

SYSTEM GUIDE

COGNIS™ 100-D

CARDIAC RESYNCHRONIZATION THERAPY
HIGH ENERGY DEFIBRILLATOR

REF N118, N119

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.

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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. |

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 |
| ABM: | Autonomic Balance Monitor |
| AF: | Atrial Fibrillation |
| AFib: | Atrial Fibrillation |
| AFR: | Atrial Flutter Response |
| AGC: | Automatic Gain Control |
| AIVR: | Accelerated Idioventricular Rhythm |

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AT:	Atrial Tachycardia
ATP:	Antitachycardia Pacing
ATR:	Atrial Tachy Response
AV:	Atrioventricular
BiV:	Biventricular
BCL:	Burst Cycle Length
BOL:	Beginning of Life
CPR:	Cardiopulmonary Resuscitation
CRT:	Cardiac Resynchronization Therapy
CRT-D:	Cardiac Resynchronization Therapy Defibrillator
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
HRV:	Heart Rate Variability
IBP:	Indications-Based Programming
IC:	Industry Canada
ICD:	Implantable Cardioverter Defibrillator
LRL:	Lower Rate Limit
LV:	Left Ventricular
LVPP:	Left Ventricular Protection Period
LVRP:	Left Ventricular Refractory Period
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

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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 1-5
- "Indications and Usage" on page 1-6
- "Contraindications" on page 1-6
- "Warnings" on page 1-6
- "Precautions" on page 1-8
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- "Patient Counseling Information" on page 1-28

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).

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 COGNIS 100 family of cardiac resynchronization therapy defibrillators (CRT-Ds) (specific models are listed in "Mechanical Specifications" on page 1-21).

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
- Cardiac Resynchronization Therapy (CRT), which treats heart failure by resynchronizing ventricular contractions through biventricular electrical stimulation
- 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)

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Leads

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

- One IS-1¹ atrial lead
- One IS-1 coronary venous pace/sense lead
- One LV-1 coronary venous pace/sense lead
- One DF-1/IS-1² 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

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.

1. IS-1 refers to the international standard ISO 5841.3:2000.
2. DF-1 refers to the international standard ISO 11315:2002.

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 cardiac resynchronization therapy defibrillators (CRT-Ds) are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy and have left ventricular (LV) dysfunction ($EF \leq 35\%$) and QRS duration ≥ 120 ms.

CONTRAINDICATIONS

There are no contraindications for this device.

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.

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- **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.
- **Atrial-only modes.** Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT.
- **Ventricular sensing.** Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition.
- **Slow VT.** Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones.

Implant Related

- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- **Patch leads.** Do not use defibrillation patch leads with the pulse generator system, or injury to the patient may occur.
- **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.
- **Biventricular pacing therapy.** This device is intended to provide biventricular pacing therapy. Programming the device to provide RV-only pacing, or programming the RV pace amplitude below the pacing threshold (resulting in LV-only pacing), is not intended for the treatment of heart failure. The clinical effects of LV-only or RV-only pacing for the treatment of heart failure have not been established.
- **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 μ A can induce ventricular fibrillation. Ensure that any line-powered equipment is within specifications.
- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not occur.
- **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.
- **AV Delay.** To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.
- **Adaptive-rate pacing.** Adaptive-rate pacing should be used with care in patients who are unable to tolerate increased pacing rates.
- **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.
- **Atrial Tachy Response (ATR).** ATR should be programmed to On if the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted if the ATR mode switch occurs.
- **Threshold test.** During the LV threshold test, RV backup pacing is unavailable.
- **Left ventricular pacing only.** The clinical effect of LV pacing alone for heart failure patients has not been studied.
- **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.** 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.
- **Left ventricular lead configuration.** Proper programming of the LV coronary venous lead configuration is essential for proper LV lead function. Program the lead configuration in accordance with the number of electrodes on the LV lead; otherwise, erratic LV sensing, loss of LV pacing, or ineffective LV pacing might occur.

- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum LV pacing rate and may inhibit CRT at higher pacing rates.
- **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 lithotripter is designed to trigger off the R-wave on the ECG, resulting in shock waves being delivered during the VRP.

- If the patient does not require pacing, program the pulse generator Brady Mode to Off.
- If the patient requires pacing, program the pulse generator to the VVI mode because atrial pacing pulses can trigger the lithotripter.
- **Ultrasound energy.** Therapeutic ultrasound (e.g., lithotripsy) energy may damage the pulse generator. If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site. Diagnostic ultrasound (e.g., echocardiography) is not known to be harmful to the pulse generator.

- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed 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
- Electrolyte imbalance/dehydration
- 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
- 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)
- 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

In addition to the implantation of a pulse generator system, potential adverse events associated with the implantation of a coronary venous lead system include:

- Allergic reaction to contrast media (i.e., renal failure, etc.)
- Breakage/failure of implant instruments
- Prolonged exposure to fluoroscopic radiation

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	Volume (cm ³)	Mass (g)	Connector Type (RV : LV)	Case Electrode Surface Area (mm ²)
N118	6.17 x 7.95 x 0.99	32.5	72.0	IS-1/DF-1 : LV-1	6670
N119	6.17 x 7.95 x 0.99	32.5	72.0	IS-1/DF-1 : IS-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.

