Boston Scientific

SYSTEM GUIDE

TELIGEN™ 100

IMPLANTABLE CARDIOVERTER HIGH ENERGY DEFIBRILLATOR

REF E102, E110

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

- DRAFT -

ABOUT THIS MANUAL

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient material. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

The text conventions discussed below are used throughout this manual.

PRM KEYS	The names of Programmer/Recorder/Monitor (PRM) keys appear in capital letters (e.g., PROGRAM, INTERROGATE).
1., 2., 3.	Numbered lists are used for instructions that should be followed in the order given.
•	Bulleted lists are used when the information is not sequential.

This product family includes single- and dual-chamber models, with feature variations. This manual is written for full description of a full-featured model (e.g., a dual-chamber model with ZIP telemetry). Some models will contain fewer features; for those devices, disregard descriptions of the unavailable features.

The screen illustrations used in this manual are intended to familiarize you with the general screen layout. The actual screens you see when interrogating or programming the pulse generator will vary based on the model and programmed parameters.

A complete list of programmable options is provided in the appendix ("Programmable Options" on page A-1). The actual values you see when interrogating or programming the pulse generator will vary based on the model and programmed parameters.

The following acronyms may be used in this System Guide:

A: Atrial
AF: Atrial Fibrillation

AFib:	Atrial Fibrillation
AFR:	Atrial Flutter Response
AGC:	Automatic Gain Control
AIVR:	Accelerated Idioventricular Rhythm
AT:	Atrial Tachycardia
ATP:	Antitachycardia Pacing
ATR:	Atrial Tachy Response
AV:	Atrioventricular
BCL:	Burst Cycle Length
BOL:	Beginning of Life
CPR:	Cardiopulmonary Resuscitation
ECG:	Electrocardiogram
DFT:	Defibrillation Threshold
EAS:	Electronic Article Surveillance
EF:	Ejection Fraction
EGM:	Electrogram
EMI:	Electromagnetic Interference
EP:	Electrophysiology; Electrophysiologic
FCC:	Federal Communications Commission
HE:	High Energy
IBP:	Indications-Based Programming
IC:	Industry Canada
ICD:	Implantable Cardioverter Defibrillator
LRL:	Lower Rate Limit
MI:	Myocardial Infarction
MPR:	Maximum Pacing Rate
MRI:	Magnetic Resonance Imaging
MSR:	Maximum Sensor Rate
MTR:	Maximum Tracking Rate
NSR:	Normal Sinus Rhythm
PAC:	Premature Atrial Contraction
PAT:	Paroxysmal Atrial Tachycardia
PES:	Programmed Electrical Stimulation
PMT:	Pacemaker-Mediated Tachycardia
PRM:	Programmer/Recorder/Monitor
PSA:	Pacing System Analyzer
PVARP:	Post-Ventricular Atrial Refractory Period
PVC:	Premature Ventricular Contraction
RADAR:	Radio Detection and Ranging
RF:	Radio Frequency
RV:	Right Ventricular
RVRP:	Right Ventricular Refractory Period
SCD:	Sudden Cardiac Death

SRD:	Sustained Rate Duration
SVT:	Supraventricular Tachycardia
TARP:	Total Atrial Refractory Period
TENS:	Transcutaneous Electrical Nerve Stimulation
V:	Ventricular
VFib:	Ventricular Fibrillation
VF:	Ventricular Fibrillation
VRP:	Ventricular Refractory Period
VRR:	Ventricular Rate Regulation
VT:	Ventricular Tachycardia
VTR:	Ventricular Tachycardia Response

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INFORMATION FOR USE

CHAPTER 1

This chapter contains the following topics:

- "New or Enhanced Features" on page 1-3
- "Device Description" on page 1-4
- "Related Information" on page 1-6
- "Indications and Usage" on page 1-6
- "Contraindications" on page 1-6
- "Warnings" on page 1-7
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• "Patient Counseling Information" on page 1-27

NEW OR ENHANCED FEATURES

These pulse generator systems include additional features as compared to previous products.

Ease of Use

- ZOOMVIEW Programmer Software: the new user interface offers the following benefits:
  - Clinical focus—features such as patient diagnostic trends and indications-based programming emphasize the patient's clinical condition over device status and parameters.
  - Consistency—ZOOMVIEW software will be available on future pulse generators, providing the same screens whether you are following a brady, tachy, or heart failure device.
  - Simplicity—screen complexity is reduced through the use of progressive disclosure (displaying the information you use frequently and minimizing the information you only rarely access) and exception-based reporting.
- Indications-Based Programming (IBP): the new ZOOMVIEW feature allows you to quickly set up programming parameters based on the patient's clinical needs and indications.

Tachy Therapy

- Rhythm ID and Onset/Stability detection: the selection between detection enhancements provides you the opportunity and flexibility to adjust for individual patient conditions.
- QUICK CONVERT ATP: in an attempt to avoid an otherwise scheduled charge and painful shock for a pace-terminable fast ventricular tachycardia (VT), the pulse generator delivers one rapid burst of antitachycardia pacing (ATP) for an episode detected in the ventricular fibrillation (VF) zone.
- Programmable Shock Vectors: this capability allows you to electronically change the shocking vectors for added flexibility in treating high defibrillation thresholds (DFTs).

Brady Therapy

- AV Search +: this feature is designed to reduce unnecessary RV pacing for patients with intact or intermittent AV conduction by allowing intrinsic AV conduction beyond the programmed AV delay during episodes of normal AV nodal function—an enhanced version of AV Search Hysteresis.

Sensing

- Sensing is designed to combine the strengths of both implantable cardioverter defibrillator (ICD) and pacemaker sensing capabilities to improve detection and therapy by reducing inappropriate mode switching, pacing inhibition, and shocks.

DEVICE DESCRIPTION

This manual contains information about the TELIGEN 100 family of implantable cardioverter defibrillators (ICDs). The TELIGEN 100 family contains the following types of pulse generators (specific models are listed in "Mechanical Specifications" on page 1-19):

- VR—single-chamber ICD combining ventricular tachyarrhythmia therapy with ventricular pacing and sensing

- DR—dual-chamber ICD combining ventricular tachyarrhythmia therapy with ventricular and atrial pacing and sensing

Therapies

This family of pulse generators has a small, thin, physiologic shape that minimizes pocket size and may minimize device migration. Pulse generators within this family provide a variety of therapies, including:

- Ventricular tachyarrhythmia therapy, which is used to treat rhythms associated with sudden cardiac death (SCD) such as VT and VF

- Bradycardia pacing, including adaptive rate pacing, to detect and treat bradyarrhythmias and to provide cardiac rate support after defibrillation therapy

Cardioversion/defibrillation therapies include:

- A range of low- and high-energy shocks using a biphasic waveform

- The choice of multiple shock vectors:
  - Distal shock electrode to proximal shock electrode and pulse generator case (TRIAD electrode system)
  - Distal shock electrode to proximal shock electrode (RV Coil to RA Coil)
  - Distal shock electrode to pulse generator case (RV Coil to Can)

Leads

The pulse generator has independently programmable outputs and accepts the following leads:

- One IS-1[1] atrial lead
- One DF-1/IS-1[2] cardioversion/defibrillation lead

The pulse generator and the leads constitute the implantable portion of the pulse generator system.

PRM System

These pulse generators can be used only with the ZOOM LATITUDE Programming System, which is the external portion of the pulse generator system and includes:

- Model 3120 Programmer/Recorder/Monitor (PRM)
- Model 2868 ZOOMVIEW Software Application
- Model 6577 Accessory Telemetry Wand

You can use the PRM system to do the following:

- Interrogate the pulse generator
- Program the pulse generator to provide a variety of therapy options
- Access the pulse generator's diagnostic features
- Perform noninvasive diagnostic testing
- Access therapy history data

1. IS-1 refers to the international standard ISO 5841.3:2000.
2. DF-1 refers to the international standard ISO 11318:2002.

RELATED INFORMATION

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

The Physician's Technical Manual is packaged with the pulse generator. It provides the technical information needed at implant.

Refer to the PRM system Operator's Manual for specific information about the PRM such as setup, maintenance, and handling.

INDICATIONS AND USAGE

Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS

These Boston Scientific pulse generators are contraindicated for the following patients:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as:
  - Digitalis intoxication
  - Electrolyte imbalance
  - Hypoxia
  - Sepsis
- Patients whose ventricular tachyarrhythmias have a transient cause, such as:
  - Acute myocardial infarction (MI)
  - Electrocution
  - Drowning
- Patients who have a unipolar pacemaker

WARNINGS

General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death.

- **Avoid shock during handling.** Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.

- **Backup defibrillation protection.** Always have sterile external and internal defibrillation protection available during implant. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death.

- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue.

- **Protected environments.** Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator.

- **Magnetic Resonance Imaging (MRI) exposure.** Do not expose a patient to MR device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

- **Diathermy.** Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents.

Programming and Device Operations

- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.

Implant Related

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

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

PRECAUTIONS

Clinical Considerations

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

Sterilization, Storage, and Handling

- **For single use only; do not resterilize devices.** Do not resterilize the device or the accessories packaged with it because the effectiveness of resterilization cannot be ensured.

- **If package is damaged.** The pulse generator blister trays and contents are sterilized with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Boston Scientific.

- **Storage temperature and equilibration.** Recommended storage temperatures are 0°C–50°C (32°F–122°F). Allow the device to reach a proper temperature before using telemetry communication capabilities, programming or implanting the device because temperature extremes may affect initial device function.

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

- **Use by date.** Implant the device system before or on the USE BY date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 2.

Implantation and Device Programming

- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector and/or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.

- **Telemetry wand.** Make sure the telemetry wand is connected to the programmer and that it is available throughout the session. Verify that the wand cord is within reach of the pulse generator.

- **STAT PACE settings.** When a pulse generator is programmed to STAT PACE settings, it will continue to pace at the high-energy STAT PACE values if it is not reprogrammed. The use of STAT PACE parameters will decrease device longevity.

- **Pacing and sensing margins.** Consider lead maturation in your choice of pacing amplitude, pacing pulse width, and sensitivity settings.

  - An acute pacing threshold greater than 1.5 V or a chronic pacing threshold greater than 3 V can result in loss of capture because thresholds may increase over time.
  - An R-wave amplitude less than 5 mV or a P-wave amplitude less than 2 mV can result in undersensing because the sensed amplitude may decrease after implantation.
  - Pacing lead impedance should be within the range of 200 Ω and 2000 Ω.

- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10 µA can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.

- **Proper programming of the shock vector.** If the shock vector is programmed to RVcoil>>RAcoil and the lead does not have an RA coil, shocking will not occur.

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

- **Defibrillation power surge.** Defibrillation that causes a power surge exceeding 360 watt-seconds can damage the pulse generator system.

- **Programming for supraventricular tachyarrhythmias (SVTs).** Determine if the device and programmable options are appropriate for patients with SVTs because SVTs can initiate unwanted device therapy.

- **Ventricular refractory periods (VRPs) in adaptive-rate pacing.** Adaptive-rate pacing is not limited by refractory periods. A long refractory period programmed in combination with a high MSR can result in asynchronous pacing during refractory periods since the combination can cause a very small sensing window or none at all. Use dynamic AV Delay or dynamic PVARP to optimize sensing windows. If you are entering a fixed AV delay, consider the sensing outcomes.

- **Do not bend the lead near the lead-header interface.** Improper insertion can cause insulation damage near the terminal end that could result in lead failure.

- **Shock waveform polarity.** For IS-1/DF-1 leads, 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 the polarity is switched physically.

- **Absence of a lead.** The absence of a lead or plug in a lead port may affect device performance. If a lead is not used, be sure to properly insert a plug in the unused port.

- **Electrode connections.** Do not insert a lead into the pulse generator connector without first visually verifying that the setscrew is sufficiently retracted to allow insertion. Fully insert each lead into its lead port and then tighten the setscrew onto the electrodes.

- **Tachy Mode to Off.** To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode is programmed to Off when not in use and before handling the device. For tachyarrhythmia therapy, verify that the Tachy Mode is activated.

- **Atrial oversensing.** For dual-chamber models, take care to ensure that artifacts from the ventricles are not present on the atrial channel, or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction.

- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15 Ω total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20 Ω, reposition the shocking electrodes to allow a greater distance between the shocking electrodes.

- **ATR entry count.** Exercise care when programming the Entry Count to low values in conjunction with a short ATR Duration. This combination allows mode switching with very few fast atrial beats. For example, if the Entry Count was programmed to 2 and the ATR Duration to 0, ATR mode switching could occur on 2 fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.

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

- **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during induction because it may shunt energy, resulting in less energy getting to the patient, and may damage the implanted system.

- **Expected benefits.** Determine whether the expected device benefits outweigh the possibility of early device replacement for patients whose tachyarrhythmias require frequent shocks.

- **Device communication.** Use only the designated PRM and software application to communicate with this pulse generator.

Environmental and Medical Therapy Hazards

- **Avoid electromagnetic interference (EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are:
  - Electrical power sources, arc welding equipment, and robotic jacks
  - Electrical smelting furnaces
  - Large RF transmitters such as radar
  - Radio transmitters, including those used to control toys
  - Electronic surveillance (antitheft) devices
  - An alternator on a car that is running
- **Elevated Pressures.** Elevated pressures due to hyperbaric chamber exposure of SCUBA diving may damage the pulse generator. The pulse generator has been tested to function normally at 1.5 Atmospheres Absolute (ATA) pressure or 15 ft (4.6 m) depth in sea water. For specific guidelines prior to hyperbaric chamber exposure, or if the patient is planning scuba diving activity, contact Technical Services at the number shown on the back cover of this manual.

Hospital and Medical Environments

- **Mechanical ventilators.** During mechanical ventilation, respiration rate trending may be misleading; therefore, the Respiratory Sensor should be programmed to Off.
- **Internal defibrillation.** Do not use internal defibrillation paddles or catheters unless the pulse generator is disconnected from the leads because the leads may shunt energy. This could result in injury to the patient and damage to the implanted system.
- **External defibrillation.** Use of external defibrillation can damage the pulse generator.

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

  1. Place the TENS electrodes as close to each other as possible and as far from the pulse generator and lead system as possible.

  2. Monitor cardiac activity during TENS use.

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

- **Electrocautery.** The use of electrocautery could induce ventricular arrhythmias and/or fibrillation, cause asynchronous or inhibited pulse generator operation, or cause the pulse generator to deliver an inappropriate shock. If electrocautery cannot be avoided, observe the following precautions to minimize complications:

  - Select Electrocautery Protection Mode. Avoid direct contact with the pulse generator or leads.

  - Monitor the patient and have temporary pacing equipment, external defibrillation equipment, and knowledgeable medical personnel available.

  - Position the ground plate so that the current pathway does not pass through or near the pulse generator system.

  - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.

  - Use a bipolar electrocautery system where possible.

Remember to reactivate the Tachy Mode after turning off the electrocautery equipment.

- **Ionizing radiation therapy.** Ionizing radiation therapy may adversely affect device operation. During ionizing radiation therapy (e.g., radioactive cobalt, linear accelerators, and betatrons), the pulse generator must be shielded with a radiation-resistive material, regardless of the distance of the device to the radiation beam. Do not project the radiation port directly at the device. After waiting a minimum of one hour following radiation treatment (to allow for a device memory check to occur), always evaluate device operation, including interrogation and sensing and pacing threshold testing.

  At the completion of the entire course of treatments, perform device interrogation and follow-up, including sensing and pacing threshold testing and capacitor re-formation.

- **Lithotripsy.** Lithotripsy may permanently damage the pulse generator if the device is at the focal point of the lithotripsy beam. If lithotripsy must be used, avoid focusing near the pulse generator site.

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

  - If the patient does not require pacing, program the pulse generator Brady Mode to Off.

  - If the patient requires pacing, program the pulse generator to the VVI mode because atrial pacing pulses can trigger the lithotriptor.

- **Ultrasound energy.** Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.

- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed to Monitor + Therapy during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy. Pacing therapy may also be inhibited unless the device is programmed to Electrocautery mode. RF ablation may cause changes in pacing thresholds; evaluate the patient's thresholds appropriately.

  Minimize risks by following these steps:

  - Program the Tachy Mode(s) to Electrocautery Protection to avoid inadvertent tachycardia detection (sensing) or therapy.
  - Monitor the patient and have external defibrillation equipment and knowledgeable medical personnel available.
  - 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.
  - Consider the use of external pacing support for pacemaker-dependent patients (i.e., using internal or external pacing methods).
  - Monitor pre- and post-measurements for sensing and pacing thresholds and impedances to determine the integrity of the lead-patient function.

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

- **Electrical interference.** Electrical interference or "noise" from devices such as electrocautery and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. If telemetry is cancelled as a result of interference, the device should be re-interrogated prior to evaluating information from pulse generator memory.

- **Radio frequency (RF) interference.** RF signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator. Examples of devices that may cause interference include:

  - Cordless phone handsets or base stations
  - Certain patient monitoring systems
  - Remote control toys

Home and Occupational Environments

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

- **Magnetic fields.** Advise patients that extended exposure to strong (greater than 10 gauss or 1 mTesla) magnetic fields may trigger the magnet feature. Examples of magnetic sources include:

  - Industrial transformers and motors
  - MRI devices
  - Large stereo speakers
  - Telephone receivers if held within 1.27 cm (0.5 inches) of the pulse generator
  - Magnetic wands such as those used for airport security and in the Bingo game

- **Electronic Article Surveillance (EAS).** Advise patients to avoid lingering near antitheft devices such as those found in the entrances and exits of department stores and public libraries. Patients should walk through them at a normal pace because such devices may cause inappropriate pulse generator operation.

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

Follow-up Testing

- **Conversion testing.** Successful VF or VT conversion during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the DFT, which may result in nonconversion of the arrhythmia post-operatively.

- **Pacing threshold testing.** If the patient's condition or drug regimen has changed or device parameters have been reprogrammed, consider performing a pacing threshold test to confirm adequate margins for pace capture.

Explant and Disposal

- **Incineration.** Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.

- **Device handling.** Before explanting, cleaning, or shipping the device, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:

  - Program the pulse generator Tachy and Brady Modes to Off.
  - Program the Magnet Response feature to Off.
  - Program the Beep When Explant is Indicated feature to Off.

- **Explanted devices.** Return all explanted pulse generators and leads to Boston Scientific. Examination of explanted pulse generators can provide information for continued improvement in device reliability and will permit calculation of any warranty replacement credit due.

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

POTENTIAL ADVERSE EVENTS

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

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac tamponade
- Chronic nerve damage
- Component failure
- Conductor coil fracture
- Death
- Elevated thresholds
- Erosion
- Excessive fibrotic tissue growth
- Extracardiac stimulation (muscle/nerve stimulation)
- Failure to convert an induced arrhythmia
- Foreign body rejection phenomena
- Formation of hematomas or seromas
- Heart failure following chronic RV apical pacing
- Inability to defibrillate or pace
- Inappropriate therapy (e.g., shocks where applicable, ATP, pacing)
- Incisional pain
- Incomplete lead connection with pulse generator
- Infection
- Insulating myocardium during defibrillation with internal or external paddles
- Lead dislodgment
- Lead fracture
- Lead insulation breakage or abrasion
- Lead tip deformation and/or breakage
- Myocardial infarction (MI)
- Myocardial necrosis

- Myocardial trauma (e.g., cardiac perforation, irritability, injury)
- Myopotential sensing
- Oversensing/undersensing
- Pacemaker-mediated tachycardia (PMT) (Applies to dual-chamber devices only.)
- Pericardial rub, effusion
- Pneumothorax
- Pulse generator migration
- Shunting current during defibrillation with internal or external paddles
- Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation
- Thrombosis/thromboemboli
- Valve damage
- Venous occlusion
- Venous trauma (e.g., perforation, dissection, erosion)
- Worsening heart failure

Patients may develop psychological intolerance to a pulse generator system and may experience the following:

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

MECHANICAL SPECIFICATIONS

Device mechanical specifications for specific models are listed in the table below.

Table 1-1. Mechanical Specifications

Model	Dimensions W x H x D (cm)	Volume (cm^3)	Mass (g)	Connector Type (RV)	Case Electrode Surface Area (mm^2)
E102 (VR)	6.17 x 7.45 x 0.99	31.5	72.0	IS-1/DF-1	6670
E110 (DR)	6.17 x 7.45 x 0.99	31.5	72.0	IS-1/DF-1	6670

Models include ZIP telemetry with a nominal RF frequency of 916.5 MHz.

Material specifications are shown below:

- **Case:** hermetically sealed titanium
- **Header:** implantation-grade polymer
- **Power Supply:** lithium-manganese dioxide cell; Boston Scientific; 401988

LEAD CONNECTIONS

Lead connections are illustrated below.

CAUTION: Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector and/or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.

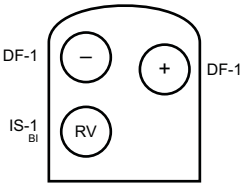


Figure 1-1. Lead connections, single chamber

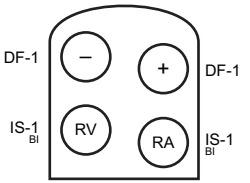


Figure 1-2. Lead connections, dual chamber

NOTE: *The pulse generator case is used as a defibrillating electrode unless the pulse generator has been programmed to the Distal Coil to Proximal Coil (or "Cold Can") Shock Vector.*

ITEMS INCLUDED IN PACKAGE

The following items are included with the pulse generator:

- One torque wrench
- Product literature
- One patient data disk

NOTE: *Accessories (e.g., wrenches) are intended for one-time use only. They should not be resterilized or reused.*

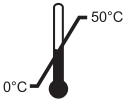
SYMBOLS ON PACKAGING

The following symbols may be used on pulse generator packaging and labeling (Table 1-2 on page 1-21):

Table 1-2. Symbols on packaging

Symbol	Description
REF	Reference number
	Package contents
	Pulse generator
	Torque wrench
	Disk for data storage
	Literature enclosed
SN	Serial number
	Use by

Table 1-2. Symbols on packaging (continued)

Symbol	Description
	Lot number
	Date of manufacture
	Non-ionizing electromagnetic radiation
	Sterilized using ethylene oxide
	Do not reuse
	Dangerous voltage
	Consult instructions for use
	Temperature limitation
	Wand placement indicator for interrogation
	Opening instruction

CHARACTERISTICS AS SHIPPED

Refer to the table for pulse generator settings at shipment (Table 1-3 on page 1-22).

Table 1-3. Characteristics as shipped

Parameter	Setting
Tachy Mode	Storage
Tachy Therapy available	ATP, Shock
Pacing Mode	Storage

Table 1-3. Characteristics as shipped (continued)

Parameter	Setting
Pacing Therapy available	DDDR (DR models) VVIR (VR models)
Sensor	Accelerometer (MV for respiratory rate trend)
Pace/Sense Configuration	RA: BI/BI (DR models)
Pace/Sense Configuration	RV: BI/BI

The pulse generator is shipped in a power-saving Storage mode to extend its shelf life. In Storage mode, all features are inactive except:

- Telemetry support, which allows interrogation and programming
- Real-time clock
- Commanded capacitor re-formation
- STAT SHOCK and STAT PACE commands

The device leaves Storage mode when one of the following actions occurs; however, programming other parameters will not affect the Storage mode:

- STAT SHOCK or STAT PACE is commanded
- Tachy Mode is programmed to:
  - Off
  - Monitor Only
  - Monitor + Therapy

Once you have programmed the pulse generator out of Storage mode, the device cannot be reprogrammed to that mode.

X-RAY IDENTIFIER

The pulse generator has an identifier that is visible on x-ray film or under fluoroscopy. This identifier provides noninvasive confirmation of the manufacturer and consists of the following:

- The letters, BOS, to identify Boston Scientific as the manufacturer
- The number, 112, to identify the Model 2868 PRM software application needed to communicate with the pulse generator

The x-ray identifier is embedded in the header of the device at the approximate location (Figure 1-3 on page 1-24).

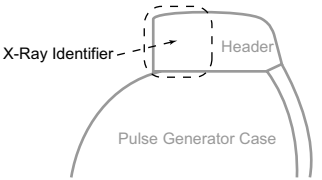


Figure 1-3. X-ray identifier

For information on identifying the device via the PRM, refer to the PRM operator's manual.

The pulse generator model number is stored in device memory and is shown on the PRM summary screen once the pulse generator is interrogated.

FEDERAL COMMUNICATIONS COMMISSION (FCC)

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

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

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

INDUSTRY CANADA (IC)

This device complies with Radio Standards Specification RSS-210. Operation is subject to the following two conditions:

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

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

PULSE GENERATOR LONGEVITY

Based on simulated studies, it is anticipated that these pulse generators have average longevity to explant as shown below.

The longevity expectations, which account for the energy used during manufacture and storage, apply at the conditions shown in the table along with the following:

- Assumes 60 ppm LRL, ventricular and atrial settings of 2.5 V pacing pulse amplitude and 0.4 ms pacing pulse width; RA Impedance 500 Ω.
- Projected longevity is calculated at 6 to 14 maximum energy charging cycles per year (depending on battery status) with automatic capacitor/battery management and maximum energy charges, and 3-channel EGM Onset set to On.

Table 1-4. Pulse generator life expectancy estimation (implant to explant) for HE models

HE Models[a]						
	Longevity (years) at 500 Ω, 700 Ω, and 900 Ω Pacing Impedance (RV)					
	500 Ohms		700 Ohms		900 Ohms	
Pacing	VR	DR	VR	DR	VR	DR
0%	8.7	8.3	8.7	8.3	8.7	8.3
15%	8.4	7.8	8.5	7.9	8.6	8.0
50%	8.1	7.3	8.2	7.5	8.3	7.6
100%	7.8	6.7	8.0	6.9	8.1	7.0

a. For RF-enabled models, assumes ZIP telemetry use for 1 hour at implant time and for 20 minutes during each quarterly follow-up.

