

Physician's System Manual

**CONTAK CD™
1823**

Heart Failure Device

CARDIAC

RHYTHM

MANAGEMENT

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

Nominal Mechanical Specifications

	Dimensions W x H x D (cm)	Volume (cc)	Mass (g)	Maximum Shock Energy (J)	Connector Size ^{b, c}	Case Electrode Surface Area (mm ²)
CONTAK CD 1823 ^a	5.9 x 7.9 x 1.6	60	110	31	LV-1, IS-1, DF-1	9464

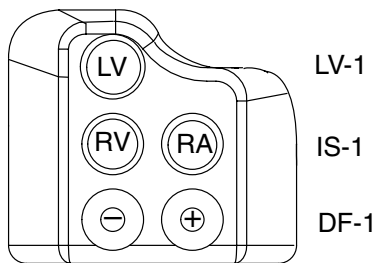
a. This model pulse generator uses its case as a defibrillating electrode.

b. For lead compatibility information, refer to Appendix C; and to the non-Guidant lead system warning on page 2.

c. LV-1 refers to the Guidant LV[®] proprietary connector. IS-1 refers to the international standard ISO 5841.3:1992. DF-1 refers to the international standard ISO 11318:1993.

Model 1823

Case material	Hermetically sealed titanium
Header material	Implantation-grade polymer
Power supply (WGL)	Two lithium-silver vanadium oxide cells



About This Manual

The Guidant CONTAK CD™ heart failure device, Model 1823, is part of the CONTAK™ heart failure product family. This physician's system manual contains a description of the CONTAK CD heart failure device, as well as the Model 2848 Software Application and the ZOOM programming system, which includes the Model 2920 Programmer/Recorder/Monitor (PRM), used to program the pulse generator.

The Table of Contents provides a view of the logical flow of subjects. The Index at the back of the manual provides an alphabetical listing of subjects in the manual; it can be used as an easy-to-use reference document.

Chapter 2 should be read to familiarize yourself with the software and the terminology. The terminology introduced in this chapter will be used throughout the manual.

Chapters 3, 4, and 5 contain information about detection and therapy functions. The early part of each chapter describes the pulse generator functions in detail, and the latter part of the chapter explains how to access the functions using the PRM system and software application. The software explanation typically includes a list of steps required to interact with the software. This format allows the information to be read with continuity or as a reference to pulse generator and system functions.

Chapters 6 through 11 offer information regarding programmer activated features, electrophysiologic testing, therapy history, and implant information.

The appendices provide topics that expand on pulse generator operation, such as lead compatibility and external cable connections. Appendix A contains a quick-reference list of programmable options for the pulse generator parameters.

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Chapter 1

DESCRIPTION AND USE

The Guidant CONTAK CD™ heart failure device, Model 1823, is designed to provide cardiac resynchronization therapy for the treatment of heart failure (HF) by using simultaneous biventricular electrical stimulation to synchronize ventricular contractions. The device also detects and terminates ventricular tachycardia (VT) and ventricular fibrillation (VF), and provides adaptive-rate bradycardia therapy. The pulse generator, an atrial lead, and two ventricular leads connected in a parallel configuration constitute the implantable portion of the heart failure system. The device accepts one IS-1¹ atrial lead, one LV-1 lead—Guidant's coronary venous pace/sense lead, and one DF-1/IS-1 cardioversion/defibrillation lead with an electrode surface area $\geq 8\text{mm}^2$. Guidant recommends cardioversion/defibrillation leads such as the ENDOTAK® ENDURANCE EZ® leads (Models 0154, 0155), or the ENDOTAK® DSP lead (Model 0125).

Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. The CONTAK CD device uses 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. The CONTAK CD device also offers a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias. Bradycardia pacing with resynchronization therapy, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy.

The ZOOM™ Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM), the Model 2848 Software Application, the Model 6860 Magnet, and an accessory telemetry wand, constitutes the external portion of the CONTAK CD system. The external components allow interrogation and programming of the pulse generator as well as access to the device's diagnostic features. The CONTAK CD system can be programmed to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

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.

Indications for Use

The CONTAK CD heart failure device is indicated for use in the following:

- Patients who have advanced symptomatic heart failure (NYHA Class III/IV) including left ventricular dysfunction ($\text{EF} \leq 35\%$) and wide QRS complex ($\text{QRS} > 120\text{ ms}$) while on heart failure drug therapy; and

NOTE: *The effects of cardiac resynchronization on advanced heart failure patients receiving sub-optimal heart failure drug therapy are not fully known. Safety and effectiveness studies have not been conducted.*

- Patients who are at high risk of sudden cardiac death due to ventricular arrhythmias. Patient populations at high risk include, but are not limited to, those with:
 - Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia.

1. Refer to the Nominal Mechanical Specifications table in the inside front cover of the manual for the defibrillating and pace/sense lead port dimensions; and refer to Appendix C for compatible Guidant leads.

- Recurrent, poorly tolerated sustained ventricular tachycardia (VT).

NOTE: *The clinical outcome of hemodynamically stable, sustained–VT patients is not fully known. Safety and effectiveness studies have not been conducted.*

- Prior myocardial infarction, left ventricular ejection fraction of $\leq 35\%$, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic (drug) have not been studied.

Contraindications

The CONTAK CD heart failure device is contraindicated for use in the following:

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

Warnings

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.
- **Lead system.** The use of non-Guidant lead systems may cause potential adverse consequences, such as undersensing cardiac activity and failure to deliver necessary therapy.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.
- **Defibrillator paddles.** Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2² pads) immediately available during conversion testing. 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.
- **MRI exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Patch leads.** Do not use defibrillation patch leads with the CONTAK CD system, or injury to the patient may occur.
- **Separate pacemaker.** Do not use the heart failure device with a separate pacemaker system. This combination could result in heart failure device/pacemaker interaction.

Precautions

Sterilization, Storage, and Handling

- **For single use only—do not resterilize devices.** Do not resterilize the device or the accessories packaged with it because Guidant cannot ensure that resterilization is effective.
- **If package is damaged.** Guidant sterilizes the pulse generator blister trays and contents 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 room temperature before programming or implanting the device because temperature extremes may affect initial device function.

2. Trademark of R2 Corporation.

- **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.** Do not implant the pulse generator after the USE BEFORE date (which appears on the device packaging) has passed because this date reflects a reasonable shelf life.

Implantation and Device Programming

- **Device communication.** Use only a Guidant Programmer/Recorder/Monitor (PRM) and the Model 2848 Software Application to communicate with the CONTAK CD pulse generator.
- **STAT PACE settings.** 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.
- **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose ventricular tachyarrhythmias require frequent shocks.
- **Drug-resistant SVTs.** Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.
- The clinical benefit of left ventricular pacing alone for heart failure patients has not been studied.

Follow-up Testing

- **Conversion testing.** If the patient's condition or drug regimen has changed or device parameters have been reprogrammed, consider performing a conversion test to ensure that the patient's tachyarrhythmias can be detected and terminated by the system.

Pulse Generator Explant and Disposal³

- **Incineration.** Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.
- **Device handling.** Program the pulse generator 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.
- Return all explanted pulse generators and leads to Guidant.

Environment and Medical Therapy Hazards

- **Avoiding EMI.** Advise patients to avoid sources of EMI (electromagnetic interference) 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, and an alternator on a car that is running.

Hospital and Medical Environments

- **Do not use internal defibrillation** paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.
- **External defibrillation.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator–lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

3. Refer to the Explantation section in Chapter 11.

Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a manual capacitor re-formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.

- **Electrical interference** or “noise” from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogation or programming of 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.
- **Electrosurgical cautery.** Do not use electrosurgery devices until the pulse generator’s tachyarrhythmia therapy is deactivated. If active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.
- **Diathermy.** Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.
- **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 may damage the pulse generator.** If lithotripsy must be used, avoid focusing near the pulse generator site.
- **Therapeutic ultrasound energy may damage the pulse generator.** If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site.
- **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 to avoid inadvertent tachycardia detection (sensing) or therapy.
 - Avoid direct contact between the ablation catheter and the implanted lead 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.

Home and Occupational Environments

- **Static 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 change. To prevent mode change in the presence of magnets, the Change Tachy Mode With Magnet feature may be programmed Off. 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 Phone

- Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices, since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Based on the literature and ICD implant experience, the following alphabetical list includes possible adverse events associated with implantation of a heart failure system:

- Acceleration of arrhythmias
- Air embolism
- Allergic reaction
- Bleeding
- Chronic nerve damage
- Death
- Elevated pacing thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Extracardiac stimulation
- Fluid accumulation
- Formation of hematomas or cysts
- Inappropriate shocks
- Infection
- Keloid formation
- Lead abrasion
- Lead discontinuity
- Lead migration/dislodgment
- Local tissue reaction
- Muscle and nerve stimulation
- Myocardial damage/irritability
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker mediated tachycardia
- Pneumothorax
- Potential mortality due to inability to defibrillate or pace
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins
- Shunting current or insulating myocardium during defibrillation with internal or external paddles
- Thromboemboli
- Venous occlusion
- Venous or cardiac perforation

Patients susceptible to frequent shocks despite antiarrhythmic medical management may develop psychologic intolerance to a implantable 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

Overview

The purpose of the VENTAK CHF/ CONTAK CD Biventricular Pacing study was to demonstrate that cardiac resynchronization therapy (CRT) slowed the progression of heart failure. The study was also designed to demonstrate safe and effective performance of the EASYTRAK[®] coronary venous pace/sense lead. A total of 581 patients were enrolled at 48 investigational centers in the United States from February 4, 1998 through December 8, 2000. Of these, 501 patients received an investigational system, 14 patients were withdrawn prior to surgery, and 66 patients were unable to have an investigational device placed.

Patients Studied

At the time of implant, patients who received the investigational system (84% male) had a mean age of 66 ± 10 years (range: 26–86 years) and a mean left ventricular ejection fraction

(LVEF) of $21 \pm 7\%$ (range: 5–35%). Electrocardiography showed mean QRS duration of 158 ± 26 ms (range: 120–264 ms) with intraventricular conduction delay patterns of left bundle branch block (57%), right bundle branch block (13%), and nonspecific (30%). Heart failure status (ischemic etiology = 69%) was characterized as NYHA class II (33%), class III (58%), and class IV (9%). Preimplant heart failure medications included ACE inhibitors or angiotensin receptor blockers (87%), diuretics (85%), digoxin (68%), and beta blockers (47%). All patients met conventional indications for an implantable cardioverter defibrillator (ICD) implant.

Objective

The primary therapy endpoint was the progression of heart failure, defined as the composite of all-cause mortality, heart failure hospitalization, and tachyarrhythmias requiring device therapy. Safety was assessed by severe device-related adverse events and operative mortality. Secondary therapy endpoints included functional status and quality of life. Secondary device endpoints included VF detection time and ATP conversion efficacy. The primary lead endpoints were chronic left ventricular pacing threshold, biventricular sensing, and biventricular lead impedance. Secondary lead endpoints included implant success rate.

Study Design

Patients were randomized on a 1:1 basis to either the investigational group [CRT + ICD + drugs, referred to as the "CRT" cohort] or to the control group [ICD + drugs, referred to as the "No CRT" cohort]. The study began with a crossover phase with 3-month follow-up and was changed to a parallel design with 6-month follow-up. The data from the first three months of the crossover phase were pooled with data obtained from the parallel phase.

Methods and Statistics

The sample size and statistical power consideration was calculated to enable comparison of the CRT and No CRT cohorts to detect a 25% reduction in heart failure progression with 80% power at a 0.05 level of significance. Enrollment and follow-up of 308 patients with 6-month data was required. The crossover phase (3-month follow-up) enrolled 248 patients and the parallel phase (6-month follow-up) enrolled 348 patients. Randomization per cohort of those patients who were implanted with the device was 248 patients to CRT and 253 patients to No CRT.

For assessing the therapy, $n = 501$ will be used based on patients who received the investigational system. For assessing safety, $n = 567$ will be used based on patients who underwent a surgical procedure for implant of the investigational system.

For assessing the EASYTRAK lead performance and lead safety, $n = 448$ will be used based on patients who received the EASYTRAK lead. For assessing procedure safety, $n = 517$ will be used based on patients who underwent a surgical procedure for implant of the EASYTRAK lead.

Results

Cardiac Resynchronization Therapy

The progression of heart failure was reduced by 18% ($p = 0.21$) as indicated by a composite index consisting of the following events, weighted in order of decreasing severity: all cause mortality, hospitalization for heart failure greater than 23 hours, and VT/VF therapy events. Supplementary analysis, which included heart failure exacerbations resulting in emergency room or outpatient interventions, demonstrated a 23% reduction ($p = 0.11$) in the progression of heart failure with CRT.

Functional Status and Quality of Life

CRT therapy was initiated one month after implant. Covariate analysis identified a subgroup of patients who remained in NYHA class III/IV after the one-month post-implant waiting period on heart failure medications alone. These patients exhibited the greatest improvement with

CRT when compared to the control (No CRT). Statistically significant and clinically important improvements were found after six months in peak VO₂ (2.1 ml/kg/min, p = 0.012), six-minute walk distance (48 m, p = 0.022), and Minnesota Living with Heart Failure score (-10.4 points, p = 0.029).

System Safety

System safety endpoints included the rate of severe, device-related adverse events; the rate of lead-related adverse events; and operative mortality. The results for all safety endpoints were within limits prospectively specified in the study design.

System, Device-Related, Severe Adverse Events

System, device-related events were those attributed to investigational devices, the implant procedure needed to implant investigational devices, or associated testing of the investigational devices. An adverse event was defined as "severe" if it led to death, permanent disability, hospitalization or prolonged hospitalization because of impending death or disability. A total of seven [1.2%, 95% CI (0.3–2.1%)] severe, device-related adverse events were reported in 567 patients.

Table 1 reports severe, device-related adverse events observed during the VENTAK CHF/CONTAK CD Biventricular Pacing Study.

Table 1. Severe, device-related adverse events (N = 567)

Adverse Event	# of pts (N = 567)	% of pts (95% CI)
Telemetry difficulty; device explanted	2	0.4 (0.0–0.9%)
Ventricular tachycardia during CPX testing	1	0.2 (0.0–0.5%)
Coronary sinus perforation	1	0.2 (0.0–0.5%)
Inappropriate shock due to oversensing	1	0.2 (0.0–0.5%)
Lead dislodgment	1	0.2 (0.0–0.5%)
Anaphylaxis in association with use of a pulmonary artery catheter	1	0.2 (0.0–0.5%)

All seven events were successfully resolved and none resulted in patient death or permanent disability.

Lead-related Adverse Events

Forty-nine lead-related adverse events were reported during the clinical investigation of the EASYTRAK coronary venous single-electrode pace/sense lead among the 448 patients who were implanted with an EASYTRAK lead. Twenty-seven procedure-related adverse events were reported among the 517 patients who underwent the implant procedure for an EASYTRAK lead. The overall lead-related adverse event rate was 13.9% [95% CI (10.9–16.9%)].

Table 2 reports lead-related adverse events and Table 3 reports procedure-related adverse events observed during the VENTAK CHF/CONTAK CD Biventricular Pacing Study.

Table 2. EASYTRAK Lead-related Adverse Events (n=448)

Adverse Event	# of pts (n = 448)	% of pts (95% CI)
Loss of capture/lead dislodgment	29 ^a	6.5% (4.2–8.8%)
Ventricular oversensing	10	2.2% (0.9–3.6%)
Extracardiac stimulation	8	1.8% (0.6–3.0%)
Insulation breach	2	0.4% (0.0–1.1%)

a. Twenty-five events were successfully corrected in a repeat procedure

Table 3. EASYTRAK Procedure-related Adverse Events (N = 517)

Adverse Event	# of pts (N = 517)	% of pts (95% CI)
Transient AV block	7	1.4% (0.4–2.4%)

Coronary venous dissection	5	1.0% (0.1–1.8%)
Coronary venous perforation	5	1.0% (0.1–1.8%)
Transient renal failure	4	0.8% (0.0–1.5%)
Pericardial effusion	2	0.4% (0.0–0.9%)
Finishing wire left in lead	1	0.2% (0.0–0.6%)
Right ventricular lead dislodgment	1	0.2% (0.0–0.6%)
Guide wire fracture	1	0.2% (0.0–0.6%)
Hypotension due to blood loss	1	0.2% (0.0–0.6%)

Operative Mortality

Operative mortality was defined as death from any cause within 30 days of implant. Operative mortality was 12/567 (2.1%). This rate is similar to that of patients who undergo implant of a conventional ICD when matched for heart failure severity and left ventricular ejection fraction.

Heart Failure Device (Pulse Generator) Performance

Mean detection time of induced VF was 2.2 seconds, which was within the limits specified at the outset of the study. The conversion rate of induced monomorphic ventricular tachycardia (MVT) was 64% and that of spontaneous MVT was 88%. The conversion rate of induced MVT was less than that hypothesized, but the conversion rate of spontaneous MVT is similar to that of commercially available ICDs.

Lead Performance

The mean chronic (> 12 months) pacing threshold (0.5 ms pulse width) of the EASYTRAK lead was 1.9 ± 1.3 V, mean chronic biventricular R-wave amplitude was 9.9 ± 4.5 mV, and mean chronic biventricular lead impedance was 352 ± 49 Ω .

The EASYTRAK lead was successfully implanted in 87% of patients who underwent the implant procedure with 71% of all patients attempted having acute pacing thresholds ≤ 2.5 V, biventricular R-wave amplitude ≥ 5 mV, and biventricular lead impedance ≥ 300 Ω first implant success rate). Success rate increased to 91 % with experience.

Table 4. Outcome of EASYTRAK Lead Implant Procedures (N = 517)

Outcome	Patients	%
Implanted	448	86.7%
Not implanted, anatomic considerations ^a	40	7.7%
Not implanted, lead dislodged while removing guide catheter	13	2.5%
Not implanted, adverse event related to lead placement ^b	6	1.1%
Not implanted, inadequate pacing thresholds	6	1.1%
Not implanted, adverse event unrelated to lead placement ^c	2	0.4%
Not implanted, extracardiac stimulation	1	0.2%
Not implanted, reason not stated	1	0.2%
Total	517	100%

a. Inability to access the coronary sinus or inability to advance the lead

b. Coronary venous dissection/perforation or transient AV block

c. Inability to place atrial pace/sense lead and venous perforation during subclavian vein puncture

The mean implant duration of the study in the 448 patients who received the EASYTRAK lead was 14.8 months (range: 0 to 27.1 months) with a cumulative implant duration of 548 patient-years.

Table 5. Lead Measurements by Follow-up Period

Time Post-Implant	LV Pacing Threshold (V)	BV R-wave Amplitude (mV)	BV Lead Impedance (Ω)
Implant	1.8 \pm 1.2	10.0 \pm 5.1	340 \pm 46
2 weeks	2.1 \pm 1.4	9.1 \pm 4.4	331 \pm 44
1 month	1.8 \pm 1.4	9.7 \pm 4.4	345 \pm 46
4 months	1.7 \pm 1.2	9.9 \pm 4.4	352 \pm 46
7 months	1.9 \pm 1.4	9.7 \pm 4.4	351 \pm 52
13 months	1.9 \pm 1.3	9.9 \pm 4.5	352 \pm 49

DEVICE FEATURES

By programming device parameters, the pulse generator is designed to treat heart failure by providing simultaneous biventricular electrical stimulation to synchronize ventricular contractions—restoring mechanical coordination to the pumping function of the heart. Left ventricular stimulation is delivered using a Guidant lead that is implanted in the coronary venous system. Also, the device can 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 ventricles. 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

Nominal Mechanical Specifications

	Dimensions W x H x D (cm)	Volume (cc)	Mass (g)	Maximum Shock Energy (J)	Lead Connectors ^{b, c}	Case Electrode Surface Area (mm ²)
CONTAK CD 1823 ^a	5.9 x 7.9 x 1.6	60	110	31	LV-1, IS-1, and DF-1	9464

a. This model pulse generator uses its case as a defibrillating electrode.

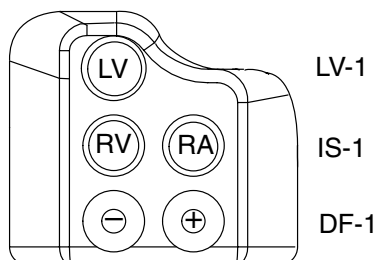
b. For lead compatibility information, refer to Appendix C; and to the non-Guidant lead system warning on page 2.

c. LV-1 refers to the Guidant LV™ proprietary connector. IS-1 refers to the international standard ISO 5841.3:1992. DF-1 refers to the international standard ISO 11318:1993.

Model 1823

Case material	Hermetically sealed titanium
Header material	Implantation-grade polymer
Power supply (WGL)	Two lithium-silver vanadium oxide cells

Lead Connections



Factory Nominal Parameter Settings

The pulse generator's parameters are preset at factory nominal values. Appendix A provides a complete list of parameters, available programmable values, nominal values and tolerances.

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 reformation. 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.

NOTE: 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.

Items Included

The following items are packaged with the CONTAK CD heart failure device:

- One vial of sterile mineral oil
- One torque wrench
- One hex wrench
- Product literature
- One Model 6627 Patient Data Disk
- One LV-1 plug

NOTE: Wrenches and the LV-1 plug are intended for one-time use only and should not be resterilized or reused.

Maintaining Device Effectiveness

Perform follow-up testing to maintain continued verification of detection and therapy efficacy. Refer to Chapter 11.

X-ray Identifier

Guidant pulse generators have an identifier that is visible on x-ray film (Figure 1). This provides noninvasive confirmation of the manufacturer and the pulse generator type. The identifier GDT 200 identifies the Model 2848 programmer software application needed to communicate with the CONTAK CD pulse generators manufactured by Guidant.

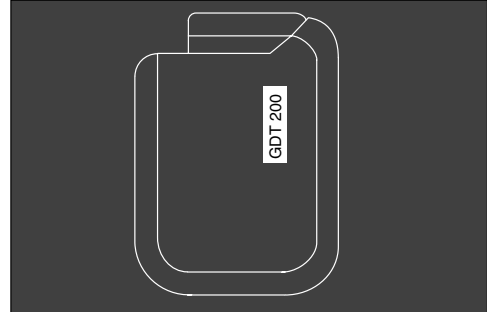


Figure 1. The pulse generator identifier is visible on x-ray as shown in this diagram.

Pulse Generator Longevity

Based on simulated studies, it is anticipated that a CONTAK CD pulse generator has an average longevity to ERI as indicated in Table 6. The longevity expectations, accounting for the energy used during manufacture and storage (approximately six months), apply at standard conditions using nominal settings. Values apply whether Electrogram Storage is programmed On or Off.

Table 6. Pulse Generator Life Expectancy Estimation (Implant to ERI)^a

Pacing and/or Sensing% (BiV Pacing)	VVI Mode (Years)	VVIR Mode (Years)	DDD Mode (Years)	DDDR Mode (Years)
	(Maximum Energy Charging Frequency is Quarterly)			
0% pacing	6.8	6.3	6.0	5.6
15% pacing	6.3	5.9	5.4	5.0
50% pacing	5.9	5.6	4.9	4.6
100% pacing	5.5	5.2	4.4	4.2

a. 60 ppm LRL; 3.5 V pacing pulse amplitude (atrium and ventricles); 0.4 ms pacing pulse width (atrium and ventricles); and 500 Ω pacing impedance (atrium), 300 Ω pacing impedance (ventricles).

NOTE: The energy consumption in the longevity table is based upon theoretical electrical principles and verified via bench testing only.

The longevity of the pulse generator decreases with an increase in the pacing rate, pacing pulse amplitude, pacing pulse width, percentage of paced to sensed events, or charging frequency, or with a decrease in pacing impedance. A maximum-energy shock is equal to approximately 5 days of monitoring.

Warranty Information

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

Patient Counseling Information

- The pulse generator is subject to random component failure. Such failure could cause inappropriate shocks, induction of arrhythmias or inability to treat arrhythmias, and could lead to the patient's death.
- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's heart failure system delivers a shock.
- Advise patients to contact their physician immediately if they hear tones coming from their device.

Patient Manual

A copy of the patient manual is provided with each device for the patient, patient's relatives, and other interested people. Discuss the information in the manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with operation of 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.

Chapter 2

USING THE PROGRAMMER/RECORDER/MONITOR

This chapter describes how to use the Model 2920 PRM System and the Model 2848 Software Application to communicate with the CONTAK CD pulse generator. The chapter is divided into three sections:

- Instructions for starting up the programmer and software application, and using the touchscreen and keys.
- Introduction to software application terminology and how to move around the software application.
- Instructions for communicating with the pulse generator (eg, interrogating, programming, therapy delivery), and quitting a session.

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

NOTE: *If using a Model 2901 or Model 2950 PRM to program the device, refer to the respective Programmer/Recorder/Monitor Operator's Manual.*

STARTING UP THE PROGRAMMER AND SOFTWARE

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.*

A communication session may be started between the PRM and the pulse generator by performing the following steps. (The operator's manual for the ZOOM Programming System contains a complete description of the programmer.)

1. Connect the power cord to the Model 2920 PRM and an outlet.
2. Raise the screen to a comfortable viewing angle.
3. Press the power switch to the On (I) position.
4. Wait for the Guidant Startup screen (Figure 2) to appear.

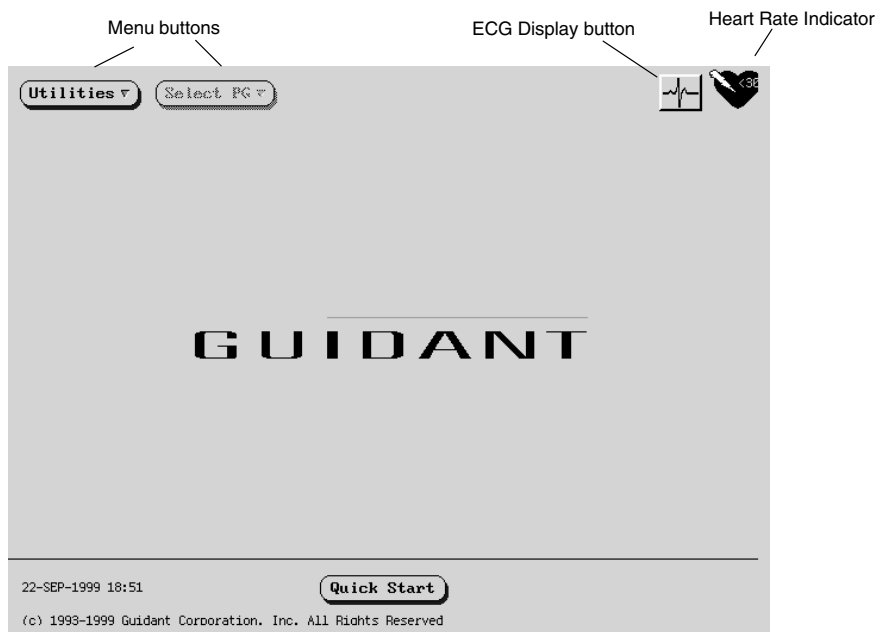


Figure 2. The Startup screen is displayed when the programmer is powered on.

The Startup screen displays the following information:

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

ECG Display

To display surface ECG signals on the PRM without device interrogation, select the ECG display button on the Startup screen (Figure 3). Refer to Appendix B for instructions on proper patient cable connections. The PRM can display three surface leads using six limb leads and one chest lead. The 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.

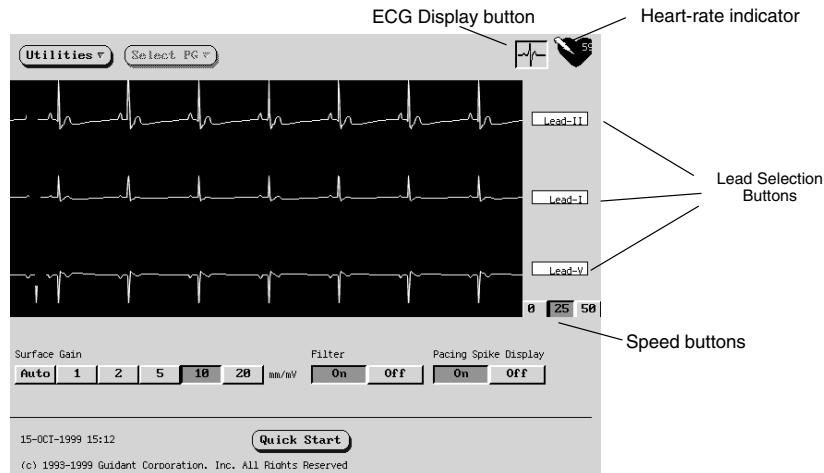


Figure 3. The ECG screen as accessed from the Startup screen.

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

- **Lead Selection Buttons**—Select each of the lead traces to be displayed.
- **Speed Buttons**—Select the desired speed button on the ECG display to freeze the traces (0) or to change the sweep speed.
- **Surface Gain**—Adjust the surface gain of the traces by selecting the appropriate value.
- **Filter**—Select the Filter ON setting to minimize noise on the surface ECG. The Filter OFF setting allows viewing surface ECGs with diagnostic filter settings.
- **Pacing Spike Display**—Program this feature ON to show detected pacing spikes, annotated by a marker on the top waveform.

NOTE: The values as set up on this screen will be the defaults used for the application traces.

To display a calibration pulse on the PRM, press the key labeled \square . Press the key labeled \square 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 B for instructions on connecting the PRM to the external recorder. Refer to the manual for the external recorder for instructions specific to its operation.

Quick Start

To automatically identify and interrogate the implanted 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 implanted device:

- **Application Startup in Progress**—If the software for the implanted device is installed on the PRM, the PRM will identify the device, open the correct application, and automatically interrogate the pulse generator.
- **Software not installed**—If the software application for the implanted device is available for the PRM but not installed on it, a message window will appear identifying the device and stating that the software is not installed on the PRM.

- **Software not available on PRM**—If an older model 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. The model number of the Model 2035 software module will also be identified.
- **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 Demo mode, use the Select PG button at the top of the screen to choose the pulse generator family instead of using the Quick Start button.

The Utilities Menu on the Startup Screen

Before accessing the pulse generator software application, you may select the Utilities menu (Figure 4) to access programmer information and clock and disk functions. To view or change the values, select the appropriate function from the Utilities menu.

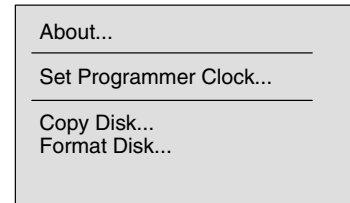


Figure 4. The Utilities menu.

The About Utility

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

Select the Institution field 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 About screen can be changed prior to accessing the application software. The institution name also is displayed in the heading of printed reports.

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

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

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

The Set Programmer Clock Utility

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 (Figure 5), which includes a display of real-time seconds, will appear. Change the values by selecting an up- or down-pointing arrow. When the desired values are displayed, select the Set Programmer Clock button to confirm the new date and time. (To cancel any changes prior to confirming the new values, select the Cancel button.)



Figure 5. The Set Date and Time window.

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

Copy Disk

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

1. Select the Copy Disk option from the File menu. A message will appear instructing the user to insert the source disk.
2. Insert into the disk drive of the PRM the disk that contains the information to be copied (the source disk) and select the Read Disk button. The 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 reformatting and erasing data from a patient data disk.

1. Insert a patient data disk into the disk drive of the PRM.
2. Select the Format Disk option from the File menu. Formatting a disk will remove all data from the disk.
3. When formatting is complete, insert another disk and select the Format Another Disk button or select the Cancel button to exit the format feature.

The Select PG Option on the Startup Screen

This option allows the device to be selected manually. Use this method of device selection to access the Demo (NO PG) mode. Otherwise, use the Quick Start feature described earlier in this chapter.

1. To display the desired software application, which allows communication with a pulse generator family, select the Select PG button.
2. The names of the available pulse generator families will appear. Select the applicable family.
3. A message window will appear. Choose Interrogate either by selecting the Interrogate button on the message window or by pressing the INTERROGATE key on the PRM. The base window will appear (Figure 6).

To become familiar with this software without interrogating a pulse generator, select the Close button. The NO PG icon will appear at the top of the base window and the message window will disappear. The windows displayed during the NO PG (demonstration) mode reflect the CONTAK CD features and programmable values.

Once familiar with the software, to proceed with an interrogation session refer to the section "Interrogating the Pulse Generator." To read data from a patient data disk, refer to the "Read Disk" section of Chapter 6.

NOTES:

- *STAT PACE, STAT SHOCK, and DIVERT THERAPY commands are functional in NO PG mode if the telemetry wand is positioned over the pulse generator.*
- *The NO PG mode will be exited if INTERROGATE or Read Disk commands are initiated.*

INTRODUCTION TO SOFTWARE TERMINOLOGY AND HOW TO MOVE AROUND

Base Window (CONTAK CD Screen)

The base window will always be displayed while interacting with the software. The sections of the base window are labeled in Figure 6 and described below.

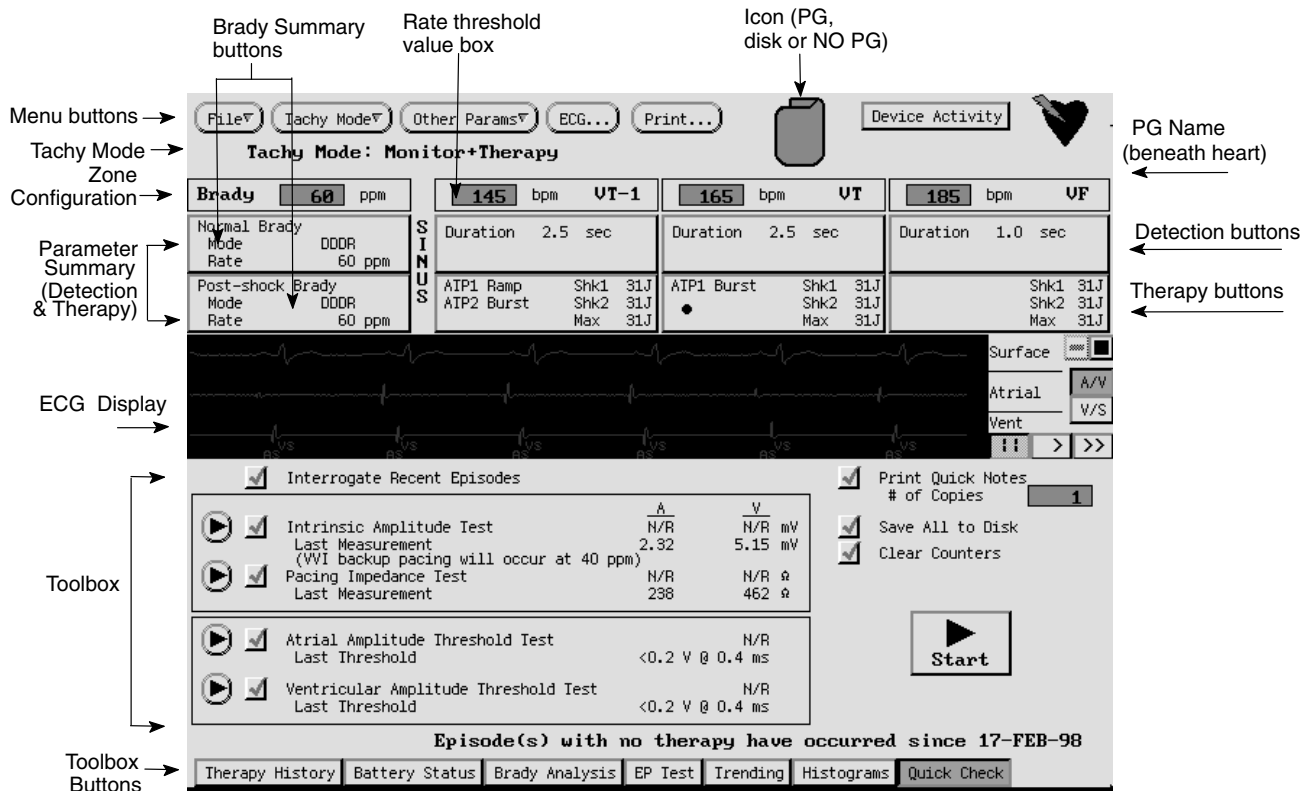


Figure 6. The Base window and its elements.

Menu Buttons

Menu buttons are located at the top of the base window. Select a menu button to display options for other features that are not found on the base window (Figure 7). Information about each menu option appears in the chapters that describe the respective option's feature.

To remove the menu options without selecting an option, touch the stylus to the screen outside the menu.

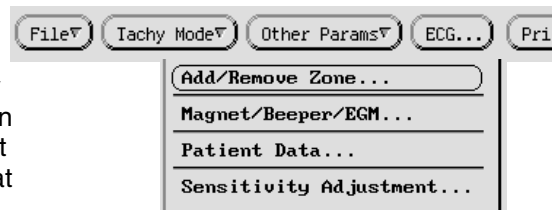


Figure 7. A list of options is displayed when a menu button is selected.

Icon

One of three icons appear in this location: a pulse generator when an interrogation has been performed, a disk when data has been retrieved only from a patient data disk (ie, no interrogation), and the words NO PG which appear when the application is initially accessed and prior to interrogating or reading a disk. The NO PG mode allows familiarization with the software without having to interact with a pulse generator.

Tachy Mode

This area of the base window indicates the current mode of tachyarrhythmia therapy. Refer to the section "Accessing the Tachy Mode Parameter" in Chapter 3.

Zone Configuration

This area indicates the number of zones programmed in the pulse generator. Each zone is identified by a box with the name of the zone (Brady, VT-1, VT, or VF) and its rate threshold. The rate threshold can be changed in the rate threshold value box. The zone configuration can be changed from the Other Params menu as described in the section “Accessing Zone Configuration and Rate Parameters” in Chapter 3.

Brady Summary

This area displays the normal and post-shock bradycardia mode and rate parameters. Additional bradycardia settings may be viewed and changed by selecting the brady summary buttons.

Parameter Summary (Detection and Therapy)

This area displays a summary of the detection and therapy parameters programmed for each tachyarrhythmia zone. Parameter settings can be changed by opening a detection or therapy **window** using the Detection and Therapy buttons (the rectangles located under each zone name). 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.

ECG Display

This display shows real-time surface ECG traces, electrograms, and markers. Refer to Chapter 6—Programmer Activated Features for details.

Toolbox and Toolbox Buttons

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 Quick Check tool is selected when the application is initially accessed). Refer to the following chapters for details about each tool—Chapter 8 for Therapy History, Chapter 6 for Battery Status, Chapter 5 for Brady Analysis, Trending, Histograms, and Quick Check, and Chapter 7 for EP Test.

General Windows Functions

Windows contain information relevant to a particular function and 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 Close or Cancel button. Refer to Figure 8.

Multiple windows can be open at one time, overlapping one another. In an active (selected) window, changes can be made to the values, and buttons within that window can be selected. To view open windows that are partially covered, touch the stylus to any part of the partially covered window. The window will become completely visible and active. To view opened windows that are completely hidden by other windows, move or close the windows that are blocking the view of the desired window (refer to the next section “Moving Windows”).

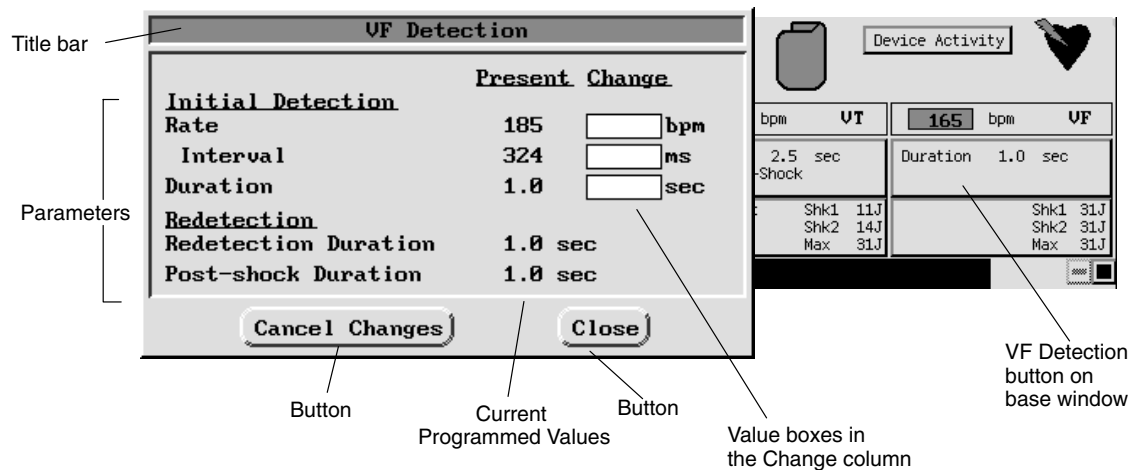


Figure 8. Illustration of a typical window.

To access and interact with windows follow these steps:

1. Select a Detection (or Therapy) button for a zone to display its window (Figure 8).
2. Select a value box in the Change column to display a palette and select the value.

Copy button: There is a simple way to duplicate parameter values from one window to another. This feature is available from the bradycardia pacing and tachycardia therapy windows.

- a. Select the Copy button. A window will appear with a Copy From and a Copy To column with buttons.
 - b. Select the desired buttons in both columns and then select the Copy button.
3. To clear all values in the Change column, select the Cancel Changes button at the bottom of the window.
 4. To program **all** changed values into the pulse generator, refer to the section “Programming the Pulse Generator” later in this chapter. The changed values will remain in the value boxes until programmed. An interrogation does not affect the value boxes.
 5. To remove the window from the display, select the Close button.

