with timing specified in absolute time (milliseconds) independent of the measured average rate. When programmed as adaptive, the intervals adjust to the patient's rhythm based on a 4-cycle average as explained in Figure 4-5. The Coupling Interval Decrement may be programmed such that the Coupling Interval decreases from one burst to the next within a multiple-burst scheme (Figure 4-6).

Note that when the Coupling Interval Decrement is programmed on, the programmed ATP scheme is called a scan. Refer to the section “Accessing Therapy Parameters” on page 4-22.



The 4-cycle average is calculated on the four cycles prior to each tachycardia therapy delivery only when no Decrement (Coupling Interval or Scan) is programmed.

Figure 4-5. Example of an adaptive Coupling Interval with the Coupling Interval Decrement and Scan Decrement turned off.

NOTE: When the Coupling Interval is programmed as adaptive and the Coupling Interval Decrement or Scan Decrement (see page 4-13) are programmed on (greater than zero), the Coupling Interval will not re-adapt following redetection because the decrement value determines the timing of the first pulse in subsequent bursts.

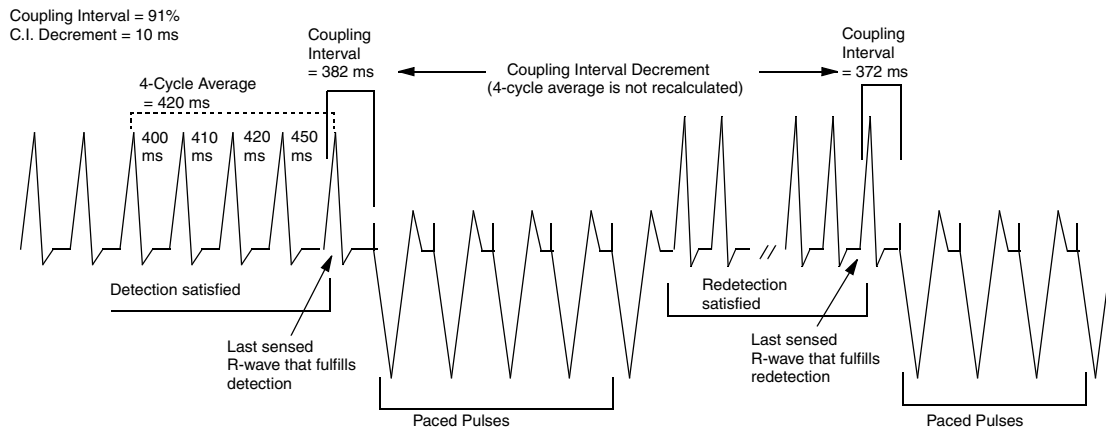


Figure 4-6. The Coupling Interval may be decreased from one burst to the next by programming the Coupling Interval Decrement. Note that the new average rate is *not* recalculated for a decremental Coupling Interval.

Burst Cycle Length (BCL)

Programmable Values: 50–97% or 120–750 ms

The Burst Cycle Length controls the interval between pacing pulses. This timing is controlled in the same fashion as the Coupling Interval; rate adaptive to the sensed tachycardia, or fixed time specified in milliseconds.

NOTE: An adaptive BCL is affected in the same manner as an adaptive Coupling Interval; the average cycle length is **not** continually recalculated for subsequent bursts if the Scan Decrement or Coupling Interval Decrement are programmed on.

There are two decrements that may be programmed to adjust the burst cycle length during an ATP scheme: a Ramp Decrement controls the pulse timing within a given burst (see page 4-13), and a Scan Decrement controls the pulse timing between bursts (see page 4-13).

Minimum Interval

Programmable Values: 120–400 ms

The Minimum Interval limits the Coupling Interval and the Burst Cycle Length (in Burst, Ramp, and Scan). If the Coupling Interval reaches the limit, subsequent Coupling Intervals will remain at the minimum value. Likewise, if the BCL reaches the limit, subsequent BCLs will remain at the minimum value. The Coupling Interval and BCL may reach the limit independently.

Burst Scheme

Programmable Values: Number of Pulses 1–30

A burst is a sequence of critically timed pacing pulses (1 to 30) intended to interrupt a reentrant loop, usually delivered at a rate faster than the patient's tachycardia. An ATP scheme is defined as a “Burst” (as indicated on the PRM screen) when the timing of all pacing intervals within a burst is the same (Figure 4-7). The first burst cycle length of each burst is determined by the programmed BCL. When the number of pulses programmed in a burst is greater than one, the BCL is used to control the timing between these paced pulses.

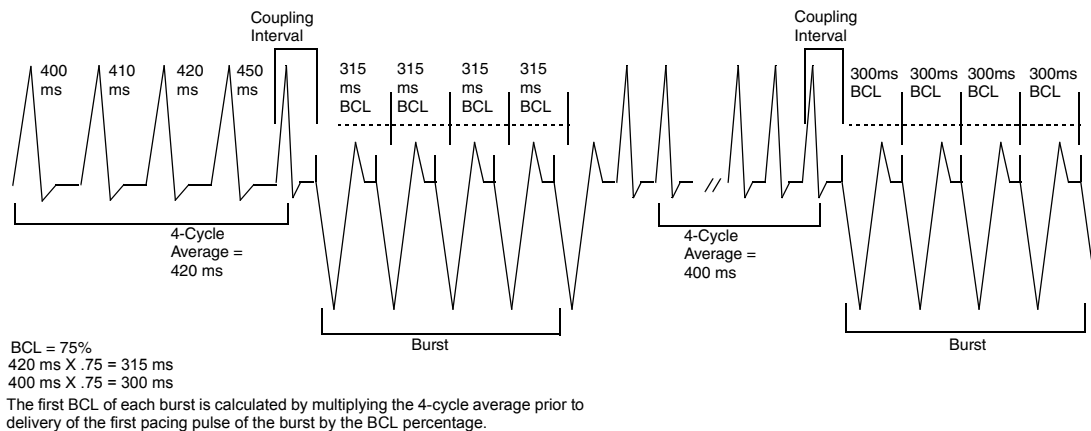


Figure 4-7. A simple adaptive-rate burst scheme, illustrating the pacing pulses in a burst and the Burst Cycle Length.

Ramp Scheme

Programmable Values: Ramp Decrement 0–30 ms

A Ramp scheme is defined as a burst in which each paced-to-paced interval within the burst is shortened (decremented). To program a Ramp scheme, the Ramp Decrement should be programmed (in ms) to specify by how much the paced-to-paced interval should be shortened, and the Scan Decrement and Coupling Interval Decrement each should be programmed to 0 ms. As each additional paced pulse in a burst is delivered, its interval is shortened by the programmed Ramp Decrement amount until the last paced pulse of the burst is delivered or the Minimum Interval is reached. If subsequent bursts are required, the programmed Ramp Decrement will be applied based on the calculated BCL of that subsequent burst. Refer to Figure 4-8.

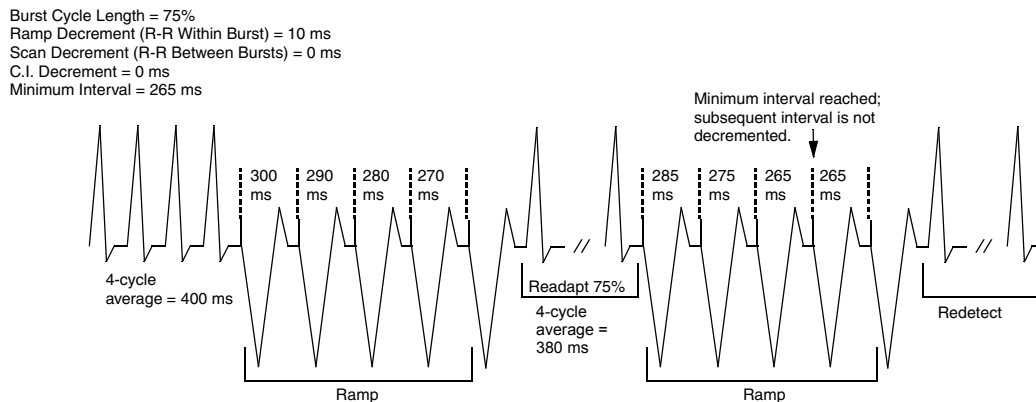


Figure 4-8. Example of an adaptive Ramp scheme with Coupling Interval Decrement and Scan Decrement programmed to zero.

Scan Scheme

Programmable Values: Scan Decrement 0–30 ms

A Scan scheme is defined as a burst in which the BCL of each burst in a scheme is systematically shortened (decremented) between successive bursts. To program a Scan scheme, the Scan Decrement should be programmed (in ms) to specify the BCL decrement, and the Ramp Decrement should be programmed to 0 ms. The

BCL of subsequent bursts is determined by subtracting the Scan Decrement from the BCL of the previous burst. Refer to Figure 4-9.

NOTE: When the Scan Decrement is programmed on, the BCL or Coupling Interval, if programmed as adaptive, will not re-adapt following redetection. The Scan Decrement determines the burst cycle length of successive bursts.

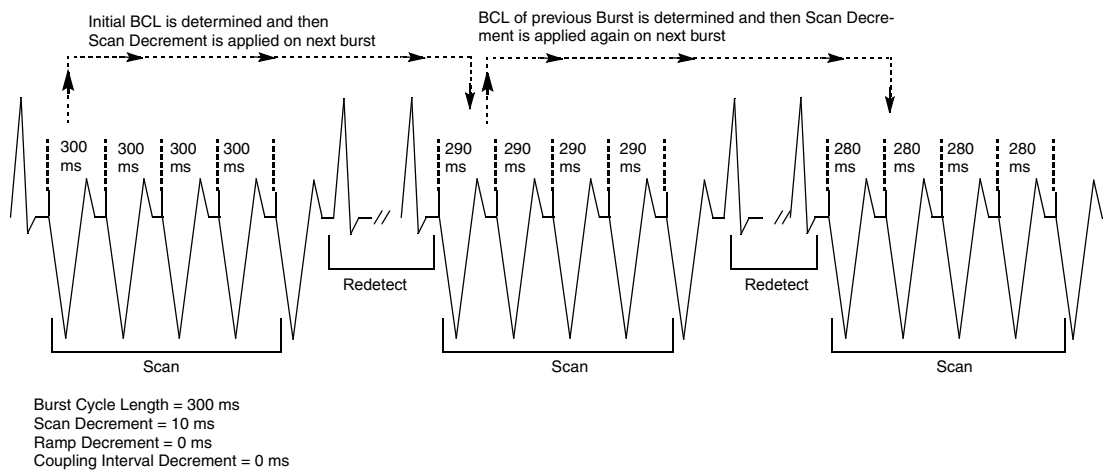


Figure 4-9. Example of a Scan scheme with nonadaptive BCL and Scan Decrement programmed on.

Ramp/Scan Scheme

A Ramp/Scan scheme is a sequence of bursts, the first of which is a Ramp scheme, followed by subsequent Scan schemes in which each burst is a Ramp. Refer to Figure 4-10. To program a Ramp/Scan scheme, both the Scan Decrement and Ramp Decrement are programmed to values greater than 0 ms.

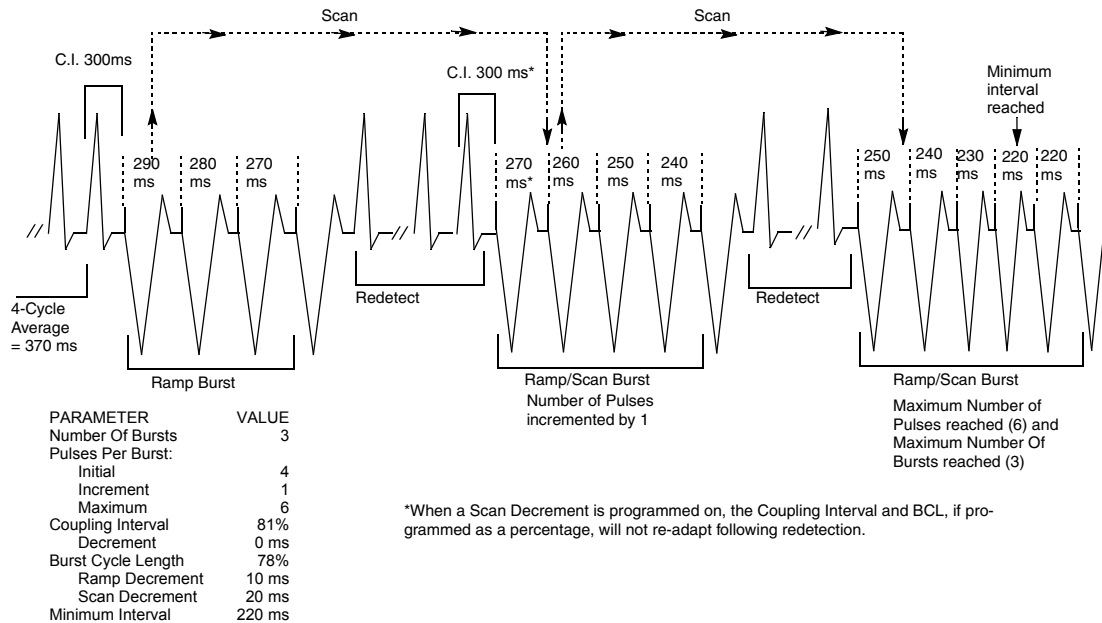


Figure 4-10. Interaction of ATP parameters in a Ramp/Scan burst scheme.

ATP Pulse Width and ATP Amplitude

Programmable Values: ATP Pulse Width 0.5–2 ms; Ventricular ATP Amplitude 0.2–7.5 V, Atrial ATP Amplitude 0.2–5.0 V, Atrial ATP Pulse Width 0.5–2 ms (DR models only); Ventricular ATP Pulse Width 0.5–2 ms; Atrial ATP Amplitude 0.2–5.0 V (DR models only); Ventricular ATP Amplitude 0.2–7.5 V

The ATP Pulse Width is the duration of a pacing pulse. The ATP Amplitude refers to the leading edge voltage of a pacing pulse. The ATP Pulse Width and ATP Amplitude parameters are programmable separately from the Brady Pacing and Post-shock Brady Pacing Pulse Width and Amplitude. However, a common ATP Pulse Width value and ATP Amplitude are programmed for all ATP schemes regardless of zone and position in a prescription. The programmable values can be changed by selecting the Therapy Features button from the Setup tool kit.

ATP Time-out

Programmable Values: 10 seconds to 60 minutes, Off

The ATP Time-out forces the pulse generator to skip over any remaining ATP therapy in a zone to begin delivering shock therapy programmed in the same zone. The timer alone does not invoke therapy; the rate and duration criteria and detection enhancements must still be satisfied in order for a shock therapy to be delivered.

The ATP Time-out may be used in any zone in which ATP therapy is programmed on. Timer values are independent although VT-1 ATP Time-out must be equal to or greater than the VT ATP Time-out.

The timer starts when the first burst is delivered and continues until a) the timer expires (Figure 4-11), b) a shock is delivered, or c) the episode ends. The time-out is examined after each redetection sequence to determine if further ATP bursts can be delivered. If the time-out has been reached or exceeded, further ATP therapy will not be initiated during that episode. The time-out will not terminate a burst in process.

NOTE: Once a shock has been delivered during an episode, antitachycardia pacing will no longer be invoked, irrespective of the time remaining on the ATP Time-out timer.

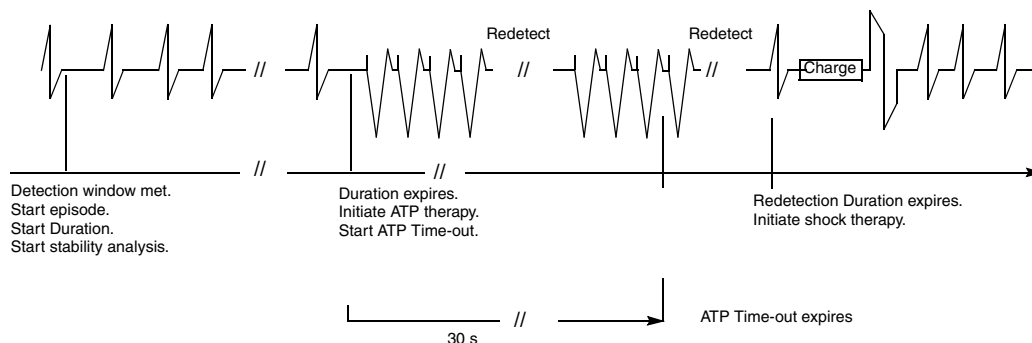


Figure 4-11. When the ATP Time-out expires, if the detection criteria remain satisfied, no further ATP therapy will be delivered; shocks, if programmed, will be initiated.

If three zones are programmed, ATP Time-out settings may be programmed in each of the lower two zones. (A single timer is used and is compared to two separate time-out values.) Figure 4-12 illustrates a three-zone configuration.

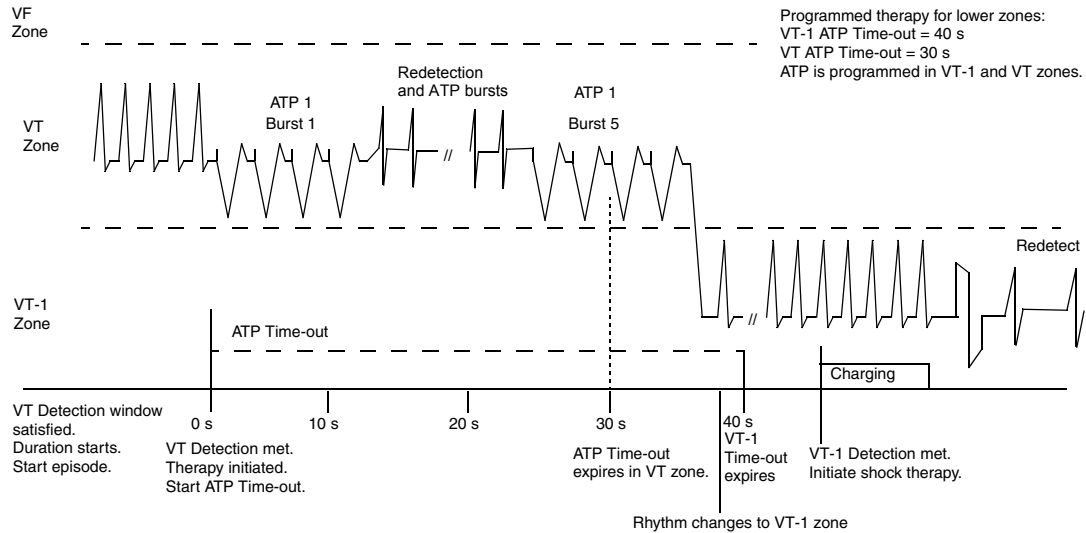


Figure 4-12. In a three-zone configuration, the two lower zones' ATP Time-outs are evaluated. As shown, if redetection in the VT-1 zone occurs after 40 seconds, shock therapy is initiated. If redetection had occurred prior to the 40-second time-out, ATP for the VT-1 zone could have been initiated. After 30 seconds, if redetection occurred in the VT zone, shock therapy would be initiated.

SHOCK THERAPY AND PARAMETERS

The pulse generator delivers truncated exponential shocks synchronous to a sensed event. The energy level, waveform, and polarity of the shocks may be programmed.

Shock Energy

Programmable Values: Off (VT-1 zone only), 0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31 J; **Number of Additional Shocks** 0, 1, 2, 3 shocks at maximum energy

The energy levels of Shock 1 and Shock 2 are programmable in each zone, and the remaining shocks' energies are nonprogrammable at the maximum-energy value.

The Number of Additional Shocks (maximum-energy) can be programmed for delivery in the VF zone. Refer to the section “Therapy Selection” on page 4-2 for more information regarding shock delivery. Shock output energy levels remain constant over the lifetime of the pulse generator, regardless of changes in lead impedance or battery voltage. The constant output is accomplished by varying the pulse width to adjust to changes in lead impedance.

Charge Time

The pulse generator typically requires 7.0 seconds to charge for delivery of a maximum-energy shock at 37°C at BOL (Beginning Of Life). Charge time is dependent upon: 1) the programmed output energy level, 2) the battery condition, and 3) the condition of the energy storage capacitors. Charge times increase as the pulse generator is programmed to higher energy output levels and as the battery depletes. Table 4-1 shows the programmable energy levels and the typical charge time required at BOL for each.

Capacitor deformation can occur during inactive periods and may result in a slightly longer charge time. To reduce the impact of capacitor deformation on charge time, the capacitors are automatically re-formed.

Table 4-1. Typical charge time required at 37°C at BOL

Energy (J) Stored ^a	Energy (J) Delivered ^b	Charge Time ^c (seconds)
0.1	0.1	0.1
0.3	0.3	0.1
0.6	0.5	0.2
0.9	0.8	0.2
1.1	1.0	0.3
1.7	1.5	0.5
2.0	2.0	0.6
3.0	3.0	0.8
5.0	4.0	1.1
6.0	5.0	1.4
7.0	6.0	1.7

Table 4-1. Typical charge time required at 37°C at BOL

Energy (J) Stored ^a	Energy (J) Delivered ^b	Charge Time ^c (seconds)
9.0	8.0	2.3
11.0	10.0	2.8
14.0	12.0	3.4
17.0	15.0	4.2
21.0	18.0	5.0
23.0	20.0	5.6
26.0	22.0	6.1
29.0	25.0	6.6
31.0	27.0	7.0

- a. Values indicate the energy level stored on the capacitors and corresponds to the value programmed for shock energy parameters.
- b. The energy delivered indicates the shock energy level delivered through the shocking electrode.
- c. Charge times shown are at BOL after capacitor re-formation.

Waveform and Polarity

Programmable Values: Waveform: Biphasic, Monophasic; Polarity: Initial, Reversed; Invert Last Shock Polarity: Yes, No

The type and polarity of the shock waveform are programmable. The waveform type (biphasic or monophasic) determines how the pulse generator delivers the energy from the capacitors (Figure 4-13). The waveform polarity reflects the relationship between the leading edge voltages on the defibrillating output electrodes, as shown in Figure 4-14. The selection of the waveform type and polarity are global, and apply to all shocks delivered by the device except the polarity of the last shock. By programming Invert Last Shock Polarity, the polarity of the last delivered shock may be changed across zones. If additional shocks are programmed in the VF zone, only the last shock in the VF zone is inverted.

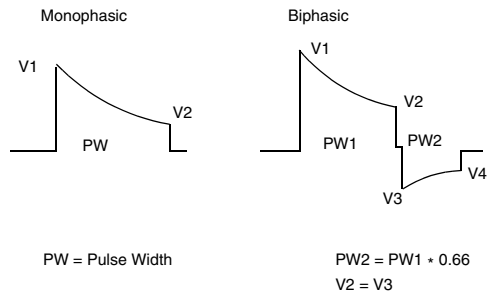


Figure 4-13. Illustration of monophasic and biphasic waveforms.

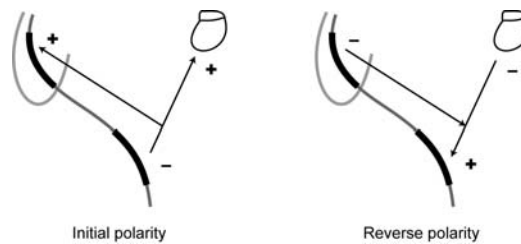


Figure 4-14. The polarity of the shock delivery can be reversed by programming the polarity feature.

COMMITTED SHOCK/RECONFIRMATION OF THE ARRHYTHMIA

Programmable Values: Yes, No

Reconfirmation refers to the monitoring performed by the pulse generator during and immediately following capacitor charging for a shock to check for spontaneous conversion of the tachyarrhythmia during the charging process. It determines whether shock therapy should be delivered or not; it does not affect the therapy selection. If the patient is subject to nonsustained arrhythmias, reconfirmation may be desirable in order to prevent delivery of an unnecessary shock to the patient. The use of reconfirmation should be balanced against the use of longer durations to minimize unwanted charge cycles.

Shock therapy can be programmed to be committed or noncommitted. If the Committed Shock feature is programmed Yes, the shock is delivered synchronously with the first sensed R-wave following a 500-ms delay after the capacitors are

charged (whether the arrhythmia is sustained or not) (see Figure 4-15). The 500-ms delay allows a minimum time for a divert command to be issued from the programmer, if desired. If there is no sensed R-wave detected within 2 seconds following the end of charging, the shock is delivered asynchronously at the end of the 2-second interval. Note that there is a forced 135-ms refractory period following the end of charging; events that occur during the first 135 ms of the 500-ms delay are ignored.

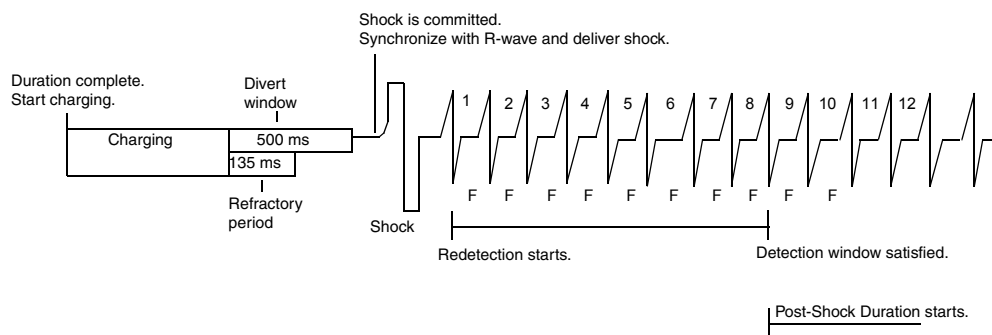


Figure 4-15. Reconfirmation is off. The Committed Shock feature is programmed to Yes.

If the Committed Shock feature is programmed No, Reconfirmation consists of the following steps (see Figure 4-16):

1. During capacitor charging, the pulse generator continues to sense the arrhythmia. Sensed and paced beats are evaluated. If 5 slow beats are counted in a 10-beat detection window, the pulse generator stops charging, and considers this a Diverted-Reconfirm.
2. If 5 of 10 slow beats are not detected and charging completes, the reconfirmation algorithm is performed after the end of charging. After the post-charge refractory and the first sensed event, the pulse generator measures up to 3 intervals following charging and compares them to the lowest Rate threshold. If 2 of the 3 intervals following charging are faster than the lowest Rate threshold, the shock will be delivered synchronously with the second fast event. If 2 of the 3 intervals following charging are slower than the lowest Rate threshold, the shock will not be delivered; and if no beats are sensed, pacing will begin at the programmed LRL following the 2-second no-sense period. If a shock is not

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delivered, or if pacing pulses are delivered, this is known as a Diverted-Reconfirm.

If the shock is not delivered, the energy remains on the capacitors until the end of the episode, at which time it is delivered to the pulse generator's internal test load; if during redetection a shock is required, the charge time for the shock may be extremely short.

The reconfirmation algorithm will not allow 2 consecutive Diverted-Reconfirm cycles in a row. If the arrhythmia is redetected after a Diverted-Reconfirm, the next shock in the episode is delivered as if Committed Shock were programmed to Yes. Once a shock has been delivered, the reconfirmation algorithm can be applied again.

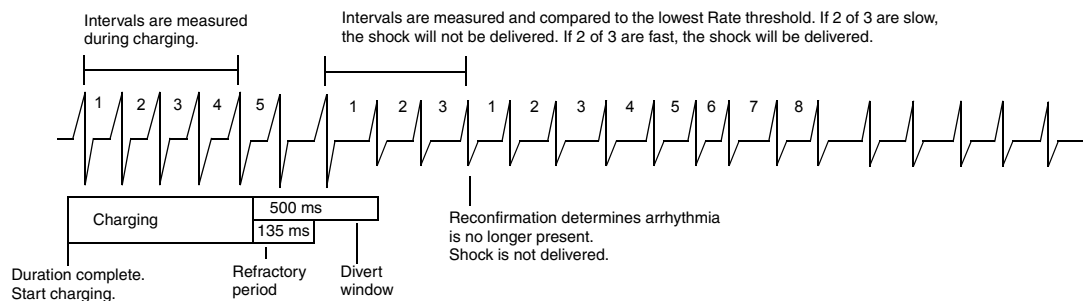


Figure 4-16. Reconfirmation is on. The Committed Shock feature is programmed to No.

ACCESSING THERAPY PARAMETERS

A summary of the currently selected therapy parameters is shown in the Zone Configuration area of the Tachy Parameters screen. A complete list of therapy parameters for a zone can be displayed as indicated below:

1. Select the desired zone's tachy therapy button with the shortcut icon from the Zone Configuration area of the Tachy Parameters screen to display a detailed therapy window (Figure 4-17).

The screenshot displays the 'Therapy parameters screen' with the following sections:

- Top Bar:** Shows three zones: Zone 1 (125 bpm VT-1, 2.5 sec SVI Inhibit), Zone 2 (145 bpm VT, 2.5 sec), and Zone 3 (165 bpm VF, 1.0 sec).
- VT-1 Therapy Section:**
 - ATP1 = Burst:** Present (4), Change (0). Parameters: Number of Bursts (4), Pulses per Burst (Initial 0, Increment 0, Maximum 0), Coupling Interval (81 ms), Decrement (0 ms), Burst Cycle Length (81 ms), Ramp Decrement (0 ms), Scan Decrement (0 ms), Minimum Interval (200 ms).
 - ATP2 = Burst:** Present (13), Change (0). Parameters: Coupling Interval (81 ms), Decrement (0 ms), Burst Cycle Length (81 ms), Ramp Decrement (0 ms), Scan Decrement (0 ms), Minimum Interval (200 ms).
 - SHOCKS:** Present (5), Change (11, 31). Parameters: Shock 1 (5 J), Shock 2 (11 J), Shocks 3-5 (31 J).
 - ATP Time-out:** 1:00 m:s.
 - Buttons:** 'Disable Therapy...' and 'Therapy Features Setup'.
- Bottom Navigation:** System Summary, Quick Check, Tachy Parameters (selected), Brady Parameters, Setup, Therapy History, Diagnostic Evaluation, EP Test.

Figure 4-17. Therapy parameters screen.

Note that when the VF Therapy window is displayed, only shock parameters are shown since ATP therapy is not available for programming in the VF zone. The number of additional maximum-energy shocks can be programmed in the VF zone. Up to 3 additional shocks can be programmed.

2. Change parameters to desired values. Notice the text at the top of the VT and VT-1 therapy windows indicates the type of ATP scheme programmed. When values are entered in the Change boxes for the Coupling Interval Decrement, Ramp Decrement, or Scan Decrement the text will change in the top line to indicate the type of ATP scheme that is specified by the changed parameters. To disable an ATP scheme, select the Number Of Bursts parameter and change its value to Off.

NOTE: To quickly disable all ATP and shocks in the VT-1 zone only, select the *Disable Therapy* button found only on the VT-1 Therapy window. This allows the VT-1 zone to act as a monitoring zone, which is helpful in gathering information on cardiac activity that is faster than the lowest zone rate threshold, but does not meet the programmed criteria required for therapy in a higher zone.

3. To access therapy parameters that are common to all zones, select the Therapy Features shortcut icon. (Alternatively, select the Therapy Features button from the Setup tool kit.) The parameters displayed affect all zones. These values also affect Temporary ATP, PES, STAT SHOCK, and Commanded Shock.

BRADYCARDIA PACING THERAPY

CHAPTER 5

This chapter contains descriptions of the programmable bradycardia pacing therapy parameters. The chapter is separated into submenu topics, as follows, with the submenu title noted at the top of each page.

- “Normal Brady and Post-shock Brady Parameter” on page 5-2
- “Sensor Submenu—” on page 5-12
- “Tachy Response Submenu—” on page 5-17
- “Rate Enhancements Submenu—” on page 5-24
- “AV Delay Submenu—” on page 5-30
- “Refractory Submenu—” on page 5-35
- “Noise Response Submenu—” on page 5-41

All parameters described in this chapter are accessible through the Brady Parameters screen and its submenus. The screen can be accessed by selecting the Brady Parameters tool button or the brady zone button.

The Brady Parameters screen (Figure 5-1) 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. To display the parameter for a particular submenu, select the button for that submenu.

Normal: DDDR		Post-shock: Off		Temporary	
		Present		Change	
Mode	DDDR	DDDR			
A-Tachy Response	On				
Lower Rate Limit	60			ppm	
Max Tracking Rate	120			ppm	
Max Sensor Rate	---	120		ppm	
AV Delay (Paced)	DYN	---		ms	
Atrial					
Pulse Width	0.4	0.5		ms	
Amplitude	3.5	2.6		V	
Refractory (PVARP)	DYN	---		ms	
Ventricular					
Pulse Width	0.4	0.5		ms	
Amplitude	3.5	2.6		V	
Refractory	DYN	---		ms	
*Post-shock Delay	3.0			sec	
*Affects Normal and Post-shock					
<div>Cancel Changes</div> <div>Copy Brady...</div>					
Sensor		AV Delay			
Tachy Response		Refractory			
Rate Enhancements		Noise Response			
		Present		Change	
Dynamic AV Delay		On			
Maximum Delay		150		ms	
Minimum Delay		80		ms	
Sensed AV Offset		-30		ms	
AV Search Hysteresis					
Search Interval		Off		cycles	
AV Increase		---		%	
<div>System Summary</div> <div>Quick Check</div> <div>Tachy Parameters</div> <div>Brady Parameters</div> <div>Setup</div> <div>Therapy History</div> <div>Diagnostic Evaluation</div> <div>EP Test</div>					

Figure 5-1. Brady Pacing parameters screen.

DESCRIPTION OF BRADYCARDIA PACING THERAPY

The VITALITY 2 VR pulse generators provide ventricular, bipolar (pace/sense), normal and post-shock bradycardia pacing. The VITALITY 2 DR pulse generators provide both atrial and/or ventricular, bipolar (pace/sense), normal and post-shock bradycardia pacing. Both dual-chamber and single-chamber devices include adaptive-rate parameters. Bradycardia pacing also can be programmed to Off. Bradycardia rhythms are detected on a cycle-by-cycle basis using modified ventricular-based timing. The bradycardia pacing function is independent of the tachycardia detection and therapy functions of the device, with the exception of interval-to-interval sensing.

The pulse generator provides the following types of bradycardia pacing:

- **Normal Bradycardia Pacing**—If the intrinsic heart rate falls below the programmed pacing rate, the device issues pacing pulses at the programmed settings. Sensor-based rate modulation allows the pulse generator to adapt the pacing rate to the patient's changing activity levels.
- **Post-shock Pacing**—Alternate bradycardia pacing therapy may be delivered for a programmed period to ensure capture after the delivery of a shock. Most post-shock parameters are programmable independently from the normal bradycardia pacing parameters. Post-shock pacing can be activated even if normal bradycardia pacing is off.
- **Temporary Brady Pacing**—Allows the clinician to examine alternate pacing therapies while maintaining the previously programmed normal parameters in the pulse generator memory.
- **STAT PACE**—Under command of the programmer via telemetry, the device initiates emergency ventricular pacing at high output settings. Refer to “STAT PACE” on page 2-33.

NORMAL BRADY PACING PARAMETERS

The pacing parameters (displayed in the Normal column of the Brady Pacing screen) are independently programmable from the Post-shock Brady and Temporary Brady parameters.

Brady Mode

The pacing modes available for dual-chamber devices are: Off, DDD(R), DDI(R), VDD(R), AAI(R), VVI(R) and OOO(R). In Temporary Brady pacing only, asynchronous and triggered modes [AOO(R), VOO(R), DOO(R), ODO, AAT, VVT] are available in addition to the normal pacing modes.

The pacing modes available for single-chamber devices are: Off, VVI(R) and OOO(R). In Temporary Brady pacing only, asynchronous and triggered modes [VOO(R), VVT, VVI(R), OVO, OOO(R)] are available in addition to the normal pacing modes.

For an explanation of the codes used in pacing, see Appendix A.

Dual-chamber modes. DDD(R) and VDD(R) modes are contraindicated as follows:

- In patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which may trigger ventricular pacing.
- In the presence of slow retrograde conduction that induces pacemaker-mediated tachycardia (PMT) which cannot be controlled by reprogramming selective parameter values.

Atrial pacing. In DDD(R), DDI(R), and AAI(R) modes, atrial pacing may be ineffective in the presence of chronic atrial fibrillation or flutter or an atrium that does not respond to electrical stimulation. In addition, presence of clinically significant conduction disturbances may contraindicate the use of atrial pacing.