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

The pulse generator longevity may increase with a decrease in any of the following:

- Pacing rate
- Pacing pulse amplitude(s)
- Pacing pulse width(s)
- Percentage of paced to sensed events

- Charging frequency

Longevity is also reduced in the following circumstances:

- With a decrease in pacing impedance
- When Patient Triggered Monitor is programmed to On
- For models with ZIP wandless telemetry, one hour of additional telemetry reduces longevity by approximately 7 days.

Device longevity may also be affected by:

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

An additional maximum-energy shock reduces longevity by approximately 19 days.

Refer to the PRM Summary screen for an estimate of pulse generator longevity specific to the implanted device.

WARRANTY INFORMATION

A limited warranty certificate for the pulse generator is packaged with the device. For additional copies, please contact Boston Scientific at the address and phone number shown on the back cover of this manual.

PRODUCT RELIABILITY

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

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

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

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

PATIENT COUNSELING INFORMATION

The following topics should be discussed with the patient prior to discharge.

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

- It is Boston Scientific's intent to provide implantable devices of high quality and reliability. However, these devices may exhibit malfunctions that may result in lost or compromised ability to deliver therapy. When Boston Scientific communicates safety advisory information, the decision whether to replace a device should take into account the risks of the malfunction, the risks of the replacement procedure, and the performance to date of the replacement device.

Patient Handbook

The Patient Handbook is provided for each device.

It is recommended that you discuss the information in the Patient Handbook with concerned individuals both before and after implantation so they are fully familiar with pulse generator operation.

For additional copies, contact your sales representative, or contact Boston Scientific at the phone number shown on the back cover of this manual.

USING THE PROGRAMMER/RECORDER/MONITOR

CHAPTER 2

This chapter contains the following topics:

- "ZOOM LATITUDE Programming System" on page 2-2
- "Indications-Based Programming (IBP)" on page 2-2
- "Manual Programming" on page 2-5
- "Software Terminology and Navigation" on page 2-6
- "Data Management" on page 2-11
- "Communicating with the Pulse Generator" on page 2-12
- "DIVERT THERAPY" on page 2-17
- "STAT SHOCK" on page 2-17
- "STAT PACE" on page 2-18
- "Safety Mode" on page 2-19

ZOOM LATITUDE PROGRAMMING SYSTEM

The ZOOM LATITUDE Programming System is the external portion of the pulse generator system and includes:

- Model 3120 Programmer/Recorder/Monitor (PRM)
- Model 2868 ZOOMVIEW Software Application
- Model 6577 Accessory Telemetry Wand

The ZOOMVIEW software provides advanced device programming and patient monitoring technology. It was designed with the intent to:

- Enhance device programming capability
- Improve patient and device monitoring performance
- Simplify and expedite programming and monitoring tasks

You can use the PRM system to do the following:

- Interrogate the pulse generator
- Program the pulse generator to provide a variety of therapy options
- Access the pulse generator's diagnostic features
- Perform noninvasive diagnostic testing
- Access therapy history data

You can program the pulse generator using two methods: automatically using IBP or manually.

INDICATIONS-BASED PROGRAMMING (IBP)

IBP is a tool that provides specific programming recommendations based on the patient's clinical needs and primary indications.

IBP is a clinical approach to programming that was developed based on physician consultation and case studies. The intent of IBP is to enhance patient outcomes and save time by providing base programming recommendations that you can customize as needed. IBP systematically presents the specific features intended for use with the clinical conditions you identify in the IBP user interface, and allows you to take maximum advantage of the pulse generator's capabilities.

IBP can be accessed from the Settings tab on the main application screen (Figure 2-1 on page 2-3).

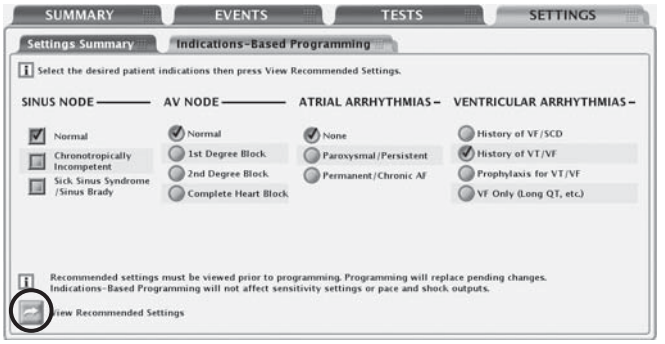


Figure 2-1. Indications-based Programming screen

Indications are clustered in general categories as illustrated above. The intent for each category of indications is described below:

- Sinus Node:
  - If Normal is selected, the intent is to provide RV pacing when necessary.
  - If Chronotropically Incompetent is selected, the intent is to provide rate-adaptive pacing.
  - If Sick Sinus Syndrome is selected, the intent is to provide atrial pacing support.
- AV Node:
  - If Normal or 1st Degree Block is selected, the intent is to provide RV pacing when necessary.
  - If 2nd Degree Block is selected, the intent is to promote intrinsic AV conduction and provide AV sequential pacing when conduction is not present.
  - If Complete Heart Block is selected, the intent is to provide AV sequential pacing.

NOTE: *The selected settings for AF and Sinus Node may affect the suggested value for the Normal/1st Degree Block setting of AV Node.*

- Atrial Arrhythmias
  - If Paroxysmal/Persistent is selected, the intent is to avoid tracking atrial arrhythmias by using dual-chamber pacing mode with ATR Mode Switch.
  - If Permanent/Chronic AF is selected, the intent is to provide rate adaptive RV pacing.
- Ventricular Arrhythmias
  - When History of VF/SCD or Prophylaxis for VT/VF is selected, a 2-zone configuration with the following rate thresholds and therapies is provided:
    - 180 bpm for the VF zone with QUICK CONVERT ATP and Maximum Energy Shocks enabled
    - 160 bpm for the VT zone with therapy disabled (Monitor Only)
  - When History of VT/VF is selected, a 2-zone configuration with the following rate thresholds and therapies is provided:
    - 200 bpm for the VF zone with QUICK CONVERT ATP and Maximum Energy Shocks enabled
    - 160 bpm for the VT zone with ATP and Maximum Energy Shocks enabled
    - Rhythm ID enabled
  - When VF Only is selected, the intent is for a single VF zone of 220 bpm is provided with only Maximum Energy Shocks enabled.

When you have chosen the patient indications, select the View Recommended Settings button to view a summary of the programming recommendations (Figure 2-2 on page 2-5).

NOTE: *You must view the settings before you can program them. Selecting the View Recommended Settings button allows you to view the settings that are recommended based on the indications that you selected. Viewing the recommended settings does not overwrite any pending (i.e., not yet programmed) parameter changes. You must choose to program or reject the recommended settings after viewing them. If you choose to reject the recommended settings, all of your pending settings will be restored. If you choose to program the recommended settings, any pending parameter changes will be overwritten, with the exception of sensitivity, shock outputs, and pacing outputs, which are independent of IBP.*

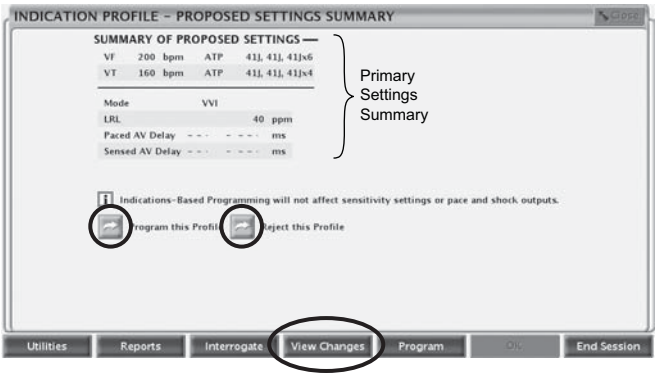


Figure 2-2. Proposed Settings Summary screen

The Proposed Settings Summary screen displays the primary programming recommendations. Additional details about all changed parameters are available by selecting the View Changes button from the toolbar. You have the option to program the proposed settings or reject them, as long as telemetry is still engaged:

- Program—select the Program this Profile button to accept the proposed settings.
- Reject—select the Reject this Profile button to reject the proposed settings; this action will return you to the main IBP screen with no changes made.

MANUAL PROGRAMMING

Manual programming controls such as sliders and menus are available to allow you to individually adjust pulse generator program settings.

Manual programming controls are located on the Settings Summary tab, which can be accessed from the Settings tab or by selecting the Settings Summary button on the Summary tab. Refer to other feature descriptions in this manual

for specific manual programming information and instructions. Refer to "Programmable Options" on page A-1 for detailed listings of available settings.

SOFTWARE TERMINOLOGY AND NAVIGATION

This section provides an overview of the PRM system.

Main Screen

The main PRM screen is shown below, followed by a description of the components (Figure 2-3 on page 2-6).

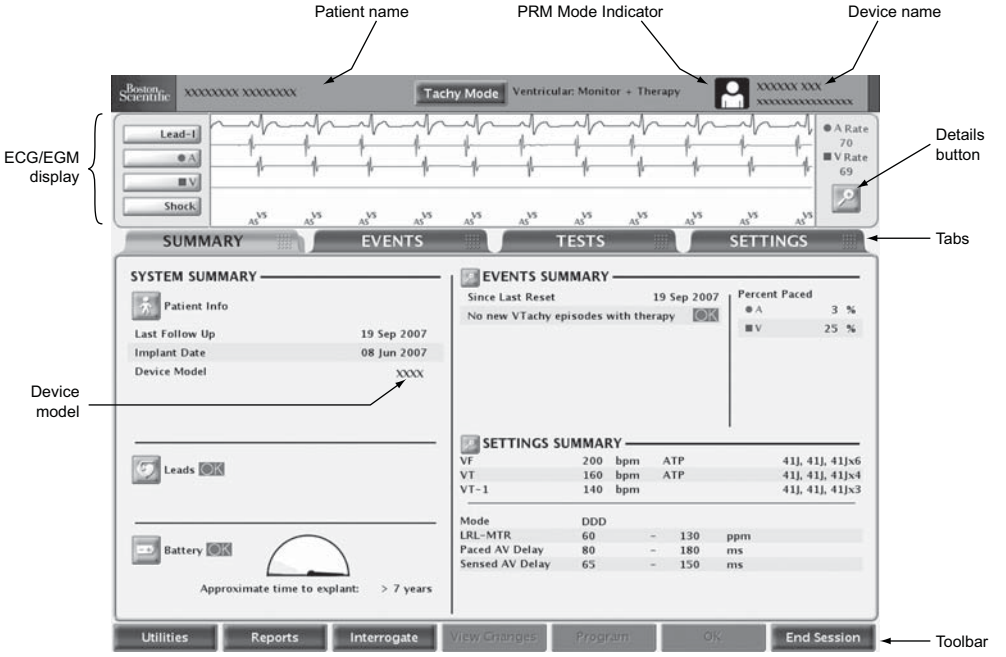


Figure 2-3. Main Screen

PRM Mode Indicator

The PRM Mode Indicator displays at the top of the screen to identify the current PRM operational mode.

Patient—indicates that the PRM is displaying data obtained by communicating with a device.

Patient Data Disk—indicates that the PRM is displaying stored data from a patient data disk.

Demo Mode—indicates that the PRM is displaying sample data and operating in demonstration mode.

ECG/EGM Display

The ECG area of the screen shows real-time status information about the patient and the pulse generator. This information is useful in evaluating system performance:

- Real-time EGMs can be transmitted from the pace/sense or shocking electrodes to evaluate lead system integrity and help identify faults such as lead fractures, insulation breaks, or dislodgments.

- Annotated event markers identify certain intrinsic cardiac and device-related events, and provide information such as sensed/paced events, decision of detection criteria, and therapy delivery.

You can select the Details button to enlarge the ECG/EGM screen. The following options are available:

- Show Device Markers—displays annotated markers
- Enable Surface Filter—minimizes noise on the surface ECG
- Display Pacing Spikes—shows detected pacing spikes, annotated by a marker on the surface ECG waveform

You can print a real-time EGM report, which includes annotated event markers, by performing the following steps:

1. Press one of the print speed keys on the PRM (for example, speed key 25).
2. Press the Paper Form Feed key. The EGM report will begin printing.

You can print a report containing the definitions of all of the annotated markers by performing the following steps:

1. From the toolbar, click the Reports button. The Reports window displays.
2. Select the Marker Legend checkbox.
3. Click the Print button. The Marker Legend Report is sent to the printer.

Toolbar

The toolbar allows you to perform the following tasks:

- Select system utilities
- Generate reports
- Interrogate and program the pulse generator
- View pending or programmed changes
- View attentions and warnings
- End your PRM session

Tabs

Tabs allow you to select PRM tasks, such as viewing summary data or programming device settings. Selecting a tab displays the associated screen. Many screens contain additional tabs, which allow you to access more detailed settings and information.

Buttons

Buttons are located on screens and dialogs throughout the application. Buttons allow you to perform various tasks, including:

- Obtain detailed information
- View setting details
- Set programmable values

When a button selection opens a window in front of the Main Screen, a Close button displays in the upper-right corner of the window to allow you to close the window and return to the Main Screen.

Icons

Icons are graphic elements that, when selected, may initiate an activity, display lists or options, or change the information displayed.

Details—opens a window containing detailed information.

Patient—opens a window with patient information details.

Leads—opens a window with details on leads.

Battery—opens a window with details on the pulse generator battery.

Run—causes the programmer to perform an action.

Check—indicates that an option is selected.

Event—indicates that an event has occurred. When you view the Trends timeline on the Events tab, event icons display wherever events have occurred. Selecting an events icon displays details about the event.

Slider Icons

Horizontal Slider—indicates that a slider object can be clicked and dragged left or right.

Vertical Slider—indicates that a slider object can be clicked and dragged up or down.

Sort Icons

Sort Ascending—indicates that Ascending sort is currently selected on a table column sort button. (e.g., 1, 2, 3, 4, 5)

Sort Descending—indicates that Descending sort is currently selected on a table column sort button. (e.g., 5, 4, 3, 2, 1)

Increment and Decrement Icons

Increment—indicates that an associated value can be incremented.

Decrement—indicates that an associated value can be decremented.

Scroll Icons

Scroll Left—indicates that an associated item can be scrolled left.

Scroll Right—indicates that an associated item can be scrolled right.

Scroll Up—indicates that an associated item can be scrolled up.

Scroll Down—indicates that an associated item can be scrolled down.

Common Objects

Common objects such as status bars, scroll bars, menus, and dialogs are used throughout the application. These operate similarly to the objects found in web browsers and other computer applications.

Use of Color

Colors are used to highlight buttons, icons, and other objects. The use of specific color conventions is intended to provide a more consistent user experience and simplify programming.

Red and yellow are used to provide Warning and Attention indications, as described below:

- Red—indicates Warning conditions such as the following:
  - The selected device parameter value is not allowed
  - Device and patient diagnostic information that requires serious consideration

- Yellow—indicates Attention conditions such as the following:
  - The selected device parameter value is not recommended, but is allowed
  - Device and patient diagnostic information that should be addressed

When a red Warning or yellow Attention button displays in the toolbar, click the button. The Parameter Interactions screen will display, with information about corrective action.

DATA MANAGEMENT

The PRM system allows you to manage patient and pulse generator data by viewing, printing, storing, or retrieving it. This section describes the PRM data management capabilities.

Patient Information

Information about the patient can be stored in pulse generator memory. The information is accessible from the Summary screen by selecting the Patient icon. This information includes, but is not limited to, the following:

- Patient and physician names
- Pulse generator serial number
- Implant date
- Lead configurations
- Implant test measurements

The information can be retrieved at any time by interrogating the pulse generator and viewing it on the PRM screen or printing it as a report.

Disk Operations

The PRM system allows you to store patient data on a removable data disk. To access the data stored on a disk, first select the Utilities button, then select the Disk tab. Insert a disk into the disk drive, and select one of the following disk options:

- Read Disk—allows you to retrieve saved data from a patient data disk

- Save All to Disk—allows you to save information to a disk, including the following:
  - Therapy history
  - Programmed parameter values
  - Trending values
  - Histogram paced/sensed counters

Print

You can print PRM reports by using the internal printer, or by connecting to an external printer. To print a report, select the Reports button. Then select the report you wish to print from the following categories:

- Follow-up reports
- Episode reports
- Other reports (includes device settings, patient data, and other information)

COMMUNICATING WITH THE PULSE GENERATOR

The PRM communicates with the pulse generator using a telemetry wand. After initiating communication with the wand, some pulse generator models can use wandless ZIP telemetry (two-way RF communication) to interface with the PRM. Wanded or ZIP telemetry is required to:

- Direct commands from the PRM system, such as:
  - INTERROGATE
  - PROGRAM
  - STAT SHOCK
  - STAT PACE
  - DIVERT THERAPY
- Modify device parameter settings
- Conduct EP testing

- Conduct diagnostic tests including the following:
  - Pacing impedance tests
  - Pacing threshold tests
  - Intrinsic amplitude tests
- Perform manual capacitor re-form

ZIP Telemetry

ZIP telemetry is a wandless, two-way RF communication option that allows the PRM system to communicate with some pulse generator models. When a wanded telemetry session is initiated, the PRM checks the pulse generator's telemetry capability. If the PRM detects a pulse generator with ZIP telemetry capability, a message will display indicating that ZIP telemetry is available and the wand can be removed. Otherwise, the session will continue with wanded telemetry.

ZIP telemetry offers the following advantages over traditional wanded telemetry:

- The faster data transmission speed means less time is required for device interrogation
- Data transmission over a longer distance (within 3 meters) minimizes the need to keep the wand in the sterile field during implant, which may reduce the risk of infection
- Continuous telemetry is possible during the entire implant procedure, allowing monitoring of pulse generator performance and lead integrity during implant

Regardless of whether ZIP telemetry is being used, wanded communication is still available.

Starting a Wanded Telemetry Session

Follow this procedure to begin a wanded telemetry communication session:

1. Make sure the telemetry wand is connected to the PRM system and is available throughout the session.
2. Position the wand over the pulse generator at a distance not greater than 6 cm (2.4 inches).

3. Use the PRM to Interrogate the pulse generator.
4. Retain the wand position whenever communication is required.

Starting a ZIP Telemetry Session

Follow this procedure to begin a ZIP telemetry communication session:

1. Start a wanded telemetry session. Verify that the wand cord is within reach of the pulse generator to enable the use of wanded telemetry should it become necessary.

2. Keep the telemetry wand in position until either a message appears, indicating that the telemetry wand may be removed from proximity of the pulse generator, or the ZIP telemetry light illuminates on the PRM system.

Ending a Telemetry Session

Select the End Session button to quit a telemetry session and return to the startup screen. You can choose to end the session or return to the current session. Upon ending a session, the PRM system terminates all communication with the pulse generator.

ZIP Telemetry Security

The pulse generator is a compliant low-power transceiver. The pulse generator can only be interrogated or programmed by RF signals that employ the proprietary ZIP telemetry protocol. The pulse generator verifies that it is communicating with a ZOOMVIEW system before responding to any RF signals. The pulse generator stores, transmits, and receives individually identifiable health information in an encrypted format.

ZIP telemetry is possible when all of the following conditions are met:

- ZIP telemetry setting for the PRM is programmed On
- The pulse generator has RF communication capabilities
- The ZIP telemetry channel is available for use
- The pulse generator is within range of the PRM system
- The pulse generator has not reached Explant; note that a total of 1.5 hours of ZIP telemetry will be available after the pulse generator reaches Explant
- The pulse generator battery capacity is not depleted

In order to meet local communications rules and regulations, ZIP telemetry should not be used when the pulse generator is outside its normal operating temperature of 20°C–43°C (68°F–109°F).

The PRM supports communication between two PRMs and two pulse generators at a time, as two independent sessions. If there are two PRMs already communicating in the vicinity, a third session will not be allowed to start; wanded communication will be necessary in this case.

The PRM notifies you if ZIP telemetry is unavailable because of other sessions already in progress.

RF signals in the same frequency band used by the system may interfere with ZIP telemetry communication. These interfering signals include:

- Signals from other pulse generator/PRM system RF communication sessions after the maximum number of independent sessions has been reached. Other nearby pulse generators and PRMs using ZIP telemetry may prevent ZIP telemetry communication.

- Interference from other RF sources.

CAUTION: RF signals from devices that operate at frequencies near that of the pulse generator may interrupt ZIP telemetry while interrogating or programming the pulse generator. This RF interference can be reduced by increasing the distance between the interfering device and the PRM and pulse generator. Examples of devices that may cause interference include:

- Cordless phone handsets or base stations
- Certain patient monitoring systems
- Remote control toys

Radio frequency interference may temporarily disrupt ZIP telemetry communication. The PRM will normally reestablish ZIP communication when the RF interference ends or subsides. Because continued RF interference may prevent ZIP telemetry communication, the system is designed to use wanded telemetry when ZIP telemetry is not available.

If ZIP telemetry is not available, wanded telemetry communication with the PRM can be established. The system provides the following feedback to indicate that ZIP telemetry is not available:

- The ZIP telemetry indicator light on the PRM turns off

- If event markers and/or EGMs are activated, transmission of the event markers and/or EGMs is interrupted

- If a command or other action has been requested, the PRM displays a notification indicating the wand should be placed in range of the pulse generator

ZIP telemetry operates consistently with wanded telemetry—no programming step can be completed unless the entire programming command has been received and confirmed by the pulse generator.

The pulse generator cannot be misprogrammed as a result of interrupted ZIP telemetry. Interruptions of ZIP telemetry may be caused by RF signals that operate at frequencies near that of the pulse generator and are strong enough to compete with the ZIP telemetry link between the pulse generator and the PRM. Significant interference may result in a break or drop-outs of real-time EGMs. If commands are interrupted, the PRM displays a message to place the wand on the pulse generator. These situations can be resolved by using standard wanded telemetry. There will be no interruption of device functionality or therapy during this period.

NOTE: *The PRM operates on a specific frequency range depending on geography. The PRM determines the ZIP frequency range that the pulse generator uses based on the specific device model. If the PRM and pulse generator ZIP frequency ranges do not match, it indicates that the patient has traveled outside their geography. The PRM will display a message indicating that ZIP telemetry cannot be used; however, the patient's pulse generator can be interrogated by using the wand.*

Considerations for Reducing Interference

Increasing the distance from the source of interfering signals may enable the use of the ZIP telemetry channel.

Repositioning the PRM antenna or repositioning the PRM may improve ZIP telemetry performance. If ZIP telemetry performance is not satisfactory, the option of using wanded telemetry is available.

Depending on the environment and PRM orientation relative to the pulse generator, the system is capable of maintaining ZIP telemetry communication at distances up to 12 m (40 ft). For optimum ZIP telemetry communication, position the PRM antenna within 3 m (10 ft) of the pulse generator and remove any obstruction between the PRM and the pulse generator.

DIVERT THERAPY

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

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

1. If you are not already in a session, 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.

3. If using wanded telemetry, 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.

NOTE: *There is a 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 may not divert 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. This function does not affect the programmed shock sequences (lower-energy shocks can be delivered following a STAT SHOCK) and does not count as one of the total number of shocks in a therapy sequence for a given episode. The output of the STAT SHOCK is at the maximum-output energy and at the programmed polarity and waveform; STAT SHOCK is always committed regardless of programmed parameters.

1. If you are not already in a session, position the telemetry wand within range of the pulse generator.

2. Press the STAT SHOCK key. A message window appears with information about the shock and instructions to initiate the shock.

3. To initiate the shock, press the STAT SHOCK key again. A different message window appears indicating that STAT SHOCK is in process. When the shock has been delivered, the message window disappears.

4. Subsequent high-energy STAT SHOCKS may be delivered by repeating the previous steps.

NOTE: *The STAT SHOCK may be diverted using the DIVERT THERAPY key.*

NOTE: *Following STAT SHOCK delivery, if the Tachy Mode is programmed to Monitor Only or Monitor + Therapy, post-shock redetection is initiated (initial detection criteria and enhancements are not used). If the Tachy Mode is programmed to Monitor + Therapy and redetection determines that further therapy is required, the programmed sequence of therapy will be resumed or initiated, including ATP and/or low-energy shocks.*

STAT PACE

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

1. If you are not already in a session, position the telemetry wand within range of the pulse generator.

2. Press the STAT PACE key. A message window displays the STAT PACE values.

3. Press the STAT PACE key a second time. A message indicates that STAT PACE is being performed, followed by the STAT PACE values.

4. Select the Close button on the message window.

5. To stop STAT PACE, reprogram the pulse generator.

CAUTION: When a pulse generator is programmed to STAT PACE settings, it will continue to pace at the high-energy STAT PACE values if it is not reprogrammed. The use of STAT PACE parameters will decrease device longevity.

SAFETY MODE

The pulse generator hardware includes a safety core feature. The safety core is intended to provide life-sustaining therapy in the event of specific failures within the pulse generator. If the pulse generator is interrogated while safety core is active, the PRM will indicate that the pulse generator is in Safety Mode.

Limited inductive telemetry and some device programming are available during Safety Mode. If you interrogate a pulse generator that is in Safety Mode, the PRM will display a warning screen directing you to call Technical Services.

Backup Pacemaker

The Safety Mode feature provides a simple VVI pacemaker programmed to 72.5 ppm, with the following output characteristics.