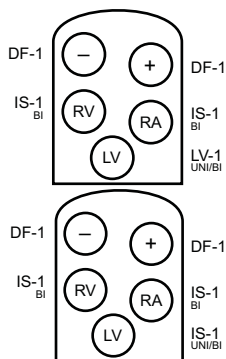


Figure 1-1. Lead connections

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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








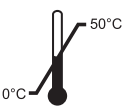


The following symbols may be used on pulse generator packaging and labeling (Table 1-2 on page 1-22):

Table 1-2. Symbols on packaging

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

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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 1-23).

Table 1-3. Characteristics as shipped

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

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Table 1-3. Characteristics as shipped (continued)

Parameter	Setting
Pacing Therapy available	DDDR
Sensor	Accelerometer (MV for respiratory rate trend)
Pace/Sense Configuration	RA: BI/BI
Pace/Sense Configuration	RV: BI/BI
Pace/Sense Configuration	LV: Off

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

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The x-ray identifier is embedded in the header of the device at the approximate location (Figure 1-2 on page 1-25).

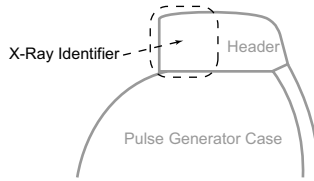


Figure 1-2. X-ray identifier

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 70 ppmLRL; DDDR mode; 100% biventricular pacing; 15% atrium pacing and 0.4 ms pacing pulse width (RA, RV, LV); 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			
Pacing Amplitude		Longevity (years) at 500 Ω and 700 Ω Pacing Impedance (RV and LV)	
RA/RV	LV	500 Ω	700 Ω
2.5 V	3.0 V	6.6	6.9
2.5 V	3.5 V	6.2	6.6
3.5 V	3.5 V	5.5	5.9
3.5 V	5.0 V	4.6	5.0

a. For RF-enabled models, assumes ZIP wandless telemetry use for 3 hours 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

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- 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 4 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.

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- 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 2-5
- "Data Management" on page 2-11
- "Communicating with the Pulse Generator" on page 2-12
- "DIVERT THERAPY" on page 2-16
- "STAT SHOCK" on page 2-17
- "STAT PACE" on page 2-18
- "Safety Mode" on page 2-18

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).

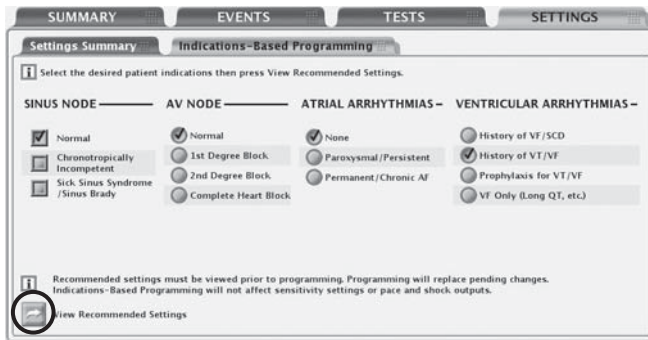


Figure 2-1. Indications-based Programming screen

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 promote intrinsic atrial events and provide CRT pacing.
 - If Chronotropically Incompetent is selected, the intent is to provide rate-adaptive CRT pacing.
 - If Sick Sinus Syndrome is selected, the intent is to provide atrial pacing support and CRT pacing.
 - AV Node:
 - The intent is for nominal Paced AV delay and Sensed AV delay settings. The SmartDelay optimization feature may be used to adjust the AV delay.
- NOTE:** *The selected settings for AF and Sinus Node may affect the suggested value for the 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
 - Onset/Stability 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.*

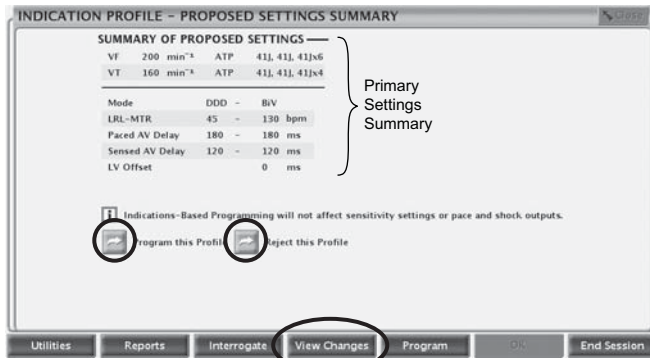


Figure 2-2. Proposed Settings Summary screen

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)