NOTE: *If a separate pacemaker is desired, a dedicated bipolar pacemaker is recommended. Refer to Appendix B for information about required pacemaker/ICD interaction testing and procedures.*

Direct any questions regarding the individualization of patient therapy to your Guidant representative.

Lower Rate Limit (LRL)

Programmable Values: 30–175 ppm

The Lower Rate Limit (LRL) is the number of pulses per minute at which the pulse generator paces the ventricle or atrium (for dual-chamber devices) in the absence of sensed intrinsic activity.

The following interactive limits are effective when programming the LRL. Exercise caution when programming permanent pacing rates below 50 ppm or above 100 ppm.

- LRL must be less than both the MTR and MSR
- LRL must be at least 10 bpm less than the lowest tachy zone threshold
- MTR and MSR (whichever is greater) must be at least 5 bpm less than the lowest tachy zone threshold

Maximum Tracking Rate (MTR)

Programmable Values: 50–175 ppm

The Maximum Tracking Rate (MTR), available in dual-chamber devices, is the maximum rate at which the paced ventricular rate will track 1:1 with sensed atrial events. The MTR is applicable to atrial synchronous pacing modes, namely DDD(R) and VDD(R). Refer to “Lower Rate Limit (LRL)” on page 5-4 for interactive limits in programming the MTR.

When the sensed atrial rate is between the programmed LRL and MTR, 1:1 ventricular pacing will occur in the absence of a sensed ventricular event within the programmed AV Delay. If the sensed atrial rate exceeds the MTR, the pulse generator will begin a Wenckebach-like behavior to prevent the paced ventricular rate from exceeding the MTR. This Wenckebach-like behavior is characterized by a progressive lengthening of the AV interval until an occasional P-wave is not tracked because it falls into the PVARP. This results in occasional loss of 1:1 tracking as the pulse generator synchronizes its paced ventricular rate to the next sensed P-wave. Should the sensed atrial rate continue to increase further above the MTR, the ratio of sensed atrial events to sequentially paced ventricular events becomes lower until eventually 2:1 block results (eg, 5:4, 4:3, 3:2, and finally 2:1).

The programmer does not allow programming an MTR interval shorter than the sum of the AV Delay and the atrial refractory period-PVARP. (PVARP refers to the post-ventricular atrial refractory period.) If the sum of the AV Delay and atrial refractory periods is less than the interval of the programmed MTR, then the ventricular pacing rate is limited to the MTR by the pulse generator's Wenckebach-like behavior.

Rapid changes in the paced ventricular rate (eg, Wenckebach-like, 2:1 block) caused by sensed atrial rates above the MTR, may be dampened or eliminated by implementation of Atrial Tachy Response, Atrial Flutter Response, and/or Rate Smoothing parameters and sensor input.

Maximum Sensor Rate (MSR)

Programmable Values: 50–175 ppm

The Maximum Sensor Rate (MSR) is the maximum pacing rate allowed as a result of sensor control. When programming MSR, give consideration to the patient's condition, age, and general health. Adaptive-rate pacing at higher rates may be inappropriate for patients who experience angina or other symptoms of myocardial ischemia at these higher rates. An appropriate MSR should be selected based on an assessment of the highest pacing rate that is well tolerated by the patient. Refer to "Lower Rate Limit (LRL)" on page 5-4 for interactive limits in programming the MSR.

In dual-chamber devices, if the pulse generator is operating in DDDR or VDDR mode, the MSR and the MTR may be programmed independently to different values.

- If the MSR setting is higher than the MTR, and the atrium is being paced, a ventricular pacing rate above the MTR may occur in the presence of high activity levels.
- If the MSR setting is lower than the MTR, pacing above the MSR can only occur in response to sensed intrinsic atrial activity.

With 1-to-1 conduction the pulse generator maintains the paced rate by extending the VA interval. This extension is determined by the degree of difference between the programmed AV Delay and the intrinsic ventricular conduction (Figure 5-2). This is often referred to as modified ventricular-based timing.

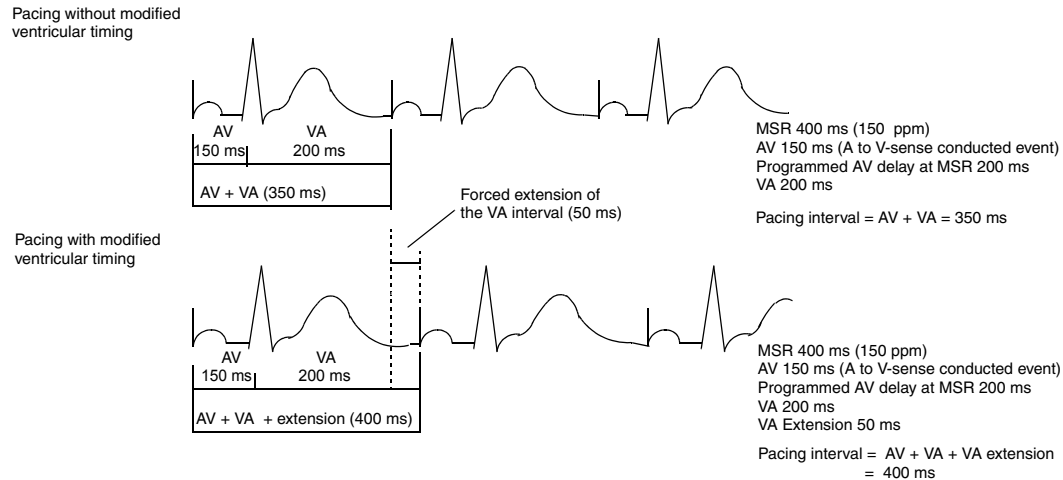


Figure 5-2. The pulse generator's timing algorithm provides effective pacing at the MSR with intrinsic conduction to the ventricle. By extending the VA interval, the A pace is prevented from exceeding the MSR at high rates.

Pulse Width

Programmable Values: Atrial or Ventricular 0.06–2.0 ms (DR models); Ventricular 0.06–2.0 ms (VR models)

The Pulse Width, or duration of the output pulse, is programmable. The atrial and ventricular pulse widths are independently programmable in VITALITY 2 DR devices.

The energy delivered to the heart is directly proportional to the pulse width. Therefore, programming a shorter pulse width increases pulse generator longevity. To prevent loss of capture, however, exercise caution when programming permanent pulse width values less than 0.3 ms.

Amplitude

Programmable Values: Atrial Off, 0.2–5.0 V, Ventricular Off, 0.2–7.5 V (DR models); Ventricular Off, 0.2–7.5 V (VR models)

The Pulse Amplitude, or voltage of the output pulse, is programmable and may be programmed Off to monitor the patient's underlying rhythm. The atrial and ventricular amplitudes are independently programmable in VITALITY 2 DR devices.

The energy delivered to the heart is directly proportional to the square of the amplitude. In other words, doubling the amplitude quadruples the energy delivered, which will decrease pulse generator longevity. Programming to a lower Amplitude while maintaining an adequate safety margin may increase battery longevity.

Dynamic Parameters

Three parameters that can be programmed for a Dynamic operation are displayed in the basic brady parameter list: AV Delay, Atrial Refractory-PVARP, and Ventricular Refractory Period-VRP (VRP). When programmed to Dynamic operation, the label DYN is indicated next to the parameter and allows a quick glance to verify that it is programmed as Dynamic without accessing the respective submenu. However, to program the parameters as Dynamic, respective submenus must be selected to display the parameter options. Refer to the sections "AV Delay" on page 5-30, "Ventricular Refractory Period-VRP" on page 5-35, and "Atrial Refractory-PVARP" on page 5-36.

If a Dynamic feature is programmed Off, the feature defaults to a fixed interval; the selection of the programmed value must then be made in the change box in the basic parameter list.

POST-SHOCK BRADYCARDIA PACING

Post-shock pacing provides alternate bradycardia pacing therapy for up to 60 minutes following delivery of any shock. All bradycardia parameters, except Noise Response, Atrial Tachy Response and sensor-indicated parameters, can be programmed independently of normal bradycardia pacing and are in effect following delivery of any shock. Noise Response, Atrial Tachy Response and sensor parameters when programmed affect both Normal Brady and Post-shock Brady pacing. The description of all bradycardia pacing parameters in Chapter 5 are applicable to post-shock pacing. Two additional parameters are pertinent only to post-shock therapy: Post-shock Pacing Delay and Post-shock Pacing Period

(described below). All post-shock parameters will be in effect for the Post-shock Pacing Period. Refer to Table 5-1 for the interaction of normal bradycardia pacing and post-shock brady pacing, and the resulting post-shock brady pacing condition.

Table 5-1. Matrix of Brady Mode and Post-shock Brady Mode

Normal Brady Pacing Mode	Post-shock Brady Pacing Mode	Post-shock Brady Pacing Results
On	Off	Post-shock pacing at normal brady settings
On	On	Post-shock pacing at post-shock brady settings
Off	On	Post-shock pacing at post-shock brady settings ^a
Off	Off	No pacing

a. Pacing will cease after the Post-shock Pacing Period is completed when Normal Brady is programmed Off, but Post-shock Brady mode is programmed on.

Post-shock Pacing Delay

Programmable Values: 1.5–10 seconds

The Post-shock Pacing Delay determines the earliest possible start of bradycardia pacing or post-shock bradycardia pacing after delivery of a shock. (Note that the Post-shock Pacing Delay is effective whether or not the Post-shock Brady Mode is used.) Immediately following the delivery of any shock, the device begins a post-shock refractory interval and a programmable Post-shock Pacing Delay.

Pacing is re-enabled at the Post-shock Pacing Delay minus the Post-shock LRL if the Post-shock Brady Mode is programmed on, or minus the normal Brady LRL if Post-shock Brady Mode is programmed off.

The timing of the initial pacing pulse in the Post-shock Pacing Period depends upon the cardiac activity during the Post-shock Pacing Delay as follows:

- If R-waves (and/or P-waves for dual-chamber pacing modes) are sensed during the Post-shock Pacing Delay, the device paces only when the sensed rate is slower than the Post-shock LRL (or the normal LRL if Post-shock Brady Mode is programmed Off). Subsequent pacing pulses are delivered as required depending on the pacing prescription.

- If no R-waves (and/or P-waves for dual-chamber pacing modes) are sensed during the Post-shock Pacing Delay or if the interval since the preceding P- or R-wave was greater than the bradycardia escape interval, a pacing pulse is delivered at the end of the Post-shock Pacing Delay. Subsequent pacing pulses are delivered as required depending on the pacing prescription.

The Post-shock Pacing Delay must be at least 275 ms longer than the bradycardia pacing escape interval (60,000/rate). If Post-shock Brady Mode is Off, the Post-shock Pacing Delay is interactive with the Normal Brady LRL; otherwise, the interactive limit applies to the Post-shock Brady LRL. The Post-shock Pacing Delay has no effect on tachyarrhythmia detection.

Post-shock Pacing Period

Programmable Values: 15 seconds–60 minutes

The Post-shock Pacing Period starts when the Post-shock Pacing Delay expires and determines how long the pulse generator operates using the post-shock parameter values. On completion of the Post-shock Pacing Period, the pulse generator reverts to the programmed normal bradycardia values, or ceases to pace if Normal Brady is programmed Off.

The Post-shock Pacing Period is restarted if further shocks are delivered before the pacing period expires. While in process, the Post-shock Pacing Period is not affected by the end of the current episode.

ACCESSING NORMAL AND POST-SHOCK BRADY PARAMETERS

Complete lists of normal and post-shock bradycardia parameters can be displayed on the PRM screen.

1. Select either the Bradycardia Summary button on the main application screen or the Brady Parameters button from the toolbox to display the bradycardia parameters (Figure 5-1).
2. Select the desired button across the top of the brady parameters screen: Normal or Post-shock. (Refer to the section “Temporary Bradycardia Pacing” on page 5-10 for information about the Temporary button.)
3. Select the desired values for the parameters. To change a parameter value, select a value box in a Change column to display value options. Select a value.

NOTES:

- *The values for the Noise Response, Atrial Tachy Response, and sensor parameters affect both normal brady and post-shock brady pacing therapies. The values can be changed on either screen; when a value is changed on one screen, the other screen is automatically updated to reflect the change.*
- *When the Normal Brady LRL value is programmed in the Brady Pacing screen, the value is automatically updated in the in the Brady Summary button on the main application screen. The Post-shock Brady LRL is unaffected.*

TEMPORARY BRADYCARDIA PACING

The pulse generator can be programmed with temporary bradycardia parameter values that differ from the programmed Normal bradycardia values. This allows the clinician to examine alternate pacing therapies while maintaining the previously programmed Normal parameters in the pulse generator memory. To use the Temporary Brady function, follow these steps:

1. Select the Temporary button from the Brady Parameters screen to display the Temporary value boxes along with the programmed Normal value. (Post-shock Brady values are not shown even if Post-shock Brady is presently in effect.) When the Temporary Brady parameters are initially displayed, they are set to the normal brady pacing values. Temporary brady pacing offers a wider choice of modes than normal bradycardia pacing. Refer to Appendix A for modes and programmable values available.
2. Select the desired values in the Temporary column; values are independent of other pacing functions.
3. Establish telemetry communication and select the Start button. Bradycardia pacing will begin at the values in the Temporary column. A message window will appear indicating that temporary brady pacing parameters are being used and includes a button to stop temporary bradycardia pacing.

Temporary bradycardia pacing cannot be started while a tachyarrhythmia episode is in progress. No other functions except emergency therapy can be initiated until the Temporary Brady function is stopped.

4. To stop temporary bradycardia pacing, remove the telemetry wand from range for longer than 250 ms or select the Stop Temp Brady button. Also, temporary

bradycardia pacing will stop when emergency therapy is commanded from the programmer or the DIVERT THERAPY key is pressed.

If the amplitude is Off during temporary programming, the pulse generator will not pace. Pacing is restored to the previously programmed permanent parameters as soon as the telemetry link is broken by moving the telemetry wand away from the pulse generator or when the Stop Temp Brady button is selected.

SENSOR SUBMENU

ADAPTIVE-RATE PACING PARAMETERS

The adaptive-rate pacing modes of the pulse generator are intended for patients who exhibit chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity.

When adaptive-rate parameters are programmed, pacing rate increases in response to increased activity and then decreases as the activity returns to a resting level. Activity involving minimal upper body motion, such as bicycling, may result in a moderate pacing response.

NOTE: *Adaptive-rate pacing has been shown to be potentially proarrhythmic. Programming of adaptive-rate features should be undertaken with caution.*

The pulse generator detects activity by means of an accelerometer sensor located in the electronic circuitry. This sensor generates an electronic signal that is proportional to the magnitude of motion resulting from body movement. Since the accelerometer is mounted on the hybrid circuit, it is not responsive to simple static pressure on the pulse generator case. If tapping or twiddling of the pulse generator causes significant movement of the pulse generator that exceeds the activity threshold, then a proportional rate response may be observed.

Maximum Sensor Rate (MSR)

This parameter is programmed from the Normal Brady pacing screen. Refer to section “Maximum Sensor Rate (MSR)” on page 5-5 for a description of Maximum Sensor Rate.

Activity Threshold

Programmable Values: V Low (very low) to V High (very high)

The Activity Threshold is the programmable parameter that represents the level of activity that must be exceeded before the sensor-driven pacing rate will increase. The pulse generator will not increase the paced rate above the LRL until the activity signal has increased above the Activity Threshold.

The programmable values range from V Low (very low) to V High (very high). A lower 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. Use 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.

Reaction Time

Programmable Values: 10–50 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 Maximum Sensor Rate for a maximum level of activity from the LRL. See Figure 5-3 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 5-3).



Figure 5-3. 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 5-4).

5-14 | BRADYCARDIA PACING THERAPY
SENSOR SUBMENU—ADAPTIVE-RATE PACING PARAMETERS

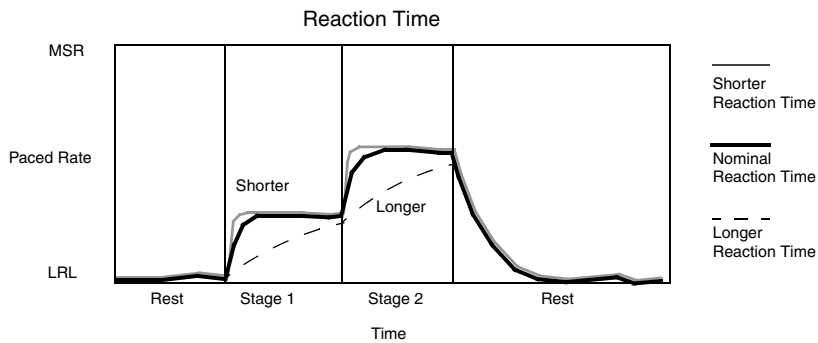


Figure 5-4. Effects of Reaction Time settings in a 2-stage exercise test.

Response Factor

Programmable Values: 1–16

The accelerometer Response Factor parameter determines the pacing rate that will occur above the Lower Rate Limit at various levels of patient activity. Figure 5-5 shows the relationship of the Response Factor settings.

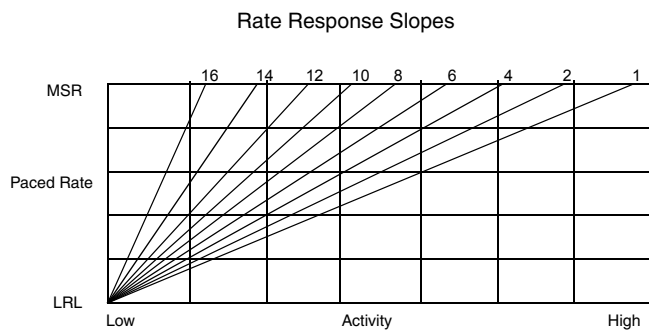


Figure 5-5. The relationship of response and paced rate depending on the programmed Response Factor setting.

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 5-6 illustrates the effect of higher and lower settings during a theoretical two-stage exercise test.

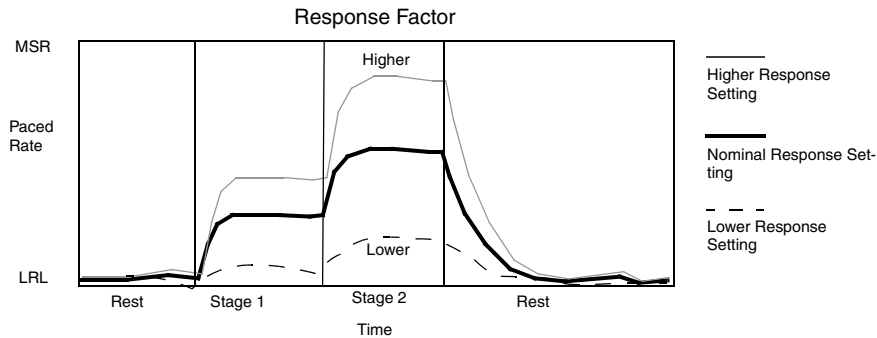


Figure 5-6. Effects of Response Factor settings in a two-stage exercise test.

The pacing rate achieved can be limited either by the detected level of activity or by the programmed Maximum Sensor Rate. If the detected activity level results in a steady-state rate below the Maximum Sensor Rate, 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.

Recovery Time

Programmable Values: 2–16 min

The Recovery Time parameter determines the time required for the paced rate to decrease from the MSR to the 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 5-7 for a graphic representation of the recovery curves.

5-16 | BRADYCARDIA PACING THERAPY
SENSOR SUBMENU—ADAPTIVE-RATE PACING PARAMETERS

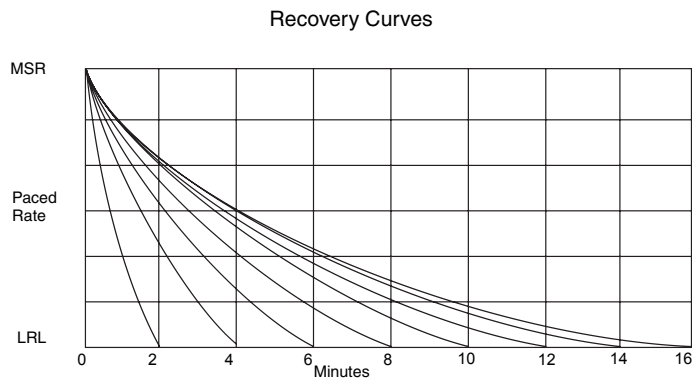


Figure 5-7. The relationship of paced rate to recovery depending on the programmed Recovery Time value. Only even-numbered settings are shown. There are 15 settings available.

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 5-8 illustrates the effect of higher and lower settings during a theoretical two-stage exercise test.

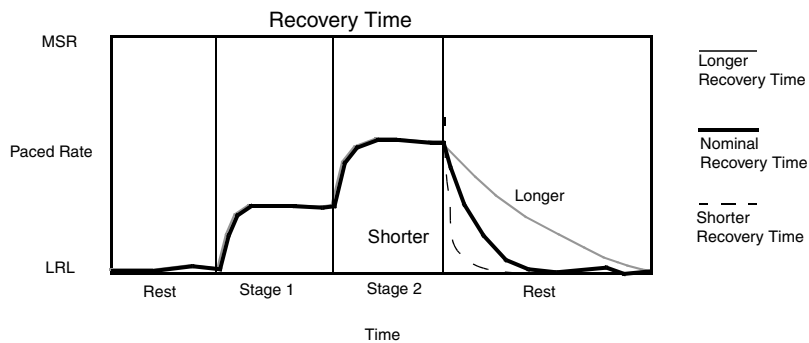


Figure 5-8. Effects of Recovery Time settings in a two-stage exercise test.

TACHY RESPONSE SUBMENU

ATRIAL TACHY RESPONSE (ATR)

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

ATR Trigger Rate

Programmable Values: Off, 100–200 ppm

ATR Trigger Rate allows the clinician to determine the rate at which the pulse generator begins to detect atrial tachycardias. The pulse generator monitors atrial events throughout the pacing cycle except during the atrial blanking period and noise interrogation intervals. Atrial events faster than the ATR Trigger Rate will increase an ATR detection counter, and events slower than the ATR Trigger Rate will decrease the counter. When the ATR detection counter reaches the programmed entry count, the ATR Duration begins. When the ATR detection counter counts down from the programmed Exit Count value to zero at any point in time, ATR Duration and/or fallback will be terminated and the ATR algorithm will be reset. Refer to Figure 5-9 on page 5-20 for an example. An event marker will be generated whenever the ATR detection counter is incremented or decremented.

NOTE: Atrial Tachy Response during post-shock pacing functions the same as in normal pacing.

ATR Duration

Programmable Values: 0–2000 intervals

ATR Duration 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 ATR Duration, mode switching occurs and the ventricular rate begins to decrease to the sensor-indicated rate or the ATR/VTR Fallback LRL, depending on the programmed Fallback Mode. This feature is intended to avoid mode switching due to nonsustained episodes of atrial

5-18 | BRADYCARDIA PACING THERAPY
TACHY RESPONSE SUBMENU—ATRIAL TACHY RESPONSE (ATR)

tachycardia. If the ATR counter reaches zero during ATR Duration, the ATR algorithm will be reset.

Entry Count

Programmable Values: 1–8 cycles

The Entry Count 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, Atrial Tachy Response Duration begins and the Exit Count is enabled.

CAUTION: Exercise care when programming the Entry Count to low values in conjunction with a short ATR duration. This combination allows mode switching with very few fast atrial beats. For example, if the Entry Count was programmed to 2 and the ATR duration to 0, ATR mode switching could occur on 2 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

The Exit Count allows the clinician to determine how quickly the ATR algorithm is terminated once the atrial arrhythmia no longer is detected. The lower the programmable value, the more quickly the pacemaker will return to an atrial tracking mode. Once the number of slow atrial events detected equals the programmable Exit Count, Atrial Tachy Response Duration and/or Fallback will be terminated and the ATR algorithm will be reset. The ATR algorithm is loaded with the programmable Exit Count value once the Entry Count criteria are fulfilled.

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

Fallback Mode

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

Once ATR Duration has expired, the pulse generator will automatically switch to the programmed Fallback Mode. After switching modes, the device gradually decreases the ventricular paced rate to the ATR/VTR Fallback LRL or the sensor-indicated rate if programmed to an adaptive-rate mode. The decrease in ventricular paced rate is controlled by the Fallback Time parameter.

Fallback Time

Programmable Values: 0–45 seconds, 1–5 minutes

The Fallback Time parameter controls how quickly the paced rate during fallback will decrease to the ATR/VTR Fallback LRL or sensor-indicated rate. During fallback, the following features will be disabled:

- Rate Smoothing (until fallback reaches ATR/VTR Fallback LRL or the sensor-indicated rate)
- Rate Hysteresis and Search Hysteresis
- AV Search Hysteresis

ATR/VTR Fallback LRL

Programmable Values: 30–175 ppm

This parameter is the programmed lower rate to which the rate will decrease during mode switching. If an adaptive-rate mode is programmed, and the sensor-indicated rate is greater than the ATR/VTR Fallback LRL, the rate decreases to the sensor-indicated rate.

The ATR/VTR Fallback LRL is also the Backup VVI pacing rate during backup pacing in the presence of detected ventricular tachyarrhythmias (VTR). Refer to the section “Ventricular Tachy Response (VTR)” on page 5-20.

When the atrial rate has decreased and is below the ATR Trigger Rate for the programmed Exit Count, the pulse generator automatically ends the ATR episode and resumes AV-synchronous operation.

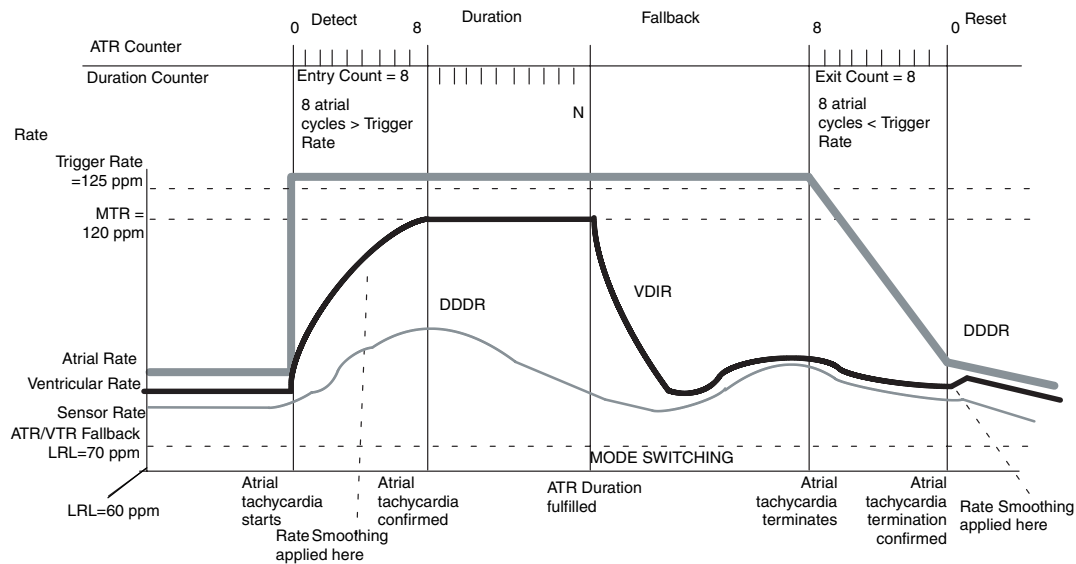


Figure 5-9. Example of ATR.

Ventricular Tachy Response (VTR)

Programmable Values: 30–175 ppm

The pulse generator automatically provides a mode switch for backup VVI pacing in the presence of detected ventricular tachyarrhythmias. When detection is satisfied in a tachycardia zone, the pacing mode switches to VVI. When the mode is switched, backup pacing is at the programmed VTR Fallback LRL (ATR/VTR Fallback LRL for dual-chamber devices) and uses the programmed ATP ventricular Pulse Width and Amplitude values. Refer to the section “Atrial Tachy Response (ATR)” on page 5-17.

VENTRICULAR RATE REGULATION (VRR)

Programmable Values: Off, On

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 Maximum Pacing Rate.

When programmed On in tracking modes, VRR is active only when an Atrial 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 pulse generator will automatically disable Rate Smoothing and reactivate Rate Smoothing once the ATR has terminated.

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

VRR Maximum Pacing Rate

Programmable Values: 60–150 ppm

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

Atrial Flutter Response

Programmable Values: Off, 130–230 ppm

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.

When both the Atrial Flutter Response and the Atrial Tachy Response are active, ATR 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 Atrial Tachy Response feature is also programmed On and ATR Duration is programmed to a value greater than zero, 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

Programmable Values: Off, On

In DDD(R) and VDD(R) pacing modes, any pacemaker may detect retrograde conducted P-waves that fall outside of PVARP, causing triggered ventricular pacing rates as high as the Maximum Tracking Rate (ie, 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 Maximum Tracking Rate 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 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 device 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 option and/or Rate Smoothing can also be useful in controlling the pacemaker's response to retrograde conduction.

The device can store PMT episodes in the Arrhythmia Logbook if the PMT Termination feature is programmed On (from the Episodes/EGMs button in the Setup tool kit). However, an EGM is not stored.

RATE ENHANCEMENTS SUBMENU

RATE HYSTERESIS

Hysteresis Offset

Programmable Values: Off, –5 to –80 ppm

Rate Hysteresis can be used in the DDD(R), DDI(R), VVI(R), and AAI(R) modes. When the pulse generator 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 device longevity.

NOTE: 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.

Rate Hysteresis in Adaptive-Rate Modes

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. In single-chamber atrial modes, Rate Hysteresis will be deactivated by a single atrial pace at the sensor hysteresis rate. In DDDR or DDIR modes, 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 Maximum Tracking Rate.

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.

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. Hysteresis will be deactivated by a single atrial pace at the hysteresis rate. In DDD and DDI modes, 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.

Search Hysteresis

Programmable Values: Off, 256–4096 cycles

When the Search Hysteresis feature is enabled, the pulse generator will periodically lower the escape rate by the programmed Hysteresis Offset in order to reveal potential intrinsic activity below the LRL or sensor rate.

During Search Hysteresis, the pacing rate is lowered by the Hysteresis Offset for up to eight 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 eight-cycle search, pacing resumes at the LRL or the sensor-indicated rate.

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 ($256 \div 70 = 3.7$).

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.

RATE SMOOTHING

Rate Smoothing controls the pulse generator'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
- Retrogradely conducted P-waves
- Pulse generator sensing of myopotential signals, EMI, crosstalk, etc.

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 Atrial 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 Maximum Pacing Rate (SSI and DDI) when programmed to DDD, DDI, DVI, VDD, or SSI. When the sensor is enabled and MSR is higher than MTR, the operational range is from LRL to 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%-25% in 3% increments) and can be independently programmed for increase or decrease.
- The pulse generator 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 dual-chamber device sets up two synchronization windows for the next cycle—one for the atrium and one for the ventricle. Single-chamber devices set up a ventricular window.
- Rate Smoothing is functional except during the eight cycles of Search Hysteresis, during ATR fallback, upon triggering of the PMT Termination

algorithm, immediately following programmed increases in LRL, and above the Maximum Tracking Rate.

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 (eg, paroxysmal atrial tachycardia [PAT]) will cause a simultaneous sudden increase in the paced ventricular rate as high as the programmed Maximum Tracking Rate. 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, 3–25%

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, 3–25%

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

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

Maximum Pacing Rate (DDI, DVI, and SSI)

Programmable Values: 50–175 ppm

When Rate Smoothing is programmed On in DDI, VVI, DVI, or AAI, the Rate Smoothing Up parameter can be programmed between the hysteresis rate and the Lower Rate Limit. The Rate Smoothing Down parameter requires the programming

of a Maximum Pacing Rate. The Rate Smoothing Down parameter will then be used only between the Maximum Pacing Rate and the LRL or the hysteresis rate.

Rate Smoothing Example for Dual-chamber Tracking Mode

The pulse generator 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 pulse generator 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 \pm Rate Smoothing value

Atrial synchronization window = (Previous R-R interval \pm Rate Smoothing value) - AV Delay

An example of how these two synchronization windows are calculated is illustrated below and in Figure 5-10:

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

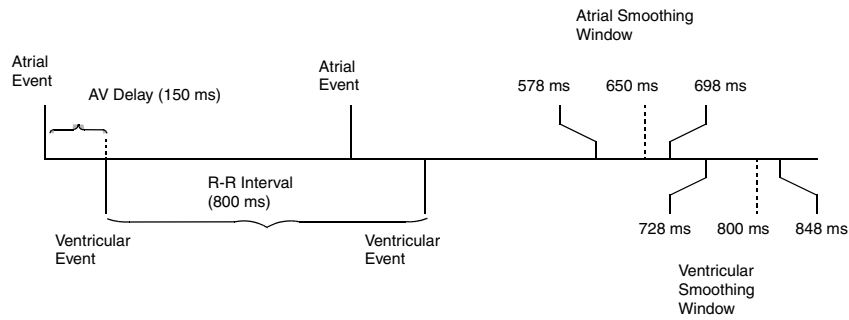


Figure 5-10. An example of the synchronization window.

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.

AV DELAY SUBMENU

NOTE: All of the AV Delay parameters are available in dual-chamber devices only.

AV DELAY

AV Delay is the programmable time period from the occurrence of an atrial event, either sensed or paced, to a paced ventricular event. Its purpose is to help preserve the heart's AV synchrony. If a sensed ventricular event does not occur during the AV delay following an atrial event, the pulse generator delivers a ventricular pacing pulse when the AV Delay expires.

AV delay can be programmed to one of two operations: 1) AV Delay—a programmable fixed interval, or 2) Dynamic AV Delay—a variable interval based on the previous A–A interval in VDD(R), DDD(R), DDIR, and DVIR modes only.

AV Delay (fixed interval)

Programmable Values: 10–300 ms

The AV Delay parameter causes the pulse generator to deliver a ventricular pacing pulse at the programmed time (in ms) in the absence of a sensed ventricular event.

Dynamic AV Delay

Programmable Values: Off, On; Minimum AV Delay 10–290 ms; Maximum AV Delay 20–300 ms

The intent of Dynamic AV Delay is to provide a more physiologic response to rate changes by automatically shortening the AV Delay with each interval during an increase in atrial rate. This helps minimize the occurrence of large rate changes at the upper rate limit and allows one-to-one tracking at higher rates.

This feature is used by programming the Dynamic AV Delay to On and selecting values for Minimum AV Delay and Maximum AV Delay. The pulse generator automatically calculates a linear relationship based on the interval length of the previous A–A cycle and the programmed values for Minimum AV Delay, Maximum AV Delay, LRL, MTR and/or MSR. (The Dynamic AV Delay is not adjusted on a PVC cycle or when the previous cardiac cycle was limited by the MTR or Rate Smoothing.) When the atrial rate is between the LRL and the higher of the MTR and

MSR, the pulse generator calculates the linear relationship to determine the Dynamic AV Delay (refer to Figure 5-11).

NOTE: The AV Delay parameters are programmed in the AV Delay submenu from the Brady Parameters screen. When Dynamic AV Delay is programmed On, the Maximum AV Delay and Minimum AV Delay values can be programmed. When Dynamic AV Delay is programmed Off, the maximum and minimum delay parameters are not available for programming. This indicates that a fixed-interval AV Delay is programmed, and the fixed-interval value is programmed from the basic brady parameter list.

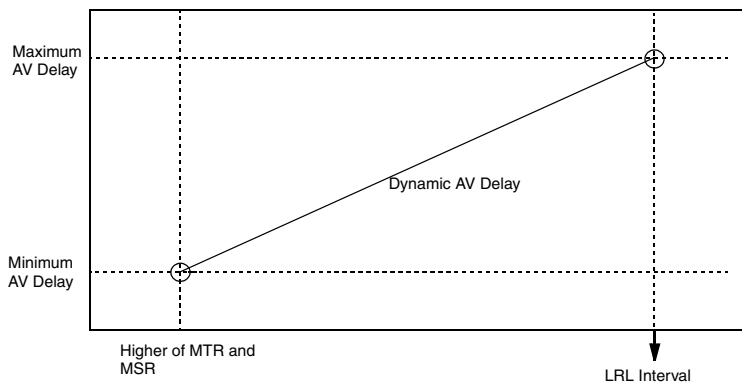


Figure 5-11. Dynamic AV Delay linear relationship.