- 5 V amplitude
- 1.0 ms pulse width

Backup Defibrillator

The Safety Mode feature provides a single-zone backup defibrillator, which can be enabled or disabled using the PRM.

Tachycardia Detection in Safety Mode

In Safety Mode, the tachycardia detection monitors RV senses using a traditional tachycardia detection window with a rate threshold of 165 bpm.

Tachycardia Therapy in Safety Mode

In Safety Mode, tachycardia therapy consists of maximum energy, committed shocks, with the following settings:

- Shock polarity—initial
- Shock waveform—biphasic
- Shock vector—V-TRIAD

Within the period of a declared episode, therapy is limited to 5 shocks.

When a magnet is detected, therapy delivery is immediately inhibited although charging may continue. After the magnet has been applied for 1 second,

the therapy is diverted and detection is inhibited. The magnet must then be removed for 2 seconds in order to allow detection to continue.

Programming the Device Safety Tachy Mode

In Safety Mode, you can perform the following steps to program the Safety Tachy Mode:

1. Select the Tachy Mode button. The Change Device Mode dialog displays.

2. Click to select the required Safety Tachy Mode setting, either Off or Monitor + Therapy. Click Apply Changes to apply the new setting, or Cancel Changes to cancel the new setting.

3. Click Close to dismiss the Change Device Mode dialog.

NOTE: *The safety tachy mode automatically will be set to Off if additional faults are detected while in Safety Mode.*

TACHYARRHYTHMIA DETECTION

CHAPTER 3

This chapter contains the following topics:

- "Device Mode" on page 3-2
- "Rate Sensing" on page 3-3
- "Ventricular Detection" on page 3-6

DEVICE MODE

The Device Mode allows you to program the device to provide the type of therapy and detection desired.

Ventricular Tachy Mode

The Ventricular Tachy Mode controls the availability of the detection and therapy functions in the ventricle (Table 3-1 on page 3-2).

You can program the Ventricular Tachy Mode to the following modes:

- Off—disables ventricular tachyarrhythmia detection and automatic ventricular therapy delivery. This mode is useful during implant or explant, when connecting the leads to or disconnecting them from the pulse generator.
- Monitor Only—enables ventricular tachyarrhythmia detection and episode storage, 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 postoperative, where alternate therapy (e.g., external defibrillation) is available.
- Monitor + Therapy—enables the full range of ventricular detection and ventricular therapy options.

Table 3-1. Device feature availability in the Ventricular Tachy Mode settings

Device features	Ventricular Tachy Mode		
	Off	Monitor Only	Monitor + Therapy
Rate sensing	X[a]	X	X
Bradycardia pacing	X	X	X
Ventricular detection/therapy history	X[b]	X	X
STAT SHOCK	X	X	X
STAT PACE	X	X	X
Real-time annotated EGMs	X	X	X
Ventricular tachyarrhythmia detection		X	X
Commanded ventricular ATP		X	X[c]
Commanded ventricular shock		X	X

Table 3-1. Device feature availability in the Ventricular Tachy Mode settings (continued)

Device features	Ventricular Tachy Mode		
	Off	Monitor Only	Monitor + Therapy
Ventricular EP test		X[d]	X[d]
Automatic ventricular tachyarrhythmia therapy			X

a. In order to enable ventricular sensing when the Ventricular Tachy Mode is programmed to Off, you must program the Brady Mode to a mode with ventricular sensing.
b. While programmed to Off Mode, the pulse generator will store only STAT SHOCK in history.
c. When the ventricular tachy mode is Monitor + Therapy, the EP Temp V Mode must be programmed to Monitor Only in order to use the commanded ventricular ATP.
d. Not all forms of EP Tests are available in this mode.

Electrocautery Protection Mode

Electrocautery Protection Mode deactivates the tachyarrhythmia detection and therapy features of the pulse generator during use of electrocautery equipment.

When Electrocautery Protection is enabled, bradycardia pacing is still functional; however, the pacing mode switches to an XOO mode (where X is determined by the programmed pacing mode). Other pacing parameters remain at the programmed settings.

After cancelling Electrocautery Protection, the following modes will revert to the previously programmed settings:

- Ventricular Tachy Mode
- Brady Mode

Except for STAT SHOCK and STAT PACE, no commanded therapies, inductions, or diagnostic tests will be allowed while Electrocautery Protection is enabled.

RATE SENSING

Rate sensing is critical to all detection decisions. The pulse generator relies on the following to determine cardiac cycle length:

- Bipolar electrodes in the atrium and right ventricle.
- Automatic gain-controlled sensing circuit for rate sensing. This circuit ensures proper rate sensing by compensating for changing or diminished signal amplitudes.

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 programmed detection parameters.

The pulse generator uses refractory periods following paced and sensed intrinsic events; intrinsic events that fall within these periods are ignored for detection purposes. The refractory periods, together with noise windows, may prevent the sensing of nonphysiologic signals and the potential delivery of unwanted therapy. The nonprogrammable refractory periods are as follows:

- 85 ms atrial refractory following an atrial sensed event
- 150 ms atrial refractory following an atrial pace in DDD(R) and DDI(R) modes
- 135 ms RV refractory following an RV sensed event or a capacitor charge
- 500 ms refractory following shock delivery (sensing is ignored in all chambers)

Ventricular Rate Thresholds and Zones

The pulse generator compares each sensed RV cardiac cycle interval against the programmed Ventricular Tachyarrhythmia Rate Threshold.

A Ventricular Tachyarrhythmia Zone is a range of heart rates defined by at least one programmed Ventricular Tachyarrhythmia Rate Threshold. You can program from 1 to 3 Ventricular Tachyarrhythmia Zones, each of which can be treated by a separate therapy prescription (Table 3-2 on page 3-4, Figure 3-1 on page 3-5).

Table 3-2. Nominal values for Ventricular Rate Threshold configurations

Ventricular Zone Configuration	VT-1 Zone	VT Zone	VF Zone
1 Zone	– –	– –	200 bpm

Table 3-2. Nominal values for Ventricular Rate Threshold configurations (continued)

Ventricular Zone Configuration	VT-1 Zone	VT Zone	VF Zone
2 Zones	– –	160 bpm	200 bpm
3 Zones	140 bpm	160 bpm	200 bpm

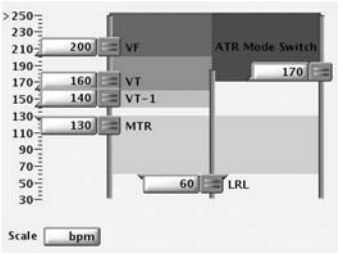


Figure 3-1. Ventricular Tachy Detection settings

- Rate thresholds in adjacent zones must differ by at least 20 bpm
- The lowest Ventricular Tachyarrhythmia Rate Threshold must be at least 5 bpm higher than the MTR, MSR, and the MPR
- The lowest Ventricular Tachyarrhythmia Rate Threshold must be at least 15 bpm higher than the LRL

Use of Atrial Information

The atrial rate may be used to:

- Inhibit ventricular therapy in the presence of atrial fibrillation or atrial flutter
- Bypass ventricular therapy inhibitors if the ventricular rate is faster than the atrial rate

The pulse generator will respond to atrial sensing regardless of whether an atrial lead is implanted. If an atrial lead is not implanted or it has a fault, program the atrial lead from Bipolar to Off (when programmed to Off, atrial sensing is not performed; atrial pacing will occur). When programming the atrial lead to Off, change the Brady Mode to prevent atrial sensing or pacing. Next, on the applicable VT/VT-1 Detection Enhancement screens, program the following features accordingly to avoid the use of erroneous atrial data:

- V Rate > A Rate—program to Off (for Onset/Stability detection enhancement suite)

- AFib Rate Threshold—program to Off (for Onset/Stability detection enhancement suite)
- Atrial Tachyarrhythmia Discrimination—program to Off (for Rhythm ID detection enhancement suite)
- Brady Mode—program to Off, VVI, or VVI(R)
- Atrial Rate EGM—do not select the atrial trace

NOTE: *An atrial EP test should not be performed if the atrial lead is programmed to Off.*

VENTRICULAR DETECTION

Ventricular detection consists of the following components:

- Initial ventricular detection
- Reconfirmation/committed shock
- Redetection and post-shock detection

Initial ventricular detection criteria consist of the programmable parameters Rate and Duration. The detection criteria may also include one of the following two detection enhancement suites, which may be used during initial and post-shock ventricular detection to add specificity beyond Rate and Duration.

- Onset/Stability
- Rhythm ID

The pulse generator initiates ventricular therapy when it determines that detection is met. Ventricular detection is met when all of the following occur:

- A ventricular zone's detection window becomes and remains satisfied throughout Duration
- The ventricular zone's Duration expires
- A higher ventricular zone's detection window is not satisfied
- Detection enhancements (if programmed to On) indicate therapy
- The last detected interval is in the ventricular zone

If the above criteria are not met, therapy is not initiated and the pulse generator continues to evaluate intervals.

Ventricular Detection Enhancement Suites

One of the following ventricular detection enhancement suites may be programmed to provide specificity beyond Rate and Duration (Table 3-3 on page 3-7):

- Rhythm ID
- Onset/Stability

Detection enhancement suites are not available in the VF zone.

Table 3-3. Detection enhancement suites available per zone

	VT-1 Zone	VT Zone	VF Zone
3-zone configuration[a]	Rhythm ID Onset/Stability	Rhythm ID Onset/Stability[c]	None
3-zone configuration (with Monitor Only zone)[b]	None	Rhythm ID Onset/Stability	None
2-zone configuration		Rhythm ID Onset/Stability	None
2-zone configuration (with Monitor Only zone)[b]		None	None
1-zone configuration			None

a. If the detection enhancement suite is enabled in a 3-zone configuration, it applies to both the VT-1 and VT zones. Detection enhancement suites cannot be independently enabled for each zone.
b. Detection enhancement suites are not available in the lowest zone of a multi-zone configuration when the zone is used as a Monitor Only zone (no therapy programmed for that zone).
c. Shock if unstable is the only Onset/Stability detection enhancement available in the VT zone of a 3-zone configuration (applies only to 3-zone configuration without a Monitor Only zone).

NOTE: *There is no clinical data to suggest that one detection enhancement suite is superior to the other for any given patient indication. Therefore, individual programming and evaluation of detection enhancement specificity is recommended.*

Rhythm ID

Rhythm ID uses Vector Timing and Correlation analysis in addition to atrial and ventricular interval analysis to determine if a patient's rhythm should be treated (VT) or if therapy should be inhibited (SVT).

With Rhythm ID, the pulse generator performs a vector timing and correlation analysis using the shock EGM and rate EGM. Based on this data, it saves a reference template of the patient's normal sinus rhythm.

During Rhythm ID analysis, the pulse generator first determines if the ventricular rate is greater than the atrial rate. If so, therapy will be initiated. If the ventricular rate is not greater than the atrial rate, Rhythm ID evaluates the following criteria to determine if therapy should be inhibited or initiated:

- Vector Timing and Correlation analysis during initial detection determines if the rhythm is SVT by comparing it to the previously stored reference template. If the rhythm is declared SVT, therapy is inhibited.

- If Vector Timing and Correlation does not declare the rhythm SVT, Stability and AFib Rate Threshold determine if the ventricular rhythm is unstable and the atrial rate is fast. If the ventricular rhythm is unstable and the atrial rate is fast, the rhythm is declared SVT and therapy is inhibited.

Rhythm ID does not consider atrial detection criteria (V Rate > A Rate or A greater than AFib Rate Threshold) for the following configurations:

- Single-chamber devices
- Dual-chamber devices if Atrial Tachyarrhythmia Discrimination is programmed to Off

When configured this way, Stability is not evaluated for initial detection. This may be useful in instances where atrial lead problems have occurred. For these configurations,therapy is inhibited at initial detection if the rhythm is declared SVT (correlated based on Vector Timing and Correlation). Otherwise, therapy is initiated.

Two methods are available for the device to automatically acquire a Rhythm ID reference template: passive and active. The active method may be useful for patients who are frequently ventricular paced.

If the passive method is enabled, the pulse generator will attempt to collect the Rhythm ID reference template every two hours using the programmed brady settings.

If the active method is enabled and seven days have passed since the last successful collection of a reference template, then every 28 hours the device automatically analyzes the patient's intrinsic rhythm by adjusting the brady parameters. During a Rhythm ID active reference template update, the following will occur:

1. The device verifies that the patient is at rest (as measured by the accelerometer input).

2. The device enables a controlled pacing rate decrease to the programmed Rhythm ID Fallback LRL. During this fallback period, the following occurs:

    - The device temporarily switches the pacing mode to DDI, VDI, VVI, AAI, or Off (according to the programmed brady mode) and extends the AV delay up to 400 ms.

    - Rate Smoothing, ATR, hysteresis, and dynamic programming (excluding Dynamic VRP) are suspended.

3. After the Fallback period, pacing parameters are restored to normal programmed parameters. Fallback periods occur no more than once per day and will typically last less than one minute.

A method for manually commanding the device to acquire a Rhythm ID reference template is also available.

NOTE: *If Rhythm ID is not enabled, a manual reference template update can still be performed. However, the acquired template will not be used in analysis to determine if the patient's rhythm is VT or SVT.*

During a manual Rhythm ID reference template update, the pulse generator will perform the following tasks:

1. Enable a controlled rate decrease to the programmed Rhythm ID Fallback LRL. During the fallback period, the following occurs:

    - The device temporarily switches to the programmed Manual Rhythm ID Brady Mode and extends the AV delay up to 400 ms.

    - Rate Smoothing, ATR, hysteresis, and dynamic programming (excluding Dynamic VRP) are suspended.

2. After the Fallback interval, pacing parameters are restored to normal programmed parameters. This process will typically last one minute.

NOTE: *Rhythm ID Fallback LRL settings should be selected such that normal sinus rhythms are promoted (e.g., normal AV node conduction). Care must be used when selecting LRL less than 50 ppm (rates that approach the patient's ventricular escape rates). Ventricular escape rhythms during Rhythm ID updates may result in inappropriate therapy decisions.*

NOTE: *A manual Rhythm ID reference template update should not be commanded immediately after shock therapy. It may take several minutes for irregularities in EGM morphology caused by the shock to subside.*

Onset/Stability

The Onset/Stability detection enhancement suite analyzes the cardiac cycle intervals to determine if a patient's rhythm should be treated (VT) or if therapy should be inhibited (SVT).

Onset/Stability allows you to program detection enhancements by identifying the desired type of rhythm discrimination: atrial tachyarrhythmia, sinus tachycardia, or polymorphic VT (Table 3-4 on page 3-10).

Table 3-4. Onset/Stability rhythm discrimination available per zone

	VT-1 Zone	VT Zone	VF Zone
3-zone Configuration	Atrial Tachyarrhythmia Sinus Tachycardia	Polymorphic VT[a]	None
3-zone Configuration (with Monitor Only zone)[b]	None	Atrial Tachyarrhythmia Sinus Tachycardia Polymorphic VT[a]	None
2-zone Configuration		Atrial Tachyarrhythmia Sinus Tachycardia Polymorphic VT[a]	None
2-zone Configuration (with Monitor Only zone)[b]		None	None
1-zone Configuration			None

a. Polymorphic VT Discrimination is only available in the VT zone.
b. Rhythm discrimination is not available in the lowest zone of a multi-zone configuration if the zone is used as a Monitor Only zone (no therapy programmed for that zone).

Reconfirmation/Committed Shock

Reconfirmation refers to the monitoring performed by the device during and immediately following capacitor charging for a shock. When the Committed Shock parameter is programmed to Off, the device is allowed to reconfirm that a shock should be delivered.

Ventricular Redetection

Ventricular Redetection occurs following any:

- Ventricular therapy delivery
- Diverted therapy due to reconfirmation analysis (diverted-reconfirm)
- Manually diverted therapy
- Therapy not available at Detection Met

Redetection uses the same ventricular detection window process and programmed tachycardia rate thresholds as initial detection to identify a tachyarrhythmia.

The primary differences between initial detection and redetection are the duration parameters used and the detection enhancements that are available:

- If ventricular shock therapy is delivered, the following will occur:
  - The redetection duration time is determined by the value of the Post-shock Duration parameter
  - Detection enhancements (except for Vector Timing and Correlation) are available during redetection
- If ventricular ATP is delivered or if therapy is diverted or unavailable, the following will occur:
  - The redetection duration time is determined by the Redetection Duration parameter
  - Detection enhancements (except for Shock if Unstable) are not available during redetection

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.

Ventricular Post-shock Detection Enhancements

When programmed to On, the following ventricular post-shock detection enhancements will be in effect following the Post-shock Duration:

- Post-shock V Rate > A Rate
- Post-shock AFib Rate Threshold

- Post-shock Stability
- Post-shock SRD
- Post-shock Rhythm ID (uses AFib Rate Threshold, Stability, V Rate > A Rate, and SRD)

With the exception of Rhythm ID, all post-shock detection enhancements perform the same as the corresponding Initial Detection enhancements (with Rhythm ID, Vector Timing and Correlation is not available post-shock).

Post-shock Stability may be used to prevent shock-induced AF from causing the pulse generator to deliver undesired additional shocks (Figure 3-2 on page 3-12.)

The AFib Rate Threshold can be programmed in conjunction with Post-shock Stability to further discriminate AF and prevent the pulse generator from delivering undesired ventricular shock therapy.

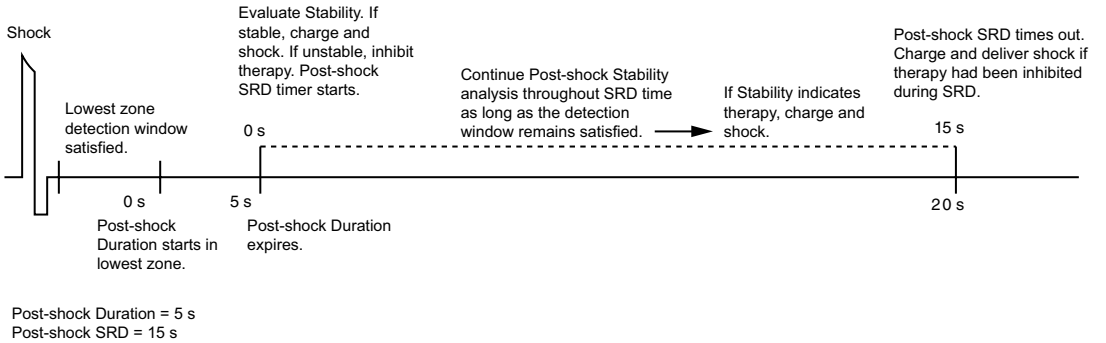


Figure 3-2. Post-shock Duration and Post-shock Stability analysis

Ventricular Detection Details

The pulse generator uses the following information to determine appropriate therapy delivery:

- Ventricular detection windows
- Duration parameter
- Redetection duration and post-shock duration
- Ventricular episodes
- Ventricular detection enhancements

Ventricular Detection Windows

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

Each ventricular zone has a detection window that consists of the 10 most recent RV 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 (i.e., above or below the rate threshold) in each detection window.

The pulse generator prepares for a potential episode when it counts 3 consecutive fast intervals. The detection window is satisfied and an episode is declared when 8 out of 10 fast intervals are counted. The detection window will remain satisfied as long as 6 of 10 intervals remain classified as fast. If the number of fast intervals falls below 6, the zone's detection window is no longer satisfied. The zone's detection window will only become resatisfied when 8 of 10 intervals are again classified as fast (Figure 3-3 on page 3-13).

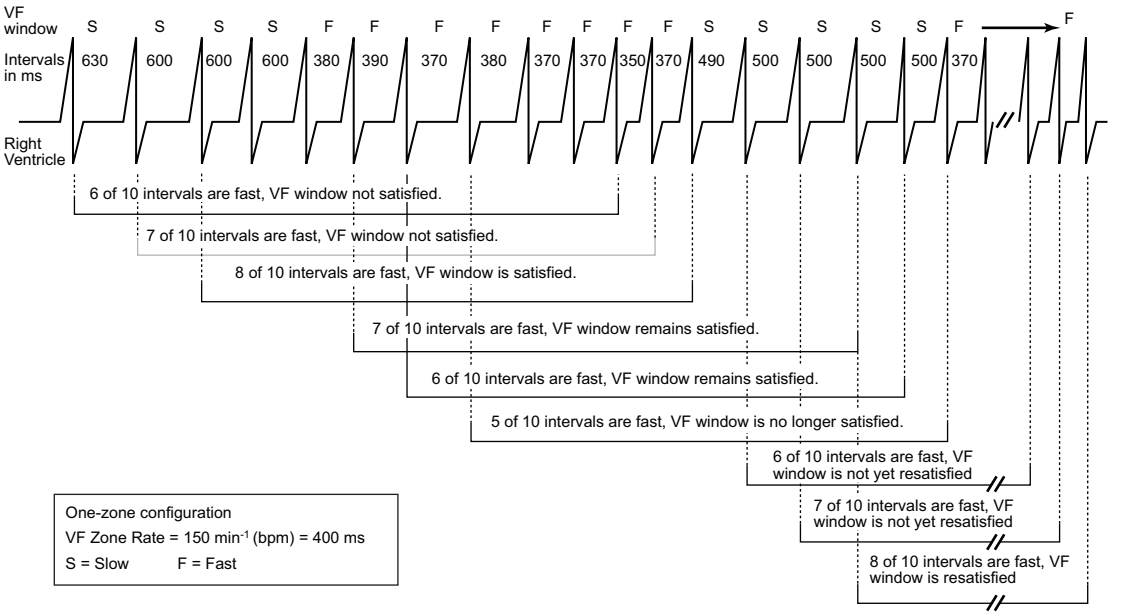


Figure 3-3. Ventricular detection window satisfied

Because Rate Threshold in the higher zones must be programmed at a value greater than Rate Threshold in lower zones, an interval classified as fast

in a higher window would also be classified as fast in any lower windows (Figure 3-4 on page 3-14).

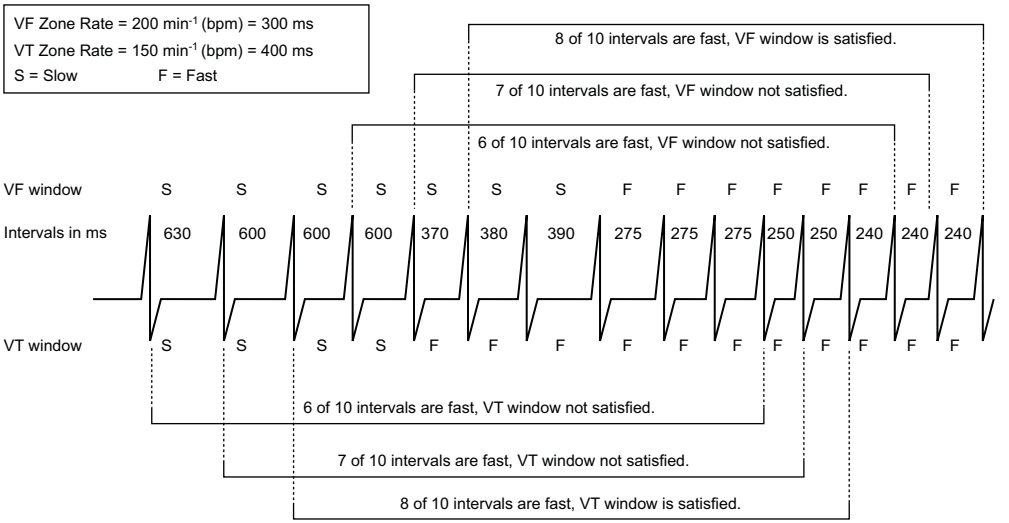


Figure 3-4. Interaction of ventricular detection windows, 2-zone configuration

Duration Parameter

The Duration parameter is a timer that measures the length of time in each zone that a rhythm must be sustained before therapy is delivered.

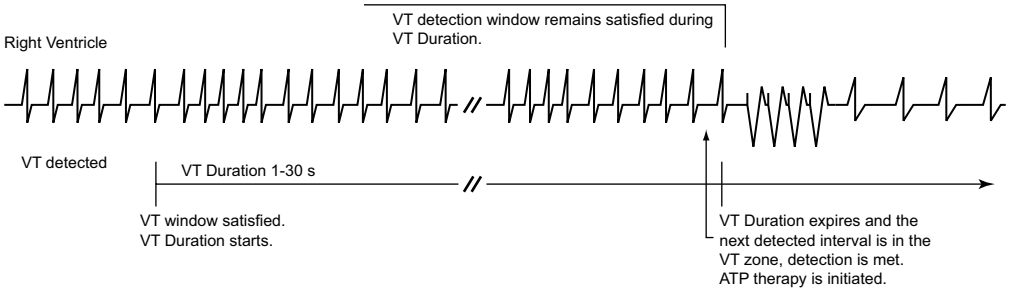
A Duration timer begins when its respective zone's detection window is satisfied. The programmed Duration time is checked following every cardiac cycle to determine if it has expired.

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.*

- As long as the zone's detection window remains satisfied, the Duration timer continues to elapse. If the last detected interval is in the zone when its Duration time expires, detection is considered met and therapy is initiated (assuming no programmed detection enhancements inhibit therapy delivery) (Figure 3-5 on page 3-15).

- If the last detected interval is not in the zone, therapy is not initiated. Each subsequent interval will be checked until an interval is in the original zone, or the window is no longer satisfied (Figure 3-6 on page 3-15).

- If at any point during Duration a zone's detection window detects fewer than 6 of 10 fast intervals, that zone's Duration is reset to 0 (Figure 3-7 on page 3-16). Duration will start again only if the detection window becomes resatisfied.