Moving Windows

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

1. Touch the stylus to the title bar at the top of the window.
2. An outline appears around the window to indicate the window can be moved. While touching the stylus to the window outline, drag the window to the desired location.
3. Lift the stylus when the outline is in the desired location. The window will move to and remain in that location until it is moved again, or until the window is closed.

Message Windows

Message windows may appear during a communication session. Some require action before continuing the session, while others simply relay information without requiring further action. The messages indicate the required action, if any. Many message windows have a Cancel or Close button at the bottom of the window. Select this button to cancel the action being performed as explained in the message and/or close the window. Figure 9 is an example of a message window.



Figure 9. A typical message window.

PRM Keys

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 five 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 (Figure 10).

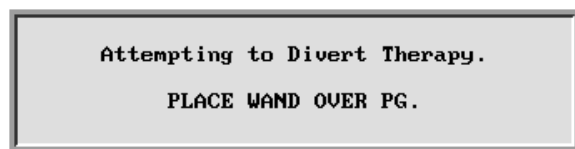


Figure 10. Divert message window.

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 five 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; and 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 (Figure 11).

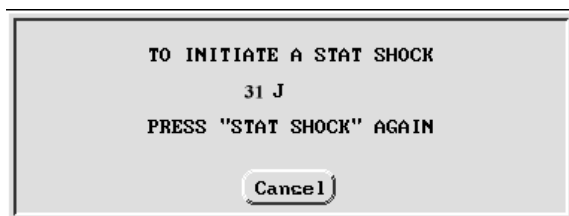


Figure 11. Stat Shock message window.

- 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 previous section, “Divert Therapy”.

- Subsequent STAT high-energy 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 Chapters 3 and 4 for information about detection and therapy.)

STAT PACE

Emergency bradycardia pacing using a STAT PACE command function sets the bradycardia operation to parameters (Table 7) intended to ensure capture and keep the patient stable.

Table 7. Emergency Bradycardia Pacing Parameter Settings (STAT PACE)

Normal Pacing parameters		Post-shock Brady Pacing parameters*	
Brady mode	VVI	Post-shock mode	VVI
Brady rate	60 ppm	Post-shock rate	60 ppm
Amplitude	7.5 V	Amplitude	7.5 V
Pulse width	1 ms	Pulse width	1 ms
Paced refractory	320 ms	Paced refractory	320 ms
Noise response	Inhibit	Noise response	Inhibit
Hysteresis	Off	Hysteresis	Off

*Pacing delay and pacing period are not reprogrammed during STAT PACE delivery. They remain the same as programmed prior to the STAT PACE command.

- Position the telemetry wand within range of the pulse generator.
- Press the STAT PACE key on the PRM panel. A message window (Figure 12) indicates the STAT PACE values.
- 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 displayed in the Present column of the Brady Pacing window, which is also visible.

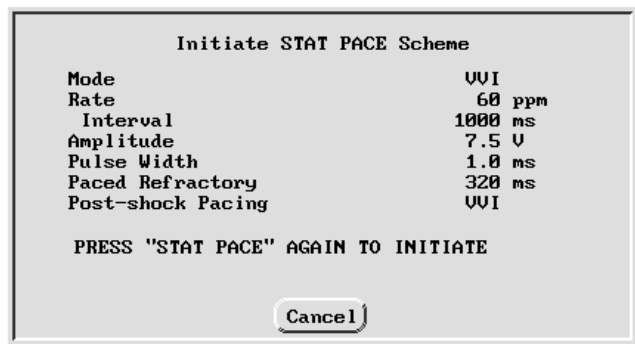


Figure 12. STAT PACE parameters.

- Select the Close button on the message window. The Brady Pacing and Post-shock Brady Pacing parameters window will be on the screen.
- 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.

PROGRAMMING AND INTERROGATION

The pulse generators are programmed through noninvasive radio frequency (RF) telemetry using the Guidant Model 2920 Programmer/Recorder/Monitor equipped with the Model 2848 Software Application and a Model 6577 Sterilizable Telemetry Wand.

During a programming sequence, the telemetry wand is positioned over the pulse generator. A series of coded RF signals sent to the pulse generator unlocks each programmable parameter.

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

Establishing Telemetry Communication

Telemetry communication is required to direct such commands from the PRM as INTERROGATE, PROGRAM, STAT SHOCK, STAT PACE, and DIVERT THERAPY, which are described in this chapter. Telemetry communication also is required to perform other features such as EP testing, lead impedance and threshold tests, device activity monitoring, and capacitor re-formation. These features are described in later chapters.

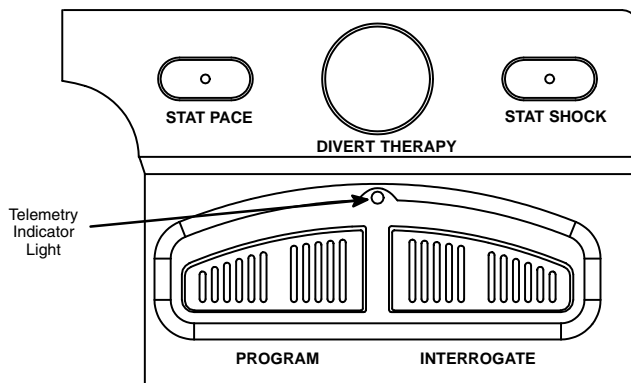


Figure 13. A portion of the PRM front panel. Activation of these keys requires telemetry communication.

NOTE: *STAT PACE, STAT SHOCK, DIVERT THERAPY, and INTERROGATE commands are functional during NO PG mode.*

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

1. Connect the telemetry wand to the PRM.
2. Position the wand over the pulse generator.
3. Direct a command from the PRM to the pulse generator (eg, INTERROGATE or PROGRAM). The telemetry indicator light (Figure 13) on the PRM panel will illuminate when telemetry is occurring or being attempted.

NOTES:

- *Even if the wand is correctly positioned, the telemetry indicator light illuminates only while telemetry communication is occurring with the pulse generator. The light extinguishes as soon as the communication sequence is successfully completed or canceled.*
- *Status windows might appear on the screen during a communication session to indicate that the pulse generator is out of range. Reposition the wand to re-establish communication or try turning the telemetry wand over. (When event markers or intracardiac electrograms are activated, a message will not appear, but the event marker or intracardiac electrograms transmission will be interrupted until telemetry is restored.)*

Interrogating the Pulse Generator

Pulse generator interrogation is the first step in any follow-up session. An initial interrogation retrieves the following information from pulse generator memory: detection and therapy,

parameter settings, patient data, and battery status. When the Quick Start button is selected on the Startup window, the PRM will identify the device, open the correct application, and automatically interrogate the pulse generator.

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

1. To initially interrogate the pulse generator, select the Interrogate button on the Sign-on screen (or the INTERROGATE key on the PRM). To perform interrogations during a session, press the INTERROGATE key on the PRM panel. A message window will appear.
2. Position the telemetry wand within telemetry range of the pulse generator. 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 base window and will remain there until the session is ended.

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

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

Load Initial 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. The affected parameters are bradycardia and tachycardia detection and therapy parameters (including number of zones); and magnet, beeper, EGM, and sensitivity features. **Note that the initial Tachy Mode setting is not reloaded and would require a separate action to do so.**

1. Select the Load Initial Values option from the File menu. A window appears with the options Load Brady Parameters, Load Tachy Parameters, and Load Magnet/Beeper/EGM/Sensitivity Parameters with adjoining boxes containing check marks. The boxes can be selected at anytime to make the check visible or not to indicate which options to reload.
2. Select the Confirm button to load the initial values of the checked options. The reloaded values appear in the Change column of the affected windows (eg, detection, therapy) and hatch marks in the base window summary windows indicate a change has been made.
3. The Cancel button on the window can be selected to delete the values from the Change column or to just close the window if Confirm had not been selected.
4. To actually change the values in the pulse generator, press the PROGRAM key on the PRM.

New Patient

The File menu offers a New Patient option that ends a current patient session, and allows a different device to be interrogated or a different patient’s data disk to be read without having

to exit the CONTAK CD/VENTAK CHF software application. If a second device is interrogated or a disk is read without ending a previous session, a message will appear indicating that the current session needs to be terminated.

1. Select the File menu from the base window.
2. Highlight and select the New Patient option. A message will appear indicating that the application is being initialized.

NOTES:

- *If therapy history data has 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” in Chapter 6.*
 - *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 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 base window will be displayed, and the options to select an INTERROGATE, Close, or Read Disk button will be available.

Quit a Session

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

1. Select the File menu from the base window.
2. Highlight and 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.)

NOTE: See the notes above in the “New Patient” section.

3. Select the Quit button to end the session and return to the startup screen. (Selecting the Close button will not end the session.)

Changing Parameter Values

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

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

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

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

Programming the Pulse Generator

When changes have been made to parameter values or zone configurations, the data appears beneath hatch marks on the screen until programmed into the pulse generator. When the PROGRAM function is initiated, **all changed data (from all windows) will be programmed.**

NOTE: *When the Tachy Mode is changed, the mode is immediately programmed. The PROGRAM key need not be selected. Refer to the section "Accessing the Tachy Mode Parameter" in Chapter 3.*

Use the following procedure to program the pulse generator parameters:

1. Make the desired parameter changes.
2. Position the telemetry wand within telemetry range of the pulse generator.
3. Select the PROGRAM key on the PRM panel. A message window will appear and the scale in the message window will indicate the progress of the programming.
4. 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 a message to appear, indicating that there is telemetry noise, or that the wand has been moved out of telemetry range. Reestablish telemetry communication to continue the programming sequence. If communication cannot be reestablished or if you wish to halt the sequence, select Cancel in the message window to stop the programming sequence.

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

SUMMARY

This concludes the overview of the PRM system and the software application. The remaining chapters will describe the features and functions of the pulse generator and how to access those features and functions using the PRM system and software.

Chapter 3

TACHYARRHYTHMIA DETECTION

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.

Tachy Mode Parameter

The Tachy Mode parameter allows the device to be programmed to one of three modes: Off, Monitor Only, and Monitor + Therapy. Refer to Table 8 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.

Table 8. Device Performance in the Three Tachy Mode Settings

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

a. While the pulse generator is in power-saving mode, the Tachy Mode displays as Storage. Once the pulse generator has been taken out of Storage mode, the programmer cannot return it to that mode. Refer to the section “Factory Preset Parameters” in Chapter 1.

b. Not all forms of EP tests are available in every mode. Refer to Chapter 7.

Rate Sensing

All detection decisions are based on cardiac cycle length. The pulse generator uses extended 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.

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 (Figure 14):

- 86 ms following an atrial sensed event
- 135 ms following a ventricular sensed event or a capacitor charge
- 250 ms following shock delivery (sensing is ignored in the atrium and both ventricles)

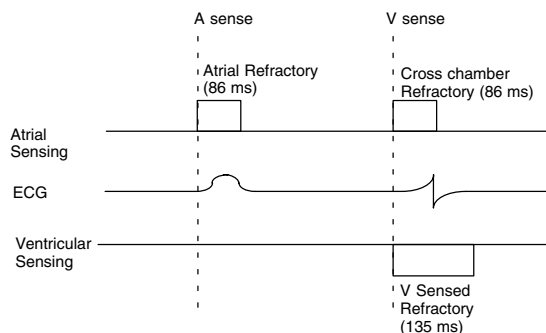


Figure 14. Nonprogrammable refractory periods.

Refer to Figure 58 in Chapter 4 for an illustration of the refractory period following a capacitor charge. Refer to Chapter 5, Bradycardia Pacing Therapy, for an explanation of the programmable, paced refractory period and noise windows.

Rate Thresholds and Zones

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. Figure 15 illustrates the various configurations and respective nomenclature for the zones.

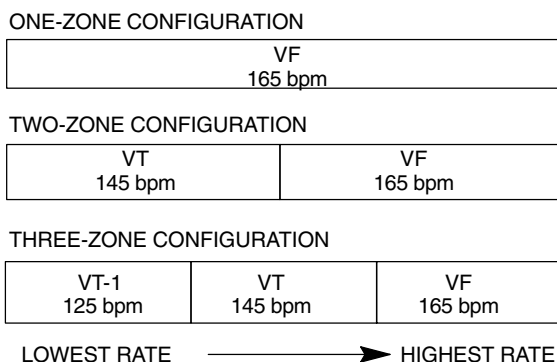


Figure 15. From one to three zones may be programmed. The Rate thresholds shown illustrate that each zone must differ by at least 20 bpm.

The Rate parameter is programmable from 90–250 bpm. The highest threshold limit for a one-zone configuration is 220 bpm, and for a two- or three-zone configuration is 220 bpm in the VT zone and 250 bpm in the VF zone. Adjacent zone's rate thresholds must differ by at least 20 bpm. The required differences between tachycardia rate thresholds and bradycardia or postshock bradycardia rates are shown below. Refer to Chapter 5 for a description of bradycardia rate parameters.

Dual Chamber Modes

Lowest Tachy Zone must be ≥ 5 ppm higher than Maximum Tracking Rate or Maximum Sensor Rate

Single Chamber Adaptive-rate Modes

Lowest Tachy Zone must be ≥ 5 ppm higher than Maximum Sensor Rate

Single Chamber Nonadaptive-rate Modes

Lowest Tachy Zone must be ≥ 10 bpm higher than the Lower Rate Limit

Initial Detection

Initial detection criteria consist of the programmable parameters Rate and Duration. The detection enhancements, Onset, Stability, and Sustained Rate Duration may be used during initial detection to add specificity beyond Rate and Duration. In addition, AFib Rate Threshold and V Rate > A Rate parameters are available during initial detection. 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, b) the zone's Duration expires, c) detection enhancements are satisfied (if programmed) and d) the **last detected interval** remains in the zone. If the last detected interval does not remain 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

Correct 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 16).

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.

One-zone configuration
 VF Zone RATE = 150 bpm = 400 ms
 S = Slow F = Fast

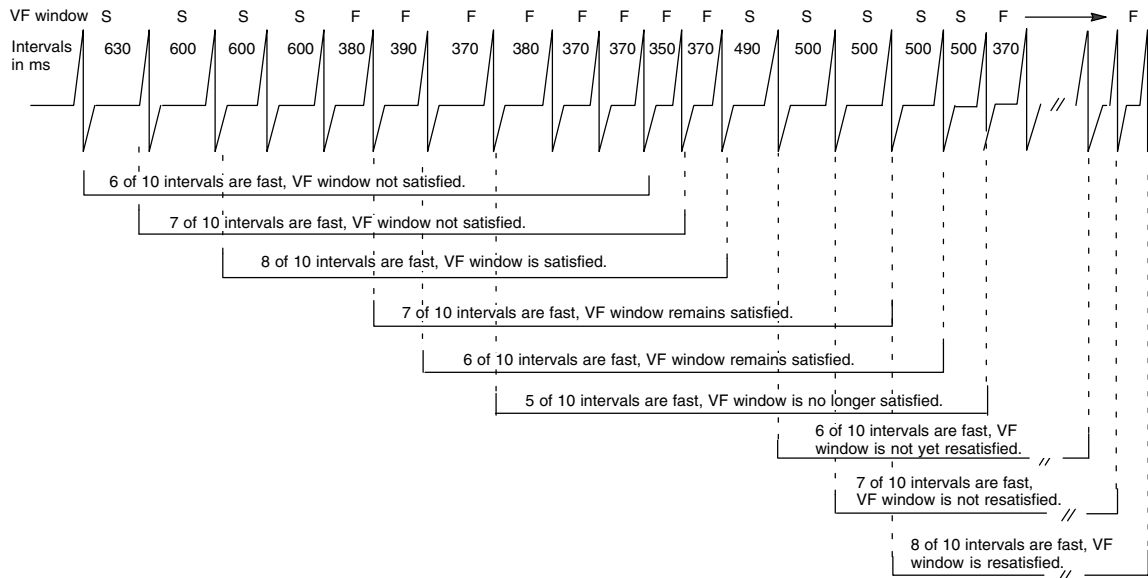


Figure 16. A detection window becomes satisfied when 8 out of the most recent 10 intervals are classified as fast. The detection window remains satisfied as long as 6 of 10 intervals are classified as fast.

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 17).

VF Zone RATE = 200 bpm = 300 ms
 VT Zone RATE = 150 bpm = 400 ms
 S = Slow F = Fast

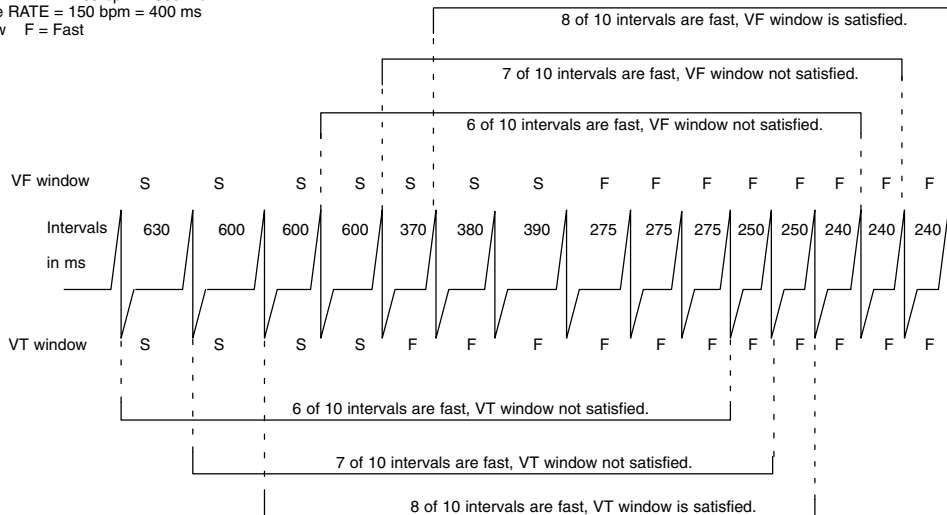


Figure 17. Interaction of detection windows in a two-zone configuration. Each interval is compared to both the VT zone and VF zone rate thresholds to determine whether it is fast or slow in each zone's detection window.

Duration Parameter

Each zone has an associated duration timer (length of time) that ensures 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

the last detected interval remains in that zone, detection is considered met; and therapy is initiated (assuming no detection enhancements are programmed) (Figure 18). If the last detected interval does not remain 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 19). 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 20). It will start again only if the detection window becomes resatisfied.

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.

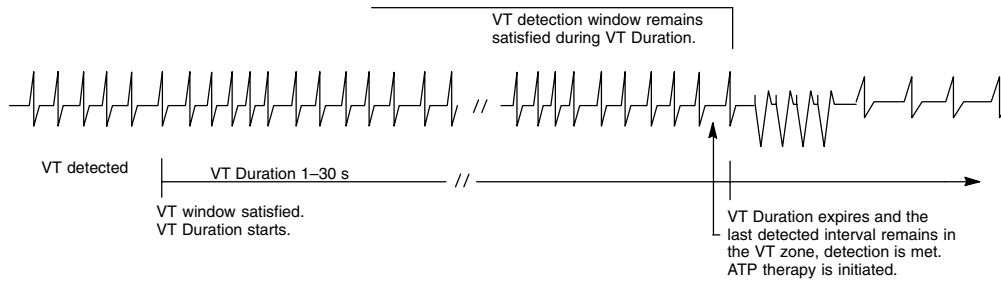


Figure 18. Duration starts when a window becomes satisfied and continues to elapse as long as the detection window remains satisfied. Detection is met when Duration is expired, and the last detected interval is in the same zone.

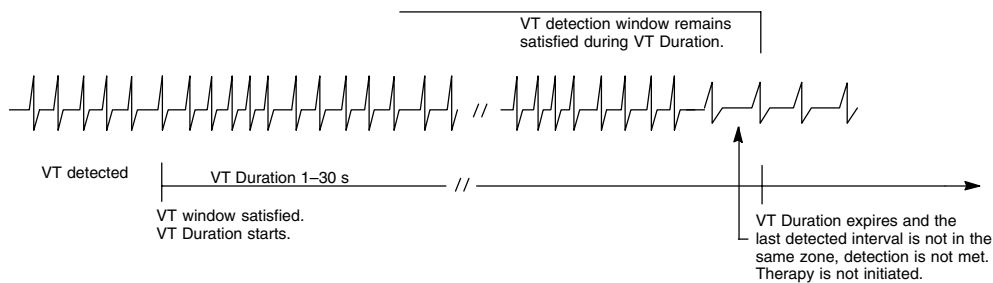


Figure 19. The last detected interval is in a different zone (in this example, it is classified as slow and in a lower zone), so detection is not satisfied. Therapy is not initiated.

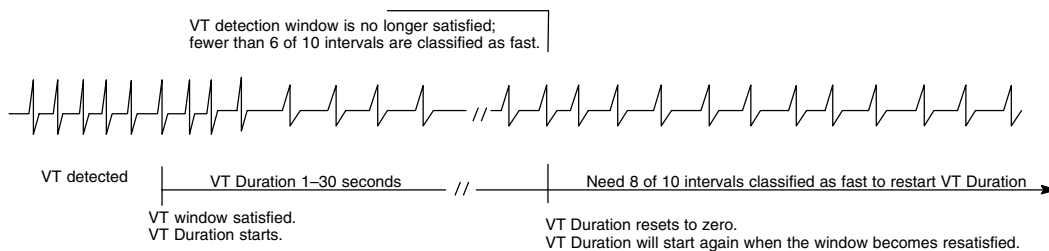


Figure 20. Duration resets during the duration period when the window is no longer satisfied.

A Duration is programmed for each zone. Different values are available, depending on the configuration programmed (overall, the range is 1–60 seconds—refer to Appendix A). Figure 21 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.

ONE-ZONE CONFIGURATION

VF 1–15 s

TWO-ZONE CONFIGURATION

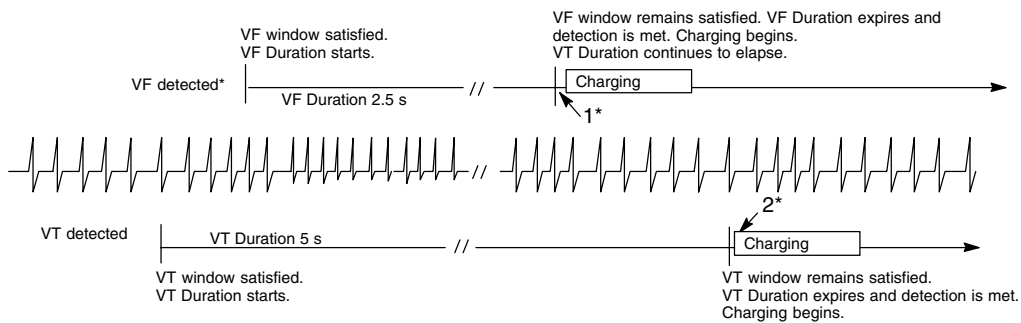
VT 1–30 s	VF 1–15 s
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THREE-ZONE CONFIGURATION

VT-1 1–60 s	VT 1–30 s	VF 1–15 s
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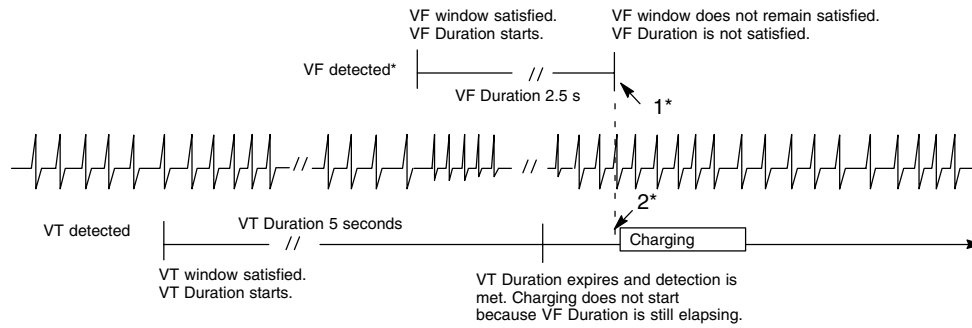
Figure 21. Each zone's detection window has an associated duration timer. The programmable ranges (in seconds) for each zone in various configurations are indicated.

Duration in a Multizone Configuration. Duration timers run independently 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 22 and Figure 23 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.



* 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 is satisfied, 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 22. 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 is satisfied. As long as the VT window remains satisfied, charging begins at the corresponding point 2 to deliver the VT therapy. If the VT window does not remain satisfied, charging would not start.

Figure 23. Interaction of Duration parameters in a two-zone configuration when charging is delayed after the VT zone's duration timer is satisfied. 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 Chapter 4—Tachyarrhythmia Therapy 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 rhythm is analyzed for onset, stability, ventricular rate greater than atrial rate, and AFib threshold, 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 Chapter 8 for details about electrogram storage and therapy history data.

Episodes can be classified as treated or nontreated (see Figure 24 through Figure 28).

- A treated episode is one in which the detection window remains satisfied and therapy is delivered.
- A nontreated episode is one in which a detection window is initially satisfied but therapy is not delivered, because the detection window drops out before Duration is satisfied or therapy was withheld for some reason. (Nontreated episodes are described in more detail in Chapter 8—Therapy History.)

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 where the pulse generator recognizes that all detection windows are no longer satisfied. The end-of-episode time interval is intended to allow the patient to stabilize before initial detection and initial therapy are 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 9). 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 either when therapy is delivered or all windows are not satisfied (see Figure 28).

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

Table 9. Episode Classification

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 (other than slaved induction) is attempted before the end-of-episode time-out, the episode is terminated immediately.

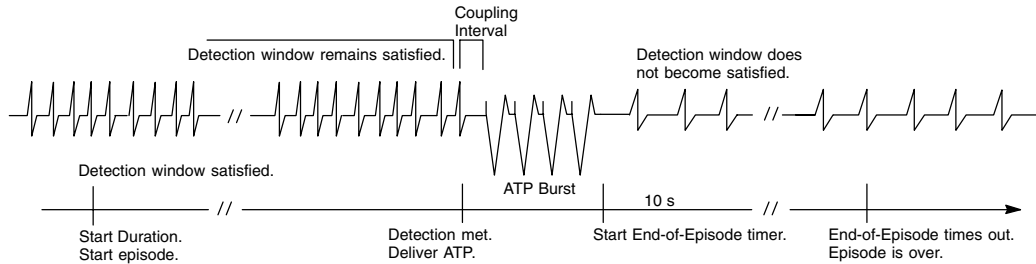


Figure 24. Treated episode when Tachy Mode is Monitor + Therapy, and ATP therapy is delivered.

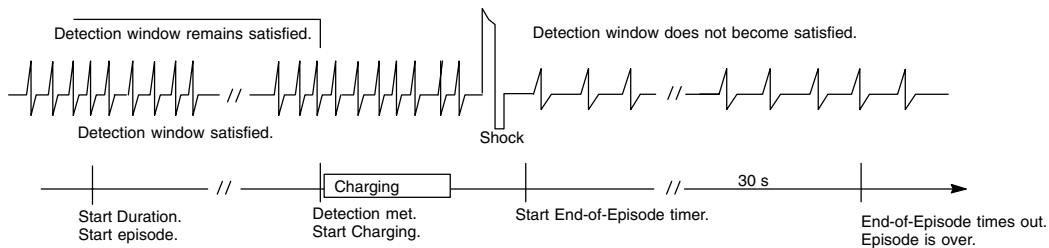


Figure 25. Treated episode when Tachy Mode is Monitor + Therapy, and shock therapy is delivered.

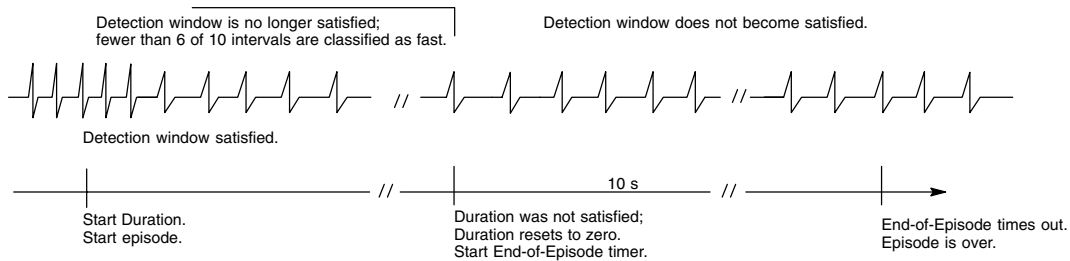


Figure 26. Nontreated episode when Tachy Mode is Monitor + Therapy or Monitor Only, and Duration is not satisfied.

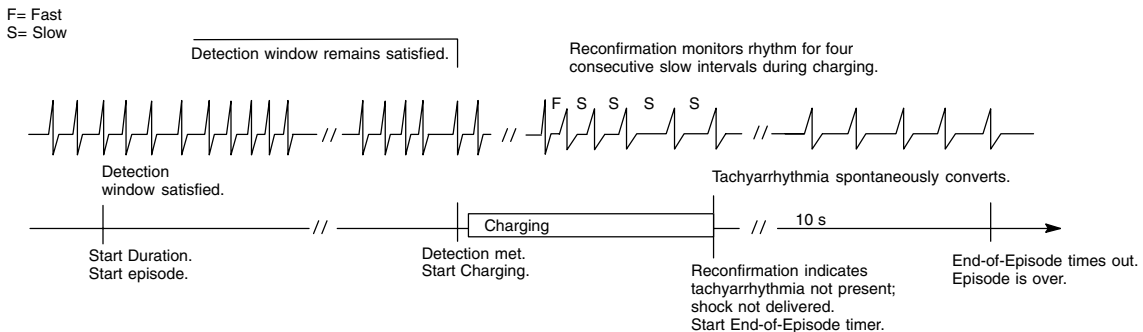


Figure 27. Nontreated episode when Tachy Mode is Monitor + Therapy, and charging is stopped (prior to shock therapy delivery). This example assumes Committed Shock is programmed to No.

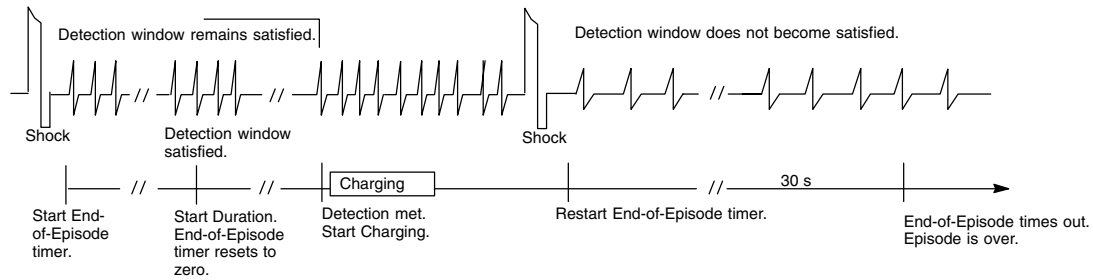


Figure 28. Treated episode when Tachy Mode is Monitor + Therapy and the End-of-Episode timer is reset to zero when a detection window becomes satisfied after therapy delivery prior to the episode time-out being reached. In this example, two shocks were delivered in the episode.

Detection Enhancements

Detection enhancements may be programmed as therapy inhibitors, inhibitor overrides, and therapy accelerators. These same enhancements (except Onset) are independently programmable as post-shock parameters. Figure 29 illustrates in which zones the detection enhancements may be programmed.

- **Therapy Inhibitor**—causes the delivery of a therapy to be delayed or inhibited if certain enhancement criteria are not satisfied at the end of duration.
 - Onset can be programmed to inhibit therapy if the patient’s heart rate increases gradually.
 - The Stability parameter can be programmed to inhibit therapy delivery if the ventricular rhythm is unstable. The Post-shock Stability parameter can be independently programmed to inhibit additional therapy following shock delivery. (Refer to the “Redetection” section of this chapter.)
 - The AFib Rate Threshold and corresponding AFib Stability enhancements can be programmed to inhibit ventricular therapy if the atrial rhythm is fast and the ventricular rhythm is unstable.
- **Inhibitor Override**—causes the therapy inhibitors to be bypassed if certain criteria are satisfied.
 - The V Rate > A Rate enhancement can be used to override the therapy inhibitors, Onset and Stability, if the ventricular rate is greater than the atrial rate.
 - The Sustained Rate Duration (SRD) parameter enables the pulse generator to override the therapy inhibitors, Onset and Stability, if the high rate continues over an extended time period. An independent Post-shock SRD is also available.
- **Therapy Accelerator**—accelerates the sequence of therapy by skipping over or interrupting an ATP scheme to initiate charging for the first programmed shock (which may be low or high energy) for the rate zone.
 - The Stability parameter can be programmed to accelerate delivery of shock therapy if the analysis of the ventricular rhythm is declared to be unstable. Refer to the section, “Stability Analysis,” for further discussion on stability.

ONE-ZONE CONFIGURATION

VF No detection enhancements

TWO-ZONE CONFIGURATION

VT	VF
Onset Stability as an Inhibitor* SRD AFib Rate Threshold/AFib Stability V Rate > A Rate or Stability as an Accelerator*	No detection enhancements

* Stability analysis cannot be programmed as both an inhibitor and an accelerator in the same zone.

THREE-ZONE CONFIGURATION

VT-1	VT	VF
Onset Stability as an Inhibitor SRD AFib Rate Threshold/AFib Stability V Rate > A Rate	Stability as an Accelerator	No detection enhancements

Figure 29. Detection enhancements may be programmed in multizone configurations.

Onset

The Onset enhancement measures the rate of transition in ventricular rhythm from slow rates to tachycardia. It is intended to differentiate physiologic sinus tachycardias, which typically begin slowly, from pathologic tachycardias, which typically begin abruptly. With Onset enabled, the device inhibits therapy in the lowest tachycardia rate zone if the rate increase is gradual.

The Onset enhancement is measured using only the ventricular rate, and it may be programmed as a percentage of cycle length, or in absolute time, with programmable ranges from 9–50% or 50–250 ms or Off. It is limited to the lowest zone of a multizone configuration. The selected Onset value represents the minimum difference that must exist between intervals that are below the lowest programmed rate threshold and intervals that are above the lowest programmed rate threshold. The pulse generator performs Onset calculations (even when it is programmed Off) for all episodes except induced episodes, and stores the results in therapy history (refer to Figure 101 in Chapter 8—Therapy History). This stored data (in ms and %) is useful in selecting an appropriate Onset value.

When a detection window becomes satisfied (episode declared and memory allotted for history data storage), the pulse generator begins calculating for sudden onset in a two-stage sequence. Stage one measures the intervals prior to the start of the episode and locates the pair of adjacent intervals where the cycle length changed the most. Stage two then compares additional intervals to verify that the Onset criterion has been met; if the change in cycle length is equal to or greater than the programmed Onset threshold, onset is declared sudden. If either stage indicates a gradual onset, initial therapy will be inhibited in the lowest zone. Therapy will only be delivered if the rate accelerates to a higher zone, the SRD timer expires, or information from the atrial lead determines that the ventricular rate is faster than the atrial rate (V Rate > A Rate programmed on).

Stability Analysis

The goal of stability analysis is to distinguish unstable ventricular rate rhythms from stable ventricular rate rhythms. This is accomplished by measuring the degree of variability of the tachycardia R–R intervals. This degree of variability, when used by itself, may allow the device to distinguish conducted atrial fibrillation (which may produce greater R–R variability) from monomorphic VT (which is typically stable and pace-terminable), and also may help differentiate MVTs from VF and polymorphic VTs (which are typically not pace-terminable). Based on this differentiation, the physician may choose whether or not to deliver therapy by

programming Stability to Inhibit If Unstable, or choose the type of therapy that should be delivered by programming Stability to Shock If Unstable.

The stability analysis algorithm calculates R–R interval differences. These differences are calculated throughout duration, and an average difference is also calculated. When Duration is satisfied, rhythm stability is evaluated by comparing the current average difference to the programmed stability thresholds. If the average difference is greater than the programmed Stability threshold, the rhythm is declared unstable. Programmable values range from 6–120 ms or Off. Independent thresholds are available for each of the Stability functions.

The pulse generator performs Stability calculations for all episodes (even when Stability is programmed Off) and stores the results in therapy history (refer to Figure 101, the Episode Detail window, in Chapter 8—Therapy History). This stored data is useful in selecting an appropriate Stability value.

Stability Programmed to Inhibit if Unstable. When programmed to Inhibit If Unstable, the Stability parameter may help to identify rhythms of ventricular origin, such as MVT, which could be pace terminated. If a rhythm is declared stable when duration is met, programmed therapy will be delivered with no further delay. If the rhythm is declared unstable, the parameter can be used to prevent (inhibit) the pulse generator from initiating therapy. This is useful for rhythms originating in the atrium that may appear unstable in the ventricle when the rate exceeds the lowest rate threshold, but the physician does not intend for those rhythms to be treated by the pulse generator. At the end of initial duration, if a tachycardia is declared unstable and therapy is inhibited, the pulse generator continues to reevaluate for stability on each new detected interval (Figure 30). It will reevaluate for stability as long as the zone’s detection window remains satisfied, or until the Sustained Rate Duration (SRD) timer has expired (if programmed On). If the rate becomes stable before the SRD timer has expired, the programmed therapy is initiated immediately.

Programming Stability to Inhibit If Unstable is limited to the lowest zone of a two- or three-zone configuration, and may be used in conjunction with SRD (refer to Figure 29).

NOTE: Therapy also can be inhibited through analysis of the stability algorithm as it is used with the AFib Rate Threshold enhancement. Refer to the section “Use of Atrial Information.”

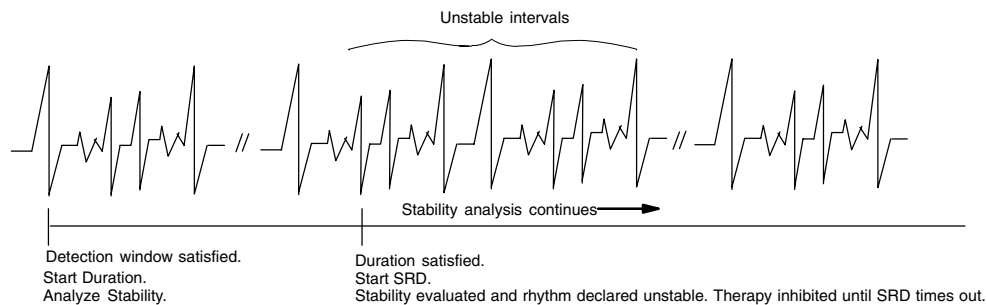


Figure 30. The pulse generator continues to reevaluate for stability on each new detected interval after being inhibited when Duration was satisfied.

Stability Programmed to Shock if Unstable. When programmed to Shock If Unstable, the Stability parameter helps determine whether the remaining ATP therapy should be skipped over in preference of the first programmed shock therapy (which may be low or high energy) for the zone (Figure 31). Dynamic ventricular arrhythmias, such as polymorphic VT or VF (that generally respond best to shock therapy), may be sensed at a rate lower than the highest rate threshold and may be sensed as unstable. Since the sensed rhythm may be detected in a lower zone in which ATP may be programmed, the Stability parameter may be used to skip over the programmed ATP therapies and instead provide shocks to the patient. Stability is evaluated on each detection/redetection cycle, including evaluation between bursts of an ATP scheme. Once a shock has been delivered in an episode, this Stability function (programmed to shock if unstable) no longer affects therapy selection.

When programmed to Shock If Unstable, the Stability parameter may be used in the VT zone of a two-zone configuration or three-zone configuration. It cannot be programmed in this manner in a two-zone configuration if Stability is already programmed to Inhibit If Unstable, or if either Post-shock Stability or Onset is programmed “On.”

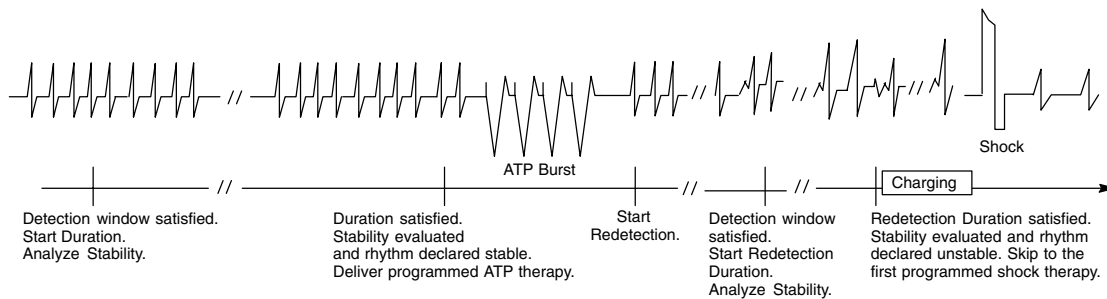


Figure 31. Stability can be programmed to deliver shock therapy instead of ATP therapy.

Use of Atrial Information (AFib Rate Threshold and V Rate > A Rate Detection Enhancements)

The pulse generator will recognize an implanted atrial lead if any of the following features are activated:

- AFib Rate Threshold (see below)
- V Rate > A Rate (see below)
- Brady Mode programmed to DDD(R) or DDI(R) (refer to Chapter 5)
- Electrogram Storage Enabled for the atrial electrode (refer to Chapter 6)
- Atrial Rate EGM trace selected (refer to Chapter 6)

The atrial rate may be used to both 1) inhibit therapy in the presence of atrial fibrillation (AFib), and 2) to bypass Onset or Stability as inhibitors if programmed On if the ventricular rate is faster than the atrial rate.