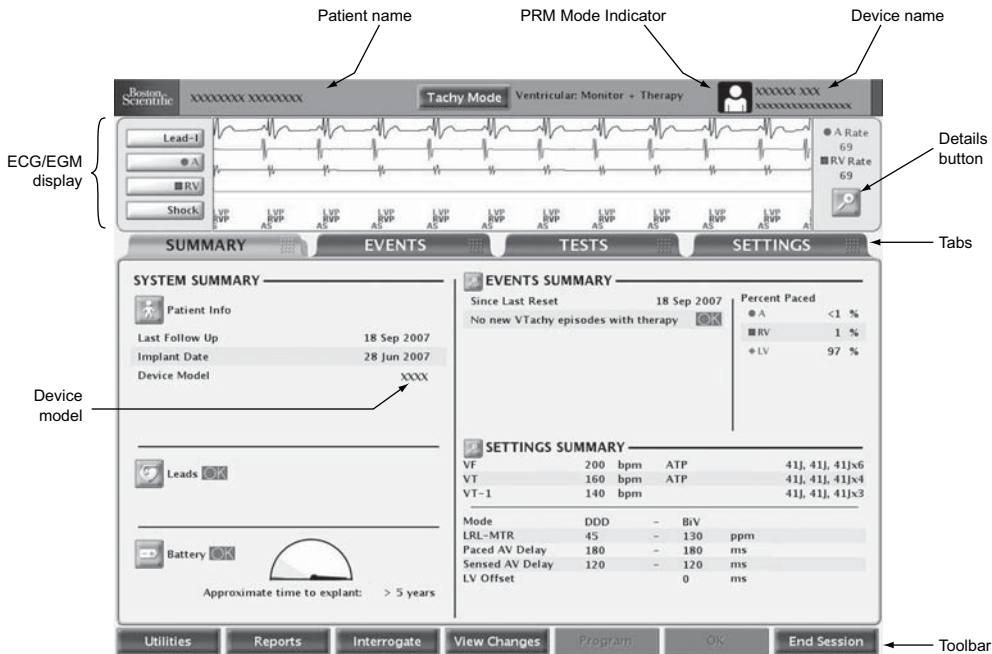


Figure 2-3. Main Screen

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
 - HRV
 - Histogram paced/sensed counts

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

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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 BiV output characteristics:

- 0 ms offset
- 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

- 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.
- While programmed to Off Mode, the pulse generator will store only STAT SHOCK in history.
- 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.
- 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/CRT Mode

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

Biventricular pacing with LV Offset programmed to zero will be delivered while Electrocautery Protection Mode is enabled if the programmed mode is a ventricular pacing mode.

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.

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- Automatic gain-controlled sensing circuit for rate sensing. This circuit ensures proper rate sensing by compensating for changing or diminished signal amplitudes.

For CRT and bradycardia therapy decisions, rate sensing is based on RV sensed and ventricular paced events.

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)

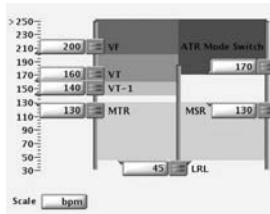
Ventricular Rate Thresholds and Zones

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 3-5, 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
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

CRT Delivery Zone and Tachyarrhythmia Zones

The device divides therapy delivery into zones based on heart rate.

- The programmed LRL and MTR/MSR/MPR define the CRT delivery zone, or the range over which CRT is delivered.
- The tachyarrhythmia zones are bounded by the lower rate threshold of the lowest tachyarrhythmia zone. It is not possible to program the CRT delivery zone and the tachyarrhythmia zones to overlap. A minimum 5 bpm difference must exist between the upper limit of the CRT delivery zone and the lower limit of the tachyarrhythmia zones.

Use of Atrial Information

The atrial rate may be used to:

- Inhibit ventricular therapy in the presence of atrial fibrillation or atrial flutter

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- 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/CRT 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

- 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.
- 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).
- 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).

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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:

- 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.
 - Biventricular Trigger, Rate Smoothing, ATR, hysteresis, and dynamic programming (excluding Dynamic VRP) are suspended. The pacing chamber is set to Biventricular; LV Offset is set to 0.
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.

- Biventricular Trigger, Rate Smoothing, ATR, hysteresis, and dynamic programming (excluding Dynamic VRP) are suspended. The pacing chamber is set to Biventricular; LV Offset is set to 0.
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

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

	VT-1 Zone	VT Zone	VF Zone
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 3-13.)

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.

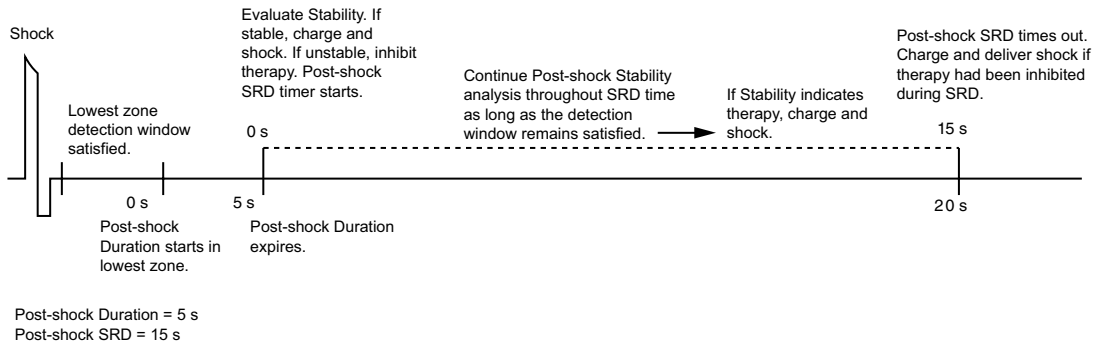


Figure 3-2. Post-shock Duration and Post-shock Stability analysis

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 3-14).