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

Figure 3-5. Ventricular Duration timer

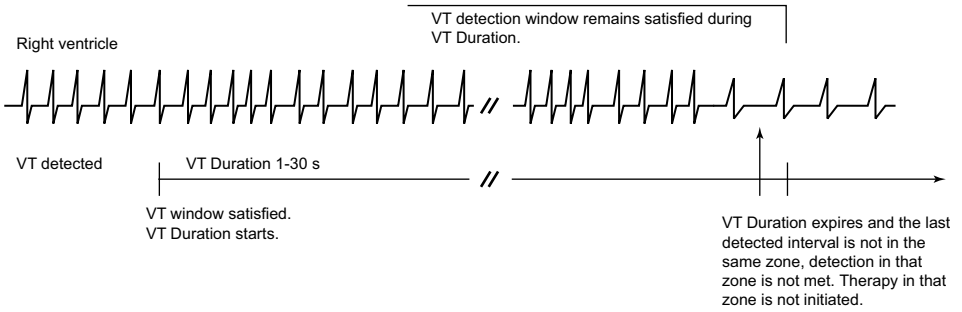
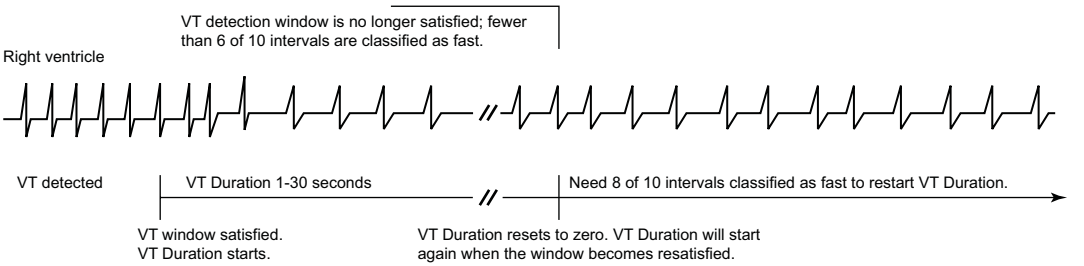


Figure 3-6. Last detected interval



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

Figure 3-7. Ventricular Duration reset

A Duration is programmed for each ventricular zone. Different values are available depending on the configuration programmed (Table 3-5 on page 3-16). The Duration programmed in lower ventricular rate zones must be greater than or equal to higher ventricular zones. Longer Durations may be used to prevent the device from initiating treatment of non-sustained arrhythmias.

Table 3-5. Duration programmable ranges by ventricular zone and configuration

Configuration	VT-1 Zone[a]	VT Zone[a]	VF Zone[b]
1 Zone	– –	– –	1–15 seconds
2 Zones	– –	1–30 seconds	1–15 seconds
3 Zones	1–60 seconds	1–30 seconds	1–15 seconds

a. The maximum redetect duration for the VT-1 and VT Zones is 15 seconds.
b. In the VF Zone, the redetect and post-shock duration is fixed at 1 second.

Duration in a Multi-zone Configuration

Duration timers run independently of each other within their respective ventricular 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 regardless of whether the lower zones' Duration timers have expired.

- If the higher zone's detection window does not remain satisfied, then the Duration timers for the lower ventricular zones are no longer ignored.

Programmed therapy for lower ventricular zones will be initiated when a lower ventricular zone's duration is met and no higher ventricular zone's window is satisfied (Figure 3-8 on page 3-17, Figure 3-9 on page 3-17).

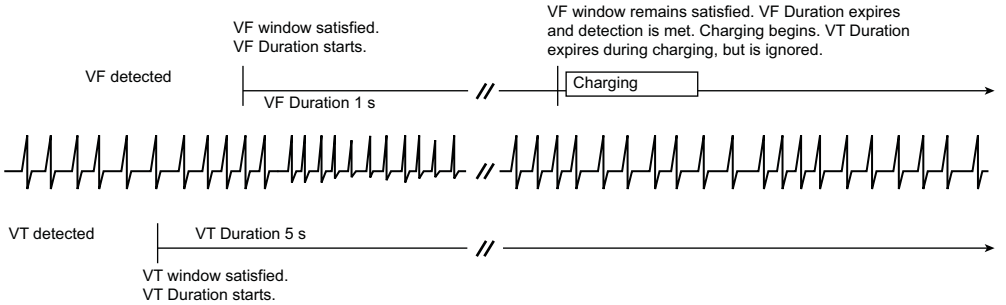


Figure 3-8. Interaction of ventricular Duration, 2-zone configuration, charging

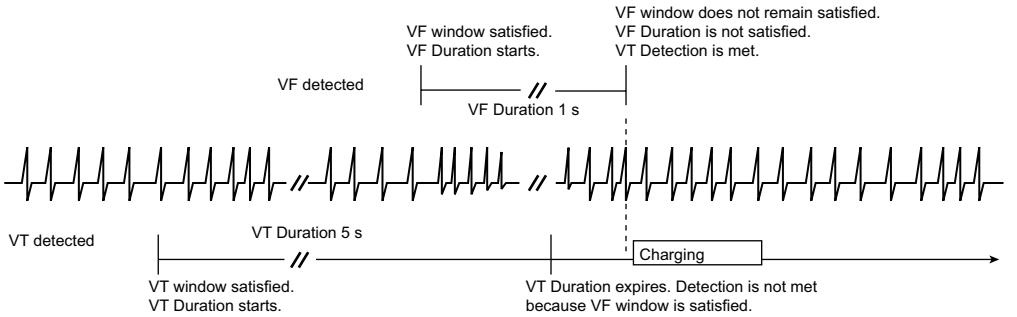


Figure 3-9. Interaction of ventricular Duration, 2-zone configuration, charging delayed

Ventricular Redetection Duration and Post-shock Duration

Duration parameters are used to identify tachyarrhythmias during the ventricular redetection process.

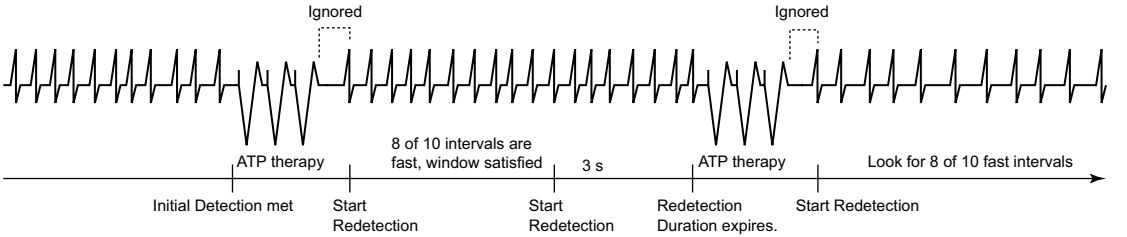
- Redetection Duration is applied following delivery of ATP therapy (except QUICK CONVERT ATP), a diverted-reconfirm, manually diverted therapy, or if therapy is unavailable at Detection Met (Figure 3-10 on page 3-18).

- Post-shock Duration is applied following shock therapy delivery (Figure 3-11 on page 3-18).

Redetection Duration is programmable in the lower ventricular zones of a multi-zone configuration. It is nonprogrammable in the VF Zone. Post-shock Duration can be programmed in the same manner; the values programmed in the lower ventricular rate zones must be greater than or equal to the values programmed in the higher zones.

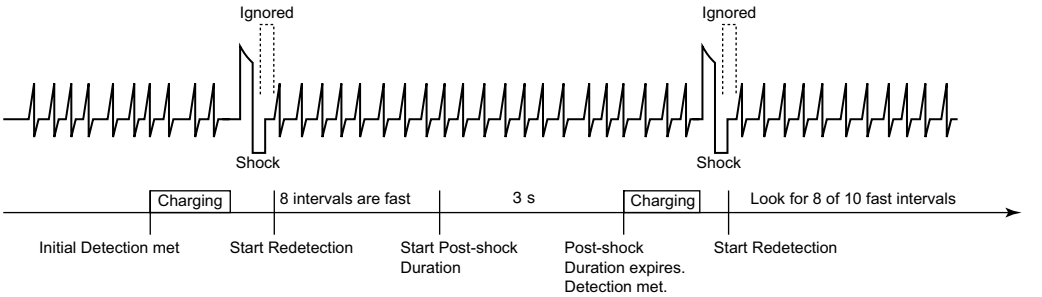
To help minimize time to potential therapy, it is recommended that Redetection Duration in the VT-1 and VT zones of multi-zone configurations be programmed at less than or equal to 5 seconds.

It is recommended that Post-shock Duration in the VT-1 and VT zones of multi-zone configurations also be programmed at less than or equal to 5 seconds. However, you may program for longer durations if shock-induced, non-sustained, high-rate rhythms, such as accelerated idioventricular rhythm (AIVR) or AF are evident. The longer durations may allow the rhythm to return to a lower rate before redetection is met.



ATP therapy programmed.
Redetection Duration programmed at 3 s.

Figure 3-10. Redetection following ventricular ATP delivery



Shock therapy programmed. Post-shock Duration programmed at 3 s.

Figure 3-11. Redetection following ventricular shock delivery

Ventricular Episodes

If three consecutive fast ventricular beats are detected, then the pulse generator performs the following:

- Increments the episode number
- Allocates memory for history data and electrogram storage
- Starts monitoring for a detection window to be satisfied

When any zone's detection window becomes satisfied, the start of a ventricular episode is declared and duration timers begin in those zones where detection windows are satisfied. The ventricular episode is declared complete when all detection windows are no longer satisfied and remain unsatisfied for a specified time.

Each ventricular tachy episodes is classified as treated or non-treated (Figure 3-12 on page 3-20 through Figure 3-16 on page 3-22).

- A treated episode is one in which therapy is delivered
- A nontreated episode is one in which no therapy is delivered

For a treated episode, an End-of-Episode timer starts after therapy is delivered. For a non-treated episode, an End-of-Episode timer starts at the point that 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 is declared complete if no detection window becomes satisfied for a specified time following the last therapy attempt (Table 3-6 on page 3-19). If any window becomes satisfied while the End-of-Episode timer is elapsing, the End-of-Episode timer is reset to zero. It will start again when either therapy is attempted or all windows are not satisfied (Figure 3-16 on page 3-22).

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

Table 3-6. End-of-Episode Timer

Episode Classification	Ventricular End-of-Episode Timer (elapsed time required to declare episode over)
Nontreated (no therapy delivered)	10 seconds

Table 3-6. End-of-Episode Timer (continued)

Episode Classification	Ventricular End-of-Episode Timer (elapsed time required to declare episode over)
Treated (only ATP therapy delivered)	10 seconds
Treated (any shock therapy delivered)	30 seconds

NOTE: *The episode is terminated immediately if the Tachy Mode is reprogrammed, an induction method or lead test is attempted before the End-of-Episode time out, or any ventricular detection or ventricular therapy parameters are reprogrammed.*

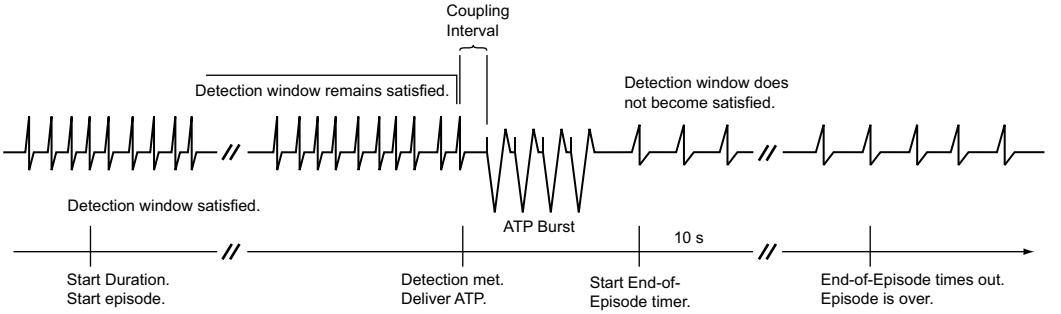


Figure 3-12. Treated episode, ventricular mode is Monitor + Therapy and ATP is delivered

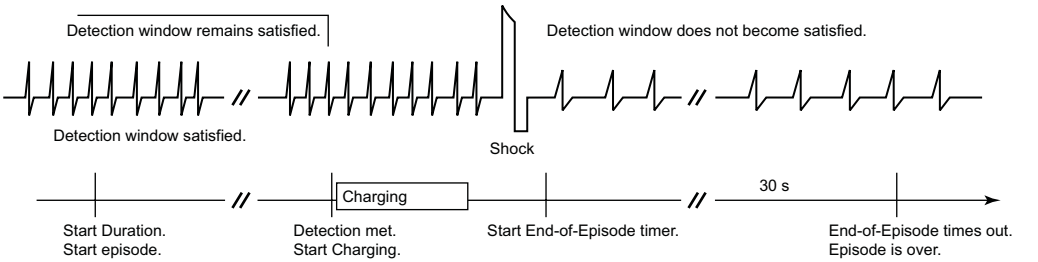


Figure 3-13. Treated episode, ventricular mode is Monitor + Therapy and shock is delivered

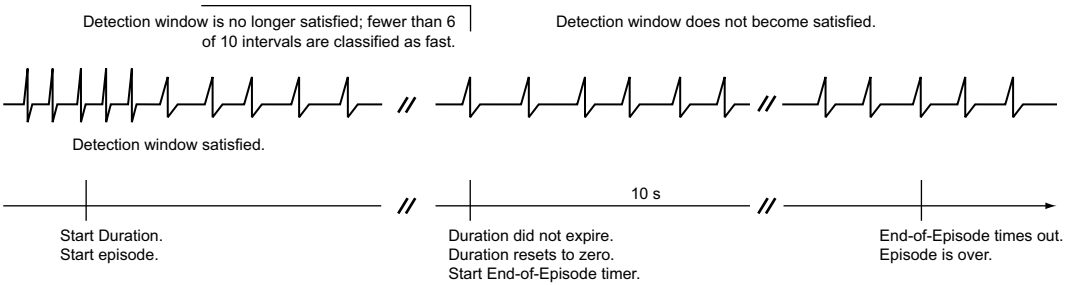
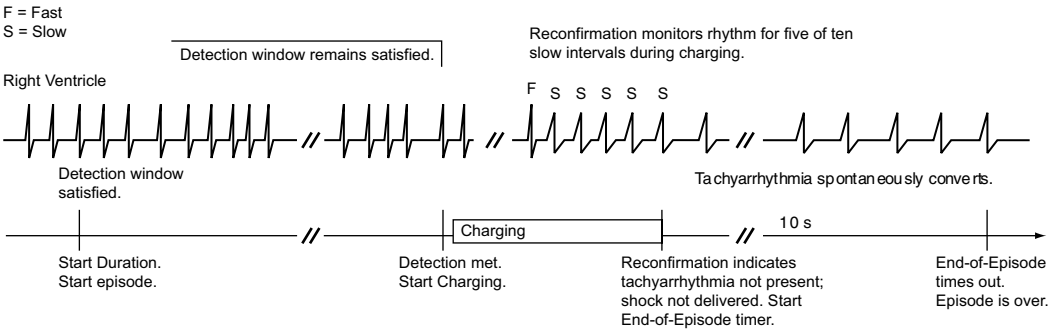
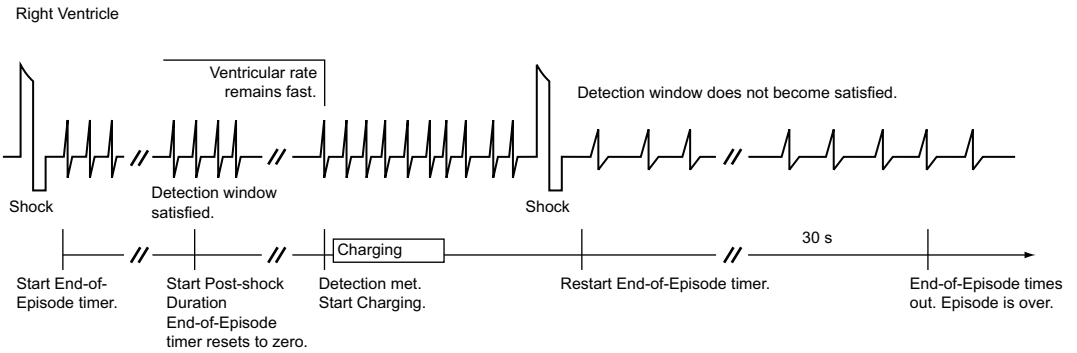


Figure 3-14. Nontreated episode, ventricular mode is Monitor + Therapy or Monitor Only, duration is not expired



This example assumes Committed Shock is programmed to Off.

Figure 3-15. Nontreated episode, ventricular mode is Monitor + Therapy and charging is stopped prior to shock delivery



This example illustrates a Treated Episode when Ventricular mode is Monitor + Therapy. The End-of-Episode timer is reset to 0 when a ventricular detection window becomes satisfied after ventricular therapy delivery, but prior to the episode time-out being reached. In this example, 2 shocks were delivered in the episode.

Figure 3-16. Treated episode, ventricular mode is Monitor + Therapy and End-of-Episode timer is reset to 0

Ventricular Detection Enhancements

Ventricular detection enhancements add specificity to the Rate and Duration detection criteria. You may program ventricular detection enhancements to perform the following:

- Delay or inhibit therapy delivery
- Override therapy inhibition
- Bypass a sequence of ATP therapy in favor of shock therapy

Ventricular detection enhancements may be programmed to one of the following:

- Rhythm ID
- Onset/Stability
- Off (i.e., rate only)

If Off is selected, only the ventricular rate and duration are used for therapy decisions.

If either Rhythm ID or Onset/Stability is selected, enhancement parameters are used in addition to ventricular rate and duration for therapy decisions (Table 3-7 on page 3-23) as follows:

- Vector Timing and Correlation inhibits therapy when the conduction vector (EGM morphology and timing) during tachyarrhythmia matches a reference conduction vector of the patient's normal sinus rhythm.
- V Rate > A Rate can be used to override the inhibit decision of Onset, Stability, Vector Timing and Correlation, and/or AFib Rate Threshold. V Rate > A Rate can be used to deliver ventricular therapy anytime the ventricular rate is greater than the atrial rate.
- AFib Rate Threshold can be programmed (together with stability) to inhibit ventricular therapy if the atrial rhythm is fast.
- Stability can be programmed to inhibit ventricular therapy delivery if the ventricular rhythm is unstable.
- Shock if Unstable can be programmed to bypass the ventricular ATP therapy and deliver shock therapy if the ventricular rhythm is declared unstable.
- Onset can be programmed to inhibit ventricular therapy if the patient's heart rate increases gradually.
- SRD enables the pulse generator to override the Stability, Onset, Vector Timing and Correlation, and/or AFib Rate Threshold parameters' decision to inhibit ventricular therapy if the high rate continues throughout the programmed time period.

Table 3-7. Enhancement parameters available with detection enhancements

Enhancement Parameter	Rhythm ID		Onset/Stability	
	Initial	Post-Shock	Initial	Post-Shock
Vector Timing and Correlation[a]	X	– –	– –	– –
V Rate > A Rate (dual-chamber devices only)	X[b c]	X[b c]	X	X
AFib Rate Threshold (dual-chamber devices only)	X[b d]	X[b d]	X[e]	X[e]
Stability (to inhibit)	X[f]	X[f]	X	X
Shock if Unstable	– –	– –	X	– –

Table 3-7. Enhancement parameters available with detection enhancements (continued)

Enhancement Parameter	Rhythm ID		Onset/Stability	
	Initial	Post-Shock	Initial	Post-Shock
Onset	– –	– –	X	– –
SRD[g]	X	X	X	X

a. This enhancement is not individually programmable.
b. When Rhythm ID is selected, this enhancement is automatically enabled when Atrial Tachyarrhythmia Discrimination is programmed to On. However, it is not available in single chamber devices or when the Atrial Tachyarrhythmia Discrimination is programmed to Off in dual chamber devices.
c. This enhancement is not individually programmable when Rhythm ID is enabled.
d. When Rhythm ID is selected, this parameter uses the same value for both initial and post-shock detection. It cannot be independently enabled or disabled for post-shock detection.
e. When Onset/Stability is selected, this parameter can be enabled and disabled independently for post-shock detection. If enabled, it uses the same value as the initial detection.
f. When Rhythm ID is enabled and Atrial Tachyarrhythmia Discrimination is programmed to On in dual chamber devices, this enhancement uses the same value for both initial and post-shock detection. In single chamber devices, or when Atrial Tachyarrhythmia Discrimination is programmed to Off, this enhancement is automatically disabled for Initial Detection, but is still enabled for post-shock detection.
g. SRD is available when detection enhancements, which inhibit therapy, are programmed.

Some of these detection enhancement parameters are also independently programmable as post-shock parameters (Table 3-7 on page 3-23).

The individual detection enhancement parameters that are available depend on the number of tachy zones that are programmed: 3, 2, or 1 (Table 3-8 on page 3-24).

Table 3-8. Individual Ventricular Detection Enhancements available in multizone configurations

	VT-1 Zone	VT Zone	VF Zone
3-zone configuration	Vector Timing and Correlation	Vector Timing and Correlation[a]	– –
	V Rate > A Rate	V Rate > A Rate[a]	
	AFib Rate Threshold	AFib Rate Threshold[a]	
	Stability to Inhibit	Stability (to Inhibit)[a]	
	Onset	Shock if Unstable	
	SRD	SRD[a]	

Table 3-8. Individual Ventricular Detection Enhancements available in multizone configurations (continued)

	VT-1 Zone	VT Zone	VF Zone
3-zone configuration (with Monitor Only zone)[b]	– –	Vector Timing and Correlation V Rate > A Rate AFib Rate Threshold Stability (to Inhibit) Shock if Unstable[c] Onset SRD	– –
2-zone configuration		Vector Timing and Correlation V Rate > A Rate AFib Rate Threshold Stability (to Inhibit) Shock if Unstable[c] Onset SRD	– –
2-zone configuration (with Monitor Only zone)[b]		– –	– –
1-zone configuration			– –

a. Enhancement is available in the middle zone of a 3-zone configuration only when Rhythm ID is enabled.
b. Detection enhancements are not available in the lowest zone of a multi-zone configuration when it is used as a Monitor Only zone (no therapy programmed for that zone).
c. Shock if Unstable cannot be programmed on in the same zone as other detection enhancements that are programmed to inhibit therapy (Onset, Stability, and AFib Rate Threshold).

When a specific rhythm discrimination is selected, preselected values are displayed for the detection enhancements that are suitable for discriminating that rhythm. However, you can modify those values at your discretion (Table 3-9 on page 3-26).

Table 3-9. Preselected values for initial detection and redetection enhancements

	Onset/Stability			Rhythm ID	
Parameter	**Atrial Tachyarrhythmia Discrimination**	**Sinus Tachycardia Discrimination**	**Polymorphic VT Discrimination**	**Atrial Tachyarrhythmia Discrimination On**	**Atrial Tachyarrhythmia Discrimination Off**
Vector Timing and Correlation	– –	– –	– –	On[a]	On[a]
V Rate > A Rate (dual-chamber models only)	On	On	– –	On[b]	– –
AFib Rate Threshold (dual-chamber models only)	170 bpm	– –	– –	170 bpm	– –
Stability (Inhibit)	20 ms (DR devices) 30 ms (VR devices)	– –	– –	20 ms (DR devices) 30 ms (VR devices)	30 ms
Onset (initial detection only)	– –	9%	– –	– –	– –
SRD Initial	3:00 minutes:seconds	3:00 minutes:seconds	– –	3:00 minutes:seconds	3:00 minutes:seconds
SRD Redetection	0:15 minutes:seconds	– –	– –	0:15 minutes:seconds	0:15 minutes:seconds
Shock if Unstable	– –	– –	30 ms	– –	– –

a. Parameter is not individually programmable.
b. Parameter is not individually programmable when Rhythm ID is enabled.

Vector Timing and Correlation

Vector Timing and Correlation compares EGM signals for an unknown rhythm with a stored reference template of the EGM signals of a normal sinus rhythm (NSR). Rhythms that are not similar to the reference template (are not correlated) are classified as VT. Rhythms that are correlated with the reference template are classified as SVT.

When an unknown fast rhythm is sensed in the VT or VT-1 zones, each beat of the fast rhythm is compared to the stored reference template. The pulse

generator calculates a Feature Correlation Coefficient and makes the following therapy decisions based on the calculation:

- If at least 3 out of 10 beats are correlated, the rhythm is classified as SVT
- If fewer than 3 out of 10 beats are correlated, the rhythm is classified as VT

Rhythm ID makes its decision to treat or inhibit therapy at the end of Duration. If the decision is made to inhibit therapy, Rhythm ID (including Vector Timing and Correlation, V Rate > A Rate, AFib Rate Threshold, and Stability) continues to be recalculated beat-by-beat throughout SRD.

V Rate > A Rate

The V Rate > A Rate (ventricular rate greater than atrial rate) enhancement compares the atrial and ventricular rates to classify the type of fast ventricular rhythm. When the ventricular rate is greater than the atrial rate, therapy will be initiated regardless of the analysis of the other programmed detection enhancements.

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 (Figure 3-17 on page 3-28). If fewer than 10 atrial intervals are available, those intervals will be used to calculate the average atrial rate. This analysis is performed using the following criteria:

- 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 average ventricular rate is not greater than the average atrial rate by at least 10 bpm (indicated as False on the Episode Detail Report), therapy may continue to be inhibited. The Episode Detail report will indicate the measured value even though the parameter may be programmed to Off.