AFib Rate Threshold. The goal of atrial rate detection is to withhold therapy in the event that the underlying cause of a moderately high ventricular rate is due to ventricular response to fibrillation in the atrium. This is accomplished by comparing the atrial rate to the preprogrammed AFib Rate Threshold and evaluating ventricular stability. If the ventricular rhythm is unstable and the atrial rate is greater than the AFib Rate Threshold, the ventricular rhythm is declared to be due to atrial fibrillation. Therapy will be withheld until the atrial rate drops below the AFib Rate Threshold or the ventricular rhythm becomes stable, or the Sustained Rate Duration timer expires.

The atrial rate is declared to be above the AFib Rate Threshold in the following manner (Figure 32): At initiation of ventricular tachyarrhythmia detection, atrial analysis begins. Each atrial interval is classified as faster or slower than the AFib Rate Threshold interval. When 6 of the last 10 intervals are classified as faster than the AFib Rate Threshold, the device declares atrial fibrillation to be present. Ventricular stability is then checked and if unstable, therapy will be inhibited. In the event that therapy is not delivered, the atrial rate will continue

to be examined; as long as 4 of 10 intervals remain classified as fast, atrial fibrillation continues to be present. Therapy will be inhibited until the atrial rate drops below the Afib Rate Threshold, the ventricular rhythm becomes stable, or if programmed on, V Rate > A rate is true or Sustained Rate Duration times out.

The AFib Rate Threshold enhancement is programmable from 200–400 bpm or Off. When programmed "On," the stability analysis algorithm is activated, and the programmed value on the programmer screen shifts from the Stability Inhibit If Unstable position to the AFib Stability position. Also, the Onset and Stability And/Or selection is automatically set to "And" in the pulse generator, which is displayed on the programmer screen. Selection of the And/Or options will not be available again until the AFib Rate Threshold is turned Off.

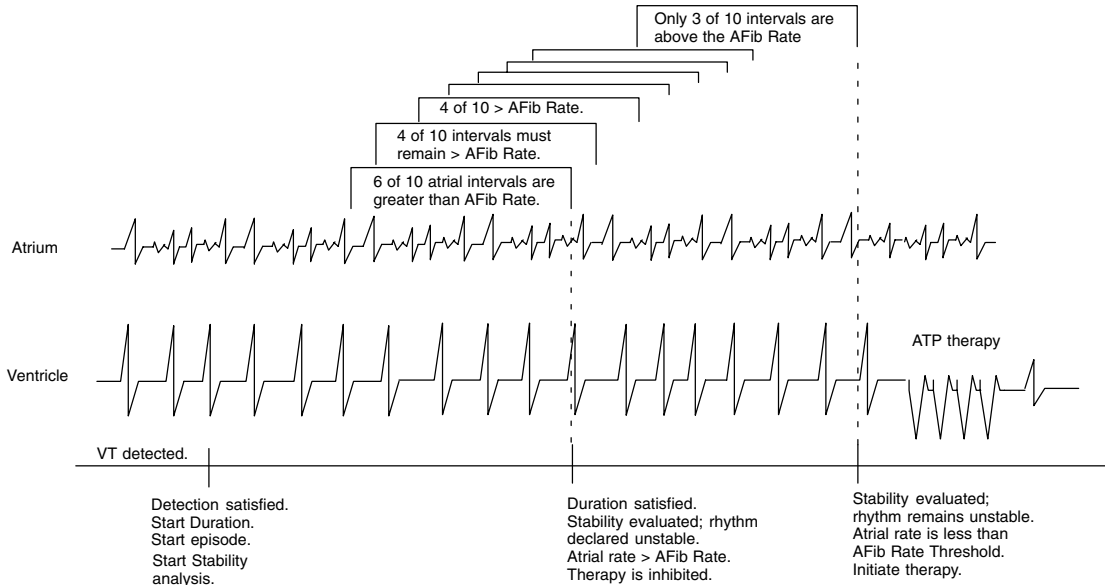


Figure 32. Illustration of the AFib Rate Threshold and AFib Stability interaction.

V Rate > A Rate. The V Rate > A Rate (ventricular rate greater than atrial rate) parameter can be programmed to bypass Onset and/or Stability as inhibitors and initiate therapy in the event that the ventricular rate is faster than the atrial rate. Analysis is made by comparing the average rate of the last 10 ventricular intervals prior to the end of duration to the average rate of the last 10 atrial intervals prior to the end of duration and after the third fast ventricular interval (Figure 33). If fewer than 10 atrial intervals are available, then the intervals available will be used to calculate the average atrial rate. 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 (indicated as True on the Episode Detail report), and therapy will be initiated. If the ventricular rate is not greater than the atrial rate (indicated as False on the Episode Detail report), then therapy continues to be inhibited.

If therapy is inhibited, the V Rate > A Rate analysis continues until either the ventricular rate is greater than the atrial rate, or the other enhancements indicate therapy treatment, at which time therapy will be initiated.

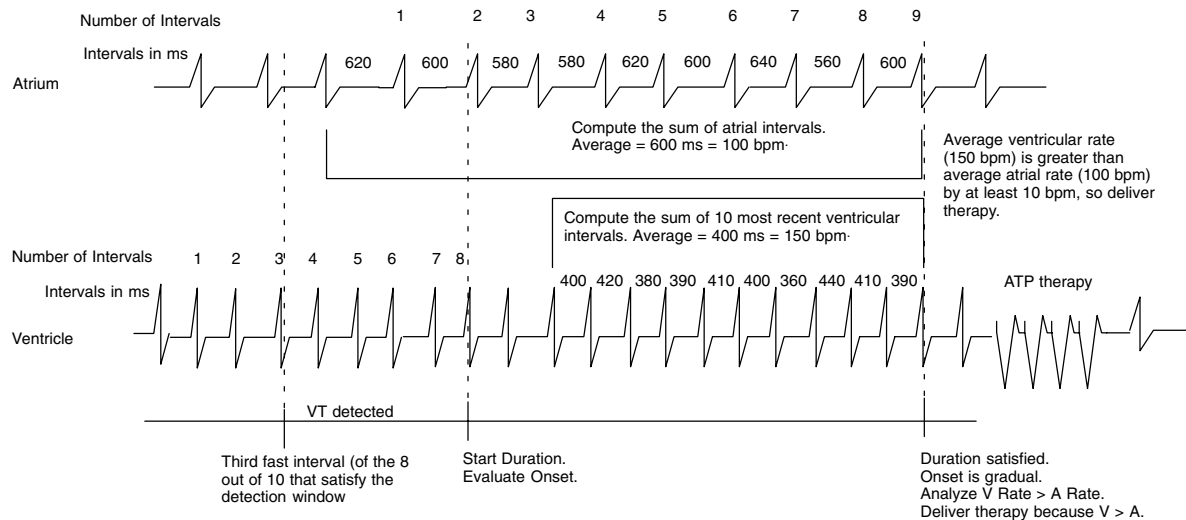


Figure 33. Illustration of V Rate > A Rate.

Combinations of Onset and Stability

When Stability is programmed to Inhibit If Unstable, it may be combined with the Onset parameter to provide even greater specificity in characterizing arrhythmias. The enhancements can be programmed to initiate therapy so that Onset **And** Stability must be satisfied; or, so that either Onset **Or** Stability must be satisfied (refer to Table 10).

If the combination programmed is Onset **Or** Stability, therapy is initiated immediately at the end of duration if either parameter is satisfied; that is, the rhythm is sudden **Or** stable (the Or condition is satisfied). If the combination programmed is Onset **And** Stability, therapy is initiated only if both parameters are satisfied; that is, the rhythm is sudden **and** stable (the And condition is satisfied). In either case, therapy will be inhibited if the And/Or conditions are not satisfied. When these two combinations (And/Or) are used in conjunction with Sustained Rate Duration (SRD), and the And/Or conditions are not satisfied, therapy will be inhibited until SRD times out. (Refer to the Sustained Rate Duration section below for a description of SRD.)

Table 10. Onset and Stability Combinations and the Resulting Therapy

Detected Rhythm	Possible Combinations	
	Onset OR Stability	Onset AND Stability ^a
Gradual, unstable	Inhibit until SRD (if On) or rhythm becomes stable OR V > A	Inhibit until SRD (if On) or V > A
Gradual, stable	Treat immediately at end of duration	Inhibit until SRD (if On) or V > A ^b
Sudden, unstable	Treat immediately at end of duration	Inhibit until SRD (if On) or rhythm becomes stable or V > A
Sudden, stable	Treat immediately at end of duration	Treat immediately at end of duration

a. The AND combination is the nominal setting when both are enabled.

b. The V Rate > A Rate is programmed "On" and is False, then therapy will be initiated because the rhythm is declared stable.

If AFib Rate Threshold/AFib Stability and Onset are both programmed On, the combination is an AND condition. That is, to initiate therapy the rhythm must have a sudden onset **and** either the ventricular rate must be stable or the atrial rate must be less than the AFib Rate Threshold. (However, if V Rate > A Rate is programmed On and is False, therapy will be inhibited if the rhythm is unstable.) If programmed On and is True, the enhancement V Rate > A Rate takes precedence over all other inhibitor enhancements.

Sustained Rate Duration (SRD)

Sustained Rate Duration allows the programmed therapy to be delivered when a tachycardia is sustained for a programmed period of time beyond Duration, but the programmed therapy inhibitors (AFib Rate Threshold, Onset, Stability programmed to Inhibit If Unstable) are not satisfied. Figure 34 illustrates SRD in relation to the inhibitor enhancements (it is not used in conjunction with Stability programmed as an accelerator).

SRD is programmable only in the lowest zone of a multizone configuration, with a range of values from 10 seconds to 60 minutes or Off. It is used only when an inhibitor enhancement is programmed On. If an inhibitor is preventing therapy and the Rate criterion in the lowest zone is maintained, the SRD timer begins at the end of Duration. If the window in the lowest 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 to a higher zone and the Duration for the higher zone is satisfied, therapy is initiated without waiting for SRD to time out. If SRD is programmed Off, an SRD timer will not be started at Duration.

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

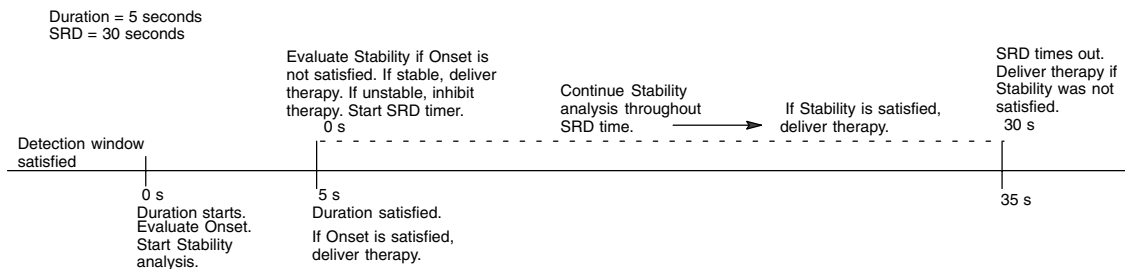


Figure 34. Illustration of the Onset OR Stability combination with SRD programmed On.

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 is the duration parameters used following therapy. The type of therapy last delivered in the current episode determines which of the two duration parameters is 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 36 and Figure 38). 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

During the redetection process (looking for 8 of 10 fast intervals), Redetection Duration is always applied—following delivery of ATP therapy, a diverted-reconfirm, or manually diverted therapy—**except** when 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. The value programmed in the lower rate zones must be equal to or greater than that in the higher zones. Figure 35 indicates the values available for each configuration. Programmable values range from 1–15 seconds. 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.

ONE-ZONE CONFIGURATION

VF 1 s

TWO-ZONE CONFIGURATION

VT 1–15 s	VF 1 s
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THREE ZONE CONFIGURATION

VT-1 1–15 s	VT 1–15 s	VF 1 s
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Figure 35. Redetection Duration programmable values are indicated in the lower zones, and the nonprogrammable value is indicated in the VF zone (in seconds).

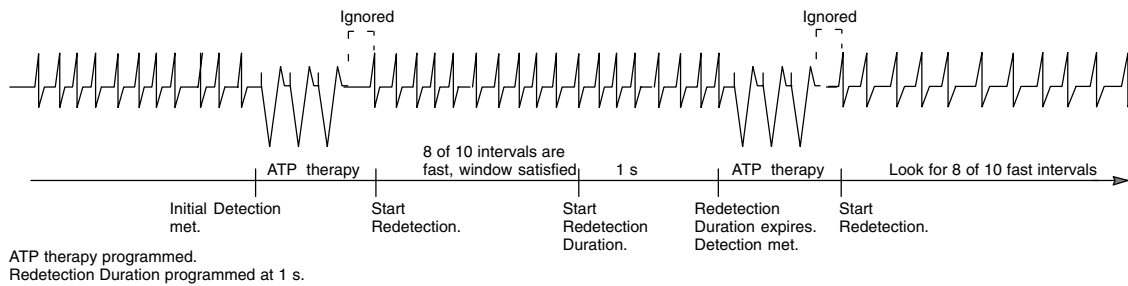


Figure 36. Illustration of redetection following ATP therapy delivery.

Post-shock Duration

Following delivery of any shock therapy, redetection looks for 8 of 10 fast intervals to satisfy a detection window and then employs the Post-shock Duration. Post-shock Duration is programmable as independent values in the lower zones of a multizone configuration, and is nonprogrammable in the VF zone. Figure 37 indicates the values available for each configuration. The Post-shock Duration programmed for the lower rate zones must be equal to or greater than that for the higher zones. Guidant recommends that Post-shock Duration in the VT-1 and VT zones of multizone configurations be programmed at less than or equal to five 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.

ONE-ZONE CONFIGURATION

VF 1 s

TWO-ZONE CONFIGURATION

VT 1–30 s	VF 1 s
--------------	-----------

THREE ZONE CONFIGURATION

VT-1 1–60 s	VT 1–30 s	VF 1 s
----------------	--------------	-----------

Figure 37. The Post-shock Duration programmable values are indicated in the lower zones, and the nonprogrammable value is indicated in the VF zones (in seconds).

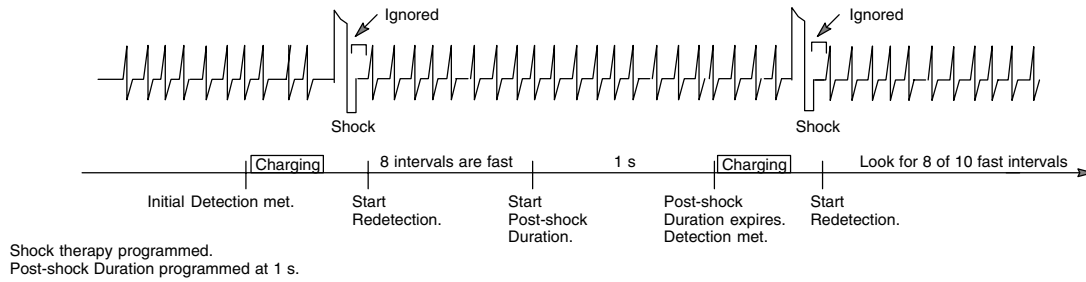


Figure 38. Illustration of redetection following shock therapy delivery.

Post-shock Stability and Post-shock SRD

In some patients, stability analysis may be performed to prevent shock-induced atrial fibrillation from causing the pulse generator to deliver an undesired additional shock. When programmed On, Post-shock Stability and Post-shock SRD are evaluated whenever Post-shock Duration is applied during redetection. Post-shock stability analysis is identical to the stability analysis applied during initial detection; however, an independent threshold is provided. Only available in the lowest zone of a multizone configuration, Post-shock Stability will evaluate tachycardias detected during Post-shock Duration (Figure 39). If at the end of Post-shock Duration the tachycardia is considered stable, additional shocks will be initiated. If the tachycardia is considered unstable, additional shocks will be inhibited until a stable rate is present, or until Post-shock SRD times out.

NOTE: *The stability inhibitor is not evaluated during redetection following ATP therapy.*

A Post-shock SRD may be programmed in conjunction with Post-shock Stability. If the tachycardia is considered unstable at the end of Post-shock Duration, the Post-shock SRD timer begins. Stability is continually reevaluated during this period, and if at any time the tachycardia becomes stable, charging for the next shock begins.

Post-shock Stability and Post-shock SRD are independently programmable from initial Stability and SRD, at value ranges of 6–120 ms and 10 seconds–60 minutes, respectively.

NOTE: *The AFib Rate Threshold can be programmed in conjunction with Post-shock Stability to further discriminate atrial fibrillation and prevent the pulse generator from delivering undesired shock therapy.*

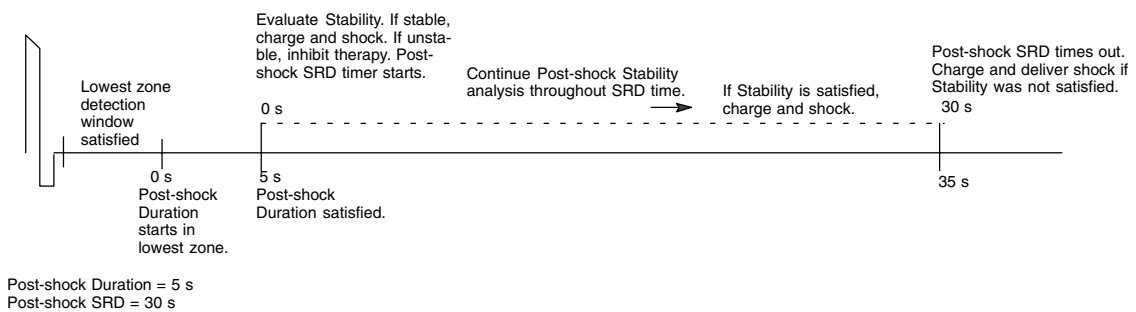


Figure 39. Illustration of Post-shock Duration and Post-shock Stability analysis.

Post-shock AFib Rate Threshold

The Post-shock AFib Rate Threshold functions the same as in initial detection and is separately programmable. Refer to page 38 for a description.

Post-shock V Rate > A Rate

The Post-shock V Rate > A Rate functions the same as in initial detection and is separately programmable. Refer to page 39 for a description.

Accessing the Tachy Mode Parameter

1. Select the Tachy Mode menu button to display the parameter options (Figure 40).
2. Select the desired option. The new value will immediately be programmed if the telemetry wand is positioned over the pulse generator. The new programmed value will appear next to the words Tachy Mode on the base window.



Figure 40. Accessing the Tachy Mode parameter.

For another method of changing the Tachy Mode, refer to the section “Performing ATP and Temporary ATP” in Chapter 7—Electrophysiology Testing.

Accessing Zone Configuration and Rate Parameters

1. Select the Add/Remove Zone option from the Other Params menu to change the number of zones and rate thresholds. The Add/Remove Zone window will appear (see Figure 41).

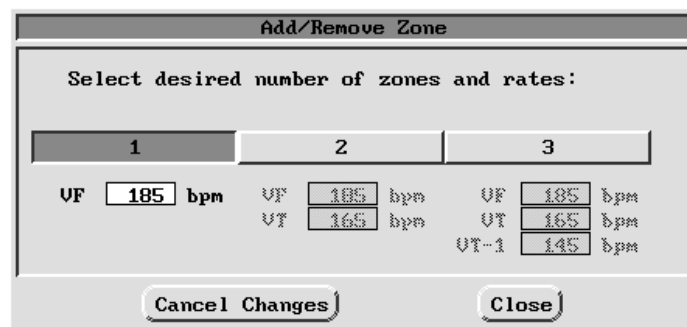


Figure 41. Accessing zone configuration and rate parameters. In this example, one zone is selected.

2. To set the number of zones, select one of the buttons labeled 1, 2, and 3. The chosen number indicates the number of tachyarrhythmia detection zones; notice that the text is faded under the configurations that are not selected (Figure 41).
3. To set the desired rate threshold, select the value box for each zone in the chosen configuration. Select the desired value from the palette that appears. Rate thresholds cannot be changed in the configurations with faded text.
4. Close the window. The changes will be displayed on the base window with hatch marks over the data. Recall that this information is not programmed into the pulse generator until the PROGRAM key is pressed while the telemetry wand is positioned over the pulse generator.

Alternatives to Change Rate Thresholds

There are two alternate methods to change rate thresholds:

1. The first alternate method is from the base window; the zone configuration area has value boxes that display the rate thresholds.
 - a. Select a rate threshold box to display a palette.
 - b. Select the desired value.
2. The second alternate method is to select a Detection button as described in the next section.

Whichever method is used to change a rate, hatch marks will appear on the respective zone’s Detection button to indicate that the new values have not been programmed into the pulse generator.

Accessing Detection, Detection Enhancement, and Redetection Parameters

A complete list of detection and redetection parameters for a zone can be viewed, as indicated below. At the start of a patient session, when the device is initially interrogated, the currently programmed values are displayed and are referred to as the initial values. Anytime during the session, the initial values can be reloaded easily if the values had been changed. Refer to the “Load Initial Values” section in Chapter 2.

1. Select a zone’s Detection button (the rectangle that indicates the zone’s duration located below the zone name) in the parameter summary area to open a Detection window (Figure 42). Several Detection buttons can be selected at one time to view more than one zone’s parameters.

	Present	Change
Initial Detection		
Rate	145	<input type="text"/> bpm
Interval	414	<input type="text"/> ms
Duration	2.5	<input type="text"/> sec
Stability		
Shock if Unstable	6	<input type="text"/> ms
Redetection		
Redetection Duration	1.0	<input type="text"/> sec
Post-shock Duration	1.0	<input type="text"/> sec

Buttons:

Figure 42. Accessing a detection window to change the rate threshold and duration, detection enhancement, and redetection parameters.

2. Select a value box in the Change column to display a list of values. Select a value.

Notice that when a Detection button is selected, the window that appears will display only parameters available in that zone. For example, in a three-zone configuration Onset is only programmable in the lowest zone, so the Onset parameter will appear as a programmable option only in the VT-1 Detection window. It will not be an option in the middle or highest zones.

3. Close the window to remove it from the display.

Parameter Interactions and Parameter Warnings

Whenever a parameter is changed in such a way that it affects another parameter, a Parameter Interaction button will appear at the top of the base window. Parameter interactions must be cleared prior to programming for safe and consistent pulse generator operation.

There are some interaction messages that do not require a change to the selected parameters values to proceed with programming, and are indicated by a Parameter Warning button. In the case of these “WARNING” messages, physician discretion is advised depending on the type of patient or other circumstances before proceeding.

To get more information and to clear the interaction, follow these steps:

1. Select the Parameter Interaction button. A message window will appear. The window describes the interaction and indicates the affected zone. Each interaction message in the window has an associated View button.

NOTE: The Parameter Interaction window along with a message will also appear if the PROGRAM command from the PRM is initiated prior to clearing the interaction. Close this window to proceed.

2. Select the View button for one message at a time. The affected detection or therapy window(s) will appear.
3. Change the setting of the affected parameters so that the interaction no longer exists.
4. Close the affected window. If the interaction has been cleared, the message will no longer appear in the Parameter Interaction window. If it has not been cleared, the message will remain.
5. When all interactions have been cleared, select the Close button to close the window; the Parameter Interaction button will disappear.

NOTE: *If a warning message is present, and the affected parameter values are not changed, the message will remain on the Parameter Interaction window, and the Parameter Warning button will remain on the base window. Programming, however, can proceed.*

Chapter 4

TACHYARRHYTHMIA THERAPY

The pulse generator is capable of delivering two types of therapy to terminate ventricular tachycardia or fibrillation: biventricular 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 leads synchronously with detected heart activity. This chapter describes therapy prescription, how the pulse generator determines which therapy to deliver (therapy selection), and the programmable ATP and shock parameters.

Therapy Prescription

A therapy prescription determines the type of therapy delivered in a particular rate zone, and can consist of a combination of biventricular antitachycardia pacing and shocks as indicated in Figure 43. 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 11 for the respective delivered energy values (in section “Shock Therapy and Parameters”).

Within each zone, therapy strength must be in ascending order

Lowest strength → Highest strength

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

Between zones, therapy strengths are not restricted

* 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. Refer to the section “Accessing Therapy Parameters” for more information.

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

Figure 43. Therapy prescription in a three-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, 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 five shocks may be delivered in an episode, of which only the first two shocks are programmable. The remaining shocks are nonprogrammable at the maximum-energy value.

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 five available shocks for that tachyarrhythmia episode. Also, commanded therapies and *STAT SHOCK* are not counted as one of the five available shocks for an episode, and they 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 44), 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 44a through Figure 44d. 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 whether further therapy is required.

Zone	ATP1	ATP2	Shock 1	Shock 2	Remaining Shocks (Maximum Shock Energy)		
VF 190 bpm			5 J	11 J	max	max	max
VT 160 bpm	Burst	Scan	3 J	9 J	max	max	max
VT-1 120 bpm	① Burst	② Ramp	③ 0.1 J	④ 2 J	⑤ max	⑥ max	⑦ max

Figure 44. 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 higher strength therapy in the right column.

In Figure 44a to Figure 44d, 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 of 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 VT-1 zone, no further therapy will be delivered in the episode unless the rate is detected in a higher zone.**

Zone	ATP1	ATP2	Shock 1	Shock 2	Remaining Shocks		
VF 190 bpm			2 J	5 11 J	max	max	max
VT 160 bpm	3 Burst	Off	4 3 J	9 J	6 max	7 max	8 max
VT-1 120 bpm	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 44a.

Zone	ATP1	ATP2	Shock 1	Shock 2	Remaining Shocks		
VF 190 bpm			11 J	17 J	max	7 max	8 max
VT 160 bpm	1 Burst	3 Scan	4 5 J	9 J	6 max	max	max
VT-1 120 bpm	2 Burst	Ramp	3 J	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 44b.

Zone	ATP1	ATP2	Shock 1	Shock 2	Remaining Shocks		
VF 190 bpm			5 J	11 J	6 max	max	max
VT 160 bpm	2 Burst	3 Scan	4 1.1 J	9 J	max	7 max	8 max
VT-1 120 bpm	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 44c.

Zone	ATP1	ATP2	Shock 1	Shock 2	Remaining Shocks		
VF 190 bpm			5 J	11 J	max	max	max
VT 160 bpm	Burst	Scan	3 J	9 J	5 max	max	max
VT-1 120 bpm	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 the Remaining Shocks are programmed Off in the VT-1 zone.

Figure 44d.

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 whether the arrhythmia has

terminated. The ATP scheme will continue with the next burst 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
- Stability analysis forces therapy to skip over ATP therapy to initiate shock therapy
- 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 or 10 fast intervals) and the Post-shock Duration, and post-shock detection enhancements if applicable, to determine whether 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 five available shocks have been delivered for an episode
- All shocks programmed (0, 1, 2, or 5) in the VT-1 zone have been delivered and the rate 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 to both ventricles 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 45 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, 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.

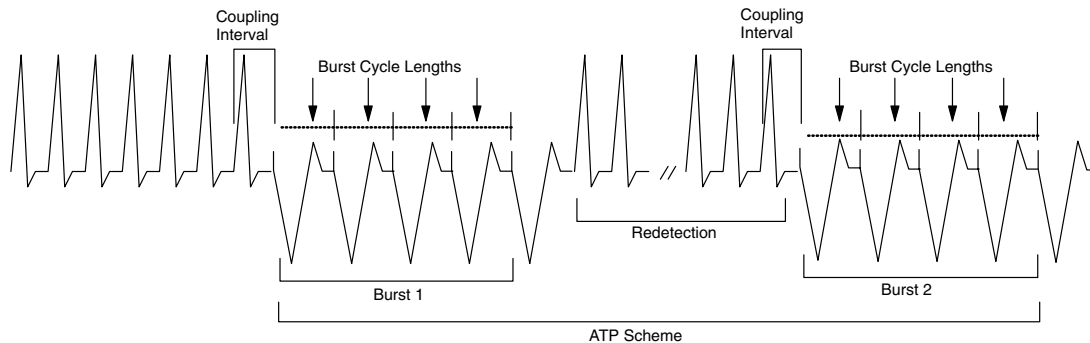


Figure 45. Bursts, burst cycle lengths, and coupling intervals are the basic components of ATP therapy.

Coupling Interval and Coupling Interval Decrement

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 independently 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 a 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 46. The Coupling Interval Decrement may be programmed so that the Coupling Interval decreases from one burst to the next within a multiple-burst scheme (Figure 47).

The Coupling Interval programmable values range from 50–97% or 120–750 ms, and the Coupling Interval Decrement programmable values range from 0–30 ms. 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,” step 2, later in this chapter.

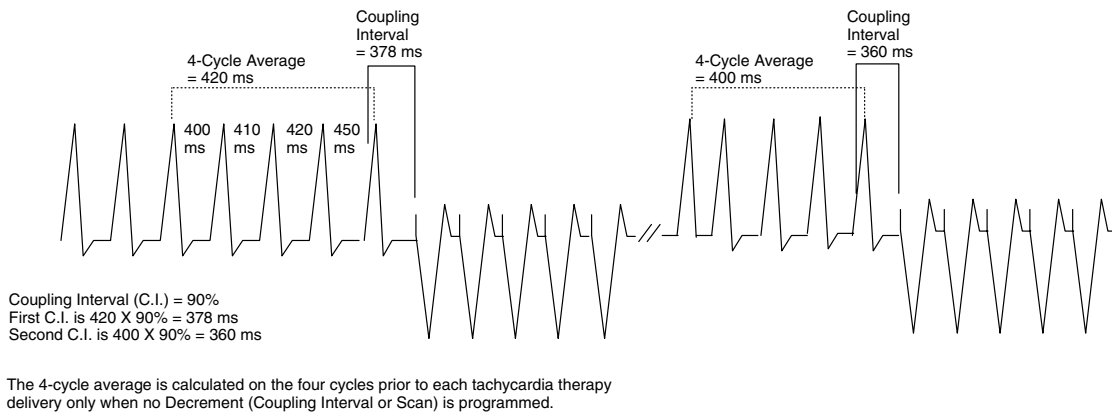


Figure 46. Example of an adaptive Coupling Interval with the Coupling Interval Decrement and Scan Decrement turned off.

NOTE: When the Coupling Interval is programmed as adaptive, and the Coupling Interval Decrement or Scan Decrement is 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.

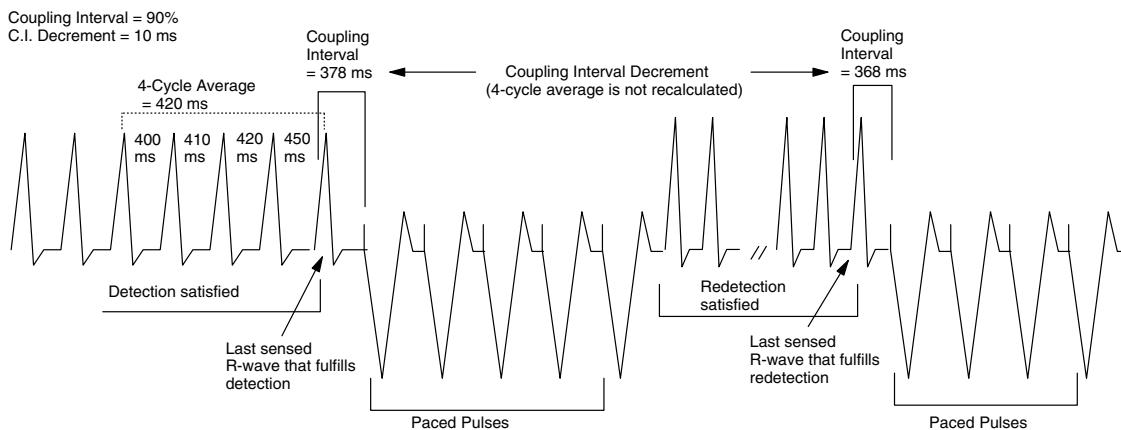


Figure 47. The Coupling Interval may be decreased from one burst to the next by programming the Coupling Interval Decrement. Note that the new average rate is *not* recalculated for a decremental coupling interval.

Burst Scheme and Burst Cycle Length (BCL)

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” when the timing of all pacing intervals within a burst is the

same (Figure 48). The first burst cycle length (interval between pacing pulses) of each burst is determined by the programmed Burst Cycle Length (BCL) (% or ms). 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. This timing is controlled in the same fashion as the Coupling Interval; rate adaptive to the sensed tachycardia, or fixed time specified in milliseconds. The Burst Cycle Length programmable values range from 50–97% or 120–750 ms.

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 is programmed On.

There are two decrements that may be programmed to adjust the burst cycle length: a Ramp Decrement controls the pulse timing within a given burst, and a Scan Decrement controls the pulse timing between bursts (see the following sections).

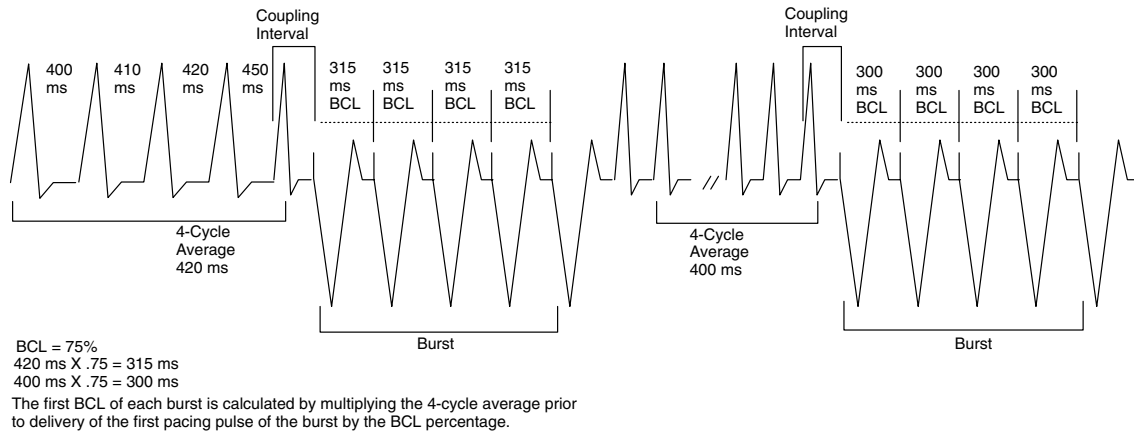


Figure 48. A simple adaptive-rate burst scheme, illustrating the pacing pulses in a burst and the burst cycle length.

Ramp Scheme

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 (R–R Within a Burst) should be programmed (in ms) to specify by how much the paced-to-paced interval should be shortened, and both the Scan Decrement and Coupling Interval Decrement should be programmed to 0 (zero) 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. If subsequent bursts are required, the programmed Ramp Decrement will be applied based on the calculated BCL of that subsequent burst. Refer to Figure 49. The programmable values for the Ramp Decrement range from 0–30 ms.

Burst Cycle Length = 75%
 Ramp Decrement (R-R Within Burst) = 10 ms
 Scan Decrement (R-R Between Bursts) = 0 ms
 C.I. Decrement = 0 ms
 Minimum Interval = 265 ms

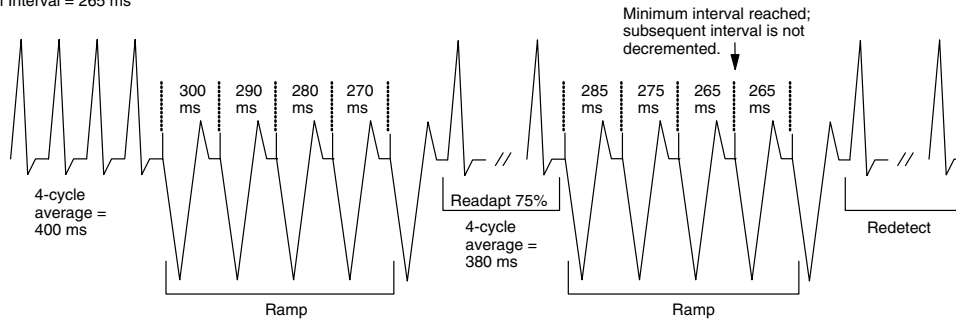
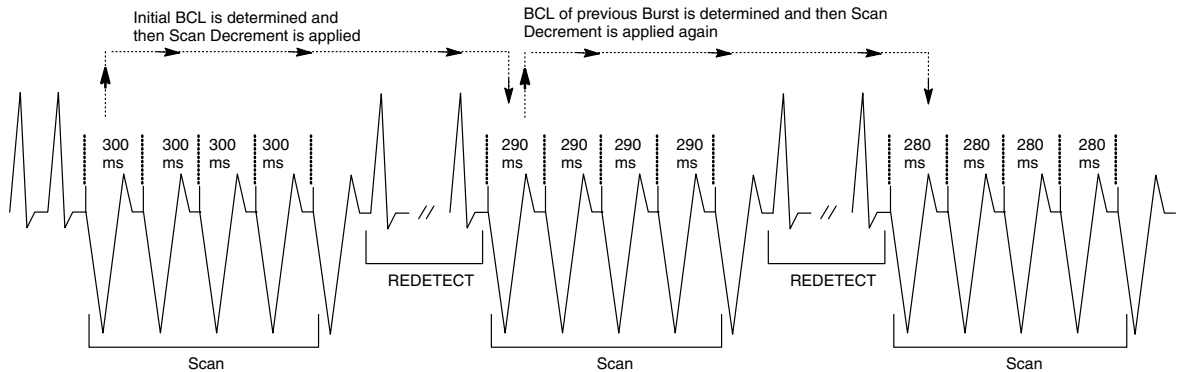


Figure 49. Example of an adaptive Ramp scheme with Coupling Interval Decrement and Scan Decrement turned off.

Scan Scheme

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 (R-R Between Bursts) should be programmed (in ms) to specify the BCL decrement, and the Ramp Decrement should be programmed to 0 (zero) ms. The BCL of subsequent bursts is determined by subtracting the Scan Decrement from the BCL of the previous burst. Refer to Figure 50. The programmable values for the Scan Decrement range from 0–30 ms.

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.

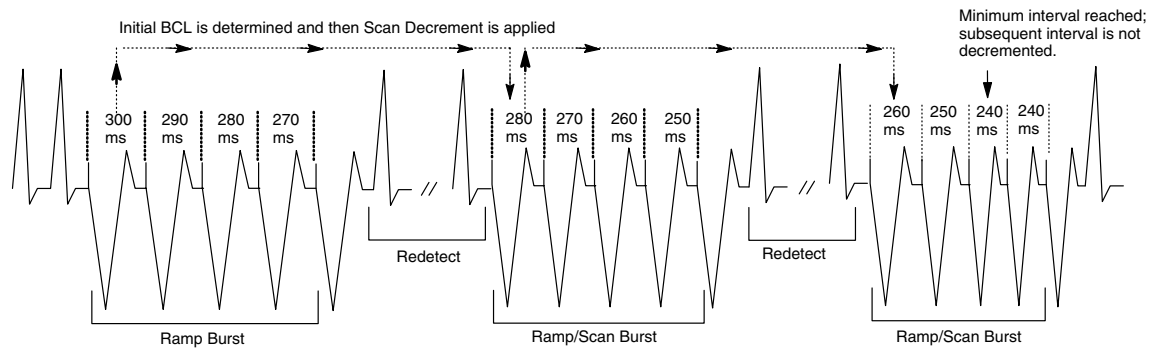


Burst Cycle Length = 300 ms
 Scan Decrement (R-R Between Burst) = 10 ms
 Ramp Decrement (R-R Within Burst) = 0 ms
 C.I. Decrement = 0 ms

Figure 50. 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 51. To program a Ramp/Scan scheme, both the Scan Decrement and Ramp Decrement are programmed to values greater than zero ms.



Initial Burst Cycle Length = 300 ms
 Minimum Interval = 240 ms
 Ramp (Decrement BCL Within Burst) = 10 ms
 Scan (Decrement BCL Between Bursts) = 20 ms

Figure 51. Example of a Ramp/Scan scheme.

Minimum Interval

The Minimum Interval is a programmable value (120–400 ms) that limits the Burst Cycle Length (in Burst, Ramp, and Scan) and the Coupling Interval. If the Coupling Interval (C.I.) reaches the limit, subsequent Coupling Intervals will remain at the minimum value. Likewise, if the Burst Cycle Length BCL reaches the limit, subsequent BCLs will remain at the minimum value. The C.I. and BCL may reach the limit independently.

Burst Parameters

All ATP schemes have several parameters in common. In addition to programming the type of scheme (burst, ramp, scan, ramp/scan) the following parameters may be 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. Programmable ranges are 1–30 bursts, or Off to deactivate the ATP scheme.
- The Initial Pulse Count parameter determines the number of pulses delivered in the first burst of a scheme. Programmable ranges are 1–30 pulses.
- The Pulse Count Increment parameter allows the number of pulses per burst to be increased for each successive burst in the scheme. Programmable ranges are 0–5 pulses.
- 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. Programmable ranges are 1–30 pulses and are effective only if the Pulse Count Increment is greater than zero.

Figure 52 illustrates the interaction of these parameters in a simple burst scheme. Figure 53 illustrates the parameters that may be programmed to deliver a ramp/scan scheme.