SENSED AV OFFSET

Programmable Values: Off, –10 to –100 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 sensing P-waves later during the atrial contraction.

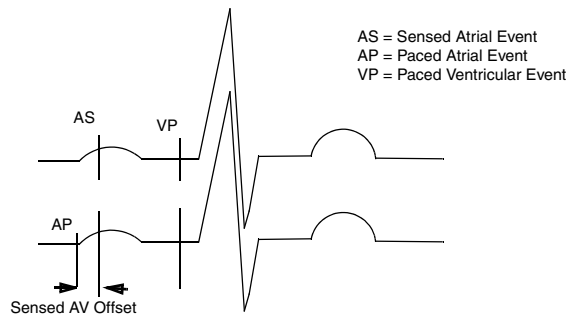


Figure 5-12. The Sensed AV Offset compensates for the difference between the paced atrial events and the sensed atrial event.

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 10 to 100 ms after an atrial sensed event. This offset is applied to the fixed AV Delay or the AV Search Hysteresis, 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 pulse generator 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 and Maximum AV Delay at the higher of the MTR or MSR (Figure 5-13).

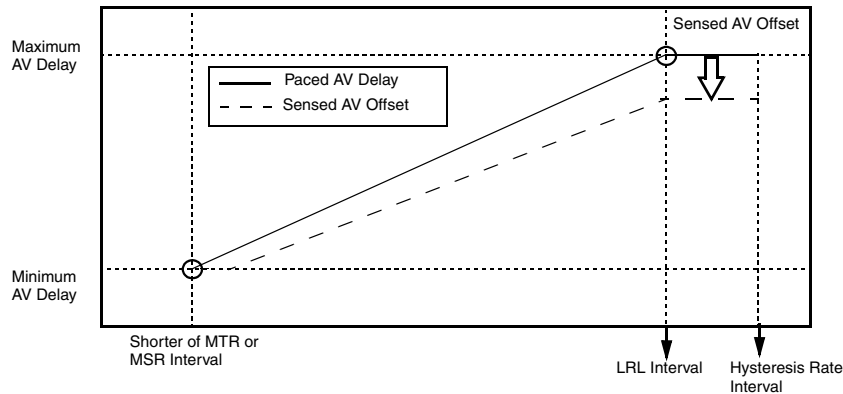


Figure 5-13. Dynamic AV Delay and Sensed AV Offset as a function of the escape interval.

AV SEARCH HYSTERESIS

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 PR intervals are shorter than the hysteresis AV Delay. The device 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

The AV Search Interval controls the frequency of the AV Search Hysteresis.

AV Increase

Programmable Values: 10–100%

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 hysteresis AV Delay will never exceed 300 ms.

NOTE: *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.*

REFRACTORY SUBMENU

NOTE: The Ventricular Refractory Period—VRP and Post-Ventricular Atrial Refractory-PVARP parameters are programmed in the Refractory submenu from the Brady Parameters screen. When Dynamic VRP or PVARP is programmed On, the respective Maximum and Minimum refractory values can be programmed. When Dynamic VRP or PVARP is programmed Off, the respective maximum and minimum refractory parameters are not available for programming. This indicates that a fixed-mode VRP or PVARP is programmed, and the fixed mode value is programmed from the basic brady parameter list.

VENTRICULAR REFRACTORY PERIOD—VRP

The Ventricular Refractory Period—VRP is the interval following a ventricular pace event during which the pulse generator is not inhibited by detected electrical activity in the ventricle. 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. It can be programmed to a fixed interval or dynamic interval.

NOTE: Guidant strongly recommends programming the refractory value at less than or equal to one-half the Lower Rate Limit in ms (single-chamber mode) or at less than or equal to the Maximum Tracking Rate and/or Maximum Sensor Rate in ms (dual-chamber modes) minus 90 ms to provide an adequate sensing window.

VRP (fixed interval)

Programmable Values: 150–500 ms

The ventricular refractory interval will remain at the programmed fixed VRP value between the LRL and the MTR and/or MSR.

Dynamic VRP

Programmable Values: Off, On

In dual-chamber devices, this feature automatically shortens the ventricular refractory interval as ventricular pacing increases from the LRL to the MTR (or the MSR, whichever is greater), allowing more time for ventricular sensing.

In single-chamber devices, this feature automatically shortens the ventricular refractory interval as the ventricular pacing rate increases from the LRL to the MSR, allowing more time for ventricular sensing.

Maximum VRP

Programmable Values: 160–500 ms

If the pacing rate is equal to or lower than the LRL (ie, hysteresis), the programmed Maximum VRP is used as the ventricular refractory period.

Minimum VRP

Programmable Values: 150–490 ms

If the average rate is equal to or higher than the MTR (or MSR) interval, the programmed Minimum VRP is used as the ventricular refractory period.

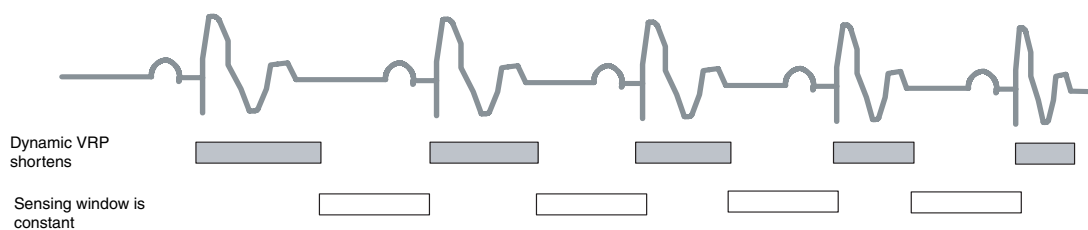


Figure 5-14. As the ventricular rate increases, the refractory interval decreases.

ATRIAL REFRACTORY-PVARP

Programmable Values: PVARP (fixed) 150–500 ms; Dynamic PVARP On, Off; Maximum PVARP 160–500 ms; Minimum PVARP 150–490 ms

The Atrial Refractory-PVARP parameter is defined according to the pacing mode. Refer to Figure 5-15 through Figure 5-18 for illustration of refractory periods.

- **For dual-chamber modes [DDD(R), DDI(R), VDD(R)],** the PVARP is defined as the time period after a ventricular event, either paced or sensed, when an atrial event does not inhibit an atrial pace nor trigger a ventricular pace. The

atrial refractory period prevents atrial sensing and tracking of retrograde activity initiated in the ventricle.

- **For single-chamber atrial modes [AAI(R) AAT],** the Atrial Refractory-PVARP is defined as the time period after an atrial event, either paced or sensed, when an atrial sensed event does not inhibit an atrial pace.

A long atrial refractory period shortens the brady atrial sensing window. Programming long atrial refractory periods in combination with certain AV delay periods can cause 2:1 block to occur abruptly at the programmed MTR. Refer to the section “Maximum Tracking Rate (MTR)” on page 5-4 for a discussion.

In DDD(R) and VDD(R) pacing modes, the pulse generator may detect retrograde conduction in the atrium, causing triggered ventricular pacing rates as high as the MTR (ie, pacemaker-mediated tachycardia [PMT]). Retrograde conduction times may vary over a patient’s lifetime as a function of changing autonomic tone. If testing does not reveal retrograde conduction at implantation, it may still occur at a later time. This problem can usually be avoided by increasing the atrial refractory period to a value that exceeds the retrograde conduction time. Also, programming PVARP After PVC, PMT Termination and/or Rate Smoothing may be useful in controlling the pacemaker’s response to retrograde conduction.

PVARP After PVC

Programmable Values: Off, 150–500 ms

This feature is designed to help prevent pacemaker-mediated tachycardia due to retrograde conduction, which is typically associated with PVCs.

Upon detection of a sensed ventricular event without a preceding atrial event (sensed or paced) (ie, a premature ventricular contraction [PVC]), the atrial refractory period is automatically extended to the programmed PVARP After PVC value for one cardiac cycle. After a PVC is detected, the timing cycles are automatically reset; thus the PVARP will be extended no more frequently than every other cardiac cycle.

V-Blank After A-Pace

Programmable Values: 45, 65, 85 ms

This cross chamber blanking period inhibits ventricular sensing following an atrial pace.

A-Blank After V-Pace

Programmable Values: 45, 65, 85 ms

This cross chamber blanking period inhibits atrial sensing following a ventricular pace.

A-Blank After V-Sense

Programmable Values: 45, 65, 85 ms, and SMARTSensing™

This cross chamber blanking period inhibits atrial sensing following a ventricular sensed event. If the value is programmed to SMARTSensing, the pulse generator automatically adjusts the amplifier gain in order to reject far-field ventricular events. This allows sensing of true atrial events that had previously fallen in the cross chamber blanking period.

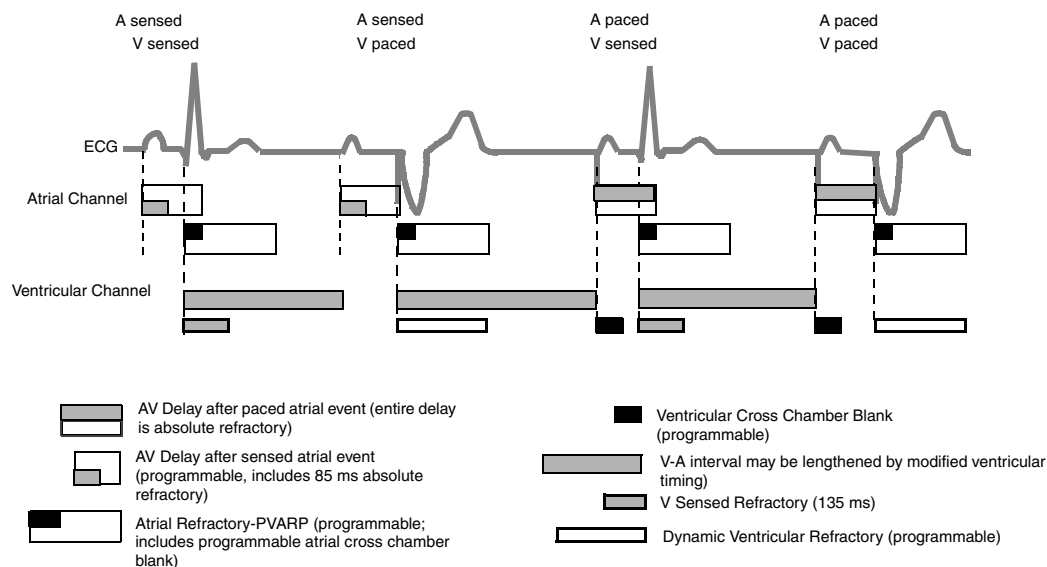


Figure 5-15. Refractory periods for dual-chamber pacing modes.

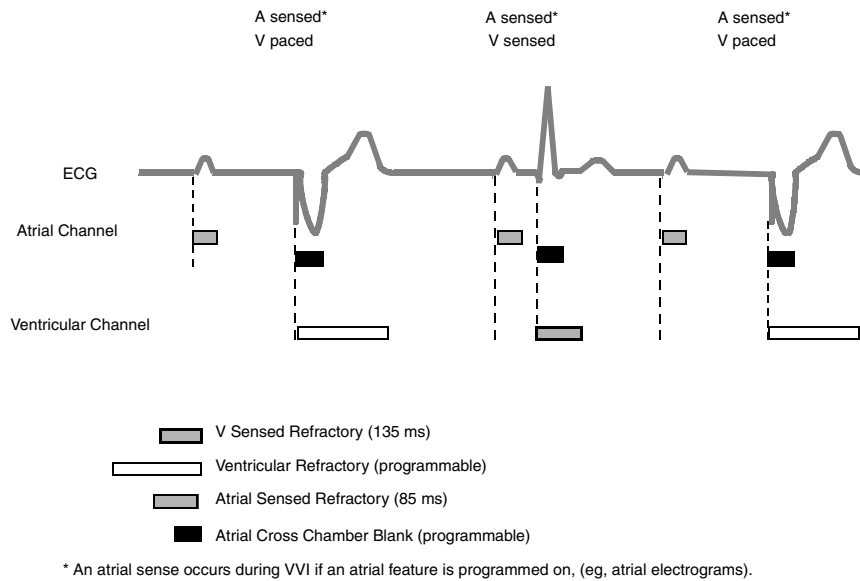


Figure 5-16. Refractory periods for VVI pacing mode.

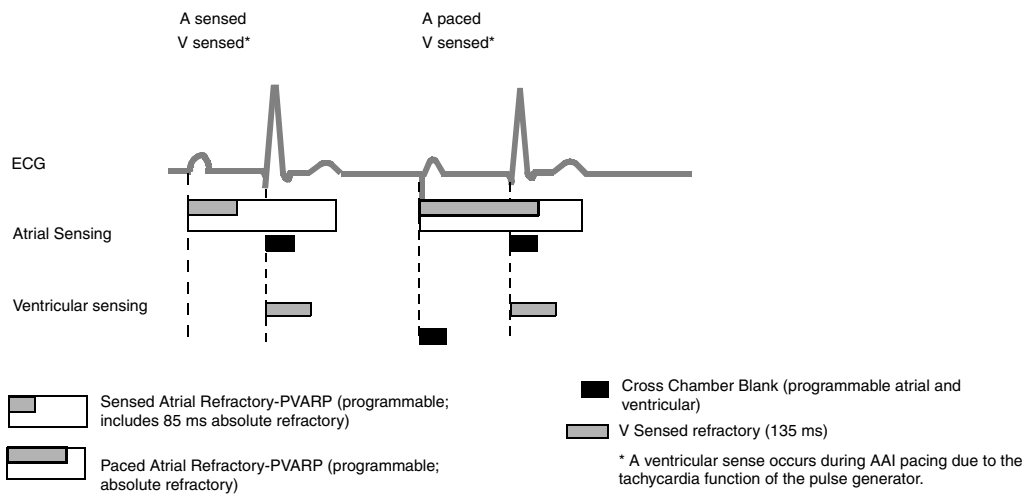


Figure 5-17. Refractory periods for AAI pacing mode.

NOISE RESPONSE SUBMENU

NOISE RESPONSE

Programmable Values: AOO, DOO, VOO, Inhibit

Each refractory and cross chamber blanking period includes a portion that is a retriggerable noise window. The 40-ms noise window is initiated by a sensed or paced event. Both the noise window and refractory period must be completed for each cardiac cycle in one chamber before the next sensed event is allowed to restart the timing in the same chamber. Recurrent noise activity may cause the noise window to restart, thereby extending the noise window and possibly the effective refractory period or blanking period.

The Noise Response parameter can be programmed to (1) AOO, DOO, or VOO mode, or (2) Inhibit mode (intended for patients whose arrhythmia may be triggered by asynchronous pacing). If Noise Response is programmed to an asynchronous mode, and if the noise persists so that the noise window is extended longer than the programmed pacing escape interval, the pulse generator paces asynchronously at the programmed pacing rate until the noise ceases.

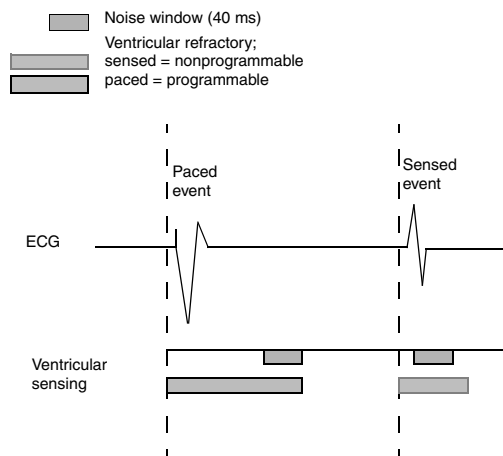


Figure 5-18. Refractory periods and noise windows.

If Noise Response is programmed to Inhibit, and the sensed noise extends the noise window beyond the programmed paced or sensed interval, the pace escape interval timing will reset and the pulse generator will not pace until one escape interval after the noise ceases. If event markers are being transmitted, depending on the chamber where noise is occurring, the marker [AS] or [VS] will occur when the noise window is triggered, followed by the marker AN or VN if the noise window is retriggered. The AN or VN marker will occur frequently if the noise window continuously retriggers.

NOTE: Use care when considering setting Noise Response to Inhibit in pacemaker-dependent patients, as pacing will not occur.

SYSTEM DIAGNOSTICS

CHAPTER 6

This chapter contains information about the system diagnostic features. The following is a brief description of each diagnostic tool included in this chapter.

- “System Summary” on page 6-2—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” on page 6-3—Provides a method of executing typical follow-up procedures from a single screen.
- “Diagnostic Evaluation” on page 6-6—Displays data and/or allows testing of the following:
 - “Battery Status” on page 6-6
 - “Intrinsic Amplitude Test” on page 6-10
 - “Lead Impedance Test” on page 6-11
 - “Pace Threshold Test” on page 6-13
 - “Daily Measurement” on page 6-16
 - “Intrinsic Rhythm ID” (Intrinsic Rhythm ID is accessed via the Diagnostic Evaluation screen, but is described in the Tachyarrhythmia Detection chapter on page 3-18).
 - “Trending” (The Trending tool is accessed via the Diagnostic Evaluation screen, but is described in the Patient Diagnostics chapter in the section “Trending Data” on page 7-20).
 - “Snapshot Viewer” (The Snapshot Viewer tool is accessed via the Diagnostic Evaluation screen, but is described in the Patient Diagnostics chapter in the section “Snapshot Viewer” on page 7-23.)

SYSTEM SUMMARY

The System Summary screen provides a summary of the data retrieved from the device at the initial interrogation. Select the shortcut icon next to the summary data to view details. The clinical events section displays the following important messages if they are customized on using the Profiles menu. For details on profile customization, refer to the section “My Patient Profile” on page 7-25.

- Tachy Mode = <mode> (displays programmed mode other than Monitor + Therapy)
- Battery at ERI
- Battery at EOL
- Patient Triggered Monitor (event stored, feature active or suspended)
- Intrinsic Amplitude and Lead Impedance (pace and shock) values falling outside the programmed range, as programmed from the Daily Measurement Setup screen
- Shock Impedance is <20, >125 Ω (indicating shock impedance out of range)
- No Episodes since <date>
- No V-Tachy Episodes since <date>
- <Number of> V-Tachy Episodes since <date>
- PMT Event Occurred
- <Number of> ATR Switches since <date>
- <Number of> Nonsustained Events since <date>

Those events ranked of high importance will display a stop sign icon. Select the stop sign icon or the message text to display details about the event.

When a VITALITY 2 device is interrogated, the System Summary screen displays graphical summary of the Intrinsic Amplitude and Lead Impedance daily measurement data (Figure 6-1). Details of the data are available on the Daily Measurement screen accessed by selecting either the shortcut icon or the Diagnostic Evaluation tool kit.

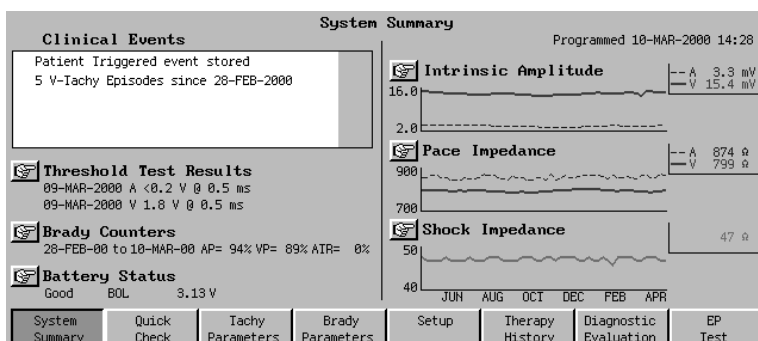


Figure 6-1. A typical VITALITY 2 System Summary screen.

QUICK CHECK

Typical patient follow-up tests, listed below, can be performed from a single PRM screen (Figure 6-2). All the tests can be performed sequentially by selecting one button (Start) or separately by selecting individual “Go” icons.

- Intrinsic Amplitude Test (atrial and ventricular)
- Pace Impedance Test (atrial and ventricular)
- Shock Impedance Test
- Atrial and Ventricular Threshold Tests

In addition, data from the tests and recent episodes can be printed in a Quick Notes summary, data can be saved to disk, and therapy counters can be reset.

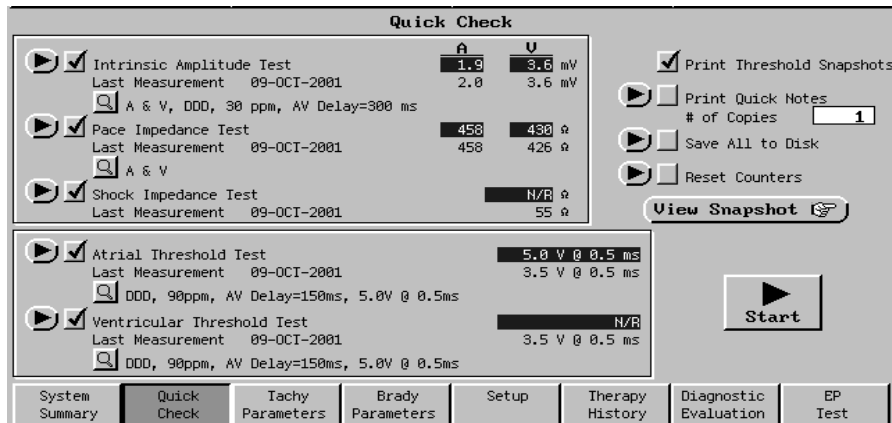


Figure 6-2. The Quick Check screen.

Follow these steps to perform a Quick Check follow-up:

1. Properly position the telemetry wand within telemetry range of the pulse generator, and maintain telemetry throughout the session. Notice that the ECG trace will display markers and selected electrograms if activated.
2. Select the Quick Check button from the toolbox on the main application screen. The values that appear on the Quick Check screen as Last Measurement are the test results from the previous session. When the test results are stated as #.#V @ #.#ms, it indicates an Amplitude test; stated as #.#ms @ #.#V, it indicates a Pulse Width test.

NOTES:


- All checked tests will be performed sequentially; if any of the tests are not desired, select the respective check box to remove the check mark.
- To perform only one test at any time during the session, select the play button icon next to the respective test. The check box will become unchecked allowing the convenience of performing tests in a different order or repeating a test. Selecting the Start button subsequently will run the remaining tests.

- *To stop any of the tests, press the DIVERT THERAPY key on the PRM or remove the wand from telemetry range and cancel telemetry. The STAT PACE and STAT SHOCK PRM keys are functional during the tests.*
- *Customized Quick Check parameters can be created, saved, and loaded by using the My Patient Profile feature. See "My Patient Profile" on page 7-25.*

3. To perform the tests, follow the steps below:

- a. Review the test parameters to be used for each test; the test parameters vary based upon device settings. If desired, select the magnifying-glass icon to the left of the test parameters to modify the test parameters, including those for amplitude or pulse width threshold tests.
- b. Make any desired change to the number of copies of Quick Notes to be printed.
- c. If Save All To Disk is selected, insert a patient data disk into the PRM.

NOTE: *For details on how each test is performed and the displayed results, refer to the section "Diagnostic Evaluation" on page 6-6.*

- d. Select the Start button; all checked tests will be performed sequentially and the measured value displayed on the window. A message requesting confirmation to continue the test will appear prior to the Intrinsic Amplitude test and the Atrial and Ventricular Threshold test. Select the Continue button to continue the test. If Cancel is selected, that test and all subsequent tests will not be performed until the Start button is selected again.
- e. If the Quick Notes box is checked on the base window, a Quick Notes report will print. This report includes therapy history, device parameter summary, device and lead system data, and Histograms. Selecting the  icon from the main application screen also will print Quick Notes.
- f. If Save All To Disk is checked on the Quick Check screen, data will be saved to disk. A message will appear requesting that a patient data disk be inserted in the disk drive if a disk has not already been inserted.
- g. If Reset Counters has been selected, a confirmation window will appear. Selecting Continue will reset all recent brady and tachy therapy counters and histograms to zero. Device Totals are not reset.

DIAGNOSTIC EVALUATION

The Diagnostic Evaluation tool displays system diagnostic data and allows access to the following submenus: Battery Status, Intrinsic Amplitude, Lead Impedance, Pace Threshold, Intrinsic Rhythm ID, Daily Measurement, Trending, and Snapshot Viewer.

1. Select the Diagnostic Evaluation button from the toolbox on the main application screen. The following sections describe the submenus. Refer to Chapter 7 for Trending (page 7-20) and Snapshot Viewer (page 7-23) and Chapter 3 for Rhythm ID (page 3-15). Real-time electrograms and markers are available while the Diagnostic Evaluation functions are active.
2. To exit the Diagnostic Evaluation tool kit, select another toolbox button; or return to the previous screen by selecting the back-arrow icon on the main application screen.

Battery Status

The Battery Status screen displays the following data that enables evaluation of battery status and charge times:

- Monitoring Voltage
- Battery Status Indicators
- Capacitor Re-formation Frequency, Last Date performed, and Charge Time
- Last Delivered Shock data
- Cumulative Charge Time
- Time Since Implant

Select the Battery Status submenu in the Diagnostic Evaluation toolbox. The data displayed is from the most recent interrogation of the pulse generator. To update the data, press the INTERROGATE key on the PRM. The last interrogation date and time will be displayed.

Monitoring Voltage and Battery Status Indicators

Every 16 seconds the pulse generator measures the Monitoring Voltage (open circuit; that is, the measurement when no load is placed on the battery), and reports the status indicator every 24 hours. The Monitoring Voltage is used as one indicator of remaining longevity. Whenever a maximum-energy therapeutic shock or capacitor re-formation occurs, the pulse generator measures the charge time. Charge time is used as an additional indicator of remaining longevity. The PRM system displays a gauge showing remaining longevity based on these measurements. The corresponding monitoring voltage for the battery status indicators is as follows:

Indicator	VITALITY 2 Models T165/T175	VITALITY 2 Models T167/T177
Beginning of Life (BOL)	> 3.0 V to > 2.80 V	> 3.0 V to > 2.80 V
Middle of Life 1 (MOL1)	2.80 V to > 2.65 V	2.80 V to > 2.65 V
Middle of Life 2 (MOL2)	2.65 V to > 2.50 V	2.65 V to > 2.48 V
Elective Replacement Indicator (ERI)	2.50 V to > 2.17 V	2.48 V to > 2.17 V
End of Life (EOL)	≤ 2.17 V	≤ 2.17 V

Elective Replacement Indicator. The ERI status indicates that pulse generator replacement must be scheduled. Once ERI is reached there is sufficient reserve battery capacity to monitor and bradycardia pace 100% under nominal conditions for 3 months and to deliver 10 maximum-energy shocks. All pulse generator functions continue to operate as programmed until the pulse generator reaches End of Life (EOL). Replace the device before it reaches EOL.

If the optional feature Beep When ERI Is Reached is programmed On, the pulse generator emits 16 R-wave synchronous tones every six hours after the pulse generator reaches its elective replacement time or until the tone is turned off via the programmer. Refer to the section “Magnet/Beeper Setup” on page 10-5.

CAUTION: Patients should be advised to contact their physician immediately if they hear tones coming from their device.

End of Life (EOL). Replace the device once EOL is reached as therapy cannot be guaranteed. Once the ERI reserve battery capacity is used, the pulse generator reaches End of Life. At EOL, the pulse generator will not allow ATP or low-energy shocks. The device attempts to deliver the programmed maximum-energy shocks unless there is insufficient battery capacity, at which time the device will revert to storage mode. Telemetry interrogation is still available and manual capacitor re-formation can be selected in EOL.

Refer to the section “Pulse Generator Longevity” on page 1-22.

Capacitor Re-formation

Capacitor deformation may occur during periods when no shocks are delivered, resulting in longer charge times. To reduce the effect of capacitor deformation on charge time, the capacitors are automatically re-formed every 90 days at BOL until MOL1 and every 30 days at MOL1 through ERI. A maximum-energy charge will not reset the automatic re-form timer. Tones will not be emitted from the pulse generator during automatic capacitor re-formations (even if the Beep During Capacitor Charge feature is On; refer to “Magnet/Beeper Setup” on page 10-5). During a capacitor re-formation, the Monitoring Voltage and Charge Time are measured and stored for later retrieval. The display indicates how often the nonprogrammable auto capacitor re-form is performed, the date of the last capacitor re-form, the measured battery voltage, and the charge time.

Manual Capacitor Re-form. Manual capacitor re-forms are not necessary but may be commanded via the programmer as follows:

1. Select the Re-form Capacitors button on the Battery Status screen and ensure that telemetry communication is occurring. A message will appear indicating that the capacitors are charging. Warbling tones from the pulse generator (if the Beep During Capacitor Charge feature is On) will sound while the capacitors are charging.
2. The entire re-form cycle takes approximately 10–20 seconds. After completion of the cycle, the capacitor energy is delivered to the pulse generator’s internal test load. If the wand is positioned in range of the pulse generator, the initial Charge Time is displayed on the Battery Status tool kit.

NOTE: *The telemetry wand may be removed and the re-formation will complete. However, the Charge Time will not be updated if the wand is not repositioned.*

Charge Time Measurement

Whenever its capacitors charge, the pulse generator measures the Charge Time. The last measured value is stored in pulse generator memory and displayed by the PRM system whenever the Battery Status screen is accessed. Charge Time from a capacitor re-formation is used as a battery status indicator in addition to Monitoring Voltage. As Monitoring Voltages approach the ERI voltage threshold, the pulse generator will declare ERI when the Monitoring Voltage is below the ERI Monitoring volt-

age or when there are two qualifying Charge Times greater than those listed in Table 6-1.

To further clarify, prior to approaching the ERI Monitoring Voltage, the pulse generator enters a mid-life Monitoring Voltage range. During this period, the Charge Time limit is extended, as illustrated in Table 6-1, in order to prevent prematurely tripping ERI due to expected mid-life rise in battery impedance.

Charge times for each device are provided to allow physicians to consider individual patient needs as they plan their therapeutic course, including the timing of device replacement.

NOTE: Regarding Charge-Time–driven ERI declaration, the pulse generator schedules a second Charge-Time measurement within 24 hours after an initial qualifying Charge-Time measurement. The pulse generator declares ERI only after the second qualifying Charge-Time measurement confirms the first within a 24-hour window. The pulse generator declares EOL after one qualifying measurement.

Table 6-1. Charge Time Limits^a

For Models	If the Monitoring Voltage is:	And the Charge Time exceeds the below value, the pulse generator will declare:
T167, T177	> 3.00 V	ERI: 13.1 sec
	3.00 V to 2.52 V	ERI: 18.9 sec
	< 2.52 V	ERI: 13.1 sec
	Any voltage	EOL: 30.0 sec
T165, T175	> 3.00 V	ERI: 13.1 sec
	3.00 V to 2.53 V	ERI: 18.9 sec
	< 2.53 V	ERI: 13.1 sec
	Any voltage	EOL: 30.0 sec

a. Values have been rounded to the nearest tenth of a second.

Last Delivered Shock

When a shock has been delivered to the patient, the date and the value for the energy level, charge time, and shocking lead impedance of the last shock delivered are stored in the pulse generator memory, and are displayed on the Battery Status

screen. This does not include auto capacitor re-forms or shocks that may have been diverted and dumped to the pulse generator's internal load. If a fault condition is encountered (ie, high or low impedance) the fault will be indicated so that corrective action may be taken.

NOTE: For shocks of 1.1 J or less, the accuracy of the impedance measurement decreases.

Cumulative Charge Time

The Cumulative Charge Time is a running total of the time in minutes and seconds that the charging circuits have been activated (ie, whenever the capacitors are re-formed and whenever the capacitors charge to deliver a shock). The Cumulative Charge Time is an indicator of the energy consumed for charging.

Intrinsic Amplitude Test

A test can be performed to measure intrinsic P- and R-Wave amplitudes for the respective chambers. (Only R-Wave measurements are available in single-chamber devices.)

Intrinsic Amplitude Test					
Atrial	1.9 mV	09-OCT-2001 22:07	Ventricular	3.5 mV	09-OCT-2001 22:11
	2.0 mV	09-OCT-2001 22:02		3.6 mV	09-OCT-2001 22:07

Chamber Tested	
Atrium	Start
Ventricle	
A & V	

	Normal	Start
Mode	DDD	DDD
Lower Rate Limit	60	30 ppm
AV Delay	DYN	300 ms

Figure 6-3. The Intrinsic Amplitude screen accessed from the Diagnostic Evaluation toolkit.

1. Select the Intrinsic Amplitude submenu from the Diagnostic Evaluation tool kit (Figure 6-3).

2. The preselected values for the test are programmed normal Brady Mode, Brady LRL at 30 ppm, and AV Delay at 300 ms. Change the values as necessary to elicit intrinsic activity in the chamber(s) being tested.
3. Select the desired button for the chamber(s) in which the leads are to be tested for dual-chamber devices.
4. Select the Start button. The atrial and/or ventricular measurements will be displayed in the tables. If the stylus is held on the button, the values will continuously update on the display until the stylus is lifted.
5. If another measurement is performed, the newest value will be displayed in the top row of the table.

NOTE: *The test results from the last measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Intrinsic Amplitude, Quick Check, and System Summary screens when initially accessed. The measurements are provided on the Quick Notes and Measured Data reports as well.*

Lead Impedance Test

Standard lead troubleshooting tests, including electrogram analysis, x-ray or fluoroscopic image review, additional maximum-energy shocks, and invasive visual inspection can be used to assess lead system integrity.

A Lead Impedance test can be performed and used as a relative measure of lead integrity over time. During a pace/sense lead impedance test, the pulse generator functions in a triggered pacing mode at a 5.0 V amplitude (or 7.5 V if the normal brady setting is programmed > 5 V) and a 0.5 ms Pulse Width (or at the normal brady setting if programmed greater than 0.5 ms) setting. The value may differ from a pacing system analyzer (PSA) measurement due to the method of calculation.

During a shock lead impedance test, the pulse generator delivers a subthreshold energy pulse through the shocking electrodes to assess lead integrity. When performed routinely at patient follow-up visits, a shock impedance test is a useful tool in detecting shocking lead integrity changes over time. (Shock impedance data are also available on the Daily Measurement screen). Evaluating this information together with the Last Delivered Shock impedance (displayed on the Battery Status screen) or a subsequent high-energy shock impedance and other noninvasive diagnostic techniques will help troubleshoot potential lead problems.

Both low-energy and high-energy impedance tests have certain clinical limitations:

- A high/maximum-energy shock test does not expose all forms of open lead conditions.

Shock lead impedance measured during a commanded maximum-energy shock may appear normal when certain types of open lead conditions exist (e.g. lead conductor fracture or a loose setscrew), as the energy delivered could jump or arc across small gaps. A commanded low-energy impedance test is a more robust tool for identifying and verifying an open shocking lead condition.

- A low-energy lead impedance test does not expose all forms of shorted lead conditions.

A low-energy impedance test(s) may appear normal when certain types of shorted lead conditions exist (e.g. abraded lead body insulation or crushed clavicle or first rib), as test energy is insufficient to jump or arc across small gaps between exposed conductors. A maximum-energy shock is a more robust tool for identifying/verifying a shorted shocking lead condition.

Figure 6-4. The Lead Impedance screen accessed from the Diagnostic Evaluation tool kit.

1. Select the Lead Impedance button from the Diagnostic Evaluation tool kit (Figure 6-4).
2. Ensure that the telemetry wand is in range of the pulse generator.

3. For a pace/sense impedance test, select the desired button for the chamber(s) in which the leads are to be tested. For a shock impedance test, select the Shock button.
4. Select the Start button. If the stylus is held on the Start button, the values will continuously update on the display until the stylus is lifted.
5. During the test a window will display the test progress. When the window disappears, the same test can be performed by once again selecting the Start button, or return to step 3 to start a different lead test.
6. When the test is complete, the impedance measurement will be displayed. If the test is repeated, the impedance measurements from the previous test and the current test will be displayed.

NOTE: The test results from the last measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Lead Impedance, Quick Check, and System Summary screens when initially accessed. The measurements are provided on the Quick Notes and Measured Data reports as well.

Pace Threshold Test

A pace threshold test may be performed on command by the programmer to determine the minimum pace amplitude and/or pulse width needed for capture.