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

NOTE: *V Rate > A Rate is not evaluated during redetection following ATP therapy.*

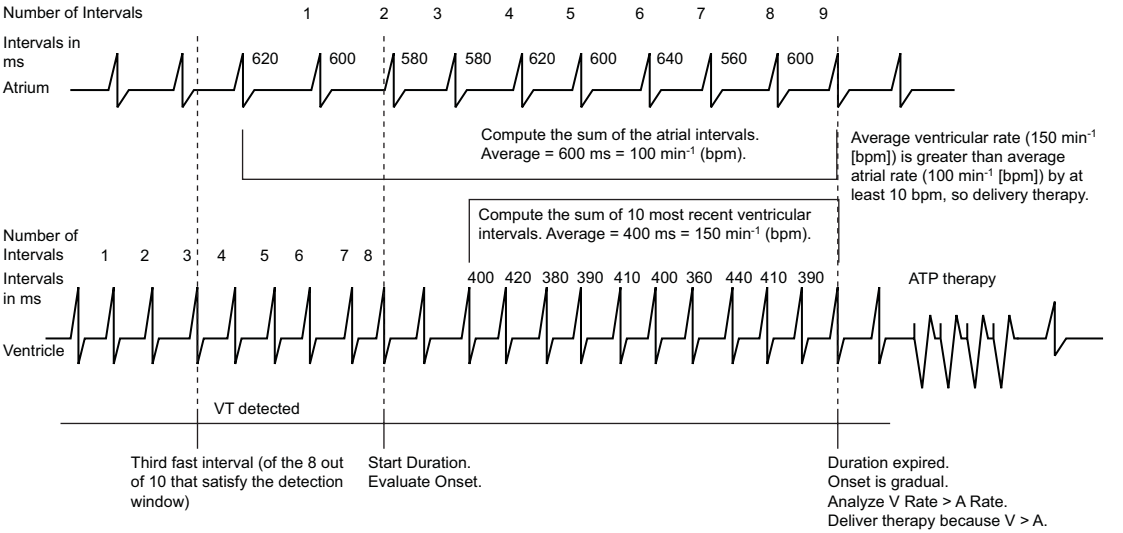


Figure 3-17. V Rate > A Rate analysis

V Rate > A Rate can be programmed to bypass inhibitors (Vector Timing and Correlation, AFib Rate Threshold, Stability, and/or Onset) and initiate therapy in the event that the ventricular rate is faster than the atrial rate.

NOTE: *Refer to "Use of Atrial Information" on page 3-5 for additional information about device performance when the atrial lead is programmed to Off.*

NOTE: *In a Rhythm ID configuration, the evaluation of V Rate > A Rate is linked to the AFib Rate Threshold. If Atrial Tachyarrhythmia Discrimination is programmed to Off, the AFib Rate Threshold and V Rate > A Rate detection enhancements are not evaluated.*

AFib Rate Threshold

AFib Rate Threshold analysis identifies AF by comparing the atrial rate to the programmed AFib Rate Threshold.

AFib Rate Threshold cannot be enabled without also enabling the Stability detection enhancement. The device analyzes both parameters to determine whether to withhold or deliver therapy.

If the intrinsic atrial rate is greater than the AFib Rate Threshold and the ventricular rhythm is classified as unstable, the ventricular rhythm is declared to be due to AF.

The intrinsic atrial rate is declared to be above the AFib Rate Threshold in the following manner (Figure 3-18 on page 3-29):

- Atrial analysis begins at initiation of ventricular tachyarrhythmia detection. 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 AF to be present.
- Ventricular stability is then checked. If unstable, therapy is inhibited.

In the event that ventricular therapy is not delivered, the atrial rate continues to be examined. As long as 4 of 10 intervals remain classified as fast, AF is considered present. Therapy is inhibited by AFib Rate Threshold/Stability until any of the following occur:

- The atrial rate drops below the AFib Rate Threshold
- The ventricular rhythm becomes stable
- If programmed to On, V Rate > A Rate is true
- SRD times out

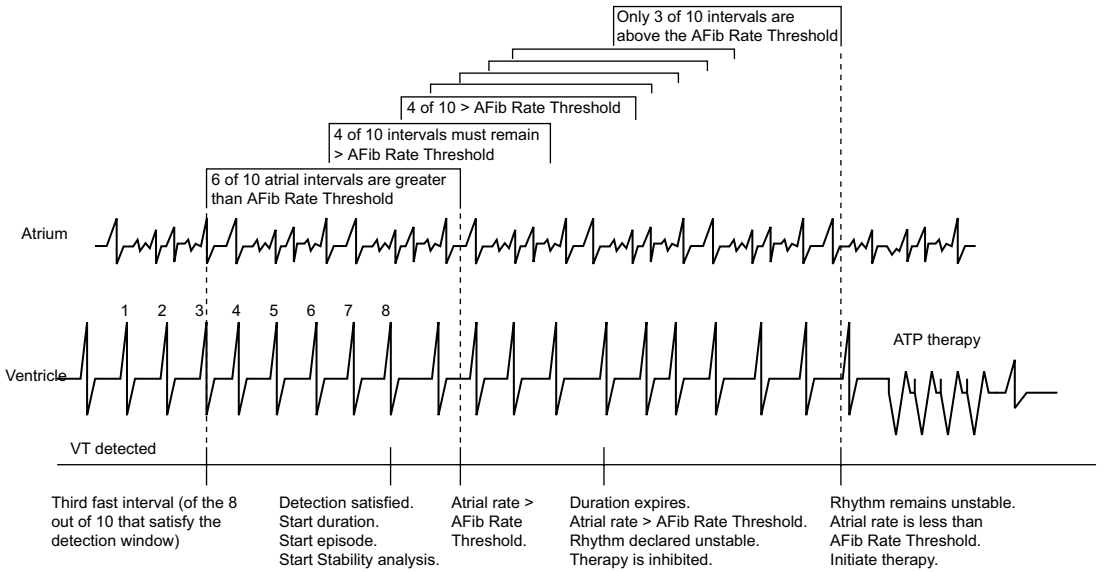


Figure 3-18. Interaction of AFib Rate Threshold and Stability

When AFib Rate Threshold and Stability are used alone, ventricular therapy is initiated when a stable rhythm is declared. Ventricular therapy is initiated for an unstable rhythm when it is determined that the atrial rate is less than the AFib Rate Threshold (Table 3-10 on page 3-30). When AFib Rate Threshold and Stability are used with other inhibitor enhancements, ventricular therapy is not always initiated when no longer inhibited by AFib Rate Threshold/Stability. Therapy may continue to be inhibited by other programmed detection enhancements, such as Onset (when the Onset/Stability detection enhancement suite is enabled) or Vector Timing and Correlation (when the Rhythm ID detection enhancement suite is enabled).

Consider the following information during these interactions:

- The AFib Rate Threshold and V Rate > A Rate detection enhancements are not evaluated if Atrial Tachyarrhythmia Discrimination is programmed to Off in a Rhythm ID configuration.

- Because the AFib Rate Threshold is not evaluated during redetection (following ventricular ATP therapy delivery, any aborted ventricular therapy, or therapy not available), the Episode Detail report will not display data for the enhancement during redetection, even though the parameter is programmed On.

- The AFib Rate Threshold enhancement is not evaluated for arrhythmia detection in the following cases; however, the Episode Detail report will still display the data for the AFib Rate Threshold enhancement based on a threshold of 170 bpm:

  – The AFib Rate Threshold is programmed to Off

  – Ventricular Zones is programmed to 1

  – No detection enhancement suite is enabled

- An atrial sense event will only be classified as AF while the AFib Rate Threshold is being evaluated for arrhythmia detection.

Table 3-10. AFib Rate Threshold and Stability combinations and resulting therapy

Detected Ventricular Rhythm[a]	Therapy Decision[b]
Unstable, A > AFib Rate Threshold	Inhibit
Stable, A > AFib Rate Threshold	Treat

Table 3-10. AFib Rate Threshold and Stability combinations and resulting therapy (continued)

Detected Ventricular Rhythm[a]	Therapy Decision[b]
Unstable, A < AFib Rate Threshold	Treat
Stable, A < AFib Rate Threshold	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. Decisions to inhibit can be overridden by V > A or expiration of SRD.

NOTE: *Refer to "Use of Atrial Information" on page 3-5 for additional information about device performance when the atrial lead is programmed to Off.*

Stability Analysis

Stability analysis distinguishes unstable (irregular) ventricular rhythms from stable (regular) ventricular rhythms. This is accomplished by measuring the degree of variability of the tachycardia R–R intervals.

This degree of variability, when used alone, may allow the device to distinguish conducted AF (which may produce greater R–R variability) from monomorphic VT (which is typically stable). It also may be used to differentiate MVTs (which are pace terminable) from polymorphic VTs and VF (which are typically not pace terminable).

Based on the patient's needs, you may choose to program Stability as an inhibitor to prevent therapy for AF, or use stability analysis to direct the type of therapy to be delivered (Shock if Unstable).

The stability algorithm calculates RV R–R interval differences. These differences are calculated throughout Duration; an average difference is also calculated. When Duration expires, rhythm stability is evaluated by comparing the current average difference to the programmed Stability threshold and/or Shock If Unstable thresholds. If the average difference is greater than the programmed thresholds, the rhythm is declared unstable. Independent thresholds are available for the Stability (to inhibit) or Shock If Unstable functions; you cannot program both in the same ventricular zone.

The pulse generator performs stability calculations for all episodes (even when Stability is programmed to Off) and stores the results in therapy history. This stored data may be used to select an appropriate stability threshold.

Stability to Inhibit

The Stability parameter may help you identify rapid rhythms originating in the atrium, such as AF. These rhythms may result in unstable ventricular rhythms whose rate exceeds the lowest rate threshold and should not be treated. If a rhythm is declared stable when Duration expires, programmed therapy will be delivered. If the rhythm is declared unstable, ventricular therapy will be inhibited.

At the end of initial Duration, if a tachycardia is declared unstable and ventricular therapy is inhibited, the pulse generator continues to evaluate for stability on each new detected interval (Figure 3-19 on page 3-32). Therapy will not be inhibited by Stability if:

- V Rate > A Rate declares the ventricular rate greater than the atrial rate
- The SRD has expired (if programmed to On)

Ventricular therapy is not always initiated when no longer inhibited by Stability. Therapy may continue to be inhibited by other programmed detection enhancements, such as Onset (when the Onset/Stability detection enhancement suite is enabled) or Vector Timing and Correlation (when the Rhythm ID detection enhancement suite is enabled).

NOTE: *Ventricular Therapy can also be inhibited through analysis of the Stability algorithm as it is used with the AFib Rate Threshold enhancement.*

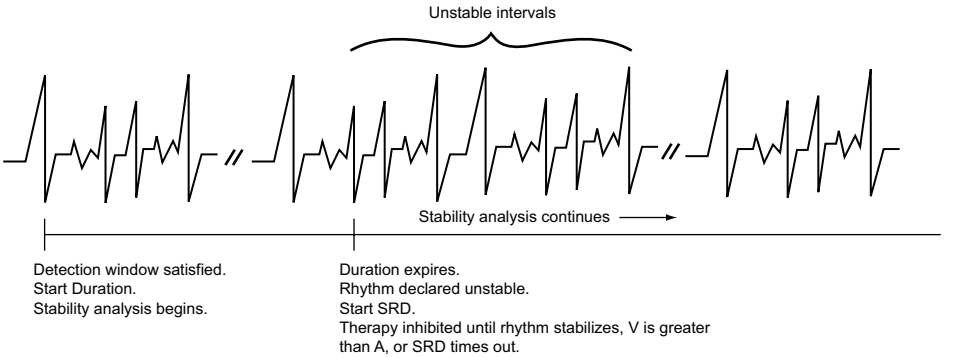


Figure 3-19. Stability evaluation when Duration expires

Shock if Unstable

When programmed to Shock if Unstable, the stability analysis helps determine if ventricular ATP therapy should be bypassed in preference for the first programmed ventricular shock therapy (which may be low- or high-energy) for the ventricular zone (Figure 3-20 on page 3-33).

Dynamic ventricular arrhythmias such as polymorphic VT or VF may be sensed at a rate lower than the highest ventricular rate threshold and can be classified as unstable. Since the sensed rhythm may be detected in a lower ventricular zone in which ATP may be programmed, the stability analysis may be used to skip over the programmed ventricular 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 ventricular shock has been delivered in an episode, the Shock If Unstable function no longer affects therapy selection.

Shock If Unstable may be used only in the VT zone of a 2- or 3-zone configuration. You cannot program it in a 2-zone configuration if Stability or Onset is already programmed to On, or if Post V-Shock Stability or AFib Rate Threshold is programmed to On.

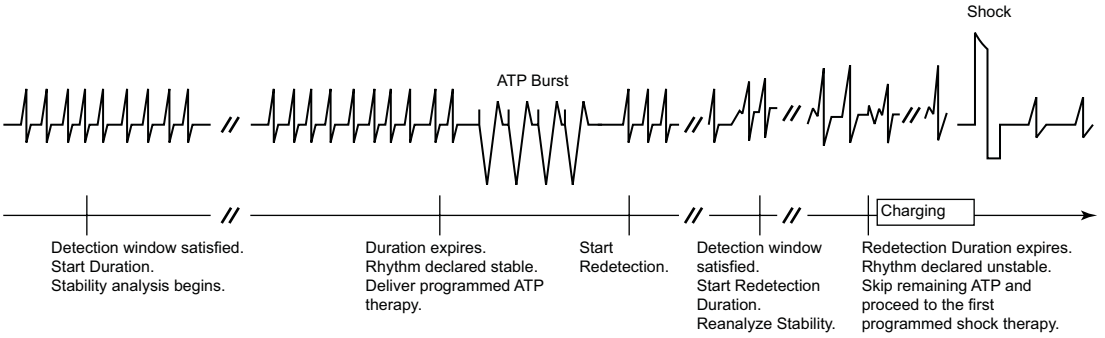


Figure 3-20. Shock if Unstable

Onset

Onset differentiates physiologic sinus tachycardias, which typically begin slowly, from pathologic tachycardias, which typically begin abruptly. It measures the rate of transition in the ventricular rhythm from slow rates to tachycardia. If the rate increase is gradual, it enables the device to inhibit ventricular therapy in the lowest tachycardia rate zone.

When a detection window becomes satisfied, the pulse generator begins calculating for sudden Onset in a two-stage sequence.

- Stage 1 measures the ventricular intervals prior to the start of the episode and locates the pair of adjacent intervals (pivot point) where the cycle length decreased the most. If the decrease in cycle length is equal to or greater than the programmed Onset value, stage 1 declares sudden Onset.

- Stage 2 then compares additional intervals. If the difference between the average interval before the pivot point and 3 out of the first 4 intervals following the pivot point is equal to or greater than the programmed Onset Threshold, stage 2 declares sudden Onset.

If both stages declare the rhythm sudden, therapy will be initiated. If either stage indicates a gradual onset, initial ventricular therapy will be inhibited in the lowest zone. Therapy will not be inhibited by Onset if:

- The rate accelerates to a higher ventricular zone

- Information from the atrial lead determines that the RV rate is faster than the atrial rate (V Rate > A Rate programmed to On)

- The SRD timer expires

Onset is measured using RV intervals only. It can be programmed as a percentage of cycle length or as an interval length (in ms). It is limited to the lowest therapy zone of a multi-zone configuration. The selected Onset value represents the minimum difference that must exist between intervals that are above and below the lowest programmed rate threshold. The pulse generator performs Onset calculations (even when the feature is programmed to Off) for all episodes except induced or commanded episodes. The measured Onset results from a two-stage calculation are stored in therapy history. This stored data may be used to program an appropriate Onset value.

Sustained Rate Duration (SRD)

Sustained Rate Duration allows delivery of the programmed ventricular therapy when a tachycardia is sustained for a programmed period beyond Duration, but the programmed therapy inhibitors (Vector Timing and Correlation, AFib Rate Threshold, Onset, and/or Stability) indicate to withhold therapy (Figure 3-21 on page 3-35).

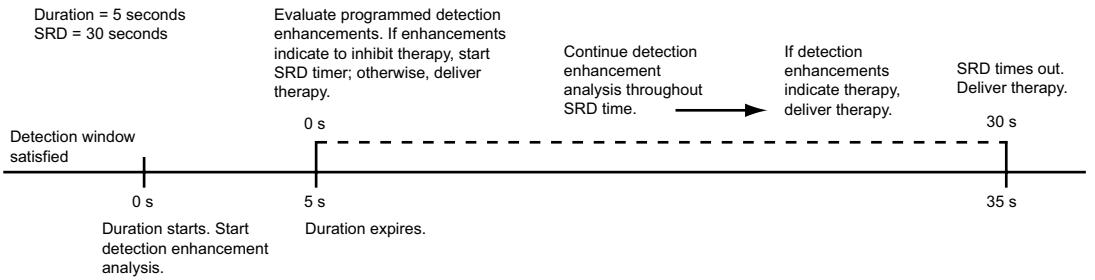


Figure 3-21. Combination of Onset OR Stability, SRD programmed on

SRD is available in a zone only when an inhibitor enhancement is programmed on in that zone. When the Rhythm ID detection enhancement suite is enabled, SRD may be programmed separately for the VT and VT-1 zones.

- If an inhibitor is withholding ventricular therapy delivery and the Rate criterion in the lowest zone is maintained, the programmed SRD timer begins at the end of the first zone's completed Duration.

- If the detection window in the lowest zone is maintained for the programmed SRD period, the programmed ventricular therapy will be delivered at the end of the VT-1 SRD period if VT-1 SRD is programmed and the rhythm is in the VT-1 zone. Therapy will be delivered at the end of the VT SRD period if VT SRD is programmed and the rhythm is in the VT zone.

- If the rate accelerates to a higher ventricular zone, detection enhancements are not programmed to On in the higher zone, and the Duration for the higher zone expires, therapy is initiated in that zone without waiting for SRD time-out in a lower ventricular zone. If SRD is programmed to Off, an SRD timer will not start when Duration expires, thus allowing detection enhancements to potentially inhibit therapy indefinitely.

An independent Post-Shock SRD value may be programmed.

Combinations of AFib Rate Threshold, Stability, and Vector Timing and Correlation

The combination of AFib Rate Threshold, Stability, and Vector Timing and Correlation add specificity to ventricular detection beyond rate and duration. In addition to using AFib Rate Threshold and Stability to identify AF, this combination of enhancements uses Vector Timing and Correlation analysis to differentiate SVT rhythms from VT rhythms based on conduction patterns within the heart.

The AFib Rate Threshold, Stability, and Vector Timing and Correlation detection enhancement combination also includes V Rate > A Rate; both AFib Rate Threshold and V Rate > A Rate are enabled when Atrial Tachyarrhythmia Discrimination is programmed to On. This combination is only available when the Rhythm ID detection enhancement suite is enabled, and only for Initial Detection (Table 3-11 on page 3-36).

If V Rate > A Rate is programmed to On (by programming Atrial Tachyarrhythmia Discrimination to On) and is True, it will take precedence over all inhibitor enhancements.

Table 3-11. AFib Rate Threshold, Stability, and Vector Timing and Correlation combinations and resulting therapy decision if Atrial Tachyarrhythmia Discrimination is programmed to On

Detected Ventricular Rhythm[a b c]	Therapy Decision[d]
Correlated, Unstable, A > AFib Rate Threshold	Inhibit
Correlated, Unstable, A < AFib Rate Threshold	Inhibit
Uncorrelated, Unstable, A > AFib Rate Threshold	Inhibit
Uncorrelated, Unstable, A < AFib Rate Threshold	Treat
Correlated, Stable, A > AFib Rate Threshold	Inhibit
Correlated, Stable, A < AFib Rate Threshold	Inhibit
Uncorrelated, Stable, A > AFib Rate Threshold	Treat
Uncorrelated, Stable, A < AFib Rate Threshold	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. If a Rhythm ID reference template is not available, the detected ventricular rhythm is considered to be Uncorrelated.
c. For post shock detection (if enabled), Vector Timing and Correlation is considered to be Uncorrelated.
d. Decisions to inhibit can be overridden by V > A or expiration of SRD.

When Atrial Tachyarrhythmia Discrimination is programmed to Off, then Vector Timing and Correlation is used for Initial Detection and Stability is used for Post-shock detection. V Rate > A Rate and AFib Rate Threshold are no longer used (Table 3-12 on page 3-36).

Table 3-12. Vector Timing and Correlation and Stability combinations with resulting therapy decision if Atrial Tachyarrythmia Discrimination is programmed to Off

Detection[a b]	Dectected Ventricular Rhythm[a c]	Therapy Decision
Initial	Correlated	Inhibit[d]
Initial	Uncorrelated	Treat

Table 3-12. Vector Timing and Correlation and Stability combinations with resulting therapy decision if Atrial Tachyarrythmia Discrimination is programmed to Off (continued)

Detection[a] [b]	Dectected Ventricular Rhythm[a] [c]	Therapy Decision
Post-shock	Unstable	Inhibit[d]
Post-shock	Stable	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. If Atrial Tachyarrhythmia Discrimination is programmed to Off, then Vector Timing and Correlation is used for Initial Detection, and Stability is used for Postshock Detection.
c. If a Rhythm ID reference template is not available, the detected ventricular rhythm is considered to be Uncorrelated.
d. Decision to inhibit can be overridden by expiration of SRD.

Combinations of AFib Rate Threshold, Stability, and Onset

The combination of AFib Rate Threshold, Stability, and Onset add specificity to ventricular detection beyond rate and duration. This combination of detection enhancements is available only when the Onset/Stability detection enhancement suite is enabled and is available only for Initial Detection. When detection enhancements are enabled, they will act to recommend or inhibit therapy for a specific zone.

If AFib Rate Threshold, Stability, and Onset parameters are all programmed to On, ventricular therapy will be initiated if the rhythm has a sudden onset provided that either the ventricular rate is stable or the atrial rate is less than the AFib Rate Threshold (Table 3-13 on page 3-37).

Table 3-13. AFib Rate Threshold, Stability, and Onset combinations and resulting ventricular therapy

Detected Ventricular Rhythm[a]	Therapy Decision[b]
Gradual, Unstable, A > AFib Rate Threshold	Inhibit
Gradual, Unstable, A < AFib Rate Threshold	Inhibit
Sudden, Unstable, A > AFib Rate Threshold	Inhibit
Sudden, Unstable, A < AFib Rate Threshold	Treat[c]
Gradual, Stable, A > AFib Rate Threshold	Treat
Gradual, Stable, A < AFib Rate Threshold	Inhibit
Sudden, Stable, A > A Fib Rate Threshold	Treat
Sudden, Stable, A < AFib Rate Threshold	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. Decisions to inhibit can be overridden by V > A or expiration of SRD.
c. If V Rate > A Rate is programmed to On and is False, ventricular therapy will be inhibited because the rhythm is unstable.

If V Rate > A Rate is programmed to On and is True, it will take precedence over all inhibitor enhancements.

Combinations of Onset and Stability

When Stability is programmed to inhibit, it may be combined with Onset to provide even greater specificity in classifying arrhythmias.

This combination of detection enhancements is available only when the Onset/Stability detection enhancement suite is enabled and is available only for Initial Detection. The enhancements can be programmed to initiate ventricular therapy if the following options are selected (Table 3-14 on page 3-38):

- Both Onset And Stability indicate to treat
- Either Onset Or Stability indicates to treat

Based on these programming decisions, ventricular therapy is inhibited when any of the following criteria is met:

- If the combination programmed is Onset And Stability, ventricular therapy is inhibited if either parameter indicates that therapy should be withheld; that is, the rhythm is gradual Or unstable (the And condition to treat is not satisfied).
- If the combination programmed is Onset Or Stability, ventricular therapy is inhibited immediately at the end of Duration only if both parameters indicate that therapy should be withheld; that is, the rhythm is gradual and unstable (the Or condition to treat is not satisfied).

In either case, ventricular therapy will be initiated only if the And/Or conditions to treat are satisfied. When these two combinations (And/Or) are used in conjunction with SRD, and the And/Or conditions are not satisfied, ventricular therapy will be inhibited until V Rate > A Rate is True or SRD times out (Table 3-14 on page 3-38).

Table 3-14. Combinations of Onset And Stability and resulting therapy

Detection Rhythm	Onset And Stability Combination[a] [b]	Onset Or Stability Combination[c]
Gradual, unstable	Inhibit	Inhibit
Gradual, stable	Inhibit	Treat

Table 3-14. Combinations of Onset And Stability and resulting therapy (continued)

Detection Rhythm	Onset And Stability Combination[a] [b]	Onset Or Stability Combination[c]
Sudden, unstable	Inhibit	Treat
Sudden, stable	Treat	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. The And combination is the nominal setting when both are enabled.
c. Decisions to inhibit can be overridden by V > A or expiration of SRD.

TACHYARRHYTHMIA THERAPY

CHAPTER 4

This chapter contains the following topics:

- "Ventricular Therapy" on page 4-2
- "Antitachycardia Pacing Therapies and Parameters" on page 4-10
- "Ventricular Shock Therapy and Parameters" on page 4-21

VENTRICULAR THERAPY

The pulse generator can deliver the following types of therapy to terminate VT or VF:

- Antitachycardia pacing (ATP)
- Cardioversion/defibrillation shocks

ATP pacing schemes are bursts of pacing pulses delivered between the ventricular pace/sense electrodes. Shocks are high-voltage biphasic pulses delivered through the shocking electrodes synchronously with detected heart activity.

Ventricular Therapy Prescription

A ventricular therapy prescription determines the type of therapy to be delivered in a particular ventricular rate zone. It consists of ventricular ATP and/or shocks. Each ventricular zone may be programmed with independent ventricular therapy prescriptions (Figure 4-1 on page 4-2).