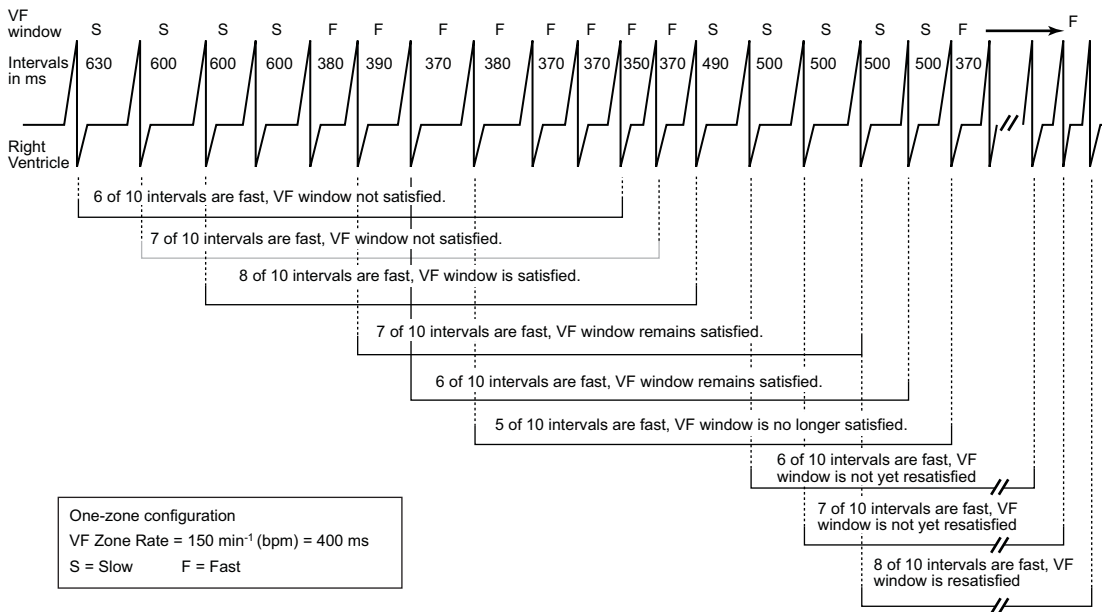


Figure 3-3. Ventricular detection window satisfied

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 3-15).

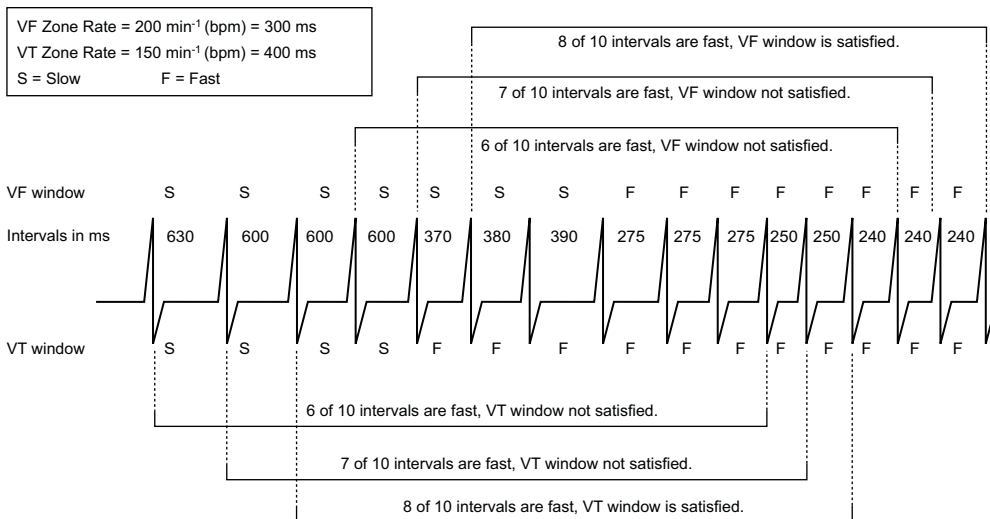


Figure 3-4. Interaction of ventricular detection windows, 2-zone configuration

Duration Parameter

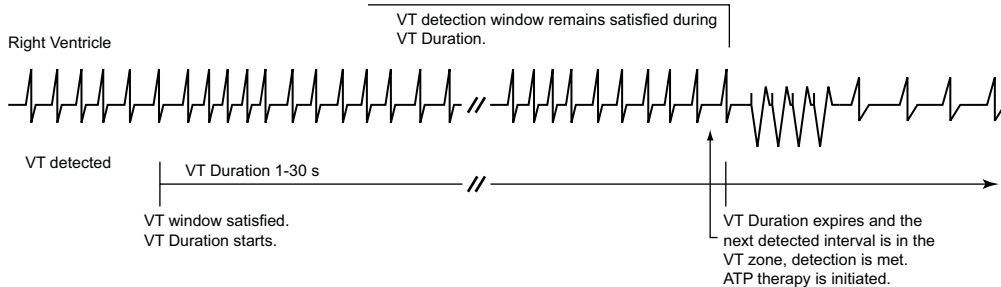
The Duration parameter is a timer that measures the length of time in each zone that a rhythm must be sustained before therapy is delivered.