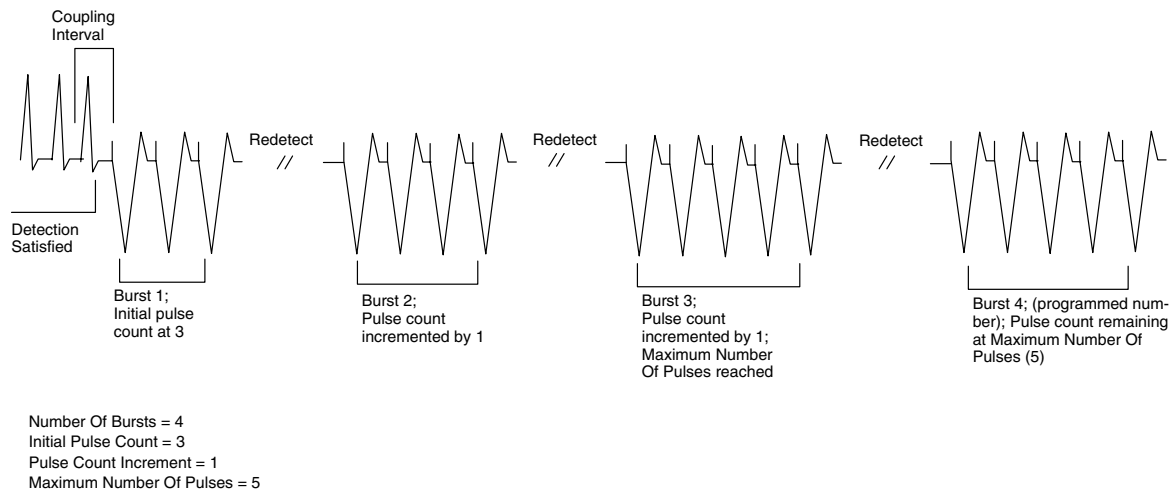


Figure 52. In this example, the programmed Maximum Number of Pulses (5) was reached before the Number Of Bursts (4) was reached, so each of the third and fourth bursts contained five pulses.

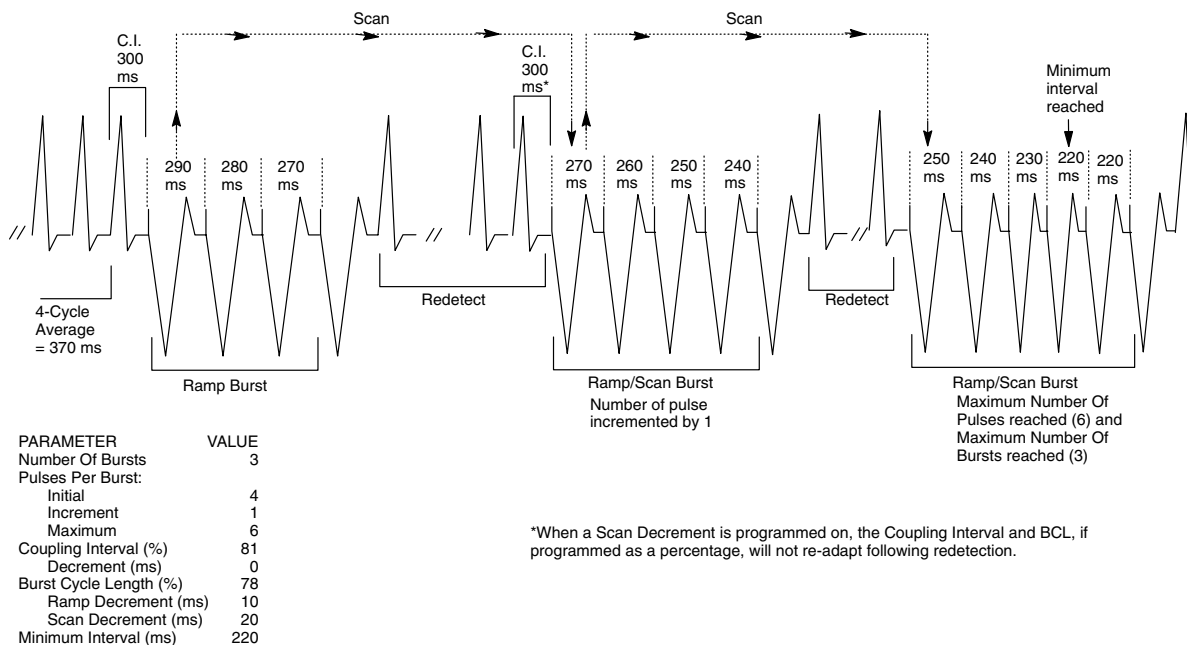


Figure 53. Interaction of ATP parameters in a Ramp/Scan burst scheme.

ATP Pulse Width and ATP Amplitude

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. Programmable values for the ATP Pulse Width range from 0.5–2 ms; and values for the ATP Amplitude in the ventricle are 5, 6, and 7.5 V. The Amplitude for the atrium is nonprogrammable at 5 V. The programmable values can be changed by selecting the Therapy Features button in a therapy window.

ATP Time-out

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 therapy to be delivered.

The ATP Time-out may be used in any zone in which ATP therapy is an option. Timer values are independent with VT-1 ATP Time-out greater than or equal to the VT ATP Time-out. The programmable values range from 10 seconds to 60 minutes, or Off.

The timer starts when the first burst is delivered and continues until a) the timer expires (Figure 54), b) a shock is delivered, or c) the episode ends. The time-out is examined after each redetection sequence to determine whether 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.

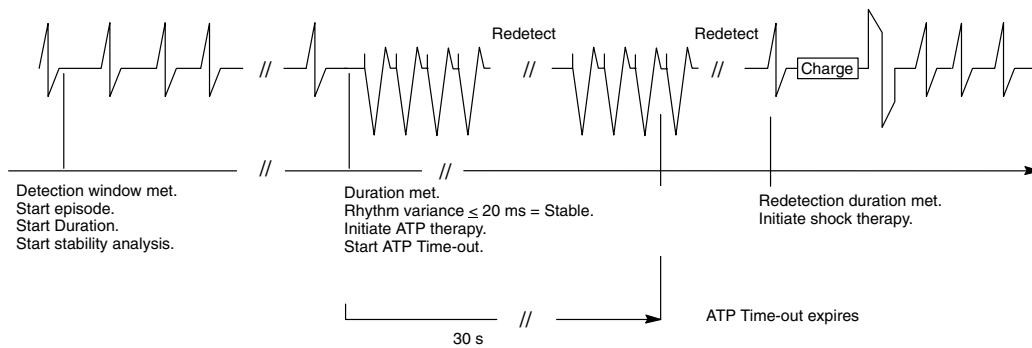


Figure 54. When the ATP Time-out expires, if the detection criteria remain satisfied, no further ATP therapy will be delivered; shocks, if programmed, will be initiated.

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 55 illustrates a three-zone configuration.

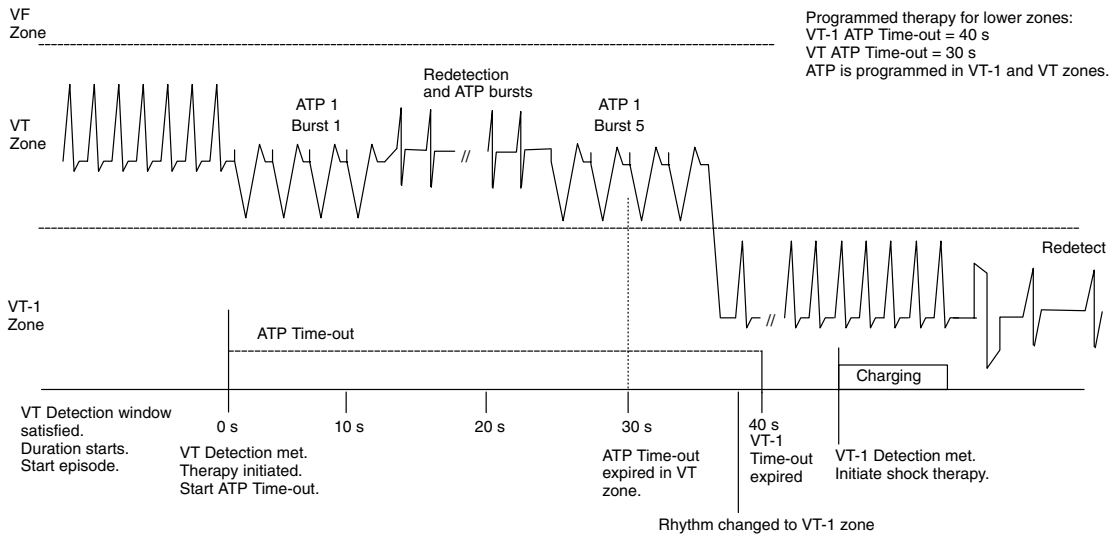


Figure 55. In a three-zone configuration, the two lower zones' ATP Time-out is evaluated. As shown, if redetection in the VT-1 zone occurs after 40 seconds, shock therapy is initiated. If redetection had occurred prior to the 40-second time-out, ATP for the VT-1 zone could have been initiated. If redetection had occurred in the VT zone, shock therapy would be initiated after 30 seconds.

Shock Therapy and Parameters

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

Shock Energy

The energy levels of the Shock 1 and Shock 2 parameters are programmable in each zone, and the remaining shocks' energies are nonprogrammable at the maximum-energy value. (Up to 5 shocks may be delivered during an episode.) 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 6–8 seconds to charge for delivery of a maximum-energy shock at 37°C at BOL (Beginning Of Life). Charge time is dependent on 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 11 shows the programmable energy levels and the typical charge time required at BOL for each capacitor.

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 11. 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	0.3
1.1	1	0.4
1.7	1.5	0.5
2	2	0.7
3	3	0.9
5	4	1.1
6	5	1.3
7	6	1.5
9	8	1.9
11	10	2.4
14	12	2.8
17	15	3.5
21	18	4.3
23	20	4.7
29	25	6.0
31	27	6.9

- a. Values indicate the energy level stored on the capacitors and correspond 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

The type and polarity of the shock waveform are programmable. The waveform type (biphasic or monophasic) determines how the pulse generator uses the energy of the capacitors (Figure 56). The waveform polarity reflects the relationship between the leading edge voltages on the two defibrillating output leads, as shown in Figure 57. The selection of the waveform type and polarity is global, and it applies to all shocks delivered by the device.

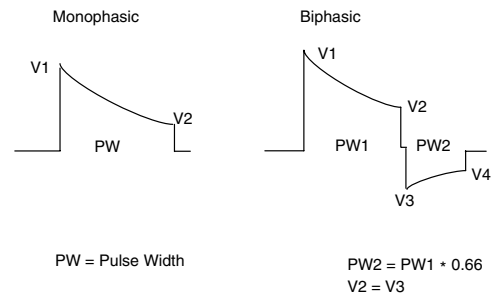


Figure 56. Illustration of monophasic and biphasic waveforms.

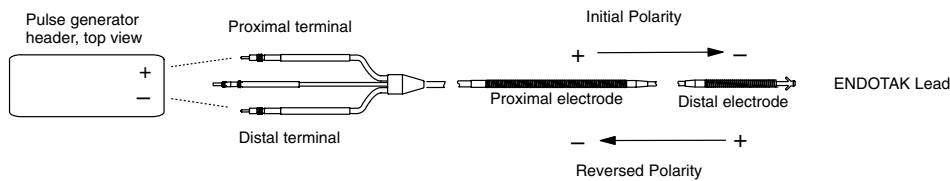


Figure 57. The polarity of the shock delivery can be reversed by programming the polarity feature.

Committed Shock/Reconfirmation of the Arrhythmia

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; 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 QRS complex following a 500-ms delay after the capacitors are charged (whether the arrhythmia is sustained or not) (see Figure 58). 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 QRS complex 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.)

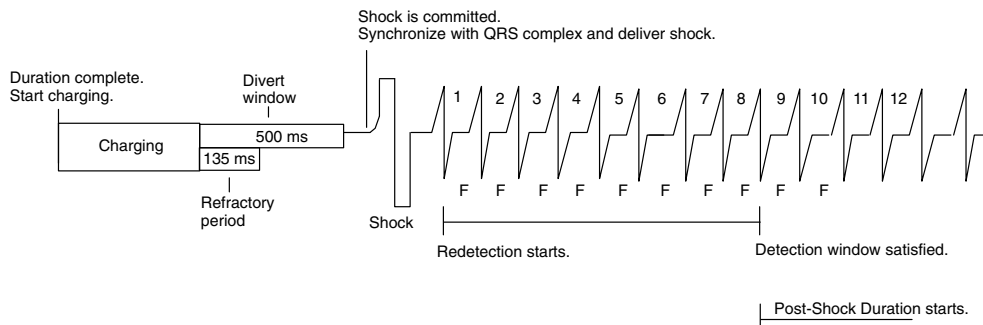


Figure 58. Reconfirmation is off. The Committed Shock feature is programmed to Yes.

If the Committed Shock feature is programmed No, Reconfirmation consists of the following steps (see Figure 59):

1. During capacitor charging, the pulse generator continues to sense the arrhythmia. If four consecutive slow intervals (less than the lowest Rate threshold) are **sensed** during

charging, the pulse generator stops charging, and begins redetection. This is considered a Diverted-Reconfirm. However, the charge is held on the capacitors.

2. If four consecutive slow intervals 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 three intervals following charging and compares them to the lowest Rate threshold. If two of the three intervals following charging are higher than the lowest Rate threshold, the shock will be delivered synchronously with the next sensed event.

If two of the three intervals following charging are at a rate less than the lowest Rate threshold, the shock will not be delivered. This is known as a Diverted-Reconfirm. If the shock is not delivered, the energy remains on the capacitors; if during redetection a shock is required, the charge time for the shock may be extremely short.

The reconfirmation algorithm will not allow two consecutive Diverted-Reconfirm cycles within an episode. 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 will be applied again.

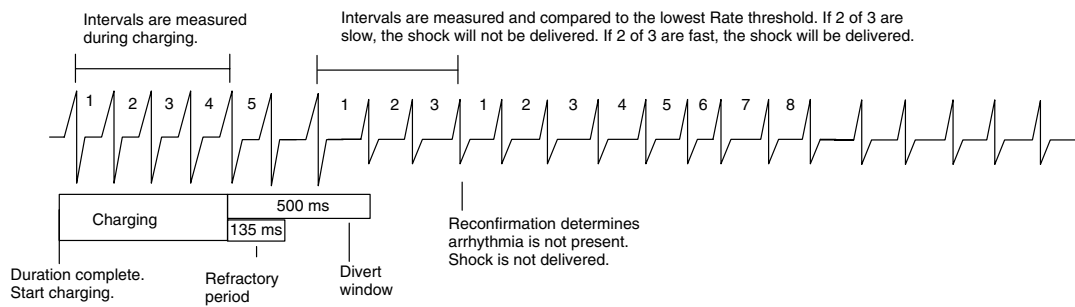


Figure 59. Reconfirmation is on. The Committed Shock feature is programmed to No.

Accessing Therapy Parameters

A summary of the currently selected therapy parameters is shown in the therapy button(s) on the base window. A complete list of therapy parameters for a zone can be displayed, as indicated below.

1. Select the desired zone's Therapy button from the base window to display a detailed therapy window (Figure 60).

UT-1 Therapy					
	ATP1 = Burst		ATP2 = Scan		SHOCKS
	Present	Change	Present	Change	Present Change
Number of Bursts	3	<input type="text"/>	2	<input type="text"/>	Shock 1 9 <input type="text"/> J
Pulses per Burst					Shock 2 14 <input type="text"/> J
Initial	4	<input type="text"/>	4	<input type="text"/>	Max Shocks 31 <input type="text"/> J
Increment	1	<input type="text"/>	1	<input type="text"/>	
Maximum	5	<input type="text"/>	6	<input type="text"/>	
Coupling Interval	81	<input type="text"/> ms	81	<input type="text"/> ms	
Decrement	0	<input type="text"/> ms	0	<input type="text"/> ms	
Burst Cycle Length	81	<input type="text"/> ms	81	<input type="text"/> ms	
Ramp Decrement	0	<input type="text"/> ms	0	<input type="text"/> ms	ATP TIME-OUT
(Within a Burst)					Begin shock at
Scan Decrement	0	<input type="text"/> ms	2	<input type="text"/> ms	1:00 <input type="text"/> min:sec
(Between Bursts)					
Minimum Interval	200	<input type="text"/> ms	200	<input type="text"/> ms	

Figure 60. Therapy parameters window.

Note that when the VF Therapy window is displayed, only shock parameters are available, since ATP therapy is not available in the VF zone.

2. To adjust any therapy parameter, select its value box in the Change column to display a value palette. Select a value.

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 Ramp Decrement, Scan Decrement, or Coupling Interval 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, access the Select the Number Of Bursts parameter and change its value to Off.

NOTE: *To quickly disable all ATP and shock values only in the VT-1 zone, 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 fast in the lowest zone, 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 button. The parameters displayed affect all zones. These values also affect Temporary ATP, PES and Slaved inductions, backup VVI output during atrial EP testing, STAT SHOCK, and Commanded Shock.

Chapter 5

CARDIAC RESYNCHRONIZATION AND BRADYCARDIA THERAPIES

The CONTAK CD heart failure device is designed to provide cardiac resynchronization therapy for the treatment of heart failure (HF) by using simultaneous biventricular electrical stimulation to synchronize ventricular contractions. The pulse generator provides bipolar atrial and extended bipolar biventricular, normal and post-shock bradycardia pacing in a variety of modes, including adaptive-rate modes. Bradycardia rhythms are detected on a cycle-by-cycle basis using modified ventricular-based timing. Bradycardia pacing can also be programmed to Off. The bradycardia pacing function is independent of the tachycardia detection and therapy functions of the device, with the exception of interval-to-interval sensing.

Guidant uses an extended bipolar configuration when pacing and sensing the right and left ventricles. In this device, extended bipolar pacing refers to a circuit where current travels between the cathode (negative [-] electrode) on the left ventricular coronary venous lead and the anode (positive [+] electrode) on the bipolar right ventricular lead. Extended bipolar sensing are the sensing of signals between the left ventricular coronary venous lead electrode and the bipolar right ventricular lead electrode.

NOTES:

- *The two ventricular leads are connected in a parallel configuration to provide simultaneous pacing and sensing in the right and left ventricles. Any and all ventricular pacing pulses will be delivered biventricularly with the pulse generator system.*
- *The biventricular pacing capability of this device does not affect the timing cycle operation of the pacing modes.*

For delivery of cardiac resynchronization therapy, overriding the PR interval is necessary to allow the device to pace biventricularly before an intrinsic beat can occur. The pulse generator provides the following types of therapies:

- **Cardiac Resynchronization Therapy**—When the patient's intrinsic atrial rate is below the maximum tracking rate and the programmed AV Delay is less than the PR interval, the device issues simultaneous pacing pulses to the right and left ventricles at the programmed settings to synchronize right and left ventricular contractions.
- **Normal Bradycardia Pacing**—If the intrinsic atrial heart rate falls below the programmed pacing rate (ie, lower rate limit), the device will continue to deliver cardiac resynchronization therapy at the programmed settings. Sensor-based rate modulation allows the pulse generator to adapt the atrial pacing rate and resynchronization therapy to the patient's changing activity levels.
- **Post-shock Bradycardia Pacing**—Higher-energy pacing pulses may be delivered for a programmed period to ensure capture after the delivery of a shock. Most post-shock parameters are programmable independently of the normal bradycardia pacing parameters. Post-shock pacing can be activated even if normal bradycardia pacing is Off.
- **STAT PACE**—Under command of the programmer via telemetry, the device initiates emergency bradycardia pacing at high output settings. Refer to Chapter 2 for details about STAT PACE.

The pulse generator together with the PRM system provides the following analysis tools, which include the following features:

- Pacing lead impedance measurement
- Pacing threshold test
- P-wave and biventricular R-wave amplitude measurement
- Temporary bradycardia pacing—allowing pacing values to be tested on a temporary basis
- Pace/Sense Histograms
- Trending for sensor-driven rate data

Normal Brady Pacing Parameters

The normal bradycardia pacing parameters are independently programmable from the post-shock and temporary bradycardia parameters.

Brady Mode

The pacing modes available are Off, DDD(R), DDI(R), VDD(R), AAI(R), VVI(R) and OOOOR. In Temporary Brady pacing only, asynchronous modes [AOO(R), VOO(R), DOO(R), DVI(R), ODO(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.
- Direct any questions regarding individualization of patient therapy to your Guidant representative or Guidant 24-hour technical services at 1-800-CARDIAC.

Lower Rate Limit (LRL)

The Lower Rate Limit (LRL) is the number of pulses per minute at which the pulse generator paces the atrium or ventricles in the absence of sensed intrinsic activity.

The pulse generator may be programmed to rates of 40–175 ppm. The LRL must be at least 10 ppm less than the lowest tachy rate zone boundary in nonadaptive-rate single-chamber modes, and at least 20 ppm less than the Maximum Tracking Rate (MTR) or Maximum Sensor Rate (MSR) in a dual-chamber mode or adaptive-rate single-chamber mode (see Table 12). Exercise caution when programming permanent pacing rates below 50 ppm or above 100 ppm.

Maximum Tracking Rate (MTR)

The Maximum Tracking Rate (MTR) 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 and VDD. The programmable values range from 60–175 ppm. The MTR must be at least 5 ppm less than the lowest tachy rate zone boundary, and at least 20 ppm greater than the LRL (see Table 12).

When the sensed atrial rate is between the programmed LRL and MTR, 1:1 biventricular 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 sensed because it falls into the atrial refractory

period. 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 damped or eliminated by implementation of either Rate Smoothing or Atrial Tachy Response or both parameters and sensor input.

Table 12. Relationship of Bradycardia and Tachycardia Programmable Rates

<p>Dual Chamber Modes LRL \leq 20 ppm below MTR (or MSR) \leq 5 ppm below Lowest Tachy Zone</p>
<p>Single-Chamber Adaptive-rate Modes LRL \leq 20 ppm below MSR \leq 5 ppm below Lowest Tachy Zone</p>
<p>Single Chamber Nonadaptive-rate Modes LRL \leq 10 ppm below Lowest Tachy Zone</p>

Adaptive-Rate Pacing Parameters

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

When adaptive-rate parameters are programmed, the 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 pacemaker case. If tapping or twiddling of the pacemaker causes significant movement of the pacemaker that exceeds the activity threshold, then a proportional rate response may be observed.

Maximum Sensor Rate (MSR)

The Maximum Sensor Rate (MSR) is the maximum pacing rate allowed as a result of sensor control. It may be programmed from 60–175 ppm. The MSR must be at least 5 ppm less than the lowest tachy rate zone boundary, and at least 20 ppm greater than the LRL (see Table 12).

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.

If the pulse generator is operating in DDD(R) mode, the MSR and the MTR may be programmed independently to different values.

- If the MSR setting is higher than the MTR, a 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 intrinsic atrial activity.

With 1-to-1 conduction at the MSR the pulse generator maintains the paced rate at the MSR by extending the VA interval according to MSR rate criteria. This extension is determined by the degree of difference between the AV delay and the intrinsic ventricular conduction (Figure 61). This is often referred to as modified ventricular-based timing.

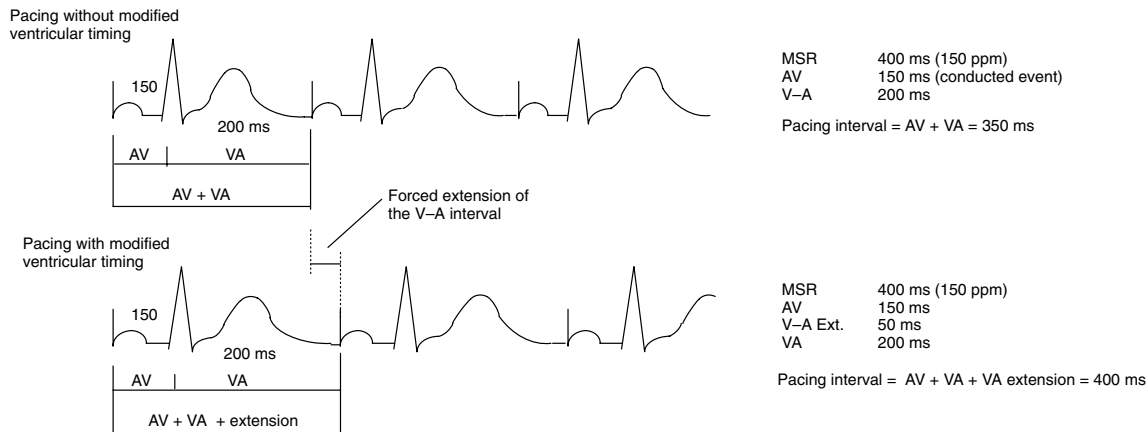


Figure 61. The pulse generator’s timing algorithm provides effective pacing at the MSR with intrinsic conduction to the ventricles. By extending the VA interval, the A pace is prevented from exceeding the MSR at high rates.

Activity Threshold

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 atrial 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

The programmed Reaction Time determines how quickly the pacing rate will rise when an increase in the level of physical activity is detected. It allows a smooth transition in rate to mimic a normal physiologic response to an increase in activity. The value selected for reaction time determines the time required for the paced rate to reach the MSR for a maximum level of activity. The programmable values range from 10–50 seconds.

Refer to Figure 62 for a graphic representation of the reaction slopes. A fast reaction value will allow the pacing rate to increase rapidly in response to patient activity. A slow reaction value will force a slower increase in pacing rate. Reaction affects only the time required for a rate increase to occur.

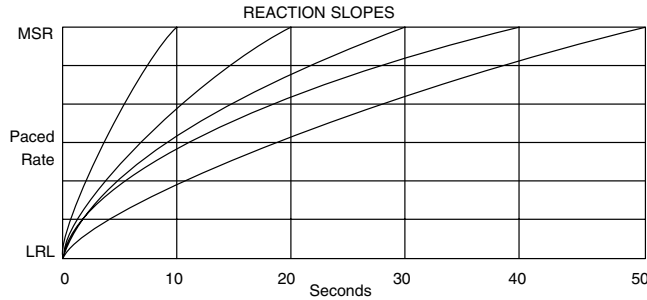


Figure 62. The relationship of reaction time and paced rate, depending on the programmed Reaction Time setting.

Response Factor

The Response Factor determines the pacing rate that will occur above the LRL and below the MSR, at various levels of patient activity. The Response Factor programmable range is 1–16. Figure 63 shows the relationship of the response settings.

The pacing rate achieved may be limited either by the detected level of activity or the programmed MSR. If the detected activity level reaches a steady-state rate below the MSR, the pacing rate can still increase when the detected activity levels increase. Pacing response to activity is affected by lower rate programming, but is independent of Reaction Time and Recovery Time parameters.

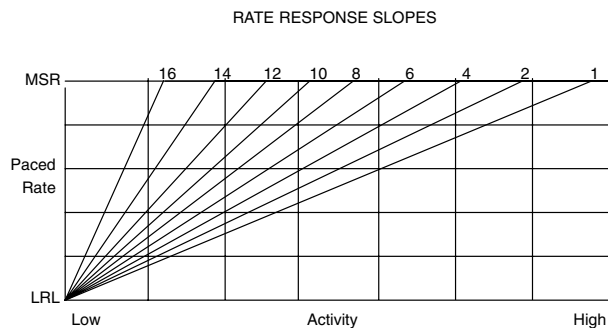


Figure 63. The relationship of response and paced rate, depending on the programmed Response Factor setting.

Recovery Time

The Recovery Time determines the minimum time required for a decrease in pacing rate to occur. This feature is intended to prevent an abrupt decrease in pacing rate concurrent with the conclusion of patient activity. It is programmable from 2–16 minutes (see Figure 65).

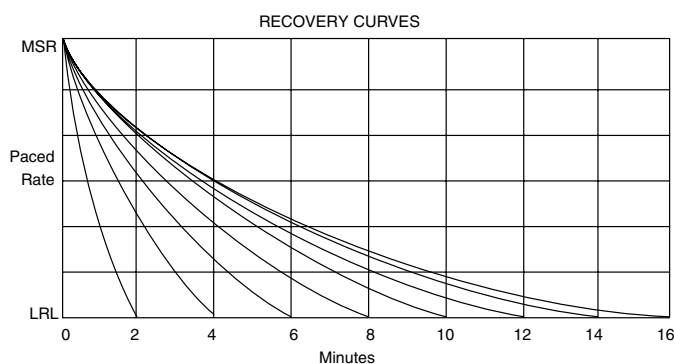


Figure 64. The relationship of paced rate to recovery, depending on the programmed Recovery Time value. Only even-numbered settings are shown. There are actually 15 settings available.

A fast recovery time will allow the pacing rate to decrease rapidly in response to lower levels of patient activity (refer to Figure 64). A slow recovery time will force a slower decrease in pacing rate. Recovery time affects only rate deceleration and is independent of other parameters.

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 ventricular-sensed event does not occur during the AV delay following an atrial event, the pulse generator delivers a ventricular pacing pulse.

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

AV Delay. 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 ventricular sensed event.

The AV Delay programmable values range from 50–300 ms, and it is active when Brady Mode is programmed to DDD(R), DDI(R), DVI(R), DOO(R), and VDD(R) modes.

Dynamic AV Delay. 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 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 65).

NOTE: The AV Delay parameters are programmed from the Brady Pacing window on the PRM 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 AV Delay parameter toggles to display as AV Delay and the Minimum AV Delay

parameter is not available for programming. This indicates that a fixed-time AV Delay is programmed.

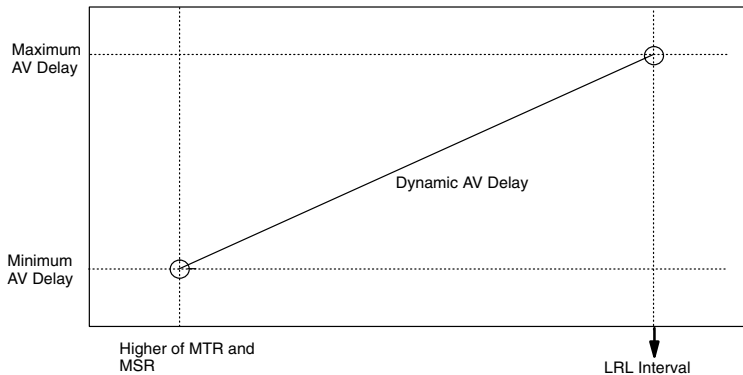


Figure 65. Dynamic AV Delay linear relationship.

Sensed AV Offset

This feature allows the pulse generator to automatically shorten the AV interval following a sensed atrial event. The decrease in AV delay is intended to compensate for the delay of sensing P-waves late during the atrial contraction. The typical application of this parameter is to shorten the AV delay by 30–60 ms after an atrial sensed event.

The Sensed AV Offset programmable values range from –10 to –100 ms or Off. It may be programmed in conjunction with Dynamic AV Delay. The pulse generator calculates the Dynamic AV Delay, then applies the Sensed AV Offset to determine the AV delay. If the resulting AV delay value is less than the Minimum AV Delay, the programmed Minimum AV Delay takes precedence over the calculated AV delay. The AV delay is not allowed to be shorter than the programmed Minimum AV Delay.

Amplitude

The atrial and ventricular pulse amplitudes, or voltage of the output pulse, are independently programmable and range from 0.2–5.0 V in the atrium and 0.2–7.5 V in the ventricles. In addition, the amplitude may be programmed Off to monitor the patient’s underlying rhythm.

The energy delivered to the heart is directly proportional to the square of the amplitude (see Figure 67). 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.

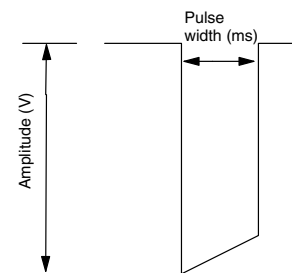


Figure 66. Pulse waveform.

Pulse Width

The Pulse Width, or duration of the output pulse, is independently programmable for atrial and ventricular chambers. However, Pulse Width is not independently programmable between the left and right ventricles. The programmable values for both atrial and ventricular pulse widths range from 0.06–2.0 ms.

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.

Ventricular Paced/LRL Refractory

The Ventricular Paced/LRL Refractory is the interval following a ventricular event during which the pulse generator is not inhibited by detected electrical activity in the ventricles. This

parameter is used in modes with ventricular pacing, and the programmable values range from 150–500 ms. Use of a long ventricular refractory period shortens the ventricular sensing window.

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

Dynamic MTR Refractory

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 (see Figure 68). It is programmable from 150–500 ms and indicates the minimum value to which it will shorten; it must be less than the Ventricular Paced/LRL Refractory. (If it is programmed at the same value as the Ventricular Paced/LRL Refractory, the Dynamic MTR Refractory is essentially turned off.) A linear calculation is performed between the minimum (Dynamic MTR Refractory) and the maximum (Ventricular Paced/LRL Refractory) refractories to determine the refractory for the next interval.

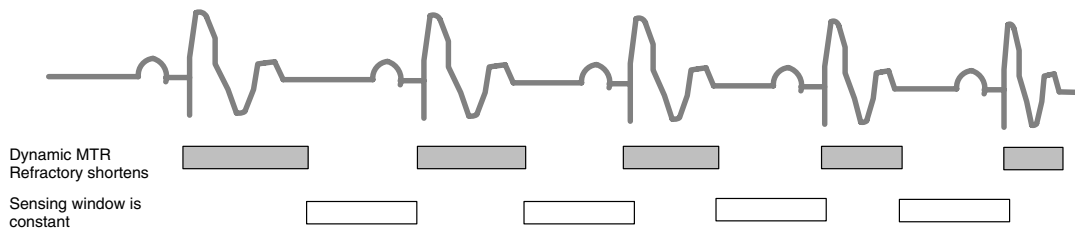


Figure 67. As the ventricular rate increases, the refractory interval decreases.

Atrial Refractory-PVARP

The Atrial Refractory-PVARP parameter, which has a programmable range from 150–500 ms, is defined according to the pacing mode. Refer to Figure 68 through Figure 70 for illustrations 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 activity in the atrium does not inhibit an atrial stimulus nor trigger a ventricular stimulus. The atrial refractory period is measured from the ventricular event to avoid atrial sensing of retrograde activity initiated in the ventricles.
- **For single-chamber atrial modes [AAI(R)],** the Atrial Refractory is defined as the time period after an atrial event, either paced or sensed, when activity in the atrium does not inhibit an atrial stimulus.

A long atrial refractory period shortens the 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” 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 either the PVARP Extension option or Rate Smoothing or both may be useful in controlling the pacemaker’s response to retrograde conduction.

PVARP Extension

When the pulse generator is programmed to the DDD(R) or VDD(R) mode, the PVARP Extension can be programmed with values ranging from 50–400 ms or Off. Upon detection of a sensed or paced ventricular event that is followed by another sensed ventricular event without an intervening atrial event (ie, a premature ventricular contraction [PVC]), the atrial refractory period is automatically extended by the programmed amount for one cardiac cycle.

This feature is designed to help prevent pacemaker-mediated tachycardia due to retrograde conduction, which is typically associated with PVCs. After a PVC is detected, the timing cycles are automatically reset.

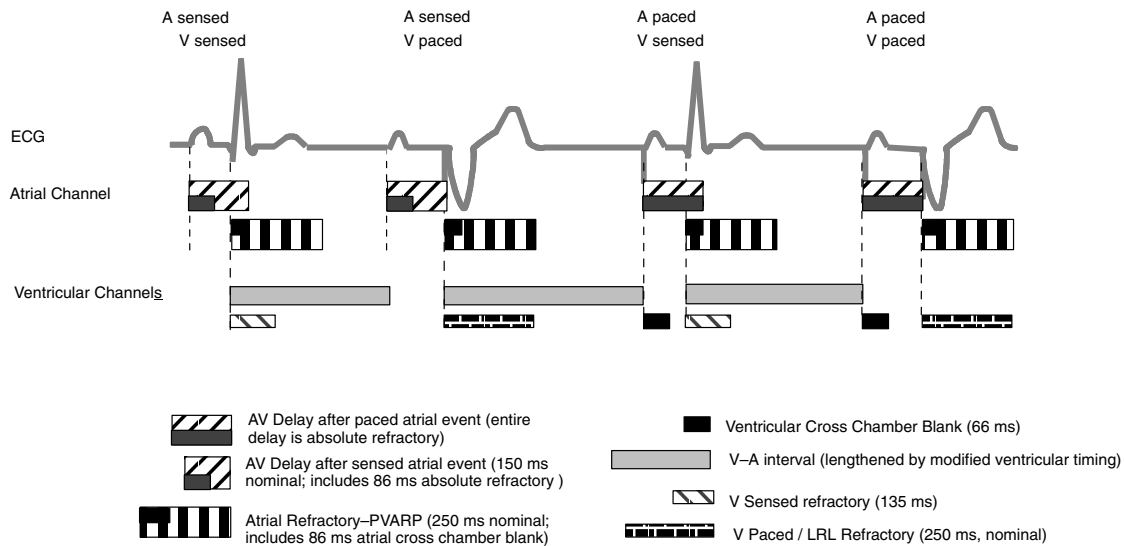


Figure 68. Refractory periods for dual-chamber pacing modes.

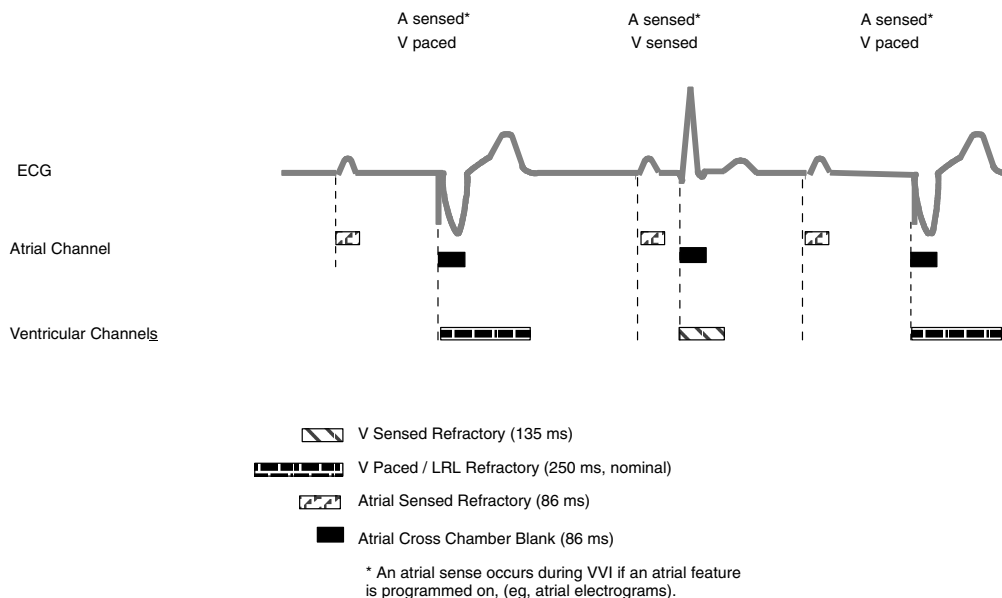


Figure 69. Refractory periods for VVI pacing mode.

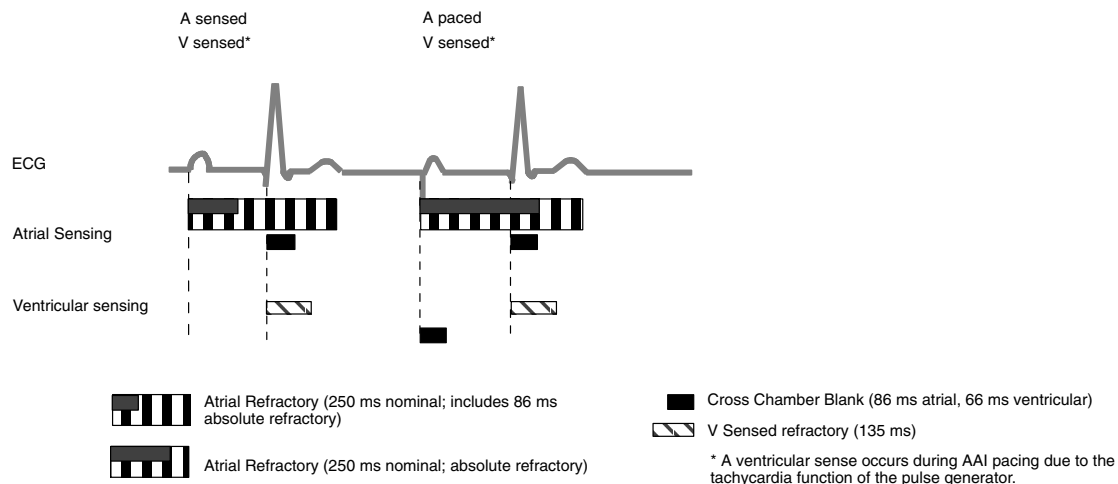


Figure 70. Refractory periods for AAI pacing mode.

Noise Response

In addition to a refractory period, the pulse generator uses a retriggerable noise window. A 40-ms noise window is initiated by a sensed or paced event (see Figure 72). 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.

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.

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, a rate noise marker will occur when the noise window exceeds the paced or sensed refractory time.

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

Hysteresis

The pulse generator can be programmed with rate hysteresis in VVI and AAI modes. Hysteresis allows the intrinsic rate to fall below the programmed Brady LRL. Once the intrinsic rate drops below the hysteresis rate setting, pacing resumes at the programmed Brady LRL (if Rate Smoothing is not in effect).