Pace Threshold Test

Atrial	Date/Time	Ventricular	Date/Time
3.5 V @ 0.5 ms	09-OCT-2001 21:17	0.5 ms @ 3.5 V	09-OCT-2001 21:16
0.6 ms @ 3.5 V	09-OCT-2001 21:16	0.3 ms @ 3.5 V	04-OCT-2001 15:32
2.0 V @ 0.5 ms	09-OCT-2001 21:16	2.4 V @ 0.5 ms	04-OCT-2001 15:31
0.5 ms @ 3.5 V	09-OCT-2001 21:13	N/R	

Test Type	Normal	Start
Amplitude	DDD	DDD
Pulse Width	60	90 ppm
	DYN	100 ms
	3.5	5.0 V
	0.4	0.5 ms
		4

Chamber Tested: ☐ Atrium ☒ Ventricle

☒ Print Threshold Snapshots

System Summary Quick Check Tachy Parameters **Brady Parameters** Setup Therapy History Diagnostic Evaluation EP Test

Figure 6-5. The Pace Threshold screen accessed from the Diagnostic Evaluation tool kit.

The test begins at a specified starting value and steps that value down as the test progresses. The PRM beeps with each decrement. The starting value for Pulse Width or Amplitude and the number of cardiac cycles between step changes is programmable. The Mode, LRL, and AV Delay values to be used during the threshold test also are programmable. These parameters are only in effect during the test. Testing for a chamber is allowed only when pacing is active for that chamber in the mode specified in the Start column.

NOTE: If DDD mode is chosen, selecting either the atrial or ventricular test will cause the pacing output to decrease only in the chamber selected.

Once the test is started, the device enters a temporary state using the parameters specified in the Start column. Using the programmed number of cycles per step, the device then decrements (steps down) the selected parameter (Pulse Width or Amplitude) until the test is complete. Real-time electrograms and annotated event markers, which include the values being tested, continue to be available during threshold testing. The display will be automatically adjusted to reflect the chamber being tested.

During the threshold test, the programmer displays the test parameters in a window while the test is in progress. To pause the test or perform a manual adjustment, select the Hold button on the window. Select the “+” or “-” button to manually increase or decrease the value being tested. To continue the test, select the Continue button.



Figure 6-6. The Threshold in Progress window is displayed during a Pace Threshold test.

After the test, the permanently programmed Amplitude and Pulse Width settings are automatically restored and the test results are displayed in the tables, with the most recent test result in the top row. The measurement stated as #.#V @ #.#ms indicates an Amplitude test; stated as #.#ms @ #.#V indicates a Pulse Width test.

NOTE: Notice that the Amplitude and Pulse Width values are preselected. The previous pace threshold measurement (for the parameter being tested) is recorded and stored at 1 step above the last value that loss of telemetry or manual selection ter-

minated the test. The pulse generator will retrieve the test result value for that parameter, add 3 step values to that parameter test result value, and display that as the starting value for the next test. The LRL also is preselected at 10 ppm above the current heart rate.

The threshold test is complete and all effects of the parameters programmed for the test are terminated when any of the following occur:

- The test is terminated via a command from the programmer (eg, pressing the End Test button or STAT key)
- The telemetry wand is removed
- The lowest available setting for Pulse Width or Amplitude is reached and the programmed number of cycles has completed

Follow the steps below to perform testing:

1. Select the Pace Threshold submenu in the Diagnostic Evaluation tool kit (Figure 6-5 on page 6-13). Notice that test results from the previous measurement appear in tables.
2. Select either the Amplitude or Pulse Width button (only one can be selected at a time).
3. For dual-chamber devices, select either the Atrium or Ventricle button in the Chamber Tested column.
4. Change the following parameter values as desired to elicit pacing in the chamber(s) being tested: Mode, Lower Rate Limit, AV Delay for dual-chamber devices, Amplitude, Pulse Width, and Cycles Per Step. For DDD mode, the normal brady MTR is used.
5. Position the telemetry wand within range of the pulse generator and select the Start button.
6. Watch the ECG display and stop the test by selecting the End Test button or removing the telemetry wand when loss of capture is observed.

If the test continues until the programmed number of cycles at the lowest setting have occurred, the test is automatically terminated and the resulting value is the lowest setting preceded by the \leq symbol. Once the test is terminated, the per-

manent normal brady pacing settings are restored. The final threshold test value (the value is one step above the value when the test was terminated) will be displayed. Also, the last 10 seconds of ECG, real-time electrograms, and markers will be captured from when the test was terminated and the trace printed.

NOTE: *If the test was terminated by removing the wand, replace the wand to retrieve and display the threshold values.*

7. To perform another test, make changes to the test parameter values if desired, then begin again with step 5. Results of the new test will be displayed at the top of the appropriate table.

NOTE: *The test results from the most recent measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Pace Threshold, Quick Check, and System Summary screens when initially accessed. The measurements are provided on the Quick Notes and Measured Data reports as well.*

Daily Measurement

The device performs Lead Impedance (pace and shock) and Intrinsic Amplitude measurements each day. The data are displayed in graphical or tabular format on the Daily Measurement screen accessed from the Diagnostic Evaluation tool kit, as well as on the System Summary screen. Intrinsic Amplitude and Lead Impedance data are obtained in the manner described below.

Intrinsic Amplitude Measurement

Once each day, the device 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 bradycardia pacing therapy. The measurement will be taken during a 255-cardiac cycle period at approximately the same time each day. When the device is operating in a dual-chamber mode, the atrial and the ventricular measurements will be conducted concurrently. If all events during the 255-cardiac cycle period were paced, an intrinsic amplitude measurement will not be available, resulting in display of “paced” or “N/R” on the Daily Measurement screen.

Daily amplitude measurements will be stored for 7 days. After 7 days, the device 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 7 days, and the weekly measurements for the last 52 weeks.

Lead Impedance Measurement

Pace/Sense Lead

Once each day, the device will automatically attempt to measure the system's pace/sense Lead Impedance for each cardiac chamber in which pacing is enabled. During a pace/sense lead impedance test, the pulse generator functions at a 5.0 V amplitude (or 7.5 V if the normal brady setting is programmed > 5 V) and a 0.5 ms Pulse Width (or at the normal brady setting if programmed greater than 0.5 ms) setting.

The measurement will be taken at approximately the same time each day. The measurement will be taken during a 255-cardiac cycle period. If all 255 cardiac cycles are sensed (not paced) events, a pace pulse will be triggered on the 256th cycle and a measurement will be taken. Measurements will not occur during an ATR or ventricular tachy episodes. When the device is operating in a dual-chamber mode, the atrial and the ventricular measurements will be conducted concurrently.

Shock Lead

Once each day, at approximately the same time each day, the pulse generator will automatically measure the shock lead impedance. During a shock lead impedance test, the pulse generator delivers a subthreshold energy pulse through the shocking electrodes.

Daily pace and shock impedance measurements will be stored for 7 days. After 7 days, the device calculates and stores a weekly average measurement. These measurements are stored for 52 weeks. So, at a given time, you can access the daily measurements for the last 7 days, and the weekly average measurements for the last 52 weeks.

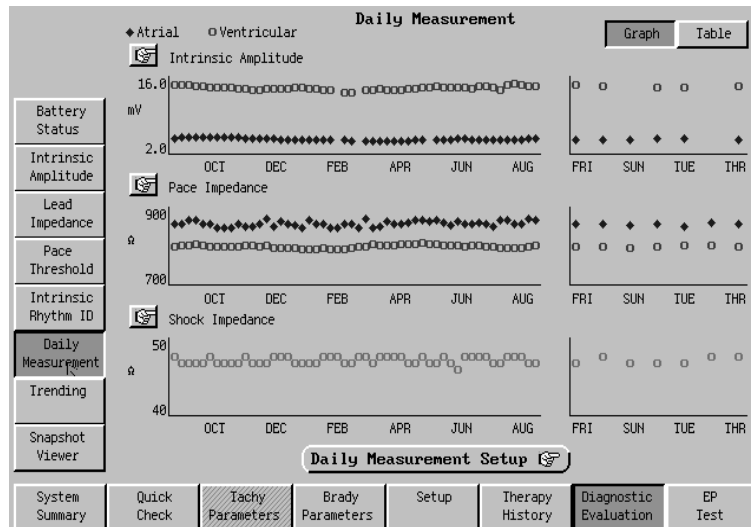


Figure 6-7. The Daily Measurement screen.

1. Select the Daily Measurement button from the Diagnostic Evaluation tool kit, or select a shortcut icon next to the desired graph on the System Summary screen.
2. Select either the Graph or Table button to display the desired format. Any gaps in the data displayed indicate an instance where no daily measurement occurred indicated as N/R in the tabular format.
 - The graphical screen displays the stored data as a point-plot graph showing the average weekly measurements and a point-plot graph showing the daily measurements for the last 7 days.
 - The tabular screen displays the measurements in reverse chronological order. The 7 daily measurements appear first, and then the latest of the average weekly values is listed. A horizontal line separates the daily from the weekly measurements. Use the scroll bar to view data farther down on the table.
3. Select the Daily Measurement Setup button to access the setup screen that allows minimum and maximum limits to be set for clinical event notification. If any measurement is outside the programmed range, a message indicating such will be displayed on the clinical events section of the System Summary screen.

If the setting of N/A is selected for either the minimum or maximum limits, the respective limit's clinical event notification will not be displayed, but the test will still be performed and the data will be available.

NOTE: A *Reset Daily Measurement* button is available from the *Daily Measurement Setup* screen; **use caution when performing this operation. Resetting the data causes the stored lead impedance (pace and shock) and intrinsic measurement data to be lost.** Once telemetry is established, some or all of the data may be cleared even if you choose the *Cancel* button during the operation.

PATIENT DIAGNOSTICS

CHAPTER 7

This chapter contains information about the patient diagnostic features Therapy History, Trending, and Patient Triggered Monitor.

- Therapy History—this tool kit allows access to the following data screens:
 - “Conversion Summary” on page 7-2
 - “Arrhythmia Logbook” on page 7-4
 - “Counters” on page 7-13
 - “Histograms” on page 7-17
- Patient Triggered Monitor—this feature allows the patient to trigger (initiate) storage of electrogram, interval, and annotated marker data during symptomatic episodes. (Accessed from the Setup tool kit, refer to page 7-18.)
- Trending—this feature allows evaluation of the pulse generator’s rate response to the detected activity level of the patient. (Accessed from the Diagnostic Evaluation tool kit, refer to page 7-20.)
- Snapshot Viewer—this feature allows a trace to be displayed and analyzed when a trace has been captured using the snapshot icon. (Accessed from the Diagnostic Evaluation tool kit, refer to page 7-23.)
- My Patient Profile—this feature allows the programming and storage of customized implant parameter files and follow-up settings. (Accessed from the Profiles icon, refer to page 7-25.)

THERAPY HISTORY

The pulse generator automatically records detection and therapy information for each detected episode. With the use of the PRM, this data can be reviewed at various levels of detail. The Therapy History tool kit provides access to the following screens:

- **Conversion Summary**—displays the total number of episodes and summarizes the type of episode.
- **Arrhythmia Logbook**—provides details about each episode: type of tachy and brady episodes, tachy episode zone, type of therapy delivered, Rhythm ID determination, and whether intervals and EGM data were stored. Further detail about electrogram, interval, and marker data is accessible from this screen.
- **Counters**—shows totals of types of episodes and types of therapy delivered.
- **Histograms**—displays the total number and percentage of paced and sensed events.

History data storage is split between the tachyarrhythmia episode history data and the bradycardia episode history data, and includes episode detail, electrograms, intervals, and annotated markers. To program the data storage split, refer to section “Episodes/EGMs - Arrhythmia Logbook Setup” on page 7-12.

Once the device memory available for episode data is filled, the data from the oldest episode is overwritten with data from the current episode unless the VF Priority Protection feature is programmed On (via the Episodes/EGMs screen in the Setup tool kit). The VF Priority Protection feature protects episodes of VF detection from being overwritten by VT and VT-1 episodes if episode memory becomes filled. Sustained VF episodes will be overwritten only by newer VT and VT-1 episodes if episode memory is completely filled with VF episodes.

Disk storage of all history data allows the entire pulse generator history to be accessed without repeated device interrogation; the patient need not be present.

THERAPY HISTORY SCREENS

The following sections describe how the Therapy History data are displayed. Access the Therapy History screens by selecting the Therapy History tool button, and then selecting the button for the desired screen. The data displayed on each screen can be printed by selecting the printer icon from the main application screen.

Conversion Summary

This screen summarizes the stored episode data by displaying the total number of episodes since the last follow-up reset or for device totals. It further categorizes the total into types of episodes and in which tachyarrhythmia zones tachy episodes

occurred. Also displayed is the percentage of first-attempt tachy therapies (single therapy) that successfully converted an arrhythmia.

In addition to tachyarrhythmia episodes, the device stores data related to Atrial Tachy Response and PMT Termination events for dual-chamber devices only, and for Patient Triggered Monitor episodes.

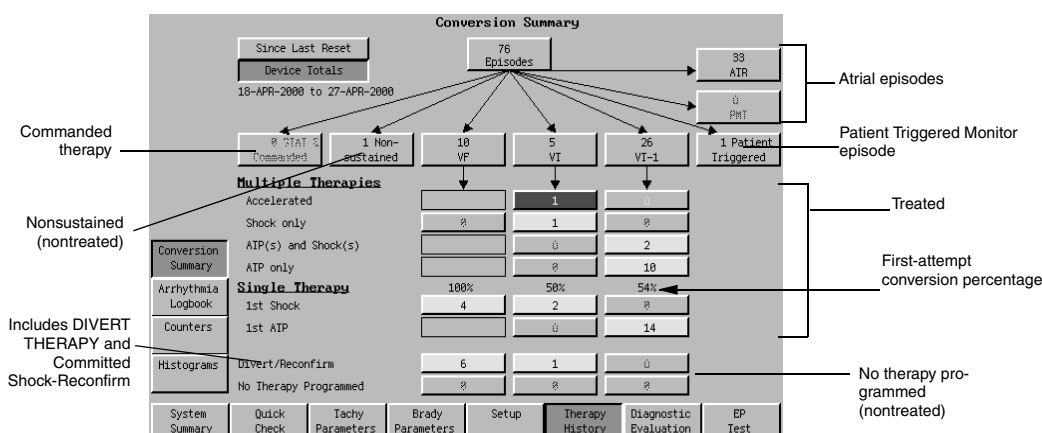


Figure 7-1. The Conversion Summary screen and its elements.

1. To access the Conversion Summary screen, select the Conversion Summary button from the Therapy History tool kit. (The Conversion Summary screen will be visible when Therapy History is initially accessed.)
2. Select any episode button to display the corresponding data on the Arrhythmia Logbook screen. The selected button will preset the episode query selection on the Arrhythmia Logbook screen.
3. To print the data, select the Printer icon from the main application screen.

Red boxes indicate a tachy episode(s) in which therapy resulted in an accelerated rhythm. Yellow boxes indicate an episode(s) occurred and details are available. Gray boxes indicate that no episodes occurred in that category. Select any of these buttons to display the corresponding data on the Arrhythmia Logbook screen.

The Conversion Summary screen displays the following episode classifications (Figure 7-1 on page 7-3). (The corresponding classifications are displayed on the

episodes portion of the Counters screen. Refer to the section “Counters” on page 7-13.)

- Treated episodes include all detected tachyarrhythmias that receive therapy, categorized by the zone of **first** therapy attempt (VF, VT, or VT-1). It indicates whether the device delivered multiple therapies or single therapy.
- Patient Triggered Monitor episodes include those in which the patient initiated data storage during symptomatic episodes.
- Diverted-Reconfirm episodes include those in which either the DIVERT THERAPY command was initiated or a shock was diverted due to failure to reconfirm.
- No Therapy Programmed episodes include those in which the Tachy Mode was programmed to Monitor Only or all therapy was turned off in the VT-1 zone.
- Nonsustained episodes include those tachy episodes in which therapy was inhibited because: a) the zone’s detection window did not remain satisfied for the programmed Duration prior to therapy delivery, or b) detection enhancement criteria indicated inhibition and the rate eventually dropped below the lowest tachy rate zone threshold. Storage for nonsustained episodes is programmable On or Off from the Episodes/EGMs screen in the Setup tool kit.
- Commanded therapy includes therapy commanded via the programmer, such as STAT SHOCK, Commanded Shock, and Commanded ATP schemes.
- Atrial episodes (dual-chamber devices only) include ATR events in which the Atrial Tachy Response (ATR) fallback is triggered, and PMT events in which the PMT Termination feature is triggered. Corresponding counters for these events are located in the Brady column of the Counters screen.

The corresponding number of episode and event counters can be seen on the Counters screen. Refer to the section “Counters” on page 7-13.

Arrhythmia Logbook

The Arrhythmia Logbook screen gives information about each episode: (a) the number and date of the episode, (b) the type of episode, (c) the type of tachy therapy delivered or attempted, (d) Rhythm ID determination, and (e) if intervals and EGMs are stored, and (f) if the episode data has been saved to a patient disk (indicated by an icon if episode data is saved to disk during the session, or if data is

read from a patient data disk). Refer to the section “Episode Detail” on page 7-6 for more information.

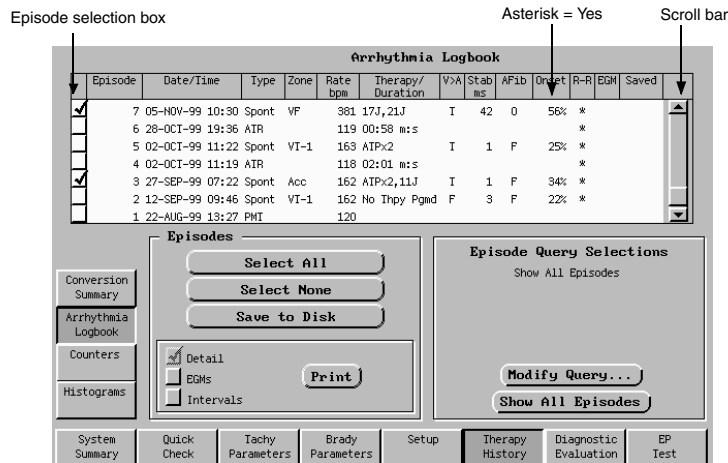


Figure 7-2. The Arrhythmia Logbook screen.

1. To display Arrhythmia Logbook data, position the telemetry wand over the pulse generator and select the Arrhythmia Logbook button from the Therapy History tool kit. The pulse generator will be automatically interrogated and current data will be displayed. Data from a patient disk also can be displayed by performing a Read Disk function from the Utilities menu.
2. While retrieving the data, the programmer will display a window indicating the progress of the interrogation. If the clinician selects the Cancel button before all of the stored data are retrieved, no new data will be displayed and the programmer will wait for the next command.
3. Use the scroll bar to view more episodes.
4. Select an episode to display its episode details, which are useful in evaluating each detection or therapy sequence.
5. To search for episodes within a specific category, select the Modify Query button to display the Query window. Select one of the query options: All, Since Last Reset, Set Dates, Type, Zone, Therapy, or a range of Detection rates. Enter

the dates if the Set Dates query is chosen. Select the Apply Query button to display the specified episodes.

6. To print or save specific episodes, select a box next to one or more episode numbers to select the episode data; a check will appear. Select the Select All or Select None buttons to easily select all episodes or deselect any checked episodes. Either select the Save To Disk button to save the checked episodes to a patient data disk, or select the Print button to print EGM or intervals for checked episodes.

Episode Detail

The Episode Detail screen displays additional details about the selected episode corresponding to the Arrhythmia Logbook. Detail includes the following:

Ventricular Tachy Episodes

Ventricular tachy episode detail includes the detection and redetection process employed with the following:

- Episode number, date, time, and type (spontaneous, induced, or Pt Trg indicating a Patient Triggered Monitor episode).
- Programmed tachy rate zone thresholds and Rhythm ID values.
- Indication if a ventricular tachy episode was immediately preceded by an ATR episode.
- Initial detected rate at duration, and in which zone (if the detection criteria is met).
- For ATP therapy, the start time of the first and last burst, number of bursts, and post-therapy rate.
- Redetected zone rate when detection met and enhancements measured.
- For shock therapy, the start time of charging, charge time, impedance, energy level, waveform, and post-therapy rate.
- Total episode time including the end-of-episode timer (10 or 30 sec).

ATR Episodes

- Episode number, date, time, and type (ATR)
- Indication if preempted by a ventricular episode
- Duration of mode switch
- Maximum atrial rate during mode switch
- Atrial and ventricular rates at ATR Fallback

PMT Episodes

- Episode number, date, time, and type (PMT)
- Atrial rate at PMT start

NOTE: *The PMT Episode Storage feature must be programmed On via the Episodes/EGMs screen in the Setup tool kit in order for PMT data to be stored.*

Patient Triggered Monitor Episodes

- Episode number
- Atrial and ventricular rates upon magnet application

Follow the steps below to view episode details:

1. Select the desired episode on the Arrhythmia Logbook screen (Figure 7-2 on page 7-5). The Episode Detail screen will appear. Some of the episode detail may not be immediately visible if several attempts occurred; use the scroll bar to view more of the description.
2. Select the Older Episodes or the Newer Episodes button to display a previous or more current episode, one episode at a time.
3. Select the Printer icon on the main application screen to print the episode detail being viewed.
4. Select the Print EGMs button to print the stored electrograms and annotated markers for the episode the PRM printer/recorder.

NOTE: A Retrigger/Setup button will be visible for a Patient Triggered Monitor episode if that feature has been enabled and a patient-triggered episode recorded or the feature's 60-day automatic time-out occurred. Select the button to display the Patient Triggered Monitor screen.

Intervals

The pulse generator stores the measured atrial and/or ventricular intervals throughout an episode until the end-of-episode is declared. Each episode may contain a maximum total of 1000 intervals.

1. Select the Intervals button from the Episode Detail screen to display the measured intervals. If all of the episode data is not visible in the window, use the scroll bar to view more data.

NOTE: Interval data may be viewed in either a tabular or graphical view. Select the Table button on the Intervals screen for a quantitative view of the intervals and the associated markers. Select the Graph button for a qualitative view of the heart rate during the course of the episode.

2. Select the Older Episodes or the Newer Episodes button to display a previous or more current episode, one episode at a time.
3. Select the Printer icon on the main application screen to print the intervals being viewed.

Stored Electrograms

The pulse generator can store annotated electrograms sensed via the shocking and ventricular pace/sense leads, and atrial pace/sense leads (in dual-chamber devices) prior to the onset of an episode and immediately before and after each therapy attempt. One or more sources from the Electrogram Storage Source must be programmed On for electrograms to be stored. The Onset EGM Storage feature must be programmed On for electrogram onset to be stored. Refer to the section "Episodes/EGMs - Arrhythmia Logbook Setup" on page 7-12.

The EGM storage capacity varies depending on which electrodes are enabled for capturing data. Table 7-1 shows the storage capacity for various combinations; the values appear on the Episodes/EGMs setup screen. The stored data are divided between ATR episodes, ATP attempts, and shock attempts. When the memory allocated to EGM storage is full, the device overwrites older EGM data segments in order to store the newer EGM data. The EGM is recorded in segments consisting of

episode onset, and pre-therapy and post-therapy storage. Episode onset refers to the 10 seconds of EGM prior to the episode declaration. Pre-therapy storage provides up to 10 seconds of information ending with therapy delivery (includes charge and reconfirmation). If the pre-therapy time exceeds 10 seconds, the last 10 seconds of data is retained (corresponding to the therapy delivery attempt). The post-therapy EGM storage starts following therapy delivery and stores up to 10 seconds of EGM. Figure 7-3 on page 7-10 illustrates EGM storage in relation to a surface ECG strip chart recording. If the time from one therapy to the next exceeds 10 seconds, a new pre-therapy buffer is started. If the time exceeds 20 seconds there will be a gap between the post- and pre-therapy EGM. ATR episodes store 10 seconds prior to the start of fallback and 10 seconds after.

NOTES:

- *For multiple-burst ATP schemes, only the EGM before the first burst and after the last burst is retained. The EGM is not recorded during or between bursts.*
- *Patient Triggered Monitor episodes store up to 2 minutes prior to magnet activation and up to 1 minute after. If a spontaneous tachy episode occurs within this time period, less than 3 minutes of electrogram will stored. Spontaneous tachy episode storage takes precedence over a patient triggered episode. If the feature is triggered by the patient during a spontaneous tachy episode, electrograms will not be stored for the Patient Triggered episode.*

Table 7-1. Storage capacity in minutes for electrograms

Electrode Enabled	Minutes	Minutes (With Patient Triggered Monitor Feature Enabled)
Shock only	19	16
Atrial only ^a	19	16
Ventricular only	19	16
Shock and Atrial ^a	9.5 each	6.5 each
Shock and Ventricular	9.5 each	6.5 each
Atrial and Ventricular ^a	9.5 each	6.5 each
Shock, Atrial, and Ventricular ^a	6.3 each	3.3 each

a. Dual-chamber devices only.

NOTE: When the Patient Triggered Monitor feature is enabled, the Tachy EGM Storage, as set up on the Episodes/EGMs screen, is adjusted to reflect the times in Table 7-1. Refer to the section “Patient Triggered Monitor” on page 7-18.

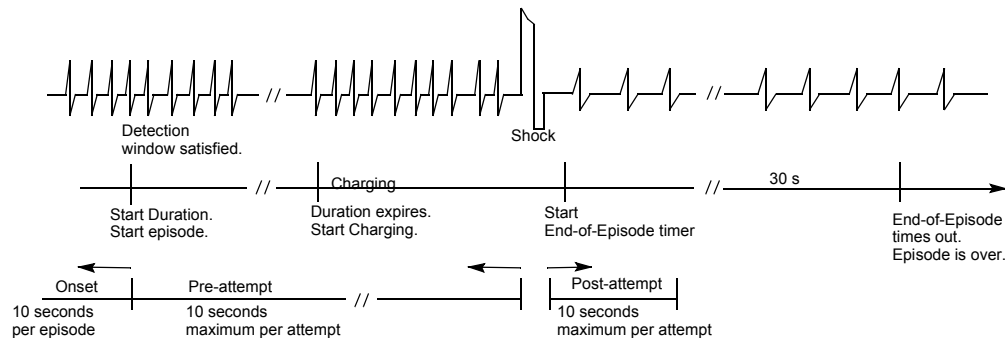


Figure 7-3. Illustration of tachy episode EGM storage in relation to a surface ECG strip chart recording.

To view the EGM data, use the following steps:

1. Select the desired episode on the Arrhythmia Logbook screen and select the EGM button to view the stored EGMs on the screen. The EGM button will not be available if an episode has no related EGM data. The telemetry wand must be positioned over the pulse generator to enable retrieval of EGM data. Refer to Figure 7-4 and the following text for an explanation of the screen display.

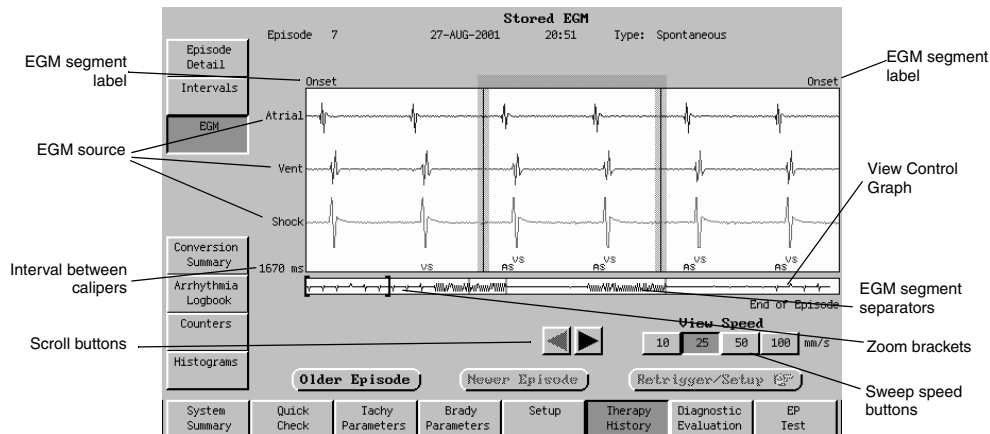


Figure 7-4. The Stored EGM screen.

- EGM strips for atrial, ventricular, and shock electrogram sources are displayed. Each strip includes the EGMs sensed during episode onset and immediately before and after each therapy delivery with the corresponding annotated markers. Orange vertical bars indicate the segment (onset, pre-attempt, post-attempt) boundaries.
- A View Control Graph allows an easy method to view other segments of a strip. The brackets on the segment separator can be moved to change which segment is visible.
- EGM segment labels indicate which segment of a strip is visible (Onset, Pre-attempt, Post-attempt, and End of Episode) corresponding to the View Control Graph brackets, along with attempt numbers.
- Scroll buttons (left and right arrows) will move the currently displayed portion of the trace left and right.
- Calipers can be moved along the trace and will display the time interval between the calipers.
- Sweep speed buttons change the trace speed in mm/s.
- A Retrigger/Setup button will be available for Patient Triggered Monitor episodes. Select the button to display the Patient Triggered Monitor Setup

screen in order to reset the feature for storing another event or to disable the feature.

2. Select either the Older Episodes or Newer Episodes button to display a different episode strip. If EGMs are not available for an episode, the Episode Detail screen will be displayed.
3. To print the trace at the currently displayed speed, select the Printer icon.

Episodes/EGMs - Arrhythmia Logbook Setup

The Episodes/EGMs button in the Setup tool kit allows selection of the type of episode data storage, the source of electrogram storage, and additional features. The data stored in the pulse generator based on these setup values are displayed on the Arrhythmia Logbook screen, which is accessed through the Therapy History tool kit. Details about the features are found in the Therapy History section of this chapter. The screen allows setup for the following information:

Episode Data Storage Setup

Episode data storage can be portioned to store both tachy and brady EGM data. The data stored for each episode include details about the episode, EGMs, and intervals. The Brady details include ATR and PMT data. The combination of tachy and brady storage capacities will total 100%. Select the Tachy value box and select the desired percentage of storage capacity. The Brady value box will change accordingly to reflect the percentage required to equal 100% capacity. Likewise, selecting a Brady value box will automatically change the Tachy value box. The EGM storage capacity will be calculated and displayed in minutes and seconds.

NOTES:

- *When the Patient Triggered Monitor feature is enabled, 3 minutes of storage are reserved for a patient triggered episode; the time for tachy episode storage is adjusted as reflected in Table 7-1 on page 7-9, and brady episode storage is suspended.*
- *The Tachy/Brady EGM storage parameters also control the apportionment of Tachy and Brady episodes shown in the Recent Therapy History section of the Quick Notes report.*

Electrogram Storage Source

The pulse generator can store annotated electrograms sensed via the shocking, ventricular pace/sense leads, and atrial pace/sense leads (for dual-chamber devices) prior to the onset of an episode and immediately before and after each therapy attempt. Select the desired value, On or Off, for atrial, ventricular, or shocking leads.

NOTE: *If the Patient Triggered Monitor feature is enabled, it must be disabled in order to change the storage sources, and then re-enabled if desired.*

Additional Features

The following additional features can be programmed On or Off: Nonsustained Episode Storage, VF Priority Protection, Onset EGM Storage, and PMT Episode Storage.

Counters

The Counters screen displays both Tachy and Brady counters; the number of counters since last reset and device totals are visible. The Counters data correspond to the episode numbers on the Conversion Summary screen; refer to section “Conversion Summary” on page 7-2 for descriptions of the episode and event classifications.

When the Tachy button is selected on the Counters screen, episode counters are displayed and include the following categories:

- Treated
- Commanded Therapy
- Nontreated: No Therapy Programmed episodes, and Nonsustained episodes (including Diverted-Reconfirm episodes as categorized on the Conversion Summary screen)
- Total episodes

Therapy counters also are displayed and include shock and ATP therapy attempts. The types of delivered therapy for both shocks and ATP include the following:

- Delivered-Detection Met is therapy delivered by the pulse generator when detection criteria are satisfied.
- Delivered-Physician Commanded is therapy commanded via the programmer, such as STAT SHOCK, Commanded Shock, or Commanded ATP schemes. Shocks delivered during Shock on T induction do not increment episode or therapy counters.

The ATP counter is incremented at the start of the delivery of the first burst of an ATP scheme. Subsequent ATP bursts in the same scheme are not counted individually during the same episode.

The types of diverted shock therapy include the following:

- The Diverted-Reconfirm counter increments if shock therapy is not delivered because the reconfirmation algorithm determined that an arrhythmia was no longer present
- The Diverted-Physician Commanded counter increments if shock therapy was diverted manually with a magnet or with the DIVERT THERAPY key

Diverted ATP schemes are not counted as diverted since the ATP delivery counter is incremented at the start of delivery of the first burst.

When the Brady button is selected on the Counters screen, the number of stored events is displayed for ventricular paced and sensed events, PVC events, hysteresis events, rate smoothing events, and atrial and ventricular paced and sensed events, and ATR and PMT events for dual-chamber devices. Time values are displayed for the ATR Minimum and Maximum Durations, representing the shortest and longest time the device was in an ATR mode switch. A percentage value is displayed for percentage of time (since last reset or for totals) that the mode switch was in effect for all events.

Follow the steps below to access and clear counters:

1. Select the Counters button from the Therapy History tool kit.
2. Select the Tachy or Brady buttons to display the desired information.
3. Select the printer icon from the main application screen to print counter data.
Counters should be printed prior to resetting counters because once

reset, the data that was in the Since Last Reset column cannot be retrieved again.

4. Select the Reset button (and ensure telemetry communication is established) to clear the Tachy, Brady, and Histograms counters stored since last reset. (The total device counters are not reset.) Clearing data from this screen, likewise, clears the corresponding recent data displayed on the System Summary, Quick Check, Conversion Summary, and Arrhythmia Logbook screens. Stored episodes, EGMs and intervals are not erased. The same data can be reset from the Quick Check screen as well. The appropriate times to reset counters are when the recent data have been reviewed and printed, or when a change in patient management has occurred, such as a new drug regimen or a change in detection or therapy parameters. Since the pulse generator classifies events according to programmed parameters, a change in these parameters without resetting the counters may present misleading data.

Example of Incrementing Counters

Figure 7-2 below illustrates how the Tachy counters are incremented on the Counters screen for various events. An asterisk (*) indicates the affected counter in each example.

Table 7-2. Example of Incrementing Counters

	A		B		C		D	
	Since Last Reset	Device Totals	Since Last Reset	Device Totals	Since Last Reset	Device Totals	Since Last Reset	Device Totals
Episode Counters								
Treated								
VF Therapy	0	6	0	6	0	6	0	6
VT Therapy	0	1	*1	*2	1	2	*2	*3
VT-1 Therapy	0	1	0	1	*1	*2	1	2
Commanded Therapy	0	0	0	0	0	0	0	0
Nontreated								
No Therapy Programmed	0	0	0	0	0	0	0	0
Nonsustained	0	1	0	1	0	1	0	1
Total Episodes	0	9	*1	*10	*2	*11	*3	*12
Therapy Counters:								
Shocks Attempted	0	7	*1	*8	*2	*9	*4	*11
Delivered-Detection Met	0	7	*1	*8	1	8	*3	*10
Delivered-Physician Commanded	0	0	0	0	0	0	0	0
Diverted-Reconfirm	0	0	0	0	*1	*1	1	1
Diverted-Physician Commanded	0	0	0	0	0	0	0	0
ATP Schemes Attempted	0	1	0	1	*1	*2	1	2
Delivered-Detection Met	0	1	0	1	*1	*2	1	2
Delivered-Physician Commanded	0	0	0	0	0	0	0	0

Column A: The numbers have been chosen to give a base for how the counters are incremented throughout the following columns.

Column B: A tachyarrhythmia is detected in the VT zone. The first shock successfully converts the arrhythmia.

Column C: A tachyarrhythmia is detected in the VT-1 zone and ATP therapy is delivered. The arrhythmia is not converted and the pulse generator charges for the first shock delivery. Shock therapy is diverted because during reconfirmation the arrhythmia was no longer present.

Column D: A tachyarrhythmia is detected in the VT zone. The first shock is unsuccessful, but the second shock converts the arrhythmia.

Histograms

The Histograms feature retrieves information from the pulse generator and displays the total number and percentage of paced and sensed events for both the atrium and ventricle in a graphical format. The ventricular event graph indicates the programmed tachy zone rate thresholds.

