
To: Boston Scientific CRM Field Representatives

From: CRV Rhythm Marketing

Date: October 2010

Subject: Boston Scientific ICD and CRT-D Primer content for INCEPTA™,
ENERGEN™, and PUNCTUA™ devices that are pending regulatory/notified
government agency approval.

This primer is intended to supplement Boston Scientific's field representative training materials in preparation for launch of Boston Scientific's next generation of ICDs and CRT-Ds.

IMPORTANT: There are several changes described in the Boston Scientific ICD and CRT-D Primer that are pending device approval. These devices and features cannot be discussed with customers until device approval in your geography has been received.

Specific devices and features include, but are not limited to:

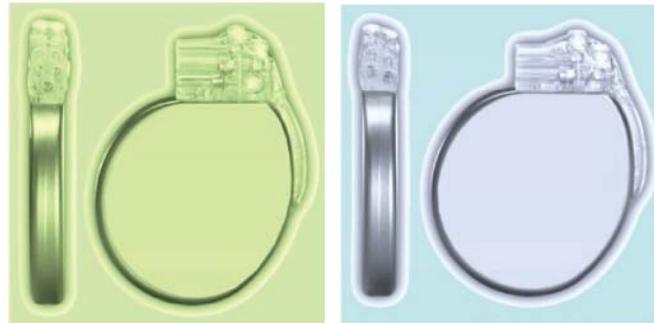
- INCEPTA ICDs and CRT-Ds
- ENERGEN ICDs and CRT-Ds
- PUNCTUA ICDs and CRT-Ds
- Respiratory Sensor
- ApneaScan™
- Respiratory Rate Trend
- RYTHMIQ™
- Rhythm ID with RhythmMatch™
- Wireless ECG
- Saving Patient Data to ZOOM LATITUDE™ hard drive and extracting to USB Pen Drive
- COGNISTM and TELIGENT™ changes included in ZOOM LATITUDE software model 2868 v2.03

If you have any questions about the status of these pending device approvals, please contact your sales manager.

Boston Scientific Primer for

ICDs & CRT-Ds

INCEPTA™ ICD and CRT-D
ENERGEN™ ICD and CRT-D
PUNCTUA™ ICD and CRT-D
PUNCTUA™ ICD and CRT-D
PUNCTUA™ NE ICD and CRT-D
COGNIS™ 100-D
TELIGEN™ 100



Boston Scientific Primer for ICDs and CRT-Ds

INCEPTA™ ICD and CRT-D

ENERGEN™ ICD and CRT-D

PUNCTUA™ ICD and CRT-D

PUNCTUA™ ICD and CRT-D

PUNCTUA™ NE ICD and CRT-D

COGNIS™ 100-D

TELIGEN™ 100

Purpose

This Primer is designed to serve as a *world-wide technical reference* for the INCEPTA, ENERGEN, COGNIS, and PUNCTUA CRT-Ds and the INCEPTA, ENERGEN, TELIGEN, and PUNCTUA ICDs. This reference does not replace, rather supplements, device instructions for use (i.e., reference guides) by describing system features and capabilities applicable to these devices for Boston Scientific employees. To determine whether a particular feature is available for a specific device, a reference table is included within the table of contents; each section also depicts applicability feature by feature. This Primer is not to be displayed or distributed to customers.

World-wide Geographies

The specific geographies described within this primer include Australia (AUS), Canada (CA), Europe (EU), Japan (JPN), and the United States (U.S.). Boston Scientific acknowledges there are many more important countries where ICDs and CRT-Ds are distributed, but in most cases regulatory approval is predicated on the approval of one or more of the specified geographies. If you have any questions about the capabilities of the products distributed within your geography, refer to the device instructions for use.

Approved and Unapproved Features

Some sub-section titles may include an icon to describe which devices the feature is available for.

Example: QUICK CONVERT ATP is available for TELIGEN ICDs, COGNIS CRT-Ds, ENERGEN ICDs/CRT-Ds, and INCEPTA ICDs/CRT-Ds as indicated by the black font and background color. It is unavailable for PUNCTUA ICDs/CRT-Ds as indicated by the gray font and gray background. If there were geographical restrictions, a comment would be included below the icon.

QUICK CONVERT ATP



<Geographical Restrictions>

NOTE: PUNCTUA references within the icon are intended to include PUNCTUA and PUNCTUA NE ICD and CRT-D models.

Features which are not approved in your geography should not be discussed with customers until appropriate approvals are obtained in your geography. To determine whether a feature is available in your geography, review the device's instructions for use.

U.S. Trademarks

The following are U.S. registered trademarks of Boston Scientific or its affiliates: ACUITY, ALTRUA, COGNIS, CONFIENT, CONTAK, CONTAK RENEWAL, CONTAK RENEWAL TR, EASYTRAK, ENDOTAK RELIANCE, GUIDANT, LIVIAN, LATITUDE, RAPIDO, RAPIDO ADVANCE, RHYTHM ID, SMARTDELAY, TELIGEN, VENTAK, VENTAK PRIZM, VITALITY, ZOOM. INCEPTA, ENERGEN, PUNCTUA.

The following are trademarks of Boston Scientific or its affiliates: 4-SITE, ApneaScan, ELECTRONIC REPOSITIONING, ONSET/STABILITY, QUICK CONVERT, REVERSE MODE SWITCH, RYTHMIQ, RhythmMatch, SAFETY CORE, Smart Blanking, ZIP, ZOOMVIEW.

Description of Changes

Revision	Description of Change
October 2010	<p>General Changes:</p> <ul style="list-style-type: none"> • Adds INCEPTA, ENERGEN, PUNCTUA, and PUNCTUA NE ICDs and CRT-Ds. • Adds new features associated with INCEPTA and/or ENERGEN including Respiratory Sensor, Respiratory Rate Trend, ApneaScan, RYTHMIQ, RID with RhythmMatch, and Wireless ECG. • Updates labeling references. System guides renamed reference guides. IFU content redistributed between the physician technical manual and the reference guide. <p>Specific Changes:</p> <p>INTRODUCTION</p> <ul style="list-style-type: none"> • Adds new world-wide geography paragraph. • Adds PG product name icon description and example with <i>Approved/Unapproved</i> features paragraphs. <p>TABLE OF CONTENTS</p> <ul style="list-style-type: none"> • Adds PG product name icon for most sections. <p>CHAPTER 1 SYSTEM</p> <ul style="list-style-type: none"> • Adds new Wanded telemetry paragraph. • Adds v2 dash numbers in Setscrew section. • Adds new Header Attach section. • Adds DF4 references and Bal-Seal Spring content in <i>IS-1/LV-1/DF4 Spring Contact</i> section. • Adds additional description on Hall Effect circuit in <i>Magnetic Sensor</i> section. • Adds new <i>LATITUDE Availability</i> section. • Replaces references to BOL with Beginning of Life and replaces references to EOL with Battery Capacity Depleted in <i>Battery</i> sections. • Adds table describing the typical maximum energy charge time over the life of the device in <i>Charge Time</i> section. • Adds ICD and CRT-D battery capacity in <i>Additional Battery Information</i>

Revision	Description of Change
	<p>section.</p> <ul style="list-style-type: none"> • <u>Adds</u> additional parameters in <i>Safety Core</i> section. <p>CHAPTER 2 IMPLANT</p> <ul style="list-style-type: none"> • <u>Adds</u> footnote regarding shelf-time change in <i>Pre-Implant</i> section. • <u>Adds new</u> ECG section. <p>CHAPTER 3 TACHYARRHYTHMIA DETECTION</p> <ul style="list-style-type: none"> • <u>Adds new</u> <i>Rhythm ID with RhythmMatch</i> section. • <u>Adds</u> additional bullets and EGMs in the <i>Notes/Additional Information</i> sub-section describing detection enhancement availability if any arrhythmia accelerates from Monitor Only zone into VT zone. <p>CHAPTER 4 TACHYARRHYTHMIA THERAPY</p> <ul style="list-style-type: none"> • <u>Adds</u> additional bullet indicating that Stat Shock is not available when the device is in Safety Core in the <i>Stat Shock</i> section. <p>CHAPTER 5 EP TESTING</p> <ul style="list-style-type: none"> • <u>Adds new</u> EP Test Shock on T, Post-Shock Delay, and Post-Shock Pacing will be enabled after Shock on T for PUNCTUA, ENERGEN, and INCEPTA. • <u>Adds new</u> EP Test Fibrillation Induction, Post-Shock Delay and Post-Shock Pacing will be enabled after V-fib High/Low for PUNCTUA, ENERGEN and INCEPTA. <p>CHAPTER 6 PACING THERAPIES</p> <ul style="list-style-type: none"> • <u>Adds new</u> <i>RYTHMIQ</i> section. • <u>Adds</u> rationale for why +LV Offsets are not available in the U.S. in <i>LV Offset</i> section. • <u>Adds</u> steps for programming LV Offset in <i>LV Offset</i> section. <p>CHAPTER 7 FOLLOW-UP</p> <ul style="list-style-type: none"> • <u>Adds</u> further description in the <i>Algorithm</i> sub-section and descriptions of the algorithms for intrinsic amplitudes, pacing impedances, and shock lead impedance in the <i>Leads Daily Measurements</i> section. • <u>Adds</u> rationale for why Auto Lead Detect has been disabled in PUNCTUA, ENERGEN, and INCEPTA in the <i>Auto Lead Detect</i> section. • <u>Updates</u> how PUNCTUA, ENERGEN, and INCEPTA perform a commanded shock lead impedance test in <i>Lead Test Detail – Impedance</i> section. • <u>Adds</u> more specific longevity impact for Patient Triggered Monitor: 60 days of PTM reduces longevity approximately 5 days in <i>Patient Triggered Monitor</i> section. • <u>Adds</u> device response when in Safety Core to the application of a magnet in the <i>Magnet Beeper</i> section. • <u>Renames</u> Patient Disk section to Data Storage; <u>adds</u> save to PRM hard drive and extract to USB pen drive content to the save to disk content. <p>CHAPTER 8 TRENDS</p> <ul style="list-style-type: none"> • <u>Adds new</u> <i>Respiratory Rate Trend</i> section. • <u>Adds new</u> <i>ApneaScan</i> section.

Revision	Description of Change
April 2010	Incorporates changes in hardware and software since initial launch. Detailed description of changes on file.
July 2008	Release for U.S. launch of COGNIS 100-D and TELIGEN 100. Updates on file.
May 2008	Initial Release of Draft Primer.

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Not available for models distributed in the United States

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Not available for ENERGEN models distributed in the U.S.

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<small>Not available for models distributed in the U.S.</small>	
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Hardware Description

INCEPTA, ENERGEN, and PUNCTUA are based on the hardware innovations that were released with COGNIS/TELIGEN. These hardware innovations were designed to improve reliability, safety, efficiency, and overall capabilities of the device. This design incorporated the Aurora philosophy, BSC CRM's continuous quality improvement program, which includes stronger supplier partnering, tightened manufacturing process controls, and statistically-based sample size testing.

Mechanical Specifications

All ICD and CRT-D models have a mass of 72.0g, a case electrode surface area of 6670 mm², a width of 6.17 cm, and are 0.99 cm thin. All dual chamber ICD and CRT-D models have an IS-1 RA connector type.

ICD						
Device Name	Model	Height (cm)	Vol (cm ³)	Connector Type (RV)	ZIP Freq (MHz)	Country
PUNCTUA	E050 (VR)	6.90	30.5	DF4-LLHH	916.5	AUS/CA/US
PUNCTUA	E051 (VR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
PUNCTUA	E052 (DR)	7.40	31.5	DF4-LLHH	916.5	AUS/CA/US
PUNCTUA	E053 (DR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
PUNCTUA	F050 (VR)	6.90	30.5	DF4-LLHH	869.85	EU/JPN

ICD						
Device Name	Model	Height (cm)	Vol (cm ³)	Connector Type (RV)	ZIP Freq (MHz)	Country
PUNCTUA NE	F051 (VR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
PUNCTUA	F052 (DR)	7.40	31.5	DF4-LLHH	869.85	EU/JPN
PUNCTUA NE	F053 (DR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
TELIGEN-100	E102 (VR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
TELIGEN-100	E103 (VR)	6.90	30.5	DF4-LLHH	916.5	AUS/CA
TELIGEN-100	E110 (DR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
TELIGEN-100	E111 (DR)	7.40	31.5	DF4-LLHH	916.5	AUS/CA
TELIGEN-100	F102 (VR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
TELIGEN-100	F103 (VR)	6.90	30.5	DF4-LLHH	869.85	EU/JPN
TELIGEN-100	F110 (DR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
TELIGEN-100	F111 (DR)	7.40	31.5	DF4-LLHH	869.85	EU/JPN
ENERGEN	E140 (VR)	6.90	30.5	DF4-LLHH	916.5	AUS/CA/US
ENERGEN	E141 (VR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
ENERGEN	E142 (DR)	7.40	31.5	DF4-LLHH	916.5	AUS/CA/US
ENERGEN	E143 (DR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
ENERGEN	F140 (VR)	6.90	30.5	DF4-LLHH	869.85	EU/JPN
ENERGEN	F141 (VR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
ENERGEN	F142 (DR)	7.40	31.5	DF4-LLHH	869.85	EU/JPN
ENERGEN	F143 (DR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
INCEPTA	E160 (VR)	6.90	30.5	DF4-LLHH	916.5	AUS/CA/US
INCEPTA	E161 (VR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
INCEPTA	E162 (DR)	7.40	31.5	DF4-LLHH	916.5	AUS/CA/US
INCEPTA	E163 (DR)	7.45	31.5	IS-1/DF-1	916.5	AUS/CA/US
INCEPTA	F160 (VR)	6.90	30.5	DF4-LLHH	869.85	EU/JPN
INCEPTA	F161 (VR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN
INCEPTA	F162 (DR)	7.40	31.5	DF4-LLHH	869.85	EU/JPN
INCEPTA	F163 (DR)	7.45	31.5	IS-1/DF-1	869.85	EU/JPN

CRT-D						
Device Name	Model	Height (cm)	Vol (cm ³)	Connector Type (RV : LV)	ZIP Freq (MHz)	Country
PUNCTUA	N050	7.70	32.0	DF4-LLHH : IS-1	916.5	US
PUNCTUA	N051	7.95	32.5	IS-1/DF-1 : IS-1	916.5	US
PUNCTUA	N052	7.70	32.0	DF4-LLHH : IS-1	916.5	AUS/CA
PUNCTUA	N053	7.95	32.5	IS-1/DF-1 : IS-1	916.5	AUS/CA
PUNCTUA	P052	7.70	32.0	DF4-LLHH : IS-1	869.85	EU/JPN
PUNCTUA NE	P053	7.95	32.5	IS-1/DF-1 : IS-1	869.85	EU/JPN
COGNIS-100	N106	7.95	32.5	IS-1/DF-1 : LV-1	916.5	AUS/CA
COGNIS-100	N107	7.95	32.5	IS-1/DF-1 : IS-1	916.5	AUS/CA
COGNIS-100	N108	7.70	32.0	DF4-LLHH : IS-1	916.5	AUS/CA
COGNIS-100	N118	7.95	32.5	IS-1/DF-1 : LV-1	916.5	US
COGNIS-100	N119	7.95	32.5	IS-1/DF-1 : IS-1	916.5	US
COGNIS-100	P106	7.95	32.5	IS-1/DF-1 : LV-1	869.85	EU/JPN
COGNIS-100	P107	7.95	32.5	IS-1/DF-1 : IS-1	869.85	EU/JPN
COGNIS-100	P108	7.70	32.0	DF4-LLHH : IS-1	869.85	EU/JPN
ENERGEN	N140	7.70	32.0	DF4-LLHH : IS-1	916.5	US
ENERGEN	N141	7.95	32.5	IS-1/DF-1 : IS-1	916.5	US
ENERGEN	N142	7.70	32.0	DF4-LLHH : IS-1	916.5	AUS/CA
ENERGEN	N143	7.95	32.5	IS-1/DF-1 : IS-1	916.5	AUS/CA
ENERGEN	P142	7.70	32.0	DF4-LLHH : IS-1	869.85	EU/JPN
ENERGEN	P143	7.95	32.5	IS-1/DF-1 : IS-1	869.85	EU/JPN
INCEPTA	N160	7.70	32.0	DF4-LLHH : IS-1	916.5	US
INCEPTA	N161	7.95	32.5	IS-1/DF-1 : IS-1	916.5	US
INCEPTA	N162	7.70	32.0	DF4-LLHH : IS-1	916.5	AUS/CA
INCEPTA	N163	7.95	32.5	IS-1/DF-1 : IS-1	916.5	AUS/CA
INCEPTA	N164	7.95	32.5	IS-1/DF-1 : LV-1	916.5	US
INCEPTA	N165	7.95	32.5	IS-1/DF-1 : LV-1	916.5	AUS/CA
INCEPTA	P162	7.70	32.0	DF4-LLHH : IS-1	869.85	EU/JPN
INCEPTA	P163	7.95	32.5	IS-1/DF-1 : IS-1	869.85	EU/JPN

CRT-D						
Device Name	Model	Height (cm)	Vol (cm ³)	Connector Type (RV : LV)	ZIP Freq (MHz)	Country
INCEPTA	P165	7.95	32.5	IS-1/DF-1 : LV-1	869.85	EU/JPN

- Single titanium casing shape and size for all CRT-D and ICD models. Size differences between models are attributed to number of header ports.
- Battery (8.6 cc) and high voltage capacitors (8 cc), the largest components inside the device, are smaller in size and shape yet all models are high energy (41J stored).
- The internal circuitry is designed to accommodate future device enhancements without change to the current size/shape. This allows current and future manufacturing to be easier.

Safety Architecture

These devices have been designed with patient safety in mind; this means device architecture is based on a foundation of clinical safety requirements—a safety architecture that helps ensure therapy will be available when it is needed.

To this end, these devices provide the following as part of their safety architecture:

- Suppresses Transient Events** – random software (firmware) events that could interrupt normal operation are anticipated and suppressed, making these transient events less likely to occur.
- Every action or instruction is error checked and is capable of being corrected on the spot.
 - Reacts to transient or recoverable faults that do occur through system fault resets, allowing the device to correct itself and return to normal operation, making these faults transparent to the physician and patient.

Advanced Fault Logging – any faults that do occur are logged, and fault history can provide engineering with important information about the seriousness and effects of the fault.

Safety Core Hardware

See the Safety Mode/Core section for more details.

ZIP Wandless Telemetry

All device models have ZIP Wandless telemetry with radio frequency (RF) antennas in their headers and a telemetry coil in the circuitry to support inductive telemetry. The telemetry capabilities available include:

- Wanded telemetry session initiation, ensuring a secure identification and communication with the device
- Encryption of patient data
- Authentication of device-bound messages

- Data transfer is three times faster than ZIP Wandless telemetry in RENEWAL RF, CONFIENT, and LIVIAN devices
- For devices transmitting on 916.50 MHz, two different programmers can interrogate a total of two devices using ZIP Wandless telemetry in close proximity

RF Frequency:

- Europe transmits on the SRD band at 869.85 MHz
- U.S., Australia, and Canada transmit on the ISM band for devices described in this primer the frequency is 916.50 MHz.
- RENEWAL 3 RF, CONFIENT, and LIVIAN transmit at a frequency of 914 MHz.

NOTE: This frequency change on the ISM band is designed to allow a clinic to support a single RENEWAL 3 RF/CONFIENT/LIVIAN RF telemetry session with any two RF telemetry sessions for devices described in this primer at the same time.

NOTE: ZIP wandless telemetry may not be approved for use in some geographies.

Wanded Telemetry

The wanded telemetry frequency has been changed for INCEPTA, ENERGEN, and PUNCTUA to support compliance requirements in certain geographies.

- COGNIS/TELIGEN devices transmit on a carrier frequency of 102.4 KHz.
- INCEPTA, ENERGEN, and PUNCTUA devices transmit on a carrier frequency of 57 KHz.

High Voltage Capacitors

The high voltage capacitors hold and deliver the high energy therapy pulse. These devices use aluminum-electrolytic capacitors¹ designed smaller and in a new symmetrical shape. In device designs before COGNIS/TELIGEN, each device had two capacitors with a right-sided and a left-sided shape that required two different capacitors per device. The devices described in this primer still have two capacitors per device but do not require a right- and left-sided capacitor—only one capacitor shape is needed. This reduction in unique components makes assembly of the device simpler.

See the Capacitor Re-formation section for more details.

Integrated Circuits (IC)

The brains of any ICD are the integrated circuits which provide the memory, microprocessor, and logic that controls the device functions.

¹ Guidant branded ICDs and CRT-Ds have always used aluminum electrolytic capacitors for high energy devices and used both aluminum electrolytic and wet tantalum for standard energy

These devices continue to incorporate the IC design changes introduced by COGNIS/TELIGEN:

- **Improved memory, microprocessor, and logic** – all located on one integrated circuit (IC). Similar functions required two ICs for previous devices.
- **Increased memory size** – 1 MB memory, which is twice the memory capacity of previous devices of 512 KB.
- **Real-time error correction** – for all operating codes and lower power consumption. Previous devices provided error correction for select portions of code only.
- **Customized 32-bit** – microprocessor to execute program code. Earlier devices used a customized Z80 8-bit microprocessor.
- **Better operating efficiency** – is more compatible with current software development conventions and tools. The microprocessor is faster and more efficient, and can complete more tasks at the same time in a short time window without having to prioritize tasks.
- **Redesigned analog IC** – the analog IC provides the interface to telemetry, pacing, and other device outputs by converting an analog signal (e.g., a sensed R-wave) to a digital signal (or vice versa) so that it can be measured, counted, and analyzed by the device logic. Technology advances now allow finer geometry providing better operating efficiency. Digital Signal Processing (DSP) provides more predictable, accurate, and stable signal processing as compared to analog methods.

Header: Setscrews, Seal plugs, Spring Contacts, 4-SITE (GDT-LLHH), Torque Wrench

To improve reliability and usability, several design changes were made to the header of the devices described in this primer. These changes aim at avoiding known issues which may occur at implant and at providing a more robust mechanical lead connection mechanism.

Setscrews

All INCEPTA, ENERGEN, and PUNCTUA devices use the V2 setscrew design. There are two versions of setscrew designs included within COGNIS/TELIGEN devices.

Boston Scientific transitioned to the V2 design in COGNIS/TELIGEN in the first half of 2009.



Version 1 (V1)

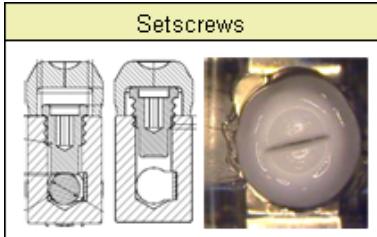
CRT-D devices launched prior to COGNIS have eight setscrews. CRT-D

devices described in this primer have five setscrews for IS-1/DF-1 devices, three setscrews for DF4/4-SITE headers—one setscrew per port for the IS-1/DF-1 devices.



The new setscrew has a top-hat shape, eliminating the retaining washer. When the setscrew is in the UP position, it disengages from the tip block and opens the seal plug to receive the wrench.

If downward force is applied at an angle while rotating the torque wrench clockwise, the setscrew may engage incorrectly or “cross-thread.”



Retainer washers, previously used to keep the setscrew from coming completely out of the header or extending too far into the port have been eliminated. Removing retainer washers will prevent issues where the setscrews became misaligned and stuck UP at implant. The new seal plugs retain setscrews in the ports.

Version 2 (V2)

Based on customer feedback and continuous improvement enhancements to the setscrew system were made and they include:

- Two (2) vent holes in the screw promote air escaping from the header and are designed to reduce piston effects during lead insertion when torque wrench is engaged.
- Pre-threaded setscrew with proper alignment to connector block designed to minimize cross-threading.
- Tapered and rounded end of setscrew designed to avoid interference with connector block thread if screw is fully retracted.
- Seal plug ribs on the underside of the seal plug designed to minimize migration of the setscrew into the connector block during shipment.

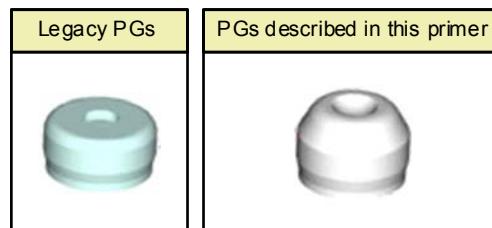


The following dash numbers² describe COGNIS/TELIGEN devices which incorporate V2 setscrews

- U.S.: -105 and above.
- EU: -X06 and above, where X depends upon the language configuration (i.e., in the UK -206). All GDT-LLHH models were launched with V2 setscrews.
- COGNIS/TELIGEN were launched in Australia and Japan with V2.

Seal Plugs

Seal plugs keep body fluids out of the connector block, but must also have a slit to allow a torque wrench access to the setscrews. The seal plugs for devices described in this primer have been redesigned as follows:



More Robust Seal – seal plugs now have a larger sealing surface and a more rigid sealing flap. This new sealing design prevents pinching of the seal between wrench and connector block or screw helping prevent possible damage to the seal plug.

² Dash number can be found on the outside packaging of the device. For example for 60E110-105 the dash number would be -105.

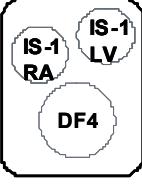
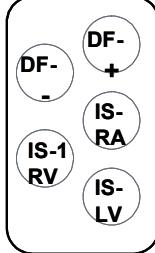
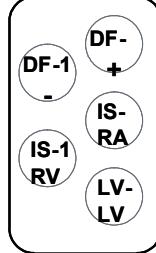
Seal plugs are now colored with a white colorant that contrasts with header assembly. The white colorant is designed to provide better visibility and allow the user to:

- Quickly identify the location of all seal plugs and gives the physician a visual target for wrench insertion.
- Determine number of seal plugs that need to be tightened and help decrease the chance of an untightened setscrew at implant.

A **Fluorosilicone Lubricant** has been added to the seal plugs. The fluorosilicone lubricant is designed to increase the reliability of the seal plug by:

- Helping prevent the reknitting or blocking of the seal plugs' silicone slits during exposure to alcohol washes and sterilization cycles.
- Decreasing the friction between the wrench and seal plug wall to help reduce shear stresses on the silicone material.
- Decreasing friction to help further reduce the amount of deflection on the silicone flap.

Lead Connections

CRT-D		
		
Models: N050, N052, N108, N140, N142, N160, N162, P108, P052, P142, P162	Models: N051, N053, N107, P107, N141, N143, N161, N163, P053, P143, P163	Models: N106, P106, N164, N165, P165
Quadrupolar CRT-D (DF4 ³ /IS-1/IS-1)	Replacement CRT-D (DF-1/IS-1-1/IS-1)	Replacement CRT-D (DF-1/IS-1/LV-1)

³ Some COGNIS models may be labeled with GDT-LLHH instead of DF4

ICD			
Model: E050, E103, E140, E160, F050, F103, F140, F160	Models: E051, E102, E141, E161, F051, F102, F141, F161	Models: E052, E111, E142, E162, F052, F111, F142, F162	Models: E053, E110, E143, E163, F053, F110, F143, F163
Quadripolar	<i>Replacement</i>	Quadripolar	<i>Replacement</i>
VR	VR	DR	DR
(DF4 ⁴)	(DF-1/IS-1)	(DF4/IS-1)	(DF-1/IS-1)

Header Attach

Several progressive improvements in header bond strength have been incorporated in the ICDs and CRT-Ds described in this primer. In Q1 2010, the header bond for COGNIS/TELIGEN was strengthened through:

- additional surface preparation on both the header and the body casing immediately before bonding
- additional bonding material around the bond seams

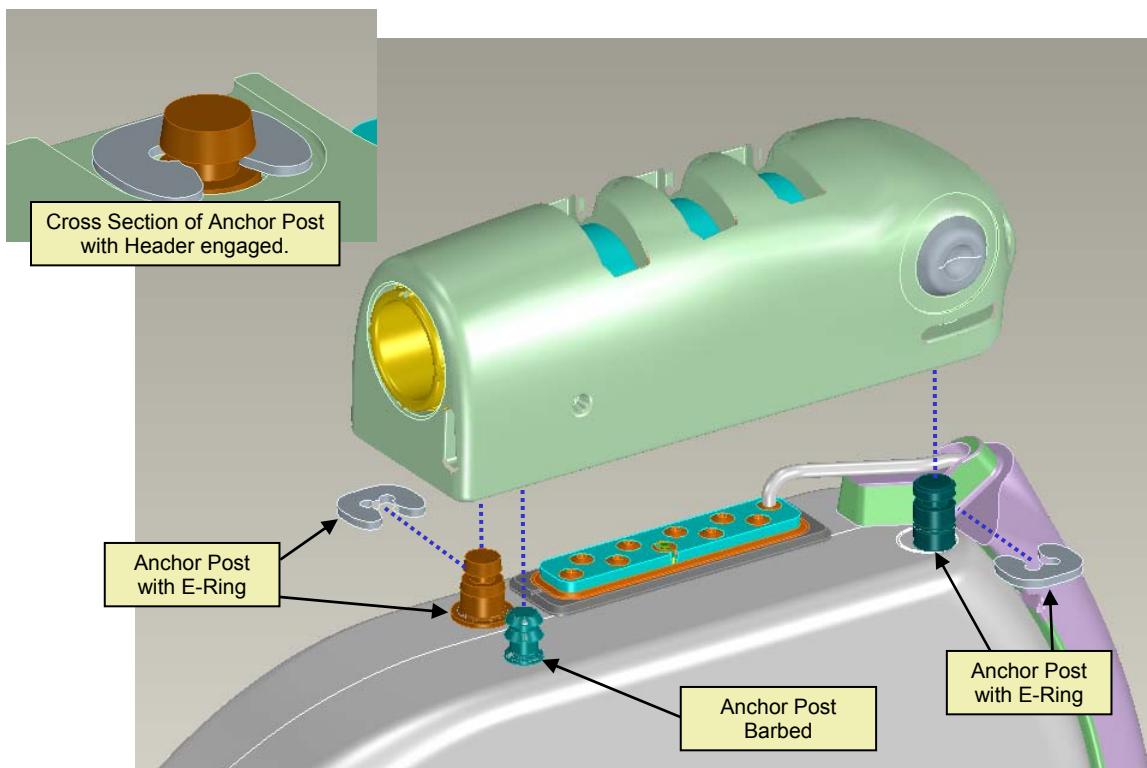
With these manufacturing process improvements, bond strength is routinely monitored by a destructive side-load test on a sample of production units. The following dash numbers⁵ describe COGNIS/TELIGEN devices which incorporate strengthened header bonds

- U.S.: -111 and above
- EU: -X11 and above where X depends upon the EU language configuration (i.e., in the UK-211). GDT-LLHH/4-SITE models were launched in Europe with the strengthened header bond.
- AUS: -855 and above for IS-1/DF-1 models. GDT-LLHH/4-SITE models were launched in Australia with the strengthened header bond.
- COGNIS/TELIGEN were launched in Japan with strengthened header bonds.

INCEPTA, ENERGEN, and PUNCTUA incorporate the changes described above for COGNIS/TELIGEN, and include a mechanical header attachment design incorporating three titanium anchor posts. Of the three anchor posts, one is barbed and anchors the header when the header is mounted on the casing. The other two anchor posts accommodate a stainless steel e-clip.

⁴ Some TELIGEN models may be labeled with GDT-LLHH instead of DF4

⁵ Dash number can be found on the outside packaging of the device. For example for 60E110-105 the dash number would be -105.



(ENERGEN VR DF4 Header Attachment, feed through wires not shown for clarity)

IS-1/LV-1/DF4 Spring Contacts

ICDs and CRT-Ds described in this primer use spring contacts within the header to complete the electrical connection between the pacing terminal pins and the device.

Spring contacts are designed to:

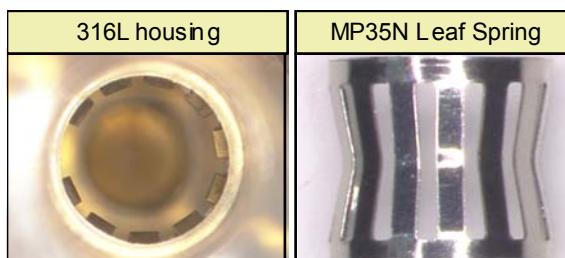
- Reduce reliance on setscrews for pacing sights
- Reduce device volume
- Simplify usability for physician customer

NOTE: The lead terminal needs to be fully seated in the lead port and setscrews need to be tightened to complete the circuit and provide pacing therapy. Pacing will not begin until the setscrew is tight.

Extensive corrosion testing has been done to verify spring contact reliability.

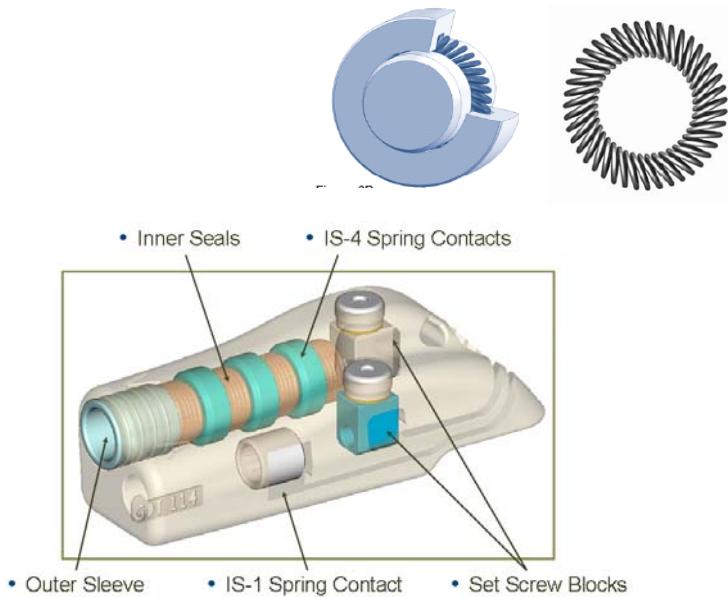
Leaf Springs – IS-1/LV-1

Spring contacts, with a 10-leaf point of contact, are incorporated as the proximal-ring terminal contacts for all IS-1 and LV-1 ports. The multi-leaf design has built-in redundancy; only 3 of 10 leaves need to be in contact with the ring to complete contact.



Bal Seal Spring – DF4

To accommodate closely spaced High Voltage electrical connections the DF4 lead connector design utilizes a Bal Seal Spring design. Bal Seal Springs are manufactured out of MP35N and support approximately 50 contact points.



DF4/4-SITE

The RELIANCE 4-SITE lead and compatible models of DF4 devices comprise the most recent connector system that features one single connection and is designed to be compatible with the international standard ISO 27186:2010. This connector replaces the three terminals and yoke of current RELIANCE leads and uses one terminal pin plugged into one port on the header, connected by one setscrew and three coil spring contacts. Pulse generators containing the header for this connector system are labeled either GDT-LLHH or DF4; leads will be labeled either GDT-LLHH (dual coil) or GDT-LLHO (single coil).



TELIGEN VR, DR, and COGNIS with a DF4 compatible header plus a RELIANCE 4-SITE lead connector

When compared to the IS-1/DF-1 connector system, the RELIANCE 4-SITE lead is designed to simplify the implant procedure and reduce pocket bulk through the consolidation of multiple terminals and setscrews into a single terminal and setscrew. In addition, the connector system provides the following advantages over IS-1/DF-1 systems:

- Isodiametric lead design can reduce the challenge of tissue dissection during a device change or lead extraction based on elimination of yoke and combining three terminals into a single connection.
- Minimize risk of complications by eliminating reversed DF+/DF- connections.
- Built upon the demonstrated performance of the RELIANCE lead.

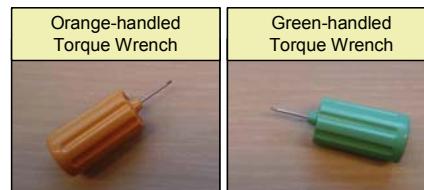
Torque Wrench

An orange-handled torque wrench (Model 6628) will be packaged with the devices. The torquing-in force (clockwise rotation) of the orange-handled wrench is the same as the green-handled torque wrench. The torquing-out force (counter clockwise rotation) is greater than the green-handled torque wrench.

- 25 inch-ounces when torquing-out (loosening) setscrew, *greater than green-handled wrench⁶*
- 15 inch-ounces when torquing-in (tightening) setscrew, *same as green-handled wrench*

NOTE: The *orange-handled wrench* is designed for use with BSC pulse generators having *white seal plugs*. The torque wrench may also be used when explanting BSC pulse generators having clear seal plugs.

Give careful attention when using this torque wrench with Boston Scientific pulse generators having *clear seal plugs*. The additional counterclockwise torque of this wrench may cause the setscrews in these pulse generators to become stuck if tightened against the stop. Similar consideration is required when using this torque wrench with lead adaptors and lead extenders that have setscrews that tighten against a stop when fully retracted.



Magnet Sensor

The magnet functions were previously triggered when an electromechanical switch (reed switch) closed in the presence of a magnetic field. Devices described in this primer have replaced an electromechanical switch with a solid-state sensor that may detect a magnetic field of 50 gauss or greater.

The solid state sensor incorporates a Hall Effect circuit located within an integrated chip on the hybrid circuitry. It is constructed and manufactured alongside and with the same methods as other transistors that control pacing, sensing, telemetry, and other functions of the pulse generator. A very small current is constantly applied through the sensor and the transverse voltage of the current is monitored. Magnets are detected based on changes in the transverse voltage of this current in the Hall Effect circuit. When no magnet is applied to the pulse generator, the transverse voltage is zero. When a doughnut magnet is applied to the pulse generator, the transverse voltage is non-zero. There are no actuating mechanical parts within this magnetic sensor that can stick.

⁶ The green-handled torque wrench (model 6942) torques in and torques out with 15 inch-ounces

LATITUDE Availability

The LATITUDE Remote Patient Monitoring system is available in the U.S. and certain European geographies. Pending regulatory approval, Boston Scientific intends to expand the availability of LATITUDE to other international geographies over time. All ICD and CRT-D models described within this primer are LATITUDE capable. PUNCTUA NE models F051, F053, and P053 may not be LATITUDE enabled in most geographies.



Battery Introduction

Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Battery chemistry	Lithium-silver-vanadium-oxide (Li/SVO)	Advanced Battery Technology: Lithium Manganese Dioxide (Li/MnO ₂) ⁷
Battery depletion curve	May exhibit a low point mid-life	Steady, gradual decline over time
Pre-implant testing	Battery status at BOL. Monitoring voltage displayed on box label. Cap re-form charge times within normal limits	Cap re-form charge times must be within normal limits
Cold temperature monitoring	None	Temperature sensor provides warning of low temperature
Capacitor re-form frequency	BOL - 90 days MOL1 thru ERI - 30 days	<ul style="list-style-type: none"> Beginning of life to 6 months after One Year Remaining status indicator is declared - 90 days 6 months after One Year Remaining indicator thru Explant - 30 days
Auto cap re-form	<ul style="list-style-type: none"> Tests the internal circuitry's ability to deliver a shock Reduce the effect of capacitor deformation on charge time and minimize internal battery impedance 	<ul style="list-style-type: none"> Tests the internal circuitry's ability to deliver a shock Reduce the effect of capacitor deformation on charge time

⁷ While INCEPTA, ENERGEN, and PUNCTUA have been designed to accept a Li/CFx-SVO battery as a supply chain contingency, Boston Scientific does not intend to distribute any of these devices with this battery.

Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Battery status indicator display	<ul style="list-style-type: none"> Determined by either monitoring voltage or charge time Monitoring voltage displayed on gas gauge that provided a measure of remaining capacity 	<ul style="list-style-type: none"> Determined by capacity consumed or charge time Battery status is indicated on a Time to Explant gauge which provides a prediction of when device will need to be replaced Monitoring voltage used as part of capacity consumed calculation and is no longer displayed to the user
Battery status indicators	BOL (Beginning of Life) MOL1 (Middle of Life 1) MOL2 (Middle of Life 2) ERI (Elective Replacement Indicator) EOL (End of Life)	<ul style="list-style-type: none"> One Year Remaining Explant⁸ Battery Capacity Depleted (formerly EOL)
Device longevity prediction	Standard table in System Guide	Standard table in System Guide, in addition, the device/programmer provide the following calculations: <ul style="list-style-type: none"> Approximate Time to Explant, based on capacity consumed Charge Remaining Power Consumption Comparison of device parameters to standard settings

Background

Since 1985, ICD systems have been powered by lithium-silver-vanadium-oxide (Li/SVO) batteries. Li/SVO powered ICDs have a strong track record for safety and reliability, but the mid-life charge time performance has not been optimal. ICDs and CRT-Ds described in this primer use Boston Scientific's Advanced Battery Technology: Lithium Manganese Dioxide (Li/MnO₂) technology⁹.

This Advanced Battery Technology was developed for the following reasons:

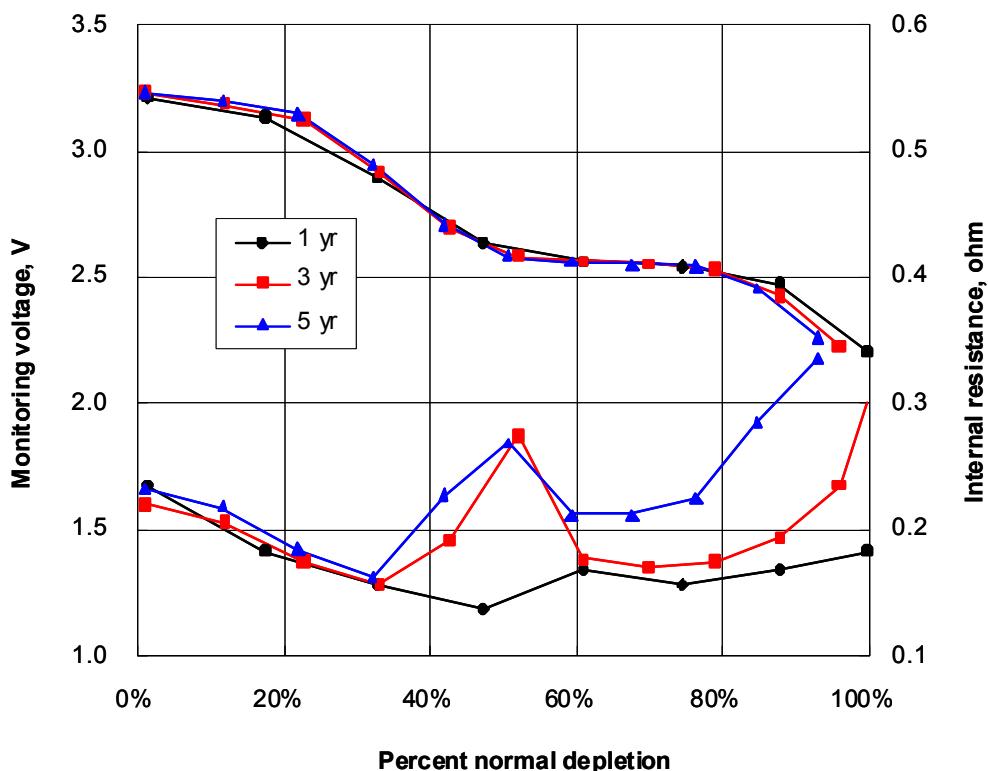
- Elimination of mid-life rise in internal resistance observed in Li/SVO batteries providing more predictable charge times over the life of the device.
- Consistent discharge behavior under a variety of use cases providing more predictable discharge performance than Li/SVO.

⁸ Up to 90 days after triggering Explant, Battery Capacity Depleted is triggered and device functionality is reduced

⁹ While INCEPTA, ENERGEN, and PUNCTUA have been designed to accept a Li/CFx-SVO battery as an Li/MnO₂ supply chain risk mitigation, Boston Scientific has mitigated the identified supply chain risks associated with Li/MnO₂ and therefore does not intend to distribute any of these devices with Li/CFx-SVO batteries.

The following charts¹⁰ compare the discharge and charge time performance differences between Li/SVO and Li/MnO₂ Advanced Battery Technology.

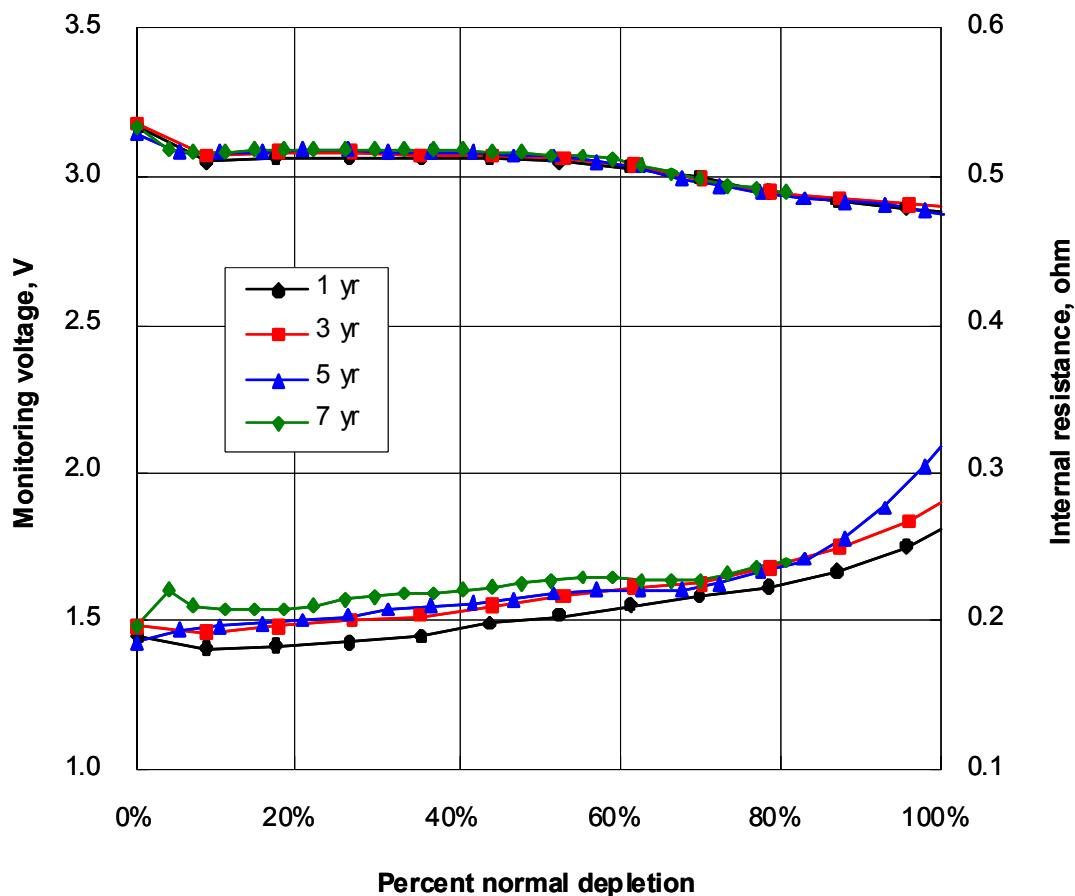
Li/SVO: Variable battery performance (top lines are voltage, bottom lines are resistance, peak at 50% depletion is ERI)¹¹

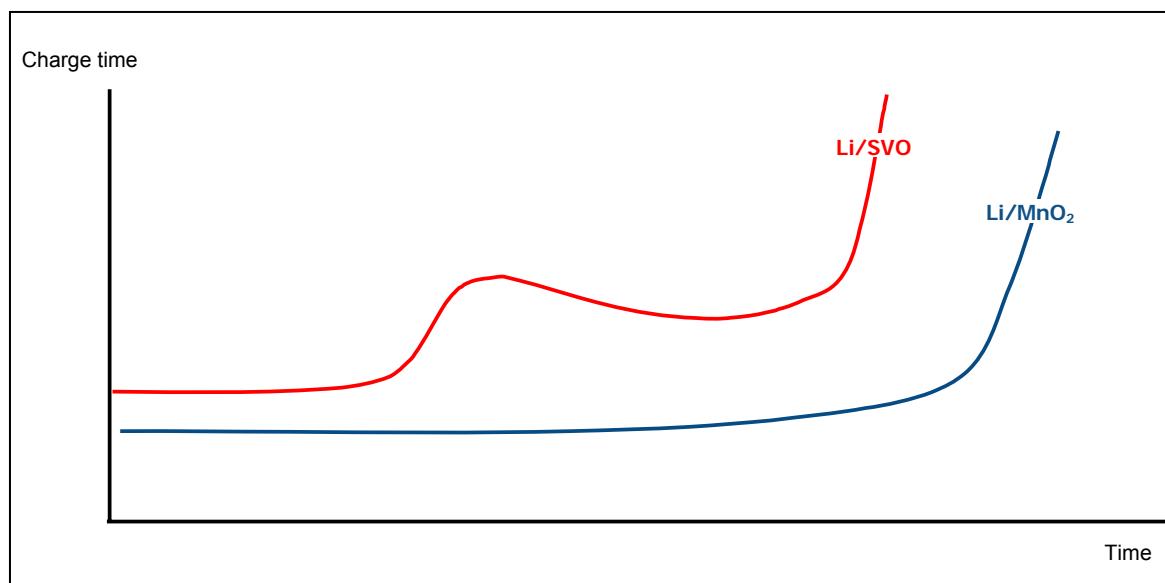


¹⁰ Data on file.

¹¹ Data on file.

MnO₂: Consistent and Stable Performance (top voltage, lower resistance, no MOL impedance increase)

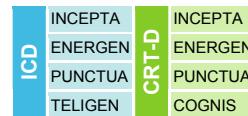


Battery comparison: Li/SVO and Li/MnO₂ charge time¹²

The evaluation of this Advanced Battery Technology is validated by testing over 7,000 batteries, including batteries with five-year, real-time bench testing using clinically realistic programming.

While other manufacturers use this chemistry, Boston Scientific's Advanced Battery Technology is a proprietary design manufactured with proprietary processes which incorporate Aurora best practices.

Battery Status Assessment



Battery status is monitored automatically by the device to provide information on how the battery is performing and how close the device is to replacement time.