Within each zone, therapy strength must be in ascending order.

Lowest strength → Highest strength

Between zones, therapy strengths are not restricted.

Zone	ATP1[2]	ATP2[2]	QUICK CONVERT ATP	Shock 1[1]	Shock 2[1]	Remaining (Maximum) Shocks[1]
VF	Not available		On/Off	0.1-max J	0.1-max J	max J
VT	All ATP types available	All ATP types available	N/A	0.1-max J	0.1-max J	max J
VT-1	All ATP types available	All ATP types available	N/A	0.1-max J	0.1-max J	max J

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

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

Figure 4-1. Ventricular therapy prescription, 3-zone configuration

The therapies within a ventricular zone must be ordered in ascending therapy strengths. All ventricular 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 by the programmed energy. In a multi-zone configuration, therapies in a higher ventricular zone may be of lesser, greater, or equal strength to those in a lower ventricular zone; however, within each zone the therapies must be programmed in equal or increasing energy output.

Ventricular Therapy Selection

The pulse generator determines which ventricular therapy to deliver based on the following rules:

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

- Each ventricular ATP scheme (which may consist of multiple bursts) can only be delivered once during a ventricular episode.

- Up to 8 shocks may be delivered in a ventricular episode. The first 2 shocks are programmable. The following maximum-energy, non-programmable shocks are available in each zone:

  – VT-1 zone: 3 maximum-energy shocks
  – VT zone: 4 maximum-energy shocks
  – VF zone: 6 maximum-energy shocks

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

Based on initial ventricular detection criteria, the pulse generator selects the first prescribed therapy in the ventricular zone in which the tachyarrhythmia is detected (i.e., detection is met; see "Ventricular Detection" on page 3-6). 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 ventricular 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 ventricular zone, the next programmed therapy in that zone is selected and delivered (Figure 4-2 on page 4-4), followed again by redetection. If the arrhythmia persists in the same zone, the therapy will progress in that zone.

- If an arrhythmia crosses ventricular zones (accelerates or decelerates) following therapy delivery and is redetected in a higher or lower ventricular zone, a therapy of equal or greater strength than the previously delivered therapy is selected from the detected zone and delivered (Figure 4-3 on page 4-5 through Figure 4-10 on page 4-8). For shock therapy, the pulse generator determines which shock to deliver prior to capacitor charging based on the detected rate threshold. If during capacitor charging, the tachyarrhythmia accelerates or decelerates from the initial detected rate, the predetermined energy will still be delivered.

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

Zone	ATP1	ATP2	QUICK CONVERT ATP	Shock 1	Shock 2	Remaining Shocks
VF			On/Off	5 J	11 J	max max max max max max
VT	Burst	Scan	N/A	3 J	9 J	max max max max
VT-1	① Burst	② Ramp	N/A	③ 0.1 J	④ 2 J	⑤ ⑥ ⑦ max max max

Figure 4-2. Therapy delivery progression, arrhythmia remains in same zone as initially detected

After each redetection cycle, therapy delivery progresses in the direction indicated by the circled numbers (Figure 4-3 on page 4-5 through Figure 4-10 on page 4-8).

- Upward sloping lines indicate acceleration of the arrhythmia to a higher ventricular zone

- Downward sloping lines indicate deceleration into a lower ventricular zone

The lowest strength therapy is in the ATP columns; the therapy strengths increase as you move to the right in the table.

NOTE: *In the VT-1 zone of a 3-zone configuration or the VT zone of a 2-zone configuration, one or two ATP schemes may be programmed as the only therapy, with all shocks in the lowest zone programmed to Off. If those pacing schemes do not terminate an arrhythmia detected in the VT-1 zone, no further therapy will be delivered in the episode unless the rate is redetected in a higher zone.*

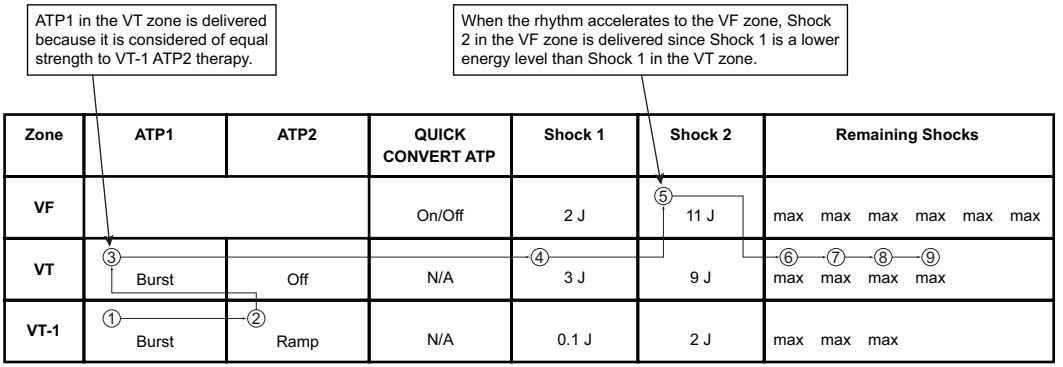


Figure 4-3. Therapy delivery progression, ATP1 in the VT zone and shock 2 in the VF zone

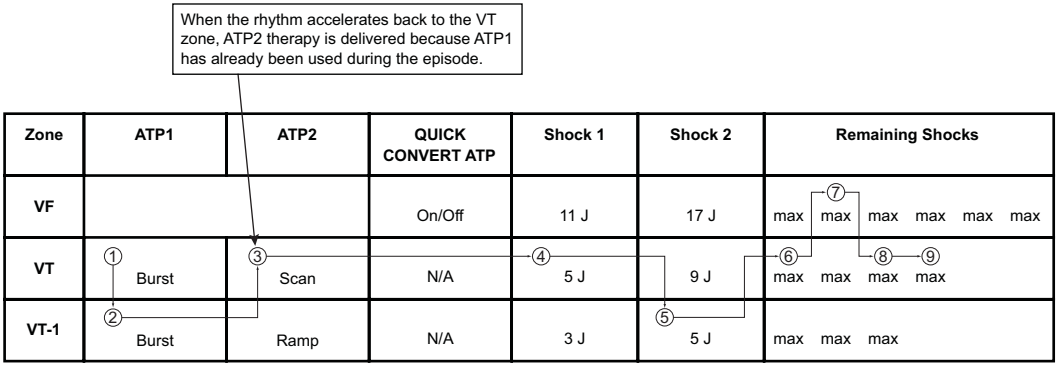


Figure 4-4. Therapy delivery progression, ATP2 therapy

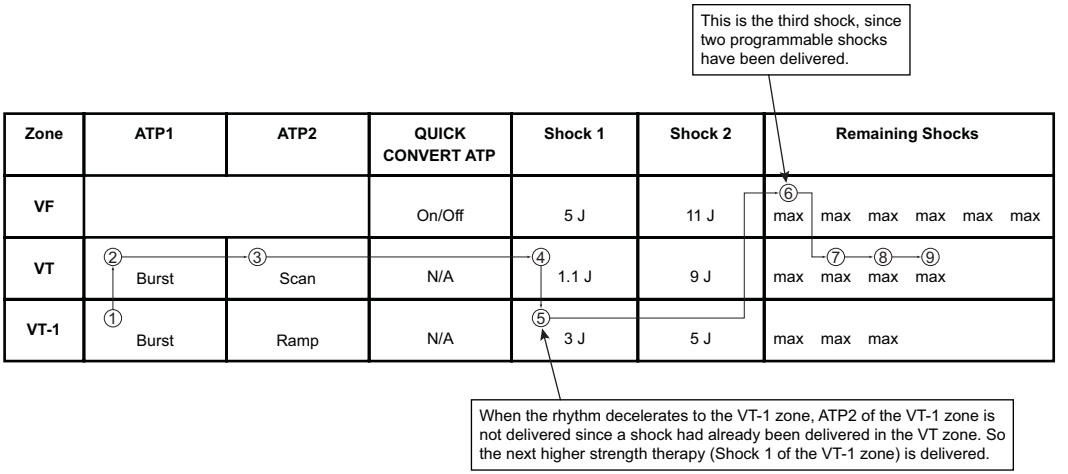


Figure 4-5. Therapy delivery progression, shock 1 in the VT-1 zone

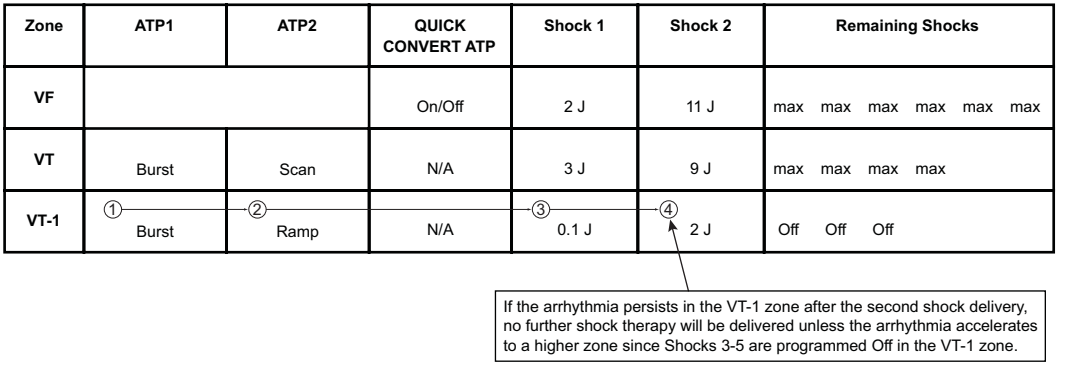
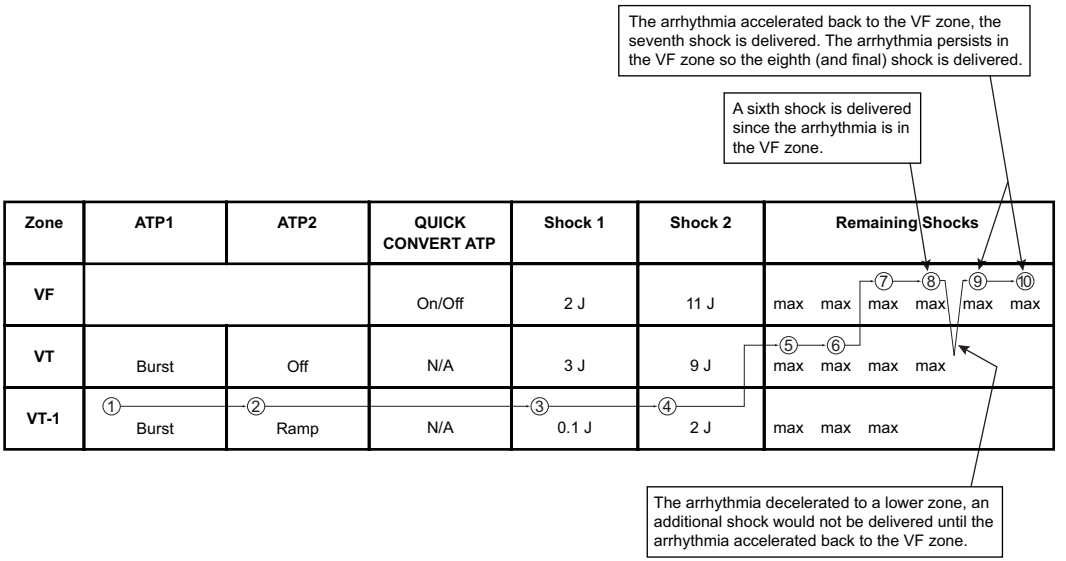
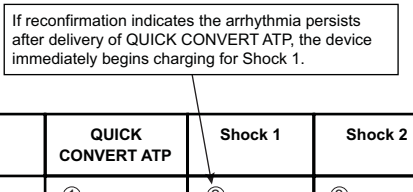


Figure 4-6. Therapy delivery progression, shocks 3 to 5 programmed to Off in the VT-1 zone



Zone	ATP1	ATP2	QUICK CONVERT ATP	Shock 1	Shock 2	Remaining Shocks
VF			On/Off	2 J	11 J	max max max max max max
VT	Burst	Off	N/A	3 J	9 J	max max max max
VT-1	① Burst	② Ramp	N/A	③ 0.1 J	④ 2 J	max max max

Figure 4-7. Therapy delivery progression, sixth shock delivered



Zone	ATP1	ATP2	QUICK CONVERT ATP	Shock 1	Shock 2	Remaining Shocks
VF			① On	② 11 J	③ 21 J	max max max max max max
VT	Burst	Scan	N/A	3 J	9 J	max max max max
VT-1	Burst	Ramp	N/A	0.1 J	2 J	max max max

Figure 4-8. Therapy delivery progression, QUICK CONVERT ATP and shock in the VF zone

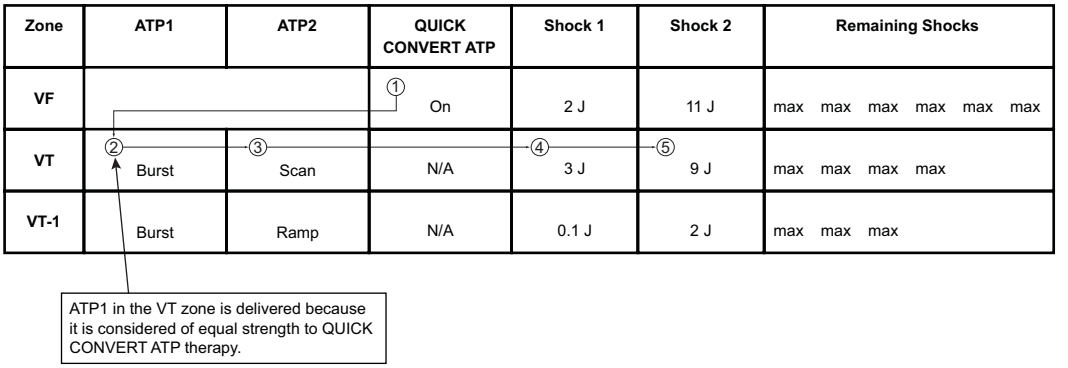


Figure 4-9. Therapy delivery progression, QUICK CONVERT ATP decelerates the rhythm, ATP1 and shock delivered in the VT zone

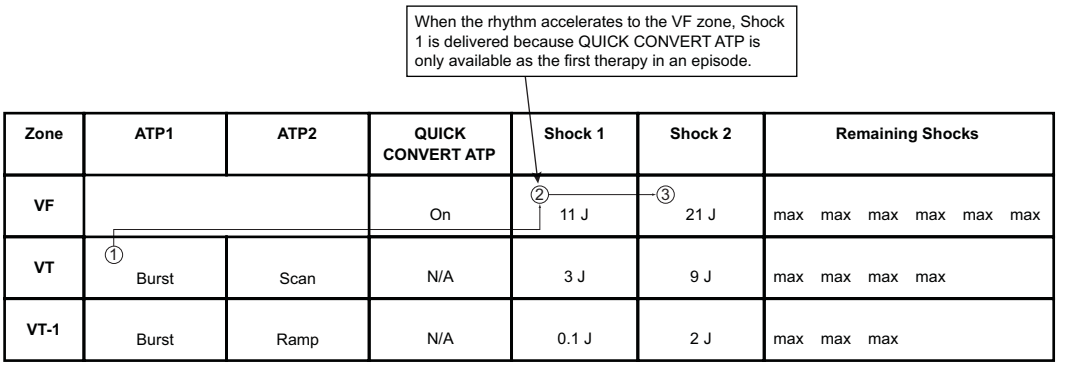


Figure 4-10. Therapy delivery progression, ATP1 in VT zone accelerates the rhythm, QUICK CONVERT ATP is skipped in VF zone

Ventricular Redetection after Ventricular Therapy Delivery

After ventricular therapy delivery, the pulse generator uses 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.

Ventricular Redetection after Ventricular ATP Therapy

Ventricular Redetection after ventricular ATP therapy determines if an arrhythmia has been terminated.

As a ventricular ATP scheme is delivered, the pulse generator monitors the cardiac rate after each burst and uses ventricular detection windows (looking

for 8 of 10 fast intervals) and the Ventricular Redetection Duration to determine if the arrhythmia has terminated.

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

- Redetection declares that the therapy has been successful (end-of-episode)
- The specified number of ATP bursts in the scheme has been delivered
- The ATP Time-out for the ventricular zone has expired
- The detected ventricular arrhythmia rate changes to a different ventricular rate zone, whereby a different therapy is selected
- Shock If Unstable forces the device to skip the remaining ATP therapy and initiate shock therapy
- A DIVERT THERAPY command is received from the PRM during delivery of a burst of a scheme
- A magnet abort occurs during delivery of a scheme
- The temporary Tachy Mode has changed
- A commanded therapy is requested
- The episode ends due to reprogrammed Tachy Mode, reprogrammed ventricular tachy parameters, or attempted induction method or lead test

NOTE: *Aborting an ATP burst terminates the affected ATP scheme. If further therapy is required, the next programmed therapy (either ATP or shocks) in the prescription is initiated.*

Ventricular Redetection after Ventricular Shock Therapy

Ventricular redetection after ventricular shock therapy determines if an arrhythmia has been terminated.

As shock therapy is delivered, the pulse generator monitors the cardiac rate after each shock and uses ventricular detection windows (looking for 8 of 10 fast intervals) and post-shock detection enhancements, if applicable, to

determine if the arrhythmia has been terminated. Shock therapy will continue until one of the following conditions is satisfied:

- Redetection declares the therapy has been successful (end-of-episode)
- All available ventricular shocks have been delivered for an episode
- The rhythm is redetected in either the VT or VT-1 zone, the available number of programmed shock(s) in those zones has been delivered and the arrhythmia stays in one of these lower zones

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

Antitachycardia Pacing (ATP) therapy and parameters enable the pulse generator to interrupt the following fast rhythms by delivering a series of critically timed pacing pulses:

- Monomorphic ventricular tachycardia
- Supraventricular tachycardias

ATP Therapy is delivered when the last sensed event fulfills the programmed detection criteria (Figure 4-11 on page 4-11).

An ATP scheme may be customized with the following parameters:

- Number of bursts delivered
- Number of pulses within each burst
- Coupling Interval
- Burst Cycle Length
- Minimum pacing interval

These parameters can be programmed to produce the following ATP therapy schemes:

- Burst
- Ramp
- Scan

- Ramp/Scan

The ATP amplitude and pulse width are common to all schemes. They are independently programmable from the normal pacing settings. The ATP amplitude and pulse width share the same programmable value as the post-therapy pacing settings.

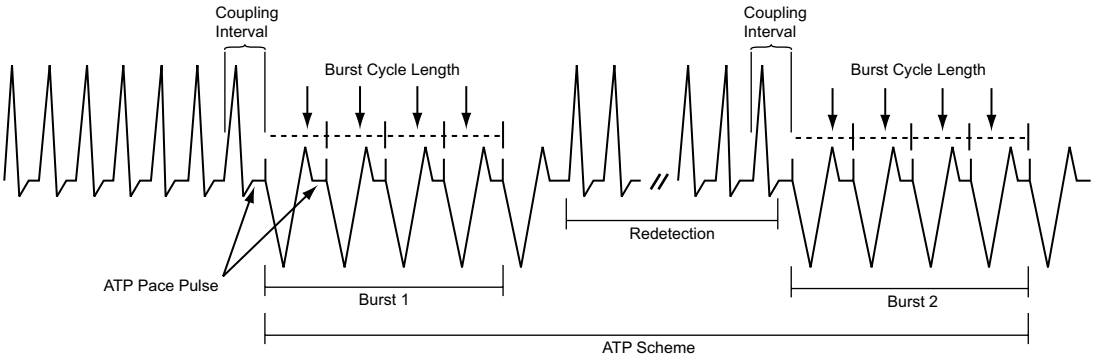


Figure 4-11. ATP therapy basic parameters are Coupling Interval, Burst Cycle Length, Number of Bursts, and Number of Pulses within each burst.

Burst Parameters

A burst is a series of critically timed pacing pulses delivered by the pulse generator during ATP therapy. By programming burst parameters, you can optimize ATP therapy for the patient.

All ATP schemes have several parameters in common. In addition to programming the type of scheme (Off, Burst, Ramp, Scan, Ramp/Scan), the following burst parameters are programmable (Figure 4-12 on page 4-12):

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

- The Initial Pulse Count parameter determines the number of pulses delivered in the first burst of a scheme.

- The Pulse Increment parameter determines the number of pulses per burst to be increased for each successive burst in the scheme.

- The Maximum Number of Pulses parameter determines the greatest number of pulses used in an ATP burst and may be programmed independently for each ATP scheme. After the maximum number of pulses is reached in a burst, each additional burst remaining in the scheme contains the programmed Maximum Number of Pulses. The parameter is available only if the Pulse Increment is greater than zero.

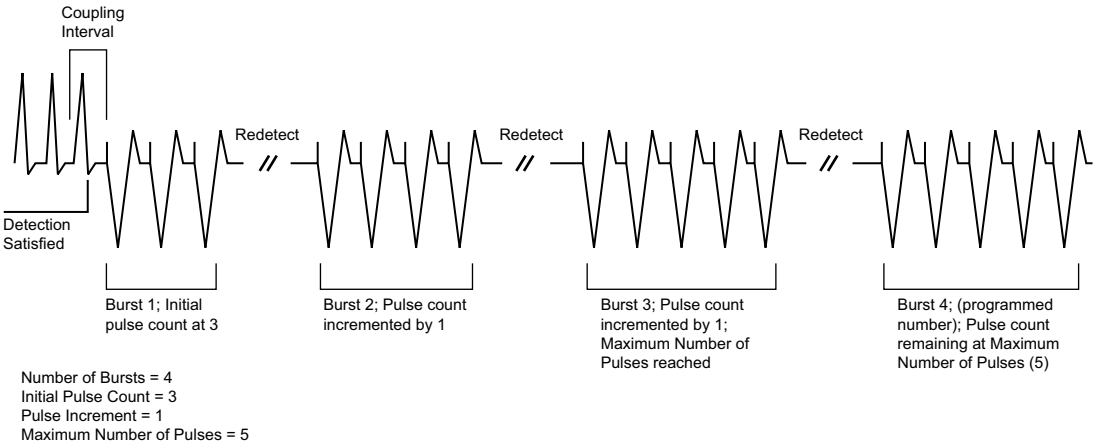


Figure 4-12. Interaction of Maximum Number of Pulses and Number of Bursts

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 pulse in a burst.

The Coupling Interval is programmed independent from the Burst Cycle Length. This allows aggressive ramps and scans to be used without compromising capture of the first pacing pulse in a burst. The Coupling Interval can be programmed as any of the following:

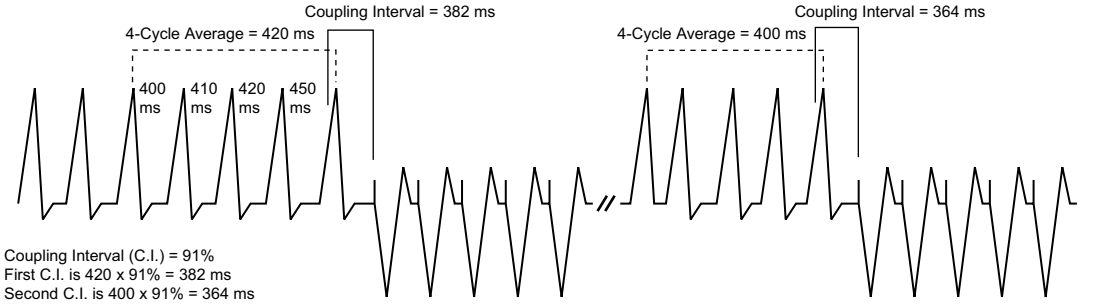
- Adaptive, with timing specified as percentages of the computed average heart rate

- A fixed interval, with timing specified in absolute time (ms) independent of the measured average rate

When programmed as adaptive, the Coupling Interval adjusts to the patient's rhythm based on a four-cycle average (Figure 4-13 on page 4-13). The Coupling Interval Decrement may be programmed such that the Coupling

Interval decreases from one burst to the next within a multiple-burst scheme (Figure 4-14 on page 4-13).

NOTE: *You cannot program an ATP burst that lasts longer than 15 seconds. The length of an adaptive burst is calculated based on the interval of the ventricular zone in which the ATP is programmed, which means it is based on worst-case timing.*



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

Figure 4-13. Adaptive Coupling Interval, Coupling Interval Decrement and Scan Decrement programmed to 0

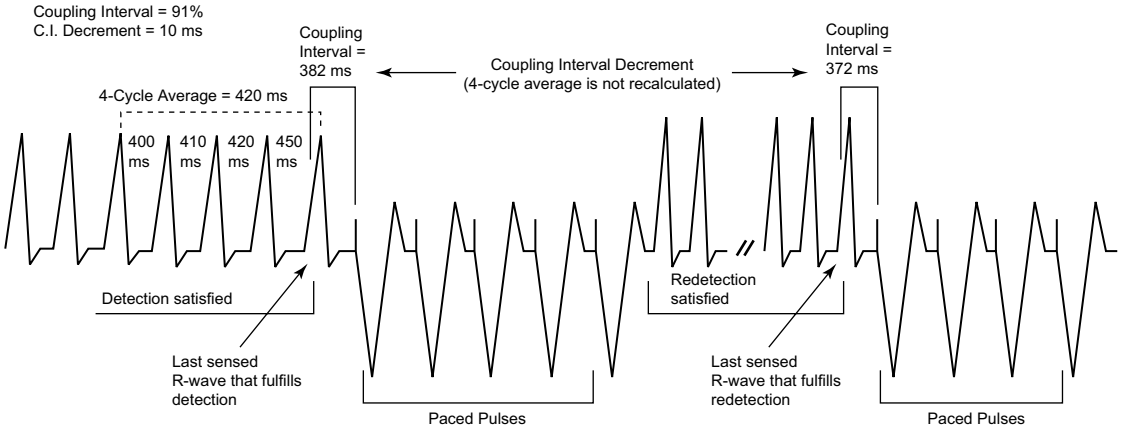


Figure 4-14. Coupling Interval Decrement

The following information should be taken into consideration when programming the Coupling Interval and Coupling Interval Decrement:

- When the Coupling Interval Decrement is programmed to On, the programmed ATP scheme is called a Scan

- When the Coupling Interval is programmed as adaptive, the Coupling Interval will not re-adapt following redetection when the following are programmed to On (greater than zero):
  - Coupling Interval Decrement—the decrement value determines the timing of the first pulse in subsequent bursts
  - Scan Decrement—the decrement value determines the timing of the second pulse in subsequent bursts

Burst Cycle Length (BCL)

The Burst Cycle Length controls the interval between pacing pulses after the Coupling Interval.