The ability to program the hysteresis rate gives the physician an opportunity to extend the length of the escape interval following a sensed event. As a result, the patient may benefit

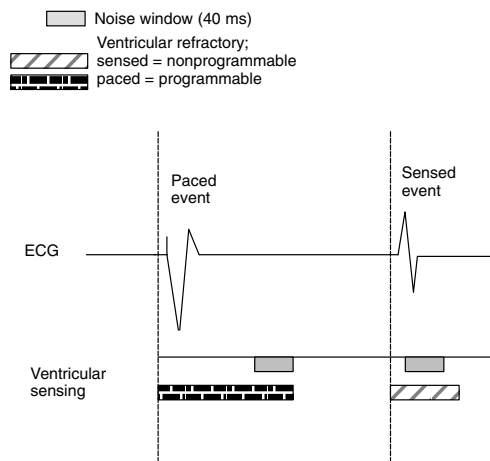


Figure 71. Refractory periods and noise windows.

from longer periods of sinus rhythm and the improved hemodynamics associated with the maintenance of AV synchrony.

The hysteresis rate can be programmed Off or from 40–170 ppm, and must be lower than the programmed LRL.

Rate Smoothing

Rate smoothing eliminates large cycle-to-cycle variations in rate by preventing the paced interval, atrial and ventricular, from changing by more than a programmed percentage from one cardiac cycle to the next.

Rate smoothing may be used to control the pacemaker's response either to atrial or ventricular dysfunctions or both that cause erratic or sudden changes in pacing intervals. These dysfunctions may include, but are not limited to, any of the following:

- Sinoatrial disease, such as sinus arrest, sinoatrial blocks, brady-tachy syndrome
- Premature atrial and/or ventricular contractions (PAC/PVC)
- Intermittent, brief, self-terminating supraventricular tachycardias, atrial flutter/fibrillation
- Retrogradely conducted P-waves
- Nonphysiologic dysfunctions, such as pacemaker sensing of myopotential signals, EMI, crosstalk, etc.

The human heart is normally incapable of sudden, large-step changes in rate except under pathologic disease conditions (eg, sick sinus syndrome). Physiologic cycle-to-cycle interval change will vary among patients. The physician 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) will cause a simultaneous sudden increase in the paced ventricular rate as high as the programmed MTR. With rate smoothing, the maximum ventricular paced rate in response to such a change may be less than the programmed MTR.*

When programmed On, rate smoothing functions as follows:

1. This feature operates between the LRL and the MTR (or MSR, whichever is greater) in DDD(R) and VDD(R) modes, and between Hysteresis and the LRL in VVI(R) and AAI(R) modes.
2. Programmable Rate Smoothing values range from 3%–25% and are a percentage of the sensed interval. It can be independently programmed to increase (Smoothing Up) or decrease (Smoothing Down), or programmed Off.
3. Rate Smoothing is in effect prior to and following an ATR episode, but is not in effect during ATR Fallback Time.
4. 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:
 - Atrial synchronization window = [Previous R–R interval \pm Rate Smoothing] – AV Delay
 - Ventricular synchronization window = Previous R–R interval \pm Rate Smoothing

Refer to Figure 72 for an example of how these two synchronization windows are calculated. 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.

Previous R-R interval = 800 ms
 Fixed AV Delay = 150 ms
 Rate Smoothing = 3%
 Ventricular Synchronization Window = $800 \pm 3\% = 800 \pm 24$ ms
 Atrial Synchronization Window = $(800 \pm 3\%) - 150 = (800 \pm 24$ ms) - 150 = 650 ± 24 ms

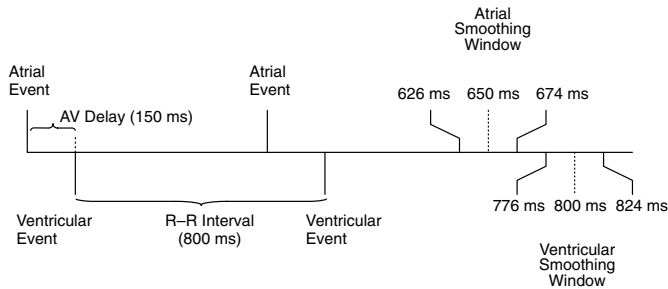


Figure 72. Example of rate smoothing windows.

Ventricular Tachy Response (VTR)

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 ATR/VTR Fallback LRL and the programmed ventricular Pulse Width and Amplitude values. Refer to the “Atrial Tachy Response” section.

Atrial Tachy Response (ATR)

The Atrial Tachy Response feature provides mode switching from DDD(R) or VDD(R) to VVI(R) in the presence of detected atrial activity that exceeds the ATR Trigger Rate (the ATR threshold). The objective of atrial tachy response is to limit the time that the ventricular paced rate is at the MTR in response to a pathological atrial arrhythmia. The ATR Trigger Rate programmable values range from 100–200 ppm or Off.

ATR Duration is a programmable parameter that allows the physician to determine the number of ventricular cycles that occur while the atrial rate is above the ATR Trigger Rate, before the ventricular rate begins to decrease to the ATR/VTR Fallback LRL (which is the mode switch’s lower rate limit), or to the sensor-indicated rate, whichever is greater. The ATR Duration programmable values range from 0–2000 intervals. The ATR/VTR Fallback LRL programmable values range from 40–175 ppm.

The ATR Fallback Time determines how quickly the rate will decrease from the MTR to ATR/VTR Fallback LRL. During fallback, the pulse generator operates in a VVI(R) mode. The pulse generator uses the last V–V cycle length to determine where fallback starts and may include a Wenkebach interval longer than the MTR. The ATR Fallback Time programmable values range from 0–45 seconds and from 1–5 minutes.

When the atrial rate has decreased and is consistently below the ATR Trigger Rate for 8 atrial beats, the pulse generator automatically ends the ATR episode and resumes AV-synchronous operation. Refer to Figure 73 for an example.

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

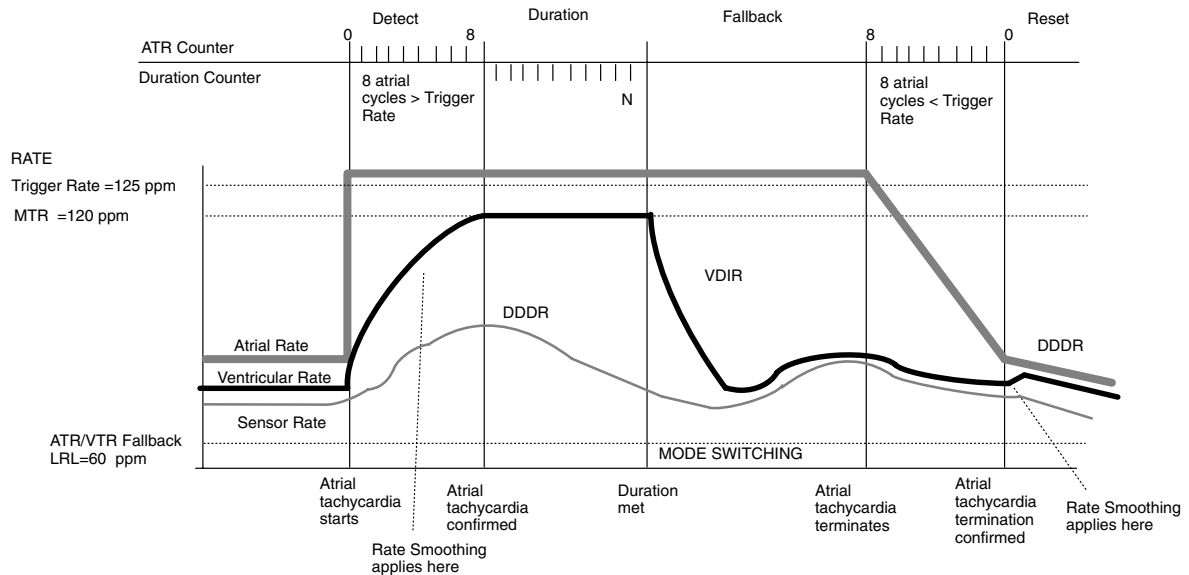


Figure 73. Example of ATR.

Post-Shock Brady Pacing Parameters

Post-shock bradycardia pacing provides high-energy, dual-chamber, biventricular bradycardia pacing for up to 60 minutes following delivery of any shock. All bradycardia parameters, except Noise Response and Atrial Tachy Response parameters, can be programmed independently of normal bradycardia pacing and are in effect following delivery of any shock. When programmed, Noise Response, Atrial Tachy Response, and adaptive-rate parameters affect both Normal Brady and Post-shock Brady pacing. Refer to the normal bradycardia section for a description of the parameters. All parameters will be in effect for the Post-shock Pacing Period. Refer to Table 13 for the interaction of normal bradycardia pacing and post-shock brady pacing, and the resulting post-shock brady pacing condition.

Table 13. Matrix of Brady Mode and Post-shock Brady Mode

Normal brady pacing	On (programmed mode)	On (programmed mode)	OFF ^a	OFF
Post-shock brady pacing	OFF	On (programmed mode)	On (programmed mode) ^a	OFF
Post-shock brady pacing results	Post-shock pacing at normal brady settings	Post-shock pacing at post-shock brady settings	Post-shock pacing at post-shock brady settings	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

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, despite the use or nonuse of the Post-shock Brady Mode.) Immediately following the delivery of any shock, the device begins a post-shock refractory interval and a programmable Post-shock Pacing Delay. When the programmed Post-shock Pacing Delay expires, pacing is enabled at the Post-shock LRL or the normal Brady LRL (depending on the programmed prescription) minus the programmed AV Delay.

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 P- and R-waves are sensed during the Post-shock Pacing Delay, after the Post-shock Pacing Delay ends, the device paces only when the sensed rate is slower than the Brady LRL or Post-shock LRL, depending on the pacing prescription.

- If no P- or R-waves 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 programmable values range from 1.5–10 seconds. It must be at least 275 ms longer than the bradycardia pacing escape interval (60,000/rate). If Post-shock LRL is Off, the Post-shock Pacing Delay is interactive with the normal Brady LRL; otherwise, the interactive limit applies to the Post-shock LRL. The Post-shock Pacing Delay has no effect on tachyarrhythmia detection.

Post-shock Pacing Period

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.

The Post-shock Pacing Period programmable values in minutes and seconds are 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.

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 the Normal Brady or Post-shock Brady button from the base window to display the appropriate window (Figure 74). Both windows display the same parameters with the addition of Post-shock Pacing Delay and Post-shock Pacing Period in the Post-shock Brady Pacing window.

NOTE: *When the pacing windows are displayed, not all parameters are visible. To enlarge the window, select the far-right button in the right corner of the title bar (Figure 74).*

2. To change a parameter value, select a value box in a Change column to display a value palette. 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 in either window; when a value is changed in one window, the other window is automatically updated to reflect the change.*
- *When the normal Brady LRL value is changed in the Brady Pacing window, the value is automatically updated in the brady zone configuration value box on the base window, and vice versa. The Post-shock LRL is unaffected.*

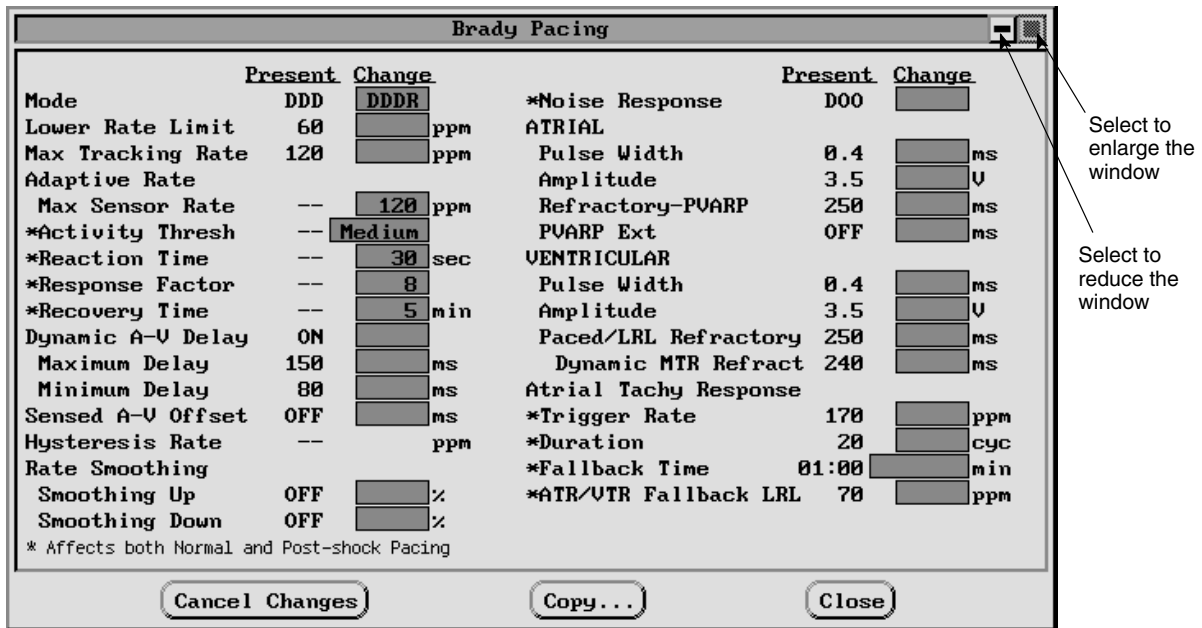


Figure 74. Brady Pacing parameters window.

Accessing Brady Analysis Tools

1. To access the Brady Analysis tools, select the Brady Analysis button in the toolbox on the base window (Figure 75). The tool kit has the following functional areas: temporary brady pacing, pace threshold test, P/R-wave amplitude measurement, and pacing impedance measurement. Refer to the following sections (a–e) for explanations and instructions specific to these functions. Real-time electrograms and markers are available while the Brady Analysis functions are active.
2. To exit the Brady Analysis tool kit, select another toolbox button.

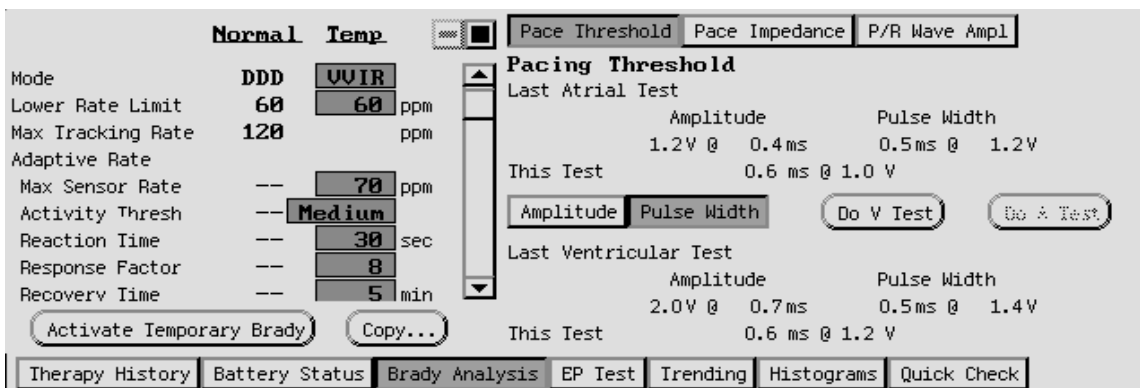


Figure 75. The Brady Analysis window with the Pace Threshold button selected.

- a. **Temporary Bradycardia Pacing**—The left side of the tool kit shows the present normal bradycardia pacing parameters along with the temporary bradycardia pacing parameter values. The Temporary Brady parameters reset to the normal brady pacing nominal values following an initial interrogation. Temporary brady pacing offers a wider choice of modes than normal bradycardia pacing. (Post-shock brady values are not shown, even if post-shock brady is presently in effect.) Refer to Appendix A for modes and programmable values available. To use the Temporary Brady function, follow these steps:

1. To change the values in the Temp column, select a value box next to a parameter and then select the desired value. Values are independent of other pacing functions.
2. Select the Activate Temporary Brady button and establish telemetry communication. Bradycardia pacing will begin at the values in the Temp column. A message window will appear indicating that temporary brady pacing parameters are being used, and this 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.

3. 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 the programmer commands an emergency therapy or presses the DIVERT THERAPY key.

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 when the programmer moves the telemetry wand away from the pulse generator or selects the Stop Temp Brady button.

- b. **Pace Threshold Test**—A pacing threshold test may be performed on command of the programmer to determine the minimum threshold needed for capture. An amplitude or pulse width measurement can be performed in either the atrium or ventricle. The test begins “stepping down” or reducing the pulse width or amplitude starting with the selected value. At each step of the test, four paced or sensed cardiac cycles will occur at the step value before it moves to the next lower step value. After four more cardiac cycles at the lower setting, the next lower setting will be selected. This continues until either a) the lowest setting is reached, b) the End Test button is selected, or c) the wand is removed from range when the clinician determines that loss of capture has occurred. For this reason, pacing threshold testing must be performed interactively.

CAUTION: Backup VVI pacing is not available during a pacing threshold test.

1. Select the Pace Threshold button in the Brady Analysis tool kit. Notice that test results from the previous measurement appear next to the label Last Test (atrial or ventricular).
2. Select either the Amplitude or Pulse Width button (only one can be selected at a time).
3. Position the telemetry wand within range of the pulse generator.
4. Select either the Do A Test (atrial) or Do V Test (ventricular) button. (If a test is initiated when a tachyarrhythmia episode is in progress, the message PG Is Busy will appear, and the test cannot be started.)
5. A message window will appear allowing test parameter values to be changed. Select the Confirm button.

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.*

As the test progresses, the values currently being tested (stepped down) will be displayed. The surface ECG and real-time electrograms and annotated markers (including the voltage values as the test steps down) can be printed to determine loss of capture. When loss of capture is observed, select the End Test button or remove the telemetry wand from range to terminate the test. If the test continues until four cardiac cycles have occurred at the lowest setting, the test is

automatically terminated, and the results are indicated as equal to or less than the lowest settings. Once the test is terminated, the brady pacing settings are restored. The final threshold test values (the value is one step above the value when the test was terminated) will be displayed next to the label This Test.

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

6. To perform another test, repeat steps 1 through 5. The values from the previous test will be displayed next to the label Last Test. The new test values will again be displayed next to the label This Test.

NOTE: *The test results from the most recent measurement are stored in pulse generator memory, and they are retrieved during the initial interrogation. They are displayed on the Brady Analysis window when it is opened initially. Also, at the next follow-up session, the starting amplitude value for the test reflects the value of the stored test result backed up three steps.*

- c. **P/R Wave Amplitude**—The P-wave and biventricular R-wave measurements can be performed. **The R-wave measurement is a combination of R-waves from the left and right ventricles.**

1. Select the P/R Wave Ampl button from the Brady Analysis tool kit.
2. Select the Measure button. The P- and R-wave values will be displayed as This Measurement.
3. If another measurement is performed, the previous values will display as Last Measurement and the most recent values will display as This Measurement.

NOTE: *The test results from the last measurement are stored in pulse generator memory, and they are retrieved during the initial interrogation. They are displayed on the P/R Wave Ampl window when it is initially opened.*

- d. **Pace Impedance**—The pacing lead impedance is measured only on command of the programmer. During a pace impedance test, the pulse generator functions in triggered mode at a 5.0-V amplitude and 0.5-ms pulse width setting. **The measured value is a parallel combination of the left and right ventricles.** The value may differ from a pacing system analyzer (PSA) measurement due to the method of calculation. The pace impedance test can be used as a relative measure of lead integrity over time.

1. Select the Pace Impedance button from the Brady Analysis tool kit.
2. Ensure that the telemetry wand is in range of the pulse generator.
3. Select the A Ohms, A&V Ohms, or V Ohms button depending on the chamber to be affected. Only one of the buttons will be accessible at a time depending on the temporary bradycardia mode selected; the other two will be grey. (If a test is initiated when a tachyarrhythmia episode is in progress, the message PG Is Busy will appear and the test cannot be started.)
4. During the test, a clock icon will display. When it disappears, another test can be performed by once again selecting the Ohms button desired.
5. 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, and they are retrieved during the initial interrogation. They are displayed on the Pace Impedance window when it is initially opened.*

Trending Data

When programmed to an adaptive-rate mode, the pulse generator collects and stores raw sensor data when the Trending feature set up has been confirmed. The Trending feature

graphically displays the sensor rate in response to the sensor data allowing 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 Trending Replay option, without having to repeat an exercise test.

1. To access the Trending window (Figure 76), select the Trending toolbox button. The currently programmed normal bradycardia adaptive-rate parameter values are displayed in the lower right corner of the window. The values on the graph's vertical axis reflect the values in the Present and/or Replay columns. The values on the horizontal axis reflect the selected trending Duration (see Figure 76).

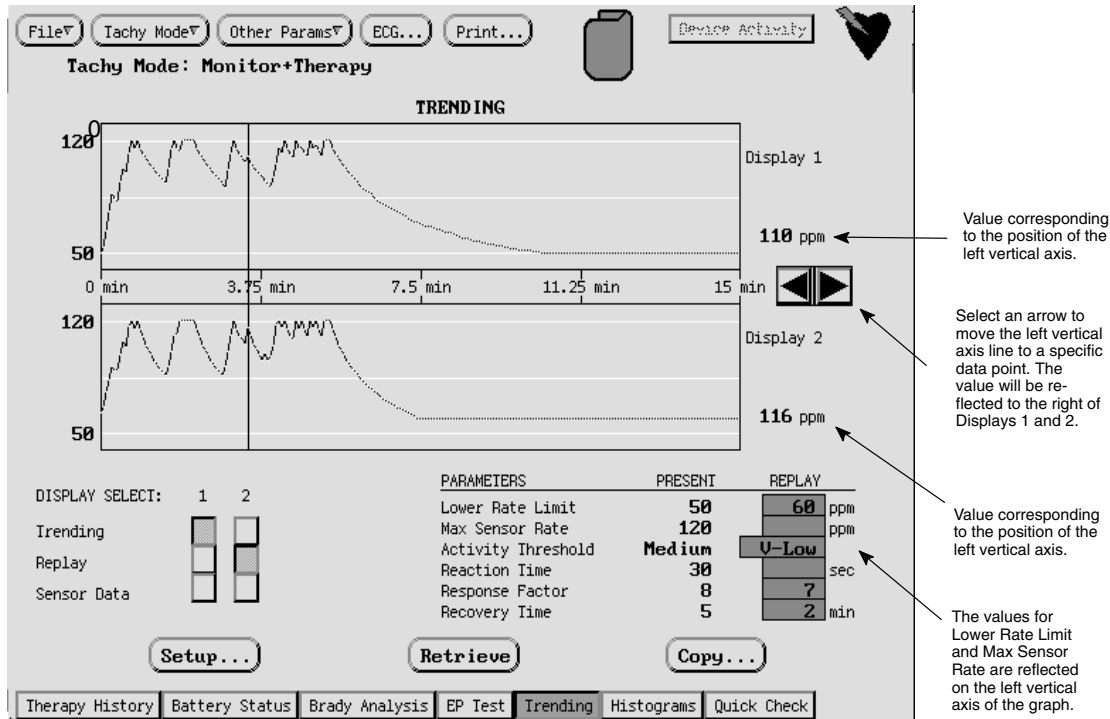


Figure 76. The Trending window.

2. To set up the trending data to be collected, select the Setup... button. The Trending Setup window will appear (Figure 77) with values for the programmable Duration and its corresponding Resolution. The Duration values indicate how long the trending period will last and the Resolution column indicates the period over which the pulse generator will average and record the sensor value.

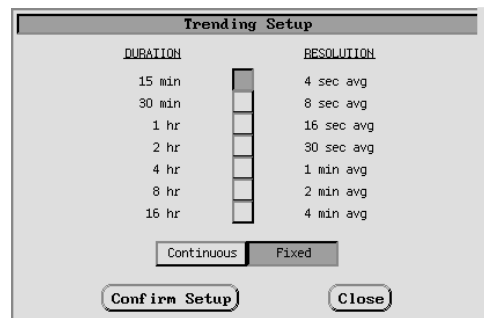


Figure 77. The Trending Setup window.

- a. Select the desired Duration value.
- b. Select either the Continuous or Fixed button to indicate the period over which values are collected. The Fixed method will begin collecting information as soon as the pulse generator is programmed, and will stop collecting after the time specified in the Duration field. The Continuous method will continuously update, so that the data displayed are the last data collected prior to interrogation.

For example, if Duration = 15 min and its corresponding Resolution = 4 sec, and the Fixed button is selected, the device will average the sensor values every 4 seconds

for the first 15 minutes after programming. This data will remain stored in the pulse generator and may be displayed at each interrogation until Trending data set up is confirmed.

- c. With the wand in telemetry range of the pulse generator, select Confirm Setup. The displayed values will be programmed in the pulse generator, and data collection will begin. The Close option closes the window without applying the new settings.
3. To determine the manner in which data are displayed, select an option from the Display Select section of the Trending window. When Trending or Replay is selected, the data will be graphed as sensor-driven rates between the LRL and the MSR; when Sensor Data is selected, the data are shown as a percentage between 0% and 100%. The Display Select columns 1 and 2 correspond to the upper and lower graphs respectively. See step 5 for a description of the Replay option.

To view the rate (or sensor) value for a specific data point on the graph, select the left or right arrow (to the right of the graph) to move the left vertical axis line (see Figure 76). Move the line to the desired data point; the rate (or sensor) value will be displayed on the right side of the graph.

4. With the wand in telemetry range of the pulse generator, select the Retrieve button to view the collected data. A quick interrogation of the pulse generator will be performed, and the data points will be displayed. Only sensor-indicated pacing rates are displayed; intrinsic activity, if present, is not displayed.
5. To view the effects of changed parameters on the trending test without performing another exercise test, use the Replay feature.
 - a. Select the Replay option either in column 1 or 2 or in both in the Display Select section.
 - b. Enter new parameter values in the Replay column. As new values are entered, the data will be displayed on the graph.
 - c. If the replay values give the desired results, select the Copy button. A window will appear with destination choices for the Replay values. Select the desired destination, select the Copy button, position the wand in telemetry range of the pulse generator, and press the PROGRAM key on the PRM panel.
6. The trending data that are displayed in the window can be printed by selecting the Print button at the top of the base window. Then select the Trending report option from the Choose Reports To Print window.
7. To exit the Trending window, select any toolbox button.

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 ventricles. The data can be displayed and printed in tabular or graphic formats.

1. To access the Histograms window, select the Histograms toolbox button. A window with a graphical format will be displayed. The window contains buttons for choosing the format in which to view data, clear counters, and retrieve the data from the pulse generator (Figure 78). Whether the display is presented in graphical or tabular form, the Histograms window buttons are available.

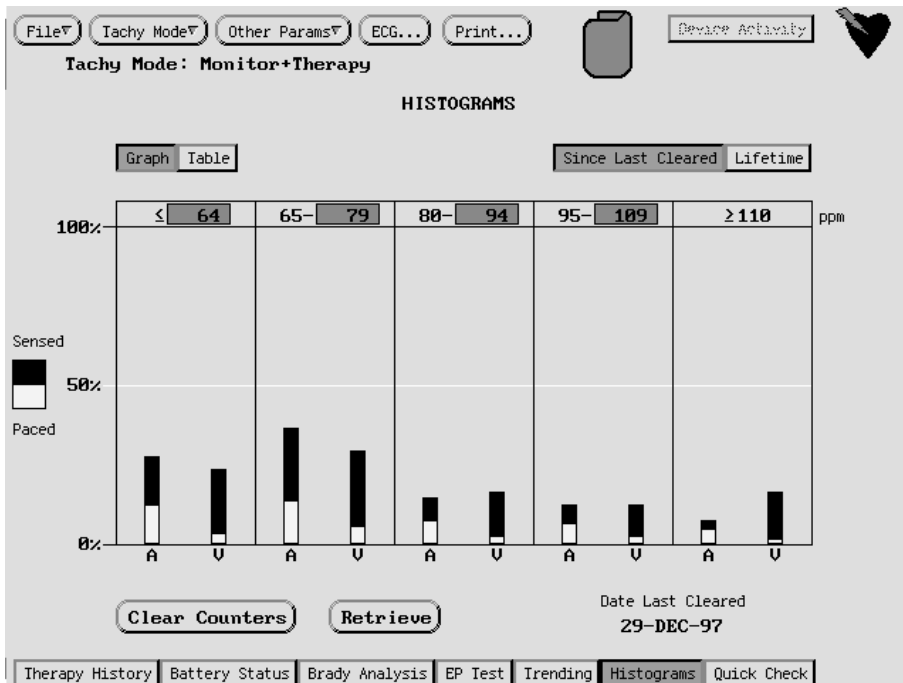


Figure 78. The Histograms window in graphical format.

2. Select the Graph or Table button to display the desired format of histograms. The Graph format presents the atrial (A) and ventricular (V) data in a bar graph for five ranges of pulse rates. The Table format displays the same data in a tabular format with numeric and percentage values in the same ranges of pulse rates. Note that the values followed by a K or M indicate thousands or millions, respectively. The displayed data will be retained when toggling between graphical and tabular formats.
3. To retrieve the pace/sense counter data from the pulse generator any time during the follow-up session, position the wand in telemetry range of the pulse generator, and select the Retrieve button. A quick interrogation of the data will be performed.
4. The initial display includes data since the last time the counters were cleared. To display lifetime data, select the Lifetime button. Both the graphical and tabular formats will display lifetime totals until the Since Last Cleared button is selected. The date that the counters were last cleared is displayed in the lower right corner of the window.
5. The values for the pulse rate ranges can be changed to allow flexibility in viewing the data. The pulse rate ranges are located at the top of the graph and table. To change the higher value of a range, select the value surrounded by a box. A list of values will be displayed; select the desired value. The following rules will apply when a rate range is changed: a) the programmable upper rate value will be more than the lower rate value by ≥ 4 ppm in the same rate range, and b) the lower rate value will be 1 ppm more than the upper rate value of the adjacent (on the left) rate range. This value is automatically updated as the upper rate value is changed.
6. Histograms data that are displayed in the window can be printed by selecting the Print button at the top of the base window. Then select the Histograms report option from the Choose Reports To Print window. Counters for both lifetime and since last cleared will be printed.
7. To clear pace/sense counters that had been stored in the pulse generator since the last time counters were cleared, select the Clear Counters button. Lifetime counters are not cleared.
8. To exit the Histograms window, select any toolbox button.

Accessing Quick Check

Typical patient follow-up tests, listed below, can be performed from a single PRM window. All the tests can be performed sequentially by selecting one button or separately by selecting individual “go” buttons (Figure 79).

- Intrinsic Amplitude Tests (atrial and ventricular)
- Pacing Impedance Tests (atrial and ventricular)
- Atrial and Ventricular Amplitude Threshold Tests

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

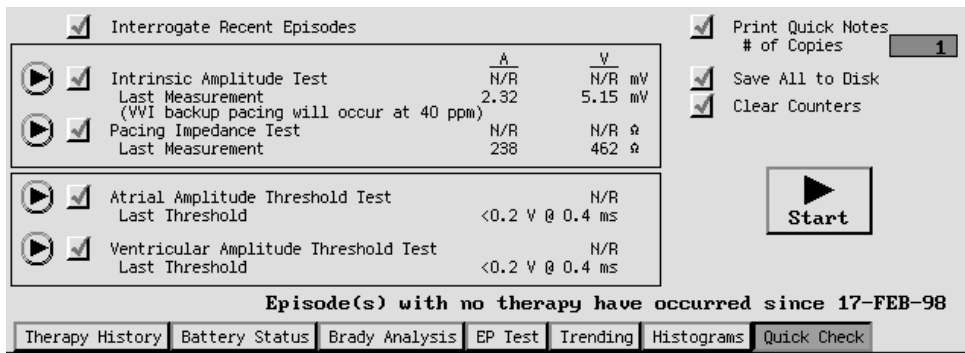


Figure 79. The Quick Check window.

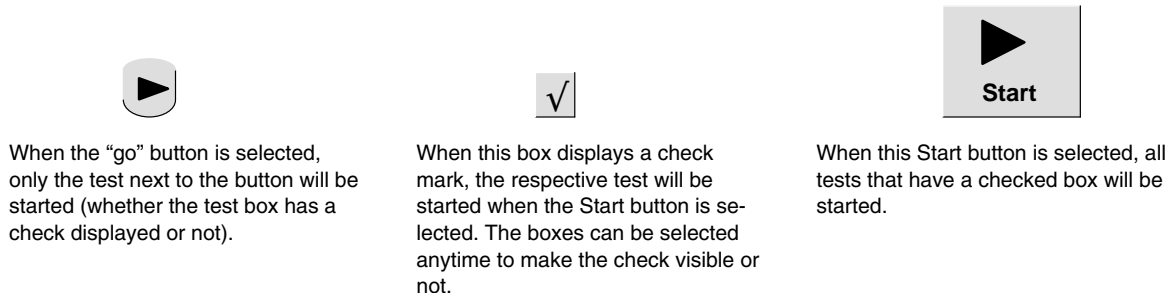


Figure 80. Buttons on the Quick Check window.

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 shock electrograms if activated.
2. To access the Quick Check tool, select the Quick Check button in the toolbox on the base window.

NOTES:

- All checked tests will be performed sequentially; if any of the tests are not desired, select the respective test box to remove the check mark.
 - To perform only one test at any time during the session, select the “go” button (see Figure 80) next to the respective test.
 - 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.
3. When the base window appears, if only the Interrogate Recent Episodes and Print Quick Notes boxes are checked, it indicates that sustained episodes have been recorded since

counters were last cleared. Proceed to steps 3.a and 3.b. If all the test boxes are checked, it indicates that therapy has not been delivered (either no episodes or nonsustained episodes have occurred) since counters were last cleared. Proceed to step 4. Prior to starting the tests, make any desired change to the number of copies of Quick Notes to be printed.

- a. Select the Start button. The programmer will initiate an interrogation of history data followed by a printed Quick Notes report. The box for Interrogate Recent Episodes will no longer be checked.
 - b. Select the boxes so a check mark appears for all the desired tests and the Clear Counters and Save All To Disk functions. Proceed to step 4.
4. The values that initially appear on the base window are the results from the previous test. To perform the tests, follow the steps below. Insert a patient data disk in the PRM.

NOTE: For details about how each test is performed and the displayed results, refer to the *Brady Analysis* section earlier in this chapter.

- a. Select the Start button; all checked tests will be performed sequentially and the measured value displayed on the window. A message will appear before the Pace Impedance test allowing selection of the chamber to be tested. Select the Confirm button to continue the test or select the Cancel button to cancel the test.
- b. Before starting the Atrial or Ventricular Amplitude Threshold test, a window will appear allowing changes to be made to the parameters. Select the Confirm button to continue the test or select the Cancel button to cancel the test. If Cancel is selected, that test and any other checked test will not be performed until the Start button is selected again.
- c. If the Quick Notes box is checked on the base window, a Quick Notes report will print out. This report includes device parameter summary, therapy history, Histograms, and pulse generator and lead system data.
- d. If Save All To Disk is checked on the base window, 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.
- e. The most recent therapy counters will be cleared from pulse generator memory if the Clear Counters box is checked on the base window.

Chapter 6

PROGRAMMER ACTIVATED FEATURES

This chapter describes features that are activated using the PRM programming system and Model 2848 Software Application to perform the following:

- Access pulse generator memory for battery status update and, if desired, manually re-form the capacitors
- Receive and transmit real-time event markers, surface ECG, and electrograms
- Set magnet, beeper, electrogram storage functions, and sensitivity adjustment
- Access patient data
- Print reports
- Disk file functions

Additional programmer activated features are found in other chapters: PROGRAM, INTERROGATE, STAT SHOCK, STAT PACE, DIVERT THERAPY, New Patient, and Quit have been described earlier in Chapter 2, electrophysiologic testing and the Device Activity display are described in Chapter 7, access to therapy history and stored electrograms is described in Chapter 8, and setting the real-time clock is described in Chapter 10—Implanting the Pulse Generator.

Battery Status

The programmer allows access to data that enables evaluation of battery status and shocking lead integrity. To display the Battery Status tool kit, select the Battery Status button in the toolbox on the base window. 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 24 hours the pulse generator measures the Monitoring Voltage (open circuit); that is, the measurement when no load is placed on the battery. 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 at BOL is ≥ 6.2 V, at ERI is 4.9 to 4.4 V, and at EOL is ≤ 4.4 V.

Elective Replacement Indicator. The status ERI indicates that a pulse generator replacement should be scheduled. Once ERI is reached, there is sufficient reserve battery capacity to monitor and bradycardia-pace 100% under nominal conditions for three months and to deliver 10 maximum shocks. All pulse generator functions continue to operate as programmed until the pulse generator reaches end of life.

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 elective replacement time or until the tone is turned off via the programmer.

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

End of Life (EOL). 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. A sequence of five maximum shock energies is available. Telemetry interrogation is still available, and manual capacitor re-formation can be selected in EOL.

Refer to Chapter 1 for pulse generator longevity information.

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. A maximum-energy charge will reset the 90-day 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). During a capacitor re-formation, the Monitoring Voltage and Charge Time are measured and stored for later retrieval. The Battery Status tool kit 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 tool kit 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 being charged. The voltage will remain on the capacitors for approximately 30 seconds.
2. The entire re-form cycle takes approximately 40 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 and energy level are displayed on the Battery Status tool kit.

NOTE: *The telemetry wand may be removed, and the re-formation will complete. However, the charge time and energy level 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 it is displayed by the PRM system whenever the Battery Status tool kit is accessed. Charge Time from a capacitor re-formation is used as a battery status indicator in addition to Monitoring Voltage. Whenever an automatic capacitor re-form or maximum-energy therapeutic charge occurs with a Charge Time greater than 18 seconds, the pulse generator will schedule a capacitor re-formation at the next 24-hour battery check. If Charge Time is again greater than 18 seconds, the pulse generator will declare ERI.

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 they are displayed on the Battery Status tool kit. 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 is encountered (open or shorted leads), the fault will be indicated in parentheses 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.

Real-time Event Markers and Electrograms

The pulse generator provides real-time event markers and electrograms (EGMs) that are useful in ascertaining system performance.

- Annotated event markers identify certain intrinsic cardiac and device-related events, and provide information such as sensed/paced events, fulfillment of detection criteria, and therapy delivery. The markers are displayed on the PRM printer/recorder and the ECG display.

- Real-time electrograms can be transmitted from the pace/sense or shocking leads to evaluate lead system integrity, such as lead fractures, insulation breaks, or dislodgments.

The PRM system can receive real-time event markers and electrograms from the implanted pulse generator, and it can output them either on its printer/recorder or the ECG display or on both. Electrograms can be transmitted also to an external strip chart recorder if connected to the programmer. The pulse generator can simultaneously transmit event markers and electrograms (atrial rate, ventricular rate, and shock, of which two of three can be selected at one time) (Table 14). Figure 81 defines marker annotations, and Figure 82 shows an example of an annotated surface ECG tracing as output to the PRM recorder.

NOTE: Marker annotation definitions can be printed by selecting the Marker Legend option on the reports window (refer to the section “Print Reports” later in this chapter), or by pressing the CALIBRATE key on the PRM while traces are active.

Table 14. Event Markers and Electrograms Output

	PRM Recorder	ECG Display	External Strip Chart Recorder
Surface ECG Simultaneously with	Yes	Yes	Yes
Event markers and	Yes	Yes	No
Rate EGMs and	Yes	Yes	Yes
Shock EGMs	Yes	Yes	Yes

AF = Atrial Fibrillation Sense	AFib = Atrial Fibrillation Met (atrial rate is above the AFib Rate Threshold)	Shock = Shock Delivered
AS = Atrial Sense	ATR = Atrial Tachy Response (mode switch occurrence)	SRD = SRD in Effect
AP = Atrial Pace	Chrg = Start/End of Charge	Suddn = Onset–Sudden
VP = Ventricular Pace	Detct = Detection Met	Gradl = Onset–Gradual
VS = Ventricular Sense	Dvrt = Therapy Diverted	Telem = Start/End Telemetry
VT-1 = VT-1 Zone Sense	Dur = Duration Expired	TN = Noise Indicator
VT = VT Zone Sense	Stb = Stable	AN = Atrial Noise
VF = VF Zone Sense	Unstb = Unstable	VN = Ventricular Noise
Epsd = Start/End of Episode	V>A = V Rate Faster Than A Rate	FB = During ATR
Hy = Hysteresis	↑ = Rate Smooth Up	ATR-FB = Fallback Start
PVC = PVC After Refractory	↓ = Rate Smooth Down	ATR-Dur = ATR Duration Start
() = During Refractory	Ns = Sense Amplitude Noise	ATR-End = Fallback End
Sr = Accelerometer	MT = Atrial Tracked/MTR	

Figure 81. Annotated marker definitions.



Figure 82. An example of annotated event markers and surface ECG as output on the programmer recorder. The numbers indicate the sensed heart rate (interval).

Displaying Surface ECGs, Electrograms, and Event Markers

Use the following options to choose the display (Figure 83):

- To view EGMs and markers on the PRM screen, select the A/V or V/S button to the right of the ECG/EGM display area to activate atrial or ventricular EGMs or event markers. To view a ventricular rate electrogram and shock electrogram (no atrial electrogram), select the V/S button on the ECG display; to view both ventricular and atrial electrograms (no shock electrogram), select the A/V button. The surface ECG and markers are not affected by these buttons.
- To view surface ECG traces, refer to Appendix B for instructions on proper patient cable connections. The surface ECG will be displayed on the screen as soon as the cables are connected. The PRM can display one of up to six limb leads or one chest lead. The 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.