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 3-16).
- 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 3-16).

- 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 3-17). 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

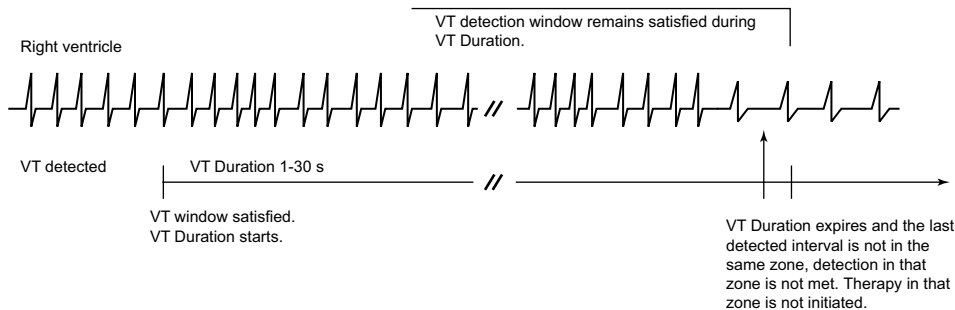
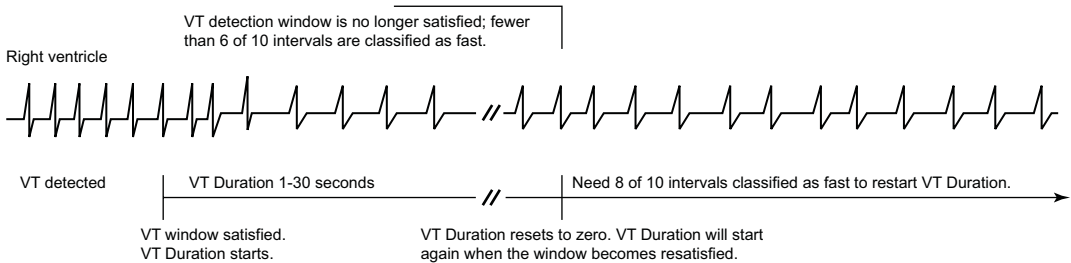


Figure 3-6. Last detected interval



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 3-17). 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 3-18, Figure 3-9 on page 3-18).

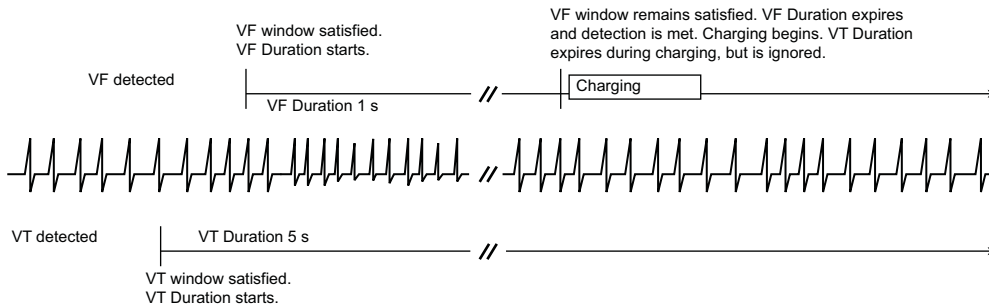


Figure 3-8. Interaction of ventricular Duration, 2-zone configuration, charging

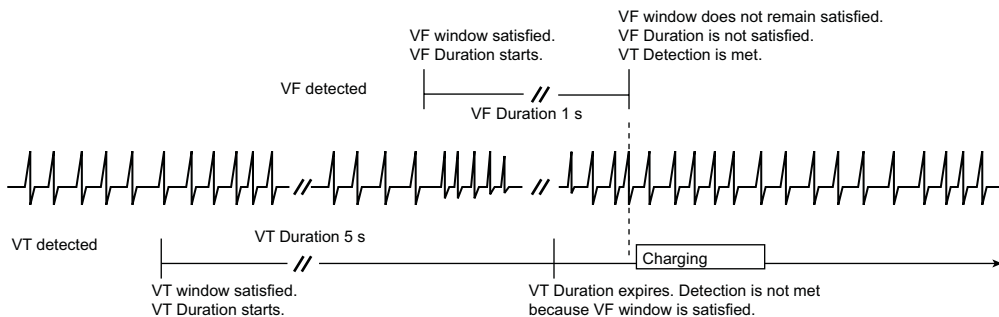


Figure 3-9. Interaction of ventricular Duration, 2-zone configuration, charging delayed