1. To access the Histograms screen, select the Histograms button in the Therapy History tool kit.

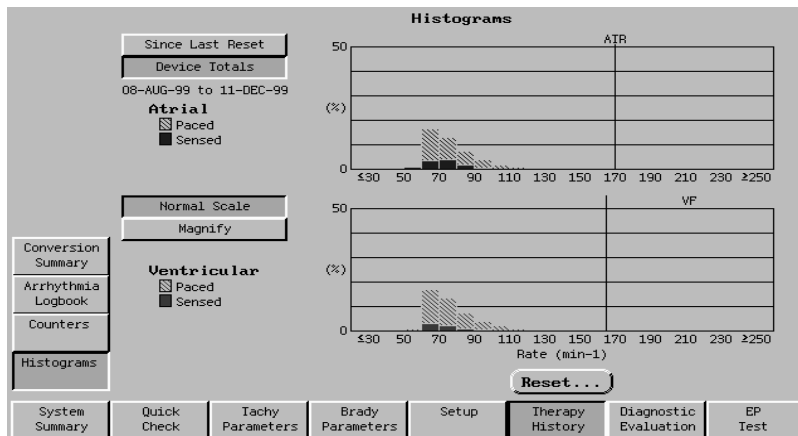


Figure 7-5. The Histograms screen.

2. The initial display includes data since the last time the counters were reset. To display device totals, select the Device Totals button. The dates of the displayed data will be shown on the screen.
3. Select the Magnify button to display enhanced detail about the ventricular events recorded in the tachyarrhythmia zones. For dual-chamber devices this will display enhanced detail about the atrial events above the ATR Trigger Rate. Notice that the vertical-axis value changes from percentage to number of events if data exist for ventricular events within the tachy zones and for atrial events above the ATR Trigger Rate. The magnification of each graph (independent of each other) will be based on the events with the greatest value; so all magnified data will be visible on the screen and will not exceed the top line of the graph. Events below the lowest tachy zone or below the ATR Trigger Rate may appear clipped during magnification. Select the Normal Scale button to return to the previous scale.

4. Histogram data that are displayed on the screen can be printed by selecting the printer icon at the top of the main application screen. Also data for both Device Totals and Since Last Reset can be printed using the Print option from the Utilities button on the main application screen.

PATIENT TRIGGERED MONITOR

This feature allows a patient to trigger (initiate) storage of EGMs, intervals, and annotated marker data during a symptomatic episode when a magnet is positioned over the device. When this feature is programmed On and triggered, it will store up to 2 minutes of patient monitor data prior to and up to 1 minute after triggering the monitoring, using the same source of electrograms programmed for Episodes/EGMs storage. Up to 2048 intervals can be stored. The stored data include the episode number, the atrial and ventricular rates at magnet application, and the start time and date of magnet application. The data remain in device memory until the device has been interrogated and cleared via the programmer. When data are stored, the corresponding episode type is recorded as "Pt. Trg." (patient triggered) in the Arrhythmia Logbook.

Use care when programming the Patient Triggered Monitor feature On, because the following conditions will exist:

- All other magnet features are disabled. The Magnet/Beeper feature will not indicate magnet position.
- Device longevity is impacted. Once the patient has triggered this feature to store episode data or the feature is suspended, the impact on device longevity is no longer present. To help reduce the longevity effect, this feature is automatically suspended after 60 days from the day it was programmed On, whether the patient triggered it or not.

CAUTION: When this feature is triggered or when 60 days have elapsed, the feature is still enabled and other magnet features are still disabled until the Patient Triggered Monitor feature is actually programmed Off. Schedule a patient follow-up visit to either turn the feature Off or to retrigger the feature.

- EGM storage is reset. Existing electrogram and interval data are removed from device memory (including VF Priority Protection data), because the memory becomes reserved for patient-triggered data storage. Consider saving EGM data to disk prior to programming this feature On.
- Bradycardia EGM data are not stored during patient triggered monitoring.

To program the Patient Triggered Monitor feature, follow these steps:

1. Select the Setup tool.
2. Select the Patient Triggered button. The screen includes On and Off buttons and displays the following information:
 - EGM storage and Tachy EGM storage in minutes:seconds and EGM Sources. The EGM source values reflect those as programmed for Episodes/EGMs and displayed in the Arrhythmia Logbook. Refer to “Episodes/EGMs - Arrhythmia Logbook Setup” on page 7-12.
 - Date the feature will be or was automatically disabled, along with a Retrigger button. When the Retrigger button is selected, the feature is re-enabled for 60 days and the existing EGM storage is erased and storage space is reserved for the patient-triggered monitoring.
 - Reminders of the effect this feature has on magnet features, EGM storage, and device longevity.
3. Select On to enable the feature. A message will appear allowing patient data to be saved to disk.

CAUTIONS:

- After selecting On, if the Retrigger button is active, it should be selected to ensure patient-triggered monitoring is enabled. If the retrigger button is not active, but On is selected, then patient-triggered monitoring has been enabled.
- Determine whether the patient is capable of activating this feature prior to giving the magnet to the patient and prior to programming the Patient Triggered Monitor feature On. Remind the patient to avoid strong magnetic fields so the feature is not inadvertently triggered.
- Consider having the patient initiate a stored EGM at the time of feature programming to assist with patient education and feature validation. Verify the activation of the feature on the status display of the EP Test screen (refer to Figure 8-1 on page 8-3). **Retrigger the feature following any practice activation.**

WARNING: Ensure that the feature is On prior to sending the patient home by viewing the settings and date on the Patient Triggered Monitor screen of the Setup

tool kit. If the feature is inadvertently left in the Off setting, the patient could potentially disable tachyarrhythmia detection and therapy.

4. Select Off to disable the feature and restore other features. A message will appear indicating that episode and EGM storage setup and magnet operations will be restored to previous settings. The patient triggered episode will not be erased, but could eventually be overwritten by new episode data. The patient triggered event can be saved to disk.

CAUTION: Ensure that the feature is Off (by viewing the Patient Triggered Monitor tool in the Setup tool kit) prior to sending a patient home and retrieve the ICD magnet from the patient whenever the use of this feature is not needed to avoid any attempt by the patient to trigger the feature. Explain to the patient that use of a magnet when this feature is Off could disable tachyarrhythmia detection and therapy.

NOTE: *The Magnet/Beeper feature and Electrogram Storage Source, as programmed from the Setup tool kit, are not available for programming when the Patient Triggered Monitor feature is programmed On.*

TRENDING DATA

When the Brady Mode is programmed to an adaptive-rate mode, the pulse generator collects and stores sensor and actual data. The Trending feature graphically displays the sensor rate in response to the sensor data, which allows evaluation of the pulse generator's rate response to the detected activity level of the patient. This feature is useful during exercise testing to assess programmed adaptive-rate parameter values. The parameter values can be adjusted with the Replay option, without having to repeat an exercise test. The pulse generator also collects and stores data in nonadaptive-rate modes; however, only actual rate data will be displayed without sensor data comparison.

Follow the steps below to access the Trending tool kit and to specify which types of data will be collected by the device and the resolution the acquired data will be stored:

1. Select the Trending button from the Diagnostic Evaluation tool kit.
2. Select the Trending Setup button. Alternatively, select the Setup tool button and then select the Trending button.
3. Choose the Recording Method to be used:

High Resolution—The device records the actual rate and sensor values every 16 seconds.

Long Duration—The pacemaker records the actual rate and sensor values every 60 seconds.

4. Choose how the data should be stored.

Fixed storage starts when the setup is confirmed and continues until device memory storage is full, allowing the clinician to view data from initial setup for a fixed amount of time.

Continuous storage has the most recent data available. It starts when setup is confirmed and continuously records the latest information overwriting the oldest data until the information is retrieved. It allows the clinician to view the data for the recording duration immediately prior to the data retrieval.

5. Select the Initiate Trending button. The pulse generator will immediately begin storing the data as specified.

Retrieving and Working with Trending Data

1. Ensure that telemetry communication is established, and select the Retrieve button from the Trending screen to retrieve the stored trending data from the device.

While retrieving the data, the programmer will display the telemetry progress, indicating how much information has been retrieved thus far. The programmer will retrieve the most recent information first. If the interrogation is interrupted, the information already retrieved will be available for analysis. The normal and replay parameters are displayed.

2. The PRM displays a graphical representation of the retrieved data. Refer to Figure 7-6 and the following text to work with the trending data.

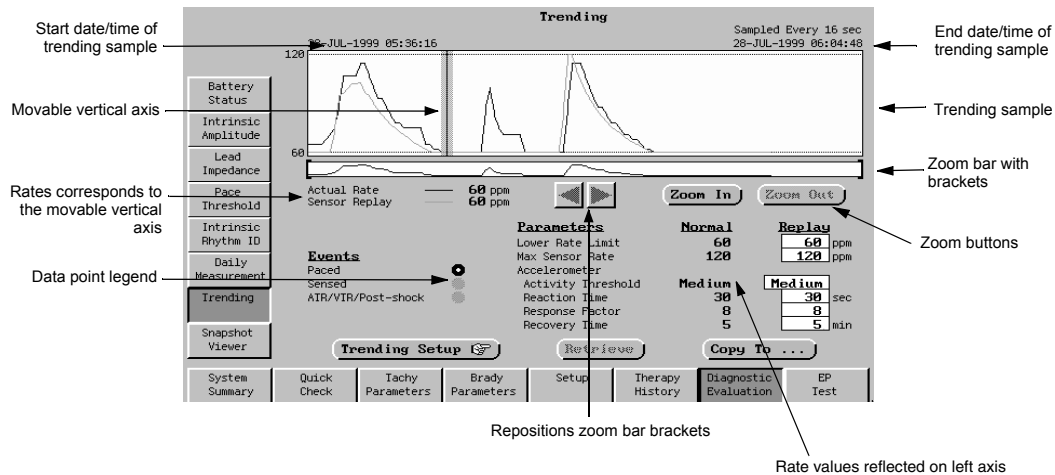


Figure 7-6. The Trending window.

- The normal bradycardia rates and accelerometer parameters are displayed. The Lower Rate Limit and Maximum Sensor Rate parameter values are reflected on the left vertical axis of the graph.
- The start and end dates and times at the top of the graph indicate the length of time covered by the visible trending sample.
- The Zoom bar displays a data line that represents the total data retrieved. The bar contains adjustable brackets that, wherever they are positioned, will reflect the portion of the total data that is represented on the larger trending sample.
- The Zoom In and Zoom Out buttons adjust the brackets on the Zoom bar. The adjustment either compresses or expands the displayed trending sample. The dates and time at the top of the graph change accordingly and reflect the compressed or expanded length of time.
- The left- and right-arrow buttons reposition the Zoom bar brackets and update the trending sample displayed.
- Individual data points on the rate and sensor data lines may be visible if the display is zoomed in enough to show that level of detail.

- The vertical axis can be moved across the graph using the stylus and the Actual and Sensor Replay rates will be displayed for that point in time. Classification of events occurring during the sample also will be indicated.
 - The Replay parameter values can be adjusted, which allows the clinician to see how changes in the adaptive-rate pacing parameters will affect the sensor response. Replay parameters cannot be modified until the trending data has been retrieved from the pulse generator.
3. Make changes to the Replay parameters to optimize the sensor response. As the Replay parameters are modified, the application will modify the sensor graph to illustrate the effects that would result from the changes.
 4. If the replayed parameters result in the optimal response, copy the changes to the Brady Parameters screen by selecting the Copy To button.
 5. To print the current trending and replay parameters, select the printer icon.

SNAPSHOT VIEWER

When a trace has been captured using the snapshot icon, the trace can be displayed and analyzed on the Snapshot Viewer screen. A trace is also recorded in the Snapshot Viewer following a pace threshold test. Surface ECG, electrograms, and annotated markers will be captured for the 10 seconds before and up to 10 seconds after the moment of capture (only 10 seconds following a pace threshold test). Up to 4 time-stamped snapshots will be retained in the PRM memory for the current session only; once the session has been terminated by exiting the application software or by interrogating a new patient, the data will be lost.

1. Select the Snapshot Viewer button on the Diagnostic Evaluation tool kit. Refer to Figure 7-7 and the following text for an explanation of the screen display.

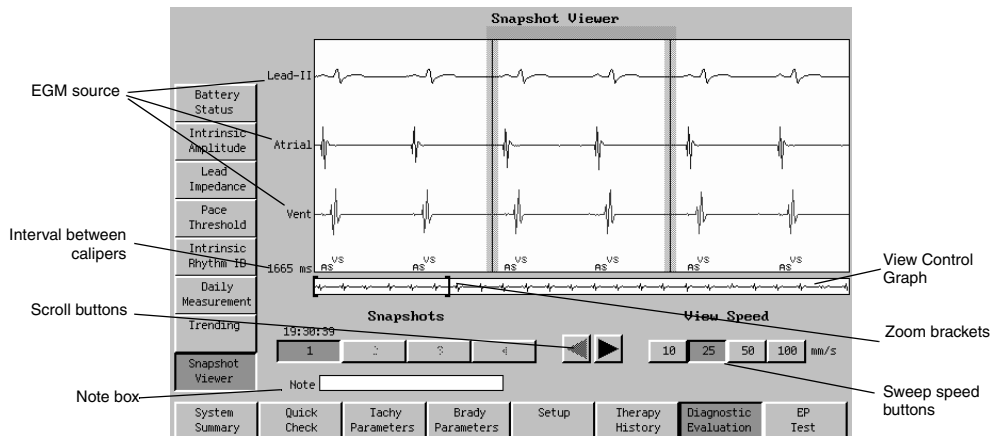


Figure 7-7. The Snapshot Viewer displays traces captured with the snapshot icon.

- ECG display, zoomed in as indicated by the view control bar.
 - View control indicates the full snapshot. The brackets on the view control can be moved to change which portion of the snapshot is visible.
 - Calipers can be moved along the trace and will display the interval in milliseconds between the calipers.
 - Snapshots with capture time. Up to 4 snapshots can be captured during a patient session and viewed separately.
 - Text can be entered in the Note box. The pace threshold test results will appear in this Note box.
 - Scroll buttons (left and right arrows) will move the currently displayed portion of the trace left and right.
 - Sweep speed buttons change the trace speed in mm/s.
2. To print a displayed snapshot, which includes the Note text and the distance between calipers, select the printer icon. Printing will automatically occur following a pace threshold snapshot.

MY PATIENT PROFILE

My Patient Profile allows the programming and storage of customized implant parameter profiles and individual patient follow-up settings. These profiles can be stored on a patient data disk or on the PRM hard drive. My Patient Profile can be accessed prior to pulse generator interrogation by selecting the Profiles button on the main application screen or after pulse generator interrogation through the Profile button within the VITALITY/VITALITY 2 software.

NOTE: *A patient data disk can store either patient data or profile information. The disk cannot store both items at the same time. For example, if a data disk is formatted to store patient data, it must be reformatted before it can store profile data. Remember that upon reformatting, any data previously stored on the disk will be lost.*

Creating a Customized Profile

The following steps explain how to create a customized parameter or follow-up profile.

1. Select the Profiles icon.
2. Select the Create button from the Profile screen. Choose the appropriate profile (parameter or follow-up) and select Begin.

NOTE: *The patient's EGM will be obscured during this operation.*

3. Choose the desired options for each clinical event by selecting the box next to the individual option. A check mark will appear to indicate that the box has been selected. Select the Next button when all desired options have been chosen for each screen.

NOTE: *Data from previous screens can be modified by selecting the Back button.*

4. Navigate each screen as needed and select the desired options. When complete, select the Finish button.
5. Save the profile by choosing the Save To option (programmer or disk) and selecting Save As. The existing profiles are displayed on the "Save Profiles" screen for reference.

NOTE: *Tachy Mode and Patient Triggered Monitor parameters cannot be saved as part of a parameter profile.*

6. Select the Profile Name value box to display a keyboard. Enter the profile name and select the Save Now button. The profile window will close and the PRM will return to the screen that was displayed prior to accessing Profiles.

Loading a Customized Profile

To retrieve or load an existing profile, select the Load button from the Profile screen and choose the Load From option (either programmer or disk). The screen will display the profile name, the type of parameters, the type of profile (parameter or follow-up), and the date the profile was created. Select the desired profile from the list and select Load Profile.

If the device's programmed parameters are changed by loading a parameter profile, hatch marks (/ / / /) will appear on the buttons associated with the modified parameters.

NOTE: *The default follow-up profile can only be loaded from the VITALITY 2 main application screen. If a new profile is set as default during an interrogation, the user must exit the application by selecting Quit and return to the startup screen to set the new profile as the active default profile.*

Editing A Profile

Both Follow-up and Parameter Profiles can be edited. To do so, choose the Edit button from the main Profile screen. Select a specific profile and select Begin. Navigate through the screens as needed; select Finish when completed. Save the profile by following the window commands. Upon completion the PRM will return to the screen that was displayed prior to accessing Profiles.

NOTE: *Upon completion of editing a profile, the available save options are Save and Save As. By selecting Save, the profile will be saved by its current name. By selecting Save As, the user will be prompted to save the profile by a different name.*

Copying a Profile

Profiles can be copied from the PRM to a disk or from a disk to the PRM by selecting the Copy/Delete button on the main Profile screen. Insert a disk into the disk drive and select the specific profile to be copied. The Copy button will display

an arrow indicating whether the profile will be copied to a disk or the PRM. Complete the task by selecting the Copy button.

Deleting a Profile

Profiles can be deleted from the PRM or a disk by selecting the Copy/Delete button on the main profile screen. Insert a disk into the disk drive and select the specific profile to be deleted. Select the Delete button and follow the menu prompt by selecting the Delete Now button.

ELECTROPHYSIOLOGIC TESTING

CHAPTER 8

This chapter contains the following Electrophysiologic Testing topics:

- Brief description of “EP Test Features” on page 8-1
- “Atrial Stimulation and Backup VVI Pacing During EP Testing” on page 8-2
- “EP Test Screen” on page 8-3
- “Induction Methods” on page 8-5
- “Commanded Therapy Methods” on page 8-12

EP TEST FEATURES

Electrophysiologic (EP) Testing features enable the physician to induce and terminate arrhythmias noninvasively in order to monitor and test the effectiveness of selected detection criteria and therapies. The EP Test features can be used in conjunction with the ECG display so that real-time traces may be viewed. The status of the pulse generator/patient interaction is displayed also.

NOTE: Any reference to atrial features is effective for dual-chamber devices only.

The features allowing noninvasive EP testing of arrhythmias include the following (except External induction which is invasive):

- Fib High/Low induction—allows the pulse generator to deliver high-rate, high output pulses through the shocking electrodes at the command of the programmer. It is intended to induce ventricular fibrillation in the patient for EP testing purposes. (Refer to page 8-6.)
- Shock on T wave induction—allows the device to deliver a series of S1 pacing pulses through the ventricular rate-sensing electrodes followed by shock delivery through the shocking electrodes. (Refer to page 8-7.)
- 50 Hz/Manual Burst pacing induction—This feature allows two separate pacing inductions. 50 Hz Burst pacing can be delivered for as long as desired to either the atrium or ventricle (refer to page 8-9). Manual Burst pacing with ramping

capability can be delivered for as long as desired to either the atrium or the ventricle. (Refer to page 8-9.)

- PES induction (programmed electrical stimulation)—allows the pulse generator to deliver a series of timed S1 pacing pulses that are followed by premature S2-S5 pulses to induce arrhythmias in the patient. The pulses can be delivered either to the atrium or the ventricle. The PRM allows flexible setup and control of each PES attempt. (Refer to page 8-10.)
- Commanded ATP therapy—allows the physician to determine the appropriate ATP scheme for arrhythmia termination. Commanded ATP allows the physician to terminate tachycardias using ATP schemes that are not programmed in the therapy prescriptions. The pulses can be delivered either to the atrium or the ventricle. (Refer to page 8-13.)
- Commanded Shock therapy—can be used to convert rhythms or to deliver a programmable shock energy with a programmable coupling interval at any time through the shocking electrodes at the command of the programmer. (Refer to page 8-12.)

ATRIAL STIMULATION AND BACKUP VVI PACING DURING EP TESTING

During EP testing, atrial stimulation is available for the following induction features:

- 50 Hz/Manual Burst
- PES
- Commanded ATP
- Commanded Shock

During atrial stimulation, backup pacing is available in the VVI mode regardless of the programmed normal and post-shock Brady Mode. The mode can be programmed Off as well. Whenever an induction method is selected from the Atrium tab, a Backup VVI button with a magnifying glass icon will be displayed. The button will be dimmed if the Ventricle button is selected. Select the button to program the Backup VVI pacing parameter values.

EP TEST SCREEN

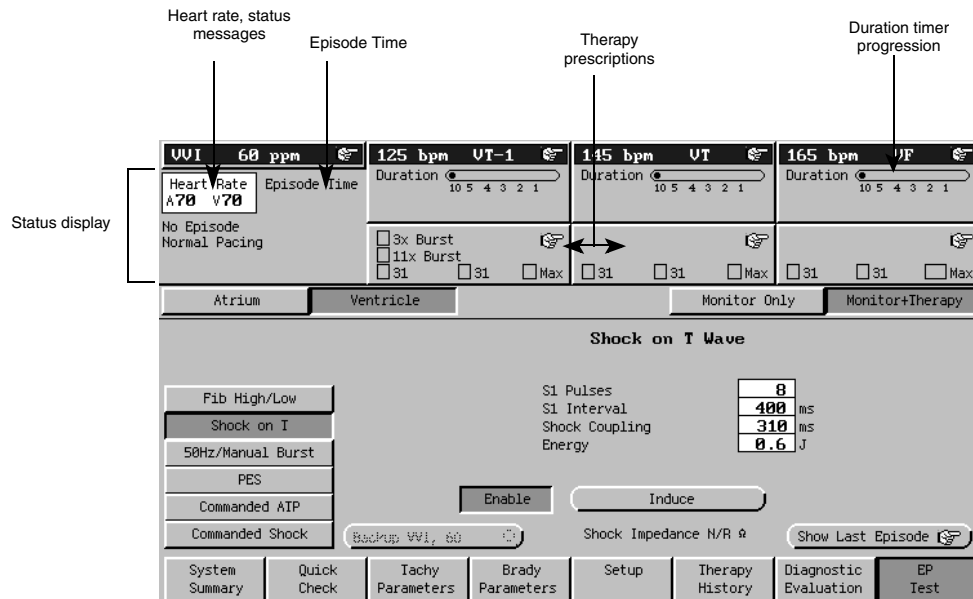


Figure 8-1. EP Test screen.

When telemetry communication is occurring, the real-time status of the detection and therapy process of the pulse generator can be viewed on the status display portion of the EP Test screen. Viewing this display allows the physician to induce and test either a programmed detection/therapy prescription or optional therapies (commanded ATP or commanded shock) while monitoring the pulse generator's progress. The status display provides the following information:

- **Heart Rate and Status Messages**—The patient's heart rate as detected by the pulse generator is continually updated with each cardiac cycle. Both the atrial and ventricular rates are displayed for dual-chamber devices. Status messages indicate detection and therapy status: line 1 indicates if detection is met, if there is no episode occurring, or if an ATR is in progress; line 2 indicates if SRD is active or met, and whether normal or post-shock pacing parameters are in effect; line 3 shows the type of therapy initiated and the zone, and line 4 shows the status of the therapy such as in progress, diverted, or delivered. If no episode is occurring, lines 3 and 4 also will display the text "Time since last ther-

apy” along with the continually updated time in minutes (up to 10 minutes and then it is displayed as > 10 minutes).

- **Episode Time**—When an episode is started, the Episode Time is activated and a running time is continually updated in minutes and seconds until the end-of-episode is declared. (The Episode Time display is not updated upon reaching 4:14 m:s). At the end of an episode, all indicators are cleared. During an ATR episode the elapsed time is displayed in hours and minutes and continually updates in 1-minute increments up to 4 hours, at which time the display will indicate > 4:00 h:m.
- **Duration Timer**—Progression of the Duration timer is graphically displayed using a scale. The black bar in the scale moves from left to right to show at most, the last 10 seconds of programmed Duration. When Duration is expired and therapy delivery begins, the bar is removed.
- **Therapy Prescriptions**—Displayed for each zone in which they are programmed. As each therapy is delivered, a check mark will appear in the box adjacent to the respective therapy. ATP therapies indicate the scheme type as well as the programmed number of bursts in the scheme. Shock therapies indicate the programmed energy level for the programmable shocks. A number will appear and increment (1, 2, etc.) in the Max box each time a maximum-energy shock is delivered. A checkbox next to SVT Inhibit indicates that the Rhythm ID (SVT Inhibit) has been programmed On.

Follow the steps below to perform EP Test functions:

1. Select the EP Test button from the toolbox (Figure 8-1). The EP Test tool kit is divided into sections: a) the top displays patient/pulse generator status, b) on the bottom, buttons are available to select the desired chamber for the EP Test methods, and c) on the right, the Tachy Mode can be changed.
2. Establish telemetry communication. **Telemetry communication between the programmer and the pulse generator should be maintained throughout all EP test procedures.**
3. Choose the desired chamber by selecting the appropriate button. Refer to the section “Atrial Stimulation and Backup VVI Pacing During EP Testing” on page 8-2.
4. Program the Tachy Mode appropriate to the EP Test method. **To change the Tachy Mode, select either the Monitor Only or Monitor + Therapy button on**

the right side of the screen; the Tachy Mode only will be immediately reprogrammed. Refer to Table 8-1 for the operational mode in which each EP Test function can be performed.

Table 8-1. Operation Mode for EP Test Functions

EP Test Method ^a	Tachy Mode		
	Monitor + Therapy	Monitor Only	Off
Commanded ATP		X	
Fib High/Low	X		
Shock on T-wave	X		
PES	X		
Commanded shocks	X	X	
50 Hz/Manual Burst	X		

a. EP functions cannot be performed if the pulse generator is programmed to Storage mode.

NOTE: *The Tachy Mode can be also changed from the Tachy Mode button on the main application screen.*

5. Perform the desired EP Test function as described in the following sections, maintaining telemetry communication throughout the session. Some of the functions require selection of an Enable button to initiate the function. If the text on an Enable button is gray, the function cannot be initiated until the appropriate Tachy Mode is programmed. Only one EP Test function is available at a time. If one function is enabled and another button or value box is selected anywhere on the screen, the originally selected EP Test function is automatically disabled.
6. To conveniently access therapy history after an induced arrhythmia is terminated, select the Show Last Episode button.

INDUCTION METHODS

Each induction method available from the EP Test screen is described below with instructions for performing the induction. During any type of induction delivery, the pulse generator recognizes the induction and performs no other activity until the

induction delivery is ceased, at which time the programmed Tachy Mode (Monitor + Therapy) will take effect and the pulse generator will respond accordingly.

NOTES:

- *All inductions and tachycardia therapy delivery are inhibited when a magnet is positioned over the pulse generator (if Enable Magnet Use is programmed on).*
- *Pacing pulses during induction are delivered at the programmed ATP Pulse Width and ATP Amplitude. These parameters are programmed from the Therapy Features screen in the Setup tool kit.*

Fib High/Low Induction

Programmable Values: Fib Low, Fib High

Fib High/Low induction uses the shocking electrodes to stimulate the ventricle at very fast rates. Two settings are available to allow use of the minimum energy necessary for induction.

- Fib Low delivers pulses at an average interval of 50 ms.
- Fib High delivers pulses at an average interval of 30 ms.

Performing Fib High/Low Induction

NOTE: *The patient should be sedated prior to delivery of fibrillation induction pulses. The large surface area of the shocking electrodes tends to stimulate the surrounding muscle and can be uncomfortable.*

1. Select the Fib High/Low button. Three buttons, Enable, Hold For Fib High, and Hold For Fib Low, will be displayed.
2. Select the Enable button. The text on the Hold buttons will no longer be gray.
3. Select the Hold button to initiate delivery of the fibrillation induction train (the Hold button will become shaded). The induction train is delivered as long as the Hold button is held and the telemetry link is maintained.

During induction the pulse generator is automatically disabled from detecting, and automatically re-enabled following induction delivery. If V Fib induction is

initiated during an episode, the end-of-episode is declared before the V Fib induction pulses are started. A new episode (with initial detection and therapy) can be declared after the V Fib induction is completed. Event markers and EGMs are interrupted during V Fib induction and will automatically restart following induction.

4. To stop the induction train, release the button (the text on the Hold button will become gray again).
5. To deliver another fibrillation induction, repeat step 2 through step 5.

Shock on T Induction

Programmable Values: Number of S1 Pulses 1–30; S1 Interval 120–750 ms; Coupling Interval Sync, 50–500 ms; Shock Energy 0.1–31 J

A Shock on T wave induction method allows the device to deliver a drive train (up to 30 equally timed pacing pulses, or S1 pulses) through the ventricular rate-sensing electrodes followed by shock delivery through the shocking electrodes (Figure 8-2). This provides a method of VF induction and should be used for induction purposes only. The initial S1 pulse follows the last sensed or paced event at the S1 interval. The shock is coupled to the last S1 pulse of the drive train.

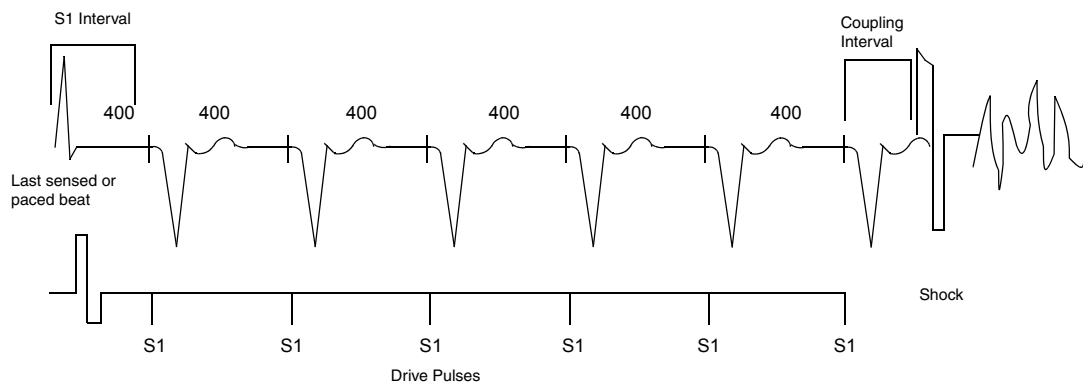


Figure 8-2. Shock on T induction drive train.

Performing Shock on T Induction

1. Select the Shock on T button. The programmable induction parameters will be displayed.
2. Select the desired value for each parameter.
3. Select the Enable button. The Induce button will no longer be gray.
4. Select the Induce button to begin delivery of the drive train. The pulses are delivered in sequence until the programmed number of pulses is reached. **Once induction is initiated, removing the telemetry wand will not stop the drive train delivery.** (The DIVERT THERAPY key can be pressed to stop induction delivery command.)
5. Shock on T induction is complete when the drive train and shock are delivered, at which time the pulse generator automatically restarts detection.

NOTES:

- *Prior to and during the drive train delivery, tones will be heard indicating capacitor charging in preparation for shock delivery.*
- *The shock delivered during Shock on T induction does not increment episode or therapy counters.*

50 Hz/Manual Burst Pacing

Programmable Values: Burst Interval 20–750 ms; Decrement 0–50 ms; Minimum Burst Interval 20–750 ms

The 50 Hz/Manual Burst pacing feature allows two separate pacing inductions within one button. The user can choose to perform either 50 Hz Burst pacing or Manual Burst pacing with ramping capability by following the instructions below.

During 50 Hz/Manual Burst pacing, pulses are delivered in VOO or AOO mode at the programmed ATP Pulse Width and ATP Amplitude through the rate-sensing leads. Detection is automatically disabled during the burst delivery and restored after delivery. Like PES, delivery of a burst will terminate any episode in progress.

Performing Manual Burst Pacing

1. Choose the cardiac chamber to be paced.
2. Select the 50 Hz/Manual Burst button.
3. Select the desired value for the Burst Interval; this indicates the cycle length of the first 8 intervals in the drive train.
4. Select the desired value for the Decrement value, which can be programmed such that each interval following the first 8 intervals will be decremented.
5. Select the desired minimum burst interval.
6. Select the Enable button. The text on the Hold For Burst button will no longer be gray.
7. To deliver the burst, select and hold the Hold For Burst button. The manual burst will be delivered as long as the Hold For Burst button is held. The intervals will continue to be decremented until the minimum burst interval is reached, then all further pulses will be at a constant rate. Event markers and EGMs will be interrupted during manual burst pacing and will automatically restart following the burst pacing.
8. To stop the burst delivery, release the Hold For Burst button. The text on the Hold For Burst button will become gray again.
9. To deliver additional manual burst pacing, repeat step 2 through step 8.

Performing 50 Hz Burst Pacing

1. Follow steps 1 and 2 above as for Manual Burst pacing.
2. Select the Enable button. The text on the Hold for 50 Hz Burst button will no longer be gray.
3. To deliver the burst, select and hold the Hold for 50 Hz Burst button. The burst will be delivered as long as the Hold for 50 Hz Burst button is held. Event markers and EGMs will be interrupted during 50 Hz burst pacing and will automatically restart following the burst pacing.

NOTE: During Hold for 50 Hz Burst pacing, the S1 interval is automatically set to 20 ms and the decrement to 0. These values will not be displayed on the screen.

4. To stop the burst delivery, release the Hold for 50 Hz Burst button. The text on the Hold for 50 Hz Burst button will become gray again.
5. To deliver additional 50 Hz Burst pacing, repeat step 2 through step 4.

After performing either 50 Hz Burst or Manual Burst pacing, the shock impedance will be displayed on the screen if a shock is delivered in response to the induction.

Programmed Electrical Stimulation (PES)

Programmable Values: Number of S1 Pulses 1–30; Intervals Off (S2–S5), 120–750 ms

PES induction allows the pulse generator 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 slightly 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 ATP Pulse Width and ATP Amplitude. Figure 8-3 illustrates a PES induction drive train and Figure 8-4 shows the selected PES values.

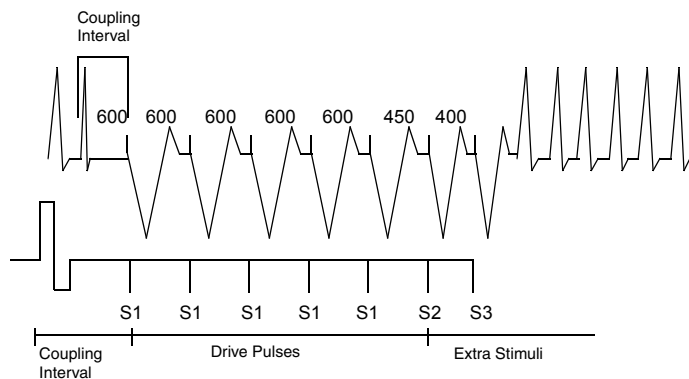


Figure 8-3. PES induction drive train.

PES

S1 Pulses

S2 Decrement ms

600 600 Off Off Off

S1 S2 S3 S4 S5

Enable Induce

+

-

Figure 8-4. PES induction options.

Performing PES Induction

1. Select the PES button. Buttons for the S1-S5 pulses and the corresponding burst cycle lengths are displayed.
2. Choose the cardiac chamber to be paced.
3. Select the desired interval value in the S1 Pulses value box.
4. Three methods are available to change the burst cycle length of each pulse:
 - a. Select a value box to the left of an S button to display the available values, 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 burst cycle length in 10-ms steps in the value box.
 - c. Select the auto-decrement feature.
5. Select (do **not** hold) the Induce button to begin delivery of the drive train. When the programmed number of S1 pulses is delivered, the pulse generator will then deliver the programmed S2-S5 pulses. The pulses are delivered in sequence until a pulse is encountered that is set to Off (eg, if S4 is Off and S5 is set to 200 ms, the S5 pulse will not be delivered).

Once induction is initiated, removing the telemetry wand will **not** stop the PES delivery. (The DIVERT THERAPY key can be pressed to stop induction 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.

If PES induction is initiated during an episode, the end-of-episode is declared before the PES induction pulses are started. A new episode (with initial detection and therapy) can be declared after the PES induction is completed.

6. PES induction is complete when the drive train and extra stimuli are delivered, at which time the pulse generator automatically restarts detection.

NOTE: When PES is used to terminate an arrhythmia that has been detected (and an episode declared), the episode is terminated when the PES is commanded regardless of whether it is successful or not. The PES itself is not recorded in therapy history; this may result in several episodes being counted in therapy history.