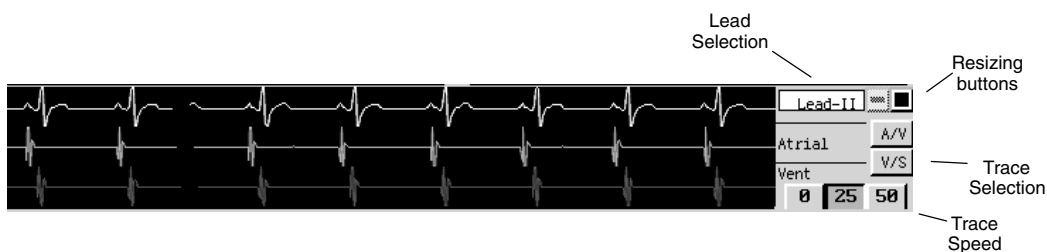


Figure 83. The ECG display shows surface ECG traces.

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

- **Lead Selection Button**—Select the lead trace to be displayed.
- **Window Resizing Buttons**—Select the button with the black square to enlarge the window. Select the box with the small bar to return the window size to normal.
- **Trace Selection Buttons**—Select whether ventricular rate electrograms and shock electrograms (no atrial electrograms) or both ventricular and atrial electrograms (no shock electrogram) should be displayed. These options may also be selected on the ECG display.

- **Trace Speed Buttons**—Select the desired speed button on the ECG display to freeze the speed of the traces (0) or to change them.

Access the ECG/Trace Selections window (Figure 84) by selecting the ECG button at the top of the screen.

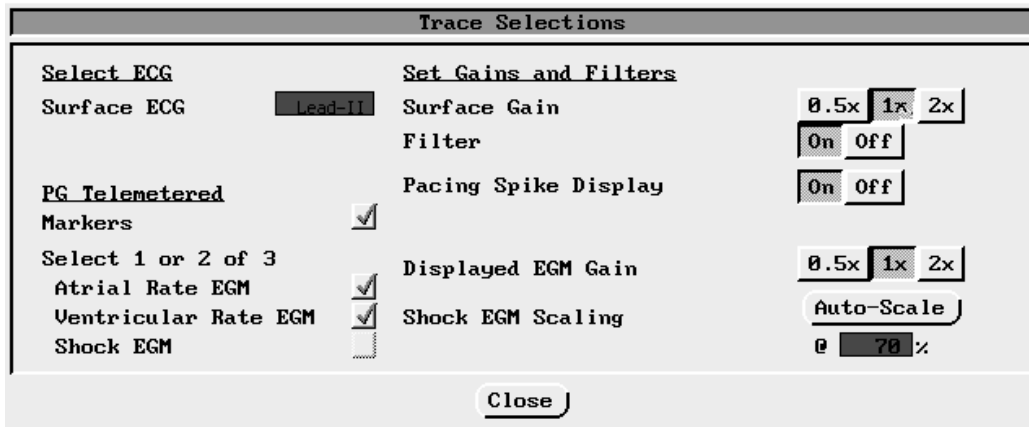


Figure 84. The ECG/Trace Selections window.

The following values may be changed in that window:

- **Select ECG**—Select the lead trace to be displayed.
- **Surface or Telemetered Gains**—Adjust the gain of the traces by selecting the appropriate Surface Gain value (0.5x, 1x, or 2x) for the surface ECGs, and the displayed EGM gain (0.5x, 1x, or 2x) for the intracardiac EGMs
- **Filter**—Select the Filter On setting to minimize noise on the surface ECG. The Filter Off setting allows viewing surface ECGs with diagnostic filter settings.
- **Pacing Spike Display**—Program this feature On to show detected pacing spikes, annotated by a marker on the top waveform.
- **PG Telemetered**—Select up to 2 of 3 EGMs atrial rate, ventricular rate, and shock. These options may also be selected on the ECG display.
- **Printed Event Marker Annotation**—Select Annotations to show the marker annotations (Figure 85) on the printout. Select Intervals to show the intervals and a limited set of annotations.

To display a calibration pulse on the PRM (Figure 85), press the key labeled \sqcup . Press the key labeled \square to force the surface trace back to baseline. To print the surface ECG on the PRM printer/recorder, select the desired speed key (10, 25, 50, or 100 mm/sec) on the printer/recorder. To stop the printer/recorder, press the speed key labeled 0 (zero).

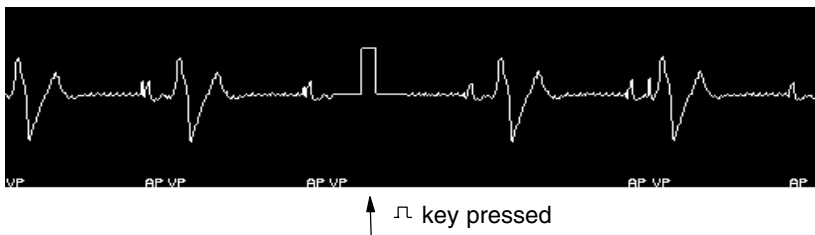


Figure 85. A 1-mV calibration pulse for surface ECGs appears on the PRM's strip when the \sqcup key is pressed. If event markers are active when the \sqcup key is pressed, a marker legend also will be printed on the PRM printer strip.

Printing Surface ECGs and Electrograms to the Internal PRM Printer/Recorder

To print electrograms, the full set of annotated event markers, intervals, and the surface ECG on the PRM printer/recorder, select the desired speed key (10, 25, 50, or 100 mm/sec) on the printer/recorder while the traces are being displayed on the PRM screen.

NOTE: Event marker annotation definitions can also be printed by selecting the Marker Legend option on the Print window.

Press the \square key (calibrate) to print a list of the event marker annotations, if they are active (Figure 81).

To stop the printer/recorder, press the speed key labeled 0 (zero) on the printer/recorder.

Printing Surface ECGs and Electrograms to an External Recorder

To view intracardiac electrograms and the surface ECG 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 B for instructions on connecting the PRM to the external recorder. Refer to the manual for the external recorder for instructions specific to its operation.

Magnet, Beeper, and EGM Features

Several optional features can be enabled or disabled via the programming system:

- **Enable Magnet Use**—This feature can be programmed On or Off to control whether magnet functions are enabled. Refer to Chapter 9 for the magnet functions that are available if magnet use is enabled. If it is programmed On, the Change Tachy Mode With Magnet function can then be programmed separately. If Enable Magnet Use is programmed Off, then the Change Tachy Mode With Magnet function cannot be programmed (see below).
- **Change Tachy Mode With Magnet** (refer to Chapter 9 for more magnet information)—This feature can be programmed On so that when a magnet is applied to the pulse generator for a continuous 30 seconds, the Tachy Mode of the pulse generator can be changed from Off or Monitor Only mode to Monitor + Therapy mode, or from Monitor + Therapy to Off mode. (The magnet cannot take the pulse generator out of Storage mode.) When the feature is programmed Off, the Tachy Mode will not change in the presence of a magnetic field, and is intended for patients who may be routinely exposed to magnetic fields. Note that this feature does **not** prevent a magnet from temporarily inhibiting therapy delivery.
- **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 Ventricular Events 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 programmer turns this feature off. 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.

- **Electrogram Storage**—If enabled, the pulse generator stores electrograms sensed prior to the onset of an episode, during episode onset, and immediately before and after each therapy delivery. Electrogram data may be captured from the atrial sensing electrodes, the ventricular sensing electrode, the shocking electrodes, or a combination of the electrodes. The episode onset segment can be programmed On or Off; when programmed On, the onset segment is available for each of the electrodes designated for capture. Refer to Chapter 8—Therapy History for more information about stored electrograms and storage capacity.

Accessing Magnet, Beeper, and EGM Features

1. Select the menu button labeled Other Params.
2. Select the Magnet/Beeper/EGM option. The Magnet/Beeper/EGM Functions window will appear.
3. Enter the desired value in the Change column.
4. Establish telemetry communication and press the PROGRAM key. The changes are now effective.

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 thresholds. The information can be retrieved anytime by interrogating the pulse generator. It can be viewed on the PRM screen or printed as a report.

Accessing Patient Data

1. To access the Patient Data window, select the Other Params menu button and then 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 window the data will appear in the window. If an interrogation has not been performed, the data boxes will be blank. Establish telemetry communication and press the PRM INTERROGATE key; the data will appear in the window.*

2. To add patient-specific data to the Patient Data window, select the desired value box using the touchscreen.
3. Either a graphic keyboard or a list of options will appear depending on the value box selected. If a graphic keyboard appears, follow steps 4 and 5. If a list of options appears, skip steps 4 and 5, and follow step 6.
4. The graphic keyboard will include the name of the value box selected. To enter characters (letters, numbers, and symbols) move the pointer to the desired character on the graphic keyboard and select the character.

Continue to select the desired characters as described. Use the slider (scroll) bar to the right of the window to view additional parameters. Select the Cancel Changes button to delete all changes, if desired.

5. To transfer the data to the Patient Data window when all characters have been entered, select the Close button on the graphic keyboard.
6. Select the desired option from the palette. The text will transfer to the Patient Data window.
7. Select the next value box and follow steps 4–6. Continue until all data are entered.
8. 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. Continue with steps 4–6.

9. To enter the data into pulse generator memory, establish telemetry communication and press the PROGRAM key on the PRM system.
10. Select the Close button on the Patient Data window to remove the window from the display.

Sensitivity Adjustment

The Sensitivity Adjustment feature permits shifting the sensing range to make it less sensitive if, in a rare situation, atrial or ventricular oversensing has been observed postimplant (ie, inhibition of bradycardia pacing or inappropriate tachy therapy).

The Sensitivity Adjustment feature can be accessed from the Other Params menu. The available settings are Nominal, Less, or Least. Refer to Chapter 11—Post-Implant Information for further information on the use of this feature.

Printed Reports

The following reports can be printed via the PRM printer/recorder so that permanent records may be retained in the patient's file. Each report heading includes patient name, 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 [NO PG] mode).

- Quick Notes—prints data from the tests performed during a Quick Check session, including therapy history, histogram data, device parameters summary, and AICD and lead system data.
- Parameters—lists all the programmed detection and therapy parameter values by zone, bradycardia parameters, and magnet/beeper/electrogram functions. The sensitivity adjustment parameter will be shown if a value other than Nominal is programmed.
- Counters—prints all the data as shown on the Counters window (see Chapter 8). The printing of this report also can be initiated from the window.
- Patient Data—includes all the data from the Patient Data window. (Refer to the previous section of this chapter.)
- Measured Data—prints data from the Battery Status and Brady Analysis tool kits including last capacitor re-form, last delivered charge, battery status, pacing threshold and impedance test data, and P- and R-wave amplitude measurement data.
- Marker Legend—prints a list of the annotated event markers.
- Net Change Parameters—shows the initial parameters for the session (interrogated and/or read from a patient data disk), all parameters that have been changed, reprogrammed, and saved to disk, and the final set of parameter values after the last reprogramming. Each reprogramming is time-stamped, and the original and new values are shown. If data had been read from a disk during the session, the initial parameters shown on the report are the oldest parameters read from the disk.
- Histogram Report—prints counter data for lifetime and since last cleared in graphical and tabular format.
- Trending Report—prints the trending data for the current trending and replay parameters.
- Episode Summary—prints out the data from the Episode Summary window including episode number, date, and type.
- Episode Detail—includes episode attempts (newest to oldest) and P–P and R–R intervals for specified episodes.

Printing Reports

The print function can be initiated at any time during a follow-up session. Use the following procedure to print reports on the PRM:

1. Select the Print menu button. The Choose Reports To Print window will appear.

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 type of Episode Detail report 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 the Print button at the bottom of the window. The printer/recorder will automatically start printing. If event markers or electrograms are currently being transmitted, the transmission will be suspended; to restart the transmission after the report is printed, select a speed key on the PRM printer panel.
4. To stop printing at any time, select the Cancel Printing button.

NOTE: *Be sure to print desired reports prior to selecting Quit or New Patient, since data are erased from programmer memory when these actions are performed.*

Printed reports, which are designed to be filed as part of the patient's medical record, also identify the manufacturer (Guidant), the institution name, the programming device, and the pulse generator name, model number, and serial number.

File Functions

There are several general functions available separately from the detection or therapy parameters and toolbox features. The File menu provides options that can be accessed at any time. To access the options, select the File menu button on the base window.

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.

1. Insert into the disk drive of the PRM a Model 6627 Patient Data Disk that contains information about the present interrogated pulse generator.
2. Select the Read Disk option from the File 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.)
 - a. If a pulse generator has not been interrogated, 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 parameter summary area of the base window. An icon shaped like a data disk will appear at the top of the base window to indicate that the data in Therapy History is from a disk.
 - b. 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 icon will not replace the pulse generator icon 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).
 - c. If disk data have been retrieved and then an interrogation command is initiated, once again 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 at the top of the base window. If the data do not match, the interrogation will not be performed.

NOTES:

- *If you insert a patient data disk containing data downloaded using a programmer other than the Model 2920 PRM, a message will appear indicating the disk is unreadable. If you reformat the patient data disk for use on the Model 2920 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.*
3. Select the Therapy History toolbox button to display the information that has been retrieved. Refer to Chapter 8 for history details.

NOTE: *After disk data have been retrieved prior to an interrogation, windows 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

This file option works the same way as the Save All To Disk button on the Episode Summary window. (Refer to the section “Episode Summary” in Chapter 8.) When a Model 6627 Patient Data Disk is inserted in the disk drive of the PRM, the following data can be saved: therapy history, programmed parameter values, sensor-driven 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 File menu. The PRM determines which episode data has already been saved to disk from previous sessions, and it 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 to that effect. 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.)

NOTES:

- *Guidant Model 6627 Patient Data Disks are not compatible with other programming systems.*
- *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 Model 6627 Patient Data Disk.

1. Select the Copy Disk option from the File menu. A message will appear—Insert Source Diskette And Select Read Disk.
2. Insert into the disk drive of the PRM the disk that contains the information to be copied (the source disk) and select the Read Disk button. The 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: Before removing the patient data disk from the disk drive, make sure the disk drive light has extinguished. Removing the disk while the drive heads are engaged can damage the disk and/or the drive.

Format Disk

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

1. Insert a patient data disk into the disk drive of the PRM.
2. Select the Format Disk option from the File menu. Formatting a disk will remove all data from the disk.
3. When formatting is complete, insert another disk and select the Format Another Disk button or select the Cancel button to exit the format feature.

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. To set the programmer and pulse generator clocks refer to Step G in Chapter 10—Implanting the Pulse Generator.

Load Initial Values

This option allows initial values to be reloaded during a patient session. Refer to the “Load Initial Values” section in Chapter 2—Using the Programmer/Recorder/Monitor.

About

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

New Patient

This option allows a different device to be interrogated, or a different patient’s data to be read without having to exit the software application. Refer to the “New Patient” section in Chapter 2—Using the Programmer/Recorder/Monitor.

Quit

This option allows the current session to be terminated and the software application to be exited. Refer to the “Quit a Session” section in Chapter 2—Using the Programmer/Recorder/Monitor.

Chapter 7

ELECTROPHYSIOLOGIC TESTING

Electrophysiologic Testing (EP) test 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 (see Chapter 6) and the Device Activity display (discussed later in this chapter) so that real-time traces may be viewed, as well as the status of the pulse generator/patient interaction.

The features allowing noninvasive EP testing of arrhythmias include the following:

- **Slaved**—allows an external lab stimulator to be used as a timing-signal source to the PRM that translates the signals into pacing commands. The pacing commands are then communicated to the pulse generator via telemetry, and pace pulses are delivered to the patient with the same timing as the lab stimulator output. The pulses can be delivered either to the atrium or the ventricle.
- **V Fib**—allows the pulse generator to deliver high-rate pulses through the shocking leads at the command of the programmer. It is intended to induce fibrillation in the patient for EP testing purposes.
- **Shock on T-wave induction**—allows the device to deliver a series of S1 pacing pulses through the rate-sensing electrodes followed by shock delivery through the shocking electrodes.
- **PES**—(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.
- **Manual Burst pacing**—pacing with ramping capability can be delivered for as long as desired to either the atrium or the ventricle.
- **Commanded Shock**—can be used to convert rhythms or to deliver a programmable energy shock with a programmable coupling interval at any time through the shocking leads at the command of the programmer.
- **Commanded ATP delivery**—allows the physician to determine the appropriate ATP scheme for arrhythmia termination. Temp ATP allows the physician to terminate tachycardias using ATP schemes that are not programmed in the therapy prescriptions. The Temp ATP pulses can be delivered either to the atrium or the ventricle.

An additional method of EP testing, the External feature, facilitates arrhythmia induction using equipment other than the PRM or pulse generator (ie, alternating current) to induce the patient's arrhythmia through invasive means.

Atrial Stimulation and Backup VVI Pacing During EP Testing

During EP testing, atrial stimulation is available for the following induction features:

- Slaved
- PES
- Manual Burst
- Temp ATP

Two buttons are available on the EP Test tool kit for selecting the cardiac chamber to be stimulated; selecting the “A” button will allow atrial stimulation.

CAUTION: The cardiac chamber selection is nominally set on V (ventricle). Be sure to select “A” for the atrial chamber when inducing atrial arrhythmias, or a ventricular arrhythmia may be induced.

During atrial stimulation, backup pacing is available in VVI mode regardless of the programmed normal and post-shock Brady Mode. The backup VVI pacing rate is the programmed rate for ATR/VTR Fallback LRL. The output is the programmed ventricular ATP parameters. Backup VVI pacing can be programmed Off by clicking on the value box next to the words “Backup VVI” on the EP Test tool kit.

CAUTION: If the ATR/VTR Fallback LRL value is reprogrammed during EP testing, remember to program it back to the desired value for normal and post-shock pacing.

Accessing EP Test Functions

1. Select the EP Test button from the toolbox (Figure 86). The EP Test tool kit is divided into three sections: a) on the left, Slaved, V Fib (Ventricular Fibrillation), PES, Shock on T wave and External test methods can be selected, b) in the center, Manual Burst and Commanded Shock can be activated, and c) on the right, Commanded ATP and Temp ATP (temporary ATP) therapy can be delivered, and 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. Program the Tachy Mode appropriate to the EP test method. Refer to Table 15 for the operational mode in which each EP test function can be performed.

Table 15. Operational Mode for EP Test Functions

EP Test Method*	Tachy Mode		
	Monitor + Therapy	Monitor Only	Off
Slaved	X		
V Fib	X		
PES	X		
Shock on T-wave	X		
External	X		
Manual burst	X		
Commanded shocks	X	X	X
Commanded ATP		X	

* EP functions cannot be performed if the pulse generator is programmed to Storage mode.

Changing the Tachy Mode. To change the Tachy Mode, select either the Monitor Only or Monitor + Therapy button on the right side of the tool kit (the selected button will be shaded); only the Tachy Mode will be reprogrammed immediately.

NOTE: In addition, the Tachy Mode can be changed from the Tachy Mode menu button.

4. Select the cardiac chamber to be stimulated by the induction (if appropriate): two buttons are available, A for atrium or V for ventricle. Refer to the “Atrial Stimulation and Backup VVI Pacing” section on the previous page.
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 EP test. 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 EP test function is automatically disabled.

- To conveniently access therapy history after an induced arrhythmia is terminated, select the Show Last Episode button.
- To exit the EP Test tool kit, select another tool from the toolbox.

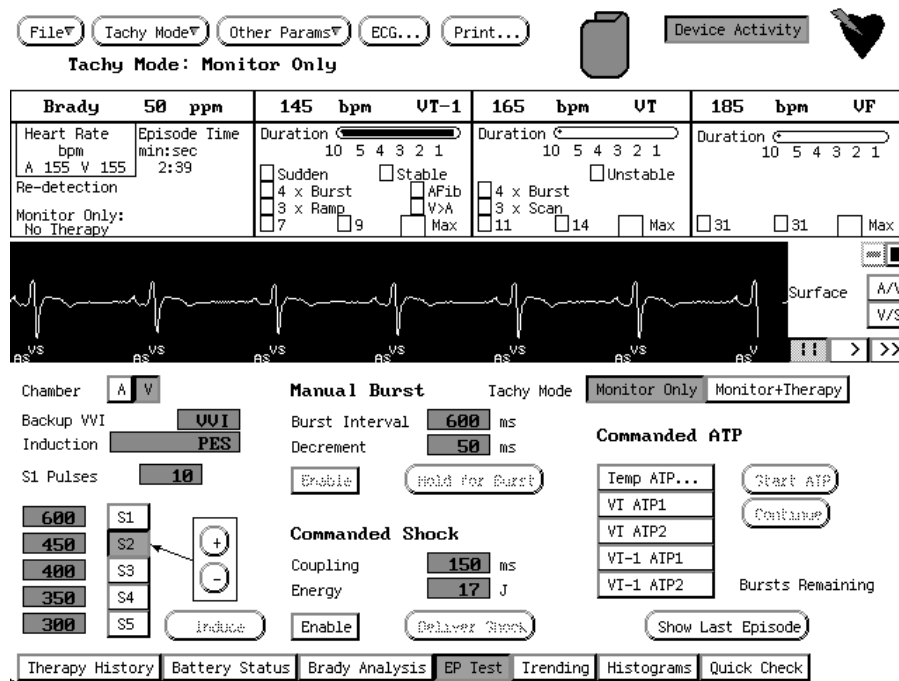


Figure 86. EP Test tool kit with the ECG and Device Activity displays activated.

Induction Methods

The type of induction method is displayed on the left side of the tool kit. Each induction method 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 has 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. However, slaved pacing is not inhibited by a magnet.
- Pacing pulses during induction are delivered at the programmed ATP Pulse Width and ATP Amplitude. These parameters are programmed from the Therapy Features window.

Slaved Induction

The PRM system and pulse generator act as a pass-through for the external stimulator when the output cable from the external stimulator is connected directly to the stimulator input jacks on the programmer. During slaved induction, the pulse generator mimics the timing of an external stimulus. The pacing output of the stimulator (to the PRM system) should be positive (+ to + and – to –) in order to sense the rising edge of the pacing output. The stimulator output should have a minimum amplitude of 2.5 V and a minimum pulse width of 0.03 ms. If the stimulator’s output is less than this, the PRM may not sense the signal.

The pulse generator can pace at intervals as short as 80 ms (750 ppm) during slaved induction. All pacing pulses will be delivered at the programmed ATP Pulse Width and ATP Amplitude when slaved induction is enabled. As each pulse is delivered, the detection windows are cleared and durations are reset. This effectively disables detection during the induction delivery and restarts it immediately after induction is completed.

NOTE: Slaved induction does not force an end-of-episode to occur as do the other induction methods.

Performing Slaved Induction

1. Select the value box next to the word Induction and select the Slaved option (Figure 86). Two slaved induction options, Enable and Disable, will be displayed.
2. Choose the cardiac chamber to be paced; select either A for atrium or V for ventricle. Backup VVI pacing is available during ventricular stimulation as well as atrial stimulation.
3. Select the Enable button to allow the pulse generator to pace as directed by the external stimulator.

The Disable button may be selected so that the pulse generator will not recognize the signal from the external stimulator, thus preventing inadvertent pacing.

NOTE: Event markers and EGMs are available while slaved induction is enabled; however, when commands are sent to pace there will be gaps in the transmission.

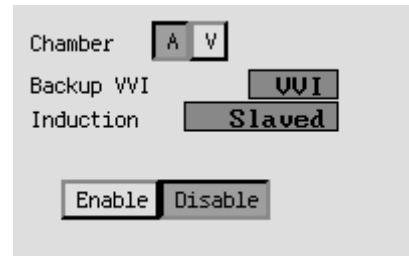


Figure 87. Slaved induction options.

V Fib Induction

V Fib 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.

- V Fib Low delivers pulses at an average interval of 50 ms.
- V Fib High delivers pulses at an average interval of 30 ms.

Performing V Fib Induction

NOTE: The patient should be sedated prior to delivery of fibrillation (V Fib) induction pulses. The large electrode surface of the shocking leads tends to capture the surrounding muscle and can be uncomfortable.

1. Select the value box next to the word Induction and select the V Fib option (Figure 87). Three buttons, Enable, Hold For Fib High, and Hold For Fib Low, will be displayed. (The A and V chamber buttons have no effect on fibrillation induction.)
2. Select the Enable button. The text on the Hold buttons will no longer be gray.
3. Select the Hold button to initiate charging and 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.

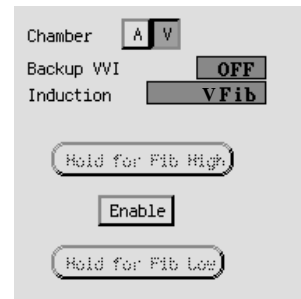


Figure 88. FIB induction options.

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 Hold button (the text on the Hold button will become gray again).
5. To deliver another fibrillation induction, repeat steps 2–5.

Programmed Electrical Stimulation (PES)

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 89 illustrates a PES induction drive train, and Figure 90 shows the selected PES values.

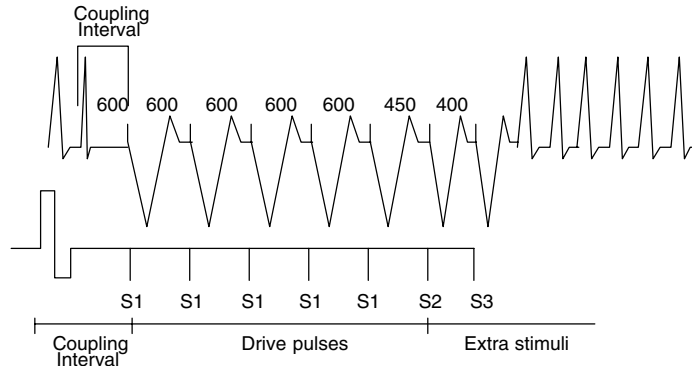


Figure 89. PES induction drive train.

Performing PES Induction

1. Choose the cardiac chamber to be paced; select either A for atrium or V for ventricle (Figure 89).
2. Select the value box next to the word Induction and select the PES option. Information about S1–S5 pulses and the corresponding burst cycle lengths is displayed.
3. To change the number of S1 pulses, select the button next to the words S1 Pulses, and select the desired value.
4. Two methods are available to change the burst cycle length of each pulse (programmed in a range from 120–750 ms or Off):
 - a. Select a value box to the left of an S button to display a palette, 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.
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. Event markers are available during PES induction.
6. PES induction is complete when the drive train and extra stimuli are delivered, at which time the pulse generator automatically restarts detection.

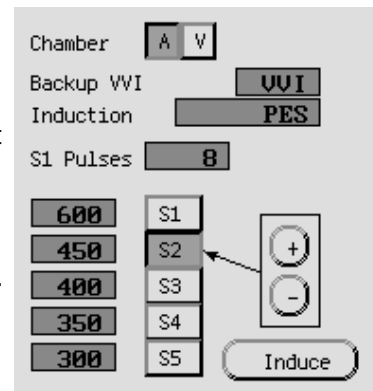


Figure 90. PES induction options.

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. The PES itself is not recorded in therapy history. This may result in several episodes being counted in therapy history.

Shock on T Induction

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 rate-sensing electrodes followed by shock delivery through the shocking electrodes (Figure 91). 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 beat (up to 3000 ms) at the S1 interval. The programmable range for the S1 interval is from 120–750 ms, and the number of S1 pulses from 1–30 pulses. The shock is coupled to the last S1 pulse of the drive train. The coupling interval is programmable from 0 (sync) to 500 ms, and the shock energy is programmable from 0.1–21 J.

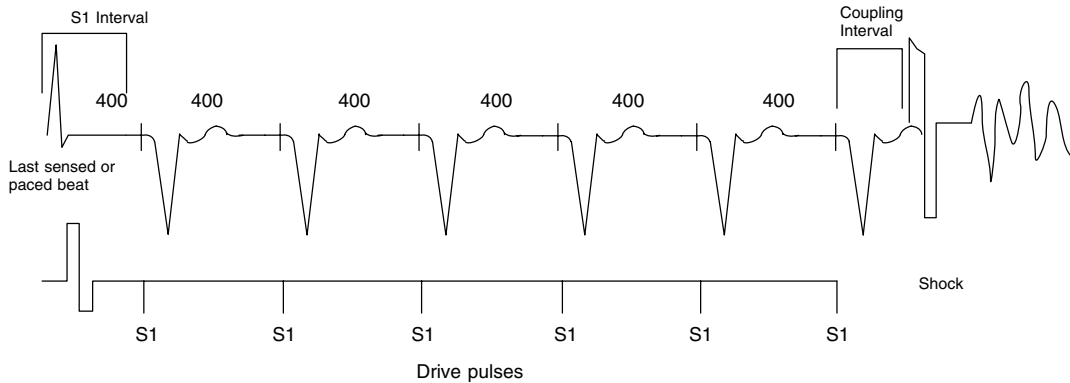


Figure 91. Shock on T induction drive train.

Performing Shock on T Induction

1. Select the value box next to the word Induction and choose the Shock on T option (Figure 92). 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 grey.
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.

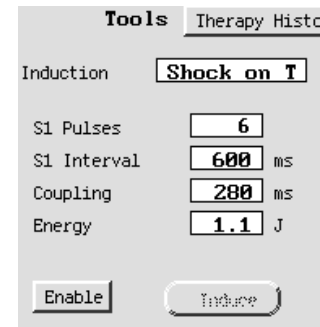


Figure 92. Shock on T induction options.

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:

- During the drive train delivery, tones will be heard indicating capacitor charging in preparation for shock delivery.
- Shocks delivered during Shock on T induction do not increment episode or therapy counters.

External Induction

When inducing the patient's arrhythmia using an external stimulation source, the pulse generator can be blinded from the induction, so it does not detect it as an arrhythmia. When

a tachyarrhythmia is induced, the pulse generator can be unblinded to detect the arrhythmia and deliver therapy.

Performing External Induction.

1. Select the box next to the word Induction, and select the External option (Figure 92). Two detection state buttons, Inhibit and Detect, will appear.
2. The A and V chamber buttons have no effect on external induction.
3. To start an external induction, select the Inhibit button to blind the pulse generator from detecting. The message Detection Inhibited will appear provided telemetry communication is occurring.

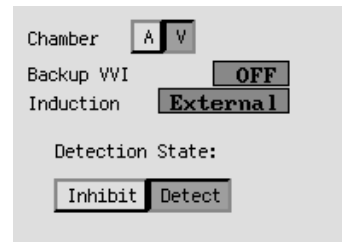


Figure 93. External induction options.

NOTE: *If the wand is removed from position while the Inhibit button is selected, the pulse generator will not be inhibited, but instead will detect until the wand is repositioned. (The Detection Inhibited message will disappear.)*

4. Induce the patient and monitor the ECG display for the presence of a tachyarrhythmia. A new episode (with initial detection and therapy) can be declared when detection is manually re-enabled. Note that the device cannot be inhibited until the episode is declared over. Selecting the Inhibit button during the episode will not reinhibit the device.
5. When the appropriate arrhythmia has been induced, select the Detect button to allow the pulse generator to detect and treat the tachyarrhythmia. (The Detection Inhibited message will disappear.) Event markers and EGMs are interrupted during external induction and will automatically restart following induction.

NOTE: *Due to their large amplitude, AC inductions applied through the shocking leads will impact the EGM sense amplifiers for up to 15 seconds and will affect stored electrograms. This will not happen as severely with internal induction methods because the pulse generator can limit the effect of its own outputs on its input circuits.*

Manual Methods

In the center and on the right side of the EP Test tool kit, three manual EP test methods (Manual Burst, Commanded Shock, and Commanded ATP) are available. These methods may be delivered independently of the programmed detection and therapy parameters. If the pulse generator is in the process of delivering therapy when a manual method is initiated, the manual method overrides and aborts the therapy in process. All manual therapy is inhibited when a magnet is positioned over the pulse generator.

Manual Burst Pacing

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 it is 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; select either A for atrium or V for ventricle (Figure 85).
2. Select the desired value for the Burst Interval; this indicates the cycle length of the first 10 intervals in the drive train and is programmable from 40–750 ms (refer to Figure 94).
3. Select the desired value for the Decrement value, which can be programmed (from 0–50 ms) so that each interval following the first 10 intervals will be decremented.
4. Select the Enable button. The text on the Hold For Burst button will no longer be gray.
5. 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 fastest pacing rate (40 ms) 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.
6. To stop the burst delivery, release the select key. The text on the Hold For Burst button will become gray again.
7. To deliver additional manual burst pacing, repeat steps 4.–6.



Figure 94. Center section of the Manual Burst tool kit.

Commanded Shock

Commanded shocks can be delivered with a programmable energy shock (0.1 to 31 J) and a programmable coupling interval (50–500 ms). All commanded shocks are Committed and delivered synchronously with the R-wave (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 interval where the shock would have been fired in Sync mode. Sensing is disabled when the Coupling interval is started, and the shock is delivered at the programmed Coupling interval. (Refer to the section “Committed Shock” in Chapter 4 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 desired value for the Coupling interval (refer to Figure 94). (The A and V chamber buttons have no effect on commanded shock delivery.)
2. Select the desired value for the 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 (see the “Therapy Counters” section in Chapter 8 for more details).

NOTE: A commanded shock may be diverted by pressing the DIVERT THERAPY key or positioning a magnet over the pulse generator.

5. To deliver subsequent shocks, repeat steps 3 and 4.

Commanded ATP and Temporary ATP

On the right side of the EP Test tool kit, Commanded ATP and Temp ATP is available. These methods may be 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.

The ATP therapy schemes that are programmed for each zone can be delivered via Commanded ATP. 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.

Temp ATP allows the physician to create and test ATP schemes that are not programmed in the therapy prescription. Temp ATP parameter values may be programmed from the EP Test tool kit (see below) and are available whether other ATP therapy schemes are programmed or not. The Pulse Width and Amplitude values used during temporary ATP are the same as programmed for ATP therapy; the values are accessible by selecting the Therapy Features button on a therapy window.

Performing Commanded ATP or Temp ATP Delivery

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 95).

NOTE: If the Tachy Mode had been programmed to Off when a mode is selected from this tool kit, the mode cannot be reprogrammed to Off from this tool kit.

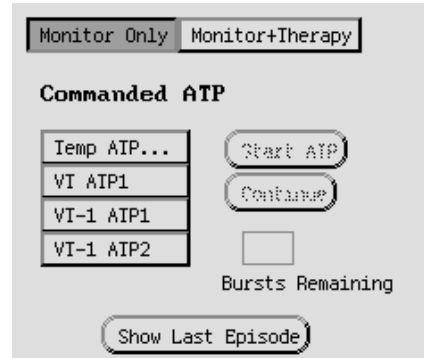


Figure 95. Commanded ATP induction parameters with V Chamber selected.

2. To start the ATP scheme delivery, select the desired scheme button (eg, Temp ATP, VT ATP1). This will highlight the Start ATP button, and the number of programmed bursts will be displayed as Bursts Remaining.

- a. If Temp ATP is selected, a Temporary ATP window will be displayed (Figure 96). Set the desired starting parameters by selecting values in the value boxes. The Temporary ATP window may remain displayed on the EP Test tool kit during ATP delivery, or it may be closed by selecting the Close button. Note that the values in the Temporary ATP window do not change as bursts are delivered.

3. Choose the cardiac chamber to be paced (Figure 86); select either A for atrium or V for ventricle.
4. Select the Start 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.

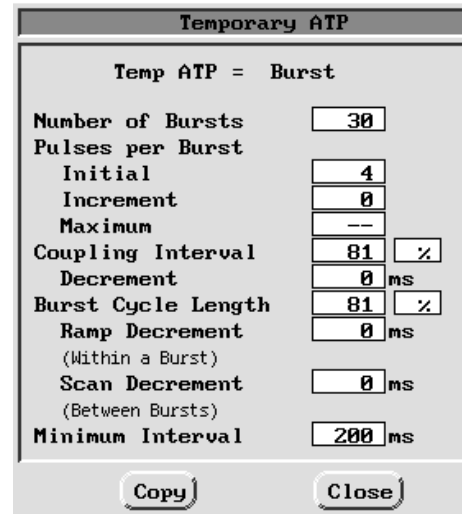


Figure 96. Temporary ATP parameter window.

5. Select the Continue button for each additional burst delivery desired. When all bursts in a scheme have been delivered, the Bursts Remaining counter will return to the initial count, the Start ATP button will become highlighted, and the Continue button will become gray.

NOTES:

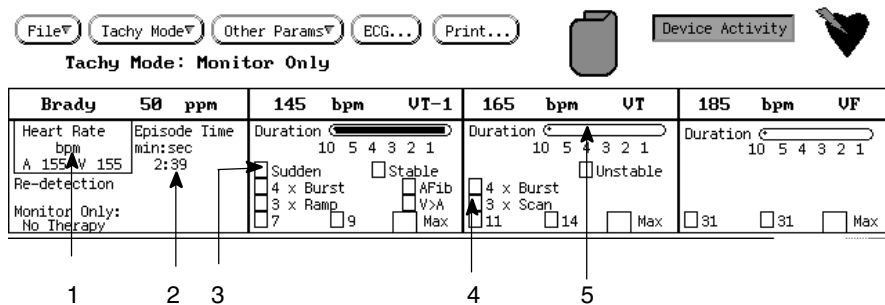
- *If the Continue button is selected during delivery of a burst, the command is ignored. The Continue button must be selected again after completion of the burst delivery in order for the next burst to be delivered.*
 - *If any button other than the Continue button is selected during delivery of a Commanded 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.*
 - *The copy feature is available from the Temporary ATP window to easily copy the ATP parameter values to another window containing ATP parameters. Refer to the subheading “Copy Button” in Chapter 2, page 20.*
6. Other ATP schemes may be selected at any time; select the desired scheme and repeat the above sequence. The Commanded ATP is recorded in therapy history (see the “Therapy Counters” section in Chapter 8 for more details).
 7. To reactivate the programmed therapy, **select the Monitor + Therapy button**. The PROGRAM key does not need to be pressed.

Viewing the Device Activity

When telemetry communication is occurring, the real-time status of the detection and therapy process of the pulse generator can be viewed on the Device Activity display. When used in conjunction with the EP Test tool kit, the physician may induce and test either optional therapies (commanded ATP or commanded shock) or a programmed detection/therapy prescription while monitoring the pulse generator’s progress. Also, a surface ECG, electrograms, and annotated event markers on the ECG display and the printer can be activated to observe and confirm the device activity.

Accessing the Device Activity Display

1. From the base window, select the button labeled Device Activity. The Device Activity display will appear over the zone configuration and parameter area (Figure 97).
2. Ensure that the telemetry link is established and maintained. If the link is broken, the display data are not updated. A message will appear in the left most box (status line), indicating the device is out of range or that telemetry commands are being sent to the device.



- 1 The patient's heart rate as sensed by the pulse generator is continually updated on each cardiac cycle. Both the atrial and ventricular rates are displayed.

Status messages indicate detection and therapy status: line 1 indicates whether detection is met or whether an episode is occurring, line 2 indicates whether SRD is active or met, 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.

- 2 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 min:sec). At the end of an episode, all indicators are cleared.
- 3 Detection enhancements (only those that are programmed) are displayed for each zone in which they are programmed. When an enhancement is satisfied, a check mark appears in the adjacent box.
- 4 Therapy prescriptions are 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 (1, 2, etc.) in the Max box each time a maximum-energy shock is delivered.
- 5 Progression of the Duration timer is graphically displayed using a visual scale. The last ten seconds of the programmed Duration are shown as the black bar in the scale moves from left to right. When Duration is satisfied and therapy delivery begins, the bar is removed.

Figure 97. Illustration of the Device Activity display for a three-zone configuration.

3. To exit the display, select the Device Activity button again; the button will no longer be shaded and the display will disappear.

Chapter 8

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 counters and episode data.
- The Counters window gives information about the type of arrhythmia detected and the therapy delivered for each episode.
- Episode Summary and Episode Detail windows provide details about each episode: number of therapy attempts, type of therapy delivered, annotated measured intervals, and annotated electrograms surrounding therapy attempts.
- Disk storage of all history data allows the entire pulse generator history to be accessed (including episode detail, stored intervals, and stored electrograms) without repeated device interrogation. The patient need not be present.

Therapy History Tool Kit

The Therapy History tool kit provides access to history counters and episode details.

1. Select the Therapy History button in the toolbox on the base window. A summary is displayed with the number of treated, nontreated, and nonsustained episodes, and the number of shock and ATP schemes delivered. Two buttons are available to access history data.
2. To access information about the history counters, select the Show Counters button. A Counters window will appear. Refer to the “Counters” section in this chapter for more information.
3. To access details about the episodes, select the Show Episodes button. An Episode Summary window will appear. Refer to the “Episode Summary” section of this chapter for more information.

NOTES:

- *If data had not been retrieved from the pulse generator or disk, a message window will appear with options to INTERROGATE, Read Disk, or Close. To retrieve therapy history from the pulse generator, position the telemetry wand within range of the pulse generator and select the INTERROGATE button. To retrieve therapy history from a patient data disk, insert a disk and select the Read Disk option. History will not be retrieved if the Close option is selected.*
- *When accessing the Counters or Episode Summary windows, the pulse generator attempts to read the latest data. If the pulse generator is not present (eg, when only disk data is being examined), a message window appears with the option to cancel telemetry.*
- *More than one disk per patient may be read before or after accessing the Therapy History window. (Refer to Chapter 6 for more information about disk functions.)*

Counters

The Counters window gives details about the type of arrhythmia detected, the therapy delivered for previous ventricular episodes, and atrial tachy response data. In addition to device lifetime totals, a corresponding counter indicates the number of events since the last time the counters were cleared. Counters typically should be cleared by the physician at each follow-up visit. (See the “Follow-up” sections in Chapter 11.)