ICDs and CRT-Ds described in this primer use a combination of several measurements to calculate battery status:

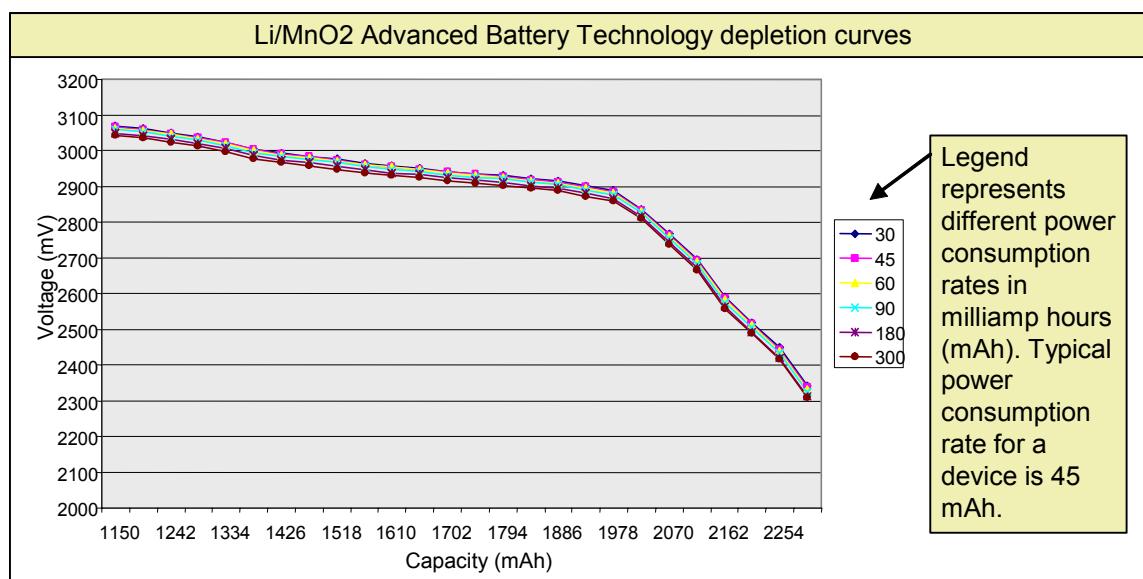
Capacity Consumed – a measure of energy the device has already used, based on programmed parameters; capacity consumed is calculated based on a coulomb counter (that measures usage), battery voltage, or a blending of the two.

Charge Time – either capacitor re-forms or therapy shocks.

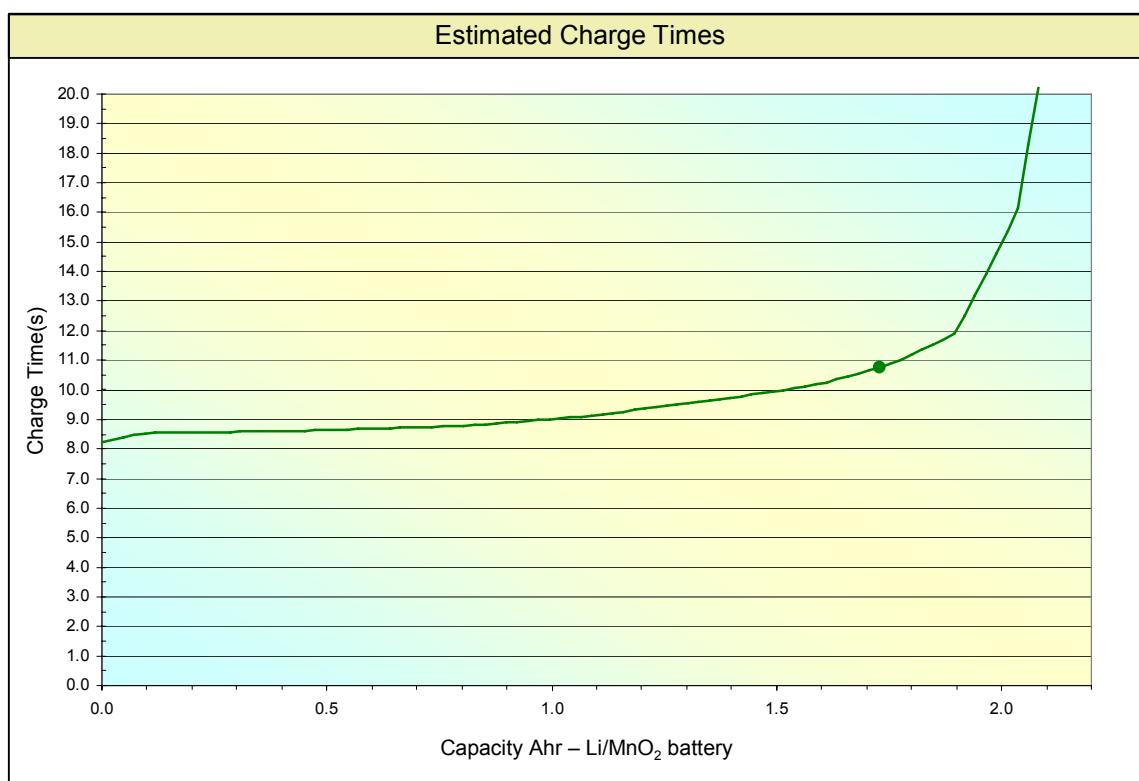
¹² Data on file.

During the early portion of the battery depletion curve, battery voltage changes are very small. In addition, voltage may temporarily decrease after a high-power event, such as a shock. Therefore, monitoring voltage is no longer provided as a measurement to the user; voltage is used as only one of the measurements that calculate overall battery status.

Battery comparison: Li/MNO₂ and Advanced Battery Technology depletion curves¹³

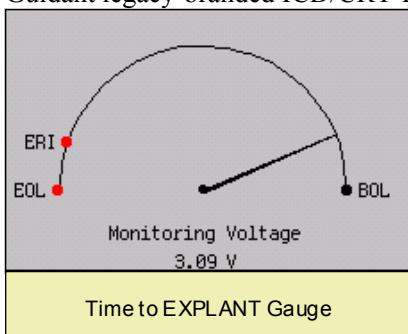


¹³ Data on file.



LiMnO₂ battery esimated charge times¹⁴

Guidant legacy-branded ICD/CRT-Ds provided a measure of capacity remaining through a gas gauge image and monitoring voltage display. These values did not reflect specifically how much time remained before the device would have to be explanted, and were not immediately impacted by changes in programming.

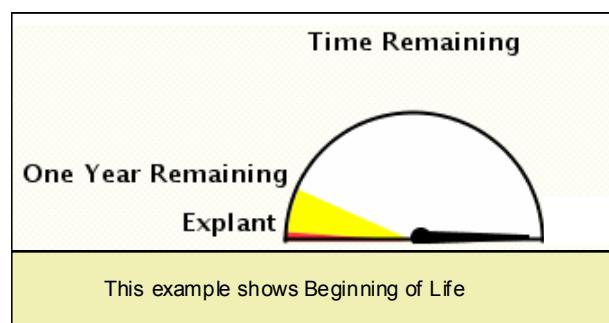


ICDs and CRT-Ds described in this primer measure actual battery capacity consumed to more specifically predict when the device requires replacement.

Battery status starts at Beginning of Life and moves through battery status life phases.

See Battery Status table.

Battery status is reported to the user as a status indicator and as a position on the Time to Explant gauge. The needle on the gauge moves to provide a visual indicator of time



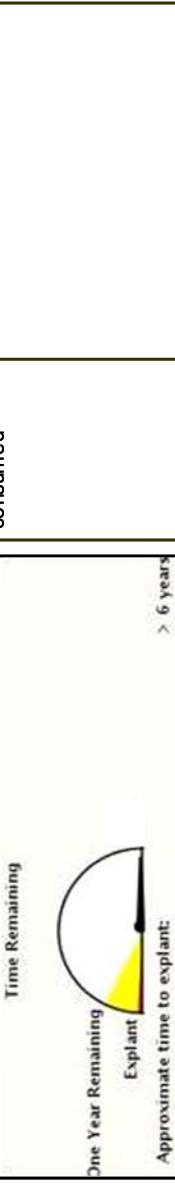
¹⁴ Data on file.

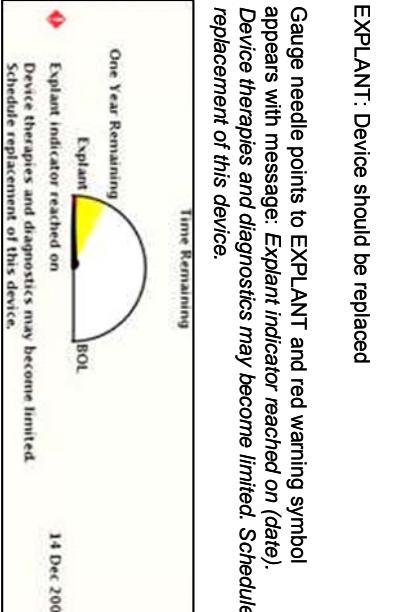
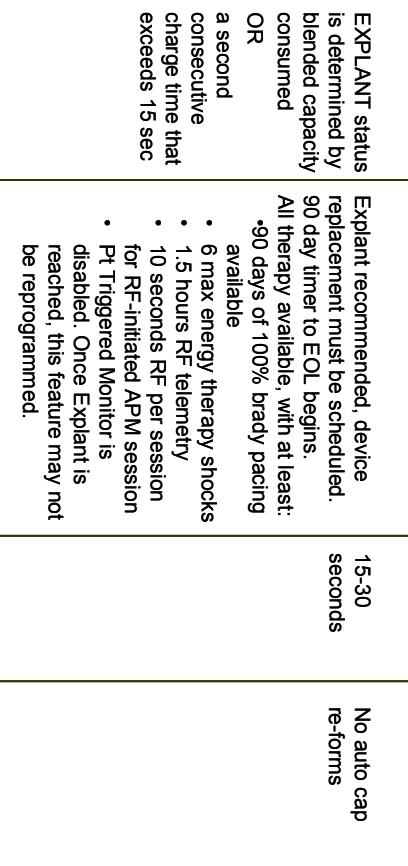
remaining (e.g., the vertical or noon position of the needle is the 50 percent or halfway point in the life of the device).

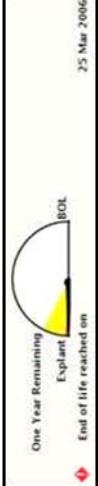
The device and programmer provide the following calculations:

- Current overall battery status, indicated by status indicator and Time to Explant gauge
- Approximate Time to Explant
- Most recent charge time
- Last delivered shock date, energy, charge time, and shock impedance
- Date and charge time for last capacitor re-form
- Charge remaining
- Power consumption at programmed parameters

Each of these calculations is described in detail in the Battery Status table that follows.

Status as shown on screen	How status is calculated	Clinical Information
		Expected C time range
<p>Beginning of Life Battery status up until 7 days after exiting Storage mode. Note: that the Approximate time to explant is not an exact number at this point.</p>	<p>Time Remaining is determined by blended capacity consumed</p>  <p>Approximate time to explant: > 6 years</p>	<p>Conduct routine follow-up examinations one month after the pre-discharge study and every three months thereafter</p>
<p>7 days after exiting STORAGE the Approximate time to explant number now has a more exact estimate, based on capacity consumed measurements.</p>	 <p>Approximate time to explant: 6.5 years</p>	<p>As implant time progresses, the gauge needle moves toward the ONE YEAR point and the Approximate time to explant is adjusted accordingly. Battery Status is still BOL.</p>

Status as shown on screen	How status is calculated	Clinical Information	Expected C time range	Auto Cap Re-form
<p>One Year Remaining: Approximately one year (\pm 2-3 months) remaining until EXPLANT status is reached.</p> <p>Gauge needle is at the One Year Remaining point and a Caution symbol appears next to the Approximate time to explant.</p>  <p>Approximate time to explant:</p> <p>One Year Remaining Explant BOL 1 year</p> <p>As implant time progresses, gauge needle moves through the yellow One Year Remaining area, and approximate time to explant is updated.</p> <p>EXPLANT: Device should be replaced</p> <p>Gauge needle points to EXPLANT and red warning symbol appears with message: Explant indicator reached on [date]. Device therapies and diagnostics may become limited. Schedule replacement of this device.</p>  <p>Explant indicator reached on Device therapies and diagnostics may become limited. Schedule replacement of this device.</p> <p>14 Dec 2005</p>	<p>One Year Remaining status is determined by blended capacity consumed OR a second consecutive charge time that exceeds 15 sec</p> <p>EXPLANT status is determined by blended capacity consumed OR a second consecutive charge time that exceeds 15 sec</p> <p>Explant recommended, device replacement must be scheduled. 90 day timer to EOL begins. All therapy available, with at least: <ul style="list-style-type: none"> • 90 days of 100% brady pacing available • 6 max energy therapy shocks • 1.5 hours RF telemetry • 10 seconds RF per session for RF-initiated APM session • Pt Triggered Monitor is disabled. Once Explant is reached, this feature may not be reprogrammed. </p>	<p>Conduct routine follow-up examinations every three months. Physician may consider more frequent (monthly) follow-ups when 6 months remain if the patient cannot hear the beeper.</p> <p>Significantly shortened if additional therapy shocks occur.</p> <p>Second six month period of One Year Remaining every 30 days</p> <p>No auto cap re-forms</p>	<p>12-15 seconds</p> <p>First six month period of One Year Remaining every 90 days</p> <p>15-30 seconds</p>	<p>Auto Cap Re-form</p>

Status as shown on screen	How status is calculated	Clinical Information
Expected C time range	Auto Cap Re-form	
<p>Battery Capacity Depleted: Device is beyond EXPLANT status and has limited therapy available</p> <p>Gauge needle stays at Explant; red warning symbol appears with message: <i>End of life reached on (date)</i></p> 	<p>Battery Capacity Depleted status is determined by:</p> <ul style="list-style-type: none"> • 90-day EOL timer • Capacity consumed calculations • A second consecutive charge time > 30 seconds 	<p>Device should be scheduled for immediate replacement.</p> <p>Device is limited to:</p> <ul style="list-style-type: none"> • Max energy shocks and manual cap re-forms only; ATP and low energy shocks no longer available • One-zone, rate cut-off 165 (non-programmable) • Brady pacing mode VVI, rate 50 bpm (non-programmable) • Approximately 90 days of brady therapy remaining • Brady enhancements no longer available • Brady Mode and Tachy Mode may be programmed to OFF; no other parameters are programmable • Therapy history and daily measurements will no longer be recorded • Diagnostic and EP test no longer available • Save to disk saves current brady mode, tachy mode and battery status; other parameters are last interrogated values or nominal. • Wanded telemetry available, but limited <ul style="list-style-type: none"> - No RF telemetry - No real-time EGMs - No large queries (history such as episodes, HRV data, trends, etc.) - 10 seconds RF per session for RF initiated APM session <p>If the device entered EOL due to either charge time or capacity consumed, it may revert to EXPLANT or ONE YEAR if the device measurements recover.</p> <p>If it reached EOL due to the 90-day EOL timer, the device is permanently in EOL.</p> <p>If 3 daily voltage measurements occur below 2.3 volts, the device reverts permanently to STORAGE Mode to preserve memory, and therapy is no longer available. STORAGE Mode is displayed as Tachy Mode = STORAGE at the top of the screen.</p>

Availability

- Battery status is reported upon each interrogation of the device, on the Summary screen and Battery Status screens, and on Device Follow-Up Reports.
- Battery status is updated automatically every 21 hours, or whenever a full energy charge is pulled from the device.

Programmable Values

None.

Algorithm

Because of the way the battery depletes over time, a combination of calculations is used to determine overall battery status. The device determines the battery status by considering either of the following:

Charge Time for the most recent charge – (cap re-form, STAT or therapy shock). Two consecutive charge times are required to change the battery status.

Daily Battery Measurement – which uses voltage, capacity consumed, and average power calculations. Three consecutive battery measurements indicating a new status are required before the battery status will be changed.

The device will use the worst of the two measurements; i.e., the measurement that is closest to total battery depletion.

NOTE: If the battery status has changed due to daily battery measurements or charge time and the measurements of charge time improve or recover, the battery status may recover over time to a better status.

NOTE: When Explant is declared the pulse generator must be scheduled for replacement. Unlike previous devices, ICDs and CRT-Ds described in this primer have a 90-day timer that starts once Explant is reached. Once the 90-day timer has expired, the device will declare BATTERY CAPACITY DEPLETED, and the device will be limited to a single zone of therapy with a fixed brady rate and mode.

See Battery Status table.

Charge Time

The device measures the charge times of automatic and manual capacitor re-forms, charges for therapy shocks, or STAT shocks. Based on battery performance testing, Boston Scientific does not expect battery status indicators to be triggered by charge times.

Charge time is used by the device as a back-up method as one of the indicators for Explant or Battery Capacity Depleted status. There are no charge time limits associated with One Year Remaining; this status are determined through the Daily Battery Measurement.

If any charge time is greater than the charge time limit for Explant or Battery Capacity Depleted, a second confirmation cap reform is scheduled one hour later. If that confirmation capacitor re-form charge time also exceeds the limit, the device declares battery status to be Explant or Battery Capacity Depleted. If the confirmation capacitor reform charge time is less than the Explant or Battery Capacity Depleted limit, the battery status will revert to the previous phase.

NOTE: Any charge time over the threshold can take the device to Explant or Battery Capacity Depleted, but only full energy, non-diverted charges will be used to improve the battery status.

Charge time limits are:

Explant	A second consecutive charge time that exceeds 15 seconds .
Battery Capacity Depleted	A second consecutive charge time that exceeds 30 seconds .

Typical Maximum-Energy charge time over the life of the device

ICD		CRT-D	
Charge Remaining (Ah) ¹⁵	Maximum-energy Charge Time Range (seconds)	Charge Remaining (Ah) ¹⁶	Maximum-energy Charge Time Range (seconds)
1.8 to 0.7	8 to 10	2.1 to 1.0	8 to 10
0.7 to 0.1	10 to 13	1.0 to 0.4	10 to 12
		0.4 to 0.3	11 to 13

NOTE: The maximum-energy charge time ranges above are based upon theoretical electrical principles and verified bench testing only.

Daily Battery Measurement

- Every 21 hours the device calculates the following to determine battery status:

¹⁵ At Explant, the remaining charge is typically 0.37 Ah, and may vary depending on the amount of therapy delivered over the life of the pulse generator. Remaining capacity is used to support device function between Explant and Battery Capacity Depleted indicators.

¹⁶ At Explant, the remaining charge is typically 0.44 Ah, and may vary depending on the amount of therapy delivered over the life of the pulse generator. Remaining capacity is used to support device function between Explant and Battery Capacity Depleted indicators.

- Voltage
 - Blended capacity consumed, which combines a coulomb counter and voltage measurement
 - Power consumption
 - Temperature used as part of the voltage measurement
- A battery measurement will be valid if the coulomb counter, the voltage, and the temperature measurements are all valid.

Voltage

- The device measures open-circuit, or monitoring voltage; this simply means the battery voltage measurement is taken when the device is not charging.
- Voltage measurements will not be considered during battery status calculations if:
 - Device is currently charging
 - During real-time telemetry
 - Device temperature is < 0° C (32° F)
 - Voltage is recovering from a recent high-power event such as RF telemetry or a high-voltage shock. Depending on how recently the high-power event occurred and the amount of temporary drop in voltage, the device may not perform the Daily Battery Measurement, or may use a calculated recovery voltage in place of the average voltage.
- Voltage measurements are used as part of the *capacity consumed calculation* and are not reported to the user.

NOTE: A voltage fault message will be triggered if the voltage is lower than expected for the capacity consumed. The fault will be based on the following:

- Previous blended capacity consumed is < 35.8 percent and
- Three consecutive daily battery voltage measurements < 3.025V or
- Previous blended capacity consumed is > 35.8 percent and < 62.5 percent and
- Three consecutive daily battery voltage measurements < 2.75 V

Coulomb Counter

The hardware for devices described in this primer measures current flow over time through a coulomb counter to determine capacity consumed by the device.

1 Coulomb (C)	The amount of electric charge carried by a current of 1 ampere flowing for 1 second.
1 Ampere	Electric current is measured in coulombs/sec or amperes; 1 coulomb/sec = 1 ampere.
1 Ampere hour (Ah)	1 Ampere of current (flow) for 1 hour; 3600 coulombs.

1 Coulomb/sec = 1 Ampere	Electric current is measured in coulombs/sec or amperes; 1 coulomb/sec = 1 ampere.
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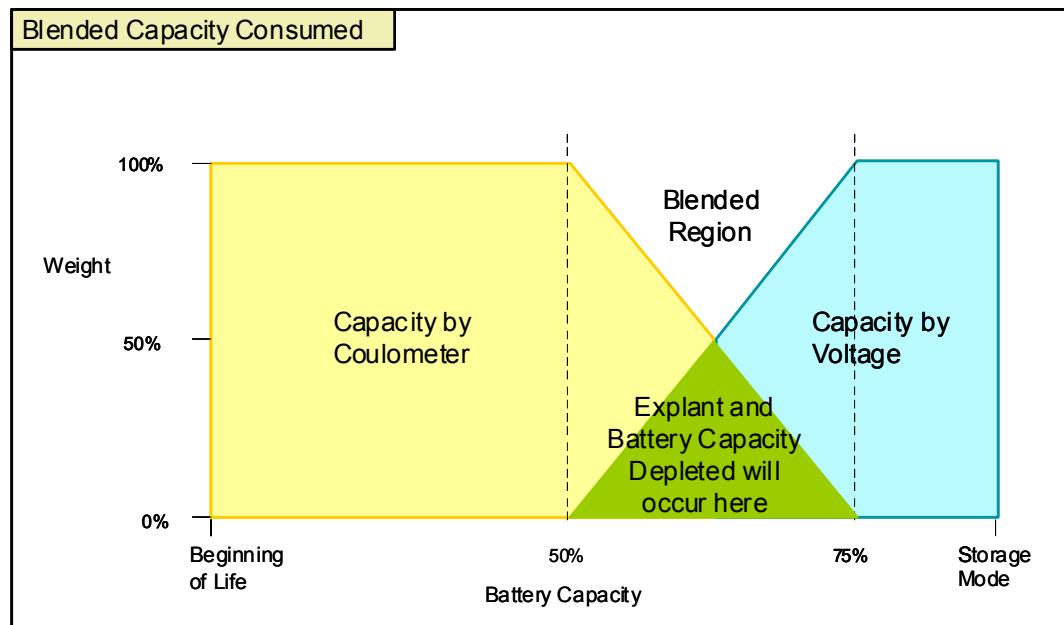
Blended Capacity Consumed

Blended capacity consumed is a calculation based on the coulomb counter, a blended calculation of coulombs consumed and monitoring voltage, or monitoring voltage alone.

The coulomb counter measurement has a calibrated accuracy of ± 10 percent, and is used as the only measure of capacity consumed in the first half of device life. Because the battery depletion curves are relatively flat early in the life of the device, voltage is not used early in the life of the device. As the device nears Explant status, the battery measurement accuracy becomes more critical. Voltage measurements have good accuracy near Explant and so become a larger part of the blended capacity later in the life of the device.

As shown on the following diagram, from BOL to 50 percent capacity consumed, the device determines capacity consumed by the coulomb counter alone. From 50-75 percent total capacity used, the device uses a blend of coulomb counter and monitoring voltage.

After 75 percent of the total battery capacity is consumed, the device determines capacity consumed by monitoring voltage alone. Explant and Battery Capacity Depleted status will occur in the blended region.



Once the Daily Battery Measurement (i.e., coulomb counter and monitoring voltage) has been calculated, the device will review both the Daily Battery Measurement and the most recent charge time to determine Battery Status. The device determines Battery Status by whichever indicator, Charge Time, or Daily Battery Measurement, is worse, i.e., *whichever measurement is closer to total*

battery depletion. At Beginning of Life and until the One Year Remaining limit is reached, the Daily Battery Measurement rather than Charge Time will be the most likely indicator of status; as the battery depletes, either Charge Time or Daily Battery Measurement could determine status.

Example 1: Charge Time (CT) for a TELIGEN device = 14 seconds.

- Daily Battery Measurement calculates battery status to be One Year.
- Battery Status will be One Year based on Daily Battery Measurement.

Example 2: Charge Time (CT) for a COGNIS device auto cap re-form is 17 seconds.

- Device schedules a second auto cap re-form for the next hourly check if it exceeds the maximum CT value. That second CT is 16.5 seconds, exceeding CT limit for Explant. (If a Tachy Episode has a shock with a Max Energy exceeding the CT limit, an auto cap-reform will be scheduled for the next hourly check, which could be in less than one hour meaning the device could have two Max Energy CTs in less than one hour).
- The Daily Battery Measurement through capacity consumed, determines status to be One Year for that same device.
- The device declares Battery Status of Explant based on CT.

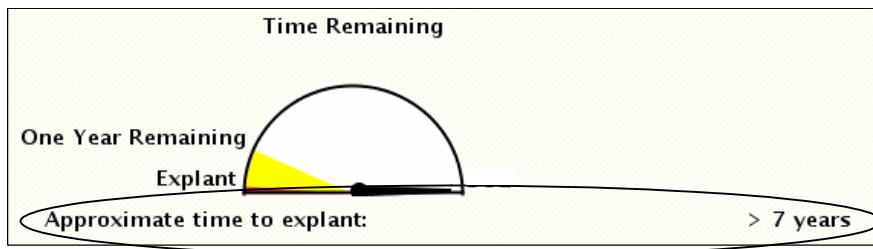
Additional Battery Information

In addition to the overall Battery Status, the device provides the following information about the battery status:

Approximate Time to Explant – projected time remaining until Explant status is reached. The device considers capacity consumed calculated for the Daily Battery Measurement and uses Charge Remaining (Amp-Hr), Power Consumption (μ W), and an estimate of shocks remaining to calculate this value.

The estimated number of shocks remaining is taken from the standard longevity tables and considers remaining capacitor re-forms as well as an estimated number of therapy shocks. Changes to the number of actual therapy shocks received may affect the accuracy of this estimate.

See the Physician Technical Manual.



NOTE: The approximate Time to Explant will be displayed as > N years until seven days after the device is taken out of Storage mode.

- For any times greater than one year, Approximate Time to Explant will be N years or N.5 years (i.e., will decrement in half-year increments).
- For times less than one year, Approximate time to Explant will be N months, decrementing in one-month increments (e.g., 11 months to 4 months) until < 3 months remain.

The calculation for Approximate Time to Explant will adjust the needle position on the Time to Explant gauge.

When insufficient usage history is available (particularly at implant), longevity predictions may change between interrogation sessions. This fluctuation is normal and occurs as the pulse generator collects new data and can calculate a more stable prediction. Longevity predictions will be more stable after several weeks of usage. If certain brady features (Brady mode, Pulse Width, Amplitude) are reprogrammed, the Approximate Time to Explant will be forecasted based on the expected changes in power consumption from the reprogrammed features. The next time the pulse generator is interrogated, the programmer will resume displaying longevity predictions based on recent usage history. As new data is collected, the longevity predictions will likely stabilize near the initial forecast.

Charge Remaining – describes the battery capacity or current supplying capability remaining until the device reaches total battery depletion. Charge Remaining is reported in ampere-hours (Ah). Charge Remaining is an indication of overall battery performance, and will not indicate when to schedule a device replacement. *Device replacement decisions should be based on the Battery Status indicator only.*

- ICD models described in this primer have 1.7 Ah at beginning of life
- CRT-D models describe in this primer have 2.0 Ah at beginning of life

Power Consumption – average daily power being used by the device based on current programmed settings. Power is the product of current and voltage; therefore, changes affecting current drawn from the battery affect power consumed. If any of the following programmed parameters are changed, this value is adjusted to reflect those changes:

- Pacing Amplitude (any chamber)
- Pacing Pulse Width (any chamber)
- Lower Rate Limit (LRL)
- Brady Pacing mode
- Max Sensor Rate (MSR)

Power consumption is reported in microwatts (μW), and is included in the calculations that determine Approximate Time to Explant and the needle position on the Time to Explant gauge.

The Battery Detail screen also provides a percentage comparison of the calculated power consumption to the standard parameters used to quote device longevity.

See the Longevity Tables published in the Physician Technical Manual for values used.

The percentage quoted is based on the standard longevity tables. If a particular device is programmed to outputs higher than those listed in the longevity tables, the calculation will show > 100 percent in this statement. Programming new values for pacing output will change the percentage comparison.

NOTE: Power consumption and percent power are calculated by the programmer based on capacity consumed measurements taken from the device. Power consumption calculations will be shown as N/R until the device has been out of Storage mode for at least seven days.

Charge Remaining	2.08 ampere-hours
Power Consumption	99 microwatts
(Measured with programmed parameters)	
 This device is using 170% of the power it would use at the following parameters:	
 A 15% pacing, 2.5 V, 0.4 ms, 500 Ω  RV 100% pacing, 2.5 V, 0.4 ms, 700 Ω  LV 100% pacing, 3.5 V, 0.4 ms, 700 Ω (These parameters are used to quote device longevity)	
Charge Remaining and Power Consumption information from Battery Detail Screen	

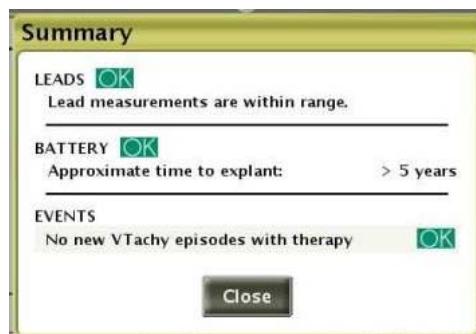
In a single programmer session, programming new pacing values will reflect a new power consumption and percent power calculation that can be used to estimate longevity. However, the device requires 30 days of data to accurately reflect power consumption based on new settings. Once a programming session is ended, a new session may not reflect changes in the average power consumption for > one month after the settings are programmed.

Example: A change to parameters may be reflected in power consumption at follow-up as a prediction, but once the parameters were actually programmed and the programmer session ended and if the device were interrogated the next day, the power consumption shown will likely be different than the predicted values and not yet reflect the changes programmed.

Changes to the power consumption value will occur approximately every seven days based on battery daily measurement data with an accurate prediction reflected after approximately four weeks.

Battery Status Screens

Summary Window – Each time a device is interrogated, a Summary window will appear, listing the lead status, battery status, Approximate Time to Explant, and whether there have been any episodes since the counters were last cleared.

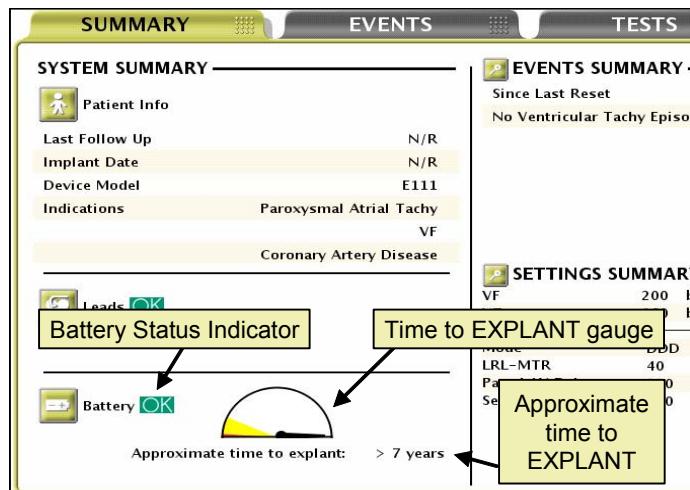


Summary Tab – the Summary screen, the first screen presented after the Summary window is cleared, also shows battery status information, including:

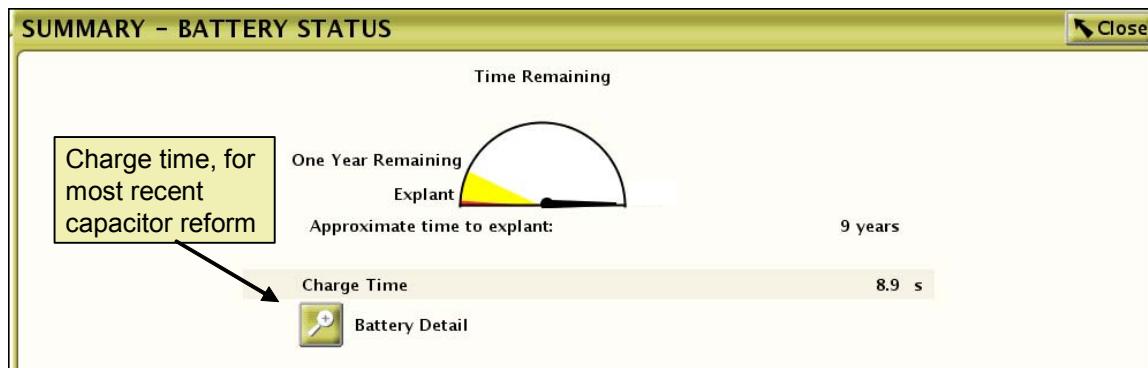
- Battery Status Indicator
- Time to Explant gauge
- Approximate Time to Explant

Summary – Battery Status

Screen – from the Summary screen select  **Battery**



to navigate to the Battery Status screen. The Battery Status screen provides the battery information needed for any follow-up.



Summary – Battery Detail Screen –

from the Battery Status screen select  **Battery Detail** to navigate to the Battery Detail screen.

In addition to the calculations already defined, the Battery Detail screen provides:

- Information about the last delivered shock: date delivered, energy delivered, charge time, and shock impedance
- Date and charge time for last capacitor re-form (manual or auto)

The Battery Detail screen also allows the user to program *Beep when Explant is indicated*, and to command a manual cap re-form.

NOTE: The device must be at least seven days out of Storage mode for any information to be reflected on this screen, but performing a Manual Re-form Capacitor when the device is taken out of Storage will populate the Last Capacitor Re-form and Charge Time information.

Beep When Explant is Indicated (Nominal: ON)

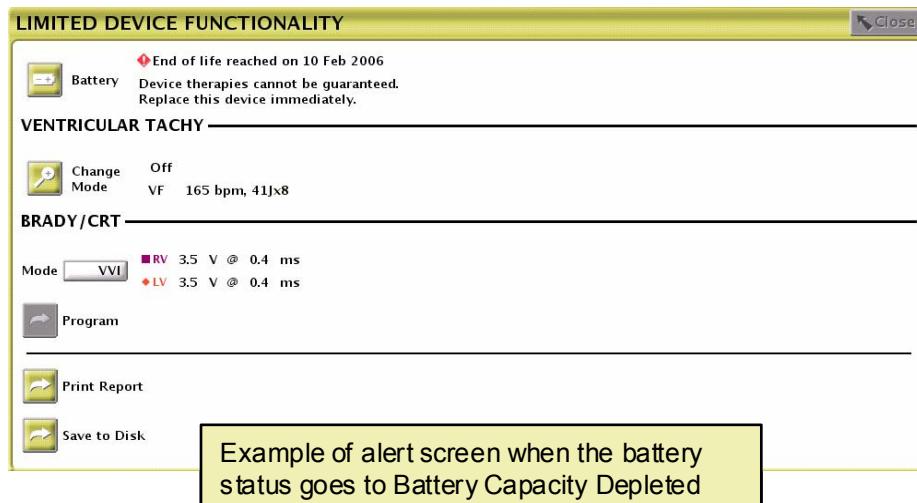
- Programmable feature that provides an audible beep tone to the patient when the device reaches battery status of Explant.
- If this feature is programmed ON, the device will beep 16 times (once each second) every six hours when Explant is reached. This feature is nominally ON.
- Once Explant is reached and the patient has been alerted, Beep on Explant may be programmed OFF to prevent further beeping.

Manual Re-form Capacitor – commands a capacitor re-form from the device to provide a measure of device charge time.

See the Capacitor Re-formation topic for more details.

Notes/Additional Information

- Lower current drain in Storage mode: devices prior to COGNIS/TELIGEN consumed 10 microamperes current, ICD and CRT-D devices described in this manual consume only 5 microamperes in Storage mode.
- If a telemetry session is in progress when the daily battery measurement is scheduled, the battery measurement will be postponed and retried in one hour.
- If an episode is in progress when the Daily Battery Measurements are scheduled, the measurement will be rescheduled for one hour later, and if another episode is in progress, the device will continue to reschedule the Daily Battery Measurement up to three times with an hour in between each attempt. After the third unsuccessful attempt, the Daily Measurements are not performed for that day.
- Once the Time to Explant gauge decreases to be less than 100 percent, it will not recover back to 100 percent.
- When the device reaches Battery Capacity Depleted status, an alert screen will be displayed upon interrogation, to remind the user of the limits of device function. This screen cannot be closed.



- While the device is in Storage mode, some conditions will trigger a fault message upon interrogation to prevent use of a device that has used or is using more battery capacity or power than expected.
- When the battery is depleted, inductive (wanded) telemetry may possibly be affected, resulting in drop-out, especially during charging. Repositioning the wand by moving the wand slightly side-to-side may improve telemetry. The optimal centering point for the wand is near the corner of the device near the header/antenna.

ICD	INCEPTA	INCEPTA
	ENERGEN	ENERGEN
	PUNCTUA	PUNCTUA
	TELIGEN	COGNIS

Capacity Re-formation

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

Background

- Automatic capacitor re-formations (hereafter called cap re-forms) have also benefited legacy Guidant ICD and CRT-D systems with Li/SVO batteries by reducing the mid-life internal battery impedance. While the Advanced Battery Technology used for ICDs and CRT-Ds described within this primer has not exhibited the mid-life internal battery impedance observed in Li/SVO batteries, automatic cap re-forms provide users with a charge time performance assessment at follow-up.
- The cap re-form process charges the high voltage capacitors to maximum energy and then dumps the energy to an internal resistor.
- Implant instruction from the physician technical manual instruct the user to perform a manual capacitor re-form before implant.

Availability

Cap re-forms are performed automatically by the device or are manually commanded through the programmer.

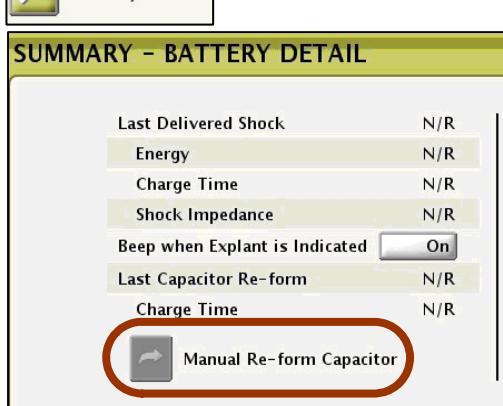
Frequency of automatic cap re-forms depends on battery status:

Battery Status	Automatic Capacitor Re-form Frequency	Manual Cap Re-forms
Storage	No auto cap re-forms are performed	Manual cap re-forms may be commanded
Beginning of Life through One Year Remaining	Every 90 days	Manual cap re-forms may be commanded

Battery Status	Automatic Capacitor Re-form Frequency	Manual Cap Re-forms
One Year Remaining	<ul style="list-style-type: none"> Every 90 days from the time One Year is declared up until six months after One-Year status is declared Every 30 days when more than six months have passed since One Year was declared 	Manual cap re-forms may be commanded
Explant	No auto cap re-forms are performed	Manual cap re-forms may be commanded
Battery Capacity Depleted	No auto cap re-forms are performed	Manual cap re-forms may be commanded. Once device reverts to Storage mode, it stays there regardless of cap re-forms.

Manual cap re-forms may be commanded through the Zoom programmer, from the Battery Detail screen:

1. From the Summary screen select 
2. From the Battery Status screen select 
3. From the Battery Detail screen select
⇒ Manual Re-Form Capacitor



Programmable Values

None; frequency and schedule of auto cap re-forms are automatically managed by the device.

Reported Values

The following capacitor re-form values are reported on the Battery Detail screen and follow-up reports:

- Last Capacitor Re-form Date for the most recent auto or manual cap re-form
- Last Capacitor Re-form Charge Time for the most recent auto or manual cap re-form

There are three reports that show cap re-form information:

- Device Follow-Up Report
- QUICK NOTES Report
- Combined Follow-Up Report

The same information is provided on all three reports.

ZOOM@View™		Report Created 10 Feb 2006
Device Follow-up Report		
Date of Birth	N/R N/R N/R	Last Office Interrogation
Device	COGNIS 100-D N107/854907	9 Feb 2006
Tachy Mode	Monitor + Therapy	Implant Date
		N/R

My Alerts
There are no alerts to display.

Events Since Last Reset (30 Jan 2006)
01 Feb 2006 11:15 VF at 400 min⁻¹, 41J

Battery OK

Approximate time to explant:	4.5 years
Charge Time	64 s
Last Capacitor Re-form	01 Feb 2005 11:15
One Year Remaining	Explant



Algorithm

The auto cap re-form is scheduled according to an internal clock; the clock begins timing from the date the battery is attached to the device when it is manufactured. However, to save energy, auto cap re-forms are not performed until the device is taken out of Storage mode.

- If the time period between battery attach and when Tachy mode is changed from Storage mode is less than 90 days, the first auto cap re-form will occur 90 days after battery attach.
- If the time period between battery attach and when Tachy mode is changed from Storage mode is greater than 90 days, the first auto cap re-form will occur between 24-48 hours after taking the device out of Storage mode.
- Manual cap re-forms reset the timer for auto cap re-forms. If the recommended manual cap re-form is performed at implant, the first auto cap re-form will occur 90 days from the manual cap re-form (implant) date.

When an automatic or manual cap re-form occurs:

- The capacitors are charged to maximum output.
- Once charge is complete, the energy is dumped to the internal resistor.
- If the charge time exceeds Explant or ERI charge time limits (15 seconds), a second auto cap re-form will be scheduled for one hour later. If the second charge time also exceeds those limits, battery status will be Explant.
- If the charge time exceeds Battery Capacity Depleted charge time limit (30 seconds), a second auto cap re-form will be scheduled for one hour later. If the second charge time also exceeds those limits, battery status will be Battery Capacity Depleted.
- Based on battery performance testing, Boston Scientific does not expect battery status indicators to be triggered by charge times.

Notes/Additional Information

- Manual cap re-forms are not included as part of a normal follow-up procedure, since the device manages cap re-forms automatically.

- If a ventricular tachy episode is in progress when an auto cap re-form is scheduled to occur, the auto cap re-form will be rescheduled for one hour later.
- If a telemetry session is active when the cap re-form is scheduled to occur (e.g., device follow-up), the auto cap re-form will be rescheduled for one hour later.
- No tachy detection occurs during cap re-form charging cycle but resumes as soon as charge is dumped to the internal resistor.
- For rate responsive modes (e.g., DDDR), sensor data is not collected during charging. If a cap re-form takes place during sensor-driven pacing, pacing would drop to the Lower Rate Limit (LRL). To avoid an abrupt drop in rate, sensor Recovery Time is enabled to slowly decrease the pacing rate toward the LRL until cap re-form process is over.
- Full Energy Charges (manual caps re-forms or max energy shocks) do reset or change the 90 or 30 day timer for auto cap re-forms. When a manual cap re-form is performed at implant, the first auto cap re-form will occur 90 days from the implant date.
- If a manual cap re-form is not performed at implant, an auto cap re-form will occur between 24-48 hours after taking the device out of Storage mode, providing it has been at least 90 days since manufacture. If it has been < 90 days since manufacture and no manual cap re-form has been performed, the first auto cap re-form will be 90 days from date of manufacture.
- During DFT testing, if the patient is induced and the rhythm breaks prior to shock delivery, cap re-form can be commanded to dump energy in order to get realistic charge time value. Devices launched prior to COGNIS/TELIGEN would dump energy in this scenario at the end of the episode.

Safety Mode/Core



The system architecture for devices described in this primer includes redundant hardware—a Safety Core—that provides basic pacing and VF shocks if non-recoverable or repeated fault conditions occur that indicate loss of integrity for the device hardware, such as the central processing unit (CPU), logic, control, and internal memory of the device.

The Safety Core is isolated from the CPU, so fault conditions that affect the CPU would not affect Safety Core operation. The Safety Core provides basic life-saving therapy of the pulse generator—available even under fault conditions—as long as sense amps, high voltage capacitor, and battery performance are available to support operation. This assumes that header connections and lead integrity is uncompromised. Safety Core is implemented in hardware; *no software is required for operation.*

The Safety Core also provides support during transient or recoverable faults while the device completes a reset, making these faults transparent to the physician and patient. In addition, the Safety Core provides wanded (ZIP is not available) telemetry support.

Availability

Safety Core is available from the pulse generator at any time, as long as the battery, high voltage capacitors, and sense amplifiers performance is available and the device is not in Storage mode.

Programmable Values

When in Safety Core permanently, the programmer will indicate the pulse generator is in Safety Mode. While in Safety Core (Safety Mode), Tachy mode can be programmed to Monitor + Therapy or OFF. Monitor Only and Electrocautery mode are not available during Safety Mode because the CPU is unavailable. No other parameters are programmable. While in Safety Core (Safety Mode), the device operates with fixed parameters.

Safety Core (Safety Mode) Parameters

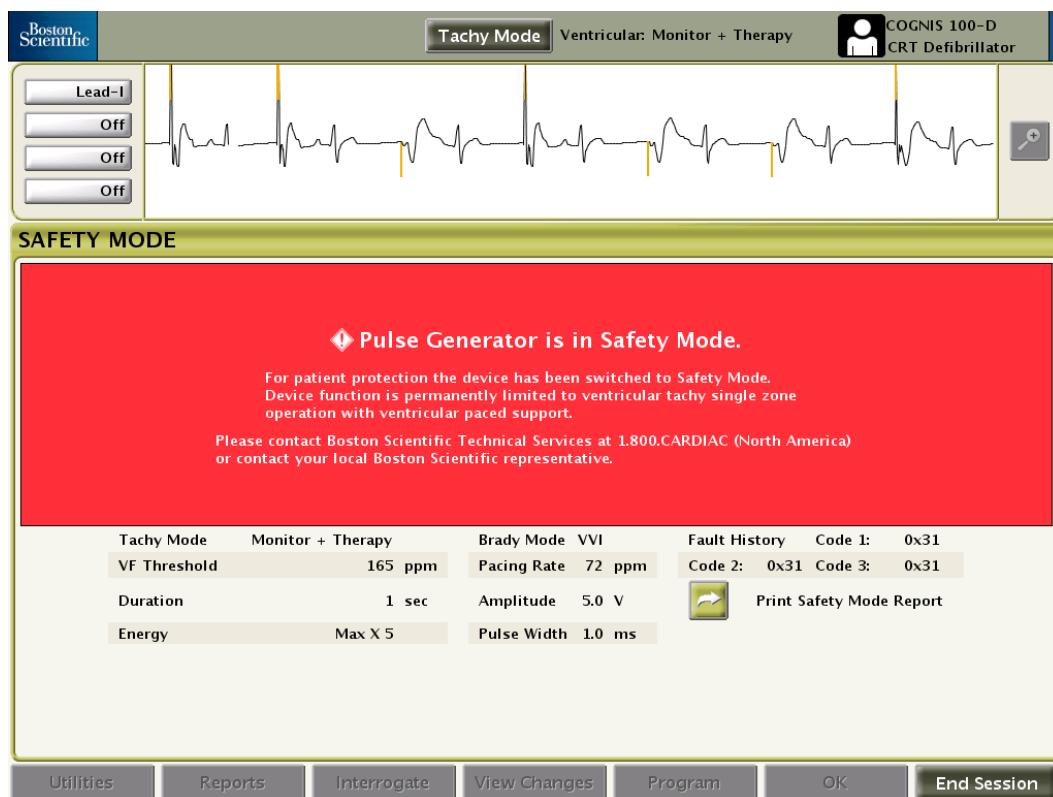
Pacing	
Brady Mode	VVI
CRT Pacing	Bi-V, no offset
Pacing Vectors	RA: disabled RV: unipolar (RV tip to Can) LV: unipolar (LV distal to Can)
Sensing Vectors	RA: disabled RV: unipolar (RV tip to Can) LV: disabled
Sensitivity	RV: 0.25mV
Pacing Rate	72.5 bpm (827 ms)
Amplitude & Pulse Width	5 V @ 1 ms

Tachy	
Mode	Monitor + Therapy, (can be programmed Off)
Zones	VF only
V Rate Threshold	165 bpm
Duration	1 second
Shocks Available	5 per episode
Shock Energy	Max energy
Shock Delivery	Committed, R-synchronous, pacing inhibited at the end of charge
Shock Polarity	Initial
Shock Waveform	Biphasic

Tachy	
Shock Vector	V-triad
Post-Shock Pacing Delay	3 seconds

Algorithm

- During normal pacing operation, the Safety Core pacemaker runs simultaneously with the primary CPU-driven pacemaker.
- The Safety Core pacemaker operates with an escape rate of 2100 ms or 28.5 bpm, providing a low rate monitor and guarantees pacing support under normal conditions.
- If normal pacing from the CPU does not occur, the Safety Core escape pace will be delivered, and a system reset is initiated.
- If the device does not return to a safe state with normal pacing from the CPU (or a state where no pacing is needed, such as Storage Mode), the escape pace and reset sequence is repeated twice more. If three resets do not restore the device, permanent Safety Core (Safety Mode) is activated.



- If a transient fault occurs, the application starts a reset sequence to recover. When the reset sequence starts, Safety Core operation begins, and operates until the device completes its reset sequence. After a reset sequence the device beeps one time. If an interrogation session is active, it is terminated and re-established by placing the wand over the device and performing an interrogation.

- Once the reset sequence is completed and the device resumes normal operation, the Safety Core pacemaker returns to monitoring status with an escape rate of 28.5 bpm, and the Safety Core defibrillator is disabled.
- If the fault cannot be reset, or if three resets occur within a 48-hour period, the device will switch to Safety Core (Safety Mode) permanently.
- While the device is in Safety Core (Safety Mode) the CPU is not used, so no software is running. Wanded (no RF) telemetry will be available to provide limited access to a fault log.
- If permanent Safety Core (Safety Mode) is activated, the device will emit beeping tones: 16 beeps every six hours. The beeping is automatically silenced when the programmer interrogates the PG.

Retrieval of Fault or Reset Data

Retrieval of fault or reset data may be helpful in further troubleshooting a device. Each fault or reset is logged and device memory allows storage of up to 32 time-stamped entries. Clearing the fault code will not delete fault log data.

- During normal operation (device is not in Safety Core), perform a Save of patient data or a data dump to retrieve fault data.
- In Safety Core (Safety Mode), the fault identifiers initiating the last three resets will be displayed on the programmer screen.