Ventricular Redetection Duration and Post-shock Duration

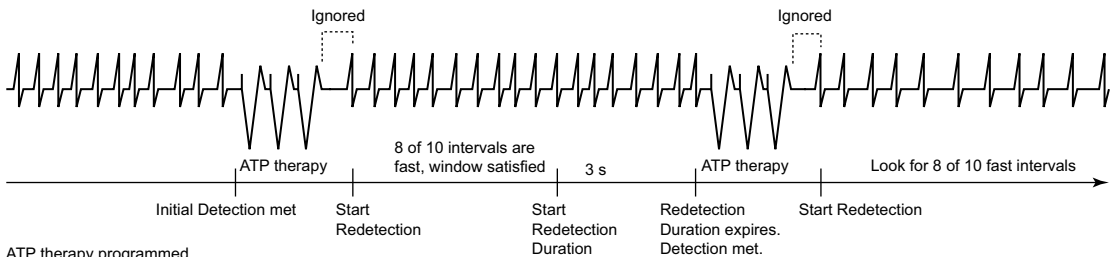
Duration parameters are used to identify tachyarrhythmias during the ventricular redetection process.

- 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 3-19).
- Post-shock Duration is applied following shock therapy delivery (Figure 3-11 on page 3-19).

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.

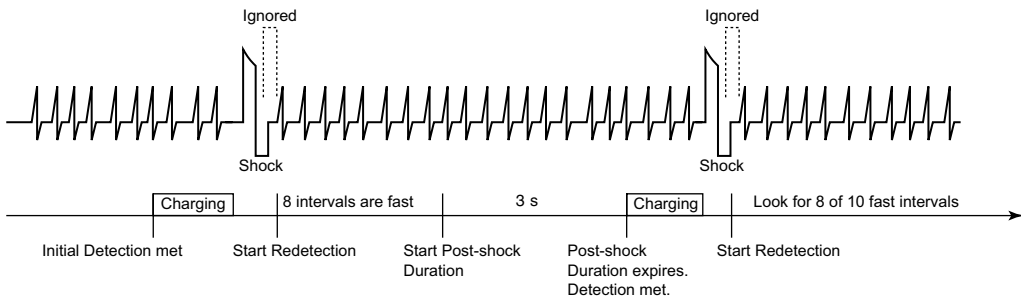
To help minimize time to potential therapy, it is recommended that Redetection Duration in the VT-1 and VT zones of multi-zone configurations be programmed at less than or equal to 5 seconds.

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 3-21 through Figure 3-16 on page 3-23).

- 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 3-20). 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 3-23).

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.

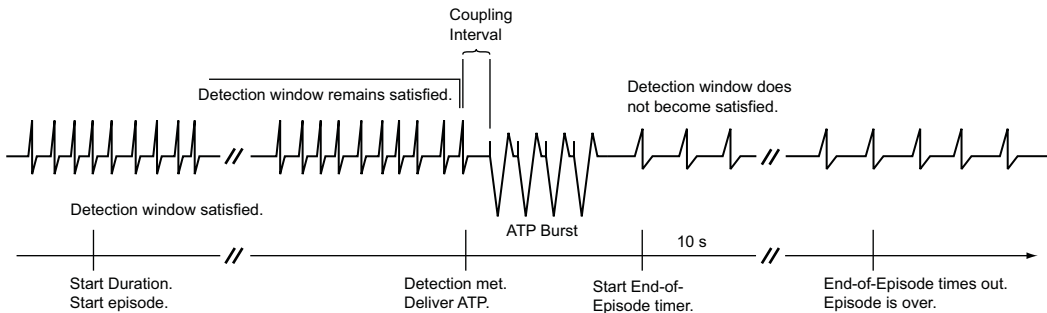


Figure 3-12. Treated episode, ventricular mode is Monitor + Therapy and ATP is delivered

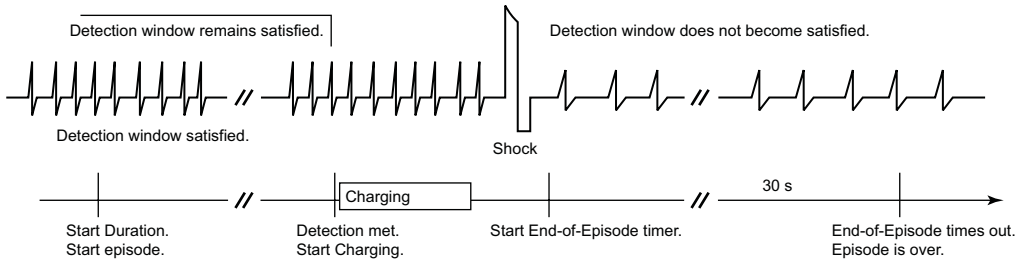


Figure 3-13. Treated episode, ventricular mode is Monitor + Therapy and shock is delivered