1. Select the button labeled Show Counters from the Therapy History window. The Counters window will appear (Figure 98). Refer to the information following Figure 98 for an explanation of the data displayed on the Counters window.

- To print the window's information, select the Print Counters button. **Counters should be printed prior to clearing counters because once cleared, the data that were in the Since Last Cleared column and the First-attempt Success Rate data cannot be retrieved again.**
- The therapy counters must be manually cleared. To clear the counters in the Since Last Cleared column, select the Clear Counters button. (The counters in the Device Totals column are not cleared.) The appropriate times to clear 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 clearing the counters may present misleading data.
- To close the window and return to the Therapy History tool kit, select the Close button.

Counters				
Recent Data Includes :		Episodes:	2 to 6	
		Dates:	11-AUG-97 to 11-AUG-97	
		Since Last Cleared		Device Totals
		11-AUG-97		
Episode Counters				
Treated				
VF Therapy		1		1
VI Therapy		2		2
VI-1 Therapy		1		2
Commanded Therapy		1		1
Nontreated				
No Therapy Programmed		0		0
Nonsustained Episodes		0		0
Total Episodes		5		6
A-Tachy Response		0		0
Therapy Counters				
Shocks Attempted				
Delivered-Detection Met		15		17
-Physician Commanded		1		1
Diverted -Reconfirm		0		0
-Physician Commanded		0		0
AIP Schemes Attempted				
Delivered-Detection Met		7		9
-Physician Commanded		0		0
First-attempt Success Rate:				
	Delivered	Converted	Accelerated	% Success
VF Zone	1	0		0
VI Zone	2	0	0	0
VI-1 Zone	1	1	0	100

Figure 98. The Counters window provides more details about the types of episodes indicated on the Therapy History tool kit.

Episode Counters

Two types of ventricular episodes are identified and are explained as follows:

- Treated episodes include all detected tachyarrhythmias that receive therapy, categorized by the zone of **first** therapy (VF, VT, or VT-1), as well as episodes whose first therapy was a commanded therapy.
- Nontreated episodes include those in which no therapy was delivered (ie, Tachy Mode is programmed to Monitor Only, or all therapy was turned off in the VT-1 zone), and nonsustained episodes. Nonsustained episodes include those in which therapy was inhibited because a) detection enhancement criteria were not satisfied, b) the zone's detection window did not remain satisfied for the programmed Duration prior to therapy delivery, or c) a command from the programmer terminated the episode before therapy delivery.

Also identified are the most recent and total number of times the Atrial Tachy Response feature caused a mode switch to occur.

Therapy Counters

This section of the Counters window shows the number of shocks and ATP schemes attempted. Therapy attempts can be categorized as being delivered or being diverted. The types of delivered therapy for both shocks and ATP include the following:

- Delivered-Detection Met is initiated with therapy delivery 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:

- Diverted-Reconfirm counter increments if shock therapy is not delivered because the reconfirmation algorithm determined that an arrhythmia was no longer present
- 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.

First-Attempt Success Rate

This section of the window summarizes the number of first-attempt therapies that converted the arrhythmia. The Delivered column shows the total number of first attempts for all the episodes; the Converted column indicates the number of first attempts that converted the arrhythmia; the Accelerated column indicates the number of first attempts that accelerated the arrhythmia to a higher zone; and a resulting success rate is calculated as a percentage. These values are categorized by the zone in which the therapy was delivered.

Examples of Incrementing Counters

The examples in Figure 99 illustrate how the counters are incremented on the Counters window for various events. An asterisk (*) indicates the affected counter in each example.

Episode Counters:		Last Cleared	Device Totals	
Treated				
VF Therapy		0	6	
VT Therapy		0	1	
VT-1 Therapy		0	1	
Commanded Therapy		0	0	
Nontreated				
No Therapy Programmed		0	0	
Nonsustained Episodes		0	1	
Total Episodes		0	9	
A-Tachy Response		0	0	
Therapy Counters:				
Shocks Attempted				
Delivered–Detection Met		0	7	
–Physician Commanded		0	0	
Diverted–Reconfirm				
–Physician Commanded		0	0	
ATP Schemes Attempted				
Delivered–Detection Met		0	1	
–Physician Commanded		0	0	
First-attempt Success Rate				
Delivered	Converted	Accelerated	%Success	
VF Zone	0	0	—	0
VT Zone	0	0	0	0
VT-1 Zone	0	0	0	0

Example A. The numbers in this example have been chosen to give a base for how the counters are incremented throughout the following examples.

Episode Counters:		Last Cleared	Device Totals	
Treated				
VF Therapy		0	6	
VT Therapy		*1	*2	
VT-1 Therapy		0	1	
Commanded Therapy		0	0	
Nontreated				
No Therapy Programmed		0	0	
Nonsustained Episodes		0	1	
Total Episodes		*1	*10	
A-Tachy Response		0	0	
Therapy Counters:				
Shocks Attempted				
Delivered–Detection Met		*1	*8	
–Physician Commanded		0	0	
Diverted–Reconfirm				
–Physician Commanded		0	0	
ATP Schemes Attempted				
Delivered–Detection Met		0	1	
–Physician Commanded		0	0	
First-attempt Success Rate				
Delivered	Converted	Accelerated	%Success	
VF Zone	0	0	—	0
VT Zone	*1	*1	0	*100
VT-1 Zone	0	0	0	0

Example B. A tachyarrhythmia is detected in the VT zone. The first shock successfully converts the arrhythmia.

Episode Counters:		Last Cleared	Device Totals	
Treated				
VF Therapy		0	6	
VT Therapy		1	2	
VT-1 Therapy		*1	*2	
Commanded Therapy		0	0	
Nontreated				
No Therapy Programmed		0	0	
Nonsustained Episodes		0	1	
Total Episodes		*2	*11	
A-Tachy Response		0	0	
Therapy Counters:				
Shocks Attempted				
Delivered–Detection Met		*2	*9	
–Physician Commanded		1	8	
–Physician Commanded		0	0	
Diverted–Reconfirm				
–Physician Commanded		*1	*1	
–Physician Commanded		0	0	
ATP Schemes Attempted				
Delivered–Detection Met		*1	*2	
–Physician Commanded		*1	*2	
–Physician Commanded		0	0	
First-attempt Success Rate				
Delivered	Converted	Accelerated	%Success	
VF Zone	0	0	—	0
VT Zone	1	1	0	100
VT-1 Zone	*1	0	0	0

Example 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.

Episode Counters:		Last Cleared	Device Totals	
Treated				
VF Therapy		0	6	
VT Therapy		*2	*3	
VT-1 Therapy		1	2	
Commanded Therapy		0	0	
Nontreated				
No Therapy Programmed		0	0	
Nonsustained Episodes		0	1	
Total Episodes		*3	*12	
A-Tachy Response		0	0	
Therapy Counters:				
Shocks Attempted				
Delivered–Detection Met		*4	*11	
–Physician Commanded		*3	*10	
–Physician Commanded		0	0	
Diverted–Reconfirm				
–Physician Commanded		1	1	
–Physician Commanded		0	0	
ATP Schemes Attempted				
Delivered–Detection Met		1	2	
–Physician Commanded		1	2	
–Physician Commanded		0	0	
First-attempt Success Rate				
Delivered	Converted	Accelerated	%Success	
VF Zone	0	0	—	0
VT Zone	*2	1	0	*50
VT-1 Zone	1	0	0	0

Example D. A tachyarrhythmia is detected in the VT zone. The first shock is unsuccessful, but the second shock converts the arrhythmia.

Figure 99. Examples of incrementing counters.

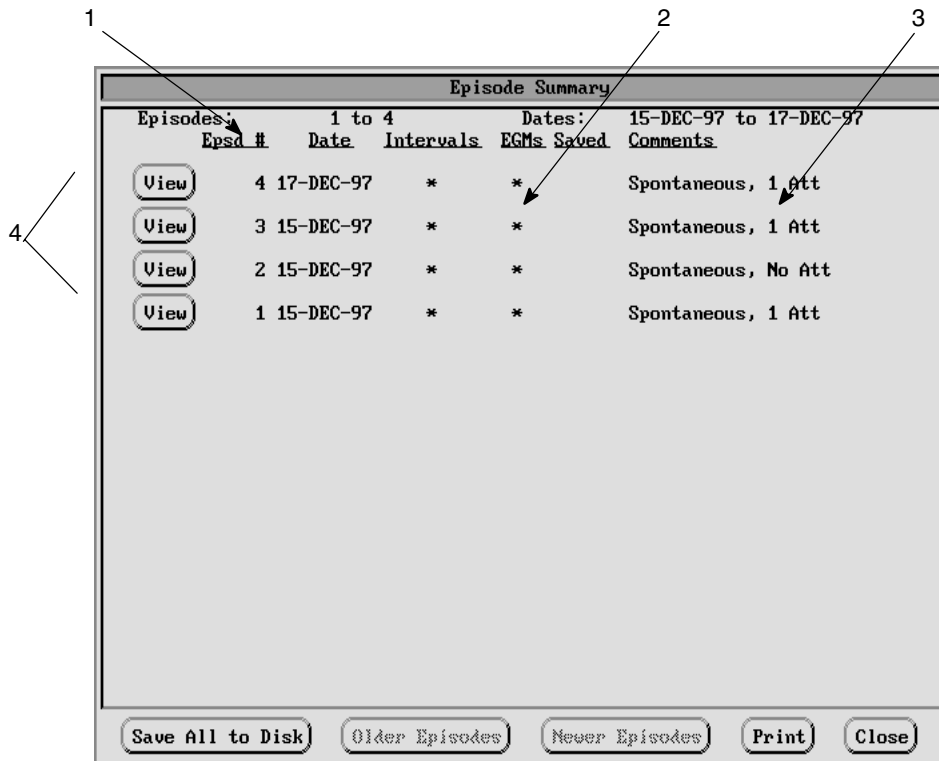
Episode Summary

The Episode Summary window gives information about each episode: a) the number and date of the episode, b) whether intervals and EGMs are stored, c) whether episode data have been saved to a patient disk, d) whether the episode was induced or spontaneous, and e) the type of therapy delivered or attempted.

1. Select the Show Episodes button from the Therapy History tool kit. The Episode Summary window will appear, displaying the 10 most recent episodes (Figure 100).
2. To display the summary of older episodes, select the button labeled Older Episodes. The older episodes will replace those episodes visible on the screen.

NOTE: *On rare occasion an older episode may be missing from the episode range; simply close the Episode Summary window, and reselect the Show Episodes button from the Therapy History tool kit to refresh the episode summary display. The missing episode will become visible.*

3. To retrieve newer episodes, select the button labeled Newer Episodes. The newer episodes will replace those episodes visible on the screen.
4. To view episode details, select the View button to the left of the desired episode. Refer to the section “Episode Details” for more information.
5. If some episodes have not been saved to disk, the patient data disk can be updated.
 - a. Insert a patient disk into the disk drive on the right side of the PRM. The arrow on the disk should be on the top and pointing toward the disk drive, and the write protect tab should be in the closed position (black tab covering the hole).
 - b. Select the Save All To Disk button and place the wand within telemetry range; the programmer will automatically interrogate the pulse generator to ensure that the latest data are saved. All episode detail, including stored EGM and annotated P–P and R–R intervals, will be saved on the patient data disk.
6. To print an Episode Summary report, select the Print button.



- 1 Episode Summary will indicate the range of available episode detail reports by number and date.
- 2 An asterisk (*) indicates whether intervals and EGM details are available for a particular episode. An asterisk under the SAVED column indicates that this information has been saved to a patient data disk.
- 3 A COMMENT section summarizes the complexity of the episode: the type of episode (spontaneous or induced); the number of attempts and if a shock was delivered, or whether the episode was nonsustained.
- 4 VIEW will display the selected episode's detail, which is useful in evaluating each detection or therapy sequence.

Figure 100. The Episode Summary window provides episode information stored in the pulse generator memory or on a patient data disk.

Episode Detail

The Episode Detail window gives detailed information about a specific episode: the date and time of occurrence, the zone in which it was detected and treated, the type of therapy delivered, the stored values for detection enhancements, and the detection and redetection process employed.

1. Select the View button for the desired episode on the Episode Summary window (Figure 100). The Episode Detail window will appear (Figure 101). Some of the episode detail may not be immediately visible if several attempts occurred; use the scroll bar on the window to view more of the description. (Episode detail can also be accessed from the EP Test tool kit.)

Note the buttons at the bottom of the window. If the text on a button is faded, that function is not available for the episode currently displayed. For instance, if this is the last episode, the Newer Episodes button will be faded, since no newer episode is available.

2. Select the Show Intervals button to display the measured P–P and R–R intervals for the episode. See the “Intervals” section that follows for an explanation of the window.
3. Select the Print Detail button, if desired, to print the episode detail on the window along with the interval data on the PRM printer/recorder. If more than one episode detail is to be printed, select the Print menu button on the base window to display the Choose Reports To Print window. Use this window to select various groups of episodes. Refer to the section “Printing Reports” in Chapter 6.
4. Select the Print Egrams button to print the stored electrograms for the episode onset and pre- and post–therapy delivery on the PRM printer/recorder.
5. Select the Older Episodes button or the Newer Episodes button to display a different episode going backward or forward, respectively, one episode at a time.
6. Select the Close button to remove the Episode Detail window; the Episode Summary window is visible again.

Episode Detail			
Episode	Date	Time	Type
8	17-Dec-98	14:24	Spontaneous
<u>Elapsed Time</u>			
	Initial Detection	VT-1 Zone	
	Pre-Attempt Avg A Rate	80 bpm	
	Pre-Attempt Avg V Rate	185 bpm	
	Measured Onset	314 ms	
	Measured Stability	4 ms	
	AFib	FALSE	
	V Rate > A Rate	TRUE	
00:34 – 00:39	Attempt 1	VT-1 ATP1 Burst	
	Therapy Delivered	2 bursts	
	Post-Attempt Avg A Rate	165 bpm	
	Post-Attempt Avg V Rate	165 bpm	
00:45	Redetection	VF Zone	
	Pre-Attempt Avg A Rate	80 bpm	
	Pre-Attempt Avg V Rate	328 bpm	
	Measured Stability	4 ms	
	A Fib	OFF	
	V Rate > A Rate	OFF	
	Attempt 2	VF Shock 1	
	Therapy Delivered	14 J Biphasic	
	Charge Time	5 sec	
	Shocking Impedance	25 Ω	
	Post-Attempt Avg A Rate	99 bpm	
	Post-Attempt Avg V Rate	99 bpm	
01:42	End of Episode		

- 1 Episode number, date, time, and type (spontaneous or induced).
- 2 Initial detected rate at duration, and zone.
- 3 Enhancements measured and stored for reference. AFib and V Rate > A Rate status displayed. The AFib status will display as True if enabled, and the atrial rate is above the AFib Rate Threshold; False if enabled, and the atrial rate is below the AFib Rate Threshold; or, Off if AFib Rate Threshold is not enabled. Its related stability value is displayed as Measured Stability. The V Rate > A Rate displays as True if programmed On, and the ventricular rate is greater than the atrial rate; False if programmed On, and the ventricular rate is not greater than the atrial rate; or, Off if the feature is not programmed On. Both the AFib and V Rate > A Rate values will display as Off (even though programmed On) during redetection following an ATP attempt, since these algorithms are not used during ATP redetection.
- 4 ATP therapy shows the start time of first and last burst, the number of bursts, and post-therapy rate.
- 5 Redetected zone rate when detection met and enhancements measured.
- 6 Shock therapy lists the start time of charging, charge time, impedance, energy level, waveform, and post-therapy rate.
- 7 Total episode time including the end-of-episode timer (10 or 30 sec).

Figure 101. Episodes are described in detail on the Episode Detail window.

P–P and R–R Intervals

The pulse generator stores the measured P–P and R–R intervals throughout an episode, until the end-of-episode is declared. Each episode may contain a maximum total of 1,000 intervals, starting with a minimum of 6 ventricular intervals prior to the arrhythmia onset. The atrial intervals associated with the same ventricular intervals are also stored.

NOTE: *If more than 44 atrial intervals are available for the time during which the ventricular intervals took place, only the 44 most recent atrial intervals will be stored.*

1. Select the Show Intervals button from the Episode Detail window (Figure 101) to display the measured intervals in milliseconds and the zone classification (Figure 102). Note that only six of eight detected intervals are annotated on the display. The dashes beneath some measured intervals indicate that the intervals are not classified in a tachyarrhythmia zone, or that the interval was not used by the detection algorithm. If all of the episode data are not visible in the window, use the scroll bar to view more data.
2. Select the Print Detail button on the Episode Detail window to print the episode detail and annotated interval data on the PRM printer/recorder.
3. Select the Close button to exit the Episode Intervals window.

Episode Intervals										
Episode	Date	Time		Type						
4	11-AUG-97	15:37		Spontaneous						
Onset	(P)	602	602	602	602	602	602	602	602	602
	(R)	--	--	--	602	--	--	--	--	--
		602	602	461	463	461	461	461	461	461
		--	602	--	602	--	461	--	463	--
										VT-1
		461	461	461	461	461	461	461	463	461
		AS	VT-1	AS	VT-1	AS	VT-1	AS	VT-1	AS
Initial Detection	(P)	461	461	461	461	461	461	461	461	461
	(R)	AS	VT-1	AS	VT-1	AS	VT-1	AS	VT-1	AS

Figure 102. Illustration of the Episode Intervals window.

Stored Electrograms

The pulse generator can store annotated electrograms sensed via the shocking, either atrial pace/sense electrograms, or electrograms from ventricular pace/sense leads or both. This occurs prior to the onset of an episode and immediately before and after each therapy attempt. The Electrogram Storage feature must be programmed On for electrograms to be stored. (Refer to the section “Accessing Magnet, Beeper, EGM Features” in Chapter 6 for instructions to enable electrogram storage.)

In addition, the first time a patient is evaluated, the gain setting for stored electrograms should be calibrated as follows. (This is commonly done when the operator takes baseline measurements and evaluates lead signals during the implant procedure.)

1. From the base window, select the menu button labeled ECG; a Trace Selections window will appear. The scaling option for the shock EGM gain is available; set the scaling percentage desired.
2. Select the Auto Scale button. The gain setting for shock EGM will be scaled for the patient.

The EGM storage capacity varies, depending on which electrodes are enabled for capturing data. Table 16 shows the storage capacity for various combinations. The stored data are divided between ATP attempts and shock attempts. When the memory allocated to EGM storage is full, the device overwrites EGM data segments, as storage for more recent EGM data is required. 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 (including charge and reconfirmation). If the pre-therapy time exceeds 10 seconds, the last 10 seconds of data are retained (tied to the therapy delivery attempt). The post-therapy EGM storage starts following therapy delivery and stores up to 10 seconds of EGM. Figure 103 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.

NOTE: 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.

Table 16. Storage capacity in minutes for electrograms.

Electrode Enabled	Minutes
Only Shock	16
Only Atrial	8
Only Ventricular	8
Shock and Atrial	5 each
Shock and Ventricular	5 each
Atrial and Ventricular	3.5 each
Shock, Atrial, and Ventricular	3 each

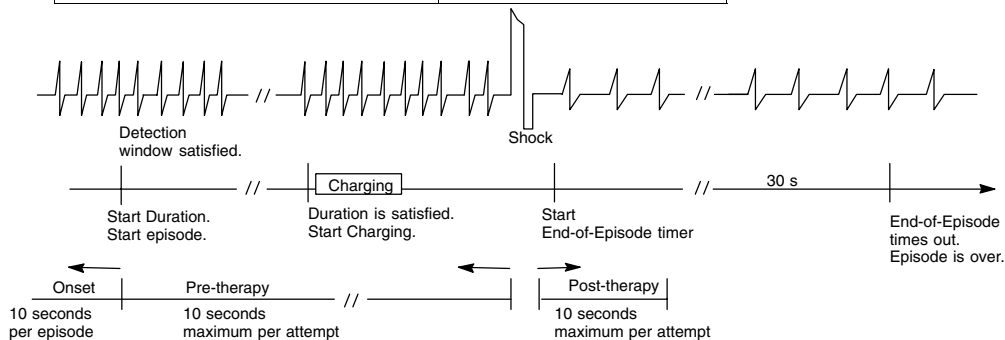


Figure 103. Illustration of EGM storage in relation to a surface ECG strip chart recording.

Select the Print Egrams button from the Episode Detail window (Figure 101) to print the information on the programmer printer/recorder. The printout contains text indicating the onset and pre- and post-therapy times, and the date, time and type of episode. Annotated markers (only AS, AP, AF, VS, VT, VT-1, VF, VP, Chrg, and SRD; see Chapter 6, Figure 81) and interval data (up to 1,000 intervals) are also available. If electrograms are not available for the episode, the Print Egrams button will not be functional (the text will be faded).

Chapter 9

USING THE MAGNET

The CONTAK CD pulse generator has the Enable Magnet Use feature that can be programmed On or Off to determine whether magnet functions are enabled. When the Enable Magnet Use feature is programmed On, the following functions can occur when a doughnut magnet (model 6860) is applied to the pulse generator.

1. The Tachy Mode of the pulse generator can be changed if the feature Change Tachy Mode With Magnet is programmed On.
2. Audible tones are emitted, which indicate the Tachy Mode of the device.
3. 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 Magnet actuates the reed switch when positioned within 3.0 cm (1.2 inches) of the CONTAK CD pulse generator. Actuation of the reed switch allows pulse generator to recognize that a magnet is present, so that magnet functions can be performed. Refer to Figure 104 for the correct magnet position.

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.*

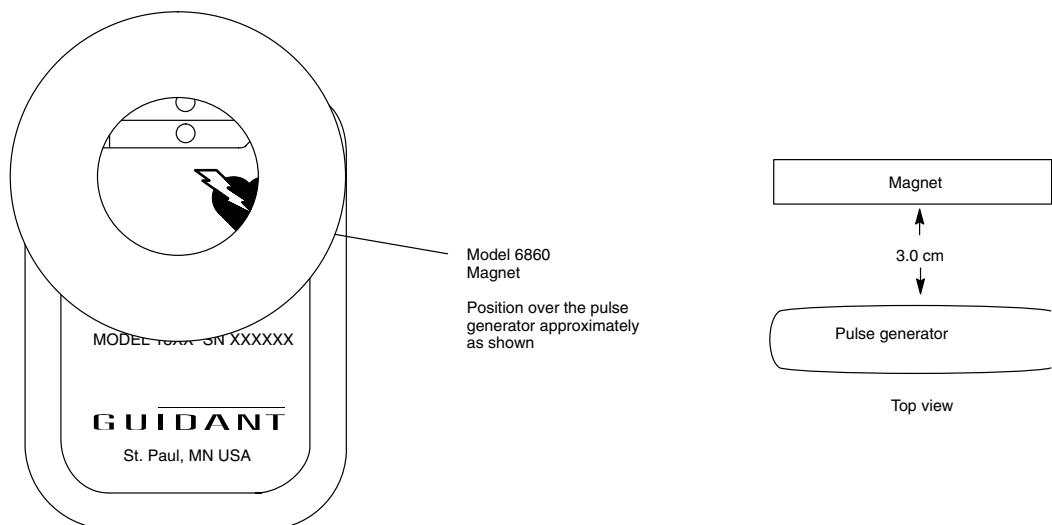


Figure 104. Proper position of the magnet to actuate the reed switch in the pulse generator.

Determine the Tachy Mode of the Pulse Generator

When the Enable Magnet Use feature is programmed On, any time an magnet is properly positioned over the pulse generator, tones indicate the currently programmed Tachy Mode of the pulse generator.

- If synchronous R-wave tones are emitted, the Tachy Mode is programmed to Monitor + Therapy, indicating that tachyarrhythmia therapy can be delivered if detection is met when the magnet is removed.
- 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 when the magnet is removed.

Change the Tachy Mode

Once it has been determined in which Tachy Mode the device is currently programmed, the Tachy Mode can be changed, provided that the Change Tachy Mode With Magnet feature is programmed On, and the Enable Magnet Use feature is programmed On.

1. Place the magnet over the pulse generator and hold it in place for at least 30 seconds. After 30 seconds the mode will change in the direction of the arrow indicated in the illustration below. A change in tones will indicate when the mode has changed. No mode change will occur if the pulse generator is in Storage mode, and the magnet cannot return the pulse generator to a Monitor Only mode.

Tachy Mode Before	Apply Magnet > 30 seconds	Tachy Mode After
Monitor + Therapy (Sync R-wave tones)	→	Off (continuous tone)
Off (continuous tone)	→	Monitor + Therapy (Sync R-wave tones)
Monitor Only (continuous tone)	→	Monitor + Therapy (Sync R-wave tones)
Storage (continuous tone)	No effect	Storage (continuous tone)

When a magnet is applied for more than 30 seconds, the Tachy Mode can be changed from one mode to the other, as indicated by the arrows.

2. To change the Tachy Mode again, remove the magnet for at least two seconds and reapply it to the pulse generator as indicated in Step 1.

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.

1. 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 it will be terminated within one to two seconds of magnet application, and the charge will be 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.
2. Remove the magnet in less than 30 seconds to allow therapy to resume.

NOTE: *Leaving the magnet in place for 30 seconds or more changes the Tachy Mode of the pulse generator if the Change Tachy Mode With Magnet feature is On.*

Chapter 10

IMPLANTING THE PULSE GENERATOR

Steps A through J below describe the recommended implant procedure for implanting a pulse generator. The pulse generator can be implanted using device-based testing or using the VENTAK External Cardioverter Defibrillator (ECD). (Refer to Appendix D for VENTAK ECD connections.)

Recommended sequence using device-based testing (DBT):

Check the Equipment, and Interrogate and Check the Pulse Generator's Nominal Settings and Battery Status (Step A)

Implant the Lead System (Step B)

Take Baseline Measurements (Step C)

Form the Implantation Pocket (Step D)

Connect the Leads to the Pulse Generator (Step E)

Evaluate Lead Signals (Step F)

Program the Pulse Generator (Step G)

Test for Ability to Convert Ventricular Fibrillation and Inducible Arrhythmias (Step H)

Implant the Pulse Generator (Step I)

Complete and Return the Heart Failure Device Warranty Validation and Lead Registration Form to Guidant (Step J)

Step A: Check Equipment, Interrogate, and Check Pulse Generator's Nominal Settings and Battery Status

Check the 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 2848 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 nontorque wrenches

During the implantation procedure, a standard transthoracic defibrillator with R2 pads or internal paddles should be available for use during defibrillation threshold testing.

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 Guidant PRM/2848 programming system. Verify that the pulse generator is programmed to the factory preset parameters as listed on the packaging labels. If otherwise, call Guidant.
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 is not at BOL (beginning of life), do not implant the pulse generator. Call Guidant at the phone number on the back of this manual.

Step B: Implant the Lead System

The pulse generator requires a lead system for sensing, pacing, and delivering shocks. The pulse generator uses its own case as a defibrillating anode.

Selection of lead configuration and specific surgical procedures is a matter of professional judgment. Several lead system configurations are available for use with the CONTAK CD pulse generator (refer to Appendix C for a list of compatible leads):

NOTES:

- *If the coronary venous lead cannot be used, and left ventricular pacing is desired, Guidant strongly recommends the use of a steroid-eluting pace/sense epicardial lead.*
- *The Model 6744 Lead Adapter is designed to connect an IS-1 lead to the LV-1 port of the pulse generator.*

WARNING: Do not use defibrillation patch leads with the CONTAK CD system, or injury to the patient may occur.

Enclosed with each lead package are 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 a pulse generator; implantation of a 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 C: Take Baseline Measurements

Once the leads are implanted, take baseline measurements and evaluate the lead signals. If performing a pulse generator replacement procedure, existing leads' signal amplitudes should be reevaluated, along with pacing, cardioversion, and defibrillation threshold testing. 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) and evaluate the placement by determining R-wave and P-wave amplitude, QRS duration, pacing threshold, and lead impedance. Pace/sense lead measurements should reflect those in Table 17. Note that the pulse generator measurements may not exactly correlate to the PSA measurements due to signal filtering.

Table 17. Lead measurements

	Measurement ^a	Acute	Chronic
Sensing ^{b,c}	Atrial	> 2.0 mV	> 2.0 mV
	Biventricular	> 5.0 mV	> 5.0 mV
	Intracardiac QRS duration ^{d,e}	< 135 ms	< 135 ms
Pacing	Atrial	< 1.5 V	< 3.0 V
	Ventricular (endocardial)	< 1.5 V	< 3.0 V
	Ventricular (epicardial)	< 2.0 V	< 3.5 V
Lead Impedance	Shocking lead	20–80 Ω	20–80 Ω
	Biventricular pacing leads (RV + LV)	200–1000 Ω	200–1000 Ω
	Conventional pacing leads (RA, RV, LV)	300–1200 Ω	300–1200 Ω

- Measured approximately 10 minutes after placement.
- 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.
- 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.
- 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.
- This measurement is not inclusive of current of injury.

Step D: Form the Implantation Pocket

Use standard operating procedures to prepare an implantation pocket, giving consideration to body habitus and pulse generator size. Choose the position of the implantation pocket based on the implanted lead configuration and the patient's anatomy. 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 whether 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.*

Gently coil the excess lead wires and place them in a separate pocket above or to the side of (not behind or below) the pulse generator, giving consideration to lead tension and device motion. It is important to place the lead into the pocket in a manner that minimizes pressure and reduces lead-on-lead and/or lead-on-can contact.

CAUTION: Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.

Step E: Connect the Leads to the Pulse Generator

Refer to Figure 104 and follow the steps below to connect the leads to the pulse generator.

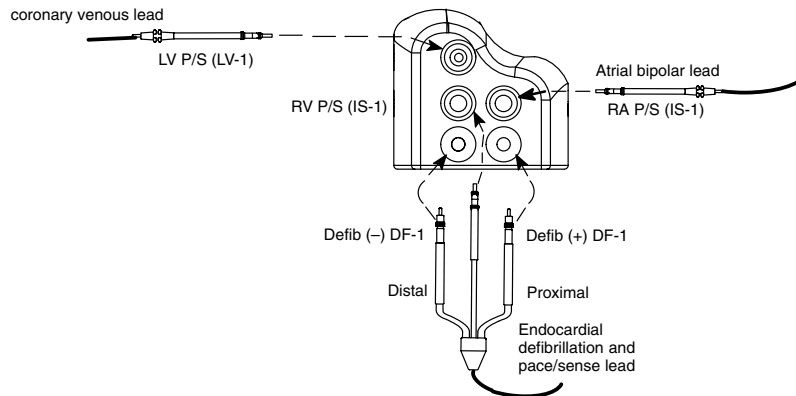


Figure 105. Leads to pulse generator connections for lead evaluation.

NOTES:

- Avoid allowing blood or other bodily fluids to enter the lead ports in the pulse generator header. If fluid inadvertently enters the ports, they should be thoroughly cleaned using sterile gauze.
1. Insert the defibrillating lead anode (+, proximal) into the pulse generator's (+) Defib DF-1 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.

NOTES:

- 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.
2. Insert the wrench into the center, preslit depression of the seal plug.

NOTE: To connect leads to the 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.

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-handed 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. Insert and secure the defibrillating cathode (–, distal) in the (–) Defib DF-1 lead port in a similar manner as above.

CAUTION: 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.

5. Insert and secure the right ventricular pace/sense lead terminal in the RV IS-1 P/S lead port.
6. Insert and secure the atrial pace/sense lead terminal in the RA IS-1 P/S lead port.
7. Insert and secure the left ventricular coronary venous pace/sense lead terminal in the LV P/S lead port.

CAUTION: Absence of an LV-1 plug or an electrode in the unused lead port of an LV-1 header may affect device performance. **If an electrode is not used, be sure to insert a plug.**

NOTES:

- The IS-1 pace/sense lead ports have two setscrews to tighten: one for the terminal pin and one for the terminal ring of the inline connector. The LV-1 pace/sense lead port and DF-1 port have one setscrew for tightening their terminal pins.
- For proper connection of Guidant LV-1, IS-1, and DF-1 leads to the pulse generator, be certain that the connector pins visibly extend through the connector block at least 1 mm (Figure 106).
- The Model 6744 Lead Adapter is designed to connect an IS-1 lead to the LV-1 port of the pulse generator.

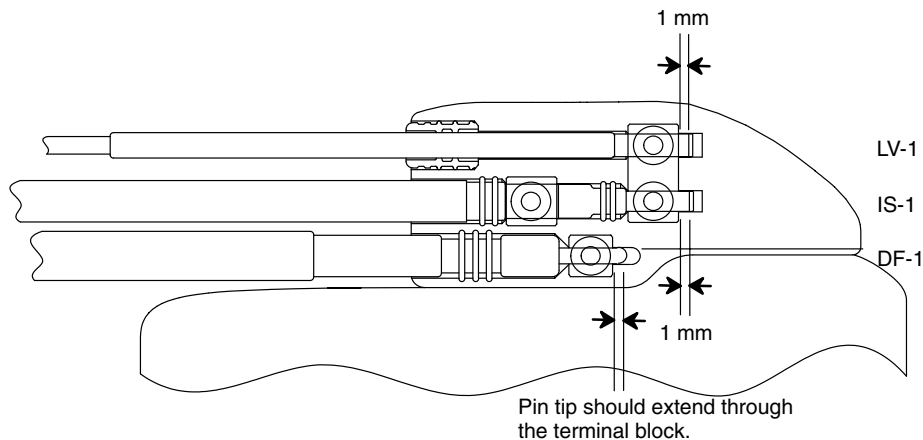


Figure 106. Properly positioned leads in pulse generator LV-1, IS-1, and DF-1 lead ports.

CAUTION: The setscrews should be tightened onto the electrode rings of the pace/sense leads. If setscrews are tightened onto the silicone rubber insulation, permanent damage to the leads could occur.

8. It is useful to program the Beep During Capacitor Charge feature On during conversion testing and implant to help recognize when the pulse generator is charging to deliver a shock.

Step F: 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. Use the Auto Scale feature to calibrate the gain on the stored electrograms (refer to Chapter 6).
3. Evaluate the atrial and ventricular pace/sense and defibrillation lead signals by viewing the real-time EGMs and markers. The two ventricular pace/sense ports are connected in

parallel inside the pulse generator header, resulting in a single lead signal. 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 lead fracture or otherwise damaged lead, or an insulation break that would necessitate lead replacement. Inadequate signals may result in failure of the system to detect an arrhythmia; or, there may be an unnecessary delivery of therapy.

4. Before closing, connect all leads to the system and obtain real-time event markers. Examine the ventricular rate-sensing electrogram for the presence of dual ventricular complexes spaced greater than 100 ms; if present, consider an alternate placement site for the left ventricular pace/sense lead since double counting and inappropriate therapy may result.

CAUTION: Care must be taken 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.

- Synchronously deliver a test shock at no greater than 1.1 J to the patient to evaluate shocking lead impedance.

CAUTION: If a defibrillating lead impedance is less than 20 Ω , the defibrillating leads should be repositioned. The pulse generator should never be implanted with a lead system that has less than 15 Ω total lead impedance. Device damage may result.

Step G: Program the Pulse Generator

1. Set the programmer clock so that the proper time appears on printed reports and PRM strip chart recordings.
 - a. Select the Set Programmer Clock option from the File menu. A Set Date And Time window will appear.
 - b. Select a box with an arrow to change each displayed number for the programmer date and time. The real-time seconds display can be selected to reset the seconds to zero.
 - c. To synchronize the programmer and pulse generator clock, Select the Synchronize button. The dates and times for the pulse generator and programmer clocks will be displayed.
 - d. Establish telemetry communication, Select the Set Programmer Clock. The window will disappear.
2. It may be useful to program the Beep During Capacitor Charge feature On during conversion testing and implantation to help recognize whether the pulse generator is charging to deliver a shock.
3. Perform a manual capacitor re-formation **if not already performed** prior to conversion testing (see step A).
4. Program the pulse generator to desired parameters appropriate for the patient. **Verify that the pulse generator's Tachy Mode is programmed to Off.**

CAUTION: Ensure that the pulse generator's Tachy Mode is Off when not in use, before handling it, and before using electrosurgery.

Step H: Test for Ability to Convert Ventricular Fibrillation and Inducible Arrhythmias

After obtaining acceptable signals from the implanted leads, perform VT and VF conversion testing to determine (1) whether the configuration and position of the implanted defibrillating leads are appropriate for the patient, and (2) whether the pulse generator's programmable shock energy or maximum shocks will be sufficient to convert arrhythmias reliably. A

conversion test consists of inducing the arrhythmia and then attempting to convert the arrhythmia with a preselected energy level.

Demonstrating conversion of ventricular fibrillation is essential before implanting a pulse generator, because a shock delivered during ventricular tachycardia has the potential to accelerate the arrhythmia. Intraoperative testing may be minimized by performing only VF testing at the time of implant and performing VT testing post-operatively in the electrophysiology lab prior to the patient's discharge.

CAUTION: Successful conversion of ventricular fibrillation or ventricular tachycardia 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.

Following unsuccessful conversion, the patient should be rescued using an appropriate transthoracic defibrillator. Early conversion is important because a prolonged arrhythmia may be more difficult to terminate. Clinical results with monophasic shock waveforms indicate that, at a given energy, the longer a patient remains in a tachyarrhythmia, the lower the conversion efficacy of the delivered shock, which increases the likelihood of a loss of consciousness; and, for VT, an increased likelihood of degeneration into VF.

WARNING: If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Before tachyarrhythmia induction, both sterile external and internal defibrillator paddles or an equivalent (eg, R2 pads) must be immediately available and ready for use.

NOTE: *If open chest surgery is performed, and a chest retractor is used, remove the retractor before conversion testing to best simulate the ambulatory conditions in which the pulse generator will operate, and to avoid potential shunting of energy.*

Induce the Patient's Arrhythmia.

An arrhythmia can be induced by using the induction features of the pulse generator.

Exercise caution with the current used to induce arrhythmias. Use the minimum amount of current necessary, with a current-limited source. Inducing through the defibrillating electrodes (rather than the pace/sense electrodes) will usually cause less tissue-stunning effects due to the larger area of stimulation. Depressed R-waves or ST changes in the pace/sense lead electrogram indicate excessive stimulating current.

Allow the patient's blood pressure and electrophysiologic status to return to baseline between arrhythmia inductions, whether successful or unsuccessful. It is also suggested to allow a minimum of one minute between inductions.

During each arrhythmia induction, note the heart rate to determine the appropriate rate threshold values. Ventricular cycle lengths that occur close to the lowest programmed rate threshold values may be detected as normal sinus rhythm. To provide sufficient opportunity for detection, the rate threshold value(s) should be programmed at least 10 bpm below the rate of the arrhythmia that is to be treated.

Perform the Induction

1. Insert the pulse generator into the implantation pocket. Because the pulse generator case acts as an active electrode, keep the leads from contacting the pulse generator case and temporarily close the pocket enough to ensure that the pulse generator will remain in position during conversion testing. Make sure the pulse generator has good contact with surrounding tissue; flush the pocket with saline solution, if necessary, to avoid a dry pocket.

2. Verify magnet function and telemetry to ensure the pulse generator is within acceptable range.
3. Program the appropriate parameters and change the pulse generator Tachy Mode to Monitor + Therapy.
4. Perform the induction using the programmer.

Determine DFT and CER. Defibrillation threshold (DFT) and Cardioversion Energy Requirement (CER) testing should be performed at implant to ensure adequate safety margins for the shock energy (safety margin = shocking energy – DFT). The DFT is the minimum energy tested that reliably converts VF or polymorphic VT in a series of arrhythmia trials with decreasing energy steps. CER is the lowest energy tested that converts each of the patient's monomorphic ventricular tachycardias (MVT), and is the minimum energy to which the first shock should be programmed for MVT.

To determine DFT, induce VF (or PVT or ventricular flutter if VF is not inducible). Attempt to convert the arrhythmia with a 21-J shock; if conversion is successful, then induce again and attempt to convert the arrhythmia at 17 J. Continue in this manner, decreasing the energy level until failure to convert VF occurs, or 3 J is successful. If the initial conversion at 21 J is unsuccessful, reposition the lead, or reverse polarity, or add an additional lead. If these options are unsuccessful, implant a higher output device. The energy level that last converted the arrhythmia successfully is the DFT. It is a matter of clinical judgment as to what constitutes a demonstration of reliable conversion.

NOTE: *Since the results of any single test may be an example of statistical variation, a one-time conversion of a rhythm disturbance at a particular energy level does not guarantee or assure that the energy level is reliable for conversion. As a safety margin, Guidant recommends performing the conversion test at the DFT two times if the DFT is 21 J, or one time if the DFT is 17 J with no failures to convert.*

To determine CER, induce the patient's MVT and attempt conversion at 6 J or less. If the conversion is successful, test lower energy levels until a level is reached that does not convert the arrhythmia. Or, if the test results in nonconversion, test successively higher energies until an energy is reached that converts the MVT. It is recommended to program the energy equal to or greater than that which converted the MVT twice.

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. Flush the pocket with saline solution, if necessary, to avoid a dry pocket. Excess lead should be placed in a separate pocket.
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 the electrosurgery procedures before reactivating the pulse generator.
5. Program the Tachy Mode to the desired value and confirm final programmed parameters.
6. Print out parameter reports and save patient data to disk.