Notes/Additional Information

- A magnet applied to a device that is in Safety Core (Safety Mode) will divert therapy and inhibit detection. The device in Safety Core will not emit beeping tones when a magnet is applied. Detection resumes two seconds after magnet is removed.
- Any charging fault occurring during Safety Core operation will automatically disable the device (even during charge) to prevent delivery attempts when there is circuitry damage or when an adequate charge cannot be achieved on the capacitors.
- Because RF telemetry is unavailable during Safety Core (Safety Mode), LATITUDE® interrogations are not possible. The LATITUDE system will notify the clinician if device data has not been received within 14 days of the expected date (based on daily checks, weekly interrogations, or scheduled remote follow-ups).

BSC did not design an option to take a device from Safety Core and return it back to normal mode.

Enhanced Parameter Interactions



The enhanced parameter interactions interface is designed to assist the user in quickly resolving parameter interactions.

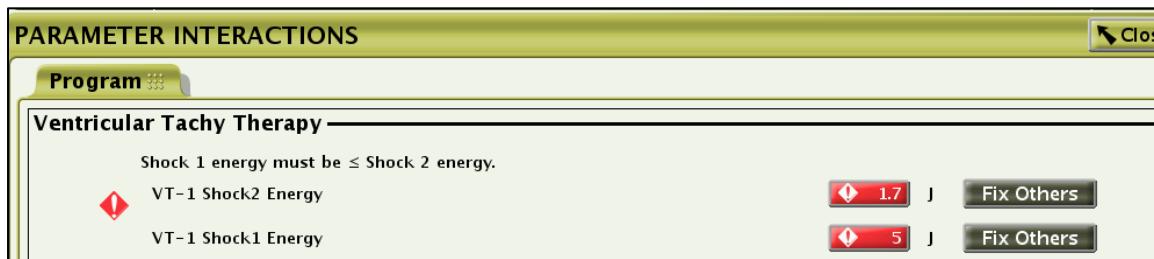
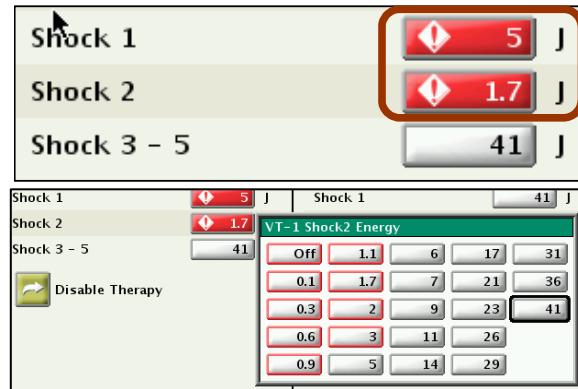
Example: Attempts to program shock energies inappropriately (e.g., programming Shock 1 energy > Shock 2 energy) will result in a red warning icon on the bottom of the screen.



The parameters in question will be flagged with an alert icon:

The parameter menu will also show a red border around the parameters that are not allowed.

Finally, touching on the warning button at the bottom of the screen will bring the user to a Parameter Interaction screen that explains the reason for the warning, and allows the user to correct the inappropriate parameter.



The Parameter Interaction screen lists the difference between caution (yellow yield symbol) and alert (red symbol) as they appear on screens for Battery Status as well as parameter interactions.

The parameter may be corrected on this screen; choosing the fix others icon presents suggested options for fixing the parameter. When the red warning icon appears at the bottom of the screen, programming will not be allowed until the parameter is corrected.

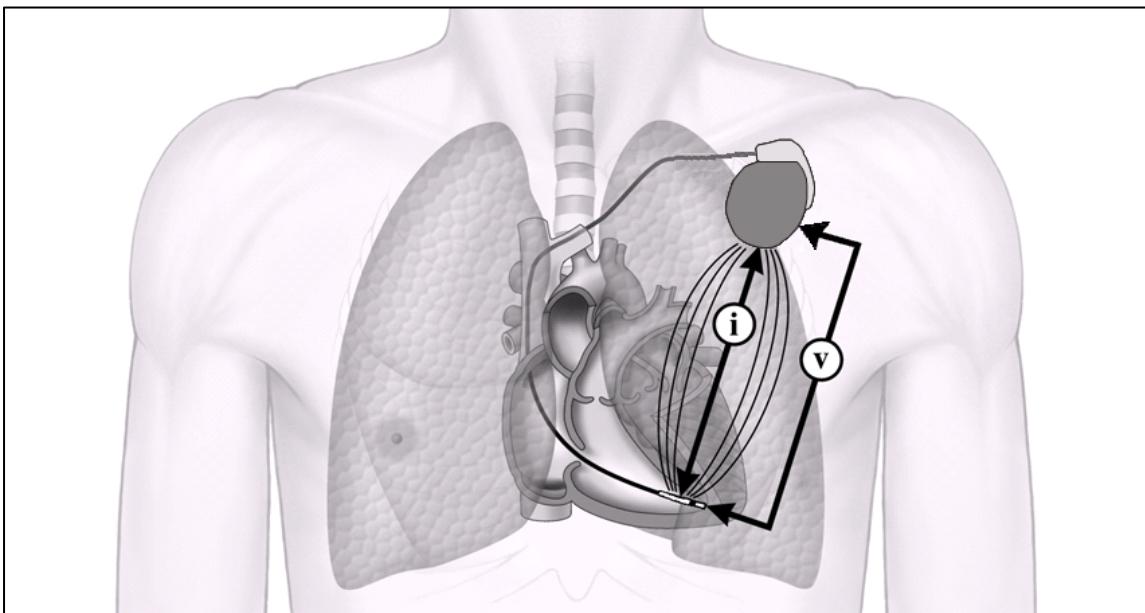
ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Respiratory Sensor

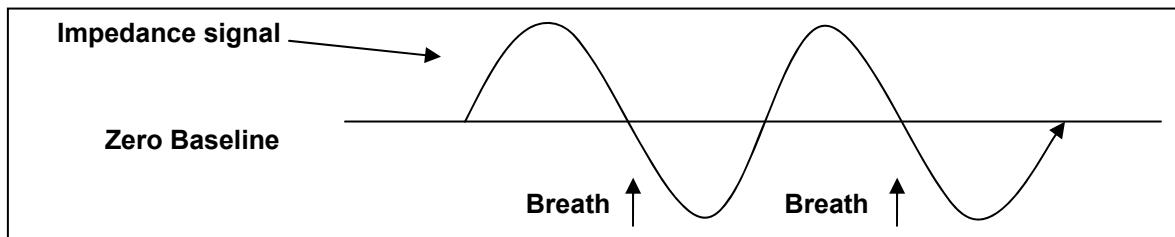
Not available
for models distributed
in the United States

The Respiratory Sensor signal is used to collect data for both the ApneaScan and Respiratory Rate Trend features.

Diagnostic data is obtained through a transthoracic impedance signal which does NOT cause an increase in heart rate. The signal is driven between the Can and RV Coil and measured from the Can to RV Tip for both integrated and dedicated bipolar leads.



- Do not program the Respiratory Sensor to ON until after the pulse generator has been implanted and system integrity has been tested and verified.
- During mechanical ventilation, respiration-based trending may be misleading; therefore, the Respiratory Sensor should be programmed to OFF.
- The Respiratory Sensor signal is delivered every 50 ms at 19.5 μ s duration with an amplitude of 80 μ A. Noise is continuously monitored and if the noise to signal ratio becomes excessive, the amplitude of the signal will increase to 320 μ A. If the noise/signal ratio becomes excessive at 320 μ A, the measurement will be suspended until the noise level decreases. When the noise/signal ratio decreases, the signal will resume at 320 μ A and decrease to 80 μ A if the noise/signal ratio returns to acceptable levels.
- Inspiration and expiration create a waveform deflection. The breath counter is incremented each time a negative waveform crosses the zero baseline.

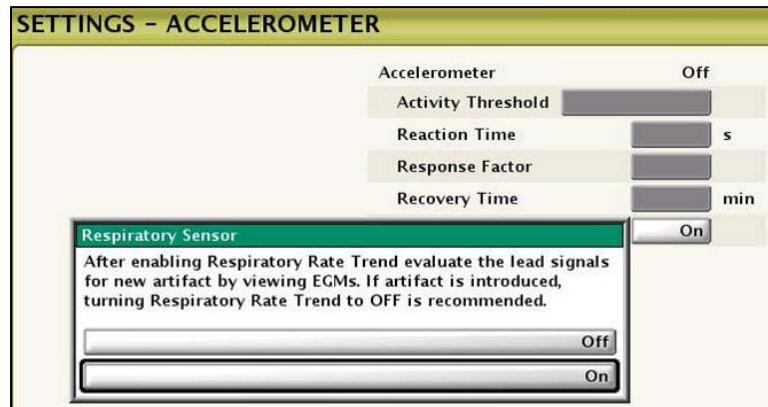


- Pacing and shock therapy do not interfere with the respiratory signal as the pulse is not delivered or measured during pace or shock delivery.
- A 4-ON procedure (as used in the Insignia MV application) is not necessary. Gain and filter settings are established automatically and no baseline measurement is necessary as the respiratory trends do not require a comparison value.
- Lead impedance for the RV Coil > Can and RV Tip > Can is evaluated every 24 hours and if both measurements are in range (20-200 ohms and 200-2000 ohms respectively), these vectors continue to be used. If either impedance is out of range:
 - For dual chamber devices, the impedance is measured for the RA Ring > Can and RA Tip > Can and if these measurements are in range, the device uses these vectors.
 - If either RA measurement is out of range, the sensor is suspended for the next 24 hours.
 - If the device successfully switches to the RA vectors, it will continue to use the RA as long as the impedances remain in range. If the RA subsequently becomes out of range, the device will evaluate and attempt to return to the RV vectors.
 - For a single chamber device, the impedance is measured from RV Ring > Can and RV Tip > Can and if either RV measurement is out of range, the sensor is suspended for the next 24 hours.

Respiratory Sensor Oversensing Mitigation

- In COGNIS/TELIGEN models, there were rare cases where the respiratory signal was detected on RV EGMs resulting in inappropriate therapy. This in turn resulted in the Respiratory Sensor Oversensing advisory in March 2009, and a subsequent software upgrade to disable the respiratory sensor.
- Although it is still possible in rare cases for the sensor to introduce artifact on the RV EGM, a change was made to the sensor behavior to prevent inappropriate therapy:
 - The respiratory sensor is now turned OFF when V Arrhythmia Onset (3 consecutive fast) is declared and remains OFF for one hour. If at the end of one hour, a V Arrhythmia Onset or a V Tachy Episode (8/10) is present, the sensor will remain OFF and the one hour timer is restarted.
 - Both Onset and Episode are utilized at the end of one hour because the Onset flag gets cleared once 8/10 is declared; so the device needs to verify if either of the status flags are present before resuming operation.
 - If neither Onset or Episode is active at the end of one hour, the lead impedance is checked as described above and the sensor is recalibrated.

- At this time, the change to the respiratory sensor behavior will be available in the INCEPTA 160 devices only.
- This message is displayed when programming the respiratory sensor.
 - This message is still displayed since it is still possible to see artifact from the respiratory sensor; but this will no longer result in inappropriate therapy to the patient as noted above.





Pre-Implant Testing

ICD	INCEPTA	CRT-D	INCEPTA
	ENERGEN		ENERGEN
	PUNCTUA		PUNCTUA
	TELIGEN		COGNIS

Prior to implanting the pulse generator should be interrogated and checked.

Interrogate and Check the Pulse Generator

To maintain sterility, test the pulse generator as described below before opening the sterile blister tray. The pulse generator should be at room temperature to ensure accurately measured parameters.

1. Interrogate the pulse generator using the programmer.
 - Verify that the pulse generator's tachy mode is programmed to Storage.
 - If otherwise, call Technical Services.
2. Perform a manual capacitor re-formation.
3. Review the pulse generator's current battery status.
 - Counters should be at zero.
 - If the pulse generator battery status is not at BOL, do not implant the pulse generator; call Technical Services.

CAUTION: Use By Date¹⁷

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.

Interpreting/Clinical Applications

Unlike prior generation PGs, the box labels for devices described in this primer no longer provide monitoring voltage. Battery status must be assessed from the programmer. Program the device from Storage to OFF mode once it is certain the device will be used. Once the device is taken out of Storage mode, it cannot be returned to Storage mode.

Storage Mode

Storage mode is a power-saving tachy mode designed to extend the shelf-life of the device. The device is shipped and stored in Storage mode. Most electronic functions are powered down, leaving tachycardia functions and bradycardia functions deactivated. The device does not perform automatic cap re-forms while in Storage mode.

While the device is in Storage mode:

- It does perform daily battery status calculations, including a daily voltage check.
- Telemetry support is available for device programming.
- Real-time clock is active.
- Battery status assessments occur.
- Manual cap re-forms are available.

In Storage mode, STAT shock and STAT pace are available; once either STAT function is commanded, the device will exit Storage mode and tachy mode will automatically change to OFF.

Once the device is taken out of Storage mode, the following occurs:

- The device cannot be programmed to Storage mode by the user.
- Monitoring functions are activated, and counters are incremented.
- The device is operating at a higher power level (no longer in power-saving mode).
- Pacing is activated (if bradycardia mode is enabled); however, pacing is inhibited for up to two seconds plus one LRL cycle following Storage mode exit to allow the rate sense amplifiers to power up.
- Automatic capacitor re-forms are enabled.

¹⁷ COGNIS and TELIGEN have a 12 month shelf life after battery attach. INCEPTA, ENERGEN, and PUNCTUA have a 24 month shelf life after battery attach.

- Enable Magnet Use is activated and the magnet sensor is turned ON (Magnet function is OFF while in Storage mode to prevent unintended magnet response).

Cold Temperatures

The effects of cold temperatures on the battery may be seen in several ways:

- Lower monitoring voltage, which may affect battery status
- Longer charge times
- Inability to communicate via RF telemetry
- Inability to communicate via inductive telemetry

CAUTION: 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.

Notes/Additional Information

- Devices described in this primer have a temperature sensor that will provide a warning message on the screen if the device temperature is too cold to support normal function. The warning message will appear if the device temperature is < 0° C (32° F).
- A warning message will appear if the cap re-form, monitoring voltage or power measurements are not within normal limits. If the device later recovers to normal limits, the device may still be used.
- When 20 percent or more of the battery capacity has been used while in Storage, a fault message will be triggered, and the device should not be used.
- If device temperature drops below 0° C (32° F), telemetry will be disabled.

CAUTION: Shock 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 lead to allow a greater distance between the shocking electrodes.

WARNING: 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.

Patient Information



This setting stores patient information such as general patient information, indications, lead data, implant data and physician data in the device memory.

Availability

Navigation:

1.

The screenshot shows the 'SYSTEM SUMMARY' tab selected. It displays the following data:

Patient Info	Last Follow Up	10 Mar 2006
Implant Date	01 Mar 2006	
Device Model	N107	
Indications	Paroxysmal Atrial Tachy	Monomorphic VT

A callout box with arrows points to the 'Last Follow Up' and 'Implant Date' fields, containing the following text:

Last Follow-Up and Device Model will automatically populate. Last Follow Up date is based on the last programmer (not LATITUDE) interrogation. All other fields are manually entered. Serial number will also automatically populate within the Implant Data tab

2.



3.

The screenshot shows the 'General' tab selected. It displays the following patient information:

Patient Name	John	Doe
Patient Address	4100 Hamline Ave. St. Paul, MN 55112	
Date of Birth	1 - Jan - 1900	
Height	5' 10"	ft/in
Weight	355	lb
Gender	Male	
Patient Phone	111-222-3333	

A callout box with an arrow points to the 'Date of Birth' field, containing the following text:

Touch within the desired field to use the pop-up keyboard or drop-down selections

Notes/Additional Information

- The Program button must be selected to store additions and changes.
- Selecting a field to populate will result in either a pop-up keyboard or a pre-populated drop-down selection menu.
- Select Accept Changes or Enter on the keyboard to input data.
- To exit the keyboard without making changes, select Cancel Changes.
- Fields will be blank or N/R until information is entered and programmed to the device.
- Last Follow Up will automatically populate starting on the date the device is first interrogated, regardless if the device is programmed out of Storage mode.
- If Load Initials is selected via the View Changes tab, all manually entered patient data during that telemetry session will be erased/reset.
- Patient data can be printed via the Reports ⇔ Patient Data.

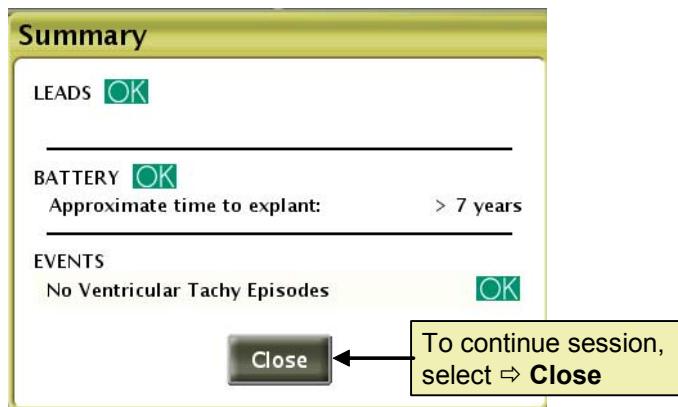
ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Summary Screen

The Summary screen provides a summary of Patient Information, Events since last reset and Device Settings as well as current Leads and Battery status. Also provided are individual links for each of these topics to allow quick navigation to further detailed information. Please refer to the subsequent related topic sections for specific information on data found when navigating to each individual link.

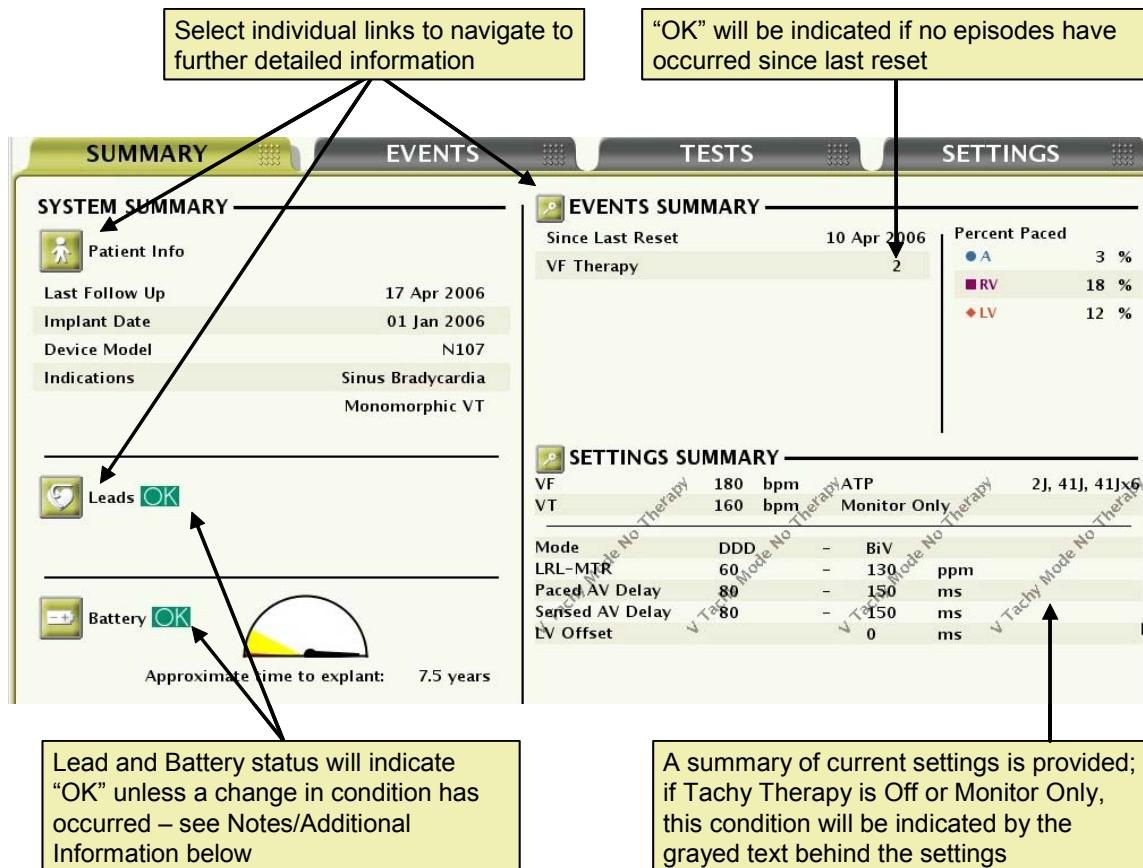
Navigation

Upon interrogation, a pop-up Summary screen is provided indicating Lead and Battery status as well as an Events notification for episodes since last reset:



After closing the initial pop-up Summary screen, the user is automatically navigated to the main Summary screen under: **SUMMARY**

NOTE: If there is an active episode upon interrogation, the user will automatically be navigated to the EP Tests screen.



Notes/Additional Information

Possible messages listed on the Summary screen:

- OK.
- Check A, RV, LV and/or Shock Lead.
- Approximate time to explant, explant indicator reached on.
- VF, VT, VT-1 Therapy. The alert symbol will appear if after therapy is delivered, the rhythm has accelerated and meets detection in a higher zone.

See the Daily Lead Measurement, Battery Status and Arrhythmia Logbook topics for further details.

Settings Summary

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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The Settings Summary screen displays an overview of key therapy parameters. The sliders provide the user with a convenient way to set and visualize key brady and tachy rate parameters. This

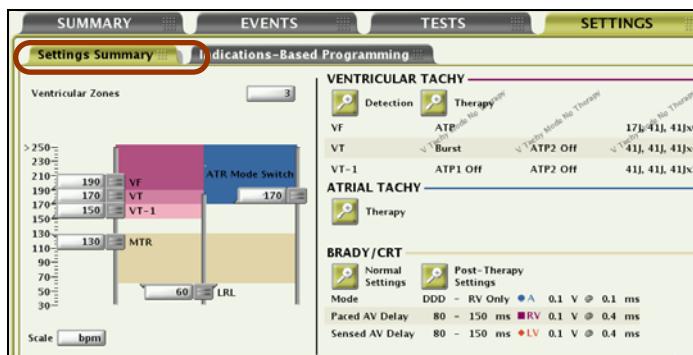
interface helps the user see how parameters relate to each other and proactively prevents parameter interactions.

Availability

This feature is always available. However, the parameters involved will appear as their availabilities dictate.

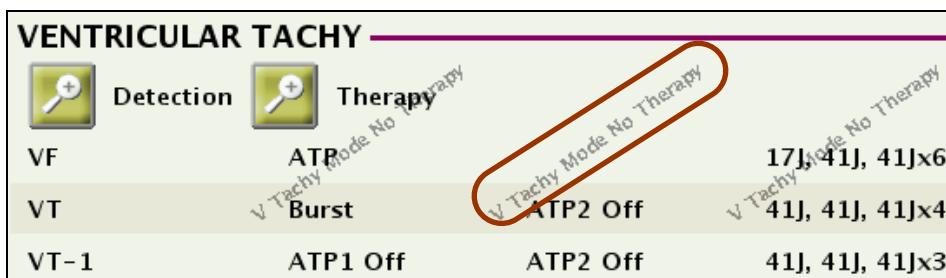
Under the Settings tab select \Rightarrow Settings Summary tab:

The left half of the screen allows the user to manipulate key rate parameters and have a visual sense of how they interact.



The right half of the screen shows summaries of key ventricular, atrial, and brady parameters. From there, users can drill down to make changes to those parameters.

NOTE: The ventricular tachy parameters displayed only have meaning if ventricular therapy is programmed ON. If the Tachy mode is anything other than Monitor + Therapy, the ventricular tachy area of the screen will have watermark text that reminds the user that therapy is turned OFF.



Programmable Values

Updating parameters via sliders is equally as valid as changing parameters on the brady or tachy parameter detail screens. Values changed in one place are synchronized in the other. The following parameters can be set via the Settings Summary sliders, depending on applicability:

- **Rate cut-off for each zone** – rates may be programmed for up to three tachy zones:

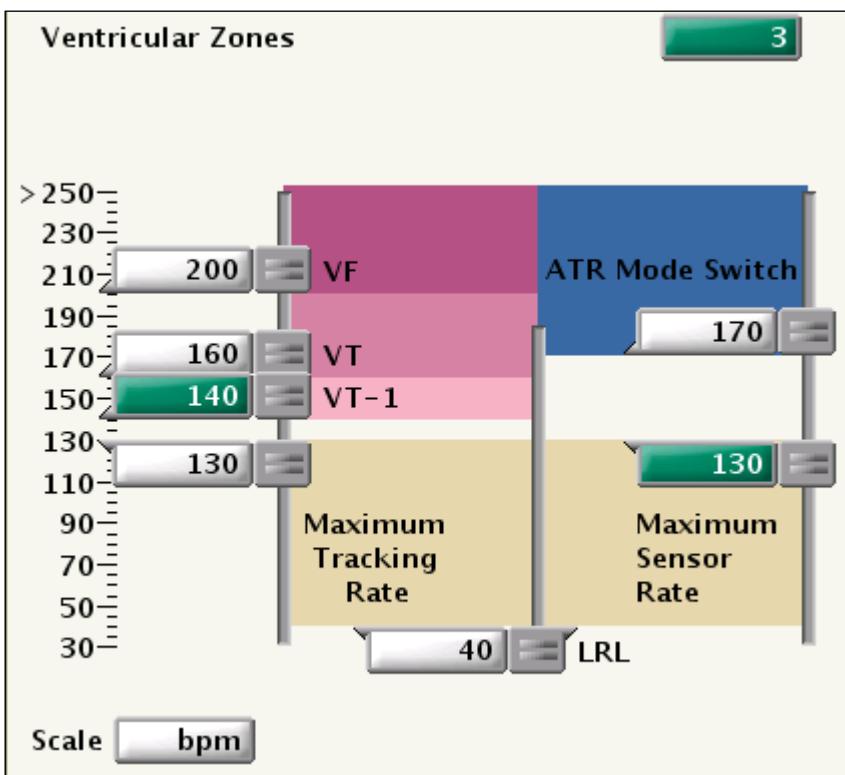
Single zone configuration	VF: 90-220 bpm
Two zone configuration	VT: 90-220 bpm

Three zone configuration	VT-1: 90-200 bpm VT: 110-220 bpm, VF: 130-250 bpm
--------------------------	---

- **ATR Mode Switch rate** – 100-300 bpm (This single parameter sets the values for ATR Trigger, AFib Rate Threshold for Ventricular detection enhancements, and AFR rate).

Maximum tracking rate	30-185 bpm
Maximum sensor rate	30-185 bpm
Maximum pacing rate	30-185 bpm
Lower rate limit	30-185 bpm

NOTE: This screen is the only place where the number of V Tachy zones can be changed.



Visual Characteristics

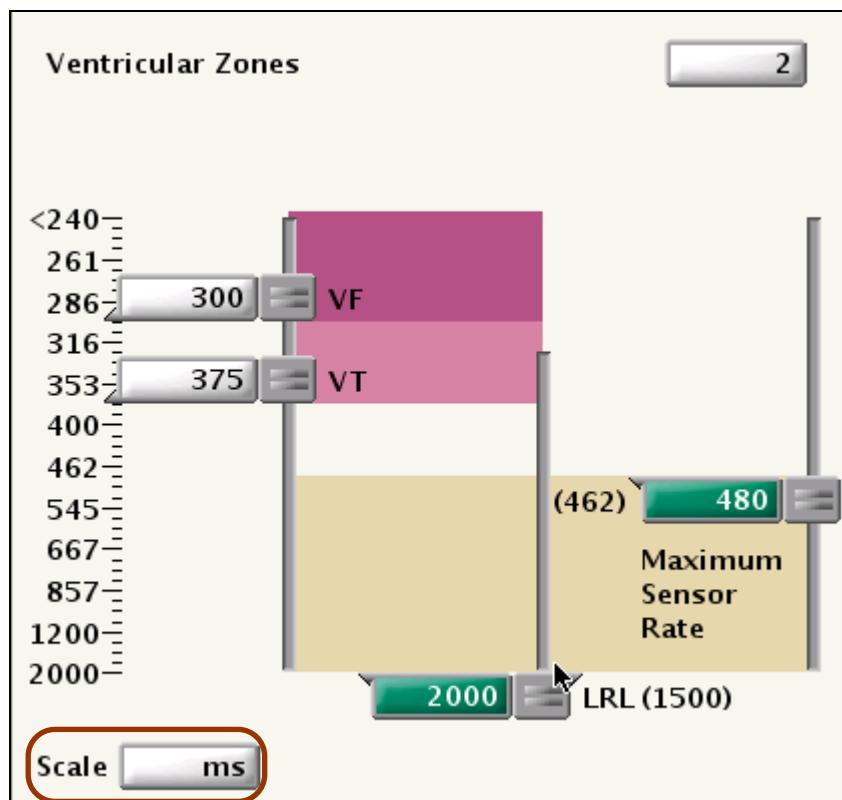
Each slider is designed to act as a control that can be pushed up or down a track. Gray bars symbolize the track and appear to be beneath the sliders. Each slider consists of a value box and a grip. The value box is on the left, and can be opened like any other parameter box. The grip is a gray box on the right. Sliders are moved by selecting the grip and dragging the stylus in the desired direction.



Slider anatomy: value box, slider grip and labels

Each slider has a label that moves with it. The label always includes the name of the parameter represented by the slider. The upper-rate brady parameters have long names and short abbreviations. These labels will automatically expand to the full name when room allows, and contract to the abbreviation if space is limited. If the current value of a slider is not the programmed value, a number in parentheses appears next to the name, indicating the currently programmed value for that parameter.

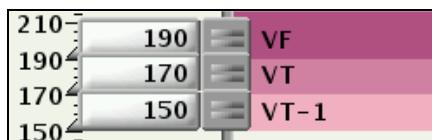
On parameter detail screens, parameters that are not available are grayed out. To provide clarity, inapplicable sliders on the Settings Summary screen disappear instead. For instance, if the number of tachy zones is set to two, only the VF and VT sliders will be visible.



Hidden sliders, milliseconds scale

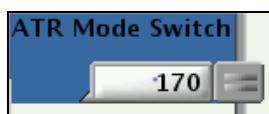
The default scale for the slider screen is beats per minute. However, if a clinician prefers to think in milliseconds, the scale button in the lower-left corner allows the scale and parameters to be displayed as milliseconds. The change will only be applied to the Settings Summary screen.

Colors are used to represent zones defined by the parameters. Ventricular tachy zones are depicted with graduated shades of purple.



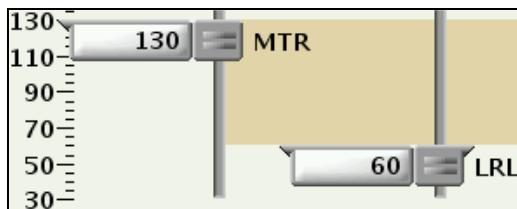
Ventricular tachy zones

The Atrial zone is marked with blue.



Atrial zone

The range between the brady upper and lower rate limits is shown in tan.



Brady upper and lower rate limits

NOTE: The brady zone may not have a color if no upper rate parameter (MTR, MSR or MPR) is applicable. The ATR zone will not have a color if atrial sensing is turned off (i.e., brady mode is VVI).

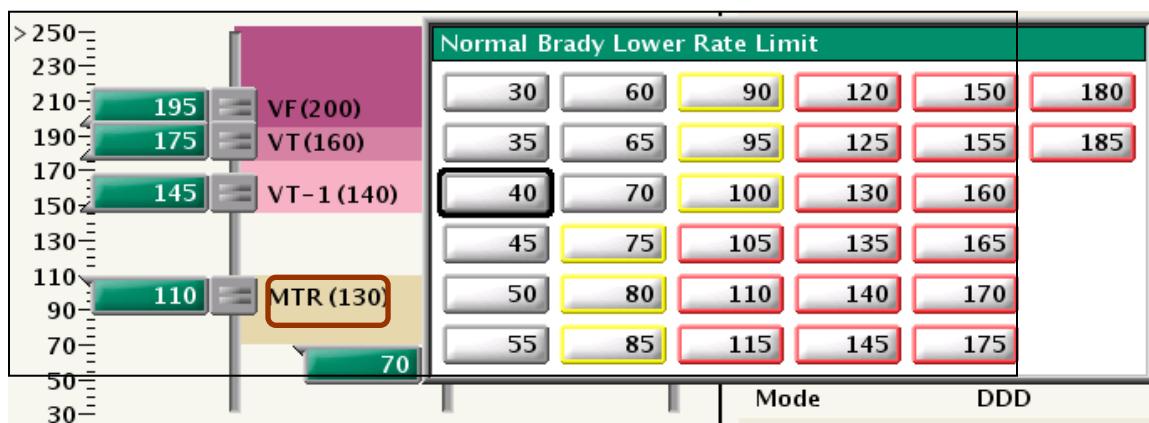
Slider Behavior

Sliders will enforce parameter interaction rules via intuitive behaviors known as *bumping* and *blocking*.

For instance, LRL and MTR must be 10 bpm apart. If the LRL slider is moved within 10 bpm of MTR and continues to move, the MTR slider will be bumped in the same direction, maintaining the minimum 10 bpm distance.

The V tachy zone parameters are considered to be of higher importance than brady parameters, so they will block under similar circumstances. If the MTR slider is moved within 5 bpm of the lowest V tachy rate cutoff, the MTR slider will stop moving, even if the user continues to drag the stylus. The lowest tachy zone blocks invalid MTR rates.

Bumping and blocking behaviors form chain reactions. For instance, sliding the VT-1 slider up may cause it to bump the VT slider, which will automatically bump the VF slider when appropriate.



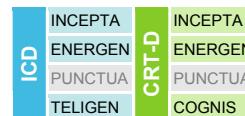
LRL slider with open palette

Values of slider parameters can also be changed by opening the value palettes, just as with regular parameters. Selecting a new value on the palette will cause the slider to hop to the new location. The slider will honor the user's choice, even if the new value breaks a parameter interaction rule. For instance, if the LRL is set to 70, the user can use the palette to select 60 as a value for MTR. The MTR slider will hop to the 60 location, and both it and the LRL slider will turn red, indicating an invalid interaction. The next time one of these sliders moves, they will attempt to automatically correct themselves. If the user attempts to slide the LRL, the MTR slider will hop to a valid location. Similarly, if the user moves the MTR slider first, the LRL slider will adjust itself accordingly. For this reason, sliding is recommended over palette value selection, because the rules are always enforced. Like all parameters, these values also can be corrected through the Parameter Interactions screen.



MTR manually set lower than LRL

Indications-Based Programming



Indications-Based Programming (IBP) provides nominal parameters based on a patient's clinical needs and primary indications. The intent of IBP is to enhance patient outcomes and save time by providing base programming recommendations that users can customize as needed.

IBP uses four categories of device indications to establish the features for an individual patient:

1. Sinus Node function – is the patient chronotropically incompetent? Does the patient have sinus bradycardia?
2. AV Node function – is there any heart block present?
3. Does the patient have a history of atrial arrhythmias?
4. Does the patient have history of ventricular arrhythmias?

By choosing an option or options in each of the four indications, the user is offered a set of programming suggestions. The user may review and program the suggestions from the same screen, decreasing the time needed to program the device.

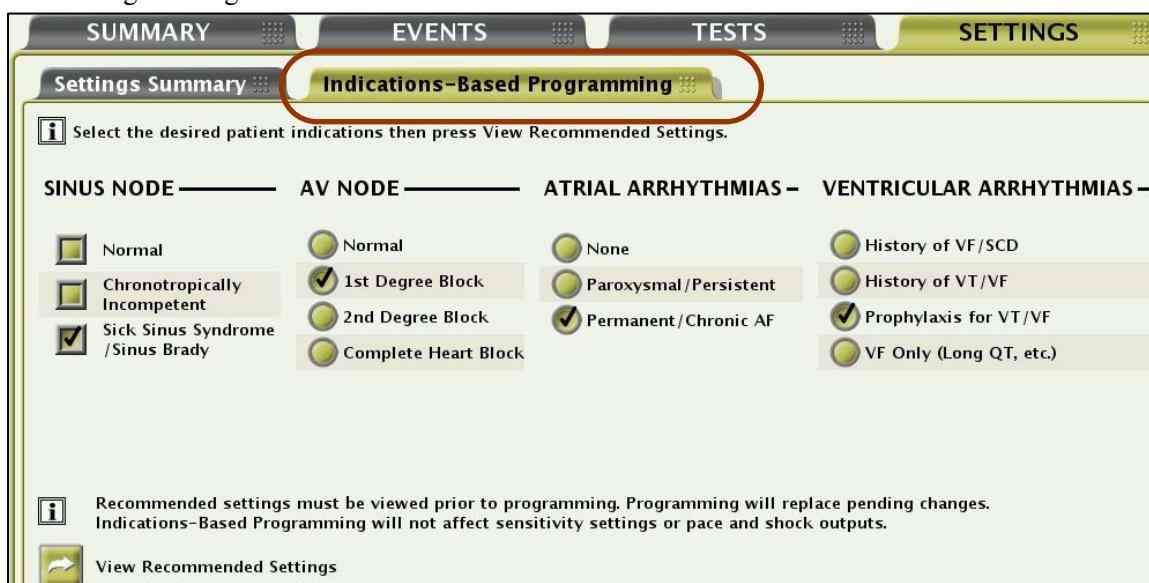
The Indications-Based Programming suggestions provide pacing mode, tachy and brady therapy options, as well as LRL, MTR, AV Delay values. The programming suggestions were chosen based on:

- Approved indications for a particular feature, as described in the System Guides.
- Consensus of a 12-physician panel.
- Standard practice or case study data.

NOTE: Sensing values, pacing outputs, and shock outputs are not affected by IBP, except in the case where IBP recommends a Monitor Only Zone, then shock therapy would be turned OFF in the lowest zone.

Availability

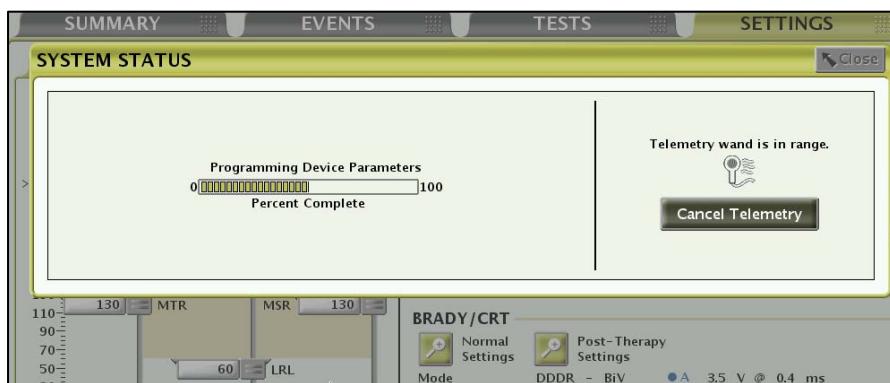
Indications-Based Programming is always available. Under the Settings tab \Rightarrow Select Indications-Based Programming tab:



- Choose a value in each indication category by selecting a check box.

NOTE: More than one value may be chosen under Sinus Node.

- Select  **View Recommended Settings**
- Review the values on the Proposed Setting Summary screen. Accept the suggested programming by selecting  **Program this Profile**



The proposed changes will be programmed into the device

- To return to the Indications-Based Programming screen without programming, select  **Reject this Profile**

Indications-Based Programming

SINUS NODE — AV NODE — ATRIAL ARRHYTHMIAS — VENTRICULAR ARRHYTHMIAS —

RECORD INDICATIONS 

INDICATION PROFILE – PROPOSED SETTINGS SUMMARY

SUMMARY OF PROPOSED SETTINGS —

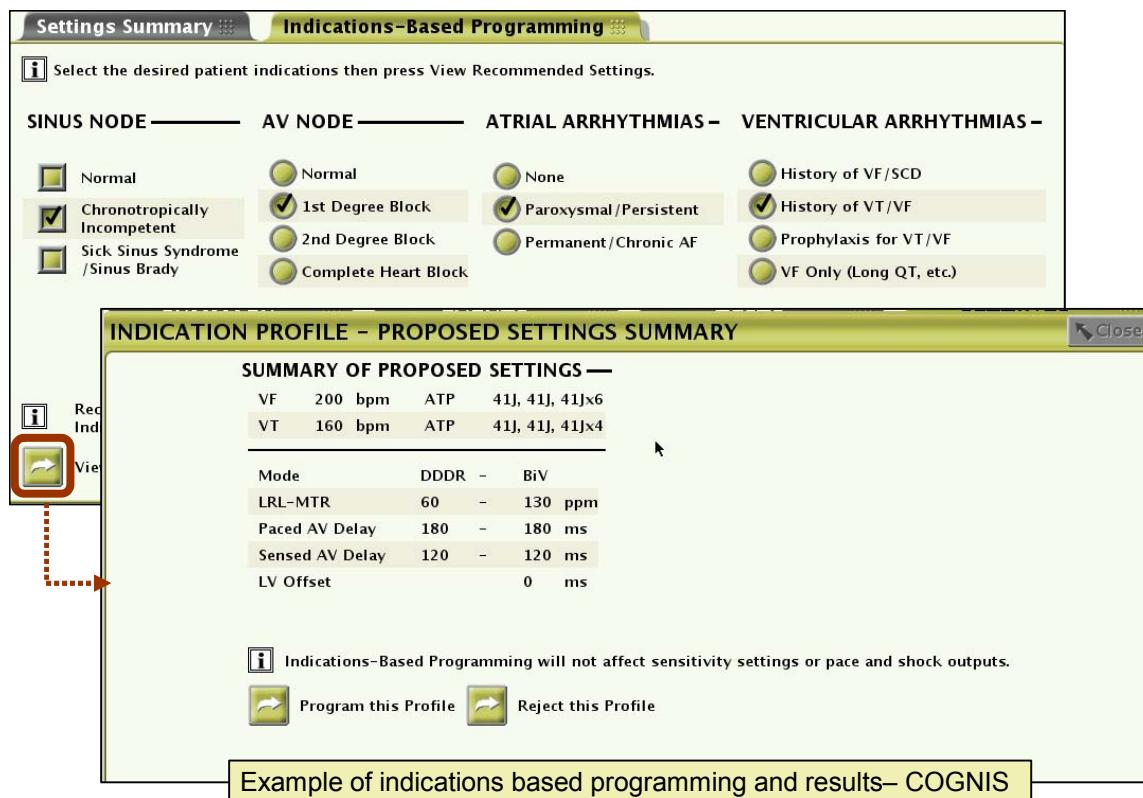
VF	200 bpm	ATP	41J, 41J, 41Jx6
VT	160 bpm	ATP	41J, 41J, 41Jx4

Mode DDD
LRL-MTR 40 – 130 ppm
Paced AV Delay 220 – 300 ms
Sensed AV Delay 220 – 300 ms

 Indications-Based Programming will not affect sensitivity settings or pace and shock outputs.

 **Program this Profile**  **Reject this Profile**

Example of indications based programming and results– TELIGEN



Programmable Values: Indications-Based Programming Features

The following table summarizes the patient indications and the features or parameters that may be programmed as a result. This is not a complete list of all recommendations but is intended to be a summary. Multiple combinations of these indications may be used; IBP provides approximately 200 possible programming combinations.

Category	Indication Selection	Programmed Features Suggested ¹⁸
Sinus Node	Normal	<ul style="list-style-type: none"> If Normal sinus node is selected and none for atrial arrhythmias, Back-up VVI pacing at 40 ppm will be suggested when AV Node Normal or 1st Degree Block If Normal sinus node is selected, DDD mode will be suggested with RHYTHMIQ/RMS¹⁹ active
	Chronotropically Incompetent (CI)	<i>Rate response pacing mode:</i> DDD, LRL=60 and MSR/MTR=130

18 All rates are described in beats per minute (bpm)

19 RMS not available in TELIGEN models distributed in the U.S. RHYTHMIQ not available in ENERGEN models distributed in the U.S

Category	Indication Selection	Programmed Features Suggested ¹⁸
	Sick Sinus Syndrome (SSS) or Sinus Brady	<i>Atrial pacing mode:</i> DDD, LRL=60 and MTR=130 bpm
AV Node	Normal/1 st degree block	<ul style="list-style-type: none"> • Back up pacing VVI at 40 bpm if Sinus Node Normal • If Sinus Node CI or SSS/Sinus Brady: DDDR, LRL=60, and MSR/MTR=130
	2 nd degree block	<ul style="list-style-type: none"> • DDR, LRL=60bpm • MTR/MSR=130 • AV search hysteresis ON
	Complete heart block	<ul style="list-style-type: none"> • DDD(R), LRL=60 • MSR/MTR=130
Atrial Arrhythmias	Normal	<ul style="list-style-type: none"> • If Sinus Node Normal: VVI with LRL=40 • If Sinus Node CI or SSS/Sinus Brady: DDDR, LRL=60, and MSR/MTR=130 bpm
	Paroxysmal/Persistent Atrial Arrhythmias	<ul style="list-style-type: none"> • DDD, LRL=40 • MTR=130 • ATR mode switch • If Sinus Node Normal: DDDR, LRL=60, and MSR/MTR=130 • If Sinus Node CI: DDD, LRL=60, MTR=130. • If SSS / Sinus Brady
	Permanent/Chronic AF	<ul style="list-style-type: none"> • VVIR • LRL=60 • MSR=130 • VRR
Ventricular Arrhythmias	History of VF/SCD	<i>Two-zones:</i> <ul style="list-style-type: none"> • VT zone at 160 set as a monitoring zone (therapy off) • VF zone at 180 bpm with QUICK CONVERT™ ATP and 6 max energy shocks
	History of VT/VF	<i>Two-zones:</i> <ul style="list-style-type: none"> • VT zone at 160 with ATP and max energy shocks, detection enhancements On • VF zone at 200 with QUICK CONVERT™ ATP and 6 max energy shocks
	Prophylaxis for VT/VF	<i>Two-zones:</i> <ul style="list-style-type: none"> • VT zone at 160 set as a monitoring zone (therapy off) • VF zone at 180 with QUICK CONVERT™ ATP and max energy shocks
	VF only (Long QT, etc.)	Single VF zone at 220 max energy shocks

NOTE: IBP recommendations for CRT-D models will include BiV pacing with BiV Trigger. During ATR Fallback mode is DDI with VRR=MIN.

Reports

Indications-Based Programming parameters are not reported separately, but are included on the Settings or Settings Changes reports.

Interpreting/Clinical Applications

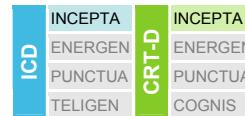
IBP is designed to be the first programming—and perhaps the only programming—done at implant. Physicians may consider programming with IBP first then adjust programming as needed.

Notes/Additional Information

The View Changes button may be used to review changes either before or after they are made. However, any non-IBP programming changes pending prior to using IBP may also appear on the View Changes screen; i.e., some of the changes showing on that screen may not be the result of IBP.

When the Indication Profile—Proposed Settings Summary screen—is shown, there are two ways to navigate further (the CLOSE button is not available):

1. Use the Accept Proposed Changes button ⇔ programs the changes into the device and returns to the Settings Summary screen.
2. Reject Proposed Settings button ⇔ returns to the Indications-Based Programming screen.



Wireless ECG

- Wireless ECG (WECG) is a form of real-time EGM that mimics a surface ECG by using a shocking lead proximal coil to can vector for measuring heart activity.
- Wireless ECGs are only available with dual-coil shock leads.

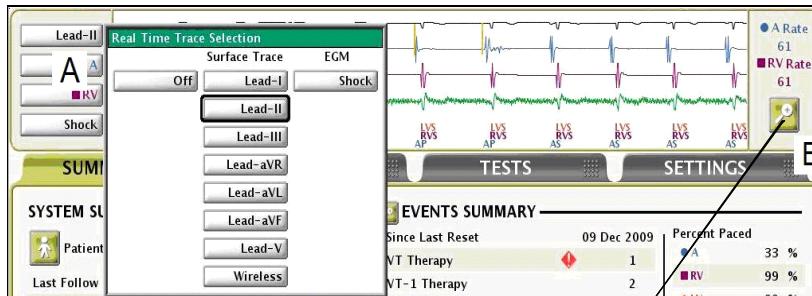
Availability

- Available whenever real-time EGMs are available.
 - PG must be interrogated (i.e., not available in MAU or other device applications).
 - Not available during Storage, Safety Core or Battery Capacity Depleted (a.k.a EOL) operation.
- WECG is the nominal Real Time Trace source for INCEPTA.

CAUTION: Wireless ECG is susceptible to RF interference, and may have an intermittent or lost signal. If interference is present, especially during diagnostic testing, consider using a surface ECG instead.

Navigation

- A. Wireless ECG can be activated by accessing the Real Time Trace Selection and selecting “wireless” from the drop down menu.



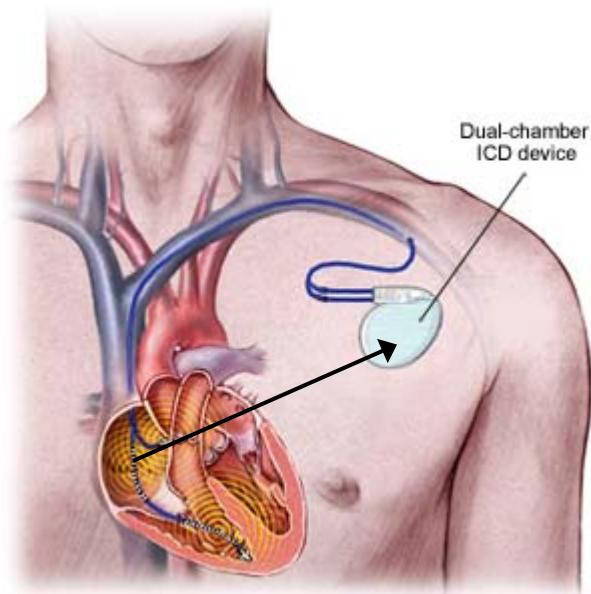
or

- B. Select the details button to enlarge the display and access further ECG configuration options.
- C. Wireless can be selected as any of the four trace selection and gain will nominally be 10mm/mV.
- D. Enable Surface Filter and Display Pacing Spike options will be grayed out unless a true surface vector is selected for any trace.