**3-22 TACHYARRHYTHMIA DETECTION
VENTRICULAR DETECTION**

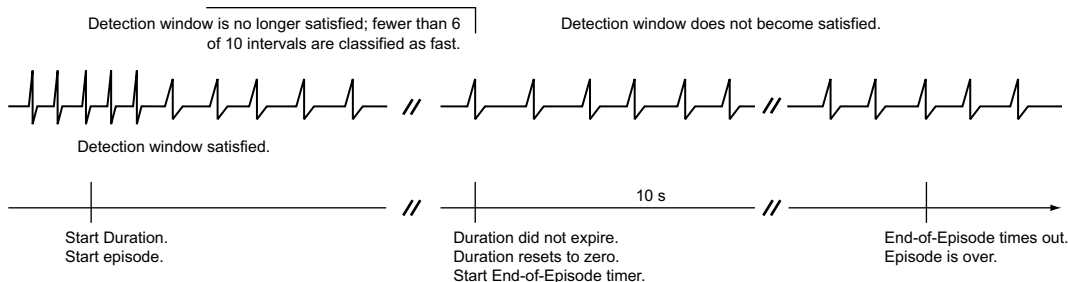
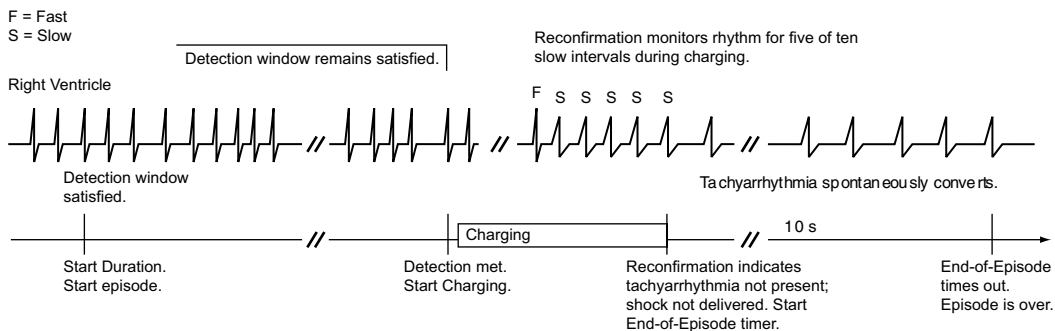
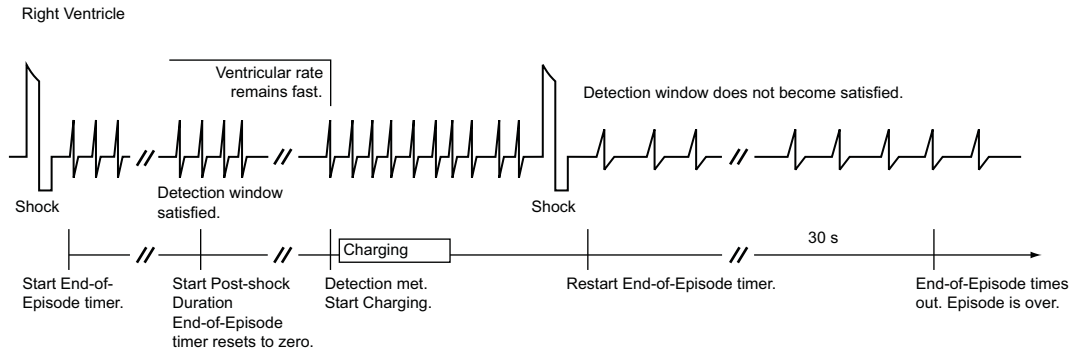


Figure 3-14. Nontreated episode, ventricular mode is Monitor + Therapy or Monitor Only, duration is not expired



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 3-24) 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 3-24).

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 3-25).

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 V Rate > A Rate AFib Rate Threshold Stability to Inhibit Onset SRD	Vector Timing and Correlation ^a V Rate > A Rate ^a AFib Rate Threshold ^a Stability (to Inhibit) ^a Shock if Unstable 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 3-27).

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

Parameter	Onset/Stability			Rhythm ID	
	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	--	--	20 ms	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

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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 3-29). 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.*

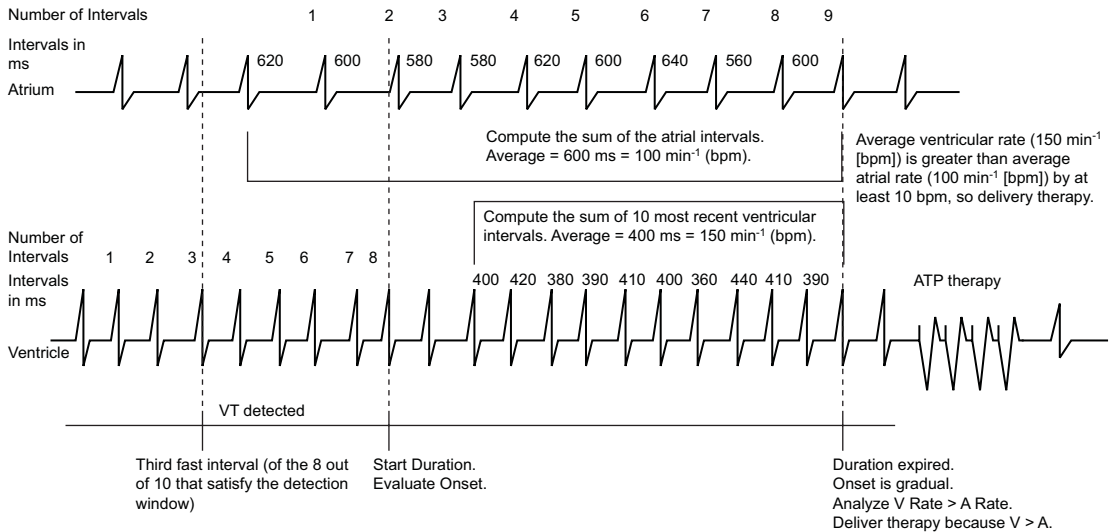


Figure 3-17. V Rate > A Rate analysis

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.