COMMANDED THERAPY METHODS

Two EP Test methods, Commanded Shock and Commanded ATP, may be delivered independently of the programmed detection and therapy parameters. If the pulse generator is in the process of delivering therapy when one of these methods is initiated, the EP Test function overrides and aborts the therapy in process. Commanded Shock and Commanded ATP delivery is inhibited when a magnet is positioned over the pulse generator, if Enable Magnet Use is programmed on.

Commanded Shock

Programmable Values: Coupling Interval Sync, 50–500 ms; Shock Energy 0.1–31 J

Commanded shocks can be delivered with a programmable shock energy and a programmable coupling interval. All Commanded Shock are Committed and delivered R-wave synchronously (when the Coupling interval = Sync). Shock waveform and polarity are identical to detection-initiated shocks but a programmed Coupling interval may be specified. The Coupling interval is initiated at the point where the shock would have been delivered in Sync mode, but is instead delivered at the programmed Coupling interval. (Refer to the section “Committed Shock/Reconfirmation of the Arrhythmia” on page 4-20 for details about committed shock delivery.) Following any Commanded Shock delivery, Post-shock Redetection is used and post-shock pacing is activated if it is programmed.

Performing Commanded Shock Delivery

1. Select the Commanded Shock button.
2. Select the desired value for the Coupling interval and Energy level.
3. Select the Enable button. The text on the Deliver Shock button will no longer be gray.
4. Select the Deliver Shock button to initiate charging. The text on the Deliver Shock button will become gray again. The Commanded Shock is recorded in therapy history.

NOTE: A Commanded Shock may be diverted by pressing the *DIVERT THERAPY* key or, if Enable Magnet Use is programmed on, positioning a magnet over the pulse generator.

5. To deliver subsequent shocks, repeat steps 3 and 4.

Commanded ATP

Commanded ATP is available (Figure 8-5) and may be manually delivered independently of the programmed detection parameters. The Tachy Mode must be programmed to Monitor Only to ensure the Commanded ATP does not interfere with detection-initiated ATP.

Commanded ATP allows the physician to deliver the programmed ventricular ATP schemes for each zone. If any ATP therapy is programmed, buttons with the programmed ATP schemes will appear on the EP Test tool kit. If no ATP parameters are programmed, buttons will not be shown. The Pulse Width and Amplitude values used during Commanded ATP are those programmed for ATP therapy; the values are accessible by selecting the Therapy Features button on the Setup screen.

Figure 8-5. Commanded ATP induction screen with Temp ATP selected.

Performing Commanded ATP

1. If the pulse generator is not currently programmed to Monitor Only, select the Monitor Only button to automatically reprogram the pulse generator to that mode (Figure 8-5).

NOTE: If the Tachy Mode had been programmed to Off or Off-Electrocautery before a new mode is selected from this tool kit, the mode cannot be reprogrammed to Off or Off-Electrocautery from this tool kit.

2. Select the Start V ATP (or Start A ATP) button to initiate the first burst in the selected ATP scheme. The Start ATP button will become gray and the Continue button will be highlighted. The Bursts Remaining counter will decrement as each burst is completed.
3. Select the Continue button for each additional burst delivery desired. If all bursts in a scheme have been delivered, the Bursts Remaining counter will return to the initial count, the Start ATP button will again become highlighted, and the Continue button will become gray.

NOTES:

- If the Continue button is selected during delivery of a burst, the programmer will emit a tone indicating the command is ignored. The Continue button must be selected again after completion of the burst delivery in order for the next burst to be delivered.
- If any button other than the Continue button is selected during delivery of a Commanded ATP scheme, the scheme will be reset and the Bursts

Remaining box will be restored to its initial value. The Start ATP button must be reselected to initiate the scheme again.

- *A copy feature is available from the Commanded ATP screen to easily copy the ATP parameter values to another window containing ATP parameters. Refer to the section "Changing Parameter Values" on page 2-29 for information about the Copy button.*
4. Other ATP schemes may be selected at any time; select the desired scheme and repeat the above sequence. The Commanded ATP is recorded as a physician-commanded therapy counter and displayed on the Counters screen.
 5. To reactivate the programmed therapy, select the Monitor + Therapy button. The PROGRAM key does not need to be pressed.

PRE-IMPLANT AND IMPLANT INFORMATION

CHAPTER 9

This chapter includes the following Pre-implant and Implant information:

- “Items Included in Device Packaging” on page 9-1.
- “Factory Nominal Parameter Settings” on page 9-1.

For “Sterilization, Storage, and Handling” information, refer to Chapter 1, page 1-4.

- “Implanting the Pulse Generator” on page 9-2.

ITEMS INCLUDED IN DEVICE PACKAGING

The following items are packaged with the VITALITY 2 pulse generator:

- One torque wrench
- Product literature
- One Patient Data Disk

NOTE: *Wrenches are intended for one-time use only and should not be re-sterilized or re-used.*

FACTORY NOMINAL PARAMETER SETTINGS

Parameter	Factory Nominal Value	
	DR models	VR models
Number of Zones	1	1
Tachy Mode	Storage	Storage
VF Rate	165 bpm	165 bpm
Shock Energy Stored	31 J	31 J
Waveform	Biphasic	Biphasic
Brady Mode	DDD	VVI
Lower Rate Limit	60 ppm	60 ppm
Amplitude	3.5 V	3.5 V
Pulse Width	0.4 ms	0.4 ms

Parameter	Factory Nominal Value	
Atrial Refractory-PVARP	Dynamic	---
Ventricular Refractory Period–VRP	Dynamic	Dynamic
AV Delay	Dynamic	---

The pulse generator is shipped in a power-saving Storage mode to extend its shelf life. All features are inactive except telemetry support (allowing interrogation, programming), real-time clock, and commanded capacitor re-formation. STAT SHOCK and STAT PACE commands also are available from the Storage mode. The device will leave the Storage mode when STAT SHOCK or STAT PACE is commanded or when the Tachy Mode is programmed to Off, Monitor Only or Monitor + Therapy. Programming other parameters will not affect the Storage mode. Once programmed out of the power-saving Storage mode, the programmer cannot return the pulse generator to that mode.

NOTES:

- *Magnet use will not be enabled if the pulse generator is brought out of Storage mode using the STAT PACE or STAT SHOCK commands.*
- *The rate-sensing circuits may take up to eight seconds to begin tracking the cardiac signal after leaving the power-saving Storage mode. Brady pacing is inhibited during this period. The device should always be programmed out of the power-saving Storage mode to the Off mode before connection to the patient leads.*

IMPLANTING THE PULSE GENERATOR

Recommended Sequence using device-based testing (DBT):

Step A: Check Equipment

Step B: Interrogate and Check the Pulse Generator

Step C: Implant the Lead System

Step D: Take Baseline Measurements

Step E: Form the Implantation Pocket

Step F: Connect the Leads to the Pulse Generator

Step G: Evaluate Lead Signals

Step H: Program the Pulse Generator

Step I: Implant the Pulse Generator

Step J: Complete and Return the Implantation Form to Guidant

Step A: Check Equipment

Guidant recommends that instrumentation for cardiac monitoring, defibrillation, and lead signal measurements should be available during the implant procedure. This includes the Guidant PRM (Programmer/Recorder/Monitor) system with its related accessories and the Model 2857 Software Application. **Before beginning the implantation procedure, become completely familiar with the operation of all the equipment and the information in the respective operator's and user's manuals.** Verify the operational status of all equipment that may be used during the procedure. Sterile duplicates of all implantable items and the following accessories should be available in case of accidental damage or contamination:

- Internal defibrillator paddles
- External defibrillator paddles
- Torque and non-torque wrenches

During the implantation procedure, a standard transthoracic defibrillator with R2¹ pads or internal paddles should be available for use during defibrillation threshold testing.

Step B: Interrogate and Check the Pulse Generator

To maintain sterility, test the pulse generator as described below before opening the sterile blister tray. The pulse generator should be at room temperature to ensure accurately measured parameters.

1. Interrogate the pulse generator using the PRM/Model 2857 software application. Verify that the pulse generator is programmed to the factory preset parameters as listed on the packaging labels. If otherwise, call Guidant Technical Services.

1. Trademark of R2 Corporation.

2. Perform a manual capacitor re-formation.
3. Review the pulse generator's current battery status. Counters should be at zero. If the pulse generator battery status is not at BOL (beginning of life), do not implant the pulse generator. Call Guidant Technical Services at the phone number on the back of this manual.

Step C: Implant the Lead System

The pulse generator requires a lead system for sensing, pacing, and delivering shocks. VITALITY 2 pulse generators use the pulse generator case as a defibrillating electrode.

Selection of lead configuration and specific surgical procedures is a matter of professional judgment. Several lead system configurations are available for use with the VITALITY 2 pulse generator:

- Endocardial cardioversion/defibrillation and pacing lead system (with or without a subcutaneous cardioversion/defibrillation electrode).
- Ventricular endocardial bipolar lead
- Atrial bipolar lead
- Two unipolar sutureless myocardial leads and, if necessary, an appropriate Guidant lead adapter
- Superior vena cava lead coupled with a ventricular patch lead
- Two-patch epicardial leads configuration

Refer to the Lead's Physician Manual for instructions for use as well as general warnings and precautions, indications, contraindications, and technical specifications. Read this material carefully for implant procedure instructions specific to the chosen lead configurations.

Whichever lead configuration is used for both pacing/sensing and defibrillating, several considerations and cautions should be heeded. Such factors as cardiomegaly or drug therapy may necessitate repositioning of the defibrillating leads or substituting of one lead system for another to facilitate arrhythmia conversion. In some instances, no lead configuration may be found that provides reliable arrhythmia termination at energy levels available from an ICD pulse

generator; implantation of an ICD pulse generator is not recommended in such cases.

Implant the leads via the surgical approach chosen.

CAUTION: Do not suture directly over the lead body as this may cause structural damage. Use the lead stabilizer to secure the lead lateral to the venous entry site.

Step D: Take Baseline Measurements

Once the leads are implanted, take baseline measurements. Evaluate the lead signals. If performing a pulse generator replacement procedure, existing leads should be reevaluated, e.g., signal amplitudes, pacing thresholds, and impedances. The use of radiography may help ensure lead position and integrity. If testing results are unsatisfactory, lead system repositioning or replacement may be required.

- Connect the pace/sense lead(s) to a pacing system analyzer (PSA). Pace/sense lead measurements should reflect those in Table 9-1. Note that the pulse generator measurements may not exactly correlate to the PSA measurements due to signal filtering.

Table 9-1. Lead measurements^a

	Pace/sense lead (acute)	Pace/sense lead (chronic)	Shocking lead (acute)	Shocking lead (chronic)
R-wave amplitude ^{b c}	> 5 mV	> 5 mV	> 1.0 mV	> 1.0 mV
P-wave amplitude ^{b c}	> 2 mV	> 2 mV		
R-wave duration ^{c d e}	< 100 ms	< 100 ms		
Pacing threshold (ventricle)	< 1.5 V endocardial < 2.0 V epicardial	< 3.0 V endocardial < 3.5 V epicardial		
Pacing threshold (atrium)	< 1.5 V endocardial	< 3.0 V endocardial		
Lead impedance	200-2500 Ω (at 5 V and 0.5 ms atrium & ventricle)	200-2500 Ω (at 5 V and 0.5 ms atrium & ventricle)	20-80 Ω	20-80 Ω

a. Measured approximately 10 minutes after placement.

- b. Amplitudes less than 2 mV may cause inaccurate rate counting in the chronic state, and result in an inability to sense a tachyarrhythmia or the misinterpretation of a normal rhythm as abnormal.
- c. Lower R-wave amplitudes and longer duration may be associated with placement in ischemic or scarred tissue. Since signal quality may deteriorate chronically, efforts should be made to meet the above criteria by repositioning the leads to obtain signals with the largest possible amplitude and shortest duration.
- d. Durations longer than 135 ms (the pulse generator's refractory period) may result in inaccurate cardiac rate determination, inability to sense a tachyarrhythmia, or in the misinterpretation of a normal rhythm as abnormal.
- e. This measurement is not inclusive of current of injury.

Step E: Form the Implantation Pocket

Using standard operating procedures to prepare an implantation pocket, choose the position of the pocket based on the implanted lead configuration and the patient's body habitus. Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure. ICD devices are typically implanted in subcutaneous tissue to facilitate magnet application, and telemetry between the pulse generator and programmer. However, deeper implantation (eg, subpectoral) may help avoid erosion or extrusion in some patients. Verify magnet function and telemetry to ensure the pulse generator is within acceptable range.

NOTES:

- *If an abdominal implant is suitable, it is recommended that implantation occur on the left abdominal side.*
- *Tunnel the leads if necessary. If a Guidant tunneler is not used, cap the lead terminal pins, gently tunnel the leads subcutaneously to the implantation pocket, and reevaluate the lead signals to determine if any of the leads have been damaged during the tunneling procedure. A Penrose drain, large chest tube, or tunneling tool may be used to tunnel the leads.*
- *If the lead terminal pins are not connected to a pulse generator at the time of lead implantation, they must be capped before closing the incision.*

Step F: Connect the Leads to the Pulse Generator

Refer to Figure 9-1 and follow the steps below to connect the leads to the pulse generator.

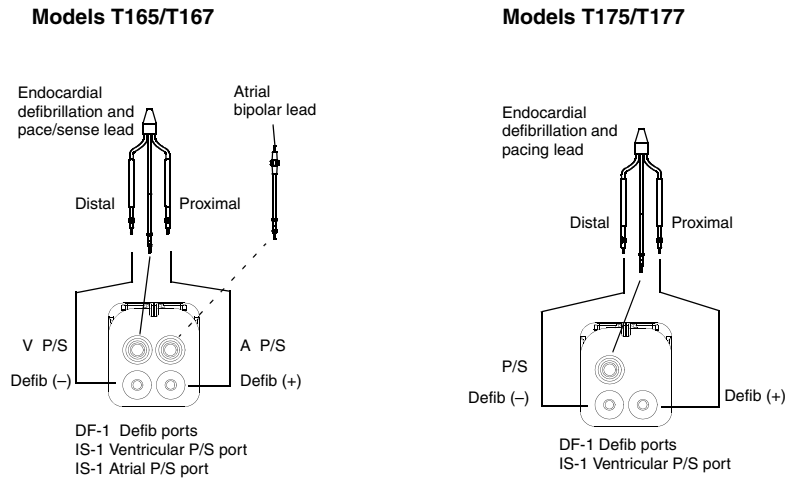


Figure 9-1. Leads to pulse generator connections for single and dual-chamber devices.

NOTES:

- Avoid allowing blood or other body fluids to enter the lead ports in the pulse generator header. If fluid inadvertently enters the ports, flush them with sterile water.
- To connect leads to the ICD pulse generator, use only the tools provided in the pulse generator tray or accessory kit to avoid damage to the seal plugs. Failure to properly insert the wrench in the preslit depression of the seal plug may result in damage to the plug and its sealing properties. Failure to use the supplied torque wrench may result in damage to the screw or connector threads. Do not implant the pulse generator if the seal plugs appear to be damaged. Retain the tools until all testing procedures are complete and the pulse generator is implanted.
- If a lead terminal encounters resistance on insertion into the lead port, insert the wrench into the preslit depression of the seal plug and angle it

gently to open the valve and allow excess air to bleed out of the seal plug.

- *If necessary, lubricate the lead connectors sparingly with sterile water to make insertion easier.*
1. Insert and secure the ventricular pace/sense lead terminal(s) into the IS-1 P/S port of the header.

NOTE: For proper connection of a IS-1 lead to the pulse generator, be certain that the connector pin visibly extends through the connector block at least 1 mm (Figure 9-2).

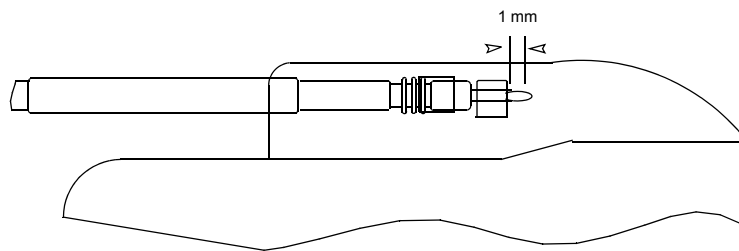


Figure 9-2. Properly positioned lead in pulse generator IS-1 lead port.

CAUTION: Do not insert a lead into the pulse generator connector without first visually verifying that the setscrew is sufficiently retracted to allow insertion. Fully insert each lead into its lead port and then tighten the setscrews onto the electrodes.

NOTE: The IS-1 pace/sense lead port(s) has two setscrews to be tightened: one for the terminal pin and one for the terminal ring of the inline connector.

2. Insert the wrench into the center, preslit depression of the seal plug.
3. Secure the lead in place by tightening the setscrew with the torque wrench. Place pressure on the lead to maintain its position in the pulse generator lead port. Be certain that the lead remains fully inserted in the lead port. The large-handled torque wrench is preset to apply the proper amount of force to the captive setscrew. Tighten the setscrew, making sure it is not crooked, until the wrench ratchets-additional force is unnecessary. Apply gentle traction to the leads to ensure a secure connection.

4. For DR models T165 and T167, insert and secure the atrial pace/sense lead terminal into the A IS-1 P/S lead port.
5. Insert the defibrillating lead anode (+, proximal) into the pulse generator's (+) Defib lead port. For proper connection, be certain that the lead terminal pin is fully inserted in the pulse generator lead port. When viewed through the side of the header, the pin tip should extend through the terminal block.
6. Insert and secure the defibrillating cathode (–, distal) in the (–) Defib lead port in a similar manner as above.

CAUTIONS:

- Never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched physically.
- 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.

Step G: Evaluate Lead Signals

1. Take the pulse generator out of power-saving Storage mode by programming the Tachy Mode to Off.

CAUTION: Ensure that the pulse generator's Tachy Mode is Off when not in use, before handling it, and before using electrosurgery.

2. Evaluate the atrial and ventricular pace/sense and defibrillation lead signals by viewing the real-time EGMs and markers. The signal from the implanted defibrillation leads should be continuous and without artifact, similar to a body-surface ECG. A discontinuous signal may indicate a poor connection, lead fracture or otherwise damaged lead, or an insulation break that would necessitate lead replacement. Inadequate signals may result in failure of the ICD system to detect an arrhythmia, inability to deliver programmed therapy, or in unnecessary delivery of therapy. Lead measurements should reflect those in Table 9-1.

CAUTION: Take care to ensure that artifacts from the ventricles are not present on the atrial channel or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction. (Applies to dual-chamber devices only.)

3. Evaluate all lead impedances using the Lead Impedance test accessed from the Diagnostic Evaluation tool.

CAUTION: Never implant the device with a lead system that has less than 15- Ω total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20 Ω , reposition the shocking electrodes to allow a greater distance between the shocking electrodes.

Step H: Program the Pulse Generator

1. Check the programmer clock and set and synchronize the pulse generator as necessary so that the proper time appears on printed reports and PRM strip chart recordings. Refer to the section “Set Clock” in the labeling.
2. It may be useful to program the Beep During Capacitor Charge feature On during conversion testing and implantation to help recognize when the pulse generator is charging to deliver a shock.
3. Perform a manual capacitor re-formation if not already performed (see step B).
4. Program the pulse generator to desired parameters appropriate for the patient for necessary testing.
5. Shocks intended for VF therapy should be programmed with a 10 J safety margin above the shock energy level that the physician determines is required for successful VF conversion.

CAUTION: Ensure that the pulse generator’s Tachy Mode is Off when not in use, before handling it, and before using electrosurgery. For tachyarrhythmia therapy, verify that the Tachy Mode is On.

Step I: Implant the Pulse Generator

1. Program the Tachy Mode to Off.
2. Ensure that the pulse generator has good contact with surrounding tissue of the implantation pocket. Gently coil excess lead and place adjacent to the pulse generator. Flush the pocket with saline solution, if necessary, to avoid a dry pocket.

WARNING:

- Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.

CAUTION:

- Do not bend the lead near the lead–header interface. Improper insertion can cause insulation damage near the terminal end that could result in lead failure.



Figure 9-3. Suture hole locations for VITALITY 2 models.

3. Close the implantation pocket. Consideration should be given to place the leads in a manner to prevent contact with suture materials. It is recommended that absorbable sutures be used for closure of tissue layers.
4. Complete any electrosurgery procedures before reactivating the pulse generator.
5. Program the Tachy Mode to the desired setting and confirm final programmed parameters.
6. Perform a Manual Intrinsic Rhythm ID for patients with high percentage ventricular pacing to create a reference vector.
7. Print out parameter reports and save all data to disk using the Save All To Disk option from the Utilities button on the main application screen.

Step J: Complete and Return the Implantation Form to Guidant

Within 10 days of implantation, complete the ICD Warranty Validation and Lead Registration form and return the original to Guidant along with a copy of the patient data disk. This information enables Guidant to register each implanted pulse

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IMPLANTING THE PULSE GENERATOR

generator and set of leads, initiate the warranty period, and provide clinical data on the performance of the implanted system. Keep a copy of the ICD Warranty Validation and Lead Registration form and programmer printouts, and the original patient data disk for the patient's file.

Complete the temporary patient identification card and give it to the patient. After receiving the validation form, Guidant sends the patient a permanent identification card.

NOTE: *A registration form is packaged with each Guidant ICD lead. If completing the ICD Warranty Validation and Lead Registration form for the pulse generator, completing separate validation forms for each lead is not necessary.*

POST-IMPLANT INFORMATION

CHAPTER 10

This chapter includes the following topics:

- “Follow-up Testing” on page 10-1
- “Sensitivity Adjustment” on page 10-3
- “Explantation” on page 10-3
- “Magnet/Beeper Setup” on page 10-5
- “Magnet Operation” on page 10-6

For pulse generator longevity information, refer to the section “Pulse Generator Longevity” on page 1-22.

FOLLOW-UP TESTING

Guidant recommends that the device’s functions be evaluated during follow-up testing.

Preferred follow-up settings can be loaded and stored using My Patient Profiles, which is accessed by selecting the Profiles button. (Refer to “My Patient Profile” on page 7-25.)

WARNING: Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

Predischarge Follow-up

During the predischarge follow-up test, the following procedures should be performed via telemetry using the PRM programming system:

1. Interrogate the pulse generator and review the System Summary screen.
2. Perform pacing thresholds and lead impedance tests, and intrinsic amplitude measurements by using the Quick Check or Diagnostic Evaluation tools.

3. Review Histograms. Refer to Chapter 7 for more information on this feature.
4. When all testing is complete, perform a final interrogation and save all the data to a patient data disk.
5. Print the Quick Notes and Patient Data reports to retain in your files for future reference.
6. **It is important to clear the therapy counters so that at the next follow-up session the most recent episode data will be displayed.** To perform this procedure, use the Quick Check screen, or select the Reset button from the Counters screen accessed from the Therapy History tool kit, or clear the counters from the Histograms screen accessed from the Therapy History tool kit.

NOTE: *Echo-doppler studies may be used to evaluate AV delay and other programming options noninvasively post-implant.*

Routine Follow-up

Routine follow-up examinations should be conducted 1 month after the predischARGE study and every 3 months thereafter. During the routine follow-up test, the following procedures should be performed via telemetry using the programming system:

1. Interrogate the device and review the System Summary screen.
2. Perform pacing thresholds and lead impedance tests, and intrinsic amplitude measurements.
3. Print and review the Quick Notes report, and retain it in your files for future reference.
4. For episodes of interest, review the Arrhythmia Logbook screen and print episode detail, intervals and, if desired, stored electrogram information.
5. **It is important to clear the therapy counters so that at the next follow-up session the most recent episode data will be displayed.** To perform this procedure, use the Quick Check screen, or select the Reset button from the Counters screen accessed from the Therapy History tool kit, or clear the counters from the Histograms screen accessed from the Therapy History tool kit.

CAUTION: Verify with a conversion test that the patient's tachyarrhythmias can be detected and terminated by the ICD system if the patient's status has changed or parameters have been reprogrammed.

SENSITIVITY ADJUSTMENT

The Sensitivity Adjustment feature permits shifting the atrial sensing range to make it less sensitive, that is, a larger signal would be required for the device to detect. It allows shifting the ventricular sensing range to make it less or more sensitive. While the Nominal setting is primarily indicated for both atrial and ventricular sensing, an adjustment can be made if, in a rare situation, atrial oversensing or ventricular oversensing/undersensing has been observed postimplant (ie, inhibition of bradycardia pacing or inappropriate tachy therapy).

Should it become necessary to adjust the sensing range in either chamber, always choose the setting that allows the greatest sensitivity but resolves the situation. The Sensitivity Adjustment feature is available from the Setup tool kit.

For atrial oversensing, program to Less or Least. For ventricular oversensing, program Nominal to Least. For ventricular undersensing, program Nominal to Most. After any change to sensitivity, evaluate for appropriate sensing for both bradycardia pacing and tachycardia detection.

If proper sensing cannot be restored with an adjustment or if any undersensing is observed after making a change, consider repositioning the lead or implanting a new sensing lead and then programming the setting back to Nominal.

CAUTION: Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing for bradycardia pacing and tachycardia detection.

EXPLANTATION

An Observation/Complication/Out-Of-Service Reporting Form should be completed and sent to Guidant when a product is removed from service. Return all explanted pulse generators and leads with product performance allegations or warranty considerations to Guidant. Examination of explanted devices provides information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

In the event of patient death (regardless of the cause), the explanted pulse generator and/or lead should be returned to Guidant along with an Observation/

Complication/Out-Of-Service Reporting Form and copies of the autopsy report, if performed. For other observation or complication reasons, also complete and return to Guidant the Observation/Complication/Out-Of-Service Reporting Form.

NOTES:

- *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant representative or call Guidant at the phone number on the back cover of this manual for a Returned Product Kit.*
- *Discoloration of the pulse generator may have occurred due to a normal process of anodization, and has no effect on the pulse generator function.*

CAUTIONS:

- Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- Program the Tachy Mode to Off, disable the magnet feature, and disable the Beep When ERI Is Reached beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.

Keep in mind the following items when explanting and returning the pulse generator:

- Interrogate the pulse generator and print a Counters report.
- Deactivate the pulse generator before explantation.
- Disconnect the leads from the pulse generator.
- If leads are also explanted, attempt to remove them intact. Do not remove leads with hemostats or any other clamping tool that may damage the leads. Resort to tools only if manual manipulation cannot free the lead.
- Wash, but do not submerge, the pulse generator and leads to remove body fluids and debris using a disinfectant solution. Do not allow fluids to enter the pulse generator's lead ports.
- Use a Guidant Returned Product Kit to properly package the pulse generator.
- Complete an Observation/Complication/Out-Of-Service Reporting Form.

- Send the form and the Returned Product Kit to Guidant.

MAGNET/BEEPER SETUP

The following magnet and beeper features are available:

- **Enable Magnet Use**—This feature can be used to turn magnet functions on/off.
- **Beep During Capacitor Charge**—When programmed On, regardless of the Tachy Mode, a warbling tone will sound continuously while the pulse generator is charging (except when charging during an auto capacitor re-form). The tone will continue until charging is complete. When this feature is programmed Off, there is no audible indication that the pulse generator is charging. This feature is useful during EP testing.
- **Beep On Sensed and Paced Ventricular Events**—When programmed On, this feature provides an R-wave synchronous tone for each cardiac cycle (tachycardia, normal, or bradycardia sensed event, or paced event). Off disables beeping so that R-wave synchronous tones are not emitted for sensed and paced depolarizations. This feature is useful during EP testing. Note that magnet activation can activate the R-wave synchronous tones whether this feature is programmed On or Off.
- **Beep When ERI Is Reached**—When this feature is On, the pulse generator emits tones upon reaching elective replacement time. The elective replacement indicator (ERI) consists of 16 R-wave synchronous tones repeated every 6 hours after the pulse generator reaches elective replacement time until the feature is turned off via the programmer. When this feature is programmed Off, there is no audible indication of ERI.

NOTE: Advise patients to have their pulse generator checked whenever tones are heard coming from the device.

Perform the following steps to program the features:

1. Select the Setup button on the main application screen.
2. Enter the desired value in the Change column.
3. Establish telemetry communication and press the PROGRAM key. The changes are now effective.

MAGNET OPERATION

The Enable Magnet Use feature can be used to turn magnet functions on/off. When the Enable Magnet Use feature is programmed On, the following functions can occur when an ICD doughnut magnet (model 6860) is applied to the pulse generator.

1. Audible tones are emitted which indicates the Tachy Mode of the device.
2. Tachyarrhythmia therapy and induction modes are inhibited or diverted to the pulse generator's internal test load.

When the Enable Magnet Use function is programmed Off, the pulse generator will not perform any of the functions listed above even though a magnet actuates the reed switch.

The Model 6860 ICD Magnet actuates the reed switch when positioned within 3.0 cm (1.2 inches) of the pulse generator. Actuation of the reed switch allows pulse generator recognition that a magnet is present, so that magnet functions can be performed. Refer to Figure 10-1 on page 10-6 for the correct magnet position.

NOTE: The magnet features are not functional when the Patient Triggered Monitor feature is enabled. Refer to the section “Patient Triggered Monitor” on page 7-18.

NOTES:

- Bradycardia pacing is not affected by any of the magnet operations.
- Magnets can damage data disks—do not expose the patient data disks to the magnet.

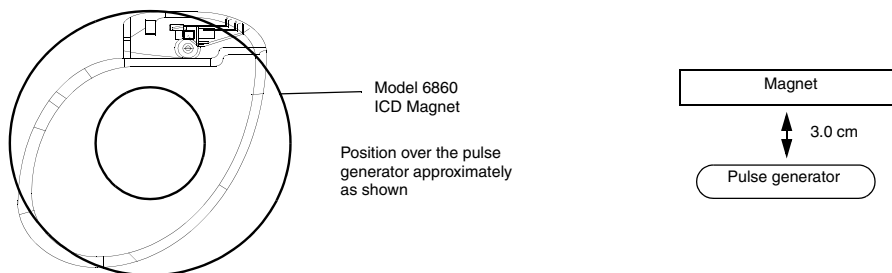


Figure 10-1. Proper position of the ICD magnet to actuate the reed switch in the pulse generator.

Determine the Tachy Mode of the Pulse Generator

When the Enable Magnet Use feature is programmed On, any time an ICD magnet is properly positioned over the pulse generator, tones indicate the currently programmed Tachy Mode of the pulse generator.

- If R-wave synchronous tones are emitted, the Tachy Mode is programmed to Monitor + Therapy, indicating that tachyarrhythmia therapy can be delivered if detection is met.
- If a continuous tone is emitted, the Tachy Mode is programmed to Storage, Off, or Monitor Only mode, indicating that tachyarrhythmia therapy (due to detection criteria being satisfied) is not available.

NOTE: The magnet features affecting the Tachy Mode are not effective when the device is programmed to Off-Electrocautery mode.

Inhibit Tachyarrhythmia Therapy and Induction

When the Enable Magnet Use feature is programmed On, initiation of tachyarrhythmia therapy and arrhythmia induction is inhibited any time the magnet is properly positioned over the pulse generator. The tachyarrhythmia detection process continues, but therapy or induction cannot be triggered.

Place the magnet over the pulse generator.

- If the Tachy Mode is in the Monitor + Therapy or Off mode when the magnet is applied, the Tachy Mode changes temporarily to the Monitor Only mode and will remain in Monitor Only mode as long as the magnet is applied. Two seconds after the magnet is removed, the mode will return to the previously programmed mode.

NOTE: If detection occurs while the magnet is in place, detailed therapy history will indicate that therapy was not delivered because the device was in Monitor Only mode.

- If the pulse generator is charging to deliver shock therapy when the magnet is applied, the charging continues but is then terminated within 1 to 2 seconds of magnet application, and the charge is diverted. This delay occurs in case the magnet is inadvertently passed over the device when therapy inhibition is not desired. Any charge on the capacitors is diverted to the pulse generator's internal test load and the pulse generator remains in

temporary Monitor Only mode while the magnet is applied. No further therapy is initiated until the magnet is removed; however, detection will continue.

- If charging is complete or completes within the delay period, holding the magnet over the pulse generator for more than 2 seconds will divert the shock. (If the magnet is removed during the delay period, the shock could still be delivered.) Shocks will not be delivered with the magnet in place.
- If the pulse generator is initiating fibrillation induction or ATP pulses, it terminates the delivery after 1 to 2 seconds of magnet application. No further induction or ATP pulse sequences are initiated until the magnet is removed.

PROGRAMMABLE OPTIONS

APPENDIX A

Table A-1. Detection Parameters for 1- Zone, 2-Zone, and 3-Zone Configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal	
Tachy Mode	3 zones	Off, Monitor + Therapy, Monitor Only, Off-Electrocautery		Storage	
	2 zones	Off, Monitor + Therapy, Monitor Only, Off-Electrocautery			
	1 zone	Off, Monitor + Therapy, Monitor Only, Off-Electrocautery			
Rate ^a (bpm) (intervals in ms)	3 zones	90, 95, ..., 200 (668-300)	110, 115, ..., 210, 220 (545–273)	130, 135, ..., 210, 220, 230, 240, 250 (463–240)	165 (VF) 145 (VT) 125 (VT-1)
	2 zones		90, 95, ..., 210, 220 (668–273)	110, 115, ..., 210, 220, 230, 240, 250 (545–240)	(Tolerance ± 5 ms)
	1 zone			90, 95, ..., 210, 220 (668–273)	
Duration ^b (sec)	3 zones	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, ..., 60	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1, 1.5, ..., 5, 6, 7, ..., 15	1.0 (VF) 2.5 (VT) 2.5 (VT-1)
	2 zones		1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1, 1.5, ..., 5, 6, 7, ..., 15	(Tolerance +1 cardiac cycle)
	1 zone			1, 1.5, ..., 5, 6, 7, ..., 15	
Redetection Duration ^b (sec)	3 zones	1, 1.5, ..., 5, 6, 7, ..., 15	1, 1.5, ..., 5, 6, 7, ..., 15	1 (nonprogrammable)	1
	2 zones		1, 1.5, ..., 5, 6, 7, ..., 15	1 (nonprogrammable)	(Tolerance +1 cardiac cycle)
	1 zone			1 (nonprogrammable)	
Post-shock Duration ^b (sec)	3 zones	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, ..., 60	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1 (nonprogrammable)	1
	2 zones		1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1 (nonprogrammable)	(Tolerance +1 cardiac cycle)
	1 zone			1 (nonprogrammable)	

- a. The Rate difference between each tachy zone must be at least 20 bpm. The lowest Tachy Rate Threshold must be > 5 bpm higher than both the Maximum Tracking Rate and Maximum Sensor Rate; the lowest Tachy Rate Threshold must > 10 bpm higher than the Lower Rate Limit.
- b. The Duration in a zone must be equal to or greater than the Duration in the next highest zone.