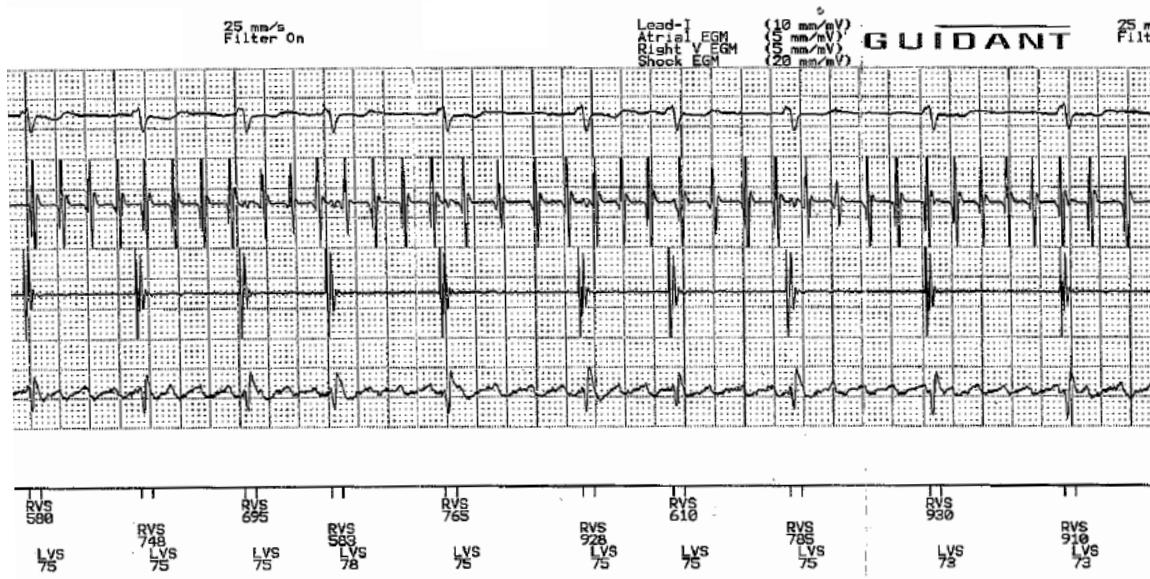
Algorithm

Wireless ECG uses a proximal-coil-to-PG sensing vector.



- Programming of shock vector or polarity does not affect WECG appearance.

- WECG is not directly correlated to a certain surface vector due to variation in can and proximal coil placement.
 - Assuming left shoulder PG placement and a SVC proximal coil position the resulting WECG vector is somewhere between Leads I and aVL.
 - Morphology will appear inverted if comparing WECG to Lead I or aVL.
- Alternate PG location (e.g. right side or abdomen) may produce a tracing, but the morphology will be altered.
- Use of a single coil lead creates an open circuit for WECG, which may result in a flat line, or noise in a variety of presentations.
- Compromised integrity of the proximal coil may result in a noisy WECG appearance.
- CRT-D – BiV pacing may cause blanking of QRS in the WECG channel due to the longer analog blanking related to RV and LV pacing.

Sample WECG signal— top trace is Lead I, bottom trace is WECG**Notes/Additional Information**

- Wireless ECG (WECG) has the same susceptibility to RF interference as real time EGMs, and may have an intermittent or lost signal. If interference is suspected, especially during diagnostic testing, consider using a surface ECG.
- WECG is subject to the same time-outs as other EGMs (e.g., loss of EGMs after 15 minutes of PRM inactivity).



Sensing and Dynamic Noise Algorithm (DNA)

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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All detection and timing decisions are based on the sensed cardiac cycle length. Cardiac signals can vary widely in size and rate; therefore the device needs the ability to:

- Sense an intrinsic beat, no matter how big or small or fast it is.
- Adjust to see varying amplitude signals, but not overreact to aberrant beats.
- After a paced beat, sense any intrinsic activity.
- Ignore T-waves.
- Ignore noise, or distinguish noise from a true arrhythmia.

Boston Scientific ICDs use digital Automatic Gain Control (AGC) to dynamically adjust the sensitivity in both the atrium and the ventricle to detect intrinsic activity in each chamber. As the rate is classified, intervals determine how the device responds. Each paced/sensed chamber has an independent AGC circuits (i.e., one for the RA, one for the RV, and one for the LV).

Each AGC circuit, whether atrial, right ventricular, or left ventricular, processes a heart signal through a *slow* moving gain, which maintains the best overall *view* of the signal, as well as a *fast* moving threshold that adjusts from beat to beat, *looking* for the next signal.

How Did the AGC in Previous Tachy Devices (i.e., PRIZM-based Devices) Work?

Legacy devices also used digital Automatic Gain Control (AGC) to adjust the sensitivity within predetermined ranges for accurate sensing in both the atrium and the ventricle, and used *slow* and *fast* AGC to accomplish this.

Slow AGC (dynamic ranges) – to ensure that cardiac signals of all sizes could be appropriately sensed, earlier devices used multiple dynamic ranges to *view* a field where a cardiac signal could occur. Hardware limitations (8-bit analog-to-digital converter) allowed only a partial view of the entire signal field, so the device adjusted from range-to-range to maintain the best view of a signal. This adjustment prohibited EGMS from measuring the actual sensed amplitude. The dynamic adjustment accommodated signals of varying amplitude in the atrium and the ventricle, especially during tachyarrhythmias.

The older AGC had 12 overlapping dynamic ranges. As long as the incoming signal's amplitude peaks remained in the upper third of a range, the AGC continued to operate in that range. If the signal amplitude changed such that the peaks of three of the last four signals were no longer in the upper third of the dynamic range, the AGC adjusted to operate in the next adjacent range. This *slow moving* adjustment allowed the device to avoid oversensing of baseline artifact or *clipping* larger signals occurring outside a sensing range.

Fast AGC (beat-to-beat gain) – when an intrinsic signal was sensed, the AGC began a decay (i.e., became gradually more sensitive) within the dynamic range. Three different templates with different starting points and decay rates were used in each channel: normal sinus rhythm, pacing, or tachyarrhythmia.

Following a sensed signal, if another was not immediately sensed, sensitivity continued to increase until it reaches the floor of the current range. If a signal was not sensed by the time the pacing escape interval elapses, the device paced.

Why Change the AGC?

Changes to the AGC are being made for several reasons:

- To provide common sensing function across brady and tachy products, improving ease of use and simplifying sensing performance.
- To use the best of both tachy and brady sensing: use a brady-like sense bandwidth to filter out unwanted signals, and use dynamic tachy sensing to adjust to varying cardiac signal sizes.
- To take advantage of new technology advances.
- Previous AGC dynamic ranges resulted in clipped EGMS, choppy, non-linear movement from gain range to gain range.
- Previous AGC programmable values of Most, Nominal, Less, and Least are not intuitive or versatile.

Filter Ranges – Taken from Proven Brady Sensing

Narrower frequency band pass sensing filter helps eliminate myopotential oversensing.

INSIGNIA	ICDs and CRT-Ds described in this primer	PRIZM
Band Pass Frequency	25 – 81 Hz	20 – 85 Hz

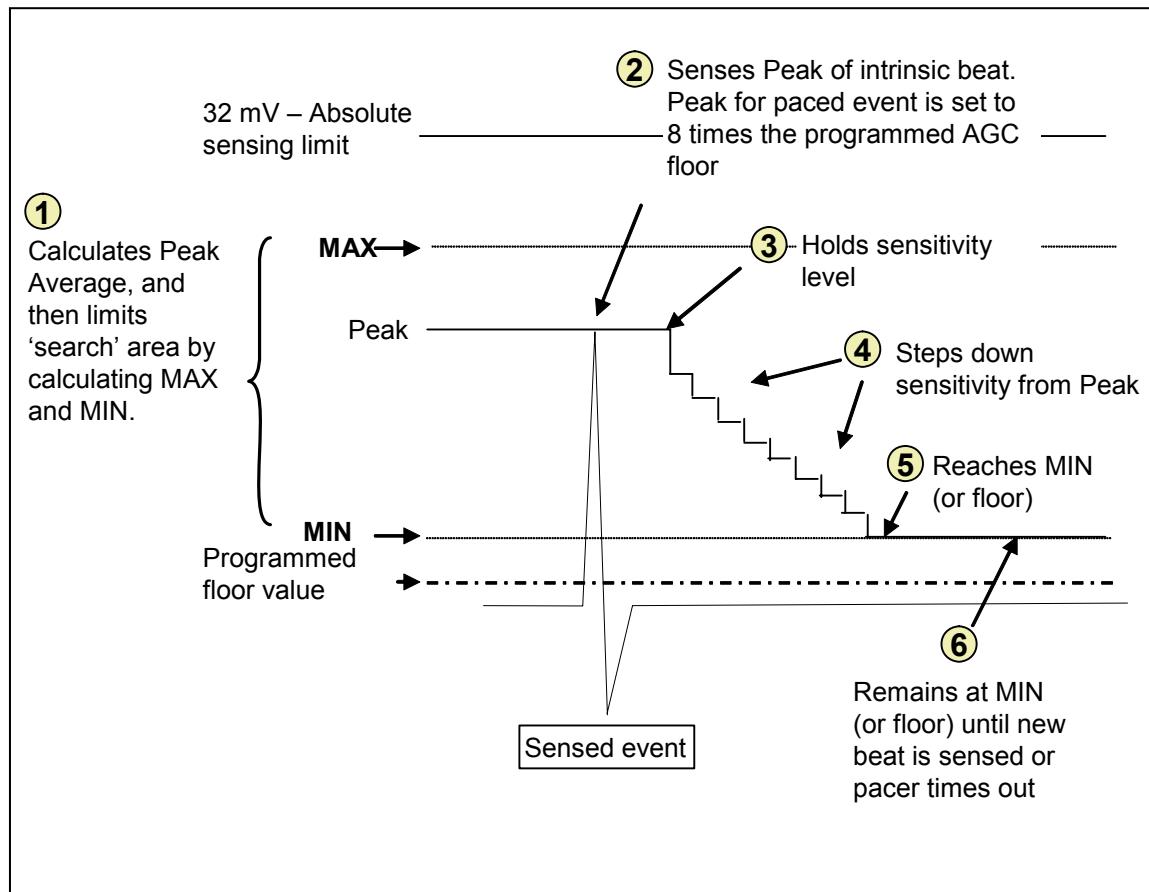
Tachy Automatic Gain Control Technology

- Sensing technology improves with use of 12-bit analog-to-digital converter rather than an 8-bit converter.
- More sophisticated hardware simplifies sensing by eliminating the need for separate dynamic ranges, making shifting from signal peak to another much smoother.
- Always sees the full R-wave or P-wave (as long as it is <32 mV).
- More sample points can be stored in memory.
- Since the AGC is not shifting dynamic ranges, the appearance of QRS amplitudes on the EGM will be more accurate.
- AGC floor parameters are programmable, and more programming choices are available for each chamber: 0.15, 0.2, 0.25, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.5 mV.
- Nominal AGC floor settings have changed based on performance experience and improvements in AGC:
 - Atrial AGC floor is nominally **0.25 mV** (0.18 mV in previous devices)
 - Right Ventricular AGC floor is nominally **0.60 mV** (0.27 mV in previous devices)
 - Left Ventricular AGC floor is nominally **1.0 mV** (1.24 mV in RENEWAL)

Details of Sensing

Devices described in this primer incorporate the use of *slow* AGC and *fast* AGC to optimize sensing of potentially rapidly changing cardiac signals. Unlike previous AGC design, however, dynamic ranges are no longer needed, and the beat-to-beat adjustments have been simplified.

Slow AGC	<ul style="list-style-type: none"> • Calculates a search area. Calculates, using a rolling average of previous signal peaks, where the next peak will likely be and bounds that area with MAX and MIN limits.
Fast AGC	<ul style="list-style-type: none"> • Senses the peak of the intrinsic beat • Holds the sensitivity level at the peak (or MAX) • Steps down or becomes more sensitive • Reaches the MIN or the floor • Remains at the MIN or floor until a new beat is sensed or pacing interval times out and pace is delivered



1. **Calculates a Search Area** – Before a sensed or paced event occurs, the device calculates a search area, using peak average, MAX and MIN. The search area narrows the probability of where the next peak will be and therefore shortens time to find the peak of the signal. This adjustment of the sensing search area is also called slow AGC.

In addition to narrowing the search area for the signal, *slow AGC* also allows gradual adjustments to sensing without overreacting to aberrant or abnormal beats (e.g., PVCs or polymorphic VT/VF).

First, the peak average is calculated:

n = current cardiac cycle

$n-1$ = previous cardiac cycle

Peak Average _n	= $\frac{3}{4} * \text{Peak Average}_{n-1} + \frac{1}{4} * \text{Peak}_{n-1}$
---------------------------	---

The formula includes the previous peak average, which included the peak average prior to the previous peak average, which considered the peak average prior to the prior beat, and so on. In other words, peak average exponentially considers all the beats that have

come before by building one average upon another. In addition, the peak average formula gives $\frac{1}{4}$ mathematical weight to the most recent peak measurement, because the most likely location of the new peak is close to the most recently sensed peak.

If the previous beat is paced rather than sensed, the peak is based on the programmed AGC floor value:

Peak value for RV/LV paced event	$= 8 * \text{programmed AGC value (floor)}_1$
Peak _n value for RA paced event	$= 12 * \text{programmed AGC value (floor)}$

Once the peak average is calculated, it is used to set MAX and MIN limits of the sensing range.

MAX sets a top (i.e., least sensitive) limit on the sensing area that will be *searched* for the next peak of the intrinsic beat:

MAX _n	$= \frac{3}{2} * \text{Peak Average}_n$
------------------	---

MIN sets a bottom (i.e., most sensitive) limit on the sensing area that will be *searched* for the next peak of the intrinsic beat.

MIN _n	$= \frac{1}{8} * \text{Peak Average}_n$
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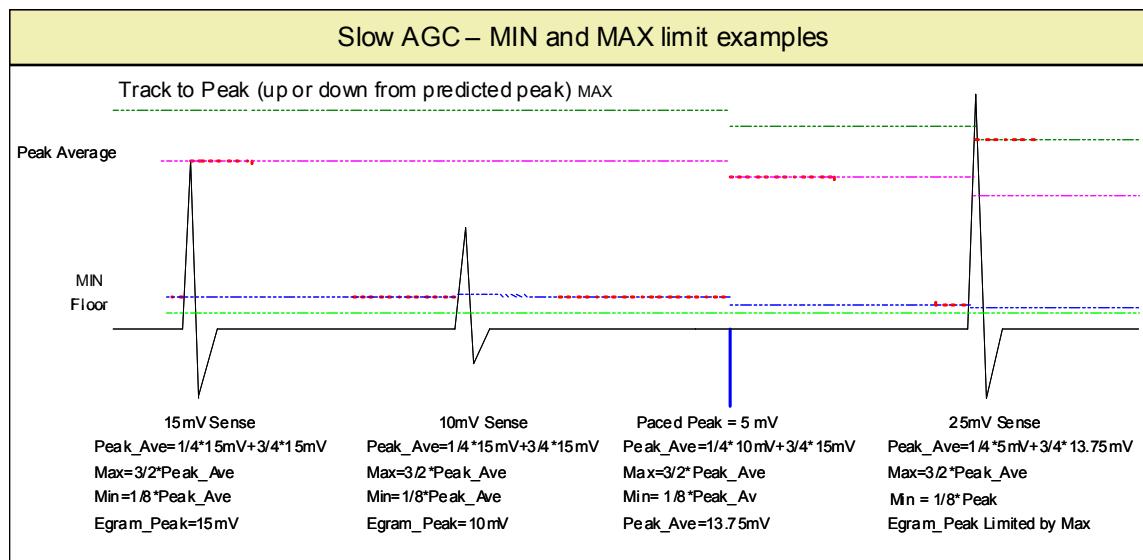
The following example shows how *slow* AGC (MAX and MIN) are calculated for cardiac signals of varying amplitudes.

Example: 1st beat is similar to previous averaged beats.

2nd beat is much smaller than previous beat.

3rd interval times out and device paces.

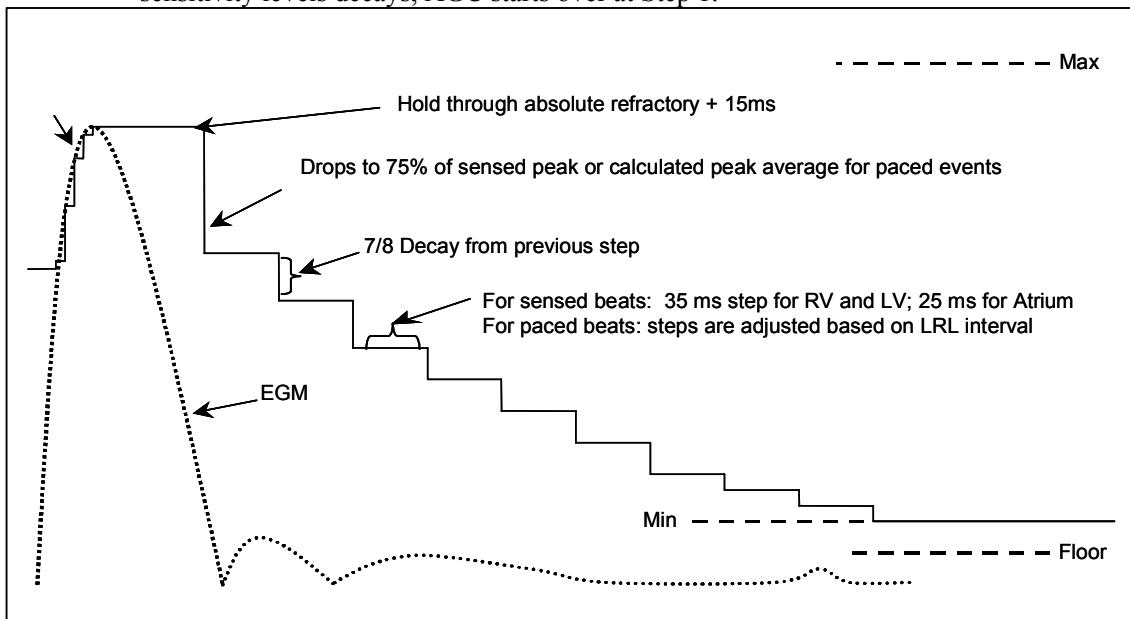
4th beat is much larger than previous beats.



2. **Senses the peak of the intrinsic beat** – when the intrinsic event occurs, the device senses the actual peak of the intrinsic beat. The device will sense the peak even if the peak falls outside the calculated search area (e.g., a PVC with an amplitude > MAX). For a paced event, the peak is set to be eight times the programmed AGC floor.
3. **Holds the sensitivity level at the peak (or MAX)** – the AGC holds the sensitivity level at the peak (or MAX) for the absolute refractory period +15 ms. During the absolute refractory time, no sensing is taking place.
 - A sense refractory: 85 ms = 30 ms absolute refractory + 40 ms noise + 15 ms absolute refractory.
 - A pace refractory: 150 ms = 110 ms absolute refractory + 40 ms noise.
 - RV sense refractory: 135 ms = 50 ms absolute blanking + 40 ms noise + 45 ms fixed refractory.
 - RV pace refractory: programmable, all absolute refractory except last 40 ms is noise window.
 - LV refractory: programmable, all absolute refractory except last 40 ms is noise window.
4. **Steps down sensitivity from peak** – after hold period, the AGC steps down, or decays, sensitivity:
 - Drops to 75 % of the peak value of sensed beat or 75 % of the calculated peak average for paced beat.
 - For a sensed event, after the initial 75 % drop the AGC steps down to 7/8 of previous value every 35 ms in the RV and LV, every 25 ms in the A. This step-down continues until either the MIN or the programmed sensing floor is reached, whichever is reached first.

- For a paced event, after the initial 75% drop the AGC also steps down to 7/8 of previous value. However, the length of time for each step is calculated according to the LRL pacing interval, so that the MIN or programmed AGC floor is reached 150 ms from next scheduled pace.

5. **Reaches the MIN or the programmed AGC floor** – if a new beat is sensed as the sensitivity levels decays, AGC starts over at Step 1.



6. **Remains at the Min or floor** until a new beat is sensed or pacing interval times out and pace is delivered.

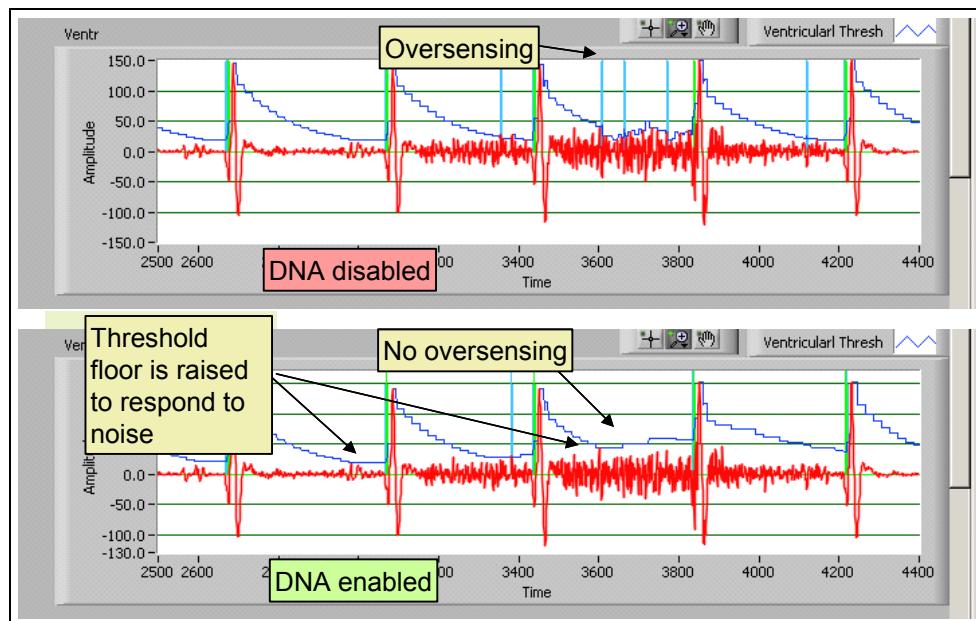
Dynamic Noise Algorithm (DNA)

This sensing algorithm includes a Dynamic Noise Algorithm (DNA) to help filter out myopotential noise. The DNA is a separate noise channel, continuously measuring the baseline signal present and adjusting the sensitivity floor to stay above any noise.

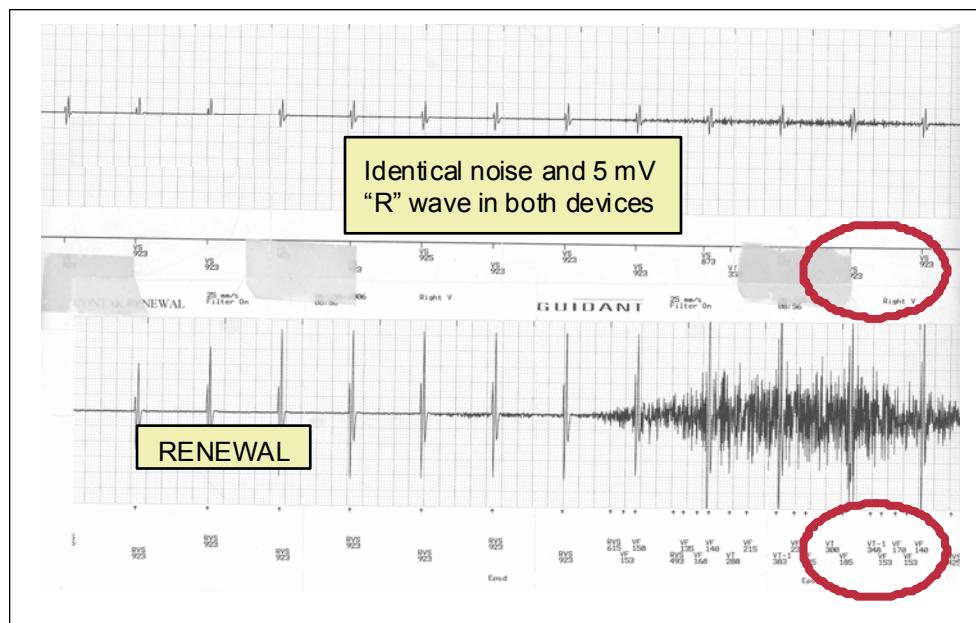
The algorithm uses the characteristics of a noise signal—frequency and energy—to identify a signal as noise. The Dynamic Noise Algorithm is automatically and independently active on all three sensing channels: When noise is present, the algorithm keeps the AGC floor above the noise, helping to prevent oversensing myopotentials and the problems that oversensing myopotentials can cause: inhibition of pacing, inappropriate tachy therapy.

Noise that affects the sensing floor would likely be visible on the intercardiac EGMs, but the signal would not be marked as sensed.

NOTE: The dynamic noise algorithm will not make the AGC immune from sensing all noise. The device could still sense EMI or other sources of high amplitude noise.



Examples of noise with and without Dynamic Noise Algorithm (DNA)



Example of signal sensed through Dynamic Noise Algorithm in ICDs and CRT-Ds described in this primer as compared to same signal sensed in RENEWAL CRT-D

Programmable Values

Nominal AGC floor settings:

Atrial AGC is nominally	0.25 mV
Right Ventricular AGC nominally	0.60 mV
Left Ventricular AGC floor is nominally	1.0 mV

Settings: 0.15, 0.2, 0.25, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.5 mV.

NOTE: It is recommended that the AGC be left at the nominal settings, unless troubleshooting determines that another setting may be more appropriate.

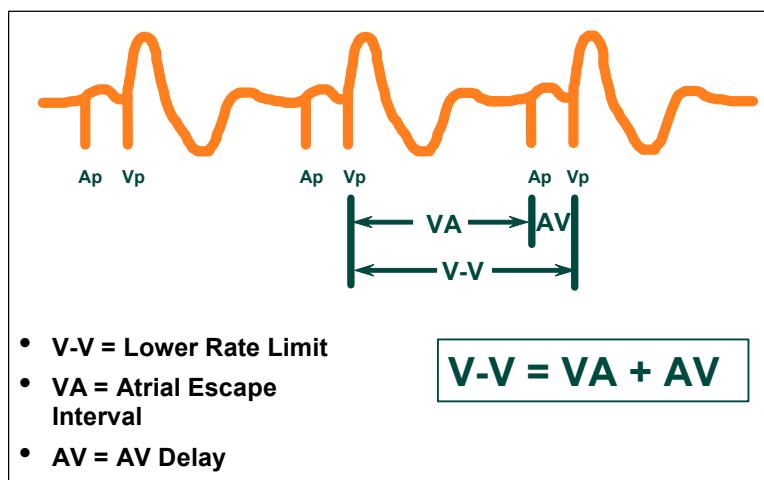


Timing Cycles

Timing cycles determine the timing of the device's response to the presence or absence of intrinsic events and are determined by numerous programmable features within the device. Features which will affect timing cycles are the programmed AV Delay, LV Offset, Refractory/Blanking Periods, and Noise Response.

See the respective topics related to these features for further details.

Basic Normal Brady Timing Cycles – the timing cycles for devices described in this primer are defined by the VA and AV interval which together equal the V-V interval:

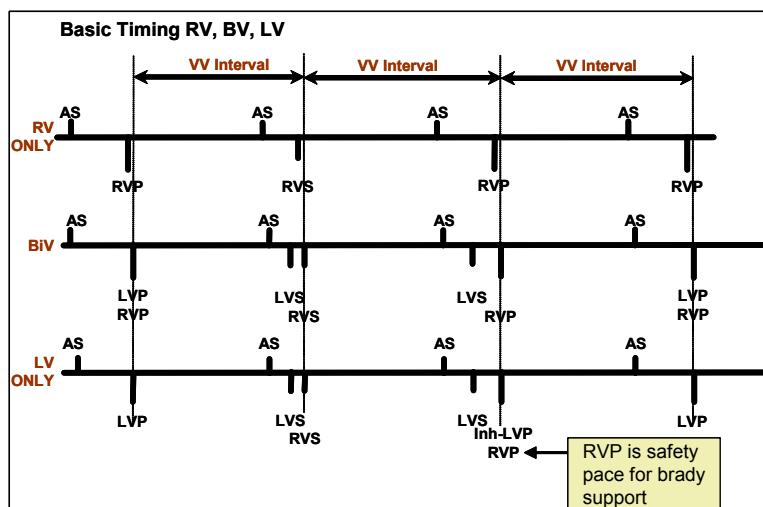


Devices described in this primer use RV-based timing; only RV-paced and RV-sensed events define cardiac cycles. Therefore, the following are based on RV events:

- Tachy Detection
- Tachy Therapy
- Brady Therapy
- Cardiac Resynchronization Therapy

RV-based timing has the effect of maintaining proven tachy therapy, reduces interactions between algorithms, and simplifies understanding of device behavior.

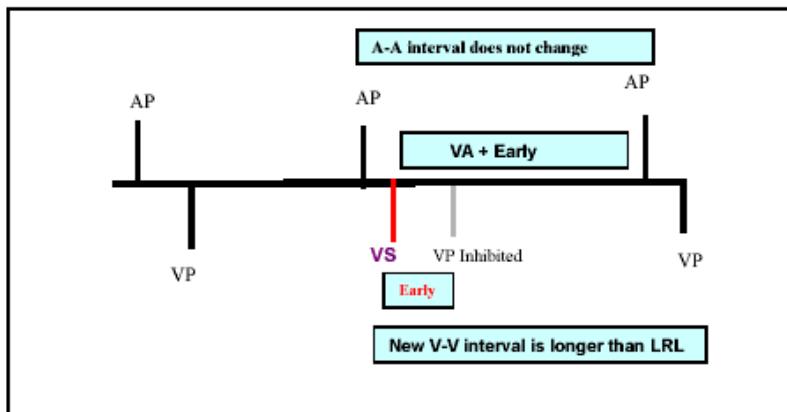
If a CRT-D device is programmed to LV-only pacing²⁰, LV-paced events will also initiate timing cycles on the RV channel. While LV-sensed events inhibit LV therapy, they do not modify the device's timing cycle.



NOTE: It is necessary that an RV lead be implanted even when utilizing LV-only pacing as all timing cycles rely on RV events.

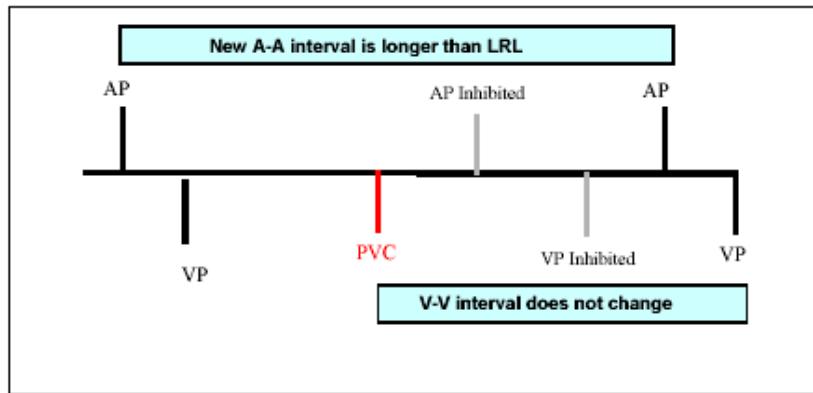
Modified Atrial Based Timing – when a patient demonstrates intrinsic conduction, a VS event will transition the device from V-based timing to A-based timing. In this situation, an extension (labeled *Early* below) is added to the V-A interval in order to maintain a consistent A-A interval. The length of this extension is determined by the difference between the paced AV Delay and the patient's intrinsic conduction time (PR interval). If this extension were not added, the V-A interval would begin at the intrinsic VS and the subsequent AP would occur above the LRL. A VP event will transition the device from A-based timing back to V-based timing. This transitional VP will occur slower than the LRL due to the extension applied to the V-A interval.

²⁰ Not available in CRT-D models distributed in all geographies



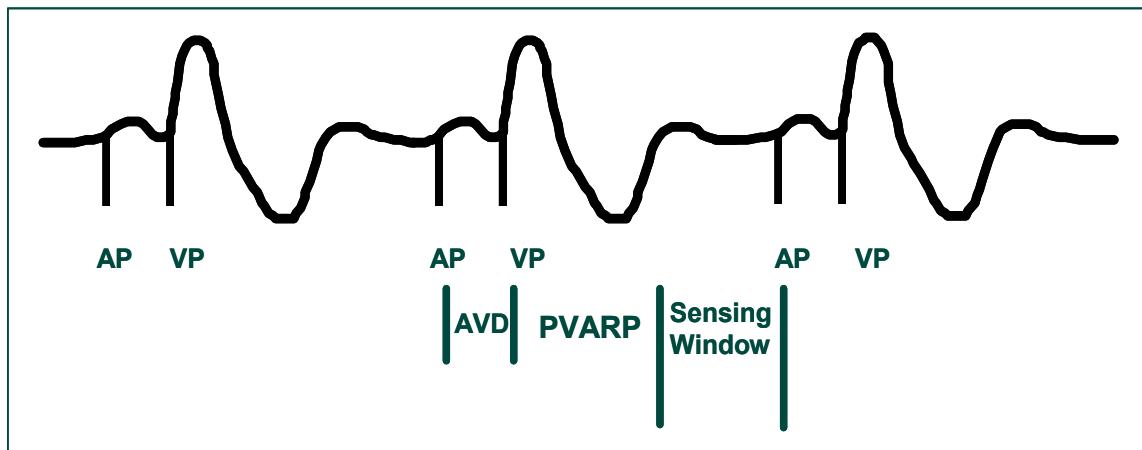
Modified atrial-based timing is applied following AP/VS and AS/VS cycles. It is not applied following [AS]/VS cycles.

PVC Timing – in the event of a PVC, the device remains in V-based timing and a PVC will end a V-V interval and begin a new V-A interval. Since a scheduled AP will be inhibited in this instance, a PVC will result in atrial rates below the LRL (usually noted in histograms).



Sensing Window – the sensing window is the portion of cardiac cycle in which intrinsic events are sensed and marked as well as initiate a timing cycle. In DDD(R) mode as in the following example, this window begins at the conclusion of PVARP and ends when an atrial event occurs.

- If an atrial sense occurs during PVARP, it is sensed and marked as [AS] but will not initiate a timing cycle.
- If an atrial sense occurs during the sensing window, it will be sensed and marked as an AS as well as initiate the AV Delay.
- In a single chamber mode, this window begins at the conclusion of the same chamber refractory period and ends at the next scheduled pace or sensed event.



Refractory Periods

ICD	INCEPTA	CRT-D	INCEPTA
	ENERGEN		ENERGEN
	PUNCTUA		PUNCTUA
	TELIGEN		COGNIS

Refractory periods are a vital aspect of device timing in which sensed intrinsic events do not initiate timing cycles.

Availability

Navigation:

From the Settings screen select  **Settings Summary**

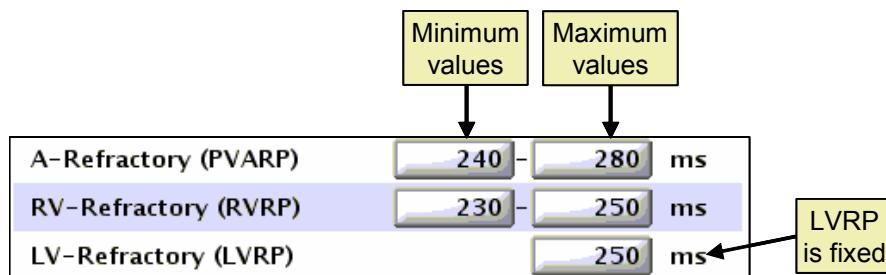
Select:  **Normal Settings**

Programmable Values

PVARP (Post Ventricular Atrial Refractory Period)	150 ms-500 ms (10 ms increments)	Nominal: Dynamic 240-280 ms
RVRP (Right Ventricular Refractory Period)	150-500 ms (10 ms increments)	Nominal: Dynamic 230-250 ms
LVRP – CRT-Ds only (Left Ventricular Refractory Period)	250-500 ms (10 ms increments)	Nominal: Fixed 250 ms

Dynamic Versus Fixed Programming – Dynamic Refractory Periods provide a shortening of the refractory period as the patient's intrinsic rate increases in order to increase the sensing window (portion of the cardiac cycle in which intrinsic events are sensed and initiate a timing cycle).

Refractory periods are nominally dynamic with a minimum and maximum programmable value. Please see below for details.



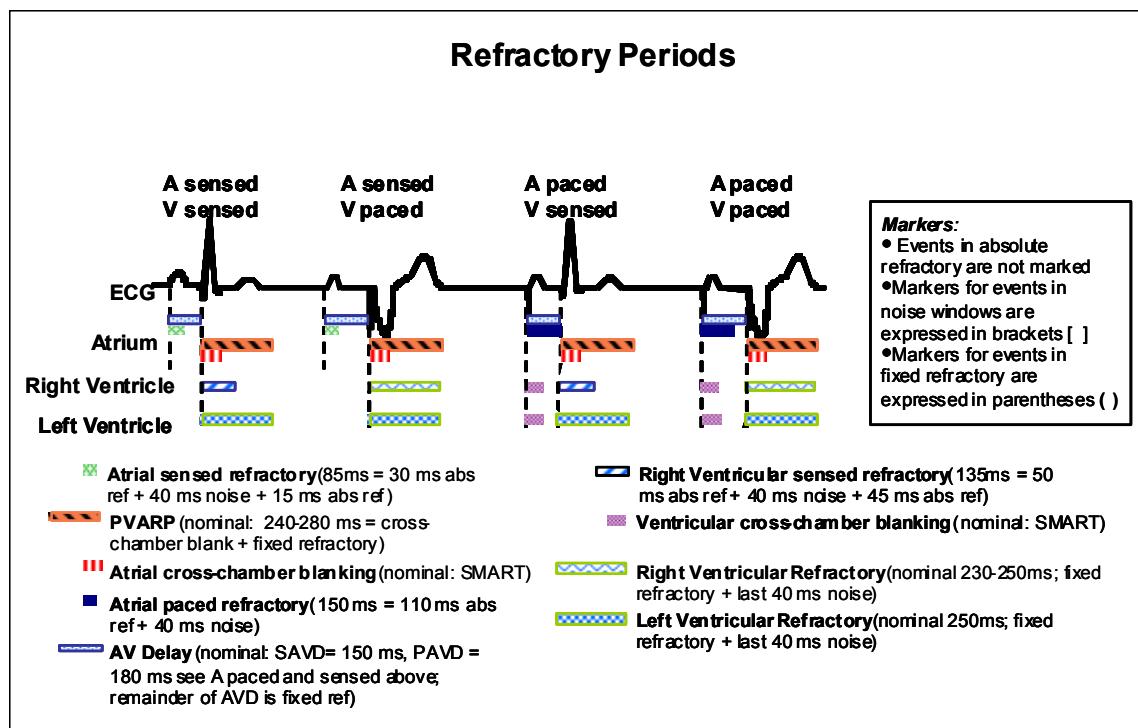
The refractory period will automatically be dynamic if the minimum value is less than the maximum value. To program a fixed refractory, set the MIN and MAX to the same value.

Algorithm

Refractory periods are initiated on all atrial and ventricular paced events and all non-refractory atrial and ventricular sensed events. Refractory periods are composed of:

Absolute Refractory	<ul style="list-style-type: none"> Begins immediately after an event occurs Sense amplifiers are completely unresponsive
Noise Window	<ul style="list-style-type: none"> Begins during or at the end of the refractory period Sensed events do not count toward timing or detection Continuous sensed events will retrigger noise windows
Fixed Refractory	<ul style="list-style-type: none"> May begin immediately after an event or at the end of refractory depending on the particular refractory period Events may be sensed and marked depending on the particular refractory period

See the corresponding topics on Noise Response and Cross-Chamber Blanking Periods for further information.



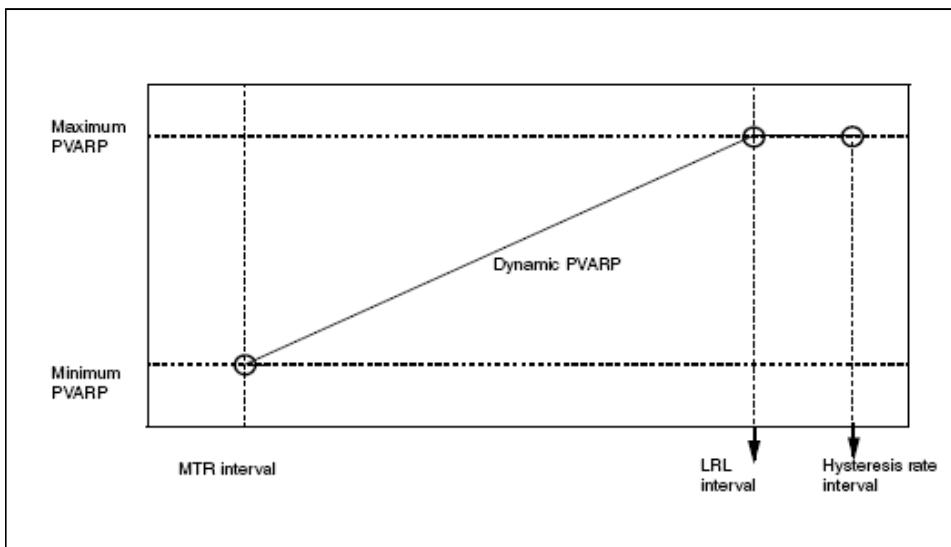
Post-Ventricular Atrial Refractory Period (PVARP) – PVARP in dual chamber modes is a programmable period after a ventricular paced or sensed event in which sensed atrial events do not initiate timing cycles or inhibit atrial pacing. PVARP may prevent the tracking of retrograde atrial events initiated in the ventricle which could trigger PMT.

- The initial section of PVARP is the cross-chamber blanking period followed by the fixed refractory period.
 - Blanked events are not sensed or marked and events in fixed refractory are marked as [AS].
 - If SMART blanking is OFF, the cross-chamber blanking period consists of an absolute refractory period and a noise window; absolute refractory events are not sensed or marked and noise events are marked as [AS].

- Although sensed events in PVARP do not initiate timing cycles, they do count toward ATR Entry Counts and AFib Rate Threshold and are included in counters/histograms.
- In CRT-Ds, this period will begin following any right ventricular paced or sensed event.
- In LV-only mode²¹, PVARP will follow LV-paced or RV-sensed events.
- In CRT-Ds, a long AV Delay and long PVARP may result in a loss of atrial tracking below the MTR and thus a loss of CRT delivery. Dynamic PVARP will help alleviate this occurrence and the clinician should consider turning Tracking Preference ON to further ensure CRT delivery below the MTR.

See the *Tracking Preference* topic for further details.

Dynamic PVARP – shortens the refractory period in order to increase the atrial sensing window and minimize upper rate behavior as the patient's intrinsic atrial rate increases. Atrial sensed events which occur faster than the TARP interval (minimum AV Delay + minimum PVARP) will not be tracked and result in upper rate behavior. Additionally, as the atrial rate increases, the atrial sensing window decreases which may lead to competitive atrial pacing. Used in conjunction with Dynamic AV Delay, the reduction of PVARP at higher rates increases the atrial sensing window, allows a higher MTR, and assists in avoiding upper rate behavior. Likewise, as the rate slows, the subsequent increase in PVARP reduces the likelihood of PMT.



²¹ Not available in CRT-D models distributed in all geographies

- PVARP will decrease linearly between the LRL and MTR based on a rolling average of the last four V-V intervals.
- The maximum value is applied if the average pacing rate is < LRL (the maximum value is applied between the LRL and Hysteresis rate).
- The minimum value is applied if the average rate is > the MTR (the minimum value is applied at the MTR regardless of the MSR rate).
- If a PVC occurs and PVARP after PVC is OFF, the PVARP for the previous cycle is applied.
- In non-tracking, non rate responsive modes, Dynamic PVARP is only available in DDI mode when Rate Smoothing Down, VRR, or BiV Trigger is ON. In this case, the minimum value is applied when the average rate is \geq the fastest of the enabled feature's MAX Pacing Rates.
- In AAI(R) mode, there is no minimum PVARP as Dynamic PVARP is only applicable after ventricular events.

NOTE: Dynamic PVARP may increase the risk of PMT if PVARP is programmed shorter than the patient's retrograde conduction interval. Physicians may consider performing retrograde conduction testing to ensure the minimum PVARP is longer than the retrograde conduction interval.

See the PMT Termination topic for an explanation of retrograde conduction testing.

Right Ventricular Refractory Period (RVRP) – RVRP is a programmable period in which right ventricular events which follow RV-paced events (or the leading LV-paced event when the LV Offset is not programmed to zero) do not initiate a timing cycle. RVRP is designed to prevent these RV-sensed events (such as a T wave) from affecting overall device timing.

- The initial section of RVRP is fixed refractory followed by a 40 ms noise window; events in fixed refractory are not sensed or marked and noise events are marked as [RVS].
- RVRP events are not included in counters/histograms.
- The use of a long RVRP shortens the RV-sensing window for ventricular tachy detection.

NOTE: To provide an adequate sensing window, it is strongly recommended to program the refractory to the following values:

- Single chamber modes to $\leq \frac{1}{2}$ LRL in ms.
- Dual chamber modes to $\leq \frac{1}{2}$ MTR and/or MSR in ms.
- Attempting to program values outside of these suggested ranges will result in a yellow *Attention* message. Select the *Attention* button at the bottom of the screen to obtain further details.

Dynamic RVRP – As noted above, a long RVRP will shorten the RV-sensing window for VT detection. By using Dynamic RVRP, the sensing window will be maintained since the RVRP will shorten as the ventricular rate increases due to atrial tracking or sensor-driven pacing. This is designed to mimic the heart's natural shortening of the QT interval with increases in sinus rate.

- RVRP will decrease linearly as the rate increases from the LRL to the MTR and is based on the previous V-V interval.
- The maximum value is applied if the pacing rate is < LRL (the maximum value is applied between the LRL and Hysteresis rate).
- The minimum value is applied if the ventricular rate is > the MTR (the minimum value is applied at the MTR regardless of the MSR rate).
- In non-tracking, non rate responsive modes, Dynamic RVRP is only available in DDI mode when Rate Smoothing Down, VRR, or BiV Trigger is ON. In this case, the minimum value is applied when the average rate is \geq the fastest of the enabled feature's MAX Pacing Rates.

Left Ventricular Refractory Period (LVRP) – LVRP is a programmable period following an LV-sensed or LV-paced event. It can also be initiated on an RV-paced event when either the LVP is inhibited or the RV pace is the leading ventricular event when LV Offset is not programmed to zero. During this period, left ventricular events are only sensed within the noise window following an LV pace. This refractory period prevents inappropriate LV pacing inhibition due to over-sensing, double-counting, T-wave sensing or LV PVCs.

- Ensure the LVRP is programmed to a sufficient duration to include the T-wave.
- The initial section of LVRP is fixed refractory followed by a 40 ms noise window.
 - Events within LVRP following an LV sense are not sensed or marked.
 - Events within LVRP following an LV pace are not sensed or marked within fixed refractory and marked as [LVS] within the noise window.
- LVRP events are not included in counters/histograms.
- LVRP works together with the LV Protection Period (the period following an LV event when the device will not pace in the left ventricle):
 - Both LVPP and LVRP are initiated upon sensing a non-refractory LV event.
 - If an LV event falls within LVRP, an LVPP is not initiated.

See the LVPP topic for further details on the combined function of LVRP and LVPP.

NOTE: Using a long LVRP shortens the available LV-sensing window for appropriate pacing inhibition.

- In RV-only mode, LVRP is only available in VDD(R) and DDD(R) modes for use during BiV pacing in ATR mode switch episodes.

Non-programmable Refractory Periods

Atrial Refractory Period after Atrial-sensed Event – atrial refractory is the time period after an atrial -sensed event when additional sensed-atrial events do not initiate timing cycles or inhibit atrial pacing.

- 85 ms (30 ms absolute refractory, 40 ms noise window, 15 ms absolute refractory).
 - Absolute refractory events are not sensed or marked and noise events are sensed but not marked.

- If the SAVD is programmed to less than the 85 ms atrial sensed refractory period, the refractory period will continue after the subsequent ventricular event occurs.

Atrial Refractory after Atrial-paced Event – Atrial refractory is the time period after an atrial-paced event when additional sensed-atrial events do not initiate timing cycles or inhibit atrial pacing.

- 150 ms (110 ms absolute refractory, 40 ms noise window).
 - Absolute refractory events are not sensed or marked and noise events are marked as [AS].
- If the PAVD is programmed to less than the 150 ms atrial paced refractory period, the refractory period will continue after the subsequent ventricular event occurs.

RV Refractory after RV-sensed Event or Capacitor Charge – RV refractory is the time period after an RV-sensed event or capacitor charge when additional sensed-RV events do not initiate timing cycles or inhibit ventricular pacing and are not included in counters.

- 135 ms (50 ms absolute refractory, 40 ms noise window, 45 ms absolute refractory).
 - Absolute refractory events are not sensed or marked and noise events are sensed but marked as [RVS] only after capacitor charge.
- Applied in all modes including AAI(R) mode as long as Tachy mode is not OFF.

All Chamber Refractory after Charge and Shock Delivery – following shock delivery, all chambers are completely blanked to prevent oversensing of the shock signal.

- There is a 135 ms post charge refractory across all three chambers, RA, RV and LV.
- 500 ms (460 ms absolute refractory, 40 ms noise window).
 - Absolute refractory events are not sensed or marked and noise events are marked as [AS], [RVS], or [LVS] depending on the chamber in which they occurred.

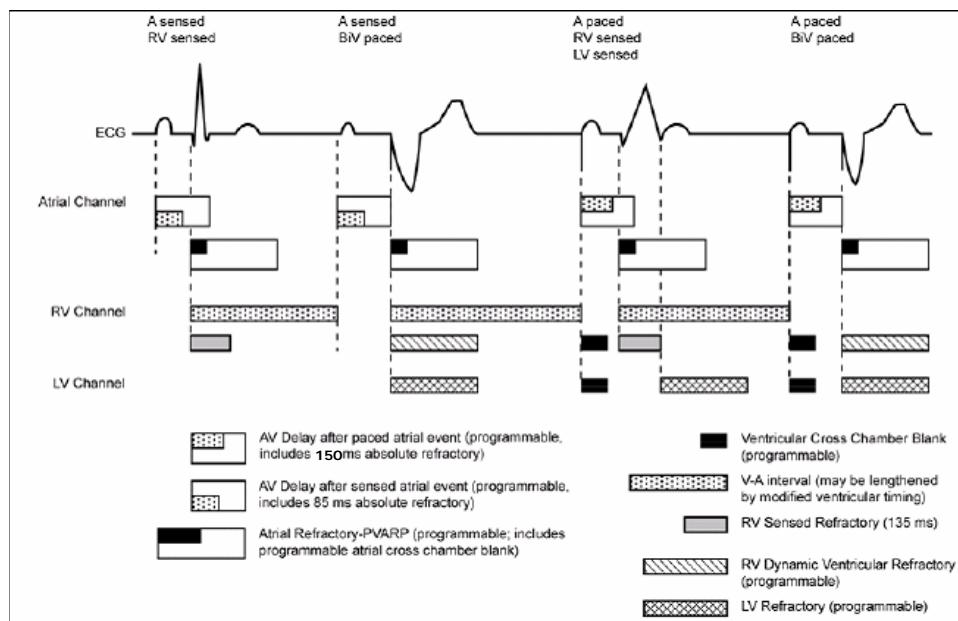
AAI(R) Mode

In AAI(R) mode, paced and sensed atrial refractory (labeled as PVARP on the programmer) is a fixed programmable period that begins following any atrial paced or sensed event. Atrial events sensed within atrial refractory do not initiate timing cycles or inhibit atrial pacing.