This timing is controlled in the same fashion as the Coupling Interval: rate adaptive to the sensed tachycardia or fixed time specified in 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 are programmed to On.*

The following parameters may be programmed to decrement the burst cycle length during an ATP scheme:

- Ramp Decrement controls the pulse timing within a given burst
- Scan Decrement controls the pulse timing between bursts

Minimum Interval

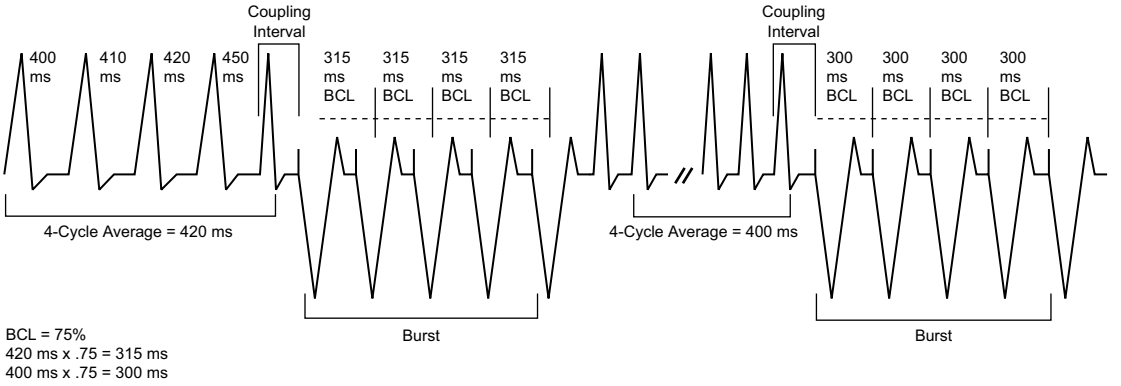
The Minimum Interval limits the Coupling Interval and the BCL in Burst, Ramp, and Scan.

If the Coupling Interval reaches the limit, subsequent Coupling Intervals will remain at the minimum value. Likewise, if the BCL reaches the limit, subsequent BCLs will remain at the minimum value. The Coupling Interval and BCL may reach the limit independently.

Burst Scheme

A Burst scheme is a sequence of critically timed pacing pulses intended to interrupt a reentrant loop, usually delivered at a rate faster than the patient's tachycardia.

An ATP scheme is defined as a Burst (as indicated on the PRM screen) when the timing of all pacing intervals within a burst is the same. The first BCL of each Burst is determined by the programmed BCL. When the number of pulses programmed in a Burst is greater than one, you can use the BCL to control the timing between these paced pulses (Figure 4-15 on page 4-15).



The first BCL of each burst is calculated by multiplying the 4-cycle average prior to delivery of the first pacing pulse of the burst by the BCL percentage.

Figure 4-15. Adaptive-rate Burst scheme

Ramp Scheme

A Ramp scheme is a burst in which each paced-to-paced interval within the burst is shortened (decremented).

To program a Ramp scheme, program (in ms) the Ramp Decrement to specify how much the paced-to-paced interval should be shortened, and the Scan Decrement and Coupling Interval Decrement each to 0 ms. As each additional paced pulse in a burst is delivered, its interval is shortened by the programmed Ramp Decrement until either of the following occur:

- The last paced pulse of the burst is delivered
- The Minimum Interval is reached

If subsequent bursts are required, the programmed Ramp Decrement will be applied based on the calculated BCL of that subsequent burst (Figure 4-16 on page 4-16).

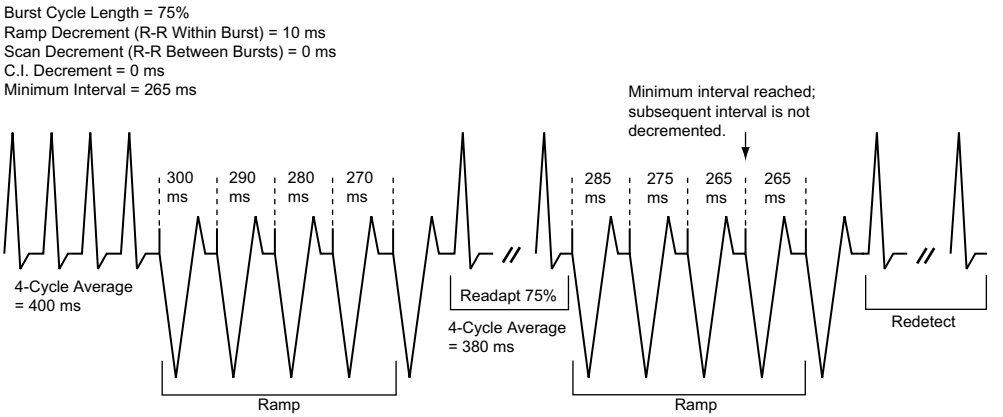
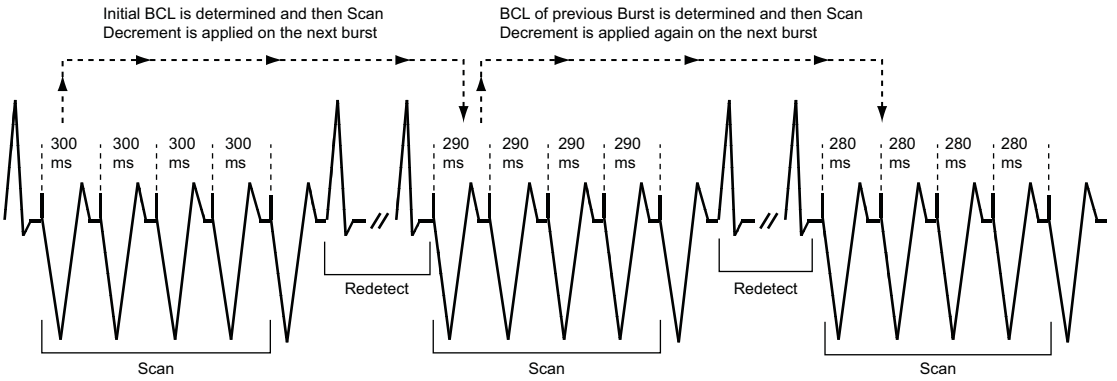


Figure 4-16. Adaptive Ramp Scheme, Coupling Interval Decrement and Scan Decrement programmed to 0

Scan Scheme

A Scan scheme is a burst in which the BCL of each burst in a scheme is systematically shortened (decremented) between successive bursts.

You can program a Scan scheme by programming the Scan Decrement to specify the BCL decrement to a value greater than 0 ms, while the Ramp Decrement is programmed to 0 ms. The BCL of subsequent bursts is determined by subtracting the Scan Decrement from the BCL of the previous burst (Figure 4-17 on page 4-17).

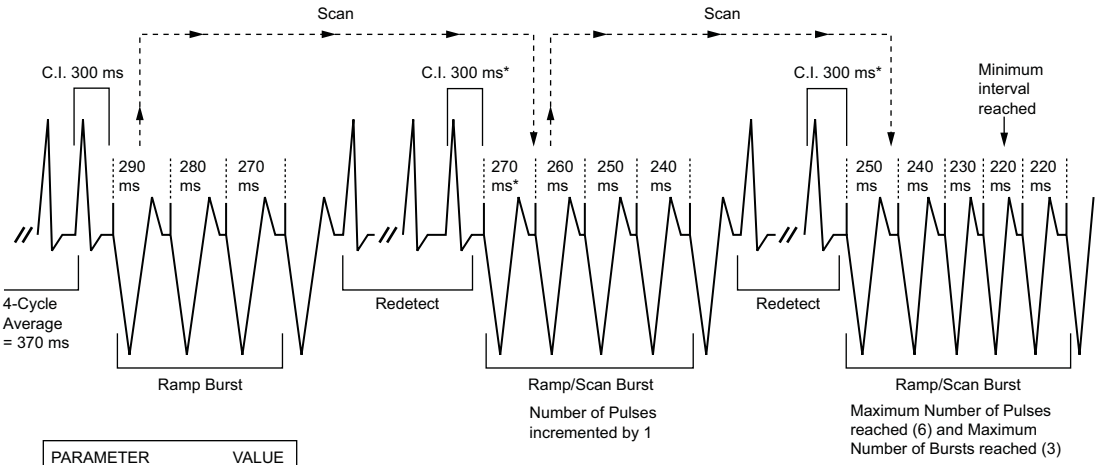


Burst Cycle Length = 300 ms
Scan Decrement = 10 ms
Ramp Decrement = 0 ms
Coupling Interval Decrement = 0 ms

Figure 4-17. Scan scheme, nonadaptive BCL and Scan Decrement programmed on

Ramp/Scan Scheme

A Ramp/Scan scheme is a sequence of bursts. Each scheme contains a Ramp Decrement and a Scan Decrement (Figure 4-18 on page 4-18).



PARAMETER	VALUE
Number of Bursts	3
Pulses per Burst:	
Initial	4
Increment	1
Maximum	6
Coupling Interval	81%
Decrement	0 ms
Burst Cycle Length	78%
Ramp Decrement	10 ms
Scan Decrement	20 ms
Minimum Interval	220 ms

* When a Scan Decrement is programmed to On, the Coupling Interval and BCL, if programmed as a percentage, will not re-adapt following redetection.

Figure 4-18. Ramp/Scan scheme, interaction of ATP parameters

To program a Ramp/Scan scheme, both the Scan Decrement and Ramp Decrement are programmed to values greater than 0 ms.

ATP Pulse Width and ATP Amplitude

The ATP Pulse Width is the duration of a pacing pulse. The ATP Amplitude is the leading edge voltage of a pacing pulse.

The ATP Pulse Width and ATP Amplitude parameters share the same value as the post therapy pacing Pulse Width and Amplitude. If the programmable value is changed for one parameter, that value will be reflected in the other parameters.

The programmed ATP Pulse Width and ATP Amplitude are shared for all ATP schemes regardless of zone and position in a prescription. The ATP amplitude and pulse width share the same programmable value as the post-therapy pacing settings.

Ventricular ATP Time-out

The Ventricular ATP Time-out forces the pulse generator to skip over any remaining ATP therapy in a ventricular zone to begin delivering ventricular shock therapy programmed in the same zone. This parameter is effective only for ventricular therapy delivery.

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

The timer starts when the first burst is delivered and continues until any of the following occur:

- The timer expires (Figure 4-19 on page 4-19)
- A ventricular shock is delivered
- The ventricular episode ends

The time-out is examined after each redetection sequence to determine if further ATP bursts can be delivered. If the time-out has been reached or exceeded, further ATP therapy will not be initiated during that ventricular episode. The time-out will not terminate a burst in process.

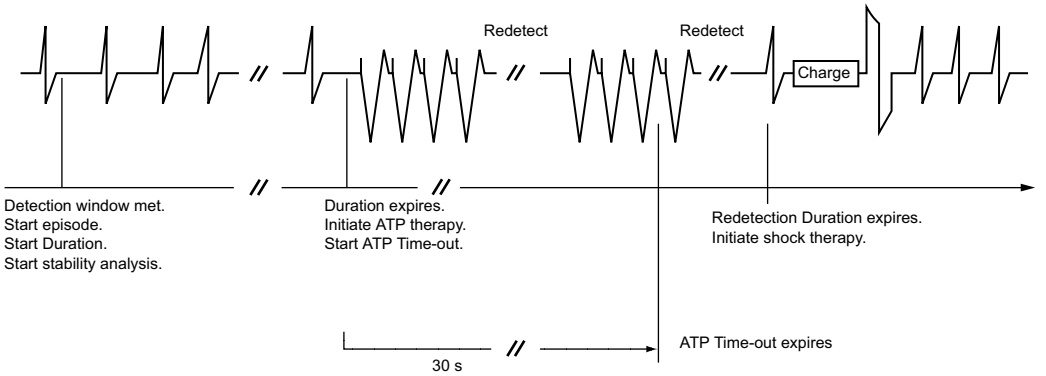


Figure 4-19. ATP Time-out expiration

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

The timer alone does not invoke therapy; the rate and duration criteria and detection enhancements must still be satisfied in order for a shock therapy to be delivered.

If three zones are programmed, you may program ATP Time-out settings in each of the lower two ventricular zones (Figure 4-20 on page 4-20).

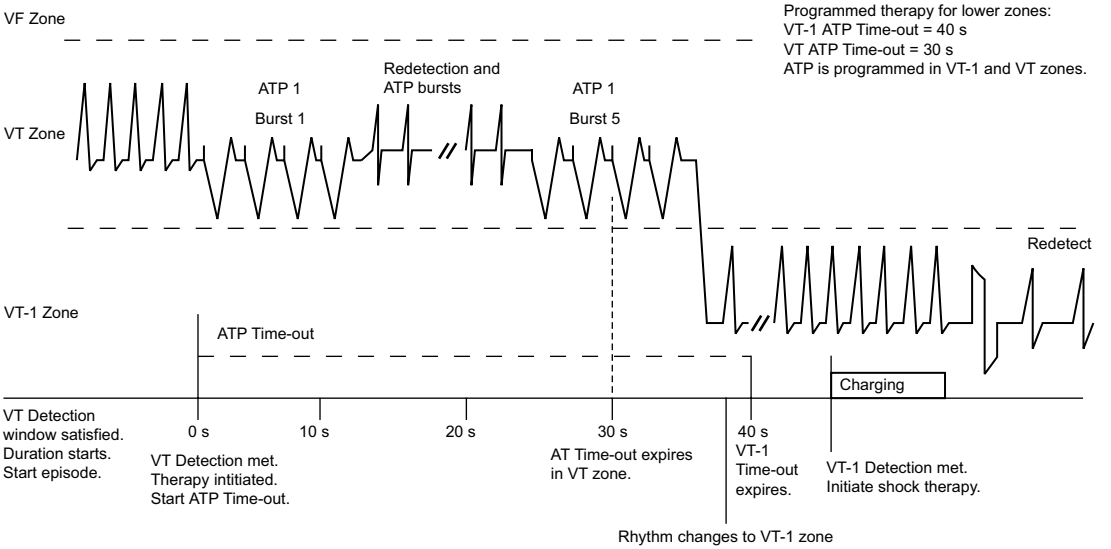


Figure 4-20. ATP Time-outs, 3-zone configuration

QUICK CONVERT ATP

QUICK CONVERT ATP provides you with an additional option to treat fast, monomorphic VT that is detected in the VF zone.

When QUICK CONVERT ATP is programmed to On, the pulse generator delivers one burst of ATP for an episode detected in the VF zone in an attempt to avoid an otherwise scheduled charge and painful shock for a pace-terminable fast VT.

When delivering QUICK CONVERT ATP therapy, the pulse generator delivers one burst of ATP for an episode detected in the VF zone. This therapy consists of 8 pacing pulses at 88% Coupling Interval and 88% BCL. It is delivered only as the first therapy attempted in an episode and is followed by reconfirmation (2 out of 3 intervals faster than the lowest rate threshold) prior to the shock sequence.

In the event that QUICK CONVERT ATP was unsuccessful in converting the rhythm and shock therapy is required, the feature's algorithm minimizes the delay to begin charging. QUICK CONVERT ATP is not applied to any rhythm above a maximum rate of 250 bpm.

VENTRICULAR SHOCK THERAPY AND PARAMETERS

The pulse generator delivers shocks synchronous to a sensed event. The shock vector, energy level, and polarity of the shocks are programmable.

Ventricular Shock Vector

The programmed Ventricular Shock Vector indicates the vector of energy delivery for ventricular shock therapy.

The following programmable configurations are available:

- RV Coil to RA Coil and Can—this vector is also known as the V-TRIAD vector. It uses the metallic housing of the pulse generator as an active electrode ("hot can") combined with the 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.

- RV Coil to Can—this vector uses the metallic housing of the pulse generator as an active electrode ("hot can"). Energy is sent from the distal shocking electrode to the pulse generator case. This configuration should be selected when using a single-coil lead.

- RV Coil to RA Coil—this vector removes the pulse generator case as an active electrode and is also known as a "cold can" vector. Energy is sent from the distal shocking electrode to the proximal electrode. This vector should never be used with a single-coil lead, as a shock will not be delivered.

Ventricular Shock Energy

Ventricular shock energy determines the strength of shock therapy delivered by the pulse generator.

Shock output remains constant over the lifetime of the pulse generator, regardless of changes in lead impedance or battery voltage. The constant

output is accomplished by varying pulse width to adjust to changes in lead impedance.

The first two shocks in each ventricular zone can be programmed to optimize charge time, longevity, and safety margins. The remaining shock energies in each zone are nonprogrammable at the maximum-energy value.

Charge Time

Charge time is the time the pulse generator requires to charge for delivery of the programmed shock energy.

Charge time is dependent on the following:

- Programmed output energy level
- Battery condition
- Condition of the energy storage capacitors

Charge times increase as the pulse generator is programmed to higher energy output levels and as the battery depletes (Table 4-1 on page 4-22).

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 reformed.

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

Energy Stored (J)[a]	Energy Delivered (J)[b]	Charge Time (seconds)[c]
11.0	10.0	1.9
17.0	15.0	2.9
26.0	22.0	4.7
41.0[d]	35.0	8.4

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 electrodes.
c. Charge times shown are at BOL after capacitor re-formation.
d. HE.

Waveform Polarity

Waveform polarity reflects the relationship between the leading edge voltages on the defibrillating output electrodes. All shocks will be delivered using a biphasic waveform (Figure 4-21 on page 4-23).

The selection of the shock polarity applies to all shocks delivered by the device. If the preceding shocks in a zone are unsuccessful, the last shock of that zone will be automatically delivered at an inverted polarity to the previous shock (initial or reversed) (Figure 4-22 on page 4-23).

CAUTION: For IS-1/DF-1 leads, 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 the polarity is switched physically.

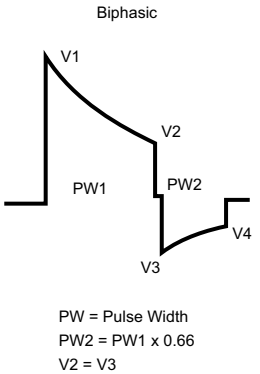
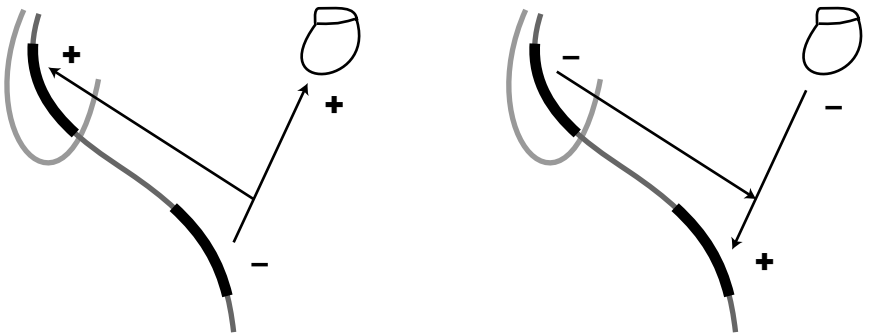


Figure 4-21. Biphasic waveform



Initial polarity Reverse polarity

Figure 4-22. Polarity of shock delivery

Committed Shock/Reconfirmation of the Ventricular Arrhythmia

Committed Shock/Reconfirmation refers to the monitoring performed by the pulse generator before delivery of a ventricular shock.

If the patient is subject to non-sustained arrhythmias, reconfirmation may be desirable in order to prevent delivery of unnecessary shocks to the patient.

The device monitors tachyarrhythmias during and immediately following capacitor charging. During this time, it checks for the spontaneous conversion of the tachyarrhythmia and determines whether ventricular shock therapy should be delivered; it does not affect therapy selection.

Ventricular shock therapy can be programmed as committed or non-committed. If the Committed Shock feature is programmed to On, the shock is delivered synchronously with the first sensed R-wave following a 500-ms delay after the capacitors are charged, whether the arrhythmia is sustained or not (Figure 4-23 on page 4-24). The 500-ms delay allows a minimum time for a divert command to be issued from the PRM, if desired. If there is no sensed R-wave detected within 2 seconds following the end of charging, the ventricular shock is delivered asynchronously at the end of the 2-second interval.

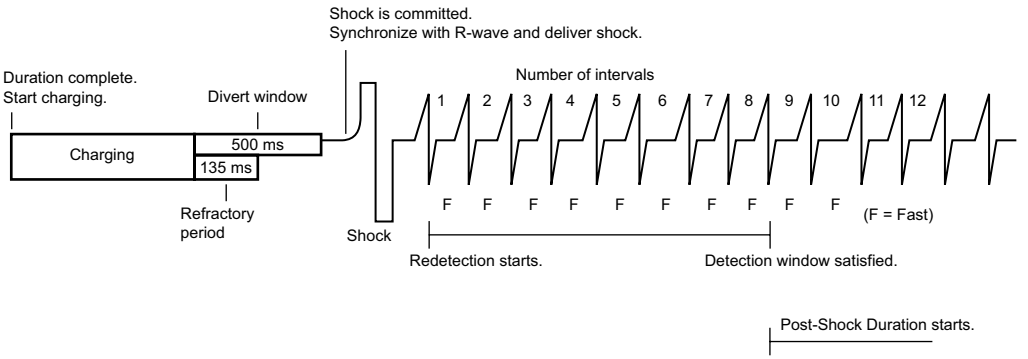


Figure 4-23. Committed Shock is programmed to On, Reconfirmation is Off

NOTE: *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.*

If the Committed Shock feature is programmed to Off, Reconfirmation consists of the following steps:

1. During capacitor charging, the pulse generator continues to sense the arrhythmia. Sensed and paced beats are evaluated. If 5 slow beats (sensed or paced) are counted in a 10-beat detection window (or 4 consecutive slow beats after an unsuccessful QUICK CONVERT ATP attempt), the pulse generator stops charging and considers this a Diverted-Reconfirm.

2. If 5 of 10 beats are not detected as slow (or less than 4 consecutive slow beats after an unsuccessful QUICK CONVERT ATP attempt) and charging completes, post-charge reconfirmation is performed after charging ends. After the post-charge refractory and the first sensed event, the pulse generator measures up to 3 intervals following charging and compares them to the lowest rate threshold.

    - If 2 of the 3 intervals following charging are faster than the lowest rate threshold, the shock will be delivered synchronously with the second fast event.

    - If 2 of the 3 intervals following charging are slower than the lowest rate threshold, the shock will not be delivered. If no beats are sensed, pacing will begin at the programmed LRL following the 2-second no-sense period. If a shock is not delivered, or if pacing pulses are delivered, this is also considered a Diverted-Reconfirm.

If a shock is required after redetection, the charge time for the shock may be short.

The reconfirmation algorithm will not allow two consecutive Diverted-Reconfirm cycles. If the arrhythmia is detected after a Diverted-Reconfirm, the next shock in the episode is delivered as if Committed Shock were programmed to On. Once a shock has been delivered, the reconfirmation algorithm can be applied again (Figure 4-24 on page 4-25).

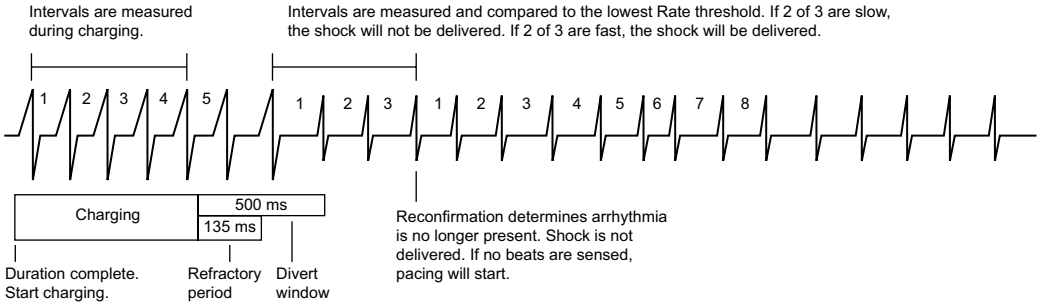


Figure 4-24. Committed Shock is programmed to Off, reconfirmation is On

Boston Scientific

Boston Scientific
4100 Hamline Avenue North
St. Paul, MN 55112–5798 USA

www.bostonscientific.com

1.800.CARDIAC (227.3422)

+1.651.582.4000

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PACING THERAPIES

CHAPTER 5

This chapter contains the following topics:

- "Pacing Therapies" on page 5-2
- "Basic Parameters" on page 5-2
- "Post-Therapy Pacing" on page 5-9
- "Temporary Pacing" on page 5-10
- "Sensors and Trending" on page 5-11
- "Atrial Tachy Response" on page 5-19
- "Rate Enhancements" on page 5-26
- "Lead Configuration" on page 5-31
- "AV Delay" on page 5-32
- "Refractory" on page 5-36
- "Noise Response" on page 5-41
- "Ventricular Tachy Sensing Interactions" on page 5-43

PACING THERAPIES

Single chamber ICDs provide ventricular bipolar (pace/sense) normal and post-therapy bradycardia pacing, including adaptive-rate modes. Dual chamber ICDs provide both atrial and ventricular bipolar (pace/sense) normal and post-therapy bradycardia pacing, including adaptive-rate modes.