Table A-2. Detection Enhancement Parameters for 2-Zone and 3-Zone Configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Rhythm ID-SVT Inhibit 3 zones	Off, On	Off, On	Not available	VT-1: On VT: Off
2 zones		Off, On	Not available	On
Sustained Rate Duration (minutes:seconds) 3 zones	Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00	Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00	Not available	VT-1: 3 min VT: 3 min (Tolerance +1 cardiac cycle)
2 zones		Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00	Not available	3 min

Table A-3. Post-shock Detection Enhancement Parameters for 2-Zone and 3-Zone Configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Post-shock Rhythm ID-SVT Inhibit 3 zones	Off, On	Off, On	Not available	Off
2 zones		Off, On	Not available	
Post-shock Sustained Rate Duration (minutes:seconds) 3 zones	Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00	Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00	Not available	15 (Tolerance +1 cardiac cycle)
2 zones		Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00	Not available	

Table A-4. Antitachycardia Pacing (ATP) Parameters

Parameter	Programmable Values (each zone)	Nominal	Tolerance
Number Of Bursts (per scheme)	Off, 1, 2, ..., 30	Off	--
Initial Pulse (pulses)	1, 2, ..., 30	4	--
Pulse Increment (pulses)	0, 1, ..., 5	0	--
Maximum Number of Pulses	1, 2, ..., 30	4	--
Coupling Interval (% or ms)	50, 53, 56, 59% 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	81%	± 5 ms
Coupling Interval Decrement (ms)	0, 2, ..., 30	0	± 5 ms
Burst Cycle Length (BCL) (% or ms)	50, 53, 56, 59% 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	81%	± 5 ms
Ramp Decrement (ms)	0, 2, ..., 30	0	± 5 ms
Scan Decrement (ms)	0, 2, ..., 30	0	± 5 ms
Minimum Interval (ms)	120, 130, ..., 400	200	± 5 ms
ATP Pulse Width ^a (ms) (atrium and ventricle)	0.5, 0.6, ..., 2.0 ms (programmed value affects all zones)	1.0	± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms
Atrial ATP Amplitude ^a (V)	0.2, 0.4, ..., 3.0, 3.5, 4.0, 4.5, 5.0 (programmed value affects all zones)	5.0	± 10% at > 3.0 V ^b
Ventricular ATP Amplitude ^a (V)	0.2, 0.4, ..., 3.0, 3.5, 4.0, ..., 7.5 (programmed value affects all zones)	7.5	± 10% at > 3.0 V ^b
ATP Time-out ^c (minutes:seconds)	Off, 0:10, 0:15, ..., 0:55 1:00, 1:15, ..., 2:00 2:30, 3:00, ..., 10:00 15:00, 20:00, ..., 60:00 (Not available in the VF zone)	60 sec	± 250 ms

a. The programmed Amplitude and Pulse Width values affect Commanded ATP and PES, but are separately programmable from Brady Pacing, Post-shock Brady Pacing, and Temporary Brady Pacing.

b. When programmed ATP Amplitude is 3.0 V or less, the pace amplitude may exceed the programmed value, but will not exceed 3.3 V. In this programmed range, the pace amplitude may also be less than the programmed value, but not by more than 0.3 V.

c. The VT-1 ATP Time-out must be greater than or equal to the VT ATP Time-out.

Table A-5. Shock Parameters

Parameter	Programmable Values	Nominal	Tolerance
Shocks 1 and 2 energy (J) ^{a b c} (stored energy)	Off, 0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31	31	± 40% for ≤ 2 J, ± 20% for 3–29 J, ± 10% for 31 J
Remaining Shocks' energy ^{a c} (J) (stored energy)	Off, 31	31	± 10%
Number of Additional Shocks	0, 1, 2, 3	0	--
Polarity ^d	Initial, Reversed	Initial	--
Last Shock Invert	Yes, No	No	--
Waveform ^d	Monophasic, Biphasic	Biphasic	--
Committed Shock	Yes, No	No	--

- a. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.
b. The Shock 2 energy level must be greater than or equal to the Shock 1 energy level.
c. In a VT-1 zone of a 3-zone configuration, all or some of the shocks may be programmed Off while other shocks in that zone are programmed in joules. However, if Shock 1 is programmed Off, Shock 2 must be programmed Off.
d. A commanded STAT SHOCK is delivered at the programmed Waveform and Polarity.

Table A-6. Bradycardia Pacing Parameters (Normal, Post-shock, and Temporary)
Pacing parameters specified into a 750 Ω load. (Sheet 1 of 4)

Parameter	Programmable Values	Nominal ^a	Tolerance
Brady Mode ^b	Normal, Post-shock: Off, AAI(R), VVI(R), VDD(R), DDI(R), DDD(R), OOOOR Temporary: Off, AOO(R), AAI(R), VOO(R), VVI(R), VDD(R), DOO(R), ODO(DR Models), OVO(VR Models), DDI(R), DDD(R), AAT, VVT, OOOOR	DDD (DR models) VVI (VR models)	--
Lower Rate Limit (LRL) (ppm) ^{c f}	30, 35, ..., 50; 51, 52, ..., 90; 95, 100, ..., 175	60	± 5 ms
Maximum Tracking Rate (MTR) (ppm)	50, 55, ..., 175	120	± 5 ms
Maximum Sensor Rate (MSR) (ppm)	50, 55, ..., 175	120	± 5 ms
Pulse Amplitude (atrium) ^{d e f} (V)	Off, 0.2, 0.4, ..., 3.0; 3.5, 4.0, 4.5, 5.0	3.5	±0.3 V at ≤3.0 V ^g ;± 10% at > 3.0 V

Table A-6. Bradycardia Pacing Parameters (Normal, Post-shock, and Temporary)
Pacing parameters specified into a 750 Ω load. (Sheet 2 of 4)

Parameter	Programmable Values	Nominal ^a	Tolerance
Pulse Amplitude (ventricle) ^{d e f} (V)	Off, 0.2, 0.4, ..., 3.0; 3.5, 4.0, ..., 7.5	3.5 (7.5 post-shock)	± 0.3 V at ≤ 3.0 V; $\pm 10\%$ at > 3.0 V
Pulse Width (atrium or ventricle) (ms) ^{d e}	0.06; 0.1, 0.2, ..., 2.0	0.4 (1.0 post-shock, ventricle only)	± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms
Activity Threshold ^h	V-Low, Low, Med-Lo, Medium, Med-Hi, High, V-Hi	Medium	--
Reaction Time (sec) ^h	10, 20, ..., 50	30	--
Response Factor ^h	1, 2, ..., 16	8	--
Recovery Time (minutes) ^h	2, 3, ..., 16	5	--
Ventricular Refractory Period–VRP ^e (ms)	150, 160, ..., 500	250	± 5 ms
Dynamic VRP	Off, On	On	--
Maximum VRP (ms)	160, 170, ..., 500	250	± 5 ms
Minimum VRP (ms)	150, 160, ..., 490	240	± 5 ms
Atrial Refractory-PVARP (ms)	150, 160, ..., 500	250	± 5 ms
Dynamic PVARP	Off, On	On	--
Maximum PVARP (ms)	160, 170, ..., 500	250	± 5 ms
Minimum PVARP (ms)	150, 160, ..., 490	240	± 5 ms
PVARP After PVC (ms)	Off, 150, 200, ..., 500	400	± 5 ms
V-Blank After A-Pace (ms)	45, 65, 85	65	± 5 ms
A-Blank After V-Pace (ms)	45, 65, 85	85	± 5 ms
A-Blank After V-Sense (ms)	45, 65, 85, Smart	Smart	± 5 ms
AV Delay (fixed/maximum) (ms)	10, 20, ..., 300	180	± 5 ms
Dynamic AV Delay	Off, On	On	--
Maximum AV Delay (ms)	20, 30, ..., 300	180	± 5 ms

Table A-6. Bradycardia Pacing Parameters (Normal, Post-shock, and Temporary)
Pacing parameters specified into a 750 Ω load. (Sheet 3 of 4)

Parameter	Programmable Values	Nominal ^a	Tolerance
Minimum AV Delay (ms)	10, 20, ..., 290	80	± 5 ms
Sensed AV Offset (ms)	Off, -10, -20, ..., -100	Off	± 5 ms
AV Search Hysteresis Search Interval (cycles)	Off, 32, 64, 128, 256, 512, 1024	Off	± 1 cycle
AV Search Hysteresis AV Increase (%)	10, 20, ..., 100	30%	$\pm 1\%$
ATR Trigger Rate ^h (ppm)	Off, 100, 105, ..., 200	170	± 5 ms
ATR Duration ^h (cycles)	0, 1, 2, ..., 10; 20, 30, ..., 90; 100, 200, ..., 2000	8	± 1 cardiac cycle
Entry Count ^h (cycles)	1, 2, ..., 8	8	--
Exit Count ^h (cycles)	1, 2, ..., 8	8	--
ATR Fallback Mode ^h	VDI(R), DDI(R)	VDI	--
ATR Fallback Time ^h (minutes:seconds)	0, 0:15, 0:30, 0:45, 1:00, 2:00, 3:00, 4:00, 5:00	1:00	$\pm 10\%$
ATR/VTR Fallback LRL ^h (ppm)	30, 35, ..., 50; 51, 52, ..., 89; 90, 95, ..., 175	70	± 5 ms
Atrial Flutter Response (bpm)	Off, 130, 140, ..., 230	Off	± 5 ms
PMT Termination	Off, On	On	--
Rate Hysteresis Hysteresis Offset (ppm)	Off, -5, -10, ..., -80	Off	± 5 ms
Rate Hysteresis Search Hysteresis (cycles)	Off, 256, 512, 1024, 2048, 4096	Off	± 1 cycle
Rate Smoothing (up, down) (%)	Off, 3, 6, 9, 12, 15, 18, 21, 25	Off	$\pm 1\%$
Rate Smoothing Max Pacing Rate (ppm)	50, 51, ..., 89; 90, 95, ..., 175	120	± 5 ms
Noise Response ^h	AOO, VOO, DOO, Inhibit	XOO	--
Post-shock Pacing Delay (sec) ⁱ (available post-shock only)	1.5; 2, 3, ..., 10	3	± 0.1 sec

Table A-6. Bradycardia Pacing Parameters (Normal, Post-shock, and Temporary)
Pacing parameters specified into a 750 Ω load. (Sheet 4 of 4)

Parameter	Programmable Values	Nominal ^a	Tolerance
Post-shock Pacing Period (minutes:seconds) (available post-shock only)	0:15, 0:30, 0:45, 1:00, 1:30, 2:00, 3:00, 4:00, 5:00, 10:00, 15:00, 30:00, 45:00, and 60:00	0:30	0.5% \pm 2 sec
Ventricular Rate Regulation	Off, On	Off	--
VRR Max Pacing Rate (ppm)	60, 65...150	110	\pm 5 ms

- The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
- Refer to the NASPE/BPEG codes below for an explanation of the programmable values. 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 categories listed in Table A-7.
- The basic pulse period is equal to the brady pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry allows the pacing rate to increase by a maximum of 190 bpm of the programmed rate before the protection circuit would inhibit pacing. Runaway protection is not an absolute assurance that runaways will not occur. Magnet application does not affect pacing rate (test pulse interval).
- Separately programmable from Antitachycardia Pacing, Temporary ATP, and Post-shock Brady Pacing.
- Values are not affected by temperature variation within the range 20°–43°C.
- The pulse generator uses an automatic gain control circuit for varying the sensitivity of its rate sensing amplifiers. Following paced pulses delivered by the pulse generator, sensitivity is set to 4.0 mV (\pm 1.2 mV) at the end of the refractory period.
- During the 255-cardiac cycle period associated with the Daily Lead Impedance Measurement (see 6-16) while the device is waiting for right atrial pacing or for right ventricular pacing, the pace amplitude in the other chamber (if programmed less than 3.0 V) may exceed the programmed value beyond the 0.3 V tolerance, but will not exceed 3.0 V.
- This parameter is used globally in Normal Brady and Post-shock Brady. Changing the value for Normal Brady will change the value for Post-shock Brady and vice versa.
- The Post-shock Pacing Delay must be at least 275 ms longer than the bradycardia escape interval, and affects brady pacing if Post-shock Brady Pacing is Off.

Table A-7. Brady Mode Values Based on NASPE/BPEG Codes

Position	I	II	III	IV	V
Category	Chambers Paced	Chambers Sensed	Response to Sensing	Programmability, rate modulation	Antitachyarrhythmia Functions
Letters	0–None	0–None	0–None	0–None	0–None
	A–Atrium	A–Atrium	T–Triggered	P–Simple Programmable	P–Pacing (Antitachyarrhythmia)
	V–Ventricle	V–Ventricle	I–Inhibited	M–Multiprogrammable	S–Shock
	D–Dual (A&V)	D–Dual (A&V)	D–Dual (T&I)	C–Communicating	D–Dual (P&S)

Table A-7. Brady Mode Values Based on NASPE/BPEG Codes

Position	I	II	III	IV	V
Mfrs. Designation Only	S-Single (A or V)	S-Single (A or V)			

Table A-8. Magnet/Beeper Functions

Parameter	Programmable Values	Nominal
Enable Magnet Use ^a	On, Off	On
Beep During Capacitor Charge	On, Off	Off
Beep On Sensed and Paced Ventricular Events	On, Off	Off
Beep When ERI Is Reached	On, Off	On

a. Magnet use will not be enabled if the pulse generator is brought out of Storage mode using the STAT PACE or STAT SHOCK commands.

Table A-9. Episodes/EGMs Functions

Parameter	Programmable Values	Nominal
Stored Electrograms		
Atrial	On, Off	On
Ventricular	On, Off	On
Shock	On, Off	On
Stored Onset Electrograms	On, Off	On
Nonsustained Ventricular Episode Storage	On, Off	On
VT Episode History Storage (%)	20, 30, ..., 100	80 (DR Models) 100 (VR Models)
Brady Episode History Storage (%)	0, 10, ..., 80	20 (DR Models) 0 (VR Models)
VF Episode History Protection	On, Off	On

Table A-9. Episodes/EGMs Functions

Parameter	Programmable Values	Nominal
PMT Episode Storage (DR devices only)	On, Off	On

Table A-10. Sensitivity Adjustment

Parameter	Programmable Values	Nominal
Atrial Sensitivity	Nominal, Less, Least	Nominal
Ventricular Sensitivity	Most, Nominal, Least	Nominal

EP Test Functions

Table A-11. Commanded ATP

Parameter ^{a b}	Programmable Values	Nominal	Tolerance
Number Of Bursts	1, 2, ..., 30	30	--
Initial Pulse Count (pulses)	1, 2, ..., 30	4	--
Pulse Increment (pulses)	0, 1, ..., 5	0	--
Maximum Number of Pulses	1, 2, ..., 30	4	--
Coupling Interval (% or ms)	50, 53, 56, 59; 63, 66, ..., 84; 88, 91, 94, 97% or 120, 130, ..., 750 ms	81%	± 5 ms
Coupling Interval Decrement (ms)	0, 2, ..., 30	0	± 5 ms
Initial Burst Cycle Length (BCL) (% or ms)	50, 53, 56, 59; 63, 66, ..., 84%; 88, 91, 94, 97% or 120, 130, ..., 750 ms	81%	± 5 ms
Ramp Decrement (ms)	0, 2, ..., 30	0	± 5 ms
Scan Decrement (ms)	0, 2, ..., 30	0	± 5 ms
Minimum Interval (ms)	120, 130, ..., 400	200	± 5 ms
Chamber	Atrium, Ventricle	Ventricle	--

a. The Commanded ATP Pulse Width and Amplitude values are the same as programmed for ATP therapy.

b. Applied to the atrium or ventricle depending on the chamber selected.

Table A-12. 50 Hz/Manual Burst Pacing

Parameter ^a	Programmable Values	Nominal	Tolerance
Number of S1 in Burst	8 (nonprogrammable)	8	--
Burst Interval (ms)	20, 30, 40, 50, ..., 750	600	± 5 ms
Minimum Interval (ms)	20, 30, 40, 50,...,750	200	± 5 ms
Decrement (ms)	0, 10, ..., 50	50	± 5 ms
Chamber	Atrium, Ventricle	Ventricle	--

a. Applied to the atrium or ventricle depending on the chamber selected.

Table A-13. Commanded Shock

Parameter	Programmable Values	Nominal	Tolerance
Shock ^a (stored energy) (J)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31	31	± 40% for ≤ 2 J; ± 20% for 3–29 J, ±10% for 31 J
Coupling Interval (ms)	Sync, 50, 60, ..., 500	Sync	+ 50/–0 ms for sync ± 10 ms for 50-500

a. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.

Table A-14. Fib High/Low Induction

Parameter	Values	Tolerance
Fib High	30 ms (nonprogrammable)	+20/–5 ms
Fib Low	50 ms (nonprogrammable)	+20/–5 ms

Table A-15. Shock on T Induction

Parameter	Programmable Values	Nominal	Tolerance
Shock ^a (stored energy) (J)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31	0.6	± 40% for ≤ 2 J; ± 20% for 3–29 J, ±10% for 31 J
Number of S1 Pulses	1, 2, ..., 30	8	--
S1 Interval (ms)	120, 130, ..., 750	400	± 5 ms
Coupling Interval (ms)	Sync, 50, 60, ..., 500	310	+ 50/–0 ms for sync ± 10 ms for 50-500

a. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.

Table A-16. PES (Programmed Electrical Stimulation)

Parameter ^a	Programmable Values	Nominal	Tolerance
Number of S1 Intervals (pulses)	1, 2, ..., 30	8	--
S1 to S1 Interval (ms)	120, 130, ..., 750	600	± 5 ms
S1 to S2 Interval (ms)	Off, 120, 130, ..., 750	600	± 5 ms
S2 to S3 Interval (ms)	Off, 120, 130, ..., 750	Off	± 5 ms
S3 to S4 Interval (ms)	Off, 120, 130, ..., 750	Off	± 5 ms
S4 to S5 Interval (ms)	Off, 120, 130, ..., 750	Off	± 5 ms
Auto Decrement (ms)	Off, 10, 20, ..., 50	Off	--
Chamber	Atrium, Ventricle	Ventricle	--

a. Applied to the atrium or ventricle as commanded by the programmer.

PACEMAKER INTERACTION

APPENDIX B

There may be certain incidences where patients may have separate temporary or permanent pacemakers. Temporary or permanent pacemakers can interact with the ICD pulse generator and can interfere with the identification of tachyarrhythmias in three ways:

1. During a tachyarrhythmia, if the pacemaker does not sense the arrhythmia and paces, and the pacing pulse detected from the rate-sensing electrode is large enough, it could cause the ICD pulse generator to interpret the pacing as a normal rhythm at the rate of the pacemaker. The ICD pulse generator would neither detect the arrhythmia nor deliver a therapy.
2. Pacemaker (a) inappropriate atrial or ventricular sensing, (b) lead dislodgment, or (c) failure to capture could present two sets of signals to the ICD pulse generator. This could cause the pulse generator's rate measurement to be faster than the actual heart rate. As a result, the pulse generator could deliver unnecessary therapy.
3. Conduction delay could cause the ICD pulse generator to count both pacemaker artifact and ventricular depolarization. This could result in unnecessary therapy.

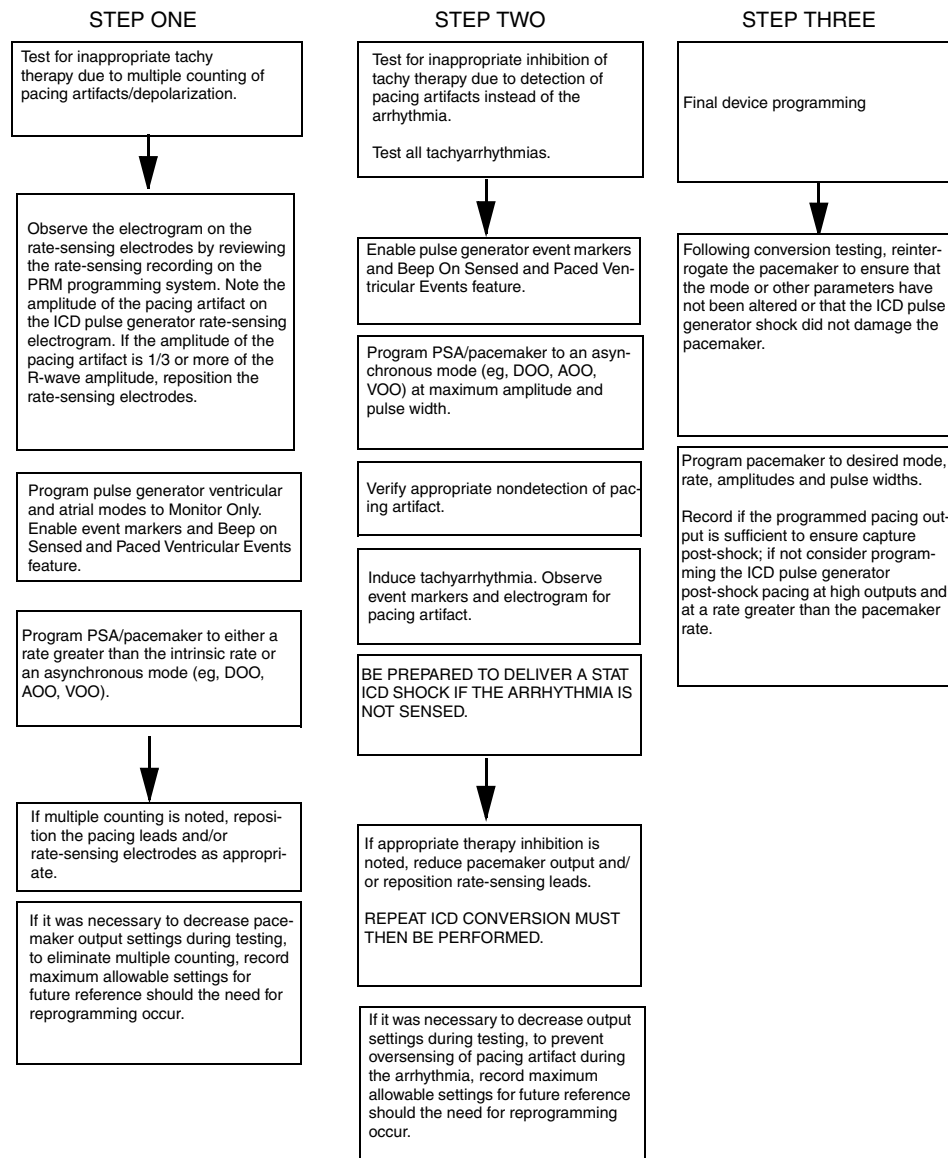
For these reasons, the use of a pacemaker that results in pacemaker and ICD pulse generator interaction is not recommended. Unipolar pacemakers are contraindicated for use with the pulse generator.

Consider the following actions if a separate pacemaker is used:

- Always deactivate a patient's ICD pulse generator when: 1) using temporary bipolar or temporary AV sequential pacing, or 2) reprogramming a separate implanted pacemaker. If cardioversion or defibrillation is needed at such times, use an external defibrillator.
- The ICD rate-sensing electrodes should be as far from the pacing electrodes as possible.
- After implanting the pacing leads, examine the signals from the ICD rate-sensing electrodes to ensure that minimal pacemaker artifacts are present.

- Since it is difficult to predict the relative magnitudes of pacemaker artifacts and various tachyarrhythmia electrograms that may occur chronically or during EP testing, it is important to reduce artifacts to the minimum.
- All of the patient's ventricular and atrial tachycardias and ventricular and atrial fibrillation should be induced while the pulse generator is activated and the separate pacemaker is programmed to an asynchronous mode at maximum output. This should provide the greatest opportunity for inhibition of arrhythmia detection due to pacemaker artifacts. Leads may have to be repositioned to eliminate artifacts.
- To reduce the possibility of pacemaker interaction, consider testing the separate pacemaker by programming: (1) the lowest amplitude allowable for safe capture in the chronic state, (2) the maximum sensitivity to ensure that pacing is inhibited during VF, and (3) the minimum cardiac rate acceptable for the patient. Also consider using rate-sensing and pacemaker leads with close interelectrode spacing (eg, 11 mm).
- Consider turning off the bradycardia pacing function of the ICD pulse generator or programming the ICD bradycardia pacing function to a rate less than the separate pacemaker rate.
- For pacing control following any ventricular and/or atrial shock therapy, consider whether to use the ICD pulse generator Post V Shock Brady or Post A Therapy bradycardia pacing feature at higher rates and outputs or the separate pacemaker.

The following test procedure aids in determining the potential for pacemaker/ICD pulse generator interaction.



NOTE: The Guidant Model 6860 Magnet also can be used to assess pacemaker interaction if the magnet function is enabled. Placing the magnet over a device in a ventricular Monitor + Therapy mode should produce R-wave synchronous tones. If there is not a one-to-one relationship between these tones and the patient's heart rate, as monitored on the electrocardiogram, further evaluation may be needed as this may indicate pacemaker interaction.

EXTERNAL CABLE CONNECTIONS

APPENDIX C

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.

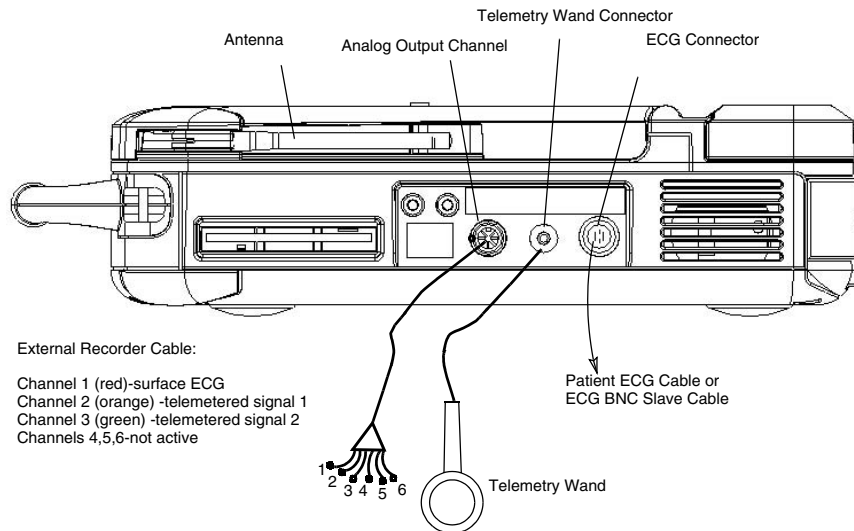


Figure C-1. Cable connections for the Model 3120 PRM.

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 C-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 C-2 on page C-3)
- Patient to PRM to external recorder (Figure C-3 on page C-4)
- Simultaneous connections from patient to PRM and patient to external recorder (Figure C-4 on page C-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 C-2.

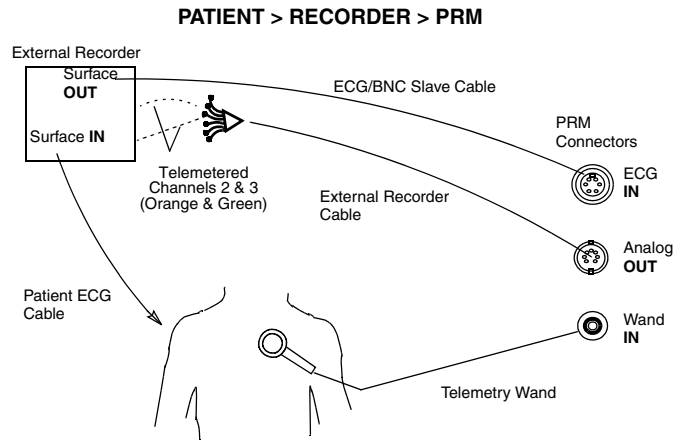


Figure C-2. External recorder gets surface signal and sends it to the PRM. PRM sends electrograms to the external recorder.

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 the section "ECG Display on the Main Application Screen" on page 2-14.

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 C-3.

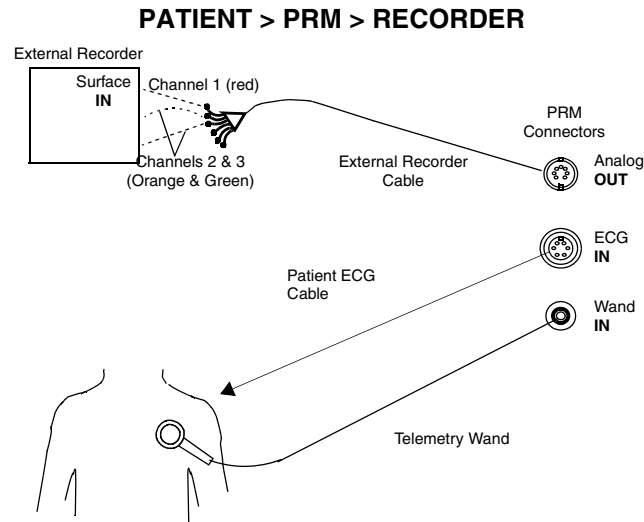


Figure C-3. PRM receives surface signal via the patient cable and then sends surface and telemetered channels to the external strip chart recorder.

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 the section "ECG Display on the Main Application Screen" on page 2-14.

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 C-4.

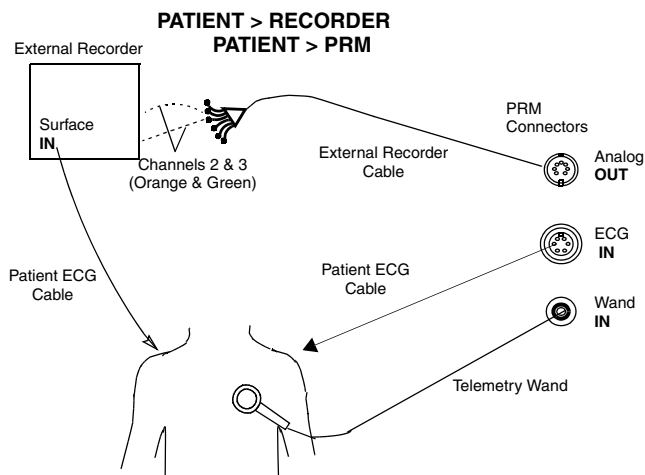


Figure C-4. Parallel connection of PRM surface ECG leads to the appropriate limb electrodes.

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 the section “ECG Display on the Main Application Screen” on page 2-14.

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.

MADIT II EXPANDED INDICATION

APPENDIX D

Guidant Cardiac Rhythm Management has received FDA approval for expanded indications for patients identified by the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) to be at high risk for sudden cardiac death.

ADVERSE EVENTS

Observed Adverse Events

The Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) was a prospective, randomized, controlled, multicenter, unblinded study conducted at 76 sites (71 in the United States and 5 in Europe) and enrolled a total of 1,232 patients. Patients were randomly assigned in a 3:2 ratio to receive an ICD (742 patients) or conventional medical therapy (490 patients). There were a total of 22 conventional therapy patients that were crossed over to the ICD group and a total of 32 patients randomized to the ICD arm that were considered crossovers. Of these 32 crossovers, 11 were due to subsequent device explants.

There were no unanticipated adverse events reported in the MADIT II study as of December 7, 2001. There were no patient deaths that occurred during implantation. Table D-1 provides information on all adverse events reported from implant through the randomization period in patients attempted or implanted with the MADIT II criteria. The table includes a total of 3,161 events reported for a total of 1,206 patients as of the data cutoff date of January 16, 2002. The number of patients is less than the total enrolled 1,232 patients because not all patients had reached the point of the one-month follow-up. The observed adverse events do not reflect an intention-to-treat analysis.

Table D-1. Adverse Events Through the Randomization Period (3,161 Events in 1,206 patients who reached one month follow-up prior to data cutoff date [1-16-02]; 24,814 total device months) (Sheet 1 of 4)

Adverse Event	# Of Events (# of pts) ^a	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observa- tions (Patients)	Observa- tions per 100 Device Months (Events)
Total of All Adverse Events (AE)	3161 (813 ^a)	49.7 (599)	7.9 (1761)	46.9 (566)	6.3 (1400)
ICD Therapy (Total AEs—treatment group)	2105 (503)	51.5 (376)	8.4 (1172)	49.9 (364)	6.7 (933)

D-2 | MADIT II EXPANDED INDICATION
ADVERSE EVENTS

Table D-1. Adverse Events Through the Randomization Period (3,161 Events in 1,206 patients who reached one month follow-up prior to data cutoff date [1-16-02]; 24,814 total device months) (Sheet 2 of 4)

Conventional Therapy (Total AEs--control group)	1056 (310)	46.8 (223)	7.0 (589)	42.4 (202)	5.5 (476)
TOTAL CARDIOVASCULAR RELATED ADVERSE EVENTS					
Device-Related Events^b					
Prophylactic replacement	7 (7)	0.6 (7)	0.0 (7)	0.0 (0)	0.0 (0)
Lead related problem	14 (13)	0.8 (10)	0.0 (10)	0.3 (3)	0.0 (4)
Battery depletion – normal (at EOL)	2 (2)	0.2 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Electromagnetic interference (EMI)	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Nonconversion of arrhythmia	3 (3)	0.2 (3)	0.0 (3)	0.0 (0)	0.0 (0)
Sense time prolonged / inappropriate	5 (5)	0.2 (3)	0.0 (3)	0.2 (2)	0.0 (2)
Generator manufacturing problem	2 (2)	0.2 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Pacemaker mediated tachycardia	79 (47)	0.0 (0)	0.0 (0)	3.9 (47)	0.4 (79)
Individual events that occurred one time	18 (18)	1.0 (10)	0.0 (10)	0.8 (8)	0.0 (8)
Subtotal Device Related Events	132 (91^a)	2.9 (35)	0.2 (37)	4.9 (59)	0.4 (95)
Procedure Related Events^b					
Infection	13 (13)	0.8 (9)	0.0 (9)	0.3 (4)	0.0 (4)
Lead problem	2 (2)	0.1 (1)	0.0 (1)	0.1 (1)	0.0 (1)
Patient bleeding	2 (2)	0.1 (1)	0.0 (1)	0.1 (1)	0.0 (1)
Pulse generator flipped (Twiddler)	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Pocket inflammation/hematoma	15 (15)	0.9 (11)	0.0 (11)	0.3 (4)	0.0 (4)
Pain	10 (10)	0.1 (1)	0.0 (1)	0.7 (9)	0.0 (9)
Fibrillation, atrial	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Deep Vein Thrombosis	3 (3)	0.1 (1)	0.0 (1)	0.2 (2)	0.0 (2)
Anxiety	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Individual events that occurred one time	17 (17)	0.8 (8)	0.0 (8)	0.9 (9)	0.0 (9)
Subtotal Procedure Related Events	68 (59^a)	2.2 (26)	0.1 (32)	3.0 (36)	0.2 (36)

Table D-1. Adverse Events Through the Randomization Period (3,161 Events in 1,206 patients who reached one month follow-up prior to data cutoff date [1-16-02]; 24,814 total device months) (Sheet 3 of 4)

Adverse Event	# Of Events (# of pts) ^a	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observa- tions (Patients)	Observa- tions per 100 Device Months (Events)
Cardiovascular Related Events (n=730 pts): ICD Therapy (treatment group)					
Arrhythmia, atrial	78 (66)	4.2 (31)	0.2 (34)	5.3 (39)	0.3 (44)
Arrhythmia, ventricular	64 (49)	5.3 (39)	0.4 (53)	1.4 (10)	0.1 (11)
Mitral valve regurgitation	1 (1)	0.1 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Congestive heart failure	444 (227)	22.9 (167)	2.2 (304)	14.1 (103)	1.0 (140)
Palpitation, pounding heart	21 (18)	1.0 (7)	0.1 (7)	1.5 (11)	0.1 (14)
Syncope	62 (50)	4.7 (34)	0.3 (40)	2.5 (18)	0.2 (22)
Infarction, myocardial	34 (28)	3.8 (28)	0.2 (34)	0.0 (0)	0.0 (0)
Angina pectoris	166 (110)	10.0 (73)	0.8 (112)	6.0 (44)	0.4 (54)
Bradycardia, sinus	8 (8)	1.0 (7)	0.1 (7)	0.1 (1)	0.0 (1)
Tachycardia	7 (7)	0.3 (2)	0.0 (2)	0.7 (5)	0.0 (5)
AV Block, Complete	1 (1)	0.1 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Cardiac allograft rejection	2 (2)	0.3 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Hypotension	28 (26)	1.4 (10)	0.1 (10)	2.2 (16)	0.1 (18)
Hypertension	6 (6)	0.1 (1)	0.0 (1)	0.7 (5)	0.0 (5)
Claudication	10 (7)	0.8 (6)	0.1 (9)	0.1 (1)	0.0 (1)
Carotid stenosis	5 (5)	0.5 (4)	0.0 (4)	0.1 (1)	0.0 (1)
Aneurysm	1 (1)	0.1 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Deep vein thrombosis	9 (9)	1.0 (7)	0.1 (7)	0.3 (2)	0.0 (2)
Pulmonary Embolus	4 (4)	0.5 (4)	0.0 (4)	0.0 (0)	0.0 (0)
Individual events that occurred one time	5 (5)	0.5 (4)	0.0 (4)	0.1 (1)	0.0 (1)
Subtotal Cardiovascular Related Events: ICD Therapy (treatment group)	956 (354)	36.8 (269)	4.6 (637)	26.8 (196)	2.3 (319)

D-4 | MADIT II EXPANDED INDICATION
ADVERSE EVENTS

Table D-1. Adverse Events Through the Randomization Period (3,161 Events in 1,206 patients who reached one month follow-up prior to data cutoff date [1-16-02]; 24,814 total device months) (Sheet 4 of 4)

Adverse Event	# Of Events (# of pts) ^a	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observa- tions (Patients)	Observa- tions per 100 Device Months (Events)
Cardiovascular Related Events (n=476 pts): Conventional Therapy (control group)					
Arrhythmia, atrial	31 (29)	3.2 (15)	0.2 (16)	3.2 (15)	0.2 (15)
Arrhythmia, ventricular	33 (26)	4.6 (22)	0.3 (27)	1.1 (5)	0.1 (6)
Arrhythmia, general report	3 (3)	0.4 (2)	0.0 (2)	0.2 (1)	0.0 (1)
Mitral valve regurgitation	1 (1)	0.2 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Congestive heart failure	212 (128)	16.6 (79)	1.5 (126)	14.3 (68)	1.0 (86)
Palpitation, pounding heart	6 (5)	0.4 (2)	0.0 (3)	0.6 (3)	0.0 (3)
Syncope	35 (31)	4.8 (23)	0.3 (24)	2.1 (10)	0.1 (11)
Infarction, myocardial	19 (17)	3.6 (17)	0.2 (19)	0.0 (0)	0.0 (0)
Angina pectoris	93 (71)	10.7 (51)	0.8 (64)	5.5 (26)	0.3 (29)
Bradycardia, sinus	8 (8)	1.7 (8)	0.1 (8)	0.0 (0)	0.0 (0)
AV Block, Complete	4 (2)	0.4 (2)	0.0 (3)	0.2 (1)	0.0 (1)
Bundle branch block	4 (4)	0.4 (2)	0.0 (2)	0.4 (2)	0.0 (2)
Hypotension	17 (13)	1.9 (9)	0.1 (12)	1.1 (5)	0.1 (5)
Hypertension	2 (2)	0.0 (0)	0.0 (0)	0.4 (2)	0.0 (2)
Claudication	6 (4)	0.6 (3)	0.1 (5)	0.2 (1)	0.0 (1)
Carotid stenosis	5 (5)	1.1 (5)	0.1 (5)	0.0 (0)	0.0 (0)
Aneurysm	3 (3)	0.6 (3)	0.0 (3)	0.0 (0)	0.0 (0)
Deep vein thrombosis	3 (3)	0.6 (3)	0.0 (3)	0.0 (0)	0.0 (0)
Pulmonary Embolus	2 (2)	0.4 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Tachycardia	2 (2)	0.2 (1)	0.0 (1)	0.2 (1)	0.0 (1)
Individual events that occurred one time	7 (7)	1.1 (5)	0.1 (5)	0.4 (2)	0.0 (2)
Subtotal Cardiovascular Related Events: Conventional Therapy (control group)	496 (222)	34.7 (165)	3.9 (329)	25.0 (119)	2.0 (165)
Subtotal Cardiovascular Related Events: Both groups	1452 (576^a)	36.0 (434)	4.3 (968)	26.1 (315)	2.2 (484)

- a. Identifies number of unique patients. Patients may have one or more adverse events.
b. Events include only patients in the ICD treatment group.