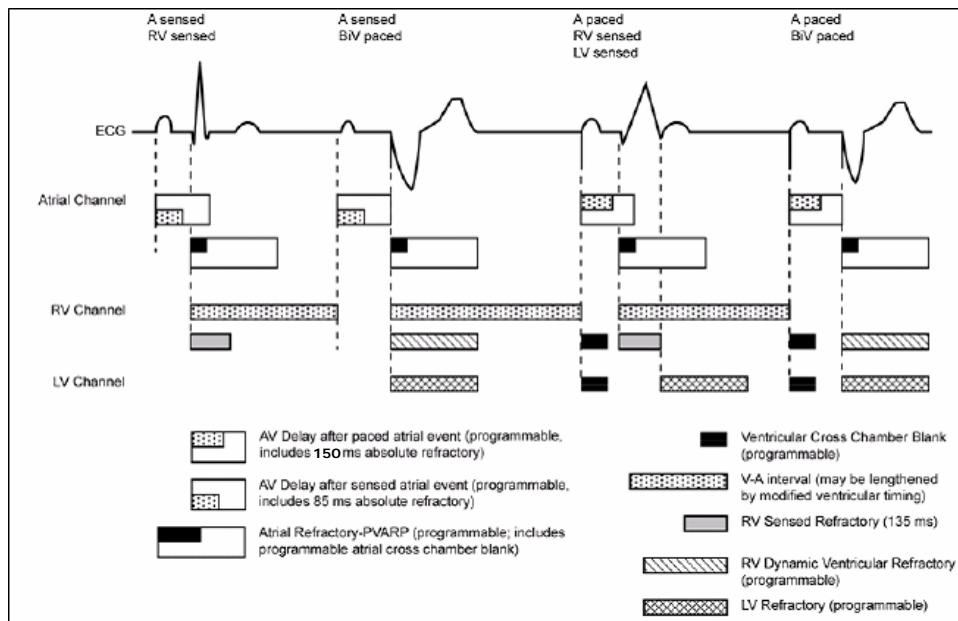
- Atrial refractory after an atrial sensed event:
 - 85 ms absolute refractory, remainder is fixed refractory.
- Atrial refractory after an atrial paced event:
 - 110 ms is absolute refractory, 40 ms noise window, remainder is fixed refractory.
- RV refractory after RV-sensed event is applied and cross-chamber blanking is available and programmable as long as Tachy mode is not OFF.

Schematics Demonstrating Refractory Periods in Various Pacing Modes and Pacing Chambers

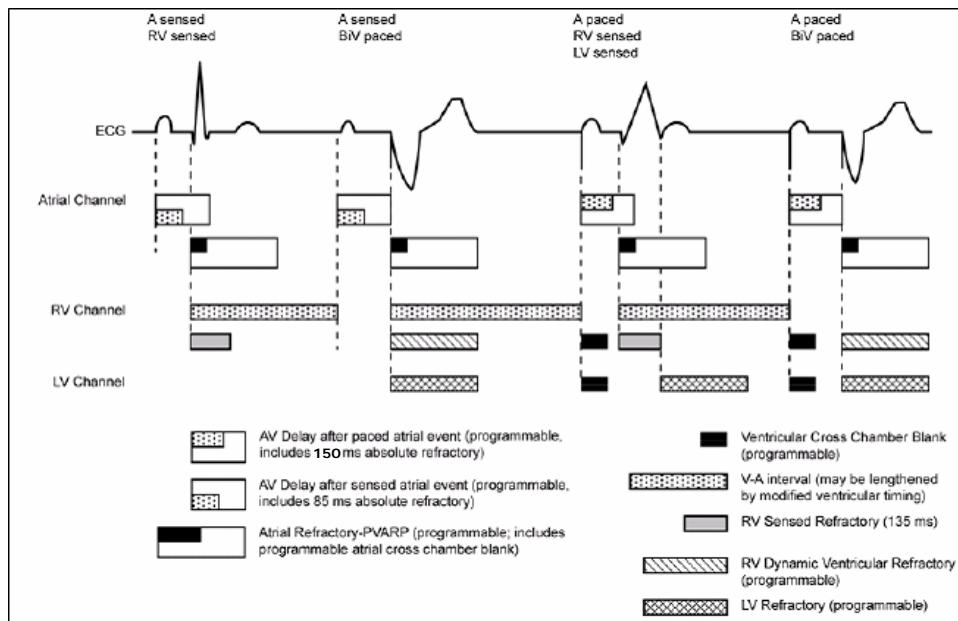
Dual Chamber Mode: RV only



Dual Chamber Mode: BiV

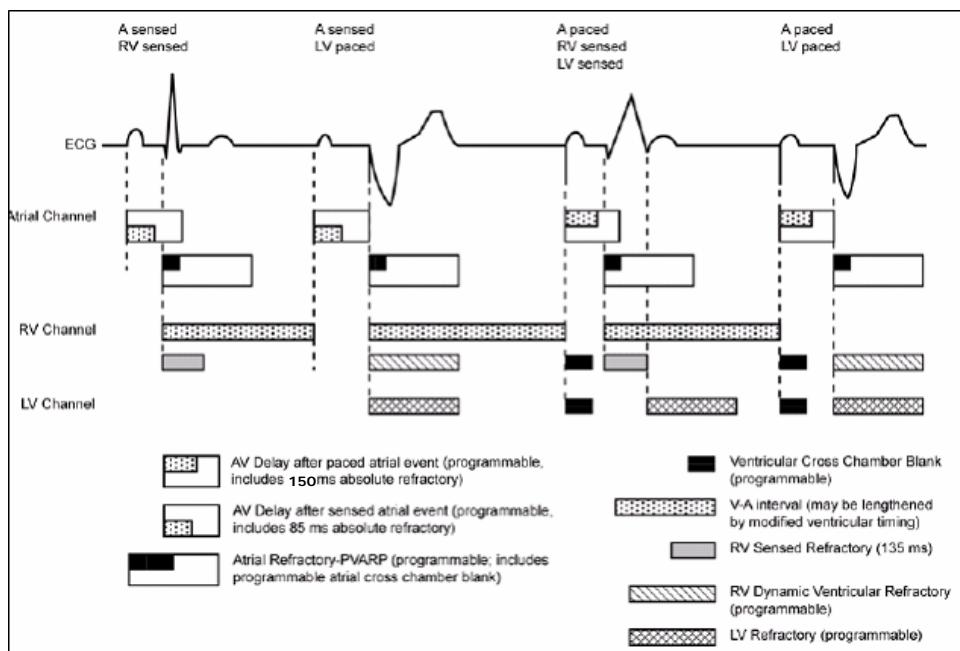


Dual Chamber Mode: LV Only²²

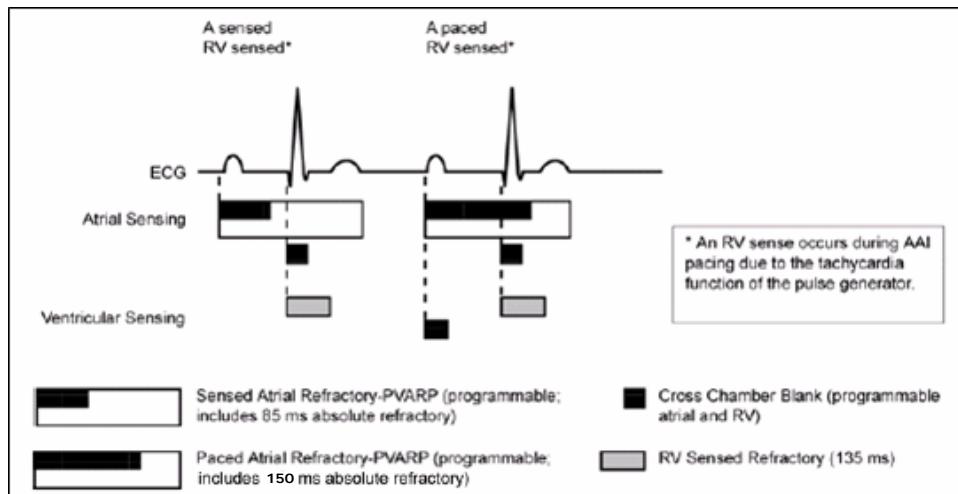


²² LV-Only pacing is not available in CRT-D models distributed in all geographies

VVI Mode: LV Only²³



AAO Mode



²³ LV-Only pacing is not available in CRT-D models distributed in all geographies

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Cross-chamber Blanking

Cross-chamber blanking *blinds* one chamber to events occurring in the opposite chamber to prevent oversensing signals to which the device should not respond.

Devices described in this primer have four cross-chamber blanking windows that are programmable:

- A-blank after RV-Sense
- A-Blank after V-pace
- RV-blank after A-pace
- LV-blank after A-pace

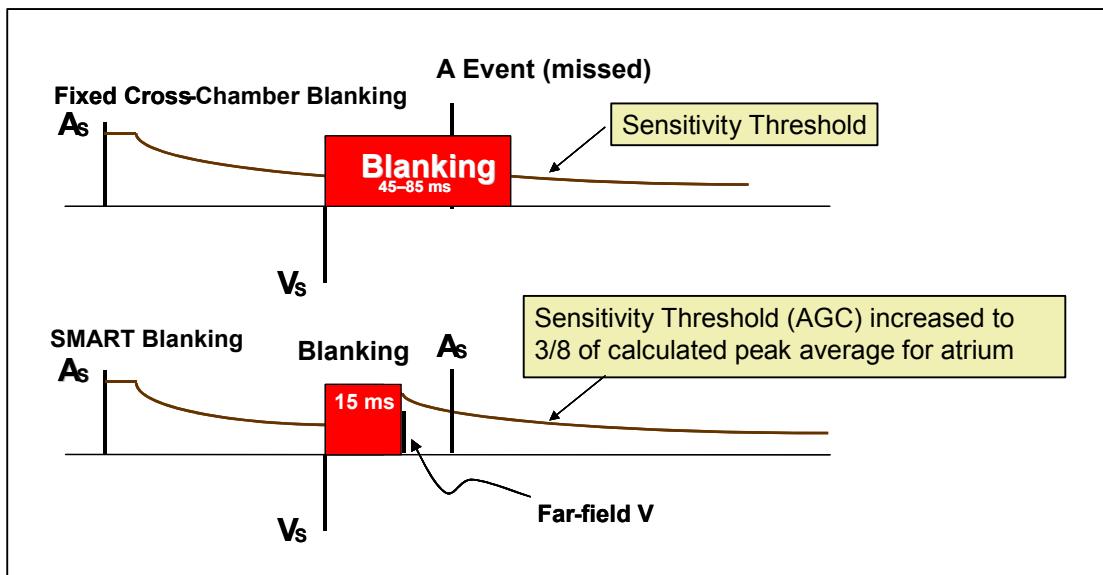
Each cross-chamber blanking window may be programmed to a fixed value or to a SMART value. Cross-chamber blanking is also programmable on the Temporary Brady screen.

SMART Blanking is designed to promote sensing by shortening the blanking period, while rejecting cross-chamber events by automatically adjusting the sensitivity in the following manner:

- Shortening the blanked period to an absolute refractory (15 ms for A-blank after V-Sense, and 37.5 ms for all other blanking windows).
- Eliminating the noise portion of the blanking window.
- Increasing the AGC setting to avoid far-field oversensing of the event in the opposite chamber; the AGC is *bumped* up to 3/8 of the current peak average.

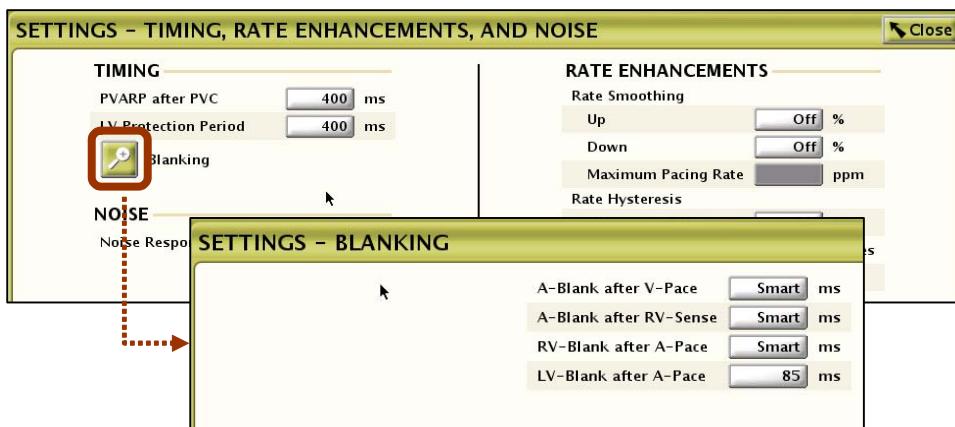
See *Sensing section* for details on how peak average is calculated.

Examples: Cross-Chamber Blanking



Availability

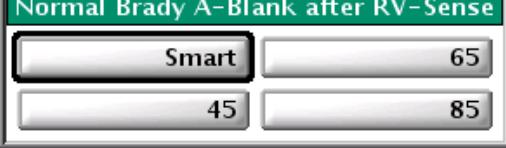
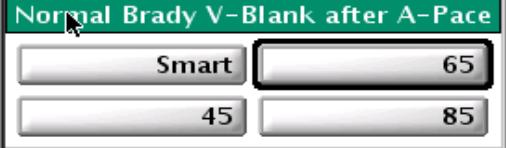
1. From the Setting screen, select  
2. On the Settings – Normal Brady/CRT screen, select 
3. On the Settings – Timing, Rate Enhancement, and Noise screen, choose Blanking:



Programmable Values

The following values may be used for both Normal Brady and Temporary Brady cross-chamber blanking.

A-Blank after V-Pace									
Nominal	SMART								
SMART	37.5 ms absolute refractory with no noise window Exception: If an atrial refractory window is <u>active when the V-pace occurs</u> , 85 ms blanking will be applied.								
Fixed Value	85 ms, 105 ms, or 125 ms (<u>CRT-D</u>) 45 ms, 65 ms, or 85 ms (<u>ICD</u>)								
CRT-D values	ICD values								
Normal Brady A-Blank after V-Pace <table border="1"> <tr> <td>Smart</td> <td>105</td> </tr> <tr> <td>85</td> <td>125</td> </tr> </table>	Smart	105	85	125	Normal Brady A-Blank after V-Pace <table border="1"> <tr> <td>Smart</td> <td>65</td> </tr> <tr> <td>45</td> <td>85</td> </tr> </table>	Smart	65	45	85
Smart	105								
85	125								
Smart	65								
45	85								

A-Blank after RV-Sense	
Nominal	SMART
SMART	<p>15 ms absolute refractory with no noise window</p> <p>Exception: If an atrial refractory window is active when the V-pace occurs, 85 ms blanking will be applied.</p>
Fixed Value	45 ms, 65 ms, or 85 ms
Normal Brady A-Blank after RV-Sense	
	
RV-Blank after A-Pace	
Nominal	<p>65 ms</p> <p>Note: The nominal was changed from SMART to 65ms: U.S. Q4 2008; EU Q1 2009; AUS and JPN always had 65ms nominal.</p>
SMART	<p>37.5 ms absolute refractory with no noise window</p> <p>Exception: If a ventricular refractory window is active when the A-pace occurs, 85 ms blanking will be applied.</p>
Fixed Value	45 ms, 65 ms, or 85 ms
Normal Brady V-Blank after A-Pace	
	

LV-Blank after A-Pace	
Nominal	SMART
SMART	37.5 ms absolute refractory with no noise window Exception: If a ventricular refractory window is active when the A-pace occurs, 85 ms blanking will be applied.
Fixed Value	45 ms, 65 ms, or 85 ms
Normal Brady RV-Blank after A-Pace 	

Algorithm

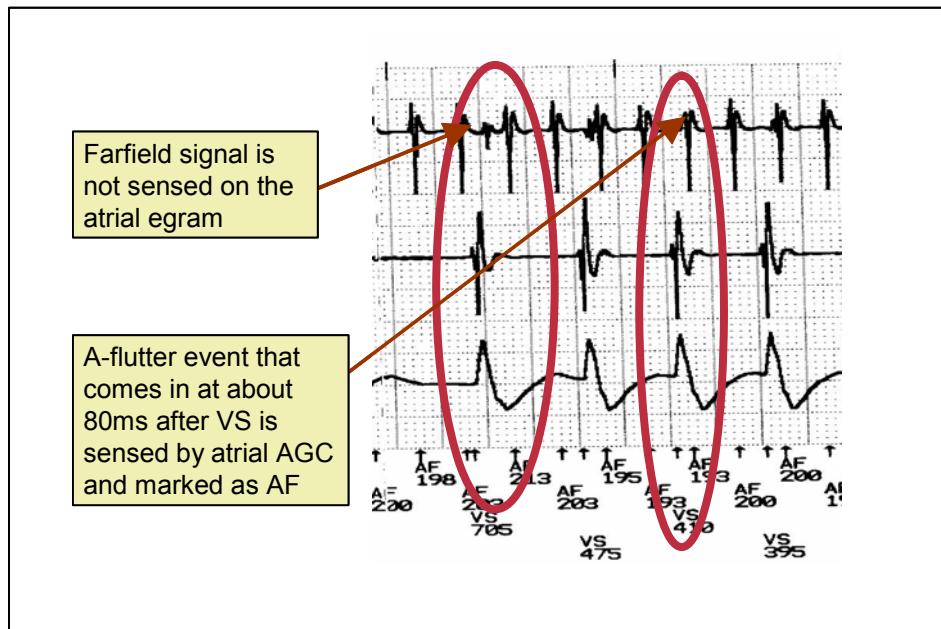
For Atrial Cross-chamber Blanking – after a V-sense or V-pace event occurs, the device applies a blanking window to the atrial channel to prevent far-field oversensing/crosstalk. The size of the blanking window depends on the programmed value.

For Ventricular Cross-chamber Blanking – after an atrial-paced event, the device applies a blanking window to the ventricular channel to prevent crosstalk. The size of the blanking window depends on the programmed value.

Example: SMART example – A-Blank after V-Sense after a ventricular-sensed (VS) event:

- Atrial channel is blanked for 15 ms.
- After the 15 ms blanking window, the atrial AGC restarts at $\geq 3/8$ of the calculated atrial peak average.
- The AGC starting point is based on how far the AGC has *decayed* when the cross-chamber event occurs.
 - If the AGC is still $> 3/8$ of the calculated peak average, the AGC will begin at the current level.
 - If the atrial AGC has decayed to $\leq 3/8$ of the calculated peak average, the AGC will restart at $3/8$ of the calculated peak average.

SMART example



NOTE: There is no retriggerable noise window in the 15 ms SMART Sensing window.

Notes/Additional Information

There is no ventricular cross-chamber blanking for an atrial sensed event.

Considerations when SMART Blanking is programmed

1. If the retriggerable noise window is in effect when the cross-chamber event occurs (e.g., atrial retriggerable noise window active when VS occurs), the device will not terminate the noise window to apply SMART Blanking, but will apply an 85 ms blanking window.
2. If a same-chamber refractory window is active when the cross-chamber event occurs (e.g., atrial refractory window is in effect when VS occurs), the device will not terminate the refractory to apply SMART Blanking, but will apply an 85 ms blanking window.

Post Shock Brady Pacing – residual energy on the defibrillation lead after shock delivery can increase the likelihood of cross-talk / far-field sensing. As this residual energy dissipates with time after shock delivery, the potential for cross-talk / far-field sensing also decreases. To reduce oversensing after shock delivery, a longer fixed value is automatically applied for all cross-chamber blanking periods during the Post-Therapy Period (nominally 30 seconds). Once the Post-Therapy Period expires, all cross-chamber blanking parameters revert back to their permanently programmed values.

- If the cross-chamber blanking period is programmed to a fixed value of 85 ms or less, or to Smart Blanking, then an 85 ms blanking period will be used during the Post-Therapy Period.

If the cross-chamber blanking period is programmed to a fixed value longer than 85 ms, the longer value will be used during the Post-Therapy Period.

ICD	INCEPTA	CRT-D	INCEPTA
	ENERGEN		ENERGEN
	PUNCTUA		PUNCTUA
	TELIGEN		COGNIS

Noise Response

Noise Response allows the physician to choose how the device will respond when continuous *noise* is sensed. Noise response may be set to inhibit pacing or pace asynchronously when continuous noise is present. Noise Response will be activated when:

- Continuous noise is detected in the noise window portion of a blanking window, and the noise window is retriggered throughout the pacing interval.
- The dynamic noise algorithm is activated in response to a noisy signal.

Noise markers and a noisy signal would be seen on the EGM in either situation.

Noise-related Definitions

Noise Window the portion of blanking or refractory in which any event sensed is treated as a noisy signal. When an event is sensed in the noise portion of a blanking window:

- The event is not used for timing or detection.
- The event is marked with a marker in brackets (e.g., [AS]) and does not have an interval value (unless the noise window is due to an in-chamber refractory following a sensed event).
- If the noisy signal is continuous, the noise window will be re-triggered as long as the noisy signal is present (or until the pacing interval times out) to help suppress any further sensing of the noise.

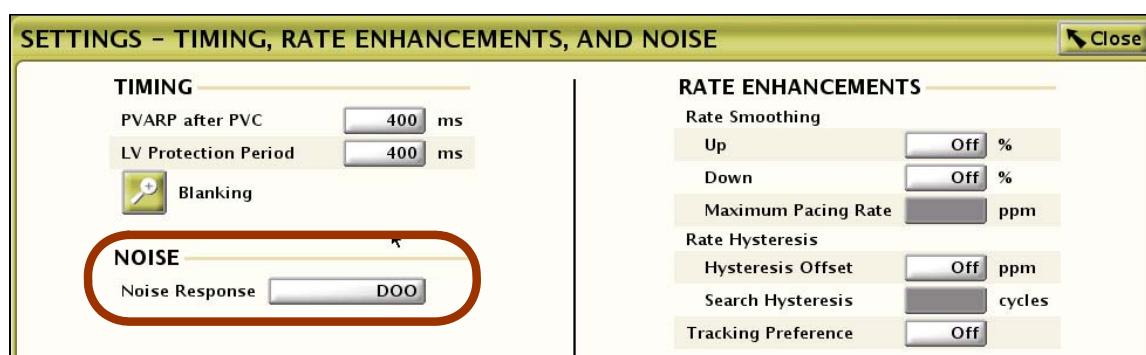
Noise Markers identify the presence of possible noise, far-field signals, or cross-talk, and aid in further troubleshooting for sources of the noise signal. Different markers are used to designate specific circumstances of noise:

- [AS], [VS], [RVS] or [LVS] designate a signal detected in the noise window portion of blanking.
- AN, VN, RVN or LVN occurs every 340 ms if the noise window is continuously re-triggered.
- AP-Ns, VP-Ns, RVP-Ns or LVP-Ns indicates asynchronous pacing due to continuous noise.

The **Dynamic Noise Algorithm** is a separate noise channel, continuously measuring the baseline signal present and adjusting the sensitivity floor to stay above any noise. When noise is present, the algorithm keeps the AGC floor above the noise, helping to prevent oversensing. (The VN marker may also be triggered).

Availability

- Not available if Brady Pacing mode = OFF.
- Noise Response will be applied to both Normal Brady and Post-Therapy Brady Pacing.
 1. From the Setting screen, select **BRADY/CRT**
 2. On the Settings – Normal Brady/CRT screen, select **Timing, Rate Enhancements, Noise**



Programmable Values

Nominal = DOO in dual-chamber devices, VOO or AOO in single-chamber devices.



Algorithm

- After a paced- or sensed-event, a noise window occurs as part of various refractory or blanking windows. A signal seen in this noise window would be marked in brackets [AS] (unless the noise window is due to an in-chamber refractory following a sensed event).
- Continuous noisy signal sensed will re-trigger this window. If the window is retriggered over 340 ms, AN, LVN, RVN, or VN markers are generated.
- If the noise window is retriggered to the point where the next paced event should occur (e.g., the LRL times out), the device will either pace asynchronously or inhibit pacing, based on how Noise Response is programmed.

AOO, VOO or DOO (Asynchronous Pacing) starts at the end of the programmable pacing escape interval and continues asynchronous pacing until noise ceases. AP-Ns, VP-Ns, RVP-Ns, and LVP-Ns markers indicate pacing as a result of continuous noise.

Inhibit Pacing occurs if continuous noise extends the Noise Window beyond the lower rate limit, pacing is inhibited for one full escape interval after noise resolves.

- Intended for patients whose arrhythmias may be triggered by asynchronous pacing.
- Use care when considering setting Noise Response to *Inhibit* in pacer-dependent patients, as pacing will not occur.
- CRT-Ds only:** If device is programmed to Inhibit Pacing in presence of noise in *Left Ventricle Only* temporary mode, and noise is not sensed in right ventricle, device will issue a right ventricular pace for brady pacing support.

Notes/Additional Information

The Noise Response window should not be considered a method of preventing oversensing during electrocautery. Consider using Electrocautery Protection to prevent oversensing in the presence of electrocautery.

Left Ventricular Protection Period (LVPP)

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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LVPP is a programmable period following an LV event when the device will not pace in the LV to prevent the device from inadvertently pacing during the LV vulnerable period which could initiate a ventricular tachyarrhythmia. If an LV event such as a premature ventricular contraction (PVC) occurs, the next scheduled LV pace could be delivered during repolarization of the PVC, inducing a VT. Unlike other refractory periods which are designed to inhibit the device's response to sensing, LVPP is designed to inhibit LV pacing during the heart's repolarization period.

Availability

- Available at all times.
- Navigation:

1. From the Settings screen, select  ⇒

2. Select  ⇒

3. Select  ⇒

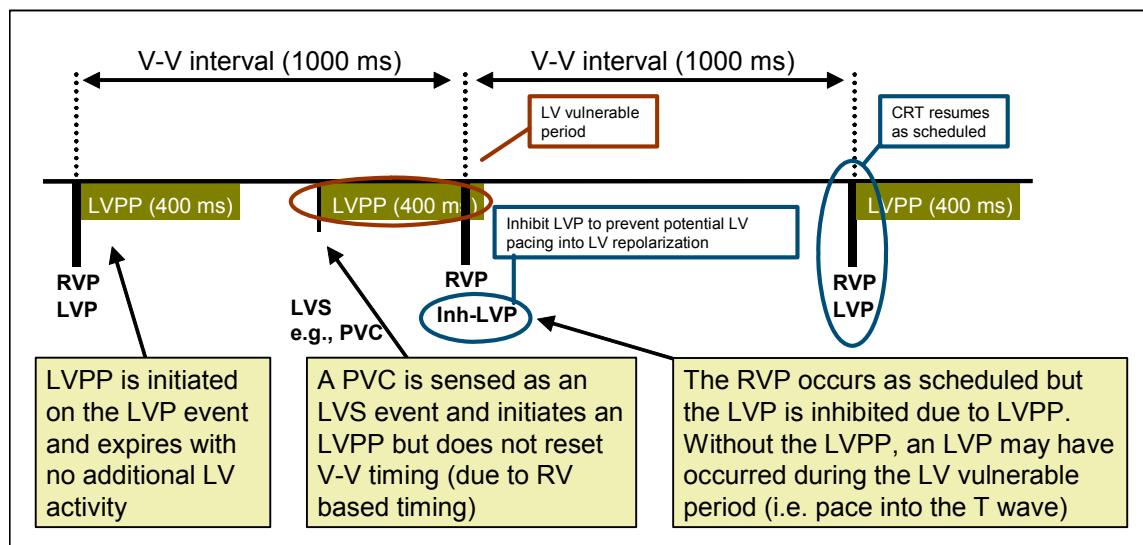
Programmable Values

PVARP (Post Ventricular Atrial Refractory Period)	300 ms-500 ms (50 ms increments)	Nominal: Dynamic 400 ms
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LVPP must be less than the MTR interval.

Algorithm

LVPP follows LV sensed- and paced-events. During LVPP, the device will not pace in the left ventricle. An LV pace inhibited by LVPP is designated as *Inh-LVP* on EGMs.



LVPP function:

- If LVPP inhibits LV pacing in LV-only mode, the device will deliver an RV safety pace for brady pacing support.
- An LVS event that occurs during LVPP will restart the LVPP interval.

CAUTION: Long LVPP

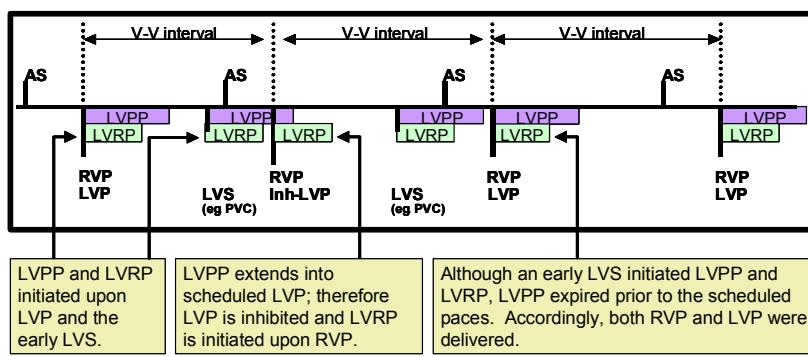
A long LVPP will reduce the maximum LV pacing rate and may inhibit CRT delivery at higher pacing rates.

NOTE: LVPP may inhibit LV pacing during threshold testing due to PVCs, an escape rhythm, or fast intrinsic rate. This may cause the clinician to inappropriately believe that the device is not working properly.

Examples of LVPP and LVRP (Left Ventricular Refractory Period) Operation

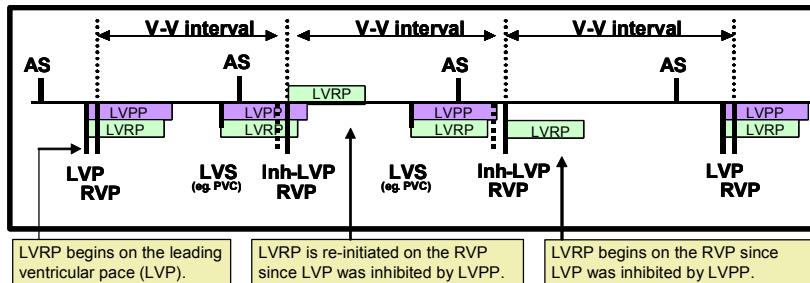
Example 1: LVRP and LVPP operation following LV sensed and LV paced events

LVPP and LVRP work together to maximize CRT while reducing the risk of accelerating the patient's rhythm to VT. The LVRP ensures that CRT delivery is not inhibited by inappropriate LV-sensed events while the LVPP ensures LV pacing does not occur during LV vulnerable periods.

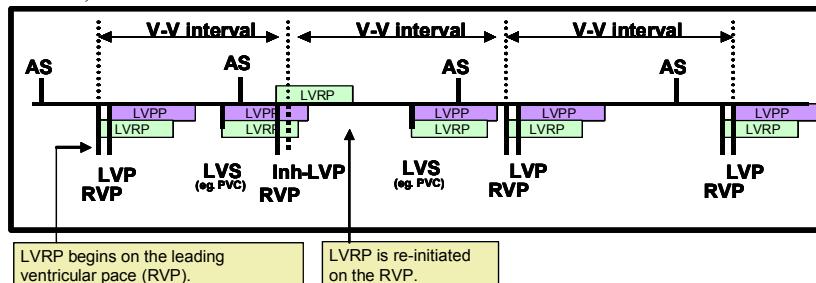


Example 2: LVRP and LVPP with an LV Offset of -100 ms (LVP precedes RVP by 100 ms)

LV Offset allows the clinician to adjust the delay between LV and RV pacing in order to coordinate the ventricular response to pacing. When LV Offset is programmed to a non-zero value, the LVRP is initiated on the leading ventricular event; either LV or RV.



Example 3: LVRP and LVPP with an LV Offset of +100 ms²⁴ (LVP follows RVP by 100 ms)

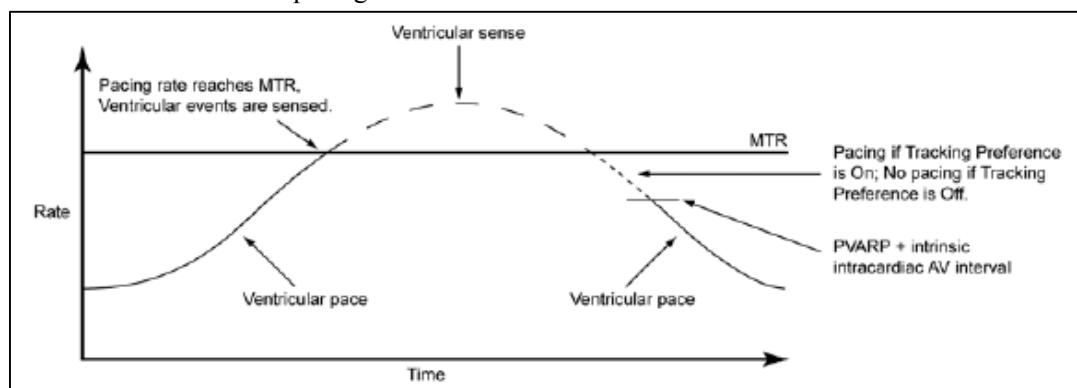


Tracking Preference

Tracking Preference promotes delivery of CRT by temporarily reducing PVARP in order to re-establish atrial-tracked ventricular pacing. Atrial tracking may be lost when any of the following results in an atrial sense within PVARP:

- PVCs
- PACs
- Atrial rates above MTR
- Rate Smoothing

Tracking Preference identifies atrial events below but near the MTR that should be tracked, but fall within PVARP. If two consecutive [AS]-VS cycles occur, PVARP is temporarily shortened to resume atrial-tracked ventricular pacing.



Atrial Tracking with and without Tracking Preference

²⁴ Positive LV Offsets are not available for CRT-D devices distributed in all geographies.

Availability

- Available in DDD(R) and VDD(R) modes.
- Navigation:

1. From the Settings screen select ⇒ **Settings Summary**
2. Select ⇒  **Normal Settings**
3. Select ⇒  **Timing,
Rate Enhancements,
Noise**

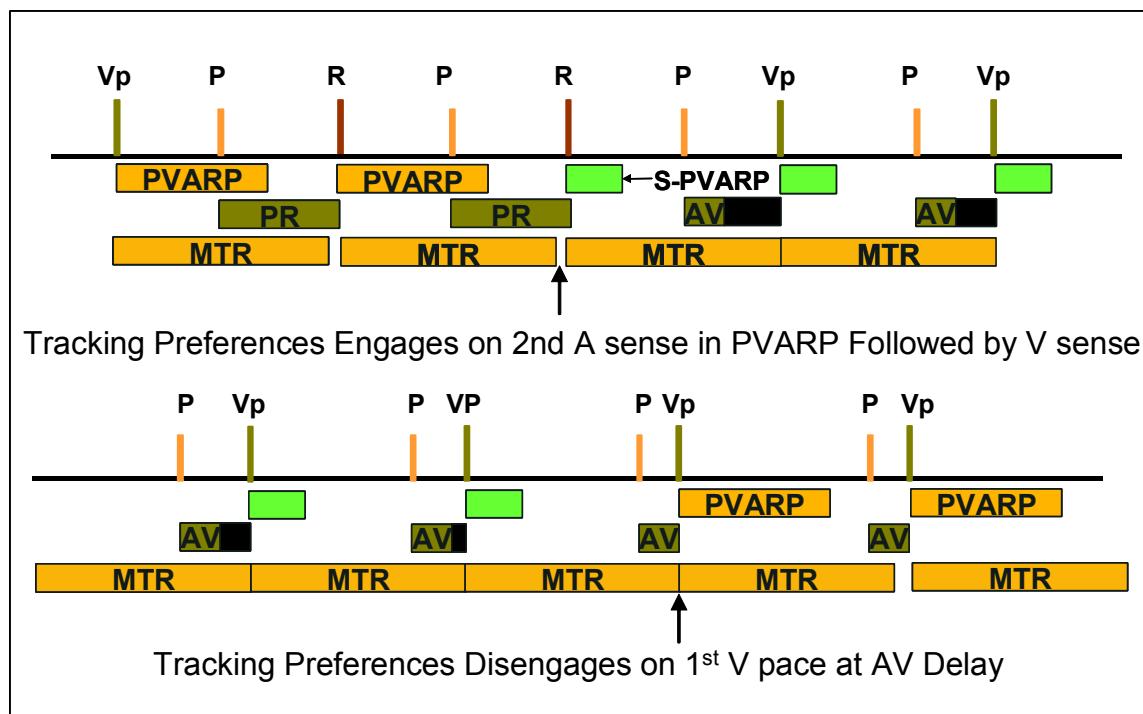
Programmable Values

Tracking Preference	ON/OFF	Nominal: ON
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Algorithm

If two successive cycles occur in which an RV-sensed event is preceded by an A-sensed event in PVARP, the device shortens PVARP until normal atrial-tracked ventricular pacing is reestablished:

- PVARP is shortened to the length of the A-Blank after RV-Sense cross-chamber blanking period (programmed fixed blank or SMART blanking value).
- The AV Delay is extended to prevent violation of the MTR.
- The shortened PVARP remains in affect until a ventricular pace occurs at the programmed AV Delay.



Shortening PVARP via Tracking Preference will not promote PMT if the atrial rate is greater than or equal to MTR because. Tracking Preference will not engage if the A-A interval is \leq MTR interval + 15 ms.

Example: MTR of 500 ms (120 bpm) + 15 ms = 515 ms (117 bpm). Tracking Preference will not engage if the atrial rate is > 117 bpm.

Tracking Preference will disengage if the A-A interval becomes \leq MTR interval + 15 ms.

Initial Ventricular Tachy Detection



ICDs and CRT-Ds described in this primer use these initial detection criteria:

Rate – is a fast rhythm present? *Fast* is designated by the programmable rate threshold for the tachy zones. As soon as the device senses three consecutive fast beats above a rate zone threshold, it begins storing information as well as monitoring a sliding window of 10 beats to see if the rhythm meets episode rate criteria. Up to three rate zones may be programmed, so that arrhythmia-specific therapy may be applied. Any rhythm falling into a particular rate zone is managed by the therapy programmed for that zone. For example, ATP may be used to pace-terminate slower monomorphic ventricular tachycardias (VT) in the VT-1 zone, but shocks may

be programmed for polymorphic VT in the VT zone, and ventricular fibrillation (VF) in the VF zone.

Duration – does the fast rhythm last long enough that it should be treated? Rhythms that fall into a rate zone must demonstrate that they are sustained and not transient. A Duration timer in each zone ensures that automatic therapy can only be initiated if an arrhythmia is sustained in that zone. In addition to expiration of the Duration timer in a tachy rate zone, the last ventricular interval must fall into that tachy rate zone in order for the Initial Detection criteria to be met. Assessment of the last interval allows the device to adjust if the rhythm begins to slow or to accelerate into a higher zone.

Rate and Duration are assessed in a sliding detection window. The detection window is the 10 most recently detected ventricular intervals. As a new interval occurs, the window slides to encompass it and the oldest interval is eliminated. This sliding detection window is used to make all ventricular tachycardia decisions. A detection window is established for each programmed tachy rate zone. Any interval classified as fast in an upper zone is also considered fast in the lower zone(s).

- If eight of the ten beats in the sliding detection window are fast, the device declares an episode, and the Duration timer for that zone begins.
- During Duration, the sliding detection window continues to be assessed. As long as six of the ten beats in the window remain fast, Duration will continue. If the rate slows so that less than six beats in the ten-beat window are fast, the Duration timer for that zone is reset and Initial Detection continues monitoring the sliding detection windows for eight fast beats.
- When the Duration timer expires in a zone, the last ventricular interval is compared to the rate threshold for that zone. This is done to assess whether the rhythm is changing, i.e., slowing or increasing in rate. If the last interval is not in that zone, or if Duration in a higher rate zone is elapsing or expired, then rhythm assessment will continue until one of the following occurs:
 - An interval matches the zone where the Duration timer expired.
 - Duration/Detection criteria in a higher zone are satisfied.
 - The rate slows so that < 6 of 10 beats are fast, causing the Duration to reset.
- At the end of the Duration time period, if the rate is still fast, and the last ventricular interval matches the zone where Duration expired, therapy may be initiated or detection enhancements applied.

Availability

Initial Detection is automatically in effect at all times except:

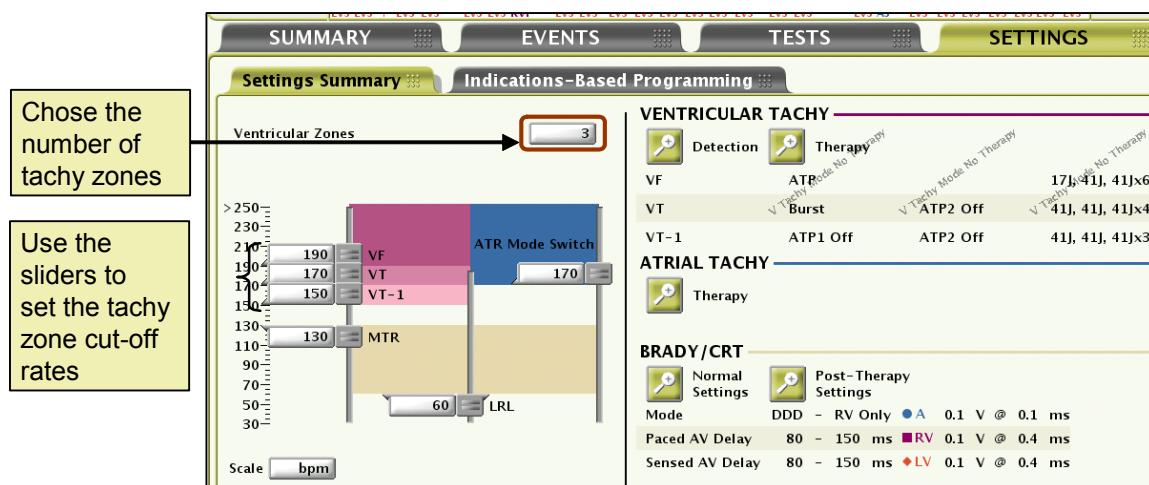
- When tachy mode is OFF
- During induction sequences
- During tachy therapy delivery
- During capacitor reform

- During diagnostic tests (pacing threshold test, intrinsic amplitude measurement, lead impedance measurement, Expert Ease, etc.)
- During temporary brady mode
- When Electrocautery Protection is enabled

Programmable Values

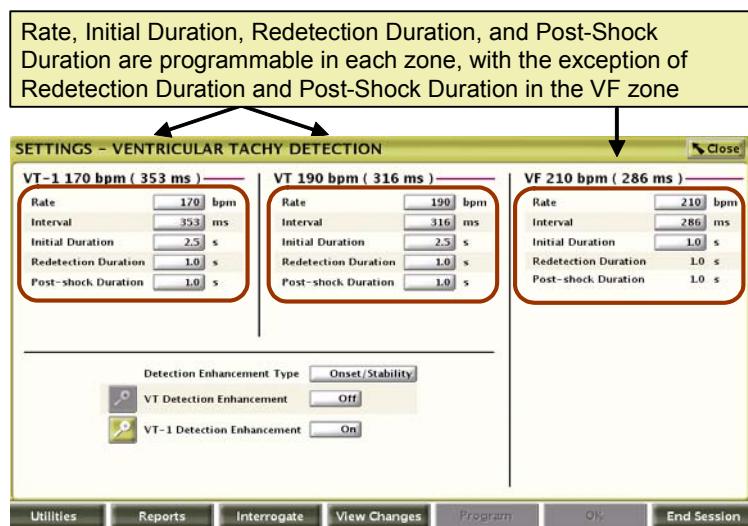
Use the Settings Summary screen to change the number of tachy zones, or to change the tachy rate zone cut-off rates. The *sliders* for the rate zones automatically maintain a minimum of 20 bpm between each zone, and prevent any overlap of tachy and brady zone rates.

The Summary screen displays all the related tachy and brady therapy zones as a picture that shows the relationships between the zones.



To navigate to detection parameters:

1. Select ⇒ **SETTINGS**
2. Select ⇒ **Settings Summary**
3. From the Settings Summary screen select ⇒ **Detection** (highlighted with a red box)



Rate cut-off for each zone: Rates may be programmed for up to three tachy zones.

Single Zone Configuration	<ul style="list-style-type: none"> • VF: 90-220 bpm, 90-220 bpm, 90-220 bpm
Two Zone Configuration	<ul style="list-style-type: none"> • VT: 90-220 bpm, 90-220 bpm • VF: 110-250 bpm
Three Zone Configuration	<ul style="list-style-type: none"> • VT-1: 90-200 bpm • VT: 110-220 bpm • VF: 130-250 bpm

The following limits are required between tachy zones, and between tachy and brady parameters. The *sliders* on the Summary screen automatically maintain these limits.

- All tachy zones must be separated by at least 20 bpm.
- For dual-chamber tracking pacing modes and/or adaptive rate pacing modes, lowest tachy rate cut-off must be 5 bpm higher than MAX tracking rate (MTR) or MAX sensor rate (MSR).
- For dual-chamber non-tracking modes, or single-chamber modes, lowest tachy rate cut-off must be 10 bpm higher than programmed pacing rate.

Duration

Duration may be programmed separately for each tachy zone, and may be separately programmed for Initial Detection, Redetection (for post-ATP, or post-divert detection) or Post Shock Redetection.

Initial Duration Parameters

Zone	Zone values	Increments	Nominal
VF	1-5 seconds 5-15 seconds	0.5 second 1.0 second	1.0 second
VT	1-5 seconds 5-15 seconds 20-30 seconds	0.5 second 1.0 second 5.0 second	2.5 seconds
VT-1	1-5 seconds 5-15 seconds 20-60 seconds	0.5 second 1.0 second 5.0 second	2.5 seconds

Algorithm

- If three consecutive fast ventricular beats are sensed, the device will begin recording event information and begin monitoring a sliding window of 10 beats.
- If eight beats in the 10-beat window are sensed above the rate cut-off of any zone (i.e., 8 of the 10 beats are fast), an episode is declared.

NOTE: Any interval classified as fast in an upper zone is also considered fast in the lower zone(s).

- Device performs Ventricular Tachy Response mode-switch by changing from DDD(R) to VDI(R) in dual-chamber devices, or from VVIR to VVI in single-chamber devices.
- Duration timer starts. During Duration, 6/10 beats must remain fast for Duration to continue elapsing.
- When the Duration timer expires in a zone, the last interval must match that zone to proceed to therapy—if not, detection continues until the last beat matches the detection zone, a higher zone is satisfied, or the rhythm drops out of detection.
- At the end of Duration, detection enhancements will be applied if any are programmed ON. If detection enhancements are not ON, then the device will proceed to therapy.

See the Detection Enhancements Overview topic.

- Initial Detection restarts after any of the following:
 - Rate drops out of detection (i.e., < 6/10 beats are fast) during Duration.
 - Rate drops out of detection (i.e., < 6/10 beats are fast) during Sustained Rate Duration (SRD).
- Initial Durations continue to be in effect until Detection criteria are satisfied.

- Redetection begins after any of the following:
 - Delivery of shock therapy
 - Diverted shock therapy
 - Delivery of an ATP burst
 - Diverted ATP burst
- Redetection follows the same steps as Initial Detection.
- Redetection/Post-Shock Durations are separately programmable values.

Interpreting Clinical Applications

When rhythm is shifting from zone-to-zone (for example from VT to VT-1 zone), the higher detection window must drop out (less than 6 /10 fast intervals) in order for lower zone to take over therapy decisions.

Notes/Additional Information

- Similar to older devices ,and for the devices described in this primer, Rate and Duration are the only criteria applied during redetection following ATP or a diverted shock—detection enhancements are available during initial detection and post-shock redetection (if programmed ON).
- If the device is programmed to AAI mode when an episode is declared, there will be no ventricular pacing during the VTR mode switch.

Ventricular Tachy Response



During a ventricular tachy episode, dual-chamber timing is not desirable since cross-chamber ventricular blanking periods (V-blank after A-Pace) could compromise the ventricular sensing window. To prevent this, the device performs an automatic mode switch when the tachy detection window is satisfied (i.e., 8/10 fast beats are sensed). Switching to single-chamber pacing after tachy detection eliminates the ventricular cross-chamber blanking, optimizing sensing windows when a fast ventricular rhythm is sensed.

- In a DR (dual chamber pacing) device, the Ventricular Tachy Response (VTR) switches the device from DDD(R) pacing mode to VDI. When the device is in VTR operation, atrial cross-chamber blanking will still occur when a V-sense or V-Pace event occurs.
- In a VR (single-chamber pacing) device, the VTR mode switch still occurs when a tachy detection is met. VTR mode switch in a single-chamber device switches from VVI(R) mode to VVI. The mode switch in a VR device is designed to improve sensing windows by maintaining a constant pacing rate with a constant refractory period.
- The rate at which VTR pacing occurs is the ATR/VTR Fallback LRL, which is separately programmable from the Normal Brady or Post-Therapy Brady parameters.