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The intrinsic atrial rate is declared to be above the AFib Rate Threshold in the following manner (Figure 3-18 on page 3-30):

- 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

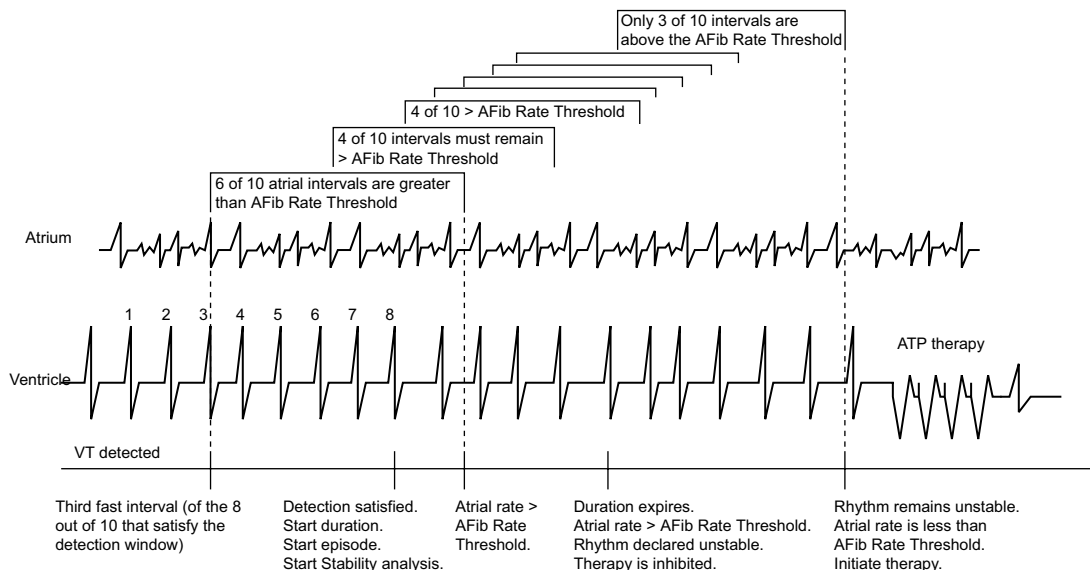


Figure 3-18. Interaction of AFib Rate Threshold and Stability

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 3-31). 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 3-33). 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.

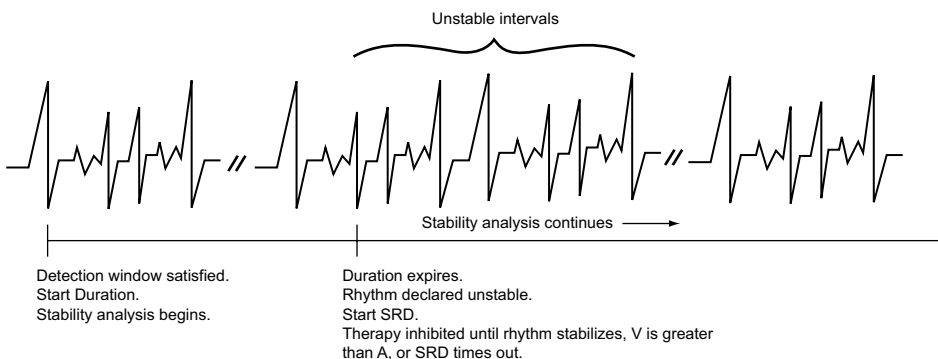


Figure 3-19. Stability evaluation when Duration expires

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 3-34).

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.

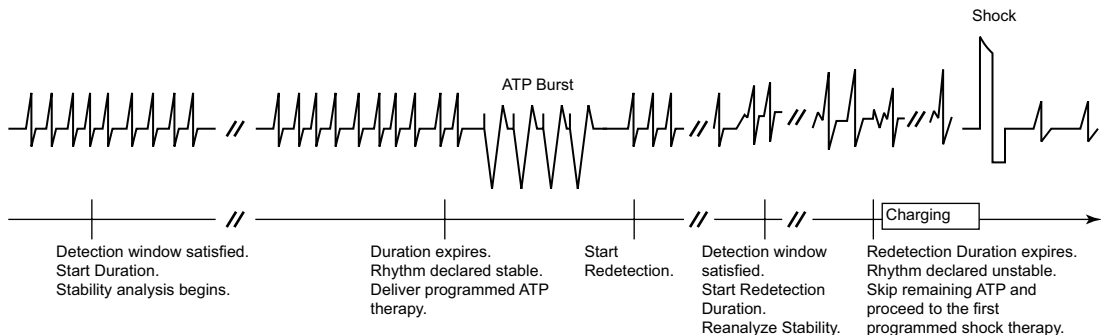


Figure 3-20. Shock if Unstable

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.