Step J: Complete and Return the Implantation Form to Guidant

Within 10 days of implantation, complete the Heart Failure Device 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 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 Heart Failure Device 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 lead. If completing the Heart Failure Device Warranty Validation and Lead Registration form for the pulse generator, completing separate validation forms for each lead is not necessary.*

Chapter 11

POST-IMPLANT INFORMATION

Follow-up Testing

Guidant recommends that detection and conversion testing (EP study) be done before the patient is discharged from the hospital to verify detection and conversion efficacy of the final programmed therapy parameters.

CAUTION: Noninvasive testing of the pulse generator should be performed only in the presence of medical personnel skilled in cardiopulmonary resuscitation (CPR). In addition, an external defibrillator and a person skilled in its use should be immediately available.

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 to review the Episode Summary from the Therapy History tool kit.
2. Review the capacitor and battery status from the Battery Status tool kit. (Refer to Chapter 6 for battery information.)
3. Perform pacing lead thresholds and impedance tests, and R-wave and P-wave measurements by using the Quick Check or Brady Analysis tools.
4. Verify that the patient's VTs can be induced, detected, and terminated by the system.
5. Verify that VF can be induced, detected, and terminated by the system.
6. When all testing is complete, perform a final interrogation and save all the data to a patient data disk.
7. Print the following reports to retain in your files for future reference: Parameters, Counters, Patient Data, and Measured Data.
8. **It is important to clear the therapy counters so that the most recent episode data will be displayed at the next follow-up session.** To perform this procedure, use the Quick Check option or select the Therapy History tool box menu, then select the Show Counters button. From the Counters window, select the Clear Counters button. Also, clear the histogram counters from the Histograms window.

An arrhythmia detection-conversion and pacing study should be performed whenever pulse generator parameters are reprogrammed or drugs that affect the electrical characteristics of the heart are changed.

NOTE: Echo-Doppler studies may be used to evaluate AV delay and other programming options noninvasively postimplant.

Routine Follow-up

Routine follow-up examinations should be conducted one month after the predischarge study and every three 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 Therapy History.
2. Review the capacitor and battery status from the Battery Status tool kit.
3. Perform pacing lead thresholds and lead impedance tests, and R-wave and P-wave measurements. If no shock has been delivered since the last follow-up, telemeter a real-time Shock Egram along with a surface ECG to check the shocking lead integrity.

4. Print the following reports to retain in your files for future reference: Parameters, Counters, Patient Data, and Measured Data.
5. For episodes of interest, review Episode Detail and print episode detail, intervals, and, if desired, stored electrogram information.
6. **It is important to clear the therapy counters so that the most recent episode data will be displayed at the next follow-up session.** To perform this procedure, use the Quick Check option or select the Therapy History tool box menu, then select the Show Counters button. From the Counters window, select the Clear Counters button. Also, clear the histogram counters from the Histograms window.

CAUTION: If the patient's status has changed or parameters have been reprogrammed, a conversion test is recommended to verify that the patient's tachyarrhythmias can be detected and terminated by the system. Save the data to a patient data disk.

Sensitivity Adjustment

The Sensitivity Adjustment feature permits shifting the sensing range to make it less sensitive, that is, a larger signal would be required for the device to detect. While the Nominal setting is primarily indicated, an adjustment can be made if, in a rare situation, atrial or ventricular oversensing 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. Begin by programming Nominal to Less and then evaluate for appropriate sensing for both bradycardia pacing and tachycardia detection operations. If further adjustment is necessary, program the setting from Less to Least and again evaluate for appropriate sensing. The Sensitivity Adjustment feature is available from the Other Params menu (refer to Chapter 6).

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. Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing for bradycardia pacing and tachycardia detection.

NOTE: *Whenever an adjustment setting has been changed, the Net Change report will indicate the programmed setting. The Selected Parameter report will show the sensitivity setting only if programmed to Less or Least.*

Explantation

Return all explanted pulse generators and leads to Guidant. Examination of explanted devices may provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

In the event of a patient's death (regardless of the cause) or explantation of either the pulse generator or lead or both, 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. There may also be observations or complications other than a death that should be reported. If so, fill in and return the same multiuse Observation/Complication/Out-Of-Service Reporting Form to Guidant.

NOTES:

- *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant representative or call Guidant at the number shown on the back cover for a Returned Product Kit.*
- *Discoloration of the pulse generator may have occurred due to a normal process of anodization, but this has no effect on the pulse generator function.*

CAUTIONS:

- The pulse generator contains sealed chemical power cells and capacitors; **never incinerate a pulse generator**. Be sure that the pulse generator is removed before cremation.
- To prevent unwanted shocks, program the Tachy Mode to Off, disable the magnet feature, and disable the Beep When ERI Is Reached beeper before explanting. **Do not remove, clean, or ship the pulse generator unless it has been disabled**. Failure to disable the pulse generator can also allow overwriting of important therapy history data that may be useful.

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.

Appendix A—Programmable Options

Detection Criteria for a One-Zone Configuration (Nominal)

Parameter	VF Zone Values	Increment	Nominal	Tolerance
Tachy Mode	Off, Monitor Only, Monitor + Therapy	—	Storage	—
Rate (interval)	90–210 bpm (667–286 ms) 220 bpm (273 ms)	5 bpm	165 bpm	±8 ms
Duration	1–5 sec 5–15 sec	0.5 sec 1 sec	1 sec	±1 cardiac cycle
Redetection Duration	1 sec (nonprogrammable)	—	1 sec	±1 cardiac cycle
Post-shock Duration	1 sec (nonprogrammable)	—	1 sec	±1 cardiac cycle

Detection Criteria for a Two-Zone Configuration (Nominal)

Parameter	VT Zone Values	VF Zone Values	Increment	Nominal	Tolerance
Tachy Mode	Off, Monitor Only, Monitor + Therapy (programmed value affects all zones)		—	Storage	—
Rate ^a (interval)	90–210 bpm (667–286 ms) 220 bpm (273 ms)	110–210 bpm (545–286 ms) 220–250 bpm (273–240 ms)	5 bpm 10 bpm	165 bpm (VF) 145 bpm (VT)	±8 ms
Duration ^c	1–5 sec 5–15 sec 20–30 sec	1–5 sec 5–15 sec	0.5 sec 1 sec 5 sec	2.5 sec (VT) 1.0 sec (VF)	±1 cardiac cycle
Onset	Off, 9, 12, 16–37, and 41–50% of interval; or, 50–250 ms absolute time of interval	Not available	3% or 10 ms	Off	±8 ms
Stability-Inhibit If Unstable ^b (used during initial detection only)	Off, 6–32 ms 35–60 ms 70–120 ms	Not available	2 ms 5 ms 10 ms	Off	±8 ms
Stability-Shock If Unstable ^b	Off, 6–32 ms 35–60 ms 70–120 ms	Not available	2 ms 5 ms 10 ms	Off	±8 ms
AFib Rate Threshold	Off, 200–400 bpm	Not available	25 bpm	Off	±8 ms
V Rate > A Rate	Off, On	Not available	—	Off	—
Sustained Rate Duration (SRD)	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Not available	5 sec 15 sec 30 sec 5 minutes	30 sec	±1 cardiac cycle
ATP Time-out	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Not available	5 sec 15 sec 30 sec 5 minutes	60 sec	±250 ms
Redetection Duration ^c	1–5 sec 5–15 sec	1 sec (nonprogrammable)	0.5 sec 1 sec	1 sec	±1 cardiac cycle
Post-shock Duration ^c	1–5 sec 5–15 sec 20–30 sec	1 sec (nonprogrammable)	0.5 sec 1 sec 5 sec	1 sec	±1 cardiac cycle
Post-shock Stability–Inhibit If Unstable	Off, 6–32 ms 35–60 ms 70–120 ms	Not available	2 ms 5 ms 10 ms	Off	±8 ms
Post-shock SRD	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Not available	5 sec 15 sec 30 sec 5 minutes	Off	±1 cardiac cycle
Post-shock AFib Rate Threshold	Off, 200–400 bpm	Not available	25 bpm	Off	±8 ms
Post-shock V Rate > A Rate	Off, On	Not available	—	Off	—

- The Rate difference between each tachy zone must be at least 20 bpm, and the VT Rate must be 5 bpm greater than the Brady MTR or MSR in a dual-chamber or single-chamber adaptive-rate mode. In a single-chamber nonadaptive-rate mode, the VT rate must be 10 bpm greater than the Brady LRL.
- In a multizone configuration, programming Stability to Inhibit If Unstable will override Stability if programmed to Shock If Unstable.
- The Duration in a zone must be equal to or greater than the Duration in the next highest zone.

Detection Criteria for a Three-Zone Configuration (Nominal)

Parameter	VT1 Zone Values	VT Zone Values	VF Zone Values	Increment	Nominal	Tolerance
Tachy Mode	Off, Monitor Only, Monitor + Therapy (programmed value affects all zones)			—	Storage	—
Rate ^a (interval)	90–200 bpm (667–300 ms)	110–210 bpm 220 bpm (545–273 ms)	130–210 bpm 220–250 bpm (462–240 ms)	5 bpm 10 bpm	165 bpm (VF) 145 bpm (VT) 125 bpm (VT-1)	±8 ms
Duration ^c	1–5 sec 5–15 sec 20–60 sec	1–5 sec 5–15 sec 20–30 sec	1–5 sec 5–15 sec	0.5 sec 1 sec 5 sec	2.5 sec (VT-1 and VT) 1.0 sec (VF)	±1 cardiac cycle
Onset	Off, 9, 12, 16–37, and 41–50% of interval; or, 50–250 ms abso- lute time of interval	Not available	Not available	3% or 10 ms	Off	±8 ms
Stability-Inhibit If Unstable (used during initial detection only)	Off, 6–32 ms 35–60 ms 70–120 ms	Not available	Not available	2 ms 5 ms 10 ms	Off	±8 ms
Stability-Shock If Unstable 30 sec	Not available	Off, 6–32 ms 35–60 ms 70–120 ms	Not available	2 ms 5 ms 10 ms	Off	±8 ms
AFib Rate Thresh- old	Off, 200–400 bpm	Not available	Not available	25 bpm	Off	±8 ms
V Rate > A Rate	Off, On	Not available	Not available	—	Off	—
Sustained Rate Duration (SRD)	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Not available	Not available	5 sec 15 sec 30 sec 5 minutes	30 sec	±1 cardiac cycle
ATP Time-out ^b	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Not available	5 sec 15 sec 30 sec 5 minutes	60 sec	±250 ms
Redetection Dura- tion ^c	1–5 sec 5–15 sec	1–5 sec 5–15 sec	1 sec (nonpro- grammable)	0.5 sec 1 sec	1 sec	±1 cardiac cycle
Post-shock Dura- tion ^c	1–5 sec 5–15 sec 20–60 sec	1–5 sec 5–15 sec 20–30 sec	1 sec (nonpro- grammable)	0.5 sec 1 sec 5 sec	1 sec	±1 cardiac cycle
Post-shock Stabil- ity–Inhibit if Unsta- ble	Off, 6–32 ms 35–60 ms 70–120 ms	Not available	Not available	2 ms 5 ms 10 ms	Off	±8 ms
Post-shock SRD	Off, 10–60 sec 1–2 minutes 2–10 minutes 10–60 minutes	Not available	Not available	5 sec 15 sec 30 sec 5 minutes	Off	±1 cardiac cycle
Post-shock AFib Rate Threshold	Off, 200–400 bpm	Not available	Not available	25 bpm	Off	±8 ms
Post-shock V Rate > A Rate	Off, On	Not available	Not available	—	Off	—

- The Rate difference between each tachy zone must be at least 20 bpm, and the VT-1 Rate must be 5 bpm greater than the Brady Maximum Tracking Rate or Maximum Sensor Rate in a dual-chamber or single-chamber adaptive-rate mode. In a single-chamber nonadaptive-rate mode, the VT-1 rate must be 10 bpm greater than the Brady LRL.
- The VT-1 ATP Time-out must be greater than or equal to the VT ATP Time-out.
- The Duration in a zone must be equal to or greater than the Duration in the next highest zone.

Antitachycardia Pacing (ATP) Parameters (Nominal)

Parameter	Programmable Values (each zone)	Increment	Nominal	Tolerance
Number Of Bursts (per scheme)	Off, 1–30 bursts	1 burst	Off	—
Initial Pulse Count	1–30 pulses	1 pulse	4 pulses	—
Pulse Count Increment	0–5 pulses	1 pulse	0 pulses	—
Maximum Number of Pulses	1–30 pulses	1 pulse	4 pulses	—
Coupling Interval	50–59, 63–84, and 88–97% or 120–750 ms	3% or 10 ms	81%	±8 ms
Coupling Interval Decrement	0–30 ms	2 ms	0 ms	±8 ms
Initial Burst Cycle Length (BCL)	50–59, 63–84, and 88–97% or 120–750 ms	3% or 10 ms	81%	±8 ms
Ramp Decrement (Within a Burst)	0–30 ms	2 ms	0 ms	±8 ms
Scan Decrement (Between Bursts)	0–30 ms	2 ms	0 ms	±8 ms
Minimum Interval	120–400 ms	10 ms	200 ms	±8 ms
Pulse Width ^a (atrium and ventricle)	0.5–2.0 ms (programmed value affects all zones)	0.1 ms	1.0 ms (A&V)	±0.03 ms at <1.8 ms, ±0.08 ms at ≥1.8 ms
Amplitude ^{a,b} (ventricle)	5, 6, and 7.5 V (programmed value affects all zones)	—	7.5 V	+10%/–15%

- The programmed Amplitude and Pulse Width values affect Temporary ATP, and PES and Slaved inductions, but are separately programmable from Brady Pacing, Post-shock Brady Pacing, and Temporary Brady Pacing.
- The atrial amplitude is nonprogrammable at 5 V.

Shock Parameters (Nominal)

Parameter	Programmable Values	Nominal	Tolerance
Shocks 1 and 2 energy ^{a,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, 29 and 31 J	31 J	±40% for 2 J or less, ±20% for 3–29 J, ±4 J for 31 J
Remaining Shocks' energy ^{a,c} (stored energy)	31 J, Off	31 J	±4 J
Polarity ^d	Initial, Reversed	Initial	—
Waveform ^d	Monophasic, Biphasic	Biphasic	—
Committed Shock	Yes, No	No	—

- Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.
- The Shock 2 energy level must be greater than or equal to the Shock 1 energy level.
- In a VT-1 zone of a three-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.
- A commanded Stat Shock is delivered at the programmed waveform and polarity.

Bradycardia Pacing Schemes (Normal and Temporary)

Parameter	Programmable Values	Increment	Nominal	Tolerance
Mode ^{f,j}	Normal: Off, AAI(R), VVI(R), VDD(R), DDI(R), DDD(R), OOO Temporary: Off, AOO(R), AAI(R), VOO(R), VVI(R), VDD(R), DOO(R), DVI(R), ODO(R), DDI(R), DDD(R), OOO	—	DDD	—
Lower Rate Limit (LRL) ^{a,d,g}	40–50 ppm 50–90 ppm 90–175 ppm	5 ppm 1 ppm 5 ppm	60 ppm	±8 ms

Maximum Tracking Rate (MTR) ^a	60–100 ppm 100–175 ppm	10 ppm 5 ppm	120 ppm	±8 ms
Maximum Sensor Rate (MSR) ^a	60–100 ppm 100–175	10 ppm 5 ppm	120 ppm	±8 ms
Activity Threshold ^c	V-Low, Low, Med-Low, Med, Med-High, High, V-High	—	Med	—
Reaction Time ^c	10–50 sec	10 sec	30 sec	—
Response Factor ^c	1–16	1	8	—
Recovery Time ^c	2–16 min	1 min	5 min	—
Pulse Amplitude ^{b,e,f,g} (atrium)	0 V 0.2–3 V 3.5–5 V	0.2V 0.5 V	3.5 V	±0.3 V at ≤ 3 V ±10% at > 3 V
Pulse Amplitude ^{b,e,f,g} (ventricle)	0 V 0.2–3 V 3.5–7.5 V	0.2V 0.5 V	3.5 V	±0.3 V at ≤ 3 V ±10%/–at 15% > 3 V
Pulse Width ^{b,e,f} (atrium or ventricle)	0.06 ms 0.1–2 ms	0.1 ms	0.4 ms (A) 0.4 ms (V)	±0.03 ms at < 1.8 ms, ±0.08 ms at ≥ 1.8 ms
Ventricular Paced/LRL Re- fractory ^f	150–500 ms	10 ms	250 ms	±8 ms
Dynamic MTR Refractory ^h	150–500 ms	10 ms	240 ms	±8 ms
Atrial Refractory-PVARP	150–500 ms	10 ms	250 ms	±8 ms
PVARP Extension	Off, 50–400 ms	50 ms	Off	±8 ms
Noise Response ^c	AOO, VOO, DOO, Inhibit	—	DOO ⁱ	—
AV Delay (fixed/maximum)	50–300 ms	10 ms	150 ms	±8 ms
Dynamic AV Delay	Off, On	—	On	
Minimum AV Delay	50–300 ms	10 ms	80 ms	±8 ms
Sensed AV Offset	Off, –10 to –100 ms	–10 ms	Off	±8 ms
Hysteresis	Off, 40–50 ppm 50–90 ppm 90–170 ppm	5 ppm 1 ppm 5 ppm	Off	±8 ms
Rate Smoothing (up, down)	Off, 3, 6, 9, 12, 15, 18, 21, 25%	—	Off	±1%
ATR Trigger Rate ^c	Off, 100–200 bpm	5 ppm	170 ppm	±8 ms
ATR Duration ^c	0, 1–10 cycles 20–90 cycles 100–2000 cycles	1 cycle 10 cycles 100 cycles	20 cycles	±1 cardiac cycle
ATR Fallback Time ^c	0, 15, 30, 45 sec 1–5 minutes	— 1 minute	1 minute	±10%
ATR/VTR Fallback LRL ^c	40–50 ppm 50–90 ppm 90–175 ppm	5 ppm 1 ppm 5 ppm	70 ppm	±8 ms
Post-shock Pacing Delay ^c	1.5 sec 2–10 sec	— 1 sec	3 sec	± 0.1 sec
Post-shock Pacing Period	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 min- utes:seconds	—	0:30 min- utes:sec- onds	±0.5% ±1 cardiac cycle

- In a dual-chamber or single-chamber adaptive-rate mode, LRL must be ≥ 20 ppm below MTR (or MSR) ≤ 5 ppm below the lowest tachy zone. In a single-chamber nonadaptive-rate mode, LRL must be ≤ 10 ppm below the lowest tachy zone.
- Separately programmable from Antitachycardia Pacing, Temporary ATP, and Post-shock Brady Pacing.
- The programmed value affects Normal Brady and Post-shock Brady Pacing.
- 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 35% 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).

- e. The minimum value of energy delivered at 5 V and 0.5 ms is 6.2 μJ with 200–500 Ω , and 3.3 μJ with 1000 Ω . resistive load at 37°C $\pm 1^\circ\text{C}$ for BOL and EOL.
- f. Values are not affected by temperature variation within the range 20–43°C.
- g. 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 2.5 mV (± 0.075 mV) at the end of the refractory period. Input impedance is 95 K Ω ± 5 K Ω .
- h. Programming Dynamic MTR Refractory the same value as Ventricular Paced/LRL Refractory disables dynamic refractory.
- i. The nominal mode may change depending on the programmed Brady Mode.
- j. 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 following categories:

Position	I	II	III	IV	V
Category	Chambers Paced	Chambers Sensed	Response to Sensing	Programmability, rate modulation	Antitachyarrhythmia Functions
Letters	O—None A—Atrium V—Ventricle D—Dual (A&V)	O—None A—Atrium V—Ventricle D—Dual (A&V)	O—None T—Triggered I—Inhibited D—Dual (T&I)	O—None P—Simple Programmable M—Multi-Programmable C—Communicating R—Rate Modulation	O—None P—Pacing (Antitachyarrhythmia) S—Shock D—Dual (P&S)
Mfrs. Designation Only	S—Single (A or V)	S—Single (A or V)			

Magnet/Beeper/Electrogram Functions

Parameter	Programmable Values	Nominal
Enable Magnet Use	On, Off	On
Change Tachy Mode with Magnet	On, Off	Off
Beep During Capacitor Charge	On, Off	Off
Beep on Ventricular Sensed and Ventricular Paced Events	On, Off	Off
Beep when ERI is Reached	On, Off	On
Stored Electrograms Atrial Ventricular Shock	On, Off On, Off On, Off	Off Off On
Stored Onset Electrograms	On, Off	On

Sensitivity Adjustment

Parameter	Programmable Values	Nominal
Atrial Sensitivity	Nominal, Less, Least	Nominal
Ventricular Sensitivity	Nominal, Less, Least	Nominal

EP TEST FUNCTIONS

Temporary ATP Parameters

Parameter ^{a,b}	Programmable Values	Increments	Nominal	Tolerance
Number Of Bursts (per scheme)	1–30 bursts	1 burst	30 bursts	—
Initial Pulse Count	1–30 pulses	1 pulse	4 pulses	—
Pulse Count Increment	0–5 pulses	1 pulse	0 pulses	—
Maximum Number of Pulses	1–30 pulses	1 pulse	4 pulses	—
Coupling Interval	50–59, 63–84, and 88–97% or 120–750 ms	3% or 10 ms	81%	±8 ms
Coupling Interval Decrement	0–30 ms	2 ms	0 ms	±8 ms
Initial Burst Cycle Length (BCL)	50–59, 63–84, and 88–97% or 120–750 ms	3% or 10 ms	81%	±8 ms
Ramp Decrement (Within a Burst)	0–30 ms	2 ms	0 ms	±8 ms
Scan Decrement (Between Bursts)	0–30 ms	2 ms	0 ms	±8 ms
Minimum Interval	120–400 ms	10 ms	200 ms	±8 ms
Chamber	Atrium, Ventricle	—	Ventricle	—

- a. The Temporary 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.

Manual Burst Pacing

Parameter ^a	Programmable Values	Increment	Nominal	Tolerance
Number of S1 intervals	10 (nonprogrammable)	—	—	—
Burst Interval	40–750 ms	10 ms	600 ms	±8 ms
Decrement	0–50 ms	10 ms	50 ms	±8 ms
Chamber	Atrium, Ventricle	—	Ventricle	—

- a. Applied to the atrium or ventricle depending on the chamber selected.

Commanded Shock Parameters

Parameter	Programmable Values	Increment	Nominal	Tolerance
Shock ^a (stored energy)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 29, and 31 J	—	31 J	±40% for ≤ 2 J, ±20% for 3–29 J ±4 J for 31 J
Coupling Interval	Sync, 50–500 ms	10 ms	Sync	–0/+50 ms

- a. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.

V Fibrillation Induction

Parameter	Programmable Values	Increment	Nominal	Tolerance
V Fib High	30 ms (nonprogrammable)	—	30 ms	+20/–5 ms
V Fib Low	50 ms (nonprogrammable)	—	50 ms	+20/–5 ms

PES (Programmed Electrical Stimulation)

Parameter^a	Programmable Values	Increment	Nominal	Tolerance
Number of S1 intervals	1–30 pulses	1 pulse	8 pulses	±8 ms
S1 to S1 interval	120–750 ms	10 ms	600 ms	±8 ms
S1 to S2 interval	Off, 120–750 ms	10 ms	600 ms	±8 ms
S2 to S3 interval	Off, 120–750 ms	10 ms	Off	±8 ms
S3 to S4 interval	Off, 120–750 ms	10 ms	Off	±8 ms
S4 to S5 interval	Off, 120–750 ms	10 ms	Off	±8 ms
Chamber	Atrium, Ventricle	—	Ventricle	—

a. Applied to the atrium or ventricle as commanded by the programmer.

Shock on T Parameters

Parameter	Programmable Values	Increment	Nominal	Tolerance
Shock ^a (stored energy)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21 J	—	0.6 J	±40% for ≤ 2 J, ±20% for 3–21 J
No. of Intervals	1–30	1	8 pulses	—
Interval timing	120–750 ms	10 ms	400 ms	±8ms
Coupling Interval	Sync, 50–500 ms	10 ms	310 ms	–0/+50 ms

a. Biphasic energy is specified. Monophasic energy is 6.7% less than biphasic energy.

Appendix B—External Cable Connections

The following cables are required for use with the Model 2920 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.

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 107 for cable connections.

NOTE: Refer to the ZOOM Programming System Operator's Manual for instructions on connecting an external monitor.

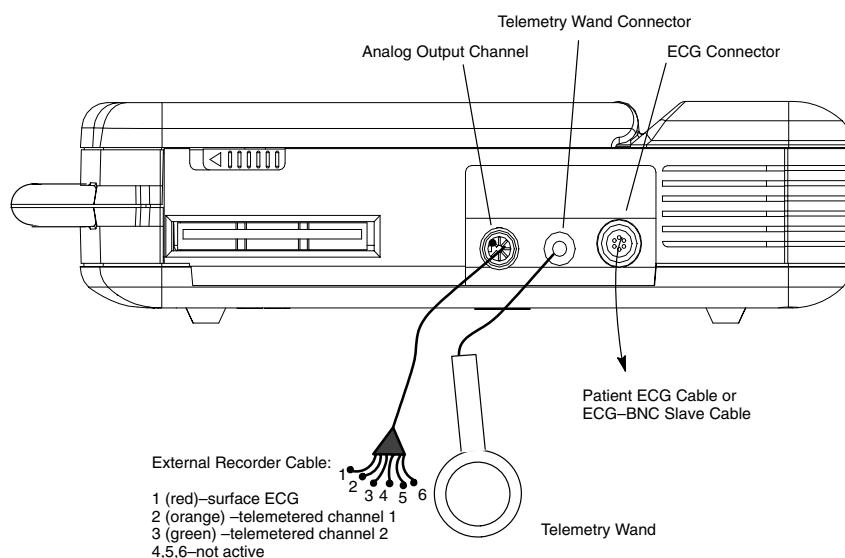


Figure 107. Cable connections for the Model 2920 PRM.

Surface ECG Connections

Three cable–electrode configurations frequently used to generate surface ECG include the following:

- Patient to external recorder to PRM (Figure 108)
- Patient to PRM to external recorder (Figure 109)
- Simultaneous connections from patient to PRM and patient to external recorder (Figure 110)

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 108.

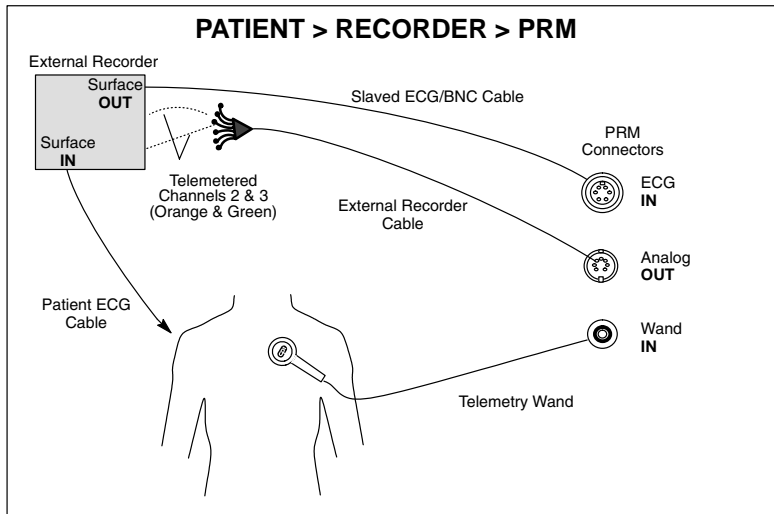


Figure 108. External recorder gets surface signal and sends it to the PRM. PRM sends electrograms to the external recorder.

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 "Accessing Traces" in Chapter 6.

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 109.

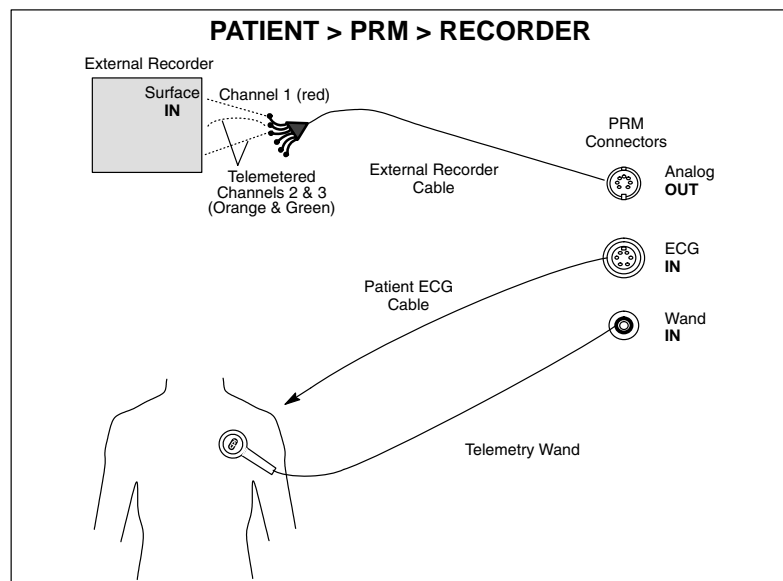


Figure 109. PRM receives surface signal via the patient cable and then sends surface and telemetered channels to the external strip chart recorder.

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 "Accessing Traces" in Chapter 6.

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 110.

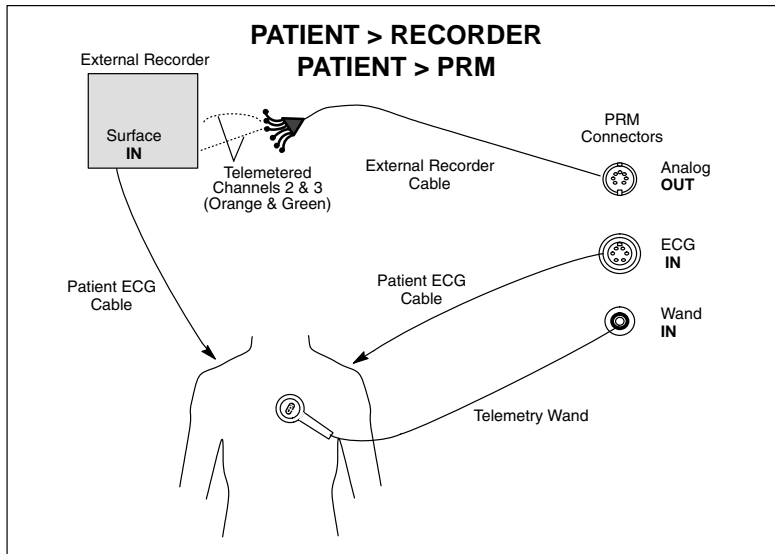


Figure 110. Parallel connection of PRM surface leads and external surface monitor.

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 three PRM-recorder configurations.

4. Adjust gain and filters on the external recorder.
5. Setup is now complete. Refer to the section “Accessing Traces” in Chapter 6.

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 (eg, 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.

Appendix C—Pulse Generator/Lead Compatibility

The CONTAK CD Model 1823 pulse generator is designed to accept defibrillating leads with DF-1 connectors and ventricular pace/sense leads with IS-1 and LV-1 connectors. The Guidant leads listed can be used with CONTAK CD pulse generators.

Nonthoracotomy rate-sensing/defibrillation leads:

ENDOTAK DSP Models 0093, 0095, 0123, and 0125

ENDOTAK C Models 0073, 0075, 0113, and 0115

ENDOTAK ENDURANCE EZ Models 0154, 0155, 0156

LV-1 coronary venous single electrode pace/sense leads:

EASYTRAK Models 4510, 4511, 4512, and 4513

The CONTAK CD Model 1823 pulse generator is designed to accept any commercially available IS-1 atrial bipolar pace/sense lead.

Appendix D—Ventak ECD Connections

The pulse generator can be implanted using device-based testing or using the VENTAK ECD. This appendix will illustrate how to use the ECD for DFT testing with a pulse generator. For implantation using device-based testing, refer to Chapter 10.

NOTE: *The ECD may be used to perform VF conversion testing only with the ENDOTAK cardioversion/defibrillation lead. The ECD may not be used to evaluate biventricular rate-sensing because the bipolar cable is incompatible with the coronary venous pace/sense lead. If an ECD is used for VF conversion testing, we strongly recommend that device-based testing be performed with the pulse generator and all leads to verify system performance.*

Recommended Implant Sequence Using a Guidant VENTAK ECD

The recommended procedure to implant a pulse generator consists of the following steps:

- Check the Equipment, and Interrogate and Check the Pulse Generator's Nominal Settings and Battery Status (see Chapter 10, Step A)
- Implant the Lead System (see Chapter 10, Step B)
- Take Baseline Measurements and Evaluate Lead Signals
- Test for Ability to Convert Ventricular Fibrillation and Inducible Arrhythmias
- Form the Implantation Pocket (see Chapter 10, Step D)
- Connect the Leads to the Pulse Generator (see Chapter 10, Step E)
- Program the Pulse Generator (see Chapter 10, Step G)
- Implant the Pulse Generator (see Chapter 10, Step I)
- Complete and Return the Warranty Validation and Lead Registration Form to Guidant (see Chapter 10, Step J)

Equipment Required

The VENTAK ECD should be fully charged prior to testing. In addition to equipment for implantation using the pulse generator, the use of a VENTAK ECD also requires the following accessories:

- Bipolar cable
- High-voltage cable
- TRIAD emulator (allows testing of a three-electrode defibrillation system)

Take Baseline Measurements and Evaluate Lead Signals

Once the leads are implanted, take baseline measurements and evaluate the lead signals. If performing a pulse generator replacement procedure, the existing leads' signal amplitudes should be reevaluated, along with pacing, cardioversion, and defibrillation threshold testing. The use of radiography may help ensure lead position and integrity. If testing results are unsatisfactory, lead system repositioning or replacement may be required.

1. Connect the coronary venous pace/sense lead to a PSA. Evaluate left ventricular lead placement by determining R-wave amplitude, pacing threshold, and lead impedance. Pace/sense lead measurements should reflect those in Table 17 in Chapter 10.

NOTE: *The rate-sensing signal obtained from the ECD bipolar cable refers only to right-ventricular sensing. The coronary venous lead is not used in ECD testing. Rate-sensing with the CONTAK CD system is biventricular and must be evaluated with device-based testing with both the left- and right-ventricular leads in place.*

2. Connect the right ventricular pace/sense lead to a PSA. Evaluate the right ventricular lead placement by determining R-wave amplitude, pacing threshold, and lead impedance. Pace/sense lead measurements should reflect those in Table 17 in Chapter 10.

3. Connect the atrial pace/sense lead to a PSA (pacing system analyzer). Evaluate atrial lead placement by determining P-wave amplitude, pacing threshold, and lead impedance. Pace/sense lead measurements should reflect those in Table 17 in Chapter 10.
4. Connect the right ventricular pace/sense lead to a PSA. Evaluate the right ventricular lead placement by determining R-wave amplitude, pacing threshold, and lead impedance. Pace/sense lead measurements should reflect those in Table 17 in Chapter 10.
5. After taking baseline measurements, connect the right ventricular pace/sense lead terminal pin(s) to the sterile bipolar cable. Connect the defibrillation lead terminal pins to the high-voltage cable. Then connect the bipolar and high-voltage cables to the respective connectors on the VENTAK ECD. (See Figure 110.)

NOTE: Make sure that the lead anode (+, proximal) is inserted into the positive port of the cables, and the lead cathode (–, distal) is inserted into the negative port.

6. Evaluate defibrillation lead signals using the PRM programming system or an external multichannel recorder. As seen on the strip chart recorder, the signal from the implanted defibrillating electrodes should be continuous and without artifact, similar to a body-surface ECG. A discontinuous signal may indicate a lead fracture or otherwise damaged lead, or an insulation break that would necessitate lead replacement. Inadequate signals from the pace/sense electrodes may result in failure of the pulse generator system to detect an arrhythmia or in unnecessary delivery of therapy.
7. Synchronously deliver a test shock at no greater than 1.1 J to the patient to evaluate defibrillating lead impedance.

CAUTION: If a defibrillating lead impedance is less than 20 Ω , the defibrillating leads should be repositioned. The pulse generator should never be implanted with a lead system that has less than 15- Ω total impedance. Device damage may result.

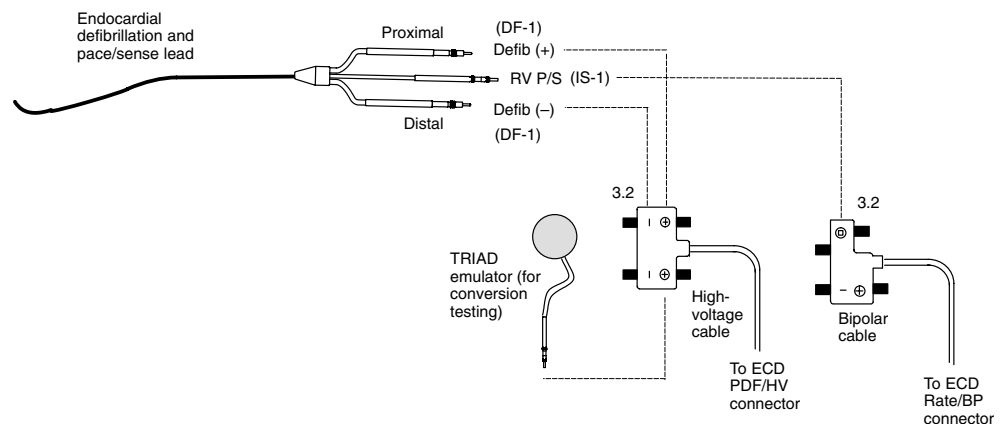


Figure 111. Lead to ECD connections for lead evaluation. Lead-only configuration of an ENDOTAK endocardial cardioversion/defibrillation and pacing lead. The TRIAD emulator connection also is shown for use during conversion testing.

Test for Ability to Convert Ventricular Fibrillation and Inducible Arrhythmias

The ECD may be used to evaluate only the ENDOTAK cardioverter defibrillator lead; however, Guidant strongly recommends that VF conversion testing be performed with device-based testing, using the entire system (the CONTAK CD pulse generator, ENDOTAK rate-sensing defibrillator lead, coronary venous pace/sense lead, and the atrial pace/sense lead).

1. Connect the TRIAD emulator to the defibrillation (+) port of the ECD high-voltage cable (Figure 111). The emulator is designed to fit in a 3.2-mm port when secured with the ECD cable thumbscrews.

2. Insert the emulator into the pocket in the same manner as described for the pulse generator in Chapter 10, Step I.
3. Connect the stimulation source to the ECD to permit induction of an arrhythmia through the ECD console.
4. After induction verify that the stimulation or fibrillation source is unplugged from the ECD. Failure to unplug the induction source from the defibrillating ports on the ECD may result in shock energy being shunted away from the patient and may damage the induction source. An AC fibrillator source also should be unplugged from the wall outlet after arrhythmia induction.

NOTE: Use a VENTAK ECD to perform conversion testing; other ECD devices may not be functionally equivalent and may exhibit different conversion thresholds. The VENTAK ECD should give test results most predictive of the pulse generator operation, since the ECD's pulse waveforms are designed to be equivalent to that of the pulse generator. Be sure to select the VENTAK ECD's waveform (mono- or biphasic) to correspond to the waveform to be programmed in the pulse generator.

5. Perform the test as indicated in Chapter 10, Step H.
 - a. When using the manual delivery mode on the VENTAK ECD, a standardized time of 10 seconds should elapse from the end of the induction to administration of the preselected first-shock energy to effectively emulate nominal pulse generator detection and charge time.
 - b. Guidant recommends that, for each of the patient's clinical VTs and for VF, the actual arrhythmia time that would elapse prior to delivery of the first shock and the second shock if the first shock failed to convert should be simulated at the programmed (or proposed) settings at least once. This includes the arrhythmia sensing time, programmed Initial Duration and Post-shock Duration, and charge time for both the first and second shocks. The second-shock energy can then be delivered to establish its conversion efficacy. Demonstrate that energy levels less than or equal to the pulse generator's programmed first energy level can convert the patient's primary arrhythmia consistently, and the programmed second-energy level can reliably convert accelerated rhythms, or prolonged periods of arrhythmias.
6. After testing is complete, remove the emulator from the pocket and disconnect the cable.

WARNING: The emulator is not intended for use as a permanent lead electrode and must be removed from the patient. It is for one-time use only. Do not resterilize.

Test Lead-to-Pulse Generator Connections

After emulator testing is complete, connect the leads (ENDOTAK, coronary venous and atrial pace/sense) to the pulse generator, evaluate the lead signals, and program the pulse generator according to details outlined in Chapter 10, Steps E through G.

Continue in the following manner:

1. Insert the pulse generator at least two-thirds of the way in the implantation pocket.
2. Activate the Beep On Sensed Ventricular Events And Paced Ventricular Events feature to verify synchronous tones during normal sinus rhythm.
3. Program the Tachy Mode to Monitor + Therapy.
4. Calibrate the gain on the stored electrograms (refer to Chapter 6).
5. Perform a 1.1-J synchronous shock to sinus rhythm to ensure that lead-to-pulse-generator connections are intact. At a minimum, two episodes of ventricular fibrillation should be tested with shock energies of 17J or less.

6. Access the Patient Data window and complete the data. Save data to a patient data disk with the Save All To Disk option on the File menu. Print reports if desired and keep for patient records.

7. **Verify that the pulse generator's Tachy Mode is programmed to Off.**

Continue the implantation procedure as outlined in Chapter 10, Steps I and J.

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GUIDANT

Guidant Corporation
Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

24-Hour Consultation
1-800-CARDIAC (1-800-227-3422)
Tel: 651-582-4000
www.guidant.com