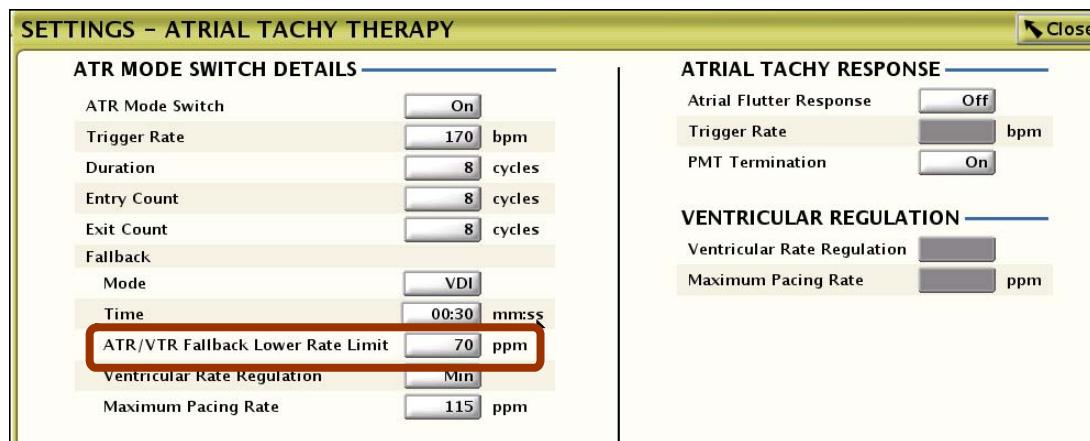
Availability

- Applied when ventricular tachy detection (i.e., 8/10 fast beats seen in a tachy detection zone)
- Not applicable if Tachy mode = OFF

Navigation



From the Settings Summary screen, choose ⇒



Programmable Values

ATR/VT Fallback LRL:

Nominal = 70 bpm.

A change to this parameter affects pacing rate for both ATR and VTR mode switch.

ATR/VTR Fallback Lower Rate Limit					
30	60	90	120	150	180
35	65	95	125	155	185
40	70	100	130	160	
45	75	105	135	165	
50	80	110	140	170	
55	85	115	145	175	

Algorithm

- When 8/10 fast beats are detected in any ventricular tachy zone, the device switches to VDI (DR models) or VVI (SR models) pacing mode, at the programmed ATR/VTR Fallback LRL.
- VDI or VVI pacing will be in effect during Duration and during charging. During Duration and charging, rhythm must maintain 6/10 fast beats for detection to remain satisfied. If detection is no longer satisfied, VTR mode switch ends and the device returns to Normal Brady pacing.

Example: Beat count during duration: 6/10, 6/10, 5/10 – fifth beat is DDD paced if necessary.

- If detection remains satisfied, the device will stay in VDI or VVI mode until therapy is delivered or diverted:
 - If shock is delivered, VTR modes switch ends and Post-Therapy Brady pacing starts.
 - If shock is diverted, VTR mode switch ends and Normal Brady pacing starts.
 - If ATP is delivered, VTR mode switch ends and Normal Brady pacing starts.
- Device will remain in Normal Brady pacing mode any time detection/redetection has not been met.

Notes/Additional Information

- CRT-Ds only: VTR pacing will be BiV. Neither BiV Trigger nor LV Offset is applied during VTR.
- If permanent AAI(R)/AOO mode programmed:
 - VTR, in essence, turns atrial output OFF – if Normal Brady mode is AAI/AOO, device turns brady OFF during VTR.
 - If programmed AAI(R) and tachycardia episode is declared, but the fast rhythm slows during Duration (already switched to VTR), device will allow six seconds of asystole, and will begin pacing again AAI(R) at programmed rate.



Detection Enhancement Introduction

Detection enhancements provide further classification of a rhythm once an episode has been declared (i.e., 8 /10 are fast) and Duration has expired (i.e., 6 /10 remained fast throughout Duration) with the last interval detected in the zone of detection. Detection enhancements are applied to the VT-1 and/or VT zones; detection enhancements are not used in the VF zone.

Detection enhancements are used to determine whether the fast rhythm is:

- VT: Ventricular Tachycardia (abnormally conducted fast rhythms originating in the ventricle). The device is intended to treat VT.
- SVT: Supra-Ventricular Tachycardia (rhythms originating above the ventricle, such as sinus tachycardia, atrial flutter or atrial fibrillation). The device can inhibit therapy for SVTs.

At the end of Duration, the device will decide whether to inhibit or deliver therapy. If the device decides to inhibit due to detection enhancements, the inhibit decision will be reevaluated on each ventricular event while the rhythm remains fast. If Sustained Rate Duration (SRD) is programmed ON, inhibition will be limited by the programmed SRD time.

If detection enhancements are not turned ON, Rate and Duration are the only criteria used for tachy therapy decisions.

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Detection Enhancements available	<ul style="list-style-type: none">• PRIZM, VITALITY DS, VITALITY AVT, RENEWAL CRT-Ds:• Atrial Tachy and Sinus• Tachy Discriminators:• Stability, Onset• V> A• A-fib Rate Threshold (AFRT)• Sustained Rate Duration (SRD) and Shock if Unstable• VITALITY 2:• Rhythm ID® which includes• V>A• vector timing correlation,• stability/AFRT	<ul style="list-style-type: none">• Either Onset/Stability or Rhythm ID are available• Onset/Stability is used as Atrial Tachy and Sinus Tachy Discriminators and includes:<ul style="list-style-type: none">• Onset, Stability, V>A, AFRT, SRD and Shock if Unstable• Rhythm ID includes:<ul style="list-style-type: none">• V>A, vector timing correlation, stability/AFRT, and SRD• Shock if Unstable not available

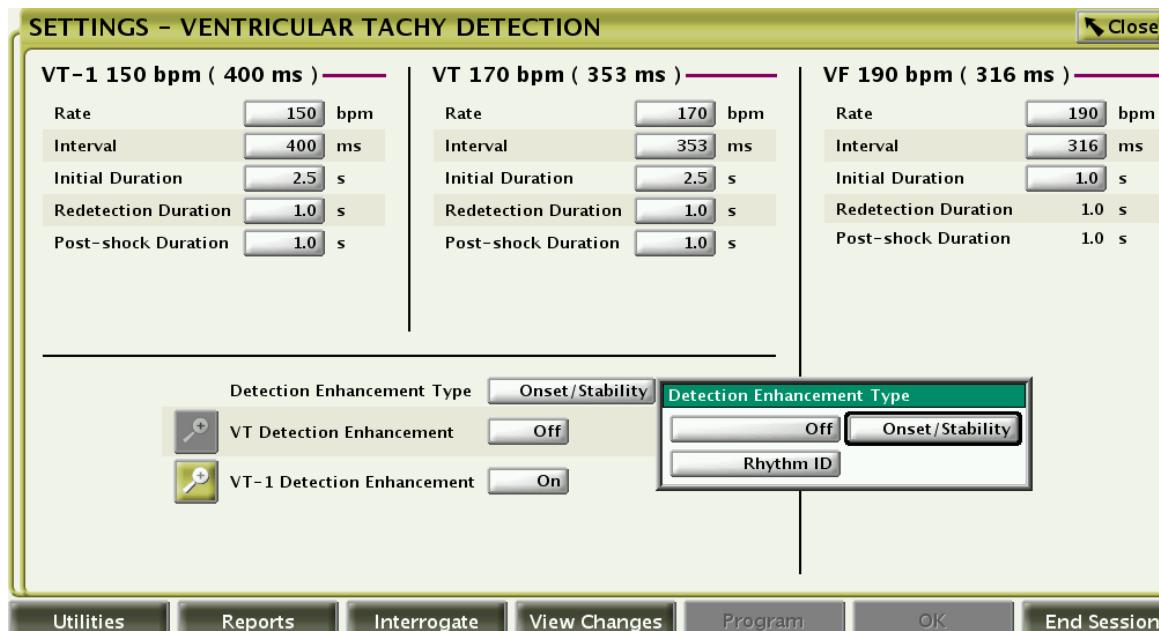
Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
	<ul style="list-style-type: none"> SRD Shock if Unstable not available 	
Number of zones where detection enhancements are available	<ul style="list-style-type: none"> PRIZM, VITALITY DS, VITALITY AVT, RENEWAL CRT-Ds: Atrial Tachy and Sinus Tachy Discriminators only available in the lowest zone of a multiple zone setup. Polymorphic VT discriminator (Shock if Unstable) available in VT zone only. No detection enhancements are available in the VF zone. VITALITY 2: Rhythm ID available in VT-1 and VT zones Not available in the VF zone. 	<ul style="list-style-type: none"> Atrial Tachy and Sinus Tachy Discriminators available in lowest zone of a multiple zone setup. Polymorphic VT discriminator available in VT zone only. No detection enhancements available in the VF zone. Rhythm ID available in VT-1 and VT zones. Not available in the VF zone.
Rhythm ID programmability	<ul style="list-style-type: none"> Rhythm ID is either On or Off, with fixed non-programmable settings. SRD may be programmed. 	<ul style="list-style-type: none"> Rhythm ID is ON or OFF, INCEPTA models include RhythmMatch Stability and AFRT values may be programmed. SRD may be programmed.
Post-shock redetection	Stability, V>A, AFRT and SRD are available during Post-shock redetection.	Stability, V>A, AFRT and SRD are available during Post-shock redetection.

Availability

Available in VT-1 and VT zones of a multi-zone configuration; not available in a one-zone configuration. Separately programmable as a post-shock parameter in both the VT-1 and VT zones.

From the Setting Summary screen, choose \Rightarrow
to select/view detection enhancements.





Two detection enhancement *packages* are available in ICDs and CRT-Ds described in this primer; either may be used to help distinguish fast ventricular rhythms that should be treated from rhythms that the device should not treat. Both are summarized here.

See individual topics for additional details.

Onset/Stability uses the familiar *one-button-detection enhancements (OBDE)*, specifically:

- Onset evaluates whether the fast ventricular rhythm began suddenly or gradually. Onset is used to distinguish VT (sudden) from sinus tachy (gradual).
- Stability evaluates the regularity or stability of the ventricular rhythm. Stability is used to distinguish fast ventricular response to a-fib (unstable) from VT (stable).
- A-Fib Rate Threshold, which further defines the stability decision by monitoring the atrial rate. Rates faster or equal to the A-Fib Rate Threshold are considered A-fib.
- V>A continually compares the average atrial rate to the average ventricular rate. If the Ventricular rate becomes faster than the atrial rate by 10 bpm, or more the device will override any inhibit decision and proceed to therapy.
- Shock If Unstable (VT zone) skips ATP therapy if a polymorphic VT is detected and goes directly to the first programmed shock.

Rhythm ID combines several familiar detection enhancements with a morphology discriminator, Vector Timing and Correlation, as its decision-making process:

- V>A continually compares the average atrial rate to the average ventricular rate. If the Ventricular rate becomes faster than the atrial rate by 10 bpm or more the device will override any inhibit decision and proceed to therapy.
- Vector Timing and Correlation compares the timing and morphology of the shock EGM waveform to a previously stored normal sinus rhythm template for the patient.

- Stability evaluates the regularity or stability of the ventricular rhythm. Stability is used to distinguish fast ventricular response to A-fib (unstable) from VT (stable).
- A-Fib Rate Threshold further defines the stability decision by monitoring the atrial rate. Rates equal to or faster than the A-Fib Rate Threshold are considered A-fib.

Sustained Rate Duration –the device makes its decision to inhibit or treat at the end of Duration. If the decision is made to inhibit therapy, the Sustained Rate Duration (SRD) timer is started (if SRD is programmed ON) and the device continues to evaluate the rhythm beat-by-beat throughout Sustained Rate Duration. The device will inhibit delivery of ventricular therapy until one of the following occurs:

- SRD timer expires.
- Ventricular rate increases to a higher zone and meets criteria for treatment in that zone.
- Detection enhancements determine that the rhythm meets treatment criteria. (For example, the ventricular rate becomes 10 bpm faster than the atrial rate, or vector timing and correlation determines the rhythm is no longer correlated).
- If the rate decreases below the lowest tachy rate zone cutoff, the SRD timer is cleared and will again be started if the rate increases, Duration expires, and inhibitors are active.

Detection Enhancement Onset/Stability



Onset/Stability uses the familiar one-button-detection enhancements (OBDE), to distinguish treatable ventricular arrhythmias (VT) from rhythms that should not be treated (sinus tachycardia and fast ventricular response to atrial fibrillation). Onset/Stability uses several parameters to make this distinction, specifically:

Atrial Tachy Discrimination which uses:

- Stability evaluates the regularity or stability of the ventricular rhythm.
- A-Fib Rate Threshold further defines the stability decision by monitoring the atrial rate.

Sinus Tachy Discrimination which uses:

- Onset evaluates whether the fast ventricular rhythm began suddenly or gradually.

Polymorphic VT Discrimination which uses:

- Stability (Shock if Unstable) overrides ATP therapy delivery and proceeds to shock therapy in the presence of a fast, unstable ventricular rhythm.

All discriminators are considered when the device is deciding whether to inhibit.

See Onset/Stability Detection Enhancement Combinations for details.

Once a decision is made to inhibit therapy, Onset/Stability uses:

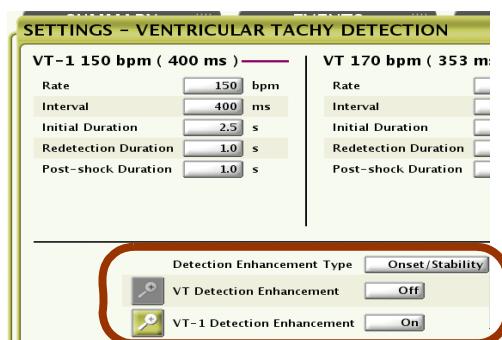
- V>A to continually compare the average atrial rate to the average ventricular rate. If the Ventricular rate becomes faster than the atrial rate by > 10 bpm, the device will override any inhibit decision and proceed to therapy.
- Sustained Rate Duration (SRD) as the time period during which inhibition will continue. SRD is described in a separate section.

Availability

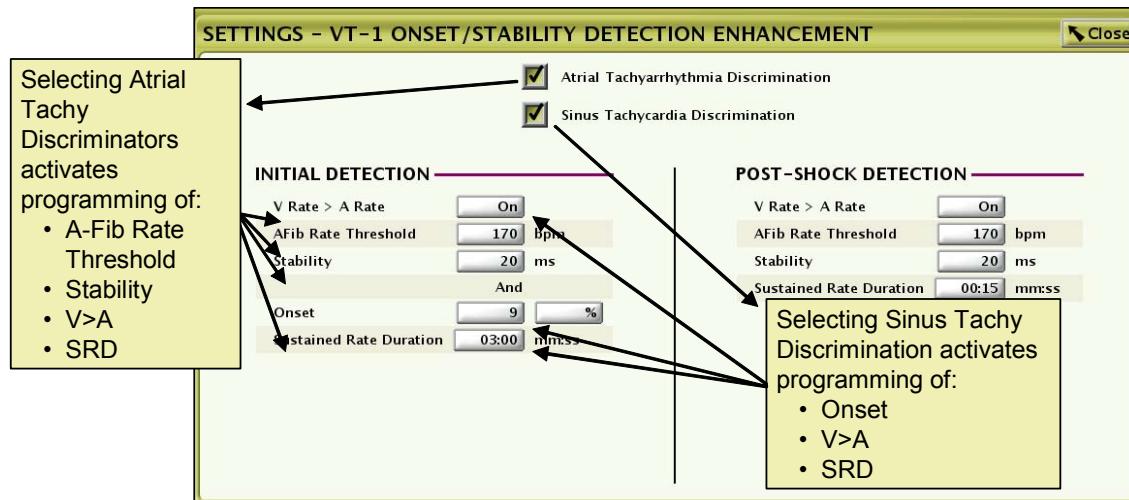
- Atrial Tachy and Sinus Tachy Discriminators available in the lowest zone of a multi-zone configuration.
- Polymorphic VT Discriminator is available in the VT zone only.
- In a two-zone setup, if Atrial Tachy or Sinus Tachy Discriminators are selected, Polymorphic VT Discriminator is not available. Likewise, in a two-zone setup, if Polymorphic VT Discriminator is chosen, neither Atrial Tachy nor Sinus Tachy discriminators are available.
- No discriminators available in a one-zone configuration (not available in VF zone).
- Separately programmable post-shock parameters are available.
- Onset/Stability is not available if Rhythm ID has been selected (i.e., the detection enhancement type chosen applies to both VT-1 and VT zones).
- Navigation to Onset/Stability parameters:

From the Setting Summary screen,
select ⇒ **VENTRICULAR TACHY** _____
to  
select/view detection enhancements.

If detection enhancements are ON in a zone, the magnifying glass button for that zone will be selectable.



Select the  button to view the detection enhancement parameters



Atrial Tachyarrhythmia Discrimination

Stability

Stability (formerly called Stability Inhibit) assesses the regularity of the ventricular rhythm. Since ventricular tachycardias, specifically monomorphic VT, tend to be very regular or stable, Stability can be used to distinguish between VT and fast ventricular response to A-fib, which tends to be irregular or unstable. Stability is measured in ms; the smaller the measured stability value the more stable the ventricular rhythm.

Stability Availability

- Available in the lowest zone of a multiple zone configuration.
- Not available in the VF zone.
- Available when Atrial Tachy Discrimination is selected.
- In a two-zone device, not available if Polymorphic VT Discriminator (Shock if Unstable) is selected.
- May be programmed independently of AFRT.
- May be programmed with separate post-shock values.
- Automatically calculated, even if programmed OFF, and stability value is reported for the event.

Stability Programmable Values

Nominal = 20 ms in dual chamber device,
30 ms in single chamber.

Initial Stability Threshold				
Off	16	28	50	100
6	18	30	55	110
8	20	32	60	120
10	22	35	70	
12	24	40	80	
14	26	45	90	

Stability is programmable as the following parameters:

- Initial Stability
- Post-Shock Stability
- Shock if Unstable (Polymorphic VT discriminator in the VT zone only – see description in this section for how that discriminator is used)

Stability Algorithm

Stability calculations start when 8/10 fast beats are seen and episode is declared, and continue as each new beat is sensed throughout Duration (and SRD).

1. Uses the last five consecutive intervals (four variances) before 8/10 is met to calculate the average variance.
2. Adjusts this average variance as new intervals are added during Duration. This average variance is weighted as follows:
 - 87.5% (weighted average variance) + 12.5% (next delta) = new weighted average variance
3. At the end of Duration, the average is compared to the Stability threshold:
 - If measured average > Stability threshold => Rhythm is classified as UNSTABLE
 - If measured average ≤ Stability threshold => Rhythm is classified as STABLE

A-Fib Fate Threshold

A-Fib Rate Threshold (AFRT) is used in combination with Stability to withhold therapy in the event that a moderately high, unstable ventricular rate is due to ventricular response to atrial fibrillation.

AFRT Availability for Onset/Stability

- Available in dual-chamber devices only.
- Available in the lowest zone of a multiple zone configuration.
- Not available in the VF zone.
- Available when Atrial Tachy Discrimination is selected.
- In a two-zone device, AFRT is not available if Polymorphic VT Discriminator is selected.
- Stability must be ON to use AFRT; AFRT is not available independent of Stability.
- AFRT may be programmed with separate post-shock values.

AFRT Programmable Values

- Nominal = 170.

The value programmed for AFRT is used by the device for all of the following:

- A-Fib Rate Threshold for atrial tachy detection discrimination (either Rhythm ID or Onset/Stability).
- ATR trigger rate for Atrial Tachy Response (mode-switch).
- Atrial Flutter Response rate.

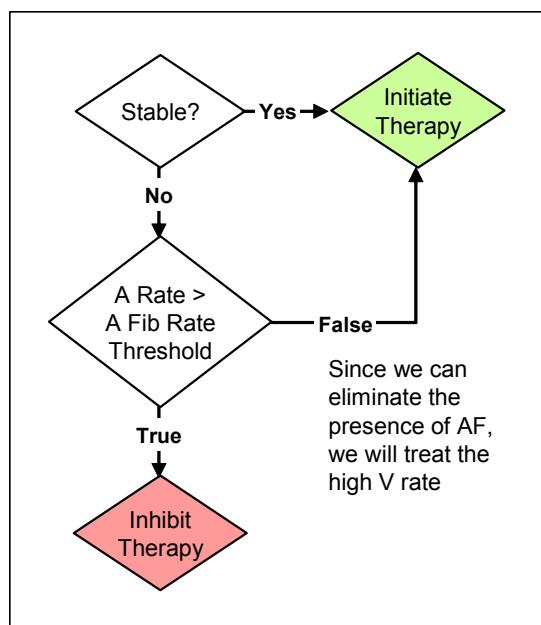
NOTE: Changing the value for any one of these parameters changes it for all three.

AFRT Algorithm:

1. When tachy detection is initiated (3rd fast ventricular interval), each atrial interval is classified as < or > AFib Rate Threshold.
2. If 6 /10 atrial intervals are faster than AFib Rate Threshold when 8/10 is satisfied, rhythm is declared to be A-fib. Atrial rate is continually measured throughout Duration and as long as 4/10 intervals are fast, AF will be declared TRUE at the end of Duration. If <6/10 atrial intervals were never faster than the AFRT, or 4/10 did not remain fast at the end of Duration, AFRT will be reported as FALSE.
3. At the end of Duration, whether AFRT is used with stability to make the decision to inhibit or deliver therapy.

If therapy is not delivered, atrial rate is continued to be measured throughout SRD, and as long as 4 /10 intervals are fast, AF continues to be declared.

This following flowchart shows how AFRT is used with Stability to make inhibit decisions.



The stability of the ventricular rhythm is assessed; if the rhythm is stable, therapy is initiated.

If the rhythm is unstable, the device further evaluates the atrial rate:

- If the rate is faster than the AFRT, the device inhibits therapy for atrial fibrillation.
- If the atrial rate is slower than the AFRT, the device initiates therapy for VT.

If therapy is inhibited at the end of Duration, it will continue to be withheld until:

- Atrial rate drops below AFib Rate Threshold (less than 4 /10)
- Ventricular rhythm becomes stable
- V Rate becomes greater than A Rate
- SRD timer expires (if programmed)

AFRT Notes/Additional Information

Four consecutive ventricular beats with no atrial beats sensed resets AFRT calculation – 6/10 must be met again to declare AFRT TRUE.

Sinus Tachy Discrimination

Onset

- Onset assesses how rapidly a ventricular arrhythmia began. Since ventricular tachycardias, specifically monomorphic VT, tend to occur suddenly, Onset can be used to distinguish between VT and sinus tachycardia, which tends to occur gradually.
- Onset is measured in either percentage or in ms; the smaller the onset value the more gradual the ventricular rhythm.
- Onset is calculated once in an episode, as soon as 8/10 fast beats are seen.

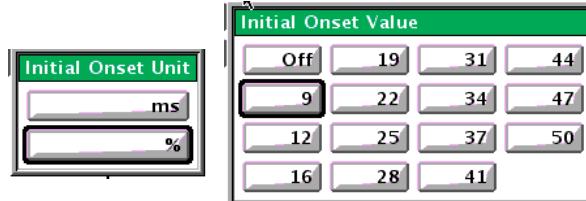
Onset Availability

- Available in the lowest zone of a multiple zone configuration.
- Not available in the VF zone.
- Available when Sinus Tachy Discrimination is selected.
- In a two-zone device, Onset is not available if Polymorphic VT Discriminator is selected in the VT zone.
- Onset is automatically calculated, even if programmed OFF, and onset value is reported for the event.

Onset Programmable Values

Nominal = 9%.

May choose Onset units of measure as either percentage (Nominal) or in ms.



Onset Algorithm

Step 1: Find Pivot Interval and Pivot Delta.

Calculation begins with interval that initially starts detection process and ends when detection satisfied (8/10).

- Device scans the available stored onset intervals to find the pivot interval (uses 16 to 32 V intervals, ignores the first six intervals and the last three intervals stored to ensure there are enough intervals for subsequent steps).
- The pivot interval is the largest decrease in cycle length found between two adjacent intervals.
- The pivot delta is the difference between the two adjacent intervals.

NOTE: If there are multiple occurrences of the largest decrease, the device uses the first occurrence.

Step 2: Determine Baseline Average and compare to intervals following pivot interval.

- Device averages 4/6 intervals prior to pivot interval to determine baseline average (first two intervals before pivot interval are skipped).
- Device calculates difference between baseline average and each of next four intervals (starting with pivot interval).
- Device identifies second smallest difference and uses for comparison in final step.

If Onset is programmed to a percentage value rather than a millisecond value, the millisecond value must first be converted to a percentage in order to perform the comparison in the unit (%) as programmed. This is done by dividing the millisecond value from either Stage 1 or 2 by the baseline average.

Final Step:

The smaller of the two values obtained from Stage 1 (Pivot Delta) and Stage 2 (second smallest difference) is compared to the programmed Onset value.

- If \geq programmed Onset value, rhythm is sudden and therapy will be delivered.
- If $<$ programmed Onset value, rhythm is gradual onset and therapy will be inhibited.

Onset Notes/Additional Information

- Decision to deliver or inhibit therapy depends on what enhancements, if any, are programmed ON.
- If arrhythmia was not induced and Onset calculations for either percentage or milliseconds are greater than zero, Onset will be calculated and displayed in therapy history. If Onset is programmed ON, and detection is in lowest zone, it will be applied.
- If arrhythmia occurs within 30 sec of an induction feature, Onset will not be applied and therapy history displays N/A.
- If arrhythmia was not induced and Onset calculations in both percentage and milliseconds are exactly zero, or a negative number, Onset will be applied (gradually) if programmed ON, but

therapy history will display N/A. It is also possible to see a number for the millisecond value and a N/A or 0 for the percentage.

V>A (Inhibitor Override)

V>A is used with therapy discriminators to override therapy inhibit decisions if the ventricular rate exceeds the atrial rate by 10bpm. V>A is first calculated at the end of Duration, and if an inhibit decision is made, recalculated as each new beat is sensed during SRD.

V>A Availability

- Available in dual-chamber devices only.
- Available only if Atrial Tachycardia Discriminator or Sinus Tachycardia Discriminator is selected.
- Available in the lowest zone of a multiple zone configuration when used with Onset/Stability.
- Not available in the VF zone.
- V>A is automatically calculated, even if programmed OFF, and value is reported for the event.

V>A Programmable Values

Nominal = ON if any detection enhancements are enabled.



Available as the following parameters:

- Initial V>A
- Post-Shock V>A

V>A Algorithm

At the end of Duration:

1. Average of last 10 V-V intervals is compared to average of last 10 A-A intervals.

NOTE: If there are fewer than 10 atrial intervals available, the available intervals will be used to average atrial rate.

2. Averages are converted to rates in bpm.

- If average V rate is faster than the average A-rate by 10 bpm or more, then V>A considered TRUE and therapy will be initiated.
- If V>A is FALSE, SRD timer starts and further evaluation of rhythm continues.

V Rate > A Rate analysis uses a continuous sliding window. Therefore, therapy will be delivered any time therapy is inhibited and V Rate becomes greater than A Rate by at least 10 bpm.

V>A Notes/Additional Information

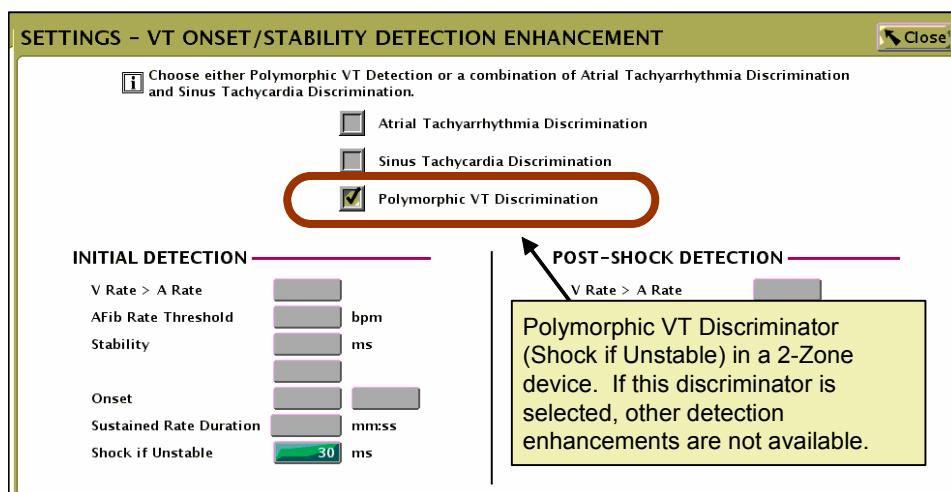
If arrhythmia is detected in lower zone and therapy is inhibited with V>A = FALSE, then V>A subsequently becomes TRUE during SRD, therapy is initiated and device reports final calculated status V>A = TRUE.

Polymorphic VT Discriminator: Shock If Unstable

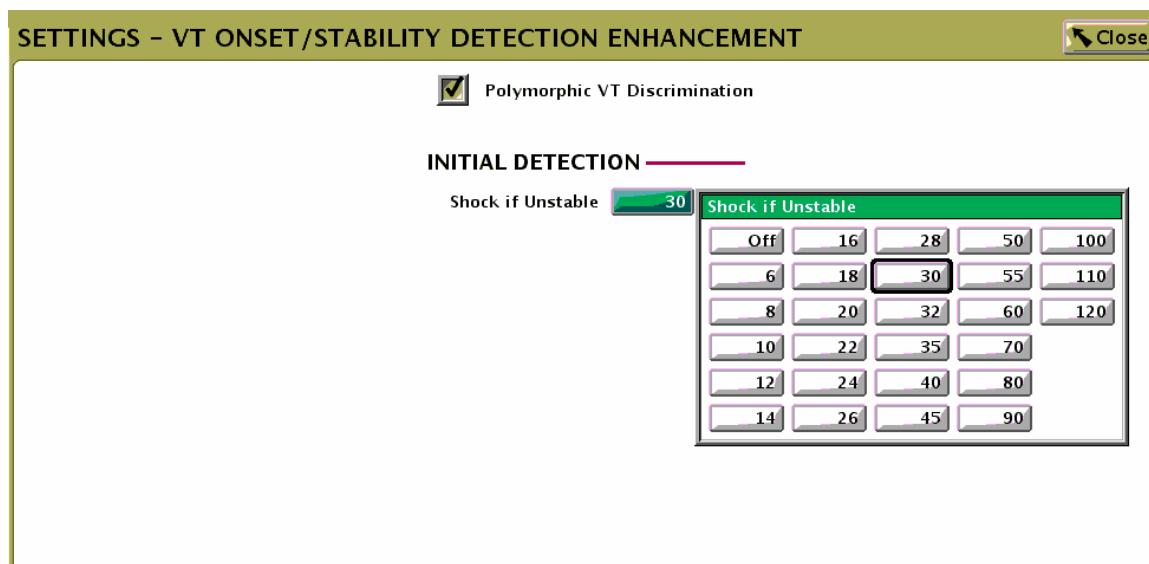
Polymorphic VT Discriminator distinguishes monomorphic VTs (MVTs) from polymorphic VTs (PVTs) and VF, within the VT zone. PVTs and VFs are typically unstable, not pace terminable. Using this discriminator, if a fast rhythm is measured as unstable, device will skip over initial or any remaining ATP therapy and proceed directly to programmed shocks. Shock if Unstable is applied during initial detection and redetection between bursts of ATP to monitor for acceleration of rhythm from MVT to PVT.

Shock If Unstable Availability

- Two-Zone Device: Must select either Atrial Tachycardia Discriminator or Polymorphic VT Discriminator in the VT zone.



- 3-Zone Device: Polymorphic VT Discriminator is available only in VT zone.





Shock IF UNSTABLE Programmable Values

Nominal = 30 ms.

Shock If Unstable Algorithm

- Uses same algorithm as Stability. Once the ventricular stability is calculated:
 - If measured Stability \leq programmed Stability then the Rhythm is classified as STABLE and ATP continues.
 - If measured Stability $>$ programmed Stability then the Rhythm is classified as UNSTABLE and ATP is discontinued and the device proceeds to Shock Therapy.

Detection Enhancement Rhythm ID



Rhythm ID uses Vector Timing Correlation analysis in addition to atrial and ventricular interval analysis (Stability, A-Fib Rate Threshold, V>A, and Sustained Rate Duration (SRD) to determine if a patient's rhythm should be treated (VT) or if therapy should be inhibited (SVT).

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

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

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

A single-chamber (VR) device uses Vector Timing Correlation, Sustained Rate Duration, and Stability, since it does not have an atrial lead and therefore no atrial information is available.

A dual-chamber (DR) device may be programmed to use or not use atrial information as part of its calculations through the Atrial Tachyarrhythmia Discrimination parameter. Setting this parameter to OFF allows Rhythm ID to use only Vector Timing Correlation and Stability, just like a single-chamber device.

NOTE: When atrial information is not used, stability (for Post-Shock only) should be evaluated and adjusted, if necessary.

NOTE: Vector Timing Correlation compares the timing and morphology of a shock EGM waveform to a previously stored normal sinus rhythm template for the patient.

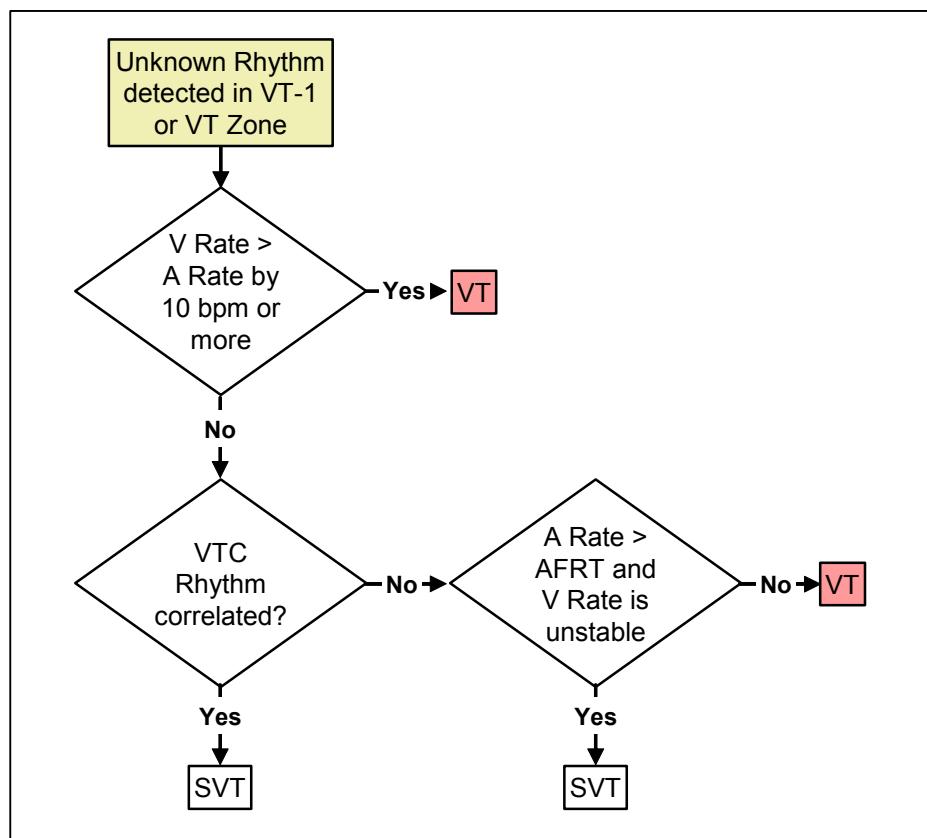
- Vector Timing Correlation is described in detail in its own section.
- Vector Timing Correlation also uses a stored, normal sinus rhythm template as a basis for its morphology comparison.
- Setup/Update of the Rhythm ID template is described in the Rhythm ID Update section.
- SRD is the inhibition timer used by both Onset/Stability and Rhythm ID detection enhancements.
- SRD is described in detail in its own section

Once an episode has been declared and Duration has expired, Rhythm ID makes its decision to inhibit or treat at the end of Duration. If the decision is made to inhibit therapy, the Sustained Rate Duration (SRD) timer is started and Rhythm ID continues to evaluate the rhythm beat-by-beat throughout Sustained Rate Duration. The device will inhibit therapy delivery until one of the following occurs:

- SRD timer expires
- Rate increases to a higher zone and meets criteria for treatment in that zone
- Rhythm ID determines that the rhythm meets treatment criteria (i.e., the ventricular rate becomes 10 bpm or more faster than the atrial rate, or vector timing and correlation determines the rhythm is no longer correlated)
- The rate slows and is no longer in a tachy detection zone

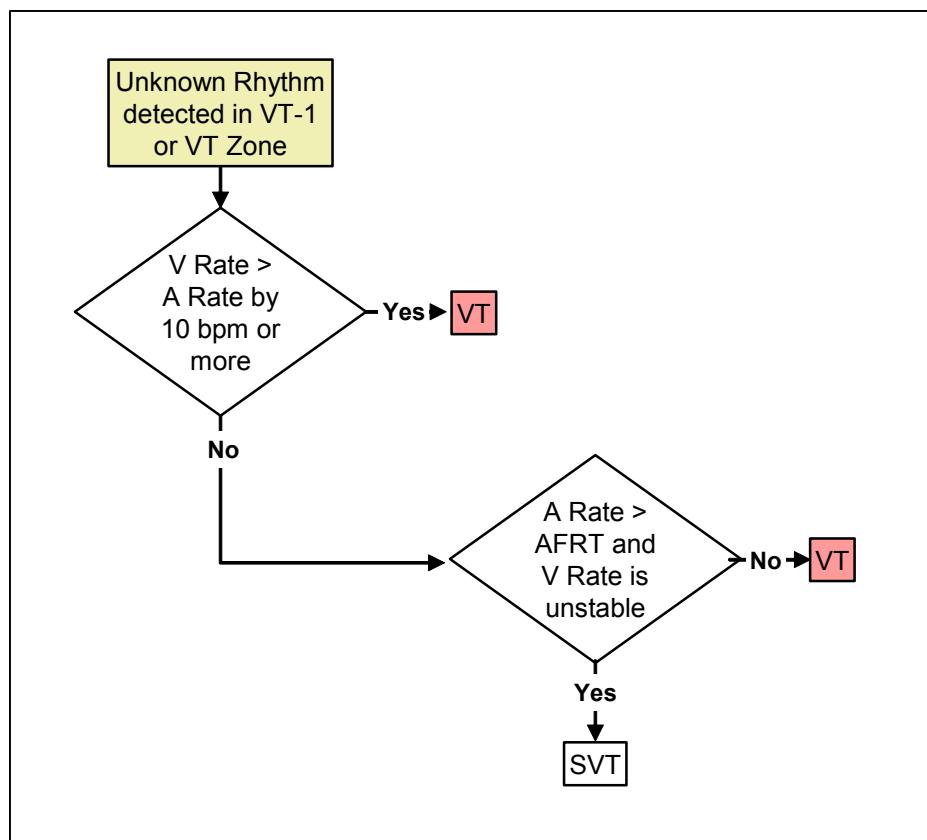
Rhythm ID with Atrial Tachyarrhythmia Discrimination ON

Once an episode has been declared and Duration has expired, Rhythm ID with Atrial Discrimination ON makes the inhibit decision as follows:



Initial Detection – Rhythm ID Atrial Tachy ON

After a shock has been delivered, Post-Shock detection enhancements can be applied to classify a fast rhythm. Since shock delivery may alter the rhythm morphology as seen by the shocking lead electrogram, Rhythm ID—Post Shock—does not use Vector Timing and Correlation as a detection enhancement component. V>A, A-fib Rate Threshold, and Stability are used without Vector Timing and Correlation.

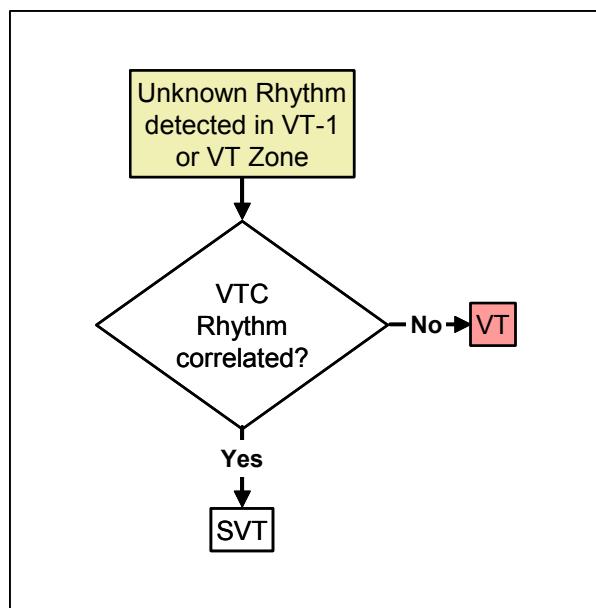


Post-Shock Detection - Rhythm ID Atrial Tachy ON

NOTE: Stability and A-Fib Rate are programmable parameters, and are linked with an AND condition. This means that the Ventricular rhythm must be both unstable AND the Atrial rate must be equal to or faster than the programmed AFRT in order to inhibit therapy.

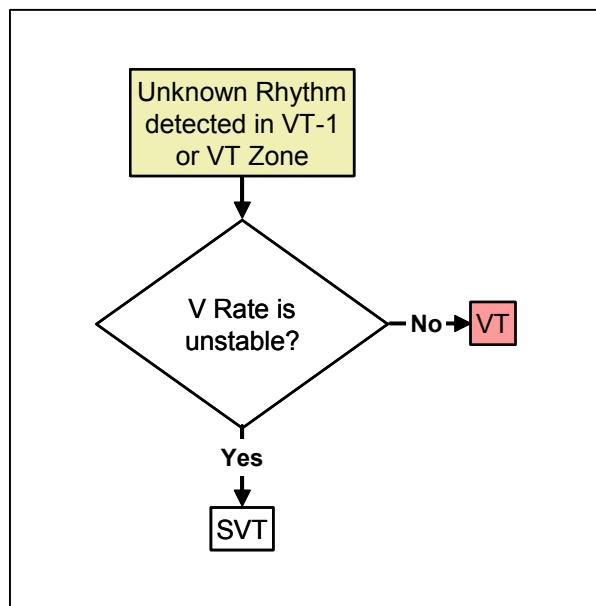
Rhythm ID in VR Devices or DR Devices with Atrial Tachyarrhythmia Discrimination OFF

Since a single-chamber device cannot provide information from the atrium, Rhythm ID in single-chamber devices or dual-chamber devices programmed with Atrial Tachy Discriminator = OFF, do not use V>A, A-Fib Rate Threshold, or Stability as part of its classification of rhythms during initial detection.



Initial Detection: Rhythm ID VR device or DR device with Atrial Tachy Discrimination OFF

After a shock has been delivered, Post-Shock detection enhancements can be applied to classify a fast rhythm. Since shock delivery may alter rhythm morphology, Rhythm ID-Post Shock does not use Vector Timing and Correlation as a detection enhancement component.



Post-Shock Detection - Rhythm ID VR device or DR device with Atrial Tachy Discrimination OFF

NOTE: Stability is a programmable parameter

Availability

- Available in both the VT-1 and VT zones, Post-Shock Rhythm ID and SRD are separately programmable in each zone. Post shock RID is nominally OFF.
- Not available in a 1-zone configuration.
- Not available in the VF zone.
- Rhythm ID is not available if Onset/Stability has been selected.
- If Rhythm ID is ON in a therapy zone, it will also report its measurements in the episode detail of episodes that take place in a monitor-only zone.

NOTE: RID+ (correlated) and RID- (uncorrelated) are reported on the real-time and stored electrogram reports.

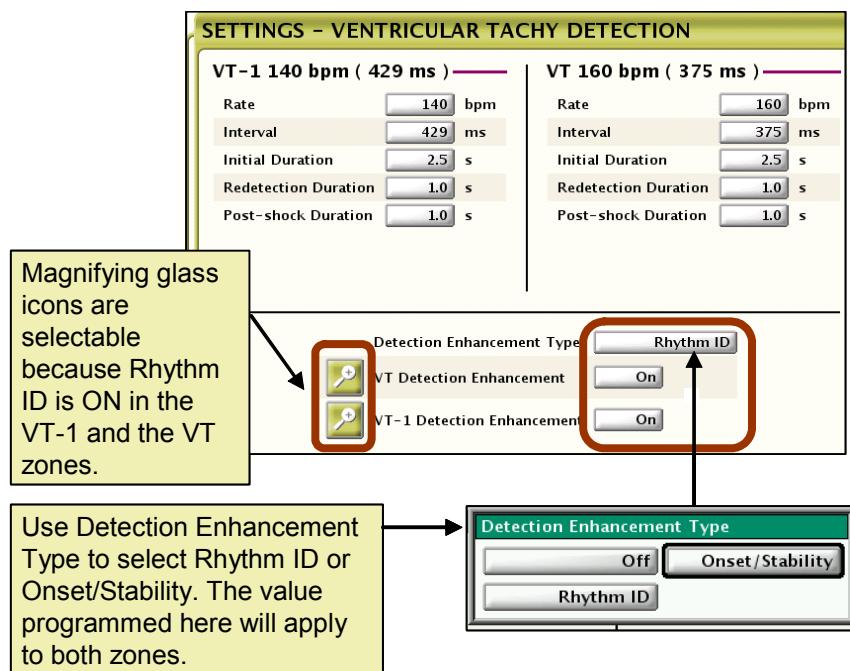
NOTE: If neither Rhythm ID nor Onset/Stability is programmed ON, Rate and Duration will be the only detection criterion used. Detection enhancements are not applied during redetection post-ATP or during redetection after a diverted shock.

- Navigation to Rhythm ID parameters:

1. From the Setting Summary screen, select  **Detection**  **Therapy**

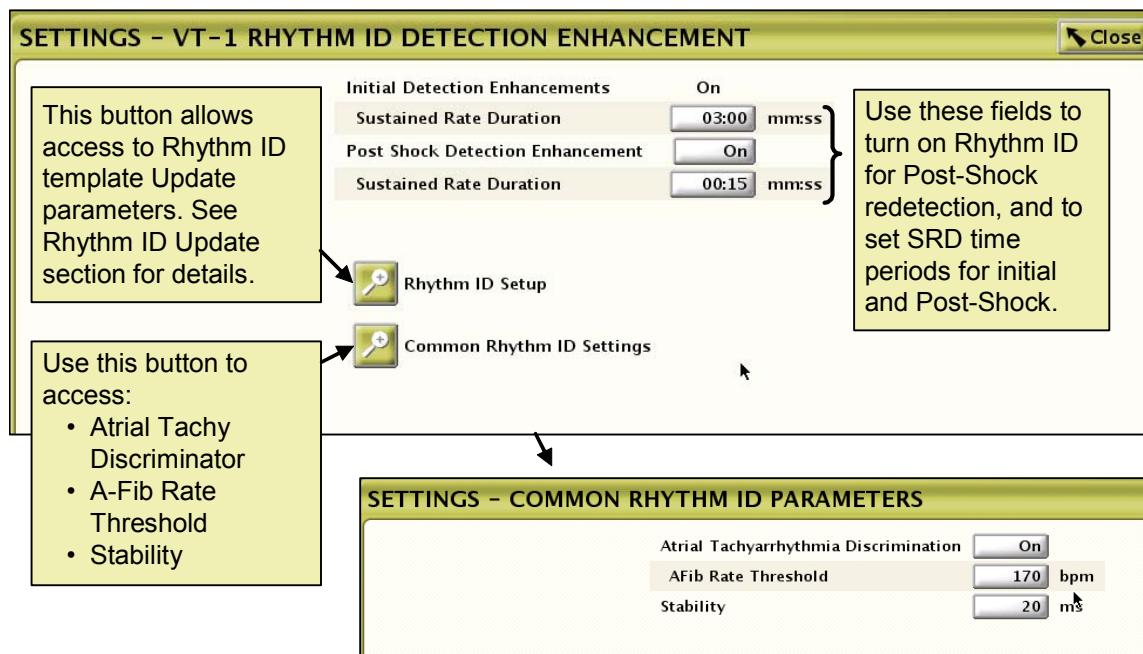
If detection enhancements are ON in a zone, the magnifying glass button for that zone will be selectable.

2. Select the  button to view the Rhythm ID detection enhancement parameters.



Programming Rhythm ID

Each of the lower zones (VT-1 and VT) in a multiple zone setup may use Rhythm ID selected as its detection enhancement. When Rhythm ID is selected, this screen allows the user to select Rhythm ID as the Post-Shock Detection Enhancement, and to set Sustained Rate Duration time periods for Initial and Post-Shock detection in a particular zone.



See the *Sustained Rate Duration* topic for details on programming SRD and/or the *Rhythm ID Update* section for details on programming the Rhythm ID template.

The Common Rhythm ID Settings button allows access to these parameters:

- Atrial Tachyarrhythmia Discriminator
- AFib Rate Threshold
- Stability

If Rhythm ID is ON in both the VT-1 and VT zones, any change to Common Rhythm ID parameters affects both zones.

The Common Rhythm ID Settings button allows access to these parameters:

- Atrial Tachyarrhythmia Discriminator
- AFib Rate Threshold
- Stability

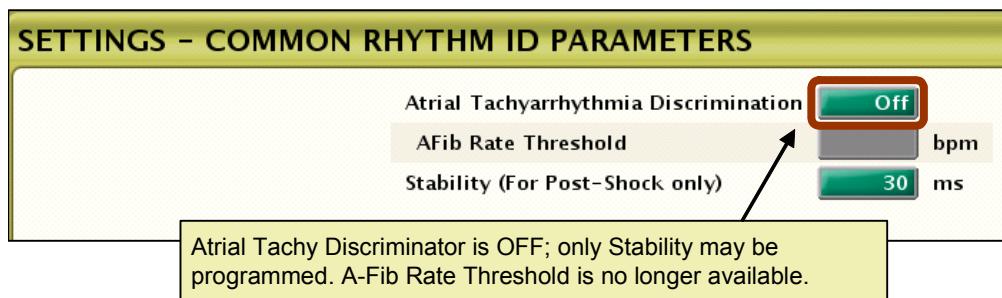
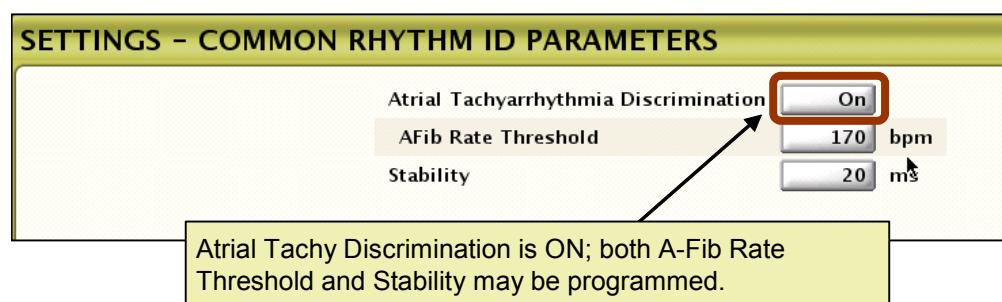
If Rhythm ID is ON in both the VT-1 and VT zones, any change to Common Rhythm ID parameters affects both zones.