Mortality

NOTE: For additional information see the section “MADIT II Summary of Clinical Study” on page D-5.

There were a total of 202 deaths that occurred during the trial and recorded as of the stop date, November 20, 2001. These deaths occurred during the study periods as shown in Table D-2 along with the cause of death as adjudicated by an independent events committee.

Table D-2. Cause of Death During the Treatment Period

Cause of Death (as a percent of total pts)	ICD Therapy (N=742) Patients (%)	Conventional Ther- apy (N=490) Patients (%)	Total (N=202)
Noncardiac	25 (3.4%)	21 (4.3%)	46 (3.7%)
Cardiac: Arrhythmic	28 (3.8%)	48 (9.8%)	76 (6.2%)
Cardiac: Nonarrhythmic	45 (6.1%)	22 (4.5%)	67 (5.4%)
Cardiac: Undetermined cause	1 (0.1%)	2 (0.4%)	3 (0.2%)
Unknown	6 (0.8%)	4 (0.8%)	10 (0.8%)
Total Deaths	105 (14.2%)	97 (19.8%)	202 (16.3%)

SUMMARY OF MADIT II CLINICAL STUDY

The Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) was designed to determine if implantation of an ICD in high-risk cardiac patients with advanced left ventricular dysfunction could improve overall survival. The previous MADIT I trial demonstrated improved overall survival with an ICD in high-risk patients with coronary heart disease, left ventricular dysfunction, asymptomatic nonsustained ventricular tachyarrhythmias and an inducible nonsuppressible ventricular tachycardia at EP study.

MADIT II SUMMARY OF CLINICAL STUDY

Guidant supported the MADIT II Clinical Study as conducted by the University of Rochester to evaluate the potential survival benefit of a prophylactically implanted ICD in patients with a prior myocardial infarction and a left ventricular ejection of ≤ 30 percent. Unlike MADIT I¹, patients enrolled in MADIT II were not required to

undergo electrophysiologic testing to induce arrhythmias prior to implant. Patients were randomized to either ICD or conventional therapy. All cause mortality was the primary endpoint of the study.

The MADIT II trial was monitored using a sequential design and on November 20, 2001, after review of the data by the Data and Safety Monitoring Board, the study was stopped. Results of the trial data indicated a 31% decrease in the mortality rate in patients implanted with an ICD device compared to patients randomized to the conventional therapy group, thus meeting its effectiveness endpoint.

The trial began July 11, 1997 and was conducted over a period of four years at 76 investigational centers both within and outside the United States. The inclusion and exclusion criteria for the study have been included in the section "Inclusion/Exclusion Criteria" on page D-7.

Study Design

MADIT II was a prospective, randomized (3:2 ICD to conventional non-ICD therapy), controlled, unblinded, multi-center trial. Randomization to the ICD group consisted of implantation of a legally marketed Guidant ICD device. Randomization to the conventional therapy group consisted of beta-adrenergic blocking drugs and angiotensin-converting enzyme (ACE) inhibitors when indicated.

Patients provided written informed consent and received a baseline reference examination that included prior clinical history, physical examination and a 12-lead ECG. Following completion of the baseline evaluation, patients were randomized by the Coordination and Data Center (CDC) in a 3:2 fashion to receive either an ICD or conventional medical therapy; randomization was done separately for each center, with blocking, to assure proper balance between the two treatment groups within each center. Each randomized patient remained counted as a member of the original randomization assignment (intention-to-treat) regardless of subsequent crossover or protocol adherence.

Patients randomized to the ICD arm were implanted with Guidant transvenous defibrillator devices by MADIT II investigators. All Guidant ICD systems used during the trial were legally approved devices and the use of investigational devices was strictly prohibited. Following randomization, patients were seen at a 1-month follow-up visit in the clinic and at 3-month intervals thereafter until termination of the study.

1. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. NEJM 1996;335:1993-40.

Primary Endpoint

The primary endpoint for MADIT II was all cause mortality.

Primary Objective

The primary objective of the trial was to determine if implantation of ICDs in moderately high-risk coronary patients would result in significant reduction in death when compared to patients treated without an ICD.

Secondary Objectives

The secondary objectives of the trial were as follows:

- Determine if (electrophysiology study) EPS inducibility at ICD implantation in the ICD group was associated with a higher appropriate ICD discharge rate during follow-up than noninducibility.
- *Determine if Holter-recorded noninvasive electrocardiologic parameters (SAECG, heart rate variability, temporal dispersion of refractoriness, T-wave alternans, and T-wave lability) can identify patients with an increased mortality rate in the non-ICD group.
- *Evaluate the cost-effectiveness of ICDs in saving lives.
- *Determine if ICD therapy is associated with an improved quality of life.

* The results of these secondary objectives were not included as part of the approval for this expanded indication.

Inclusion/Exclusion Criteria

Study ***inclusion*** criteria were as follows:

- Patients must have an ejection fraction ≤ 0.30 obtained ≤ 3 months prior to enrollment by angiographic, radionuclide, or echocardiographic methods. This ejection fraction must be obtained at least 30 days following the most recent myocardial infarction, coronary artery bypass graft surgery, or coronary revascularization procedure.
- Patients must have had at least one or more documented Q-wave or other enzyme positive infarctions. If enzyme information is not available, then there

must be clear evidence of an infarct identified as a Q-wave on an ECG, fixed defect (scar) on a thallium scan, or infarcted area on a coronary angiogram or echocardiography.

- Patients must be men or women greater than 21 years of age (no upper cut-off).

Study **exclusion** criteria were as follows:

- Previous cardiac arrest or syncopal ventricular tachycardia unassociated with an acute myocardial infarction (existing ICD indication)
- Patients meeting MADIT I criteria with $EF \leq 0.35$, nonsustained VT, and inducible-nonsuppressible VT at electrophysiologic study (existing ICD indication)
- Cardiogenic shock, symptomatic hypotension while in a stable baseline rhythm
- NYHA functional Class IV
- Current use of antiarrhythmic agents except when indicated for atrial arrhythmias
- Coronary artery bypass graft surgery or PTCA within the past 3 months
- Enzyme-positive myocardial infarction ≤ 30 days prior to enrollment
- Patients with angiographic evidence of coronary disease who are candidates for coronary revascularization and are likely to undergo coronary artery bypass graft surgery or PTCA in the foreseeable future
- Patients with irreversible brain damage from preexisting cerebral disease
- Women of childbearing potential not using medically prescribed contraceptive measures
- Presence of any disease, other than the patient's cardiac disease, associated with a reduced likelihood of survival for the duration of the trial, eg, cancer, uremia ($BUN \geq 70$ mg% and/or creatinine ≥ 30 mg%)
- Patients participating in other clinical heart disease trials

- Patients unwilling or unable to cooperate with the study due to dementia, psychological, or other related reasons
- Patients who were unable to participate due to one or more logistical considerations
- Patient's primary care physician refuses to allow patient to participate
- Patients who are on the heart transplant list. If the patient is pending evaluation for the heart transplant list, the patient cannot be enrolled in MADIT II until it is definitively determined that the patient will NOT be placed on the transplant list
- ICD cannot be implanted due to anatomical abnormality or other medical problem

Follow-up Schedule

Following randomization, patients were seen at a 1-month follow-up visit in the clinic and at 3-month intervals thereafter until termination of the study. During each clinic visit, an appropriate clinical evaluation was completed. Patients with an ICD device underwent device testing according to an agreed-upon protocol at the investigational center. Patients were followed from between 6 days and 53 months averaging 20 months.

Patient Status

There were a total of 1,232 patients with a prior myocardial infarction and a left ventricular ejection fraction of ≤ 0.30 enrolled in the MADIT II trial. A total of 742 patients were randomized to receive an ICD and 490 patients were randomized to conventional therapy. Figure D-1 provides an overview of the patient enrollment.

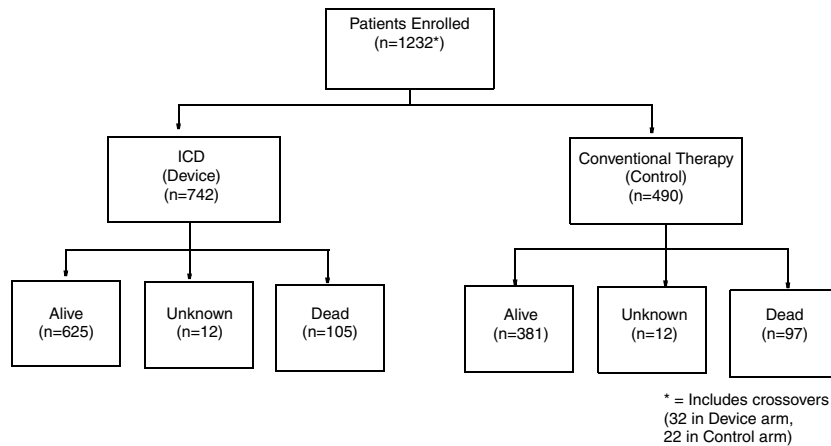


Figure D-1. MADIT II Patient Enrollment Cascade Primary Endpoint

Primary Endpoint

The primary endpoint for MADIT II was death from any cause. Analysis was performed according to the intention-to-treat principle. The trial was designed to have 95 percent power to detect a 38 percent reduction in the two-year mortality rate among the patients in the ICD group, given a postulated two-year mortality rate of 19 percent among patients assigned to conventional therapy, with a two-sided significance level of 5%. For proportional-hazards modeling, power was maintained for a true hazard ratio of 0.63, after allowance for crossovers. A triangular sequential design was used, which was modified for two-sided alternatives. The data was corrected to account for any lag in obtaining data accrued (during weekly monitoring), but not reported before the termination of the trial with preset boundaries to permit termination of the trial if the ICD therapy was found to be superior to, inferior to, or equal to conventional medical therapy.

Secondary analyses were performed with use of the Cox proportional hazards regression model. Survival curves were determined according to the Kaplan and Meier method, with comparisons of cumulative mortality based on logarithmic transformation. The p-values were termed nominal when they were not adjusted for sequential monitoring. All p-values were two-tailed.

At the recommendation of the Data and Safety Monitoring Board (DSMB), the trial was stopped on November 20, 2001, when it was revealed that the difference in

mortality between the two groups had reached the prespecified efficacy boundary ($p=0.027$) (see Figure D-2).

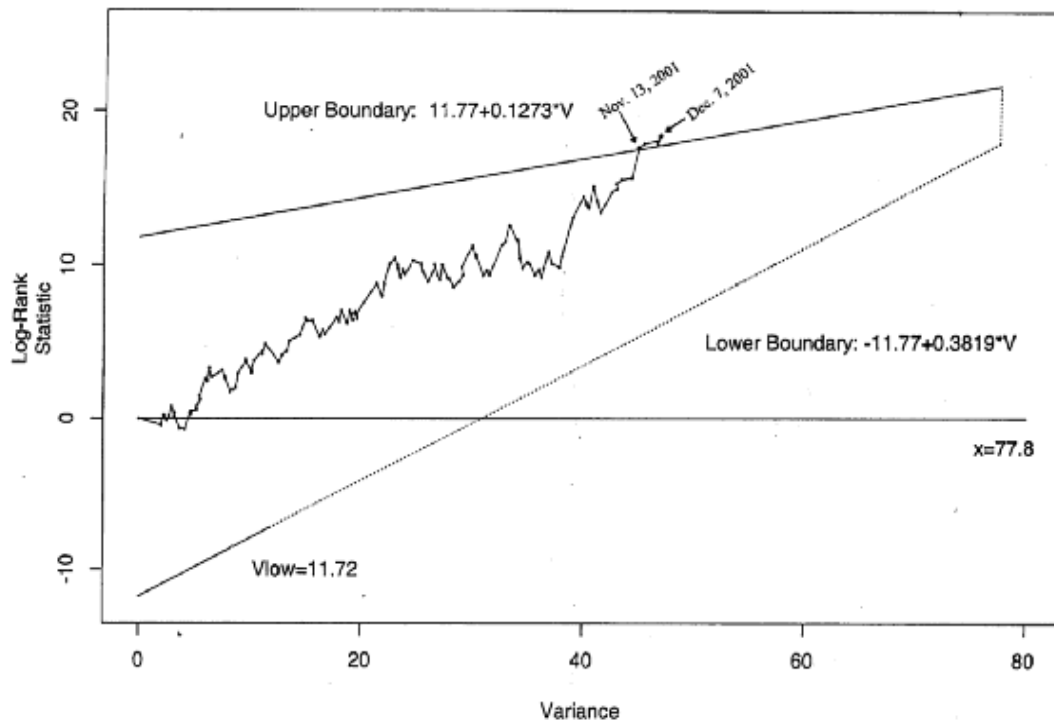


Figure D-2. Sequential Monitoring in the Triangular Design

Study Results

Study Duration

Study duration, measured in months, is displayed in Table D-3. The mean duration was similar between the ICD group and the conventional therapy group. As expected, the ICD group accumulated >15,000 months of follow-up.

Table D-3. MADIT II Study Duration in Months

Therapy	No.	Mean	±SD	Minimum	Maximum	Cumulative
ICD Therapy	742	20.5	12.9	0.2	51.7	15,190
Conventional Therapy	490	19.6	12.6	0.2	52.3	9,624

Baseline Characteristics

Table D-4 provides a summary of the general characteristics of the enrolled MADIT II patient population. Characteristics were balanced across therapy groups and no statistical differences were found during data analysis as indicated by the p-values in the table.

Table D-4. Patient Population Characteristics (Sheet 1 of 2)

Characteristic	ICD Patients (n=742)	Conventional Therapy Patients (n=490)	p-value
Age at Enrollment • ≥ 65 years (patients, %) • Mean +/- Standard Deviation (years)	397 (53.5%) 64.4 +/- 10.4	262 (53.5%) 64.6 +/- 10.3	0.99
Gender (patients, %) • Male	623 (83.9%)	417 (85.1%)	0.59
LVEF (%) • Mean +/- Standard Deviation	23.1 +/- 5.4	23.2 +/- 5.6	0.93
LVEF ^a • ≤ 25% (patients, %)	502 (76.7%)	330 (67.3%)	0.91
New York Heart Association Classification 3 months before enrollment (patients, %) • No CHF • Class I • Class II • Class III • Class IV • Unknown	179 (24.1%) 75 (10.1%) 258 (34.8%) 187 (25.2%) 33 (4.5%) 10 (1.4%)	129 (26.3%) 58 (11.8%) 162 (33.1%) 111 (22.7%) 20 (4.1%) 10 (2.0%)	0.64
Canadian Heart Association Classification • Class I • Class II, III, IV • Angina Decubitus • No Angina Pectoris • Unknown	126 (16.9%) 168 (23.1%) 35 (4.7%) 402 (54.1%) 11 (1.4%)	81 (16.5%) 120 (24.4%) 15 (3.1%) 268 (54.7%) 6 (1.2%)	0.62

Table D-4. Patient Population Characteristics (Sheet 2 of 2)

Characteristic	ICD Patients (n=742)	Conventional Therapy Patients (n=490)	p-value
Ventricular arrhythmias requiring treatment (patients, %)	74 (10.0%)	64 (13.1%)	0.24
Atrial Arrhythmias requiring treatment (patients, %)	201 (27.1%)	120 (24.4%)	0.56
History of Hypertension (patients, %) • Hypertension	411 (55.3%)	277 (56.5%)	0.71
Blood Urea Nitrogen (patients, %) • > 25 mg %	213 (28.7%)	153 (31.2%)	0.52
Diabetes Mellitus (patients, %)	246 (33.2%)	184 (37.6%)	0.45
Non-CABG Revascularization Procedures (patients, %)	331 (44.6%)	205 (41.8%)	0.56
CABG Surgery (patients, %)	428 (57.7%)	274 (55.9%)	0.53
Permanent Pacemaker (patients, %)	62 (8.4%)	30 (6.1%)	0.22
EP Study prior to enrollment (262 patients) • Inducible	n=150 (20.2%) 8 (5.3%)	n=112 (22.8%) 2 (1.8%)	0.27 0.25

a. Two patients enrolled with EF > 30%.

Medications

Table D-5 provides a summary of the medication utilization for the patients enrolled. The two treatment groups were balanced and appropriately treated with standard cardiac therapy. There were no differences in ACE inhibitors, beta blockers, or digitalis therapy between the ICD therapy group and the conventional therapy patients.

Table D-5. Patient Population Medication Therapy (Sheet 1 of 2)

Medication	ICD Patients (n = 742)	Conventional Therapy Patients (n = 490)	p-value
ACE inhibitor use (patients, %)			
Baseline/Enrollment	574 (77.4%)	377 (76.9%)	0.47
Last Follow-up	533 (71.8%)	363 (74.1%)	0.31

Table D-5. Patient Population Medication Therapy (Sheet 2 of 2)

Medication	ICD Patients (n = 742)	Conventional Therapy Patients (n = 490)	p-value
Amiodarone use (patients, %)			
Baseline/Enrollment	49 (6.6%)	36 (7.3%)	0.41
Last Follow-up	94 (12.7)	51 (10.4%)	0.23
Antiarrhythmic use (patients, %)			
Baseline/Enrollment	18 (2.4%)	15 (3.1%)	0.37
Last Follow-up	21 (2.8%)	12 (2.4%)	0.43
Aspirin use (patients, %)			
Baseline/Enrollment	503 (67.8%)	344 (70.2%)	0.30
Last Follow-up	477 (64.3%)	332 (67.8%)	0.20
Beta blocker use (patients, %)			
Baseline/Enrollment	469 (63.2%)	295 (60.2%)	0.28
Last Follow-up	529 (71.3%)	351 (71.6%)	0.46
Digitalis use (patients, %)			
Baseline/Enrollment	441 (59.4%)	277 (56.5%)	0.29
Last Follow-up	451 (60.8%)	290 (59.2%)	0.41
Diuretics use (patients, %)			
Baseline/Enrollment	541 (72.9%)	379 (77.3%)	0.09
Last Follow-up	562 (75.7%)	396 (80.8%)	0.04
Lipid Lowering use (patients, %)			
Baseline/Enrollment	492 (66.3%)	315 (64.3%)	0.37
Last Follow-up	556 (74.9%)	339 (69.2%)	0.04
Sotalol use (patients, %)			
Baseline/Enrollment	7 (0.9%)	3 (0.6%)	0.38
Last Follow-up	18 (2.4%)	4 (0.8%)	0.05

All Cause Mortality

The Kaplan Meier mortality curves depicting mortality for the two groups are shown in Figure D-3. Although the conventional and ICD survival curves remain close during the first nine months, they progressively separate thereafter. Table D-6 presents information derived from these curves, with the conclusion that 3-year cumulative all-cause mortality is estimated to be reduced by 29% in those with an ICD.

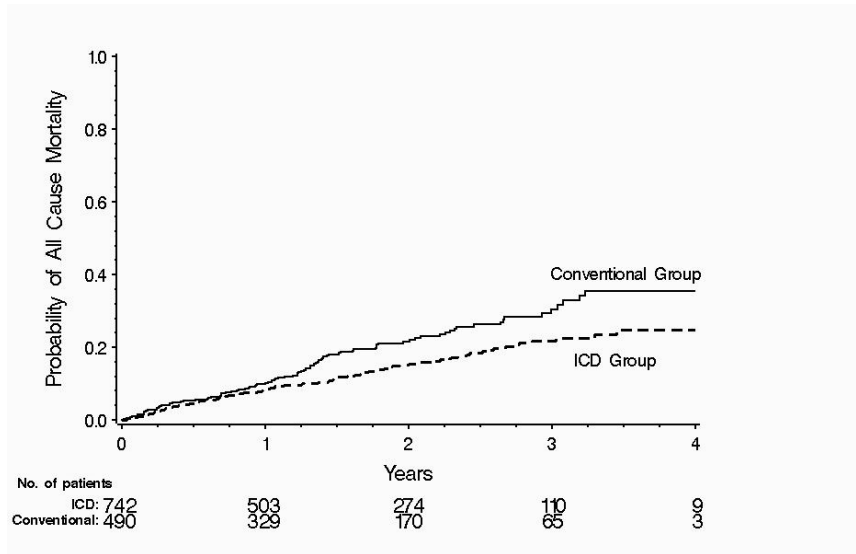


Figure D-3. Kaplan-Meier Mortality Curves Conventional vs ICD Groups

Table D-6. Cumulative Mortality and Percentage Reduction

Year	Conventional Arm	ICD Arm	Difference	Reduction	CI ^a %	p-value ^b
1 Year	9.9	8.8	1.1	11%	-29, 39	0.53
2 Years	21.5	15.5	6.0	28%	5, 46	0.02
3 Years	30.4	21.6	8.8	29%	6, 46	0.02

a. Indicates Confidence Interval for the percentage reduction in cumulative mortality. The cumulative mortality (and associated standard errors) is taken from the Kaplan-Meier analyses; percentage reduction analyses are based on a log transform method.

b. For null hypothesis that the percentage (%) reduction is zero.

The pre-specified primary analysis of the trial was based on computation of a hazard ratio, based on an assumption that the two survival curves satisfy a proportional hazards condition (one is a power —the 'hazard ratio'— of the other), and recognizing the sequential stopping rule of the trial. The hazard ratio is interpreted as the ratio of instantaneous risks of dying, at each point in time, in the two treatment groups. The hazard ratio for the ICD group relative to the conventional therapy group was found to be 0.69, indicating a 31% reduction in instantaneous

risk (95% confidence interval, 0.51 to 0.93; $p=0.016$, reduced from $p=0.027$ when reaching the stopping boundary, by incorporation of lagged data). The Cox regression analyses used for this purpose were stratified by enrollment centers, thus allowing for somewhat different patient pools at differing locations.

The proportional hazards assumption was evaluated by several standard statistical methods, all providing support. One method is derived from finding parallelism in so-called log (-log) plots of the cumulative hazards. Another is from fitting models that allow for differing hazard ratios in differing intervals of time, and demonstrating that any apparent differences among the period-specific hazard ratios can be attributed to chance. One such analysis is summarized in Table D-7.

Table D-7. Year-Specific Hazard Ratios (HR)

Year	Estimate	CI
1 Year	0.87	0.59, 1.29
2 Years	0.56	0.29, 1.07
3+ Years	0.61	0.28, 1.34
Overall	0.69	0.51, 0.93

The p -value = 0.16 for differences among the 3 HRs, and the p -value = 0.016 for the overall HR. The exponential mortality curves fit the data very well, with risks of mortality of 0.0100 each month for patients in the conventional therapy group and 0.0069 each month in the ICD group, with the ratio, 0.69, in agreement with that reported above.

Verification of ICD Shock Therapy Treatment

Of the 710 patients that were implanted with an ICD, 134 received appropriate therapy for ventricular tachycardia/ventricular fibrillation (VT/VF) and the probability of therapy increased over time. There was a 34% cumulative probability that ICD patients received therapy from the device for VT/VF within three years (see Figure D-4). The probability of first appropriate shock for VF only at one year was 4% and increased to 10% after four years. These percentages are closely related to the survival probability differences observed between the ICD and conventional therapy groups (1% and 11%, respectively) as shown in Figure D-3.

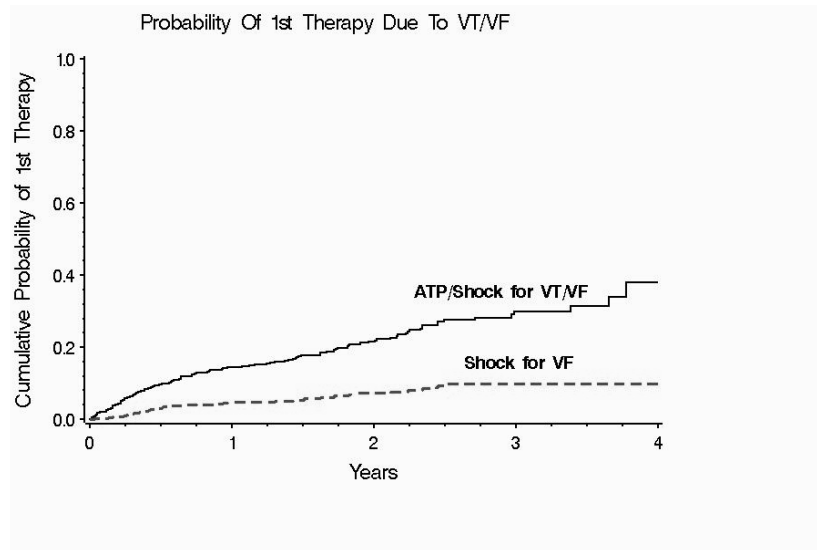


Figure D-4. Probability of First Therapy Due to VT/VF.

The probability of appropriate ICD shocks for ventricular fibrillation (Figure D-4) correlates closely to the difference in the cumulative number of deaths between the ICD and conventional groups as shown in Figure D-3.

Hospitalization Results

The rate of occurrence of patients requiring hospitalization due to adverse events was 0.29 per year of observation in both the conventional therapy patients and in the ICD patients. Table D-8 provides the summary of all hospitalizations that occurred as a result of adverse events. Adverse events that resulted in hospitalizations do not differ significantly between groups.

Table D-8. Adverse Events Requiring Hospitalizations (Rate/Year) (excludes adverse events that resulted in death)

Treatment Group	Cumulative Years of Observation	Total Number of Individuals with Adverse Events	Rate per Year of Individuals with Adverse Events	p-value
Conventional (n=490)	703.6	201 (41%)	0.29	0.85
ICD Therapy Group (n=742)	1155.97	337 (45%)	0.29	

Table D-9 provides a summary of hospitalizations that were required as a result of congestive heart failure (CHF) related adverse events. There were 78 of the 490 patients in the conventional group and 161 of the 742 ICD patients who had one or more hospitalizations that did not result in death. The annual rate of hospitalization for CHF for each treatment group was calculated by dividing the number of patients with one or more hospitalizations for new or worsening CHF by the cumulative years of observation. The rate of hospitalization for CHF per year was somewhat higher in the ICD group ($161/115.97 = 0.14$) compared to the conventional therapy group ($78/703.6 = 0.11$); however, this difference in the rate of hospitalization for CHF was not statistically significant ($p=0.11$).

Table D-9. Heart Failure Adverse Events Requiring Hospitalization (Rate/Year) (excludes adverse events that resulted in death)

Treatment Group	Cumulative Years of Observation	Total Number of Individuals with Adverse Events	Rate per Year of Individuals with Adverse Events	p-value
Conventional (n=490)	703.6	78 (16%)	0.11	0.11
ICD Therapy Group (n=742)	1155.97	161 (22%)	0.14	

Reasons for Crossover

The MADIT II study was an intention-to-treat analysis, therefore, any patient receiving therapy outside of their randomized therapy group was counted as a crossover. Table D-10 details crossovers by treatment group.

Table D-10. Reasons for Crossovers by Treatment Group

Description	ICD Therapy (n=742)	Conventional Therapy (n=490)
Refusal of therapy	21	0
Met ICD implant criteria	N/A	21
Heart transplant	9	0
Sepsis related to CABG surgery	1	0
Nonconversion of arrhythmia	1	0
Physician Discretion	0	1
Total Crossovers (54)	32	22

A crossover patient was defined as a patient who, at the time of a specified data cutoff date, was receiving treatment that was different than their originally randomized assignment. Crossovers from the conventional therapy group to the ICD group were strongly discouraged unless a patient was determined to have a strong clinical justification such as positive inducibility during EP testing or spontaneous ventricular arrhythmia event(s) requiring hospitalization that would be an approved indication for receiving an ICD.

Follow-up Compliance

The compliance rate is calculated by dividing the number of successful visits by the sum of the visits expected for the designated month sequence. Table D-11 details reported visit compliance in six-month intervals. Compliance to follow-up was $\geq 88\%$ at the majority of required visits. There was no difference in the follow-up rates between the two groups.

Table D-11. Follow-up Compliance

Follow-up Sequence Month	% Compliant ICD Group	% Compliant Conventional Therapy Group
1–6 months	98	96
7–12 months	97	95
13–18 months	96	93
19–24 months	95	93

Table D-11. Follow-up Compliance

Follow-up Sequence Month	% Compliant ICD Group	% Compliant Conventional Therapy Group
25–30 months	93	89
31–36 months	97	90
37–42 months	95	85
43–51 months	96	100
Total Average	96	94

Subgroup Analysis of MADIT II Patient Population

Figure D-5 provides the hazard ratios and 95 percent confidence intervals for death from any cause in the ICD group as compared to the conventional therapy group according to selected clinical characteristics.

The hazard ratios in the various subgroups were similar, with no statistically significant interactions. The dotted vertical line represents the results for the entire study (nominal hazard ratio, 0.66, without adjustment for the stopping rule). The horizontal lines indicate nominal 95 percent confidence intervals.

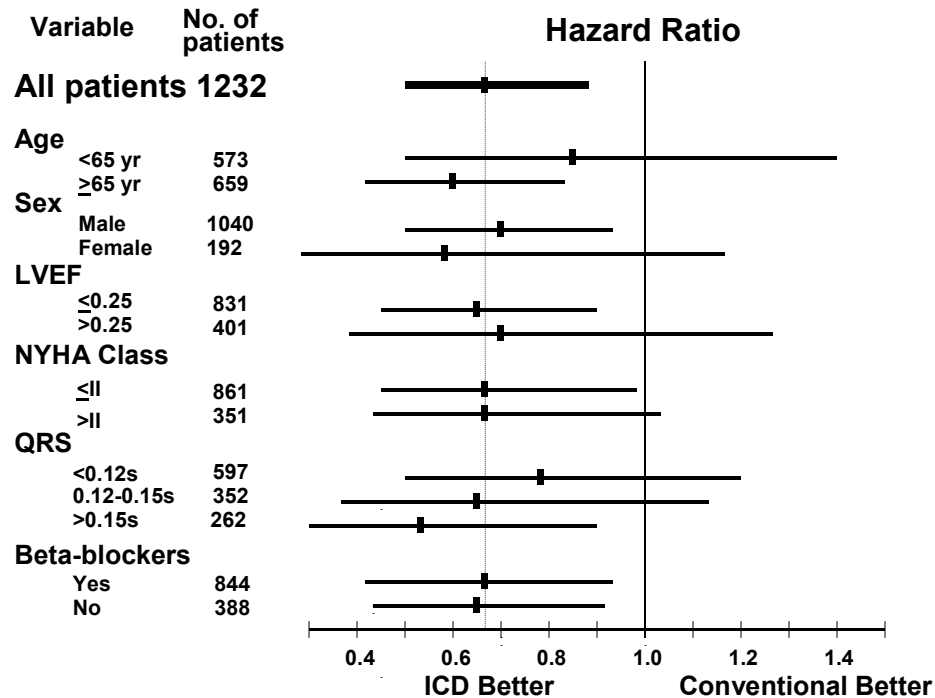


Figure D-5. Hazard Ratios and 95 Percent Confidence Intervals

Analysis of Inducibility as a Risk Factor

There were 583 patients enrolled in MADIT II who had EP testing performed either prior to or during ICD implant. The definition for inducibility was the same one used for the MADIT I study. Of these 583 patients, 373 (63%) were not inducible and the remaining 210 (36%) were inducible. Of the 210 patients who were inducible, 180 (88%) had EP testing performed at implant using a catheter method and 24 (12%) using the ICD for induction; there was no data on the method of induction for 6 patients.

The Occurrence of ICD Therapy for VT, VF, or VT/VF Combined

Therapy for VT was defined as antitachycardia pacing (ATP) or ICD shock delivered by the device in an attempt to stop an arrhythmia as reported by the enrolling center. Therapy for VF was defined as the delivery of ICD shock therapy. The endpoint for

VT/VF was defined by the occurrence of either VT or VF therapy. The occurrence of therapy for each of these groups is provided in Table D-12. All analyses were Cox regression analyses, stratified by enrollment center, with time to VT, time to VF or time to VT/VF therapy as the respective endpoint.

Table D-12. ICD Patients Receiving One or More Therapies^a

Type of ICD Therapy	Number of Patients	Percent of Patients with Therapy Episodes
VT (ATP or shock)	89	15.4%
VF (Shock only)	36	6.2%
VT/VF VF (ATP + shock)	114	19.7%

a. Some patients received both types of therapy.

Predictions of VT and VF Therapy in ICD Patients

A statistical analysis was performed to evaluate whether inducibility at EP testing provides predictability of the potential effectiveness of an ICD. To this end, the occurrence of each of the three endpoints defined above (VT, VF and VT/VF), in ICD patients with EP testing were evaluated. Analyses were done by Cox proportional hazards regression, stratified by enrollment center. (See Figure D-13.)

A list of potential risk factors was considered for these endpoints, such as age, gender, and standard cardiological variables like NYHA class, EF, etc., and developed a parsimonious regression model in the 583 ICD patients identified above. GENDER and BUN (dichotomized at up to 25 versus 26 and over) were observed as potential risk factors for these endpoints, with males and elevated BUN associated with increased occurrence of these endpoints. Further analysis investigated whether inducibility added any additional, independent predictive power for each of these endpoints.

The conclusion was that inducibility increases the risk of VT events by perhaps 60% ($p=0.07$) and decreases the risk of VF events by perhaps 50% ($p=0.08$). As a consequence of these opposite directional effects of similar magnitudes, there was no reliable evidence that inducibility affects the frequency of VT/VF events ($p=0.26$); it may be associated with a slight increase since VT events occur more frequently than VF.

Table D-13. Therapy Predictability Based on Induced Arrhythmia

Therapy Delivered for the Following Type of Arrhythmia		Inducible	
		Yes	No
VF	Yes	7	29
	No	202	341
VT	Yes	43	46
	No	166	324
VT/VF	Yes	48	66
	No	161	304

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