The bradycardia pacing function is independent of the tachycardia detection and therapy functions of the device, with the exception of interval-to-interval sensing.

The pulse generator provides the following types of therapies:

Normal Bradycardia Pacing

- If the intrinsic heart rate falls below the programmed pacing rate (i.e., LRL), the device delivers pacing pulses at the programmed settings
- Sensor-based rate modulation allows the pulse generator to adapt the pacing rate to the patient's changing activity levels

Post-Therapy Pacing—alternative bradycardia pacing therapy may be delivered for a programmed period to ensure capture after delivery of a shock.

Additional Options

- **Temporary Bradycardia Pacing**—allows the clinician to examine alternate therapies while maintaining the previously programmed Normal pacing settings in the pulse generator memory.
- **STAT PACE**—initiates emergency ventricular pacing at high output settings when commanded via the PRM using telemetry communication.

BASIC PARAMETERS

Normal Settings include the following:

- Pacing parameters, which are independently programmable from post-therapy and temporary pacing parameters
- Pacing and Sensing
- Leads
- Sensors and Trending

Post-Therapy Settings include the following:

- Pacing parameters, which are independently programmable from normal and temporary pacing parameters
- Post-ventricular shock

Brady Mode

Brady modes provide you with programmable options to help individualize patient therapy.

This pulse generator includes the pacing modes identified in the Programmable Options appendix.

Dual-Chamber Modes

Do not use DDD(R) and VDD(R) modes in the following situations:

- 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 PMT, which cannot be controlled by reprogramming selective parameter values

Atrial Pacing Modes

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

WARNING: Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.

NOTE: *If a separate pacemaker is desired, a dedicated bipolar pacemaker is recommended.*

NOTE: *Refer to "Use of Atrial Information" on page 3-5 for additional information about device performance when the atrial lead is programmed to Off.*

If you have any questions regarding the individualization of patient therapy, contact your sales representative or call Technical Services at the number shown on the back cover of this manual.

Lower Rate Limit (LRL)

LRL is the number of pulses per minute at which the pulse generator paces in the absence of sensed intrinsic activity.

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

- LRL must be less than:
  - MPR
  - MSR
  - MTR (dual-chamber)
- LRL must be at least 15 ppm less than the lowest tachy zone threshold
- The greater of the following values must be at least 10 ppm less than the lowest tachy zone threshold:
  - MPR
  - MSR
  - MTR (dual-chamber)

Runaway Protection

Runaway protection is designed to prevent pacing rate accelerations for most single-component failures. This feature is not programmable and operates independently from the pulse generator's main pacing circuitry.

The basic pulse period is equal to the pacing rate and the pulse interval (without hysteresis). Runaway protection prevents the pacing rate from increasing above 205 ppm.

NOTE: *Magnet application does not affect the pacing rate (pulse interval).*

NOTE: *Runaway protection is not an absolute assurance that runaways will not occur.*

During PES, Manual Burst pacing, and ATP, runaway protection is temporarily suspended to allow for high-rate pacing.

Maximum Tracking Rate (MTR)

The MTR is the maximum rate at which the paced ventricular rate tracks 1:1 with nonrefractory sensed atrial events. MTR applies to atrial synchronous pacing modes, namely DDD(R) and VDD(R).

The following are considerations for programming the MTR:

- Interactive limits ("Lower Rate Limit (LRL)" on page 5-4).
- When the sensed atrial rate is between the programmed LRL and MTR, 1:1 ventricular pacing will occur in the absence of a sensed ventricular event within the programmed AV Delay. If the sensed atrial rate exceeds the MTR, the pulse generator might 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 delay until an occasional P-wave is not tracked because it falls into the PVARP. This results in an 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 (e.g., 5:4, 4:3, 3:2, and finally 2:1).
- The PRM will not allow you to program an MTR interval shorter than TARP (AV Delay + PVARP = TARP). If TARP is less than the interval of the programmed MTR, then the pulse generator's Wenckebach-like behavior limits the ventricular pacing rate to the MTR. With TARP, the PRM does not consider the AV Search AV Delay. If AV Search is on, Wenckebach-like behavior may occur at rates lower than the MTR.
- Rapid changes in the paced ventricular rate (e.g., Wenckebach-like, 2:1 block) caused by sensed atrial rates above the MTR may be dampened or eliminated by the implementation of any of the following:
  - AFR
  - ATR
  - Rate Smoothing parameters and sensor input
  - VRR

Maximum Sensor Rate (MSR)

MSR is the maximum pacing rate allowed as a result of sensor control from accelerometer input.

The following considerations are important when programming MSR:

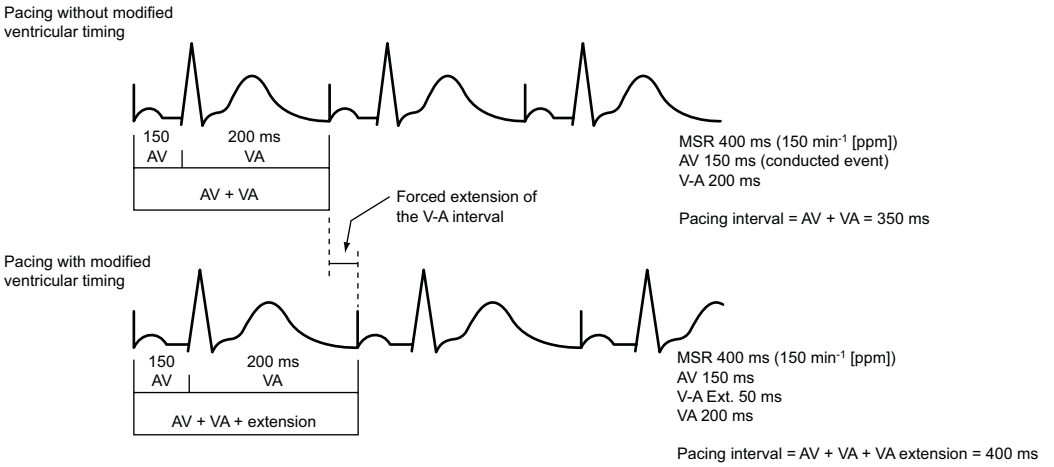
- Patient's condition, age, and general health:
  - Adaptive-rate pacing at higher rates may be inappropriate for patients who experience angina or other symptoms of myocardial ischemia at these higher rates
  - An appropriate MSR should be selected based on an assessment of the highest pacing rate that the patient can tolerate well
- Interactive limits ("Lower Rate Limit (LRL)" on page 5-4)

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

MSR is independently programmable at, above, or below the MTR. If the MSR setting is higher than the MTR, a pacing rate above the MTR may occur in the presence of high activity levels.

Pacing above the MSR can only occur in response to sensed intrinsic atrial activity.

With 1:1 conduction, the pulse generator maintains the A–A pacing rate by extending the V–V pacing rate. This extension is determined by the degree of difference between the AV Delay and the intrinsic ventricular conduction—often referred to as modified atrial-based timing (Figure 5-1 on page 5-7).



The pulse generator's timing algorithm provides effective pacing at the MSR with intrinsic ventricular conduction. Extending the VA interval prevents the A pace from exceeding the MSR at high rates.

Figure 5-1. VA interval extension and MSR

Pulse Width

Pulse Width, also referred to as pulse duration, determines how long the output pulse will be applied between the pacing electrodes.

The following considerations are important when programming Pulse Width:

- Pulse widths are independently programmable.
- 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, exercise caution when you are programming permanent pulse width values of less than 0.3 ms (Figure 5-2 on page 5-8).

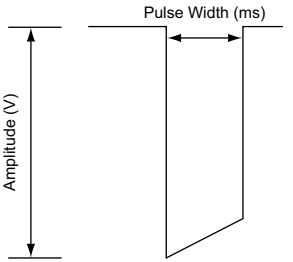


Figure 5-2. Pulse waveform

Amplitude

The pulse Amplitude, or voltage of the output pulse, is measured at the leading edge of the output pulse (Figure 5-2 on page 5-8).

Amplitudes are independently programmable. The following considerations are important:

- During temporary programming, the brady pacing mode may be programmed to Off. In effect, this turns Amplitude off to monitor the patient's underlying rhythm.
- A minimum 2x voltage safety margin is recommended for each chamber based on the capture thresholds, which should provide an adequate safety margin and help preserve battery longevity.
- The energy delivered to the heart is directly proportional to the square of the amplitude. In other words, doubling the amplitude quadruples the energy delivered, which will decrease pulse generator longevity. Programming to a lower Amplitude while maintaining an adequate safety margin may increase battery longevity.

Sensitivity

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

All detection and timing decisions are based on the sensed cardiac cycle length. These pulse generators use an automatic gain control circuit to dynamically adjust the sensitivity.

- High Sensitivity (low value)—when Sensitivity is programmed to a very sensitive setting, the pulse generator may detect signals unrelated to cardiac depolarization (oversensing, such as sensing of myopotentials)

- Low Sensitivity (high value)—when Sensitivity is programmed to a less sensitive setting, the pulse generator may not detect the cardiac depolarization signal (undersensing)

POST-THERAPY PACING

Post-therapy pacing provides alternate pacing therapy following the delivery of any shock.

The pacing mode and pacing therapies used following a shock are the same as the programmed Normal pacing settings.

The following pacing parameters can be programmed independently from the Normal pacing settings:

- Pacing Parameters—LRL, Amplitude, and Pulse Width
- Post Therapy Period

Post-Shock Pacing Delay

The Post-Shock Pacing Delay determines the earliest possible start of post-shock pacing following the delivery of a ventricular shock and is fixed at 3 seconds.

The timing of the initial pacing pulse in the Post-Therapy Period depends on the cardiac activity during the Post-Shock Pacing Delay.

- If R-waves (and/or P-waves for dual-chamber pacing modes) are sensed during the Post-Shock Pacing Delay, the device paces only when the sensed rate is slower than the post-therapy LRL.

- If no R-waves (and/or P-waves for dual-chamber pacing modes) are sensed during the Post-Shock Pacing Delay or if the interval since the preceding P- or R-wave was greater than the 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.

Post-Therapy Period

The Post-Therapy Period determines how long the pulse generator operates using the post-therapy parameter values.

The Post-Therapy Period functions as follows:

- The period starts when the Post-Shock Pacing Delay expires
- On completion of this pacing period, the pulse generator reverts to the programmed Normal pacing values
- While in process, the pacing period is not affected by the end of the current episode

TEMPORARY PACING

The pulse generator can be programmed with temporary pacing parameter values that differ from the programmed Normal Settings. This allows you to examine alternate pacing therapies while maintaining the previously programmed Normal Settings in the pulse generator memory. During the Temporary function, all other bradycardia features are disabled.

NOTE: *Post-therapy values are not affected.*

To use this function, follow these steps:

1. From the Tests tab, select the Temp Brady tab to display the temporary parameters. When the parameters are initially displayed, they are set to the Normal Settings values ("Programmable Options" on page A-1).

NOTE: *Post-therapy values are not shown even if post-therapy is presently in effect.*

2. Select the desired values; these values are independent from other pacing functions.

3. Establish telemetry communication, then select the Start button. Pacing begins at the temporary values. A dialog box indicates that temporary parameters are being used, and a Stop button is provided.

NOTE: *Temporary pacing cannot be started while a tachyarrhythmia episode is in progress.*

NOTE: *Emergency therapy is the only function that can be initiated until the Temporary function is stopped.*

4. To stop the Temporary pacing mode, select the Stop button. The Temporary pacing mode also stops when you command emergency therapy from the PRM or when you press the DIVERT THERAPY key. Once stopped, the pacing reverts to the previously programmed Normal/Post-Therapy settings.

SENSORS AND TRENDING

Sensor and trending therapies include the parameters as described.

Sensor Trending

Sensor Trending provides a graphical display of the sensor rate based on sensor data. This feature evaluates the pulse generator's rate response to the patient's detected activity level and provides useful information during exercise testing.

The pulse generator collects and stores rate and sensor data. The rate data represents the programmed parameters. The Sensor Replay option allows you to adjust the parameter values and view the result without having to repeat an exercise test. The pulse generator also collects and stores data in nonadaptive-rate modes; however, without the sensor data comparison, only rate data will be displayed.

The Sensor Trending screen is accessible from within Normal Settings (Figure 5-3 on page 5-11).

Figure 5-3. Sensor Trending screen

Setup includes the following options:

- Recording Method—programmable:
  - 30-Second Average
  - Beat to Beat
- Duration—programmable:
  - When Recording Method is set to Off or 30-Second Average—fixed, approximately 25 hours
  - When Recording Method is set to Beat to Beat—fixed, approximately 40 minutes at 75 bpm
- Data Storage—programmable:
  - Continuous—contains the most recent data available. Storage starts when setup is confirmed and continuously records the latest information, overwriting the oldest data until the information is retrieved. This option allows you to view data for the recording duration immediately prior to data retrieval.
  - Fixed—storage starts when setup is confirmed and continues until device memory storage is full. This allows you to view data from initial setup for a fixed amount of time.
  - Off—when Sensor Trending is programmed to Off, no trending data is gathered.

Select the View button to vary the time period for how much data is visible; options exist for 1–25 hours. To adjust the vertical axis, move the slider bar at the bottom of the display window.

Adaptive-rate Pacing

In adaptive-rate pacing modes, sensors are used to detect changes in the patient's metabolic demand and increase the pacing rate accordingly. Adaptive-rate pacing is intended for patients who exhibit chronotropic incompetence and who would benefit from increased pacing rates that are concurrent with physical activity.

When adaptive-rate parameters are programmed, the pacing rate increases in response to increased activity, then decreases as the activity returns to a resting level.

NOTE: *Activity involving minimal upper body motion, such as bicycling, may result in only a moderate pacing response.*

NOTE: *Adaptive-rate pacing has been shown to be potentially proarrhythmic. Use caution when programming adaptive-rate features.*

Accelerometer

The accelerometer detects motion that is associated with a patient's physical activity and generates an electronic signal that is proportional to the amount of body motion. Based on accelerometer input, the pulse generator estimates the patient's energy expenditure as a result of exercise, then translates it into a rate increase.

The pulse generator senses body motion by means of an integrated circuit accelerometer located on the hybrid circuit. The accelerometer sensor responds to activity in the frequency range of typical physiologic activity (1–10 Hz). The accelerometer evaluates both the frequency and the amplitude of the sensor signal.

- Frequency reflects how often an activity occurs, such as the number of steps taken per minute during a brisk walk
- Amplitude reflects the force of motion (e.g., the more deliberate steps taken while walking)

Once detected, an algorithm translates the measured acceleration into a rate increase above the LRL.

Because the accelerometer is not in contact with the pulse generator case, it does not respond to simple static pressure on the device case.

There are three Accelerometer settings: Off, On, and ATR Only. When you program the respective rate-responsive modes for Normal Settings and ATR Fallback, that action automatically updates the Accelerometer setting. If the pulse generator is permanently programmed to a nonadaptive-rate mode, it is possible to program the ATR Fallback mode to an adaptive-rate mode using the accelerometer sensor. In this case, the Accelerometer field will display ATR Only.

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

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

Activity Threshold

Activity Threshold prevents rate increases due to low-intensity, extraneous motion (e.g., motion caused by respiration, heart beat, or in some cases tremor associated with Parkinson's disease).

Activity Threshold represents the activity level that must be exceeded before the sensor-driven pacing rate will increase. The pulse generator will not increase the paced rate above the LRL until the activity signal increases above the Activity Threshold. An Activity Threshold setting should allow a rate increase with minor activity, such as walking, but be high enough so the pacing rate will not increase inappropriately when the patient is inactive (Figure 5-4 on page 5-14, Figure 5-5 on page 5-15).

- Lower setting—less motion is required to increase the pacing rate
- Higher setting—more motion is required to increase the pacing rate
- Nominal setting—shown to be appropriate for the majority of patients in a previous Guidant study; therefore, it is recommended for use in monitoring the rate response prior to programming changes

NOTE: *Programming the Activity Threshold for Normal Settings also changes the corresponding selection for Post-Therapy Settings.*

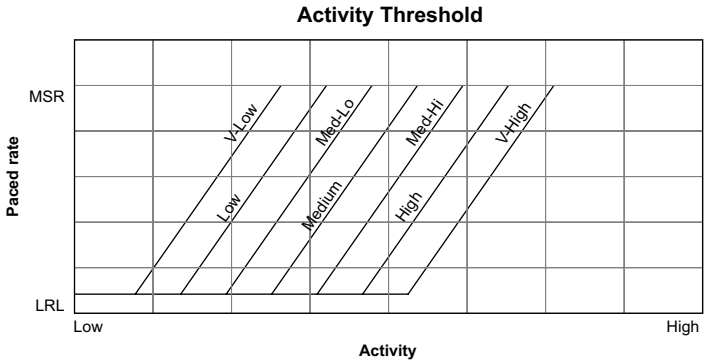
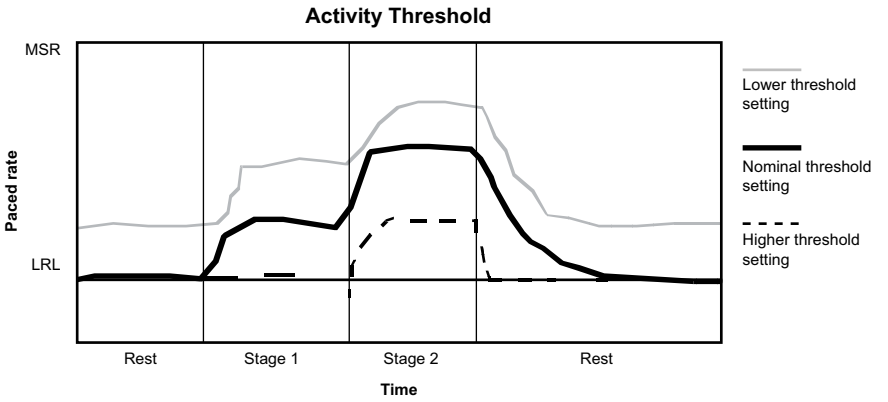


Figure 5-4. Activity Threshold and rate response



This figure demonstrates the effect of increased or decreased Activity Threshold settings in response to a theoretical two-stage exercise test.

Figure 5-5. Activity Threshold in exercise test

Reaction Time

Reaction Time determines how quickly the pacing rate will rise to a new level once an increase in activity level is detected.

Reaction Time affects only the time required for a rate increase to occur. The value selected determines the time required for the paced rate to move from the LRL to the MSR for a maximum level of activity (Figure 5-6 on page 5-16 and Figure 5-7 on page 5-16).

- Short Reaction Time: results in a rapid increase in the pacing rate
- Long Reaction Time: results in a slower increase in the pacing rate
- Nominal setting: shown to be appropriate for the majority of patients in a previous Guidant study; therefore, it is recommended for use in monitoring the rate response prior to programming changes

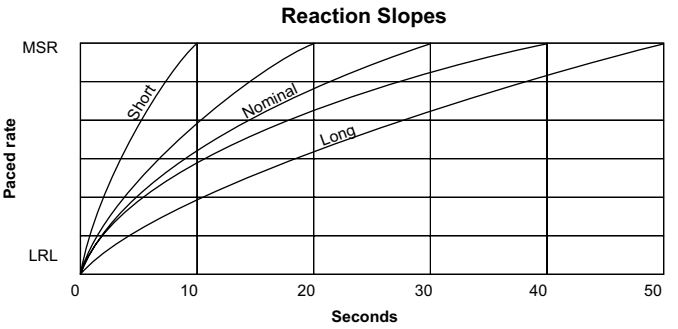


Figure 5-6. Reaction Time and paced rate

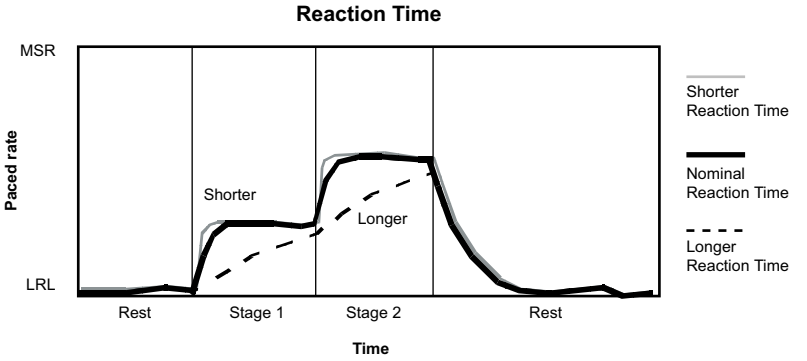


Figure 5-7. Reaction Time in exercise test

Programming Reaction Time for Normal Settings also changes the corresponding selection for Post-Therapy Settings.

Response Factor (Accelerometer)

Response Factor (accelerometer) determines the pacing rate that will occur above the LRL at various levels of patient activity (Figure 5-8 on page 5-17).

- High Response Factor—results in less activity required for the pacing rate to reach the MSR
- Low Response Factor—results in more activity required for the pacing rate to reach the MSR
- Nominal setting—shown to be appropriate for the majority of patients in a previous Guidant study; therefore, it is recommended for use in monitoring the rate response prior to programming changes

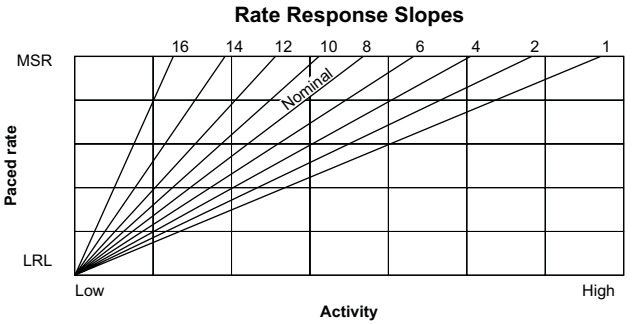
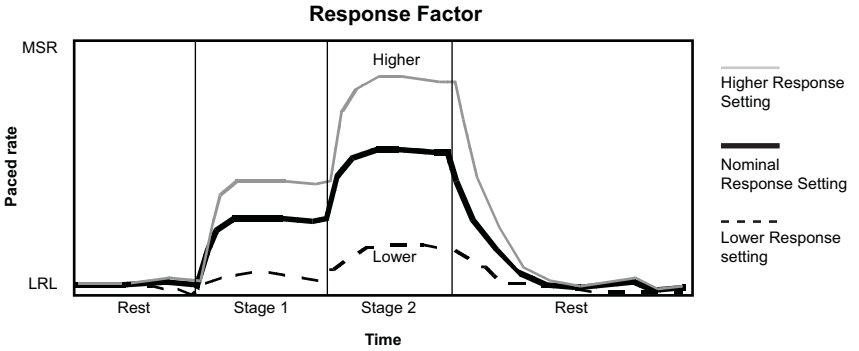


Figure 5-8. Response Factor and paced rate

The pacing rate achieved can be limited either by the detected activity level or the programmed MSR. If the detected activity level results in a steady-state rate below the MSR, the pacing rate can still increase when the detected activity levels increase (Figure 5-9 on page 5-17).



This figure shows the effect of higher and lower settings during a theoretical two-stage exercise test.

Figure 5-9. Response Factor in exercise test

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

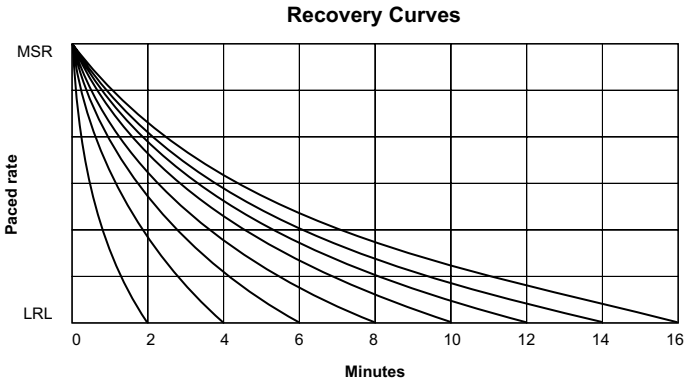
The Passive setting can be used to allow accelerometer trending without a rate response. In this setting, the Brady Mode is programmed to a non–rate-adaptive mode and the Recording Method for sensor trending is not programmed to Off.

Programming Response Factor for Normal Settings also changes the corresponding selection for Post-Therapy Settings.

Recovery Time

Recovery Time determines the time required for the paced rate to decrease from the MSR to the LRL in the absence of activity. When patient activity concludes, Recovery Time is used to prevent an abrupt decrease in pacing rate (Figure 5-10 on page 5-18 and Figure 5-11 on page 5-19).

- Short Recovery Time—results in a faster decrease in pacing rate after patient activity lowers or stops
- Long Recovery Time—results in a slower decrease in pacing rate after patient activity lowers or stops



There are 15 settings available; only the even-numbered settings are shown.

Figure 5-10. Recovery Time and paced rate