Atrial Tachyarrhythmia Discrimination

Atrial Tachy Discrimination is used by dual chamber devices, and allows use of atrial information in Rhythm ID decisions. Specifically, if Atrial Tachy Discrimination is ON, Rhythm ID will use V>A and A-Fib Rate Threshold as part of its detection criteria.

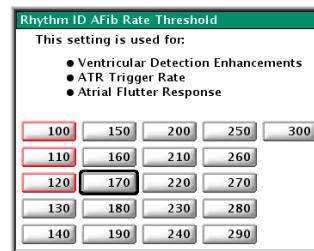
Atrial Tachy Discrimination Programmable Values: ON or OFF.

- Nominally ON in DR devices, not available in VR devices.
- If Rhythm ID is ON in both the VT-1 and VT zones, any change to this parameter will affect both zones.



A-Fib Rate Threshold

A-Fib Rate Threshold (AFRT) is used as part of Rhythm ID in DR devices. A-Fib Rate Threshold further refines the detection of atrial arrhythmias and allows the device to inhibit therapy in the event that a moderately high, unstable ventricular rate is due to ventricular response to atrial fibrillation.



AFRT Availability for Rhythm ID

- Available in dual-chamber devices only
- Available in the VT-1 and VT zones in a multi-zone set-up
- Not available in the VF zone
- Available when Atrial Tachy Discrimination is selected

AFRT Programmable Values

Nominal = 170

AFRT must be programmed at least 5 bpm faster than:

- Normal Brady Max Tracking Rate
- Normal Brady Max Sensor Rate
- Normal Brady Max Pacing Rate

The value programmed for AFRT is used by the device for all of the following:

- A-fib rate threshold for atrial tachy detection discrimination (either Rhythm ID or Onset/Stability)
- ATR trigger rate for Atrial Tachy Response (mode-switch)
- Atrial Flutter Response rate

Changing the value for any one of these parameters changes it for all three.

NOTE: A-Fib Rate Threshold AND Stability must be satisfied in order to inhibit therapy.

AFRT Algorithm – if Rhythm ID has determined that the V rate is not equal to or greater than the A rate by at least 10 bpm, and the current rhythm is not correlated to the stored template, Stability and A-Fib Rate Threshold are considered.

1. When tachy detection is initiated (third fast ventricular interval), each atrial interval is classified as \leq or $>$ A-Fib Rate Threshold.
2. If 6/10 atrial intervals are faster or equal to A-Fib Rate Threshold when 8/10 is satisfied, rhythm is declared to be A-fib. Atrial rate is continually measured throughout Duration and as long as 4/10 intervals are fast, AF will be declared TRUE at the end of Duration. If $<6/10$ atrial intervals were never equal to or faster than the AFRT, or 4/10 did not remain fast at the end of Duration, AFRT will be considered FALSE.
3. At the end of Duration, AFRT is used with stability as part of the Rhythm ID classification.
4. If therapy is inhibited, atrial rate continues to be measured throughout SRD, and as long as 4/10 intervals remain fast, AF continues to be considered TRUE.

When using Rhythm ID, device will report the A-Fib Rate Threshold decision as marker A-Fib V on the EGM.

Notes/Additional Information

- 6 seconds of atrial asystole causes A-Fib Rate Threshold window to be reset to 0/10.
- 6/10 would have to be met again to consider A-fib Rate thresholds re-satisfied (i.e., AFRT = TRUE).

Stability

Stability is a measure of regularity of the ventricular rhythm. Unstable or irregular ventricular rhythms, while fast enough to meet the VT-1 or VT tachy rate zone cutoff, may be the result of irregularly conducted atrial fibrillation and therefore the physician may choose not to treat these rhythms. In contrast, stable ventricular rhythms are more likely to be VT, and therefore should be considered for treatment.

Stability further refines Rhythm ID's classification of fast rhythms by measuring changes in ventricular interval from one cycle to the next.

Stability Availability – available in dual-chamber or single-chamber devices

- Available in the VT-1 and VT zones in a multi-zone setup
- Not available in a single-zone setup
- Not available in the VF zone

Stability Programmable Values

- If Atrial Tachy Discrimination = ON, Nominal = 20 ms
- Single-chamber devices or if Atrial Tachy Discrimination = OFF, Nominal = 30 ms
- If Rhythm ID is ON in both the VT-1 and VT zones, any change to this parameter will affect both zones

Stability				
6	18	30	55	110
8	20	32	60	120
10	22	35	70	
12	24	40	80	
14	26	45	90	
16	28	50	100	

Algorithm

If Rhythm ID has determined that the V rate is not 10 bpm or faster, than the A rate, and the current rhythm is not correlated to the stored template, Stability AND A-Fib Rate Threshold are considered. Stability computes an average variance in ventricular beats to determine whether the rhythm is variable or stable over a period of time. Stability calculations start when 8/10 fast beats are seen and episode is declared, and continue as each new beat is sensed throughout Duration (and SRD).

- Uses the last five consecutive intervals (four variances) before 8/10 is met to calculate the average variance.
- Adjusts this average variance as new intervals are added during Duration. This average variance is weighted as follows:

$$87.5\% \text{ (weighted average variance)} + 12.5\% \text{ (next delta)} = \text{new weighted average variance}$$

- With each new interval in duration, a new weighted average is calculated and compared to the Stability threshold.
- At the end of Duration, the average is compared to the Stability threshold. The device will determine whether the rhythm is stable or unstable and apply this decision to the overall Rhythm ID classification as appropriate.

- If measured average > Stability threshold => Rhythm is classified as UNSTABLE
- If measured average \leq Stability threshold => Rhythm is classified as STABLE

Notes/Additional information

A-Fib Rate Threshold AND Stability must be satisfied in order to inhibit therapy. The device will report Stability decision on the EGM with markers: Stb (stable) or Unstb (unstable).

V>A (As Used In Rhythm ID)

- Once an episode has been declared and Duration has expired, V>A is a measure that compares the rates of the atrium and ventricle to further classify the type of fast ventricular rhythm.
- If the ventricular rate is faster than the atrial rate by at least 10 bpm or more, the rhythm will be considered a VT and the device will proceed to therapy.
- If the ventricular rate is not faster than the atrial rate, Rhythm ID will perform further analysis of the rhythm.

Availability

- Active in dual-chamber devices only
- Not considered in single-chamber devices or if Atrial Tachy Discrimination = OFF
- Active in the VT-1 and VT zones in a multi-zone setup
- Not used in a single-zone setup
- Not used in the VF zone

Programmable Values

V>A is not programmable

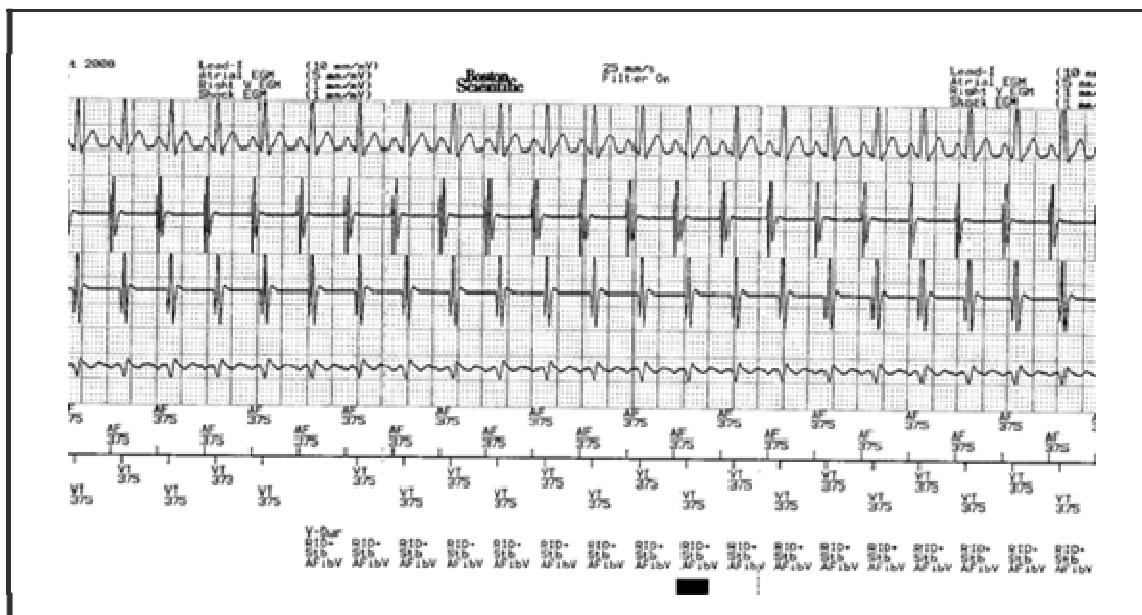
Algorithm

At the end of Duration:

1. Average of the last 10 V-V Intervals is compared to the average of the last 10 A-A intervals.
2. Averages are converted to rates in bpm.
3. If the average V rate is 10 bpm (or more) faster than the average A rate, then V>A shall be considered TRUE and therapy will be initiated.
4. If V>A is FALSE, further evaluation of the rhythm shall continue (Vector Timing Correlation, Stability, and A-Fib Rate Threshold).

Notes/Additional information

The device will report calculated V>A decision with V>A marker on the EGM. The example below includes stability, Atrial Fib Rate Threshold and RID markers.



Example showing markers.

RHYTHM ID with RhythmMatch



RhythmMatch adds further programmability to Rhythm ID (RID):

- Allows the clinician to adjust the threshold for the correlation % (Feature Correlation Coefficient or FCC%) used in Vector Timing Correlation.
 - Reports whether an individual shocking lead EGM signal is correlated to the stored Rhythm ID template for every QRS.
 - Reports the correlation decision for the overall rhythm.

For Vector Timing Correlation:

- If the calculated correlation % for an individual QRS is \geq the programmed RhythmMatch threshold, the QRS is *correlated* to the stored template.
 - If the calculated correlation % for an individual QRS is $<$ the programmed RhythmMatch threshold, the QRS is *uncorrelated* to the stored template.

NOTE: RID never makes a rhythm decision to inhibit or treat based on one beat's measurement.

- Although RhythmMatch values are measured and displayed for each QRS, the device still uses a rolling window of 10 beats to determine whether a rhythm is correlated to the template.
- RID uses Vector Timing and Correlation in conjunction with Stability, (plus V>A and AFRT in dual-chamber devices) to determine if a rhythm should be treated (VT) or inhibited (SVT).

See the RID Overview document for a description of the RID decisions, or see the Vector Timing Correlation (VTC) section for a discussion of how the correlation % is calculated.

Availability

- Used when Rhythm ID Detection Enhancement is ON for Initial Detection (VT-1 or VT zones).
- RhythmMatch is only used during the initial Rhythm ID decision – not applied in Post-Shock, post ATP or post divert.
- RhythmMatch values are measured and reported on the Event summary (provided a reference template has been acquired), even if RID is OFF, or if Onset/Stability is the programmed detection enhancement, or if only one zone is programmed.

Navigation to RhythmMatch Threshold

1. From the Setting Summary screen Select  to view detection enhancements.



to view detection

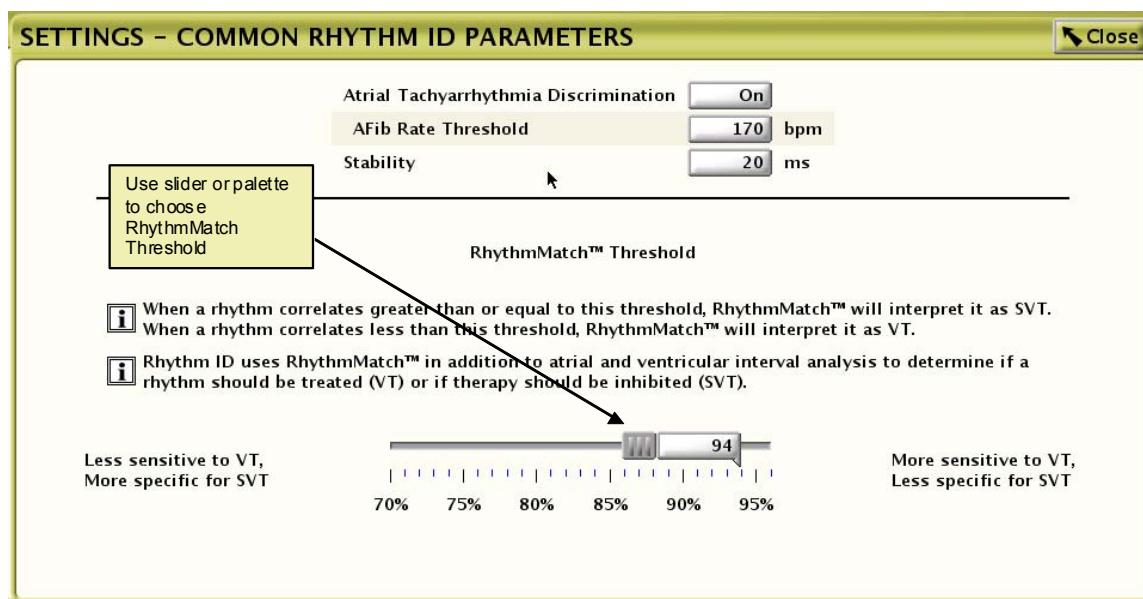
2. If detection enhancements are ON in a zone, the magnifying glass button for that zone will be selectable.



3. Select  to view the Rhythm ID detection enhancement parameters.

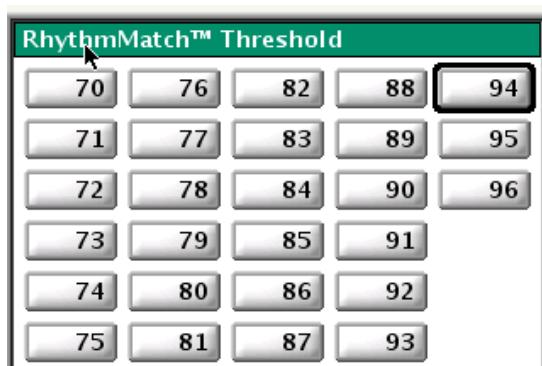
4. From the Settings – V Rhythm Detection Enhancement screen





Programmable Values

- 70 to 96 %. Nominal = 94%
- Starting with the first beat after the three fast beats that trigger the event, RID calculates a correlation % for each QRS and compares that value to the programmed RhythmMatch threshold.
- If calculated % for an individual QRS is \geq the programmed RhythmMatch threshold, the QRS is correlated to the stored template.
- If calculated % for an individual QRS is $<$ the programmed RhythmMatch threshold, the QRS is uncorrelated to the stored template.



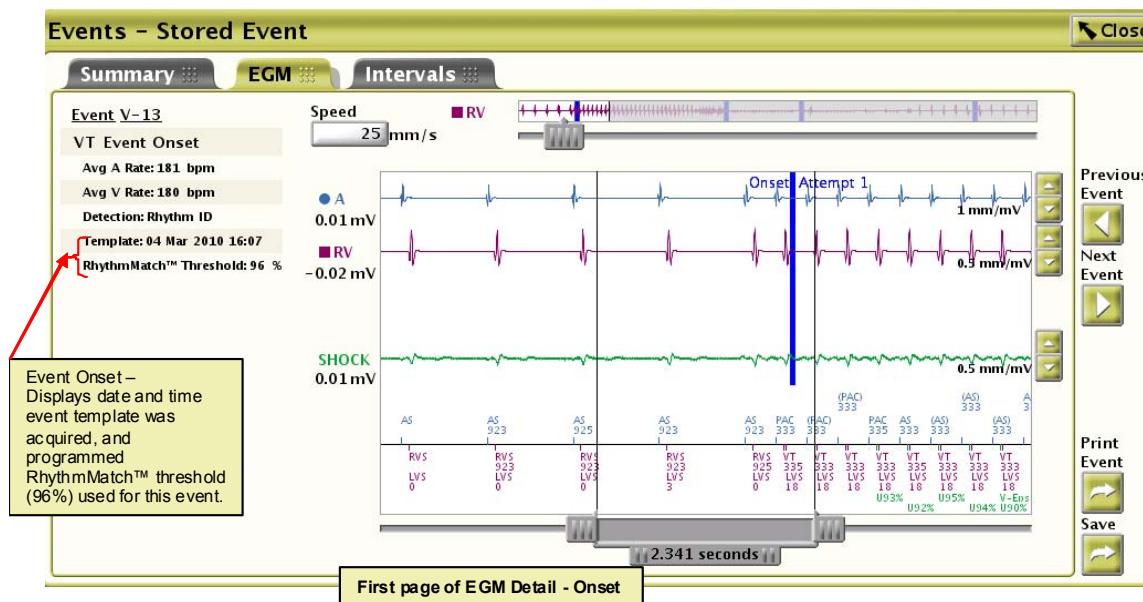
RhythmMatch Reporting

RhythmMatch provides additional reporting for events, including:

- Template acquisition date and timestamp
- Programmed RhythmMatch value
- RhythmMatch measurement that determined inhibit or treat decision. This decision will be reported when the device *first* decides to inhibit, and again when Detection is met
- Beat-by-beat QRS correlation %
- RID Correlated decision, based on rolling 10-beat window
- RID+/- decision (whether the rhythm is correlated or uncorrelated) on the EGM, based on rolling 10-beat window, reported beat-by-beat

- RhythmMatch calculations and template date and timestamp will be reported on the Event report for every event, including:
 - Events where RID is the programmed detection enhancement
 - Events where Onset/Stability was the programmed detection enhancement
 - Events in the VF zone or a single-zone set-up, where detection enhancements are not applicable
 - Calculations will not be displayed if a template has not been stored.
 - Beat-to-Beat calculations are only provided if RID is enabled.

RID Decisions on the Event Report/Screen



Template

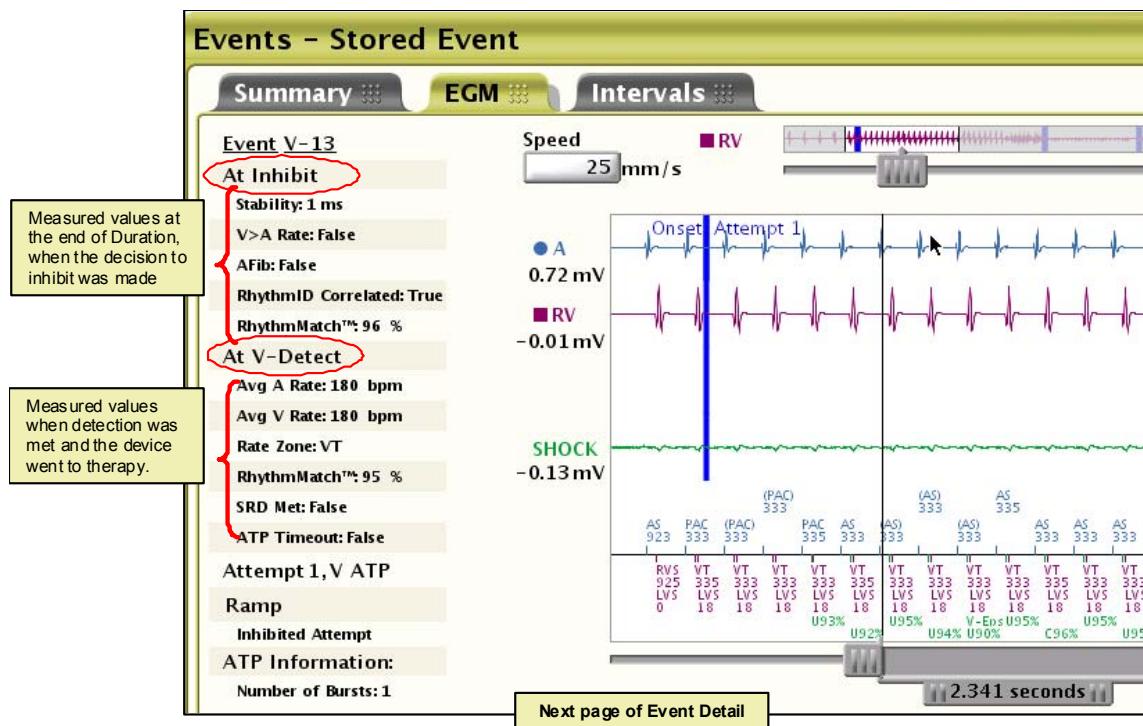
Acquisition date and time for the template that was or could have been used to make correlation decisions during this event. A date and time will be reported if a template has ever been stored, even if RID is not used for this event (e.g., Onset/Stability is programmed ON, or the device is programmed to a single zone).

NOTE: N/R will be reported if no template has been stored.

RhythmMatch Threshold

The programmed correlation value that will be used when assessing whether an individual beat matches (i.e. is correlated to) the stored normal sinus template.

NOTE: Programmed RhythmMatch Threshold will still be reported if no template has been stored.



At Inhibit

- In events where RID makes an inhibit decision, *At Inhibit* lists detection enhancement decisions, in particular, the RhythmMatch measured value and RID evaluations at the time the decision to inhibit was made (i.e., at the end of Duration).
- Once the device decides to inhibit, it re-evaluates the inhibit decision with each new QRS.
- In the example above, the device is inhibiting because V>A is False and the rhythm is correlated.

NOTE: If there is more than one inhibit decision, only the first decision will have a RhythmMatch % reported. Any subsequent inhibit decisions (e.g., when a Monitor Only zone is used) will not display the measured RhythmMatch values.

At V-Detect

- In events where RID makes a detect decision, *At V-Detect* lists the RhythmMatch measured values and RID evaluations at the time the decision to treat was made.
- In the example above, the device decided at first to inhibit, but the reported RhythmMatch % of 95% shows that the rhythm has become uncorrelated when it dropped below than the programmed value (For this example, RhythmMatch was programmed to 96%).

NOTE: If there is more than one Detect decision, only the first decision will have a RhythmMatch % reported. Any subsequent *at V-Detect* decisions (e.g., when a Monitor Only zone is used) will not display the measured RhythmMatch values.

RhythmMatch is the only enhancement that is reported twice if the device first inhibits, then detection is met.

See *Detection Enhancement Onset/Stability* for a description of how AFRT, Stability, or V>A is calculated.

RhythmMatch Values

- RID determines if a rhythm is correlated (RID+ or RID -) by assessing the correlation percentages of each beat in a 10-beat window. The value reported on the Event Summary is based on this 10-beat window.
- The first RhythmMatch value is reported at the end of Duration, and/or when the device decides to treat the rhythm (i.e., when Detection is met). The possible RhythmMatch values are listed in the table below.

NOTE: The current beat is not usually included in the 10-beats used to make the RID+/- decision and to determine the RhythmMatch value. This is because the correlation of the current beat is not known until the entire waveform is captured and analyzed, approximately 260 ms after the R-wave is detected by the device (typically on the rising edge of the waveform, before the peak). However, there are some beats that can be immediately classified:

- Paced beats are immediately classified as correlated.
- VF beats are immediately classified as uncorrelated.
- Beats that are too fast (≤ 260 ms) for RID to calculate correlation are immediately classified as uncorrelated.

If a beat's correlation classification is known, it is included in the 10 beats used to classify the rhythm and determine the RhythmMatch value.

RhythmMatch Value in Event Summary	Description
NN%	The measured rhythm correlation percentage when the decision to inhibit or treat was made. In any group of ten beats, RID requires at least three beats to be correlated to be classified as SVT (and to therefore inhibit). The reported RhythmMatch value will be the third highest percentage in the 10-beat window, i.e. the beat that determines whether SVT correlation criteria are met. The actual percentage is reported only if the third highest percentage is not that of a 'paced' or 'too fast' beat.
Paced	A correlation percentage cannot be calculated because at least three of the last 10 beats were paced, or three no-sense events. (A 'no-sense' event is 2 seconds of ventricular asystole when ventricular pacing is not programmed On (e.g. AAI mode).) Paced events are considered 100% correlated; since the third highest correlation % would be one of these beats, the RhytMatch value is reported as 'Paced.'

RhythmMatch Value in Event Summary	Description
Too Fast	A correlation percentage cannot be calculated because <ul style="list-style-type: none"> • At least 8 of the last 10 beats were in the VF zone <u>or</u> • At least 8 of the last 10 beats had an R-R interval ≤ 260 ms These beats are considered uncorrelated without considering their calculated correlation %; since the third highest correlation % would be one of these beats, the RhythmMatch value is reported as 'Too Fast.'
N/R	A correlation percentage cannot be calculated because no RID template has yet been stored.

NOTE: It is possible that fewer than 10 beats have been analyzed for Vector Timing Correlation when Duration or Detection is met. The third fast beat in an event begins storage of the EGM; the correlation of beats is calculated only after the third fast beat occurs, starting with the fourth beat. Depending on the rate of the rhythm, the device could decide to inhibit or treat as early as the 10th beat in the event; there may be as few as 7 beats with correlation % available.

If fewer than 10 beats' correlation % have been calculated, the device will use one of the following:

- RhythmMatch value of the second highest of the available correlation %
- *Paced* if at least two of the available beats were paced
- *Too Fast* if all or all but one of the beats are VF beats or ≤ 260 ms

RhythmMatch Beat-by-Beat EGM Markers

- FCC% is calculated and reported as a marker on the stored EGM for each QRS, starting after the 3rd consecutive fast beat. The FCC% is reported beat-by-beat until Detection is met and therapy is requested, or the rhythm slows and drops out of Detection.
- Markers in the EGM indicate whether an individual beat is correlated (C) or uncorrelated (U). This marker will appear on stored EGMs only; it will not appear on real-time strips

NOTE: If no template has been stored, the rhythm will be uncorrelated and the beat-to-beat correlation % will not be reported on the stored EGM.

Marker	Description
CNN%	Correlated (SVT) (NN is the actual measured correlation percentage) Correlation % for an individual QRS is \geq the programmed RhythmMatch threshold, so the QRS is correlated to the stored template.
UNN%	Uncorrelated (VT). (NN is the actual measured correlation percentage). <ul style="list-style-type: none"> • Correlation % for an individual QRS is $<$ the programmed RhythmMatch threshold <u>or</u> • QRS is in the VF zone and the interval is > 260 ms. Any QRS in the VF zone will be classified uncorrelated regardless of the percentage calculation.

Marker	Description
C--	<ul style="list-style-type: none"> • Correlated (SVT) – no % listed because this is a paced beat. RV-paced beats, including RV-triggered paced beats, are always correlated. • If ventricular pacing is not enabled (e.g. the pacing mode is programmed to AAI), two seconds of ventricular asystole would also cause a C-- classification.
U--	Uncorrelated (VT) – no % listed because QRS rate was faster than 230 bpm (260 ms).

NOTE: The correlation % can only be displayed as whole numbers. The device will round down the correlation % that is displayed for the event.

Example: RhythmMatch threshold is programmed to 94%.

Correlation % calculated is 94.3%; QRS is correlated. Marker on EGM is C94%.

Correlation % calculated is 94.0%, QRS is correlated. Marker on EGM is C94%.

Correlation % calculated is 93.9%, QRS is uncorrelated. Marker on EGM is U93%.

RID+/RID-

- The RID+ and RID- markers provide the Rhythm ID decision, indicating whether the last 10-beat window of beats is correlated or uncorrelated. This represents the overall correlation decision that Rhythm ID uses to determine whether to inhibit or treat.

NOTE: Although the marker appears under individual beats, RID +/- represents a 10-beat decision; it does not indicate whether or not that individual beat is correlated.

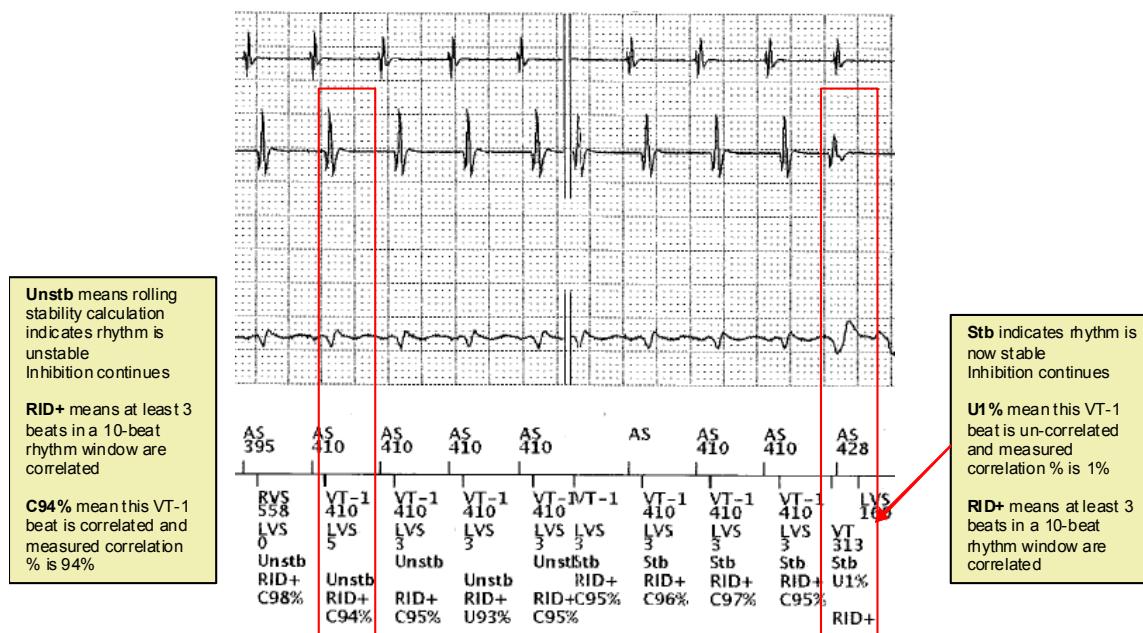
- **RID+** indicates the last 10-beat window had at least 3/10 correlated beats; rhythm is correlated.
- **RID-** indicates the last 10-beat window had 8/10 beats uncorrelated; rhythm is uncorrelated.
- The first time this marker will appear is at the end of Duration. If the device decides to inhibit therapy, SRD starts and a RID + or RID- marker will appear with each new beat until detection is met or the rhythm drops out of detection all together.

Using RhythmMatch information to assess RID Decisions

Review the markers and RID decisions and compare the patient's rhythm to the desired outcome for that rhythm.

- The higher the programmed RhythmMatch Threshold, the more likely an arrhythmia will be classified as VT (i.e. treat decision).
- The lower the programmed RhythmMatch Threshold, the more likely an arrhythmia will be classified as SVT (i.e. therapy inhibit decision).

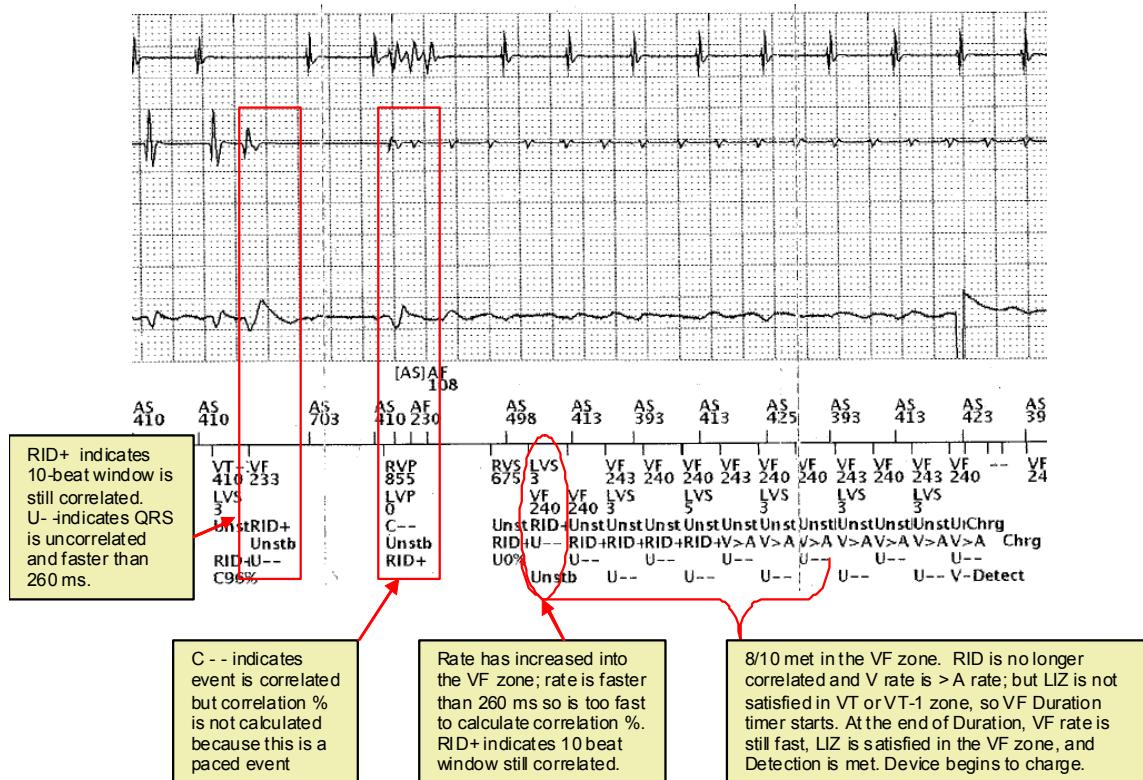
EGM Examples



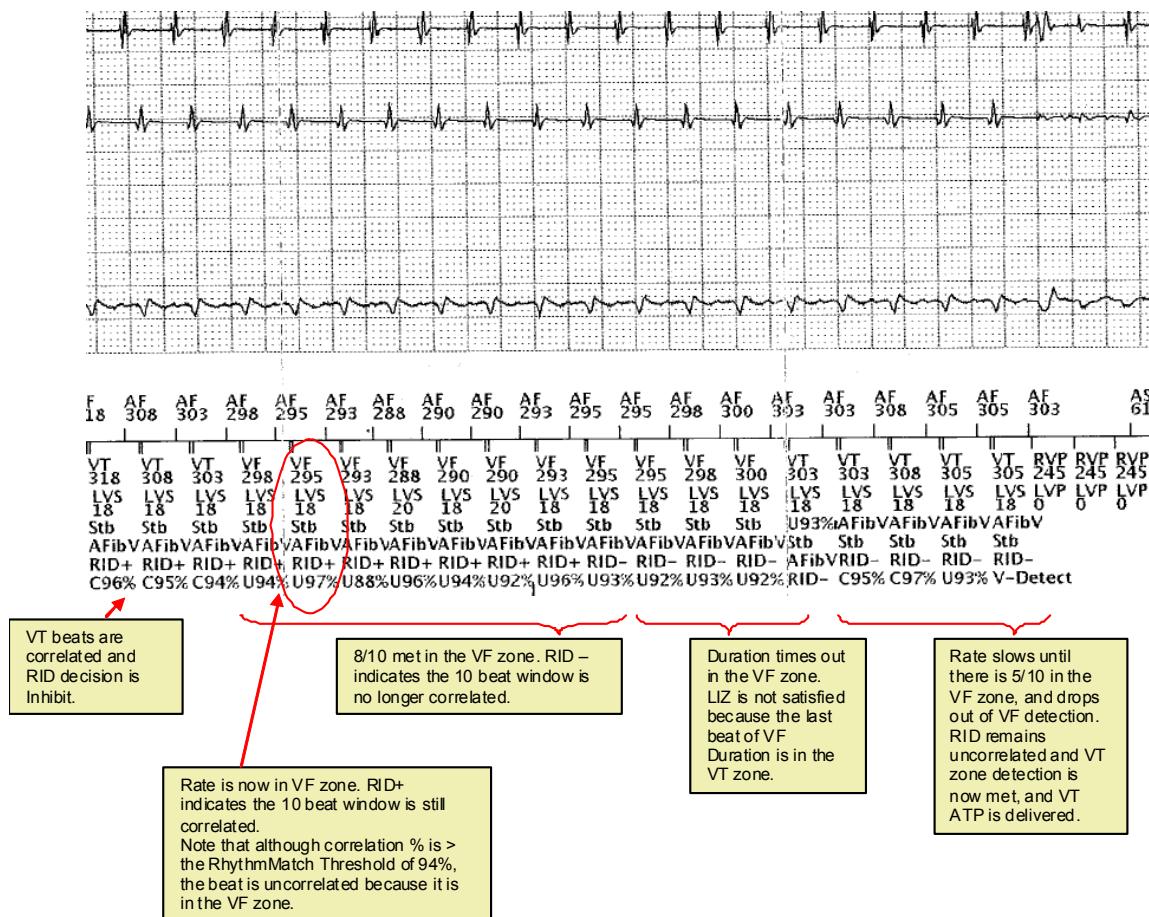
Example 1 RID inhibiting

- RhythmMatch is programmed to 94%
- Correlated rhythm, RID inhibits, strip shows a portion of markers during SRD.
- Occasional PVC (uncorrelated beat).

Example 2 RID inhibiting, rate increases into VF zone



- RhythmMatch is programmed to 94%.
 - RID is inhibiting in the VT zone.
 - Rate increases into the VF zone.

Example 3 RID inhibiting, rate increases to VF zone, then decreases to VT zone


- RhythmMatch is programmed to 94%.
- RID is inhibiting in the VT zone.
- Rate increases into the VF zone.
- Rate decreases into the VT zone.

Detection Enhancement Sustained Rate Duration (SRD)



Once the detection enhancements have made the decision to inhibit therapy, Sustained Rate Duration (SRD) limits how long the device will inhibit therapy. SRD ensures that therapy is delivered for a sustained high rate, even if Rhythm ID or Onset/Stability have decided to inhibit. When SRD expires,

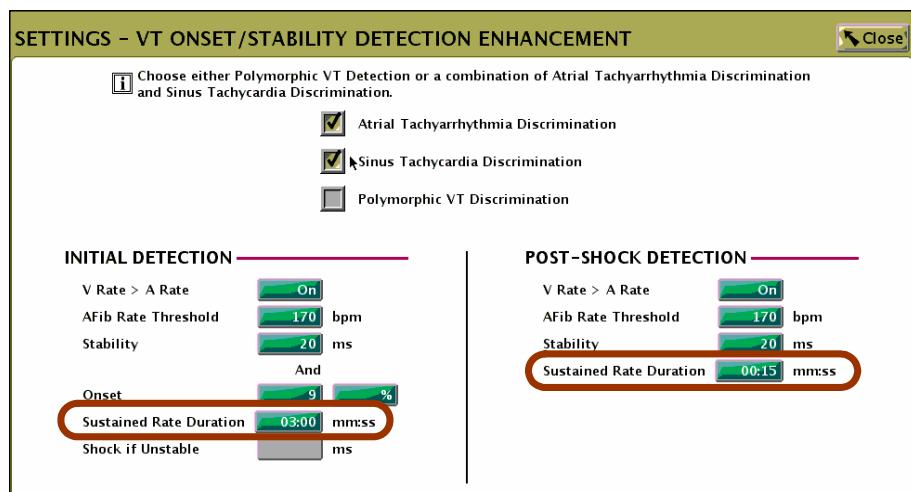
detection enhancements will no longer be allowed to inhibit therapy in the applicable tachy rate zone, allowing therapy delivery if all other detection criteria are met.

Availability

From the Setting Summary screen, select  to select/view detection enhancement.



If detection enhancements are ON in a zone, the  button will be available. Select the button to view the detection enhancement parameters.



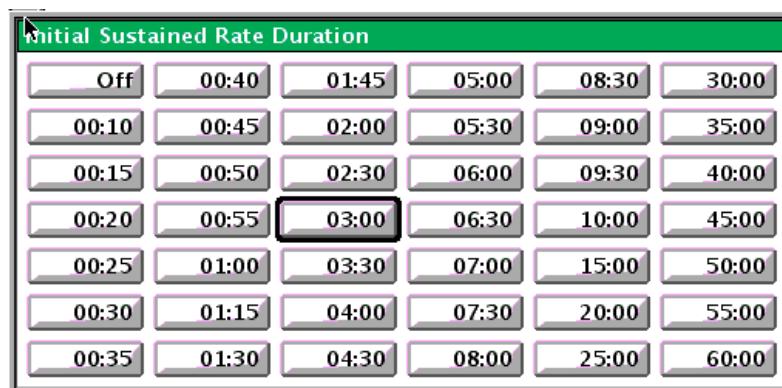
Available in VT-1 or VT zones when detection enhancements (Onset/Stability or Rhythm ID) are programmed ON. Separately programmable as a Post-Shock Parameter if Post-Shock detection enhancements are programmed ON, when RID is active in both lower zones, Sustained Rate Duration (SRD) is programmable independently in:

- VT-1 zone initial detection
- VT-1 zone post-shock detection
- VT zone initial detection
- VT zone post-shock detection

SRD is not available post ATP or after a diverted shock.

Programmable Values

Initial Sustained Rate Duration:



- OFF
- 10 secs to 60 minutes (nominal: 3:00 min)

Algorithm

The SRD timer starts when the device had made the decision to inhibit therapy at the end of Duration. During SRD, therapy delivery is inhibited until one of the following occurs:

- The rate changes to another zone and detection criteria for that zone are met.
- The rhythm no longer meets rate criteria (i.e., fewer than 6/10 beats remain at or above the tachy rate-cut-off). The SRD timer is cleared.
- The SRD timer expires (therapy is initiated if all other applicable detection criteria continue to be met).
- Onset/Stability detection enhancements decision to inhibit changes because the rhythm become stable, AFRT is FALSE, or V>A = TRUE (therapy is initiated if applicable detection criteria are met).
- Rhythm ID classification changes to VT due to any of the following (therapy is initiated if all other applicable detection criteria are met):
 - Vector timing and correlation indicates VT (rhythm is uncorrelated to NSR template).
 - For dual-chamber devices programmed with atrial tachy discriminator ON:
 - V-rate becomes greater than the A-rate by 10 bpm or more
 - AFRT is FALSE or the rhythm is stable

Notes/Additional Information

- If SRD is programmed to OFF, therapy can be inhibited indefinitely, as long as detection enhancements are inhibiting and the episode continues.
- Since the SRD timer is examined synchronously at the end of each cardiac cycle, the actual SRD may extend up to one cardiac cycle beyond the programmed value.
- SRD does not reset when transitioning between zones.

Example: The initial detection is in the VT-1 zone, and during SRD, the rhythm accelerates to the VT zone and detection and Duration are met in the VT zone. Rhythm ID still classifies the rhythm as SVT, even though the rate has increased, and the SRD timer continues.

- When a device is set up with Rhythm ID and a three-zone configuration, interactive limits may appear based on the following rules:
 - VT initial duration must be \leq VT-1 duration. This requirement ensures that if a rhythm in the VT zone slows into the VT-1 zone, it meets VT-1 Duration before going into SRD.
 - SRD cannot be programmed OFF in the VT zone if it is On in the VT-1 zone.
 - SRD in the VT zone must be \leq to SRD in the VT-1 zone (only if SRD is not off in the VT-1 zone).
 - If therapy is disabled in the VT-1 zone without previously turning off detection enhancements in that zone, you will still get the SRD interaction warnings when trying to program SRD in the VT zone. This is confusing because the ability to program detection enhancements in the VT-1 zone is “grayed out” when VT-1 is a monitor-only zone. To resolve any interactions, follow this sequence:
 1. Turn on some therapy in the VT-1 zone.
 2. Turn off detection enhancements in the VT-1 zone
 3. Disable therapy for the VT-1 zone.
- Now the SRD parameter in the VT zone will not interact with the ‘phantom’ SRD in the VT-1 zone.

Detection Enhancement Rhythm ID Reference Template Update



Intrinsic Rhythm ID (or template) is a set of data points representing the baseline template of a patient's normal sinus rhythm (NSR). To create the template, Rhythm ID samples rhythm originating in the atrium, locates QRS peaks on the ventricular rate sense EGM, and also locates eight specific data points on corresponding shock EGM waveforms. Data points are stored for use as the basis of comparison for unknown fast rhythms.

Rhythm ID compares a new fast rhythm to the template to determine whether this fast rhythm originates in the sinus (correlates to Rhythm ID template) or in the ventricle (does not correlate to Rhythm ID template).

Updating Rhythm ID Template

Regular updates of the Rhythm ID template are desirable to accommodate possible changes in a patient's EGM morphology over time. Rhythm ID provides automatic periodic updates of the template. Automatic updates are referred to as *ambulatory* because they occur during normal patient activity and do not require a command from the programmer.

When a template update is attempted, the following occurs:

- If the template update is successful, the stored template is replaced with new NSR template.

- If the template update is unsuccessful, the stored template in use is retained and used by Rhythm ID until the next successful template update occurs.

Availability

- Available whenever Rhythm ID is chosen as a detection enhancement in a multiple-zone setup.
- Rhythm ID is not available in single-zone (VF zone) setup or when Onset/Stability is selected as the detection enhancement.

Navigation to Automatic Rhythm ID Setup

1. From the Setting Summary screen select  VENTRICULAR TACHY

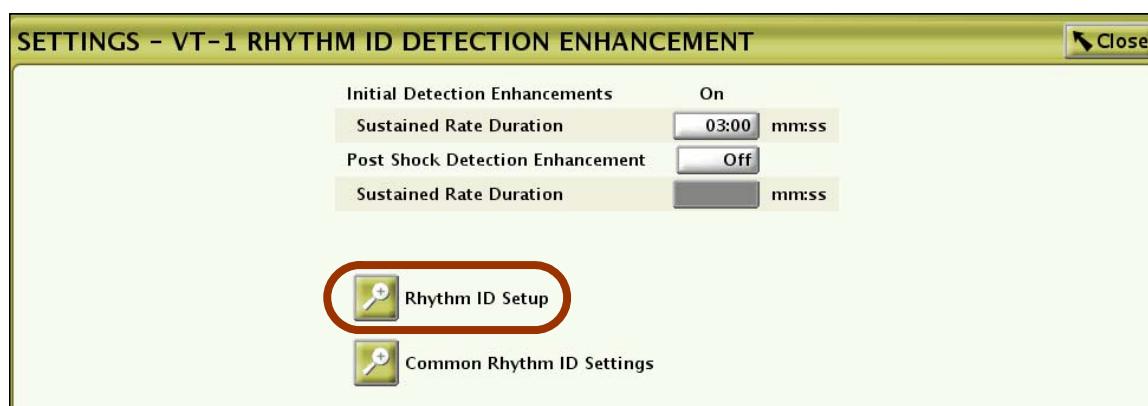
2. From the Settings – Ventricular Tachy

Detection screen select  ⇒

for the zone where
detections enhancements

are programmed ON. The Detection Enhancement screen appears.

NOTE: Rhythm ID must be selected as the Detection Enhancement to access this screen.



3. Select  to access the Intrinsic Rhythm ID Setup parameters.



Programmable Values

Ambulatory Update of Rhythm ID: ON, OFF (nominally ON)

- The device attempts Automatic Intrinsic Rhythm ID update every two hours.
- Automatic updates start between two and four hours after the device is taken out of Storage mode, if at least two hours have elapsed since the last communication between the device and programmer.
- If OFF is chosen, no Automatic Rhythm ID updates will occur.



NOTE: Because template updates occurs automatically after the device is taken out of Storage mode (Automatic Intrinsic Rhythm ID Update is nominally ON), consider waiting to take device out of Storage mode until just before implant.

Temporary LRL (Either of Two Options)

- Can be programmed to use the normal Lower Rate Limit that is programmed in the Brady parameters; or
- Can be programmed to use a temporary value, different from the normal Lower Rate Limit. This temporary LRL can vary between 30 –105 bpm and is used during fallback mode.

See Section 2.

Rhythm ID Template Updates (1 of 3 options described below)

- Ambulatory Automatic Update (no change to LRL)
- Ambulatory Automatic Update with fallback LRL
- Manual Update commanded through programmer

Option 1: Ambulatory Automatic Update (no change to LRL rate)

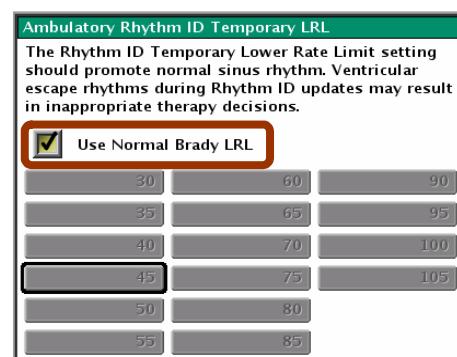
Programmable Value

Ambulatory Rhythm ID Temporary LRL

- Use Normal Brady LRL is nominally selected.
- Template update will be attempted without changing the Normal Brady LRL currently programmed; also called *passive* update.

Device assesses patient's ongoing rhythm, without changing parameters, in 3 steps

Step 1: Device assesses patient's rhythm for valid intrinsic (NSR) beats. Valid NSR data:



- Intrinsic AV conduction.
- Ventricular paced beats are excluded from template.

NOTE: During persistent atrial pacing, if conducted AV interval is < 140 ms, template acquisition is unsuccessful. Any atrial pacing artifact in proximity of QRS complex is excluded from template.

- Rate must be < 110 bpm (545 ms).
- Rate must be < rate of lowest tachy zone rate cutoff + 32 ms.
- Ventricular rate variability must be < 150% of the R-R average (most conducted atrial fibrillation will meet rate variability requirement for template update).
- PVCs are excluded from template; PVCs are defined as ventricular beats that are < 87.5% of a rolling R-R average.

NOTE: Device uses sliding 20-beat window to assess variability. At least 10/20 beats must be > 87.5% (not a PVC) and < 150% of a rolling R-R average.

- As long as rhythm includes valid intrinsic beats, template update will continue. If rate and variability criteria or other criteria are not met, template update will be halted and is considered unsuccessful.

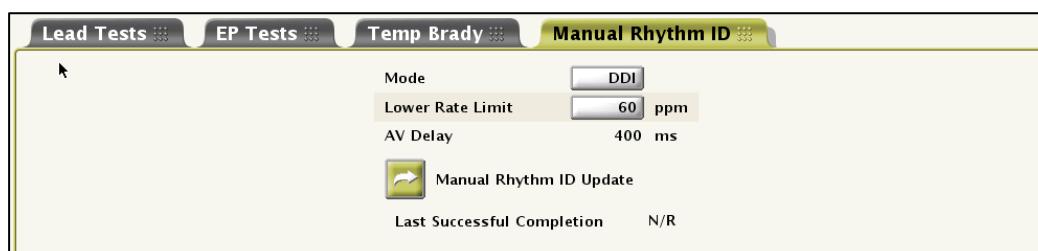
Step 2: Device creates a candidate template.

- The device averages 16 R-wave complexes to create a *candidate template*. Using the same eight points that are used during vector timing correlation, device averages 16 waveforms to create an averaged waveform with eight averaged points.

Step 3: Device compares candidate template to ongoing intrinsic rhythm.

- Using vector timing correlation, device compares candidate template to patient's ongoing rhythm to make sure that candidate template is representative of patient's intrinsic rhythm.
- If ongoing rhythm correlates with candidate template, candidate template is stored as new template.
- If ongoing rhythm does not correlate with candidate template, original stored template is retained.

Device reports date and time of last successful template update on Manual Rhythm ID screen (same data also appears on the Device Follow-UP Report).



Any of following events will cause automatic template update to be postponed for at least 2:00 hours after occurring (may temporarily affect shock EGM morphology):

- Any ventricular EP Test screen functions
- Ventricular ATP
- Ventricular Therapy Shock
- STAT Shock is delivered
- Any communication between PG and PRM causes automatic template update to be postponed for at least two hours

If template update is in progress and one of following occur, template update will be halted and attempted again in two hours:

- Tachy detection window (three consecutive fast beats) starts.
- Tachy mode is changed to OFF-Electrocautery.
- Any ventricular EP Test screen function is performed.
- Device is pacing at sensor indicated rate, and pacing rate is at least 5 bpm greater than LRL.
- Telemetry session starts.

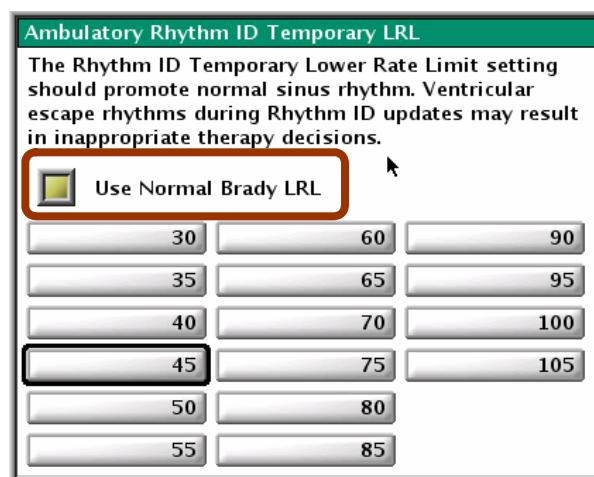
Option 2: Ambulatory Update with Fallback LRL

Programmable Value

Ambulatory Rhythm ID Temporary LRL

- Use Normal Brady LRL is deselected and fallback rate selected.
- Temporary LRL rate: 30-105.
- Nominal = 45 bpm.

During template update attempt, Normal Brady LRL will be changed to Ambulatory Rhythm ID Temporary LRL; also called update with fallback LRL.



See *Ambulatory Automatic Update (no change to LRL rate)* if a change in LRL is not desired.

If an Automatic Update with Temporary LRL rate is programmed, Ambulatory Update with Fallback LRL will be attempted as follows:

- Within 30 hours of taking device out of Storage mode (28 hours after first unsuccessful Ambulatory Update), if no template has been stored.
- After seven days of unsuccessful automatic template updates without fallback.
- 28 hours after an unsuccessful update attempt with fallback (either a manually commanded attempt or an automatic attempt), if updates without fallback are unsuccessful during this period.

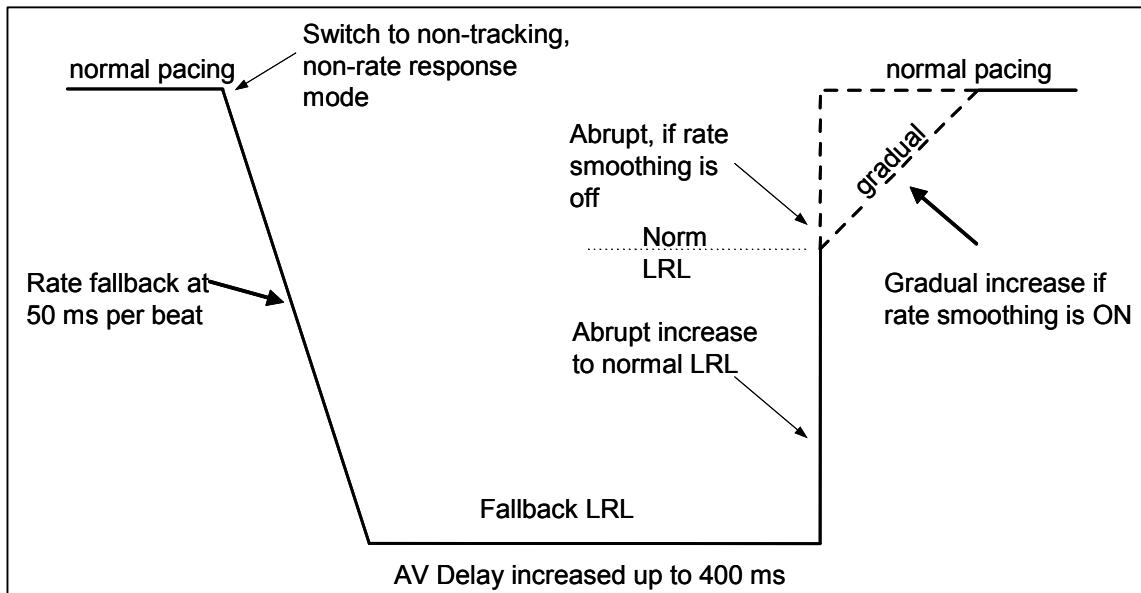
28 hour timing was chosen because:

- First update attempt with Fallback should occur at least 24 hours after implant
- Patient will not be subjected to rate changes for fallback update more than once a day.
- Fallback attempts will occur at different times of day.

Ambulatory Update with Fallback LRL takes up to three minutes to complete following:

1. Device verifies patient is at rest:
 - Sensor indicated rate must be within 5 bpm of LRL.
 - Sensor/activity recovery time is complete.
2. Device temporarily turns OFF tracking and rate response:
 - Mode changes to non-rate response and non-tracking (e.g., DDDR→DDI, or VVIR→VVI)
3. Temporarily turns OFF or adjusts following dynamic/enhanced Brady parameters:
 - Rate smoothing
 - Rate hysteresis
 - VRR
 - PMT algorithm
 - ATR
 - AFR
 - Dynamic PVRP becomes 150 ms (fixed)
 - Dynamic VRP remains unchanged
4. Gradually lower rate to Ambulatory Rhythm ID Temporary LRL.
 - Falls back at rate of 50 ms/beat—takes about 5-7 seconds
 - Abort fallback sequence if patient activity initiated or continued pacing occur
5. Attempts to acquire a new template. If rhythm is correlated with the candidate template, store the new template.
6. Turns Normal Brady parameters back on.

Abruptly increases rate to Normal LRL (If Rate Smoothing ON, device will gradually increase rate to indicated pacing rate).



Ambulatory Update with Fallback LRL pacing will not be done

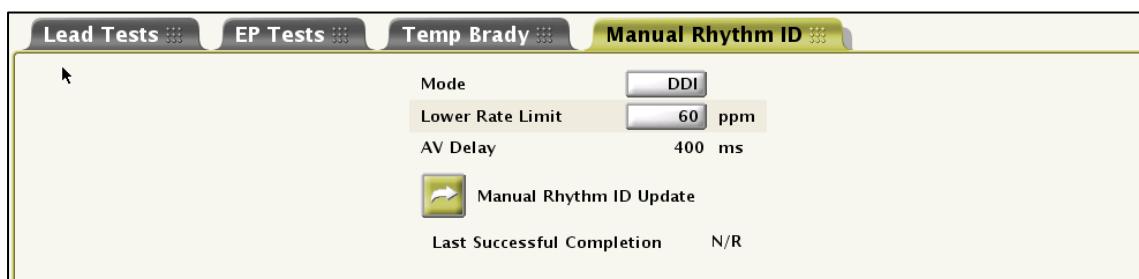
- If Ambulatory Update of Rhythm ID = OFF
- If Temporary LRL = OFF
- If Tachy mode is Storage, OFF, or Off-Electrocautery mode
- If there is only one tachy zone programmed
- If a user test is in progress
- If a ventricular episode is in progress
- During periods of patient activity or sensor recovery time

Option 3: Manual Rhythm ID Update

Programmable Values

- Mode: DDI, VDI, VVI, AAI, OFF.
- Lower Rate Limit: 30-105 ppm.
- AV Delay: non-programmable—device will automatically compute to allow intrinsic conduction; may be as long as 400 ms.
- Commanded from Tests ⇒ Manual Rhythm ID tab ⇒ **Manual Rhythm ID Update**
- Manual Intrinsic Rhythm ID Update uses the same steps as Automatic Intrinsic Rhythm ID with Fallback, with the additional ability to select a pacing mode.
- Manual update may be used at implant to collect the first Intrinsic Rhythm ID Template after implant, or at follow-up.

NOTE: Performing manual template update immediately after DFT testing may capture EGM morphology that has transient alterations from defibrillation threshold testing.



Once user presses Manual Rhythm ID Update button, the device performs the following steps (takes up to three minutes and a progress bar appears):

1. Device switches to temporary Brady parameters.
2. Device applies mode and LRL user entered in Manual Rhythm ID tab.
3. Temporarily turns OFF or adjusts following dynamic/enhanced Brady parameters:
 - Rate smoothing
 - Rate hysteresis
 - VRR
 - PMT algorithm
 - ATR
 - AFR
 - Dynamic PVRP becomes 150 ms (fixed)
 - Dynamic VRP remains unchanged
4. Temporarily (automatically) sets longest possible AV Delay per interaction rules (up to 400 ms).
5. Gradually drops rate to Ambulatory Rhythm ID temporary LRL.
 - Falls back at a rate of 50 ms/beat—takes about 5-7 seconds
 - Aborts fallback sequence if patient activity initiated or continued pacing occur
6. Attempts to acquire a new template.
 - If rhythm is correlated with the candidate template, store the new template
7. Turns Normal Brady parameters back on.
8. Abruptly increases rate to Normal LRL (if Rate Smoothing ON, device smoothes to indicated rate).

Upon completion, status is reported as either *Manual Rhythm ID Update Completed Successfully* or *Manual Rhythm ID Update Did Not Complete Successfully*.

A commanded template may not be done:

- If Tachy Mode is Storage or Off-Electrocautery Mode
- If a user test activity is in progress
- If VT detection window is active (i.e., three fast consecutive beats were seen)
- If a ventricular episode is in progress

Rhythm ID at Implant/Pre-Discharge

At implant or pre-discharge, physician may choose to collect a manual template update for the first Rhythm ID template. The following are possible steps:

1. Set up number of Tachy Zones on Settings Summary screen to either two or three.
2. Choose Rhythm ID as the Detection Enhancement Type on the Settings – Ventricular Tachy Detection screen in zones.
3. Click VT Detection magnifying glass to adjust SRD and post-shock parameters.
4. Click the magnifying glass for Common Rhythm ID Settings to adjust Stability and A-Fib Rate Threshold.
5. Click the magnifying glass for Rhythm ID *Setup Ambulatory Update of Rhythm ID*.
6. Under the TESTS screen on Manual Rhythm ID screen, set Mode and LRL and touch Start to begin manual capture of NSR template.

The following three scenarios represent typical clinical practices observed by technical services for collecting first template:

1. After implant of pulse generator and assessment of system (PG+leads) performance, prior to DFT testing.

Manual template update should not be performed until ventricular rate sense and shock coil leads are fixed and any current of injury appearing on rate or shock EGMs has resolved.

2. After DFT testing and patient is stabilized in recovery area.

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

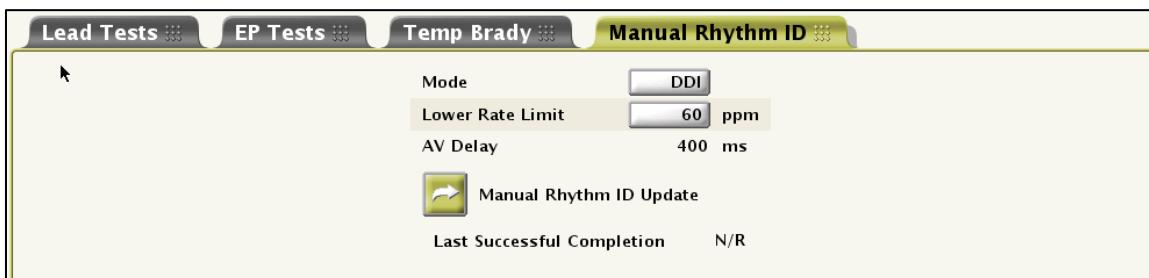
3. At pre-discharge follow-up.

Usually occurs day after device implant and patient's heart rhythm is likely to have returned to normal.

Rhythm ID at Follow-Up

Suggested steps to include in follow-up for Rhythm ID:

1. Verify device has a current template by checking date/time of last template update (updates are reported on Manual Rhythm ID tab and Device Follow Up Report).
 - Last Successful Completion date/time applies to both Manual and Automatic updates.
2. Perform Manual Rhythm ID Update if needed.



3. Review any individual events for rhythm and Rhythm ID classification.

Troubleshooting

Why would device not collect an Ambulatory Rhythm ID template?

- Ventricular Pacing (> 10%)—pacing can be seen on real-time EGMs and diagnostic screen.
- Rate > 110 bpm—would be apparent on screen.
- Rate is > tachy rate cutoff (i.e., patient is in a tachy episode).
- Rate is too variable.
- If none of preceding is true, but persistent atrial pacing with AV interval < 140ms, try manual update with an OFF pacing mode.

What happens if I can't acquire a manual template?

- Try changing parameters—LRL or pacing mode.
- If template is still not acquired, dual-chamber device will use V Rate > A Rate, Stability, A-Fib Rate Threshold, and SRD for tachy detection enhancements. A single-chamber device, or a device programmed with Rhythm ID Atrial Discrimination = OFF will use rate criteria only if no template is acquired.

What if the device delivers inappropriate therapy?

Consider the following options:

- If device inhibited therapy until SRD expired, consider increasing SRD time period or turning SRD OFF, if appropriate.
- Verify that tachy rate zone cut offs are appropriate for patient's rhythm.

- If there has been no Rhythm ID template updates since before episode in question occurred, perform manual template update.
- If rate-dependent morphology change is suspected, perform manual template update at the rate necessary to invoke the rate-dependent morphology change.
- Can consider using AAI mode to create template at an elevated rate (rate must be < 105 bpm). If template is successfully acquired using this method and do not wish to have template automatically replaced again, consider turning Ambulatory Rhythm ID update OFF and updating manually at next follow-up.
- If atrial undersensing is occurring, ensure SMART is selected for A-Blank after V-Sense to allow more atrial beats to be sensed. May also consider programming Rhythm ID Atrial Discrimination to OFF.

Detection Enhancement RHYTHM ID Vector Timing Correlation



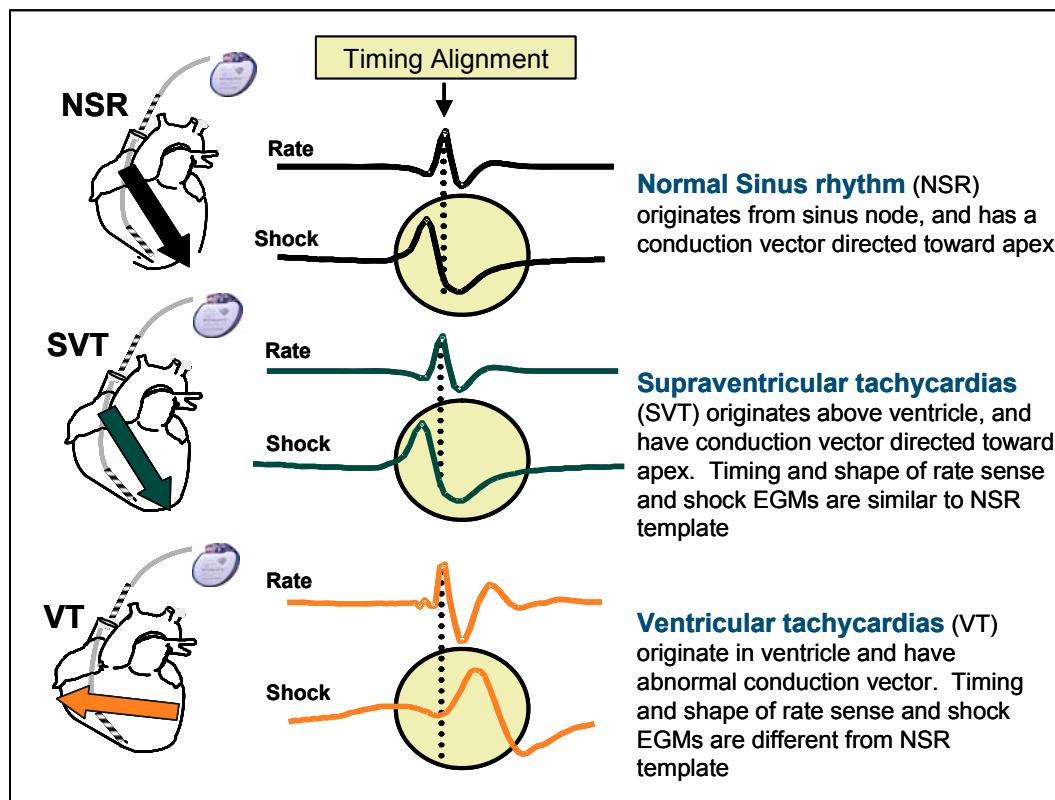
Vector Timing and Correlation compares EGM signals for an unknown rhythm with a stored reference template of the EGM signals of a normal sinus rhythm (NSR).

- 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.

Vector – three-dimensional direction or flow of a depolarization wave through heart. Shape, or morphology, of shock EGM is used as an indicator of vector direction.

Timing – relative timing of depolarization wave captured by rate sense and shock EGMs. Timing is based on peak signal of rate sense electrogram, and alignment of eight characteristic points on shock EGM relative to that peak.

Correlation – Comparison of the vector and timing of an unknown rhythm detected in the VT-1 or VT zones to the stored template.



Availability

Used when Rhythm ID Detection Enhancement is ON for Initial Detection.

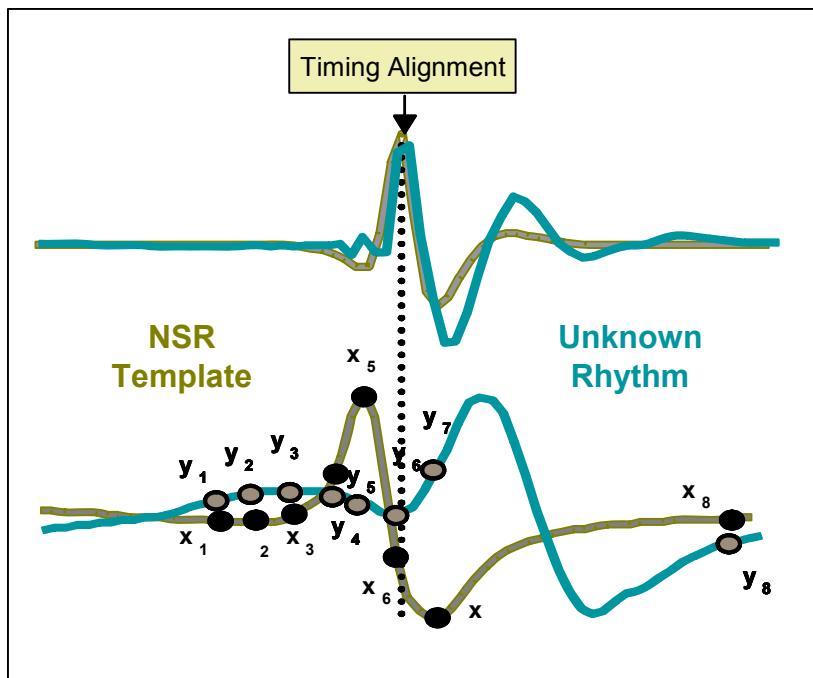
Programmable Values

Vector Timing and Correlation is not programmable; it is used as part of Rhythm ID.

Algorithm

When an unknown fast rhythm is sensed in VT-1 or VT zones, each beat of fast rhythm is compared to stored NSR template:

- Peaks of Rate Sense EGMs for each QRS in unknown rhythm are aligned with Rate Sense EGM peak on NSR template.



- Eight characteristic points are measured on shock EGM of unknown rhythm. For each point one through eight, two pieces of data are stored: time relative to rate sense peak, and signal amplitude.
- Eight points from shock EGM of unknown rhythm (shown as Y1-Y8) and eight points from NSR template (shown as X1-X8) are fed into a correlation equation to calculate Feature Correlation Coefficient (FCC).

$$FCC = \frac{(8 \sum_{i=1}^8 x_i y_i - (\sum_{i=1}^8 x_i)(\sum_{i=1}^8 y_i))^2}{(8 \sum_{i=1}^8 x_i^2 - (\sum_{i=1}^8 x_i)^2)(8 \sum_{i=1}^8 y_i^2 - (\sum_{i=1}^8 y_i)^2)}$$

- If FCC is > 0.94 (correlation $> 94\%$), QRS complex is considered correlated to NSR template.
- If FCC is ≤ 0.94 (correlation $\leq 94\%$), QRS is considered uncorrelated with NSR template.

NOTE: FCC is based on Pearson Correlation Coefficient, a common calculation for measuring relationship between two data sets. Calculation of FCC will yield numbers from 0 to 1, with 1 indicating perfect correlation.

- FCC is calculated for each QRS until therapy is requested starting with third fast beat of onset.
- Rhythm is classified as SVT (correlated) or VT (uncorrelated) based on FCC calculations for 10 most recent beats. Sliding window of 10 beats is used to make Rhythm ID Vector timing and correlation decision, beginning at end of Duration: If at least 3/10 beats are correlated, the rhythm is classified as SVT. If at least 8/10 are uncorrelated, the rhythm is classified as VT.
- Rhythm ID makes its decision to inhibit or treat at end of Duration. If decision is made to inhibit therapy, Rhythm ID (including Vector Timing and Correlation, V > A, A-Fib Rate Threshold, and Stability) continues to be recalculated beat-by-beat throughout Sustained Rate Duration (SRD).

Vector Timing and Correlation Summary

Vector Timing and Correlation classifies rhythm at every beat from end of Duration until therapy is requested, based on FCC values of last 10 beats as follows:

1. Uses stored NSR template to align Rate Sense channel peaks of new QRS with template Rate Sense Peak.
2. Measures eight characteristic points from tachyarrhythmia shock EGM, at specific time reference points defined by normal sinus rhythm template.
3. Stores timing and amplitude for each of eight points.
4. Calculates FCC (correlation) using eight points from tachyarrhythmia shock EGM, together with corresponding eight points from NSR template shock EGM.
5. Determines whether beat is correlated based on FCC result.
6. Repeats calculation as each new QRS is sensed.
7. At end of Duration, if 3 of the last 10 beats are correlated, rhythm will be classified as correlated and SVT inhibit RID+ marker is printed. If 8/10 beats are not correlated at the end of Duration, rhythm is classified as VT and RID- marker is printed.

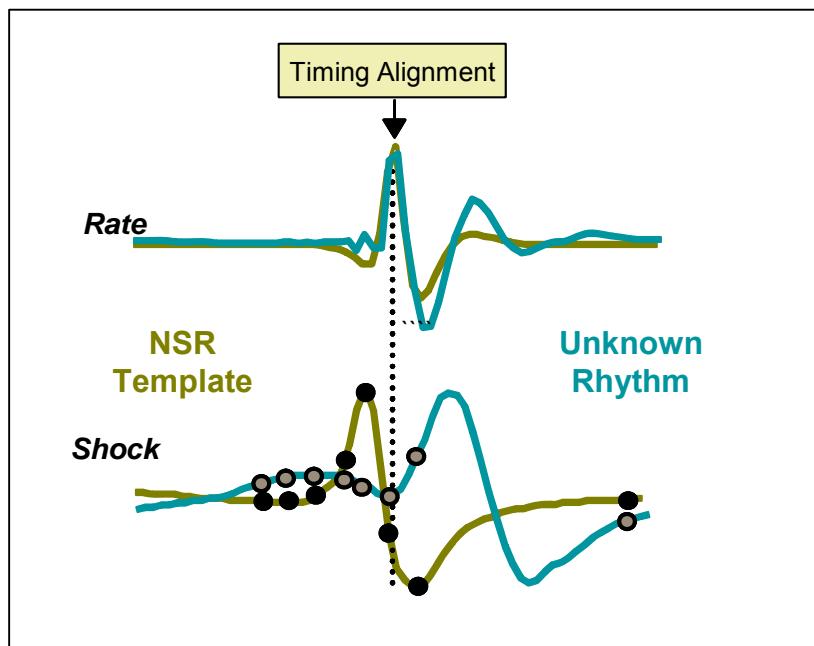
Notes/Additional Information

- Vector Correlation is only one part of Rhythm ID. Depending on how the device is programmed and where in the episode detection occurs (initial or post-shock), other detection enhancement components may also be performed:
 - V > A
 - Stability
 - A-Fib Rate Threshold.

See Rhythm ID Overview for more information.

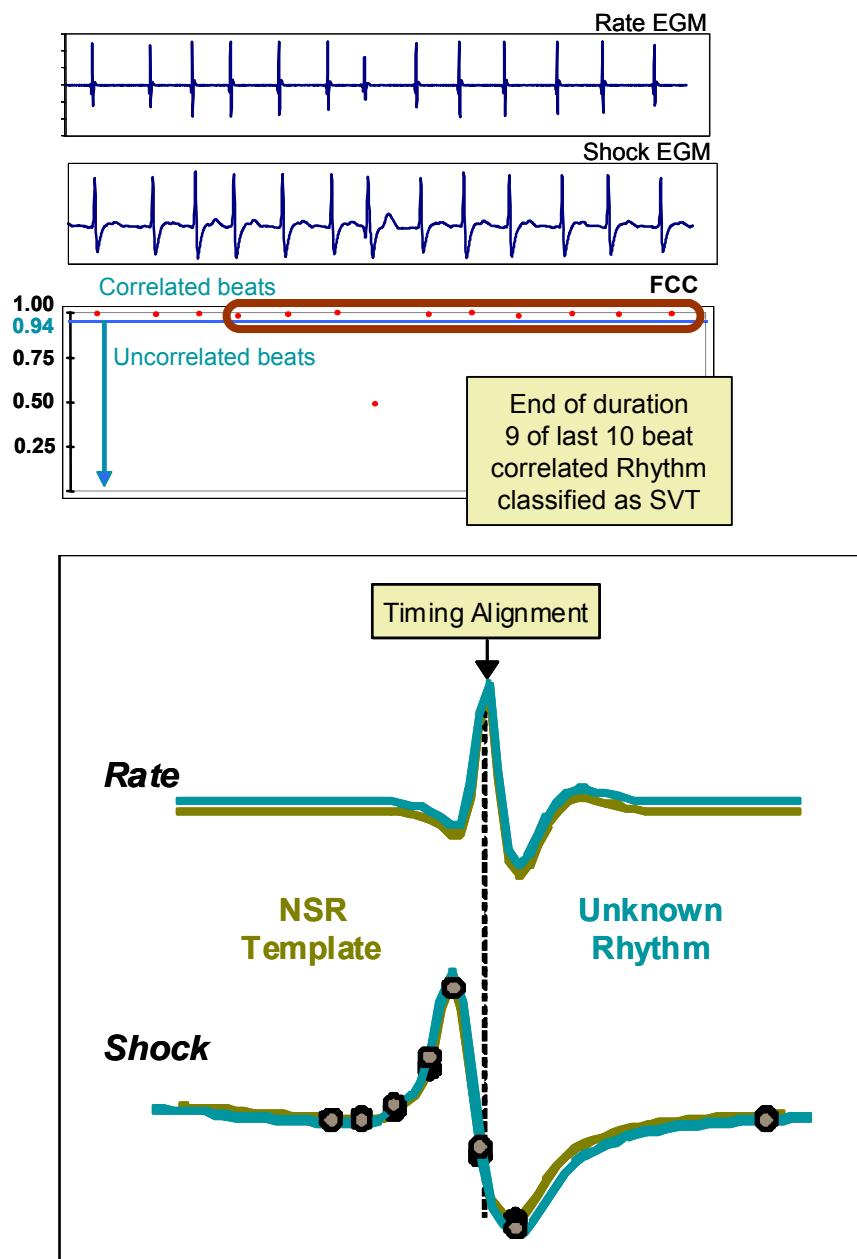
- Shock EGM is measured using the Coil-to-Can vector only. This configuration was not possible with VITALITY 2 because shock vector could not be programmed.

Example: Correlated Beat (SVT) – for an individual QRS, rate sense timing alignment and eight points on shock EGM are compared to rate sense timing and eight points on stored NRS template. This illustration shows a QRS from an unknown rhythm that correlates with stored NSR template.

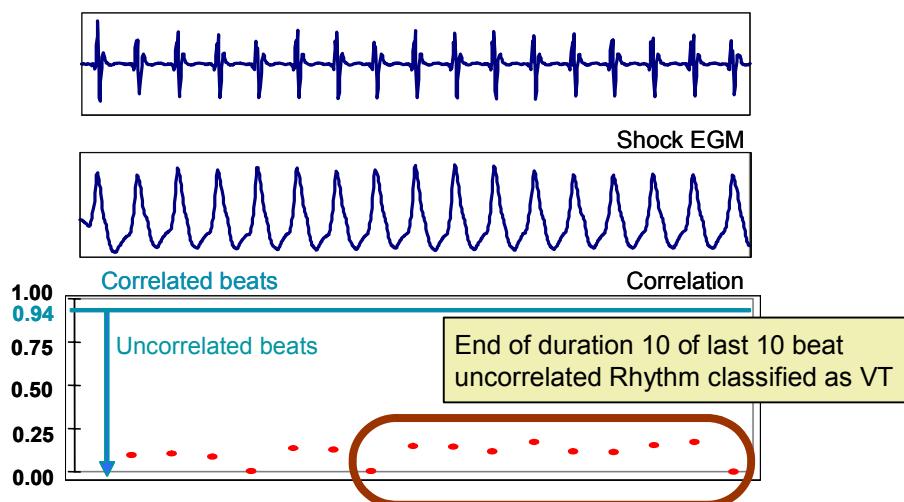


Correlated Rhythm (SVT) – this illustration shows rate sense and shock EGMs for a fast rhythm. Rhythm is therefore correlated to Intrinsic Rhythm ID template, and is classified as SVT.

NOTE: FCC for nine of last ten beats is > 0.94 . This satisfies requirement that at least 3 of 10 beats are correlated.



Uncorrelated Beat (VT) – for an individual QRS, rate sense timing alignment and eight points on shock EGM are compared to rate sense timing and eight points on stored NSR template. This illustration shows a QRS from an unknown rhythm that does not correlate with stored NSR template.



Uncorrelated Rhythm (VT) –this illustration shows rate sense and shock EGMS for a fast rhythm. Rhythm is therefore uncorrelated to Intrinsic Rhythm ID template, and is classified as VT.

NOTE: FCC for 10 of last 10 beats is < 0.94. This satisfies requirement that 8/10 beats are uncorrelated.

Reconfirmation

ICD	INCEPTA	ENERGEN	PUNCTUA	TELIGEN	CRT-D	INCEPTA	ENERGEN	PUNCTUA	COGNIS
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- Shock therapy may be programmed as committed or non-committed.
- If shock therapy is committed, once the device begins to charge, the shock will be delivered, regardless of any changes in rhythm.
- If shock therapy is non-committed, the device will use the Reconfirmation algorithm to assess the rhythm during and at the end of charge.

Reconfirmation monitors a patient's rhythm during charging and at the end of charge to verify that the rhythm is still fast and should be treated. It allows the device to divert a shock for rhythms that are:

- No longer fast, such as runs of nonsustained VT

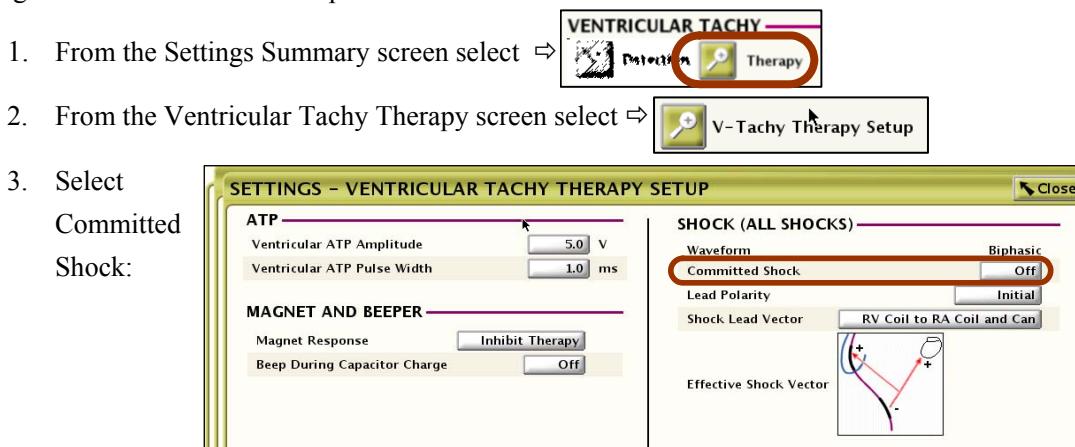
- Arrhythmias that convert spontaneously
- Benign rhythms that sensed above the tachy rate threshold for short periods of time

FAST Ventricular beats – Reconfirmation classifies a rhythm as fast if it still meets the rate cutoff of any zone, regardless of the therapy programmed in that zone. Reconfirmation classifies intervals with VT-1, VT, or VF markers as FAST.

SLOW Ventricular beats – intervals slower than lowest zone's rate threshold. Reconfirmation classifies intervals with VS and VP markers as SLOW.

Availability

- Committed Shock applies to shock therapy in all zones.
- Navigation to Committed Shock parameter:



Programmable Values

- Nominal OFF (non-committed).
- ON – shock is committed.
- OFF – device will use Reconfirmation to check the rhythm, both during charge and at the end of charge, to verify that the rhythm is still fast, before delivering a shock.



Algorithm

Committed Shock = ON

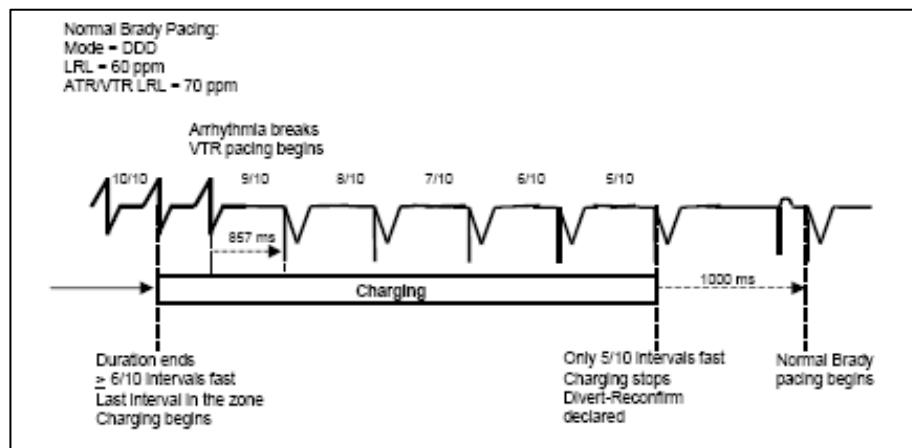
- Once charging begins, the rhythm will not be reassessed.
- When charging is completed, the device waits up to two seconds to synchronize to an R-wave to deliver the shock. If no R-wave is sensed, the shock will be delivered two seconds after charge is complete.

Committed Shock = OFF (Reconfirmation)

Reconfirmation begins when charging starts, and has two phases:

1. During Charge

- To continue charging, 6 /10 intervals must remain classified as FAST. FAST intervals are intervals that satisfy any rate zone cutoff (i.e., intervals with markers of VT-1, VT, or VF).
- If the number of FAST intervals in the window drops to 5/10, charging stops and a Divert-Reconfirm decision is declared. Reconfirmation classifies intervals slower than lowest zone's rate threshold as SLOW (i.e., those with VS and VP markers).
- If an arrhythmia spontaneously converts and pacing is required, paced pulses can decrement the count to 5/10 fast resulting in a Divert-Reconfirm decision.
- Once the Divert-Reconfirm decision is declared, normal brady pacing can continue.
- If QUICK CONVERT preceded the shock attempt, reconfirmation looks for four consecutive slow beats. If four consecutive slow beats are detected, charging stops and a Divert-Reconfirm is declared. This is due to the detection windows being cleared during the QUICK CONVERT attempt.



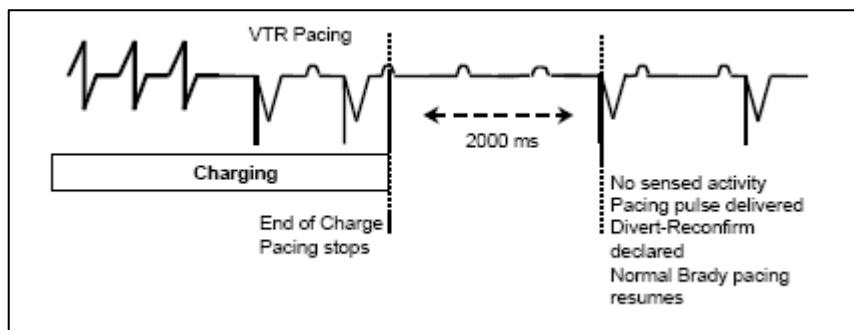
2. At the end of charge

If the charging cycle completes, the device:

- Inhibits pacing (if occurring) at the end of charging
- Ignores the first interval (annotated with “- -”) after the end of charge marker

NOTE: When charging stops, the end of charge marker (CHRG) forces an interval internally. The 135-ms refractory associated with that marker may contain events that would not be sensed nor generate interval markers. Therefore, the first interval after the CHRG marker, created by the first sensed R-wave after refractory, does not reflect an R-R interval but rather an end-of-charge to R-wave interval. For this reason, this first interval after charge is not used by the reconfirmation algorithm, and is indicated by a “- -” interval marker annotation on the stored EGM. Neither the CHRG marker nor the “- -” marker have an interval associated with them.

- Evaluates the rhythm. If 2/3 intervals are fast, the device delivers the shock. If 2/3 are slow, the device diverts the shock. If there are no sensed events for two seconds, a ventricular pacing pulse is delivered after two seconds, and the shock is diverted.



NOTE: A two-second timer starts when charging ends. If an R-wave is sensed prior to this two-second time elapsing, the timer restarts. As long as R-waves continue to be sensed within two seconds of the previous R-wave (≈ 30 bpm) the algorithm continues to look for 2/3 intervals to make its decision. This is to confirm whether the arrhythmia did indeed spontaneously terminate or that the signal amplitude of the arrhythmia deteriorated to the point that it was no longer able to be sensed. If there is a slow escape rhythm, but one that is faster than about 30 bpm (2000 ms), the patient can go without pacing support for several seconds while the device looks for two slow intervals to divert the shock.

- If required, normal brady pacing resumes after the diverted shock. Post-shock brady pacing occurs after a delivered shock (if programmed).

Divert-Reconfirm

When a divert-reconfirm decision is declared, pacing resumes at Normal Brady pacing parameters, and redetection begins.

- The device does not dump residual energy after a divert-reconfirm, but holds the charge on the capacitors. This may mean an extremely short charge time if recharging becomes necessary prior to energy completely dissipating.
- If the arrhythmia is redetected in a zone where ATP therapy is the next therapy, ATP can be delivered if no shocks have yet been delivered in the current episode.
- Device will not allow two consecutive divert reconfirms. If redetection occurs before End-of-Event timer expires, any resulting shock will be committed.
- All Committed Shocks are delivered immediately after capacitors charge, waiting only long enough to synchronize with an R-wave (or up to 2 seconds if no intrinsic events occur).

Notes/Additional Information

- In dual-chamber devices with Normal Brady pacing mode programmed AAI(R), there is no ATR/VTR pacing available. Consequently if a patient has a VT event which breaks during charge and there is no underlying rhythm, there is potential for a prolonged period of asystole. If no rhythm is sensed for two seconds, the shock is diverted. The device will still force a pace at end of post-charge timeout if no intrinsic rhythm detected.

- If the device charges to deliver therapy in one zone, but the rhythm slows to a zone where no therapy is programmed (that is, a *monitor only* zone), reconfirmation will still call the rhythm FAST as long as it meets the rate cut off of any zone.

Brady-Tachy Response (BTR) AV Squeeze

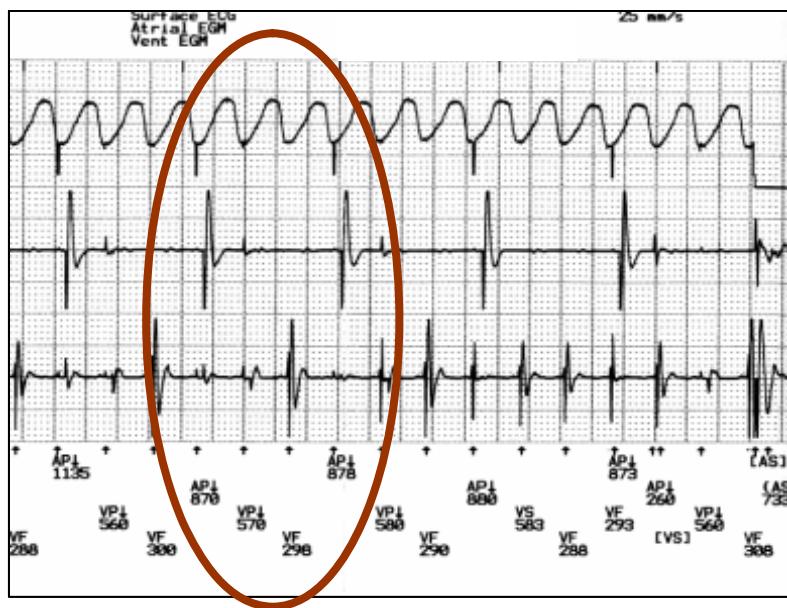


Brady-Tachy Response (BTR) is an algorithm designed to reduce undersensing conditions when certain programmed parameter combinations may interfere with ventricular tachy detection when the device is programmed with a dual-chamber pacing mode. Conditions present for undersensing which may lead to under detection of a ventricular arrhythmia when:

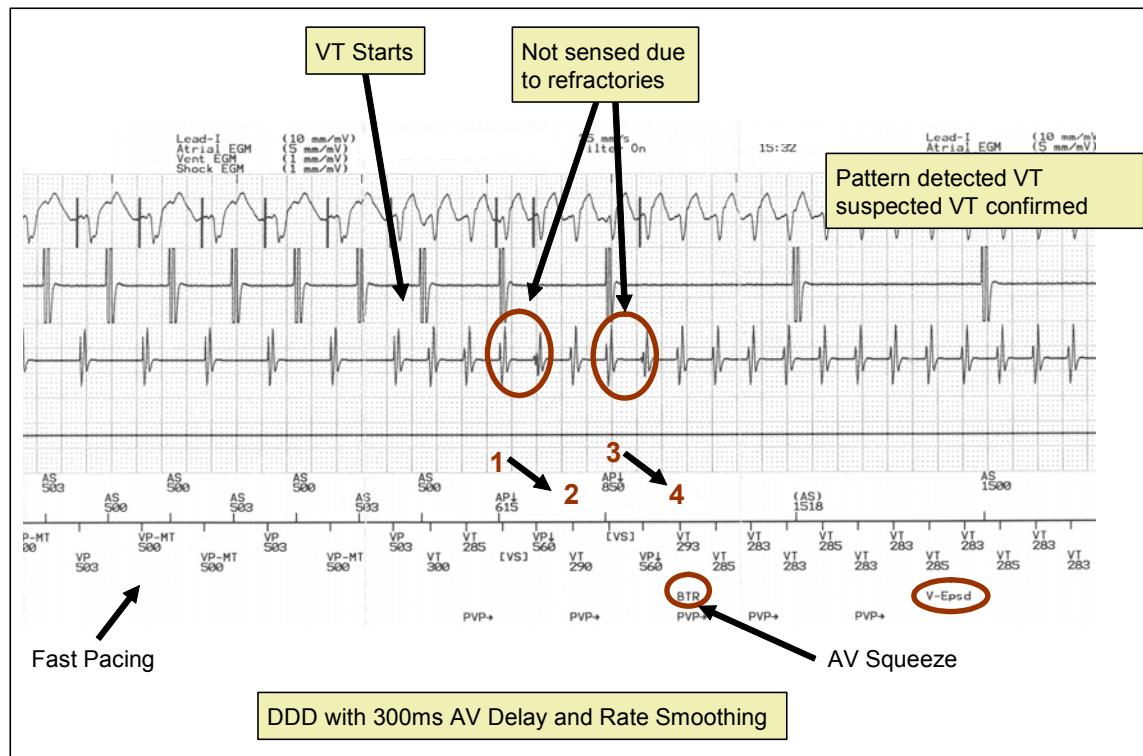
- The device is programmed to a dual-chamber pacing mode, and
- The calculated pacing rate, calculated AV Delay, and tachy rate zone cut-off are such that the lowest tachy rate cut-off interval \geq calculated pacing rate – calculated AV Delay.

While the presence of these conditions does not assure that an arrhythmia will be undersensed; however, it is mathematically possible for undersensing to occur if an arrhythmia is present, the equation is satisfied, and the device is atrial pacing. Rate enhancements, such as Rate Response, Rate Smoothing, VRR, ATR, APP/ProAct, have been observed to exacerbate the situation, because they elevate the pacing rate. It is possible to satisfy the equation (one of the necessary conditions) with LRL pacing provided that the tachy zone and AV Delay will also satisfy the equation.

The ultimate root cause of the undersensing is that a ventricular beat of an arrhythmia happens to coincide with the ventricular refractory/blanking period that is initiated in the ventricular sense channel following an atrial pace. Subsequent beats (of the arrhythmia) may also coincide with ventricular refractory/blanking periods that are initiated in the ventricular sense channel following either a ventricular pace or another atrial pace. The functional undersensing may be present for one or just a few beats, or it may persist.

Example:

This strip is a portion of a real-time induction, showing under detection. In this case, A-pace due to rate smoothing sets up a cross-chamber blanking window in the ventricle, blanking the VT beat. AV delay times out and V-pace occurs; refractory for the V-pace blanks another VT beat. Detection criteria (8/10) are never met. Patient was externally resuscitated.



BTR is designed to recognize and eliminate this under detection situation by automatically shortening the AV Delay (by increasing V-A timing) when a certain pattern of fast atrial pacing and fast ventricular beats is detected. When BTR is activated, the AV Delay is shortened and the V-A interval

is increased (i.e., the A-pace occurs later than the original timing indicated). When the atrial pacing is out of the way, the device can now confirm/deny the presence of the arrhythmia using the normal means. AV Delay is returned to normal if an arrhythmia is not confirmed.

Availability

- Applied during Normal Brady or Post-Therapy Brady pacing.
- Not applied during Temporary Brady pacing.
- Applied only during DDD(R) or DDI(R) pacing modes.
- Not applied:
 - During commanded device tests
 - Pacing thresholds
 - Intrinsic amplitude
 - Lead impedances
- Not applied if Tachy mode = OFF

Programmable Values

- None.
- Automatically activated when entry conditions met.
- Deactivated when exit conditions met.

Algorithm

Terminology:

- *fast AP*: Vx to AP interval that is fast (<) relative to lowest Tachy Rate Zone interval (LTRZi)
- *fast VS*: Vx to VS interval that is fast relative to LTRZi
- *slow V*: VP or Vx to VS interval that is slow (>) relative to LTRZi
- *safe V_AP interval*: LTRZi + 5ms
- *BTR*: Brady Tachy Response (i.e., the response of the pacemaker to a suspected ventricular arrhythmia – not to be confused with a response for Brady Tachy syndrome)

1. Monitor Conditions for VT Undersensing:

- If a fast AP occurs and it is eventually followed by a fast VS within this cardiac cycle or the next three cycles, then go to Confirm Conditions for VT Undersensing.
- If (after a fast AP) four slow V are detected prior to a fast V, then start over with Monitor Conditions for VT Undersensing.

- If a second or third (etc.) fast AP occurs prior to four slow V, then restart the slow V count at 0 (i.e., allow more time to detect a fast VS).
2. Confirm Conditions for VT Undersensing:
- Following the fast VS that was detected in the monitoring phase.
 - If four slow V occur, then start over with Monitor Conditions for VT Undersensing.
 - If a fast AP occurs and it is eventually followed by a fast VS, then go to Activate BTR.
 - Whenever a fast AP occurs prior to four slow V, then restart the slow V count at 0 (i.e., allow more time to detect a fast VS).
3. Activate BTR
- Output a BTR marker when BTR is initially activated.
 - For each subsequent cycle, if the regularly calculated V_AP interval is faster than ($<$) the Safe V_AP interval, then it is necessary to squeeze the AV Delay:
 - Squeeze the AV Delay by scheduling/using the Safe V_AP interval rather than the regularly calculated V_AP interval.
 - Check that the Safe V_AP interval still provides for at least 80 ms of AV Delay relative to the regularly calculated V to VP interval (i.e., the time of the next scheduled escape VP (not tracked VP): V to VP minus Safe V_AP should be greater than 80 ms).
 - × If at least an 80 ms AV Delay is not provided, then extend the escape VP by the amount that will provide for an 80 ms AV Delay – i.e., set the escape VP interval to the Safe AP interval + 80 ms.
 - × If at least an 80 ms AV Delay is provided, then don't change the regularly scheduled escape VP interval.
 - × Note that modified atrial-based timing will be included (if appropriate) in determining the regularly scheduled V_AP interval and escape VP interval.
 - For each subsequent cycle, if the regularly calculated V_AP interval is slower than (\geq) the Safe V_AP interval, then it is not necessary to squeeze the AV Delay for this cycle (i.e., just use the regularly calculated V_AP interval because the AV Delay is already short enough to not interfere with tachy sensing).
4. Deactivate BTR: Brady-Tachy Response will end when any of the following occur:
- Brady-Tachy is no longer applicable – e.g., episode declared, temporary brady, etc. (see below).
 - Pacing mode is changed to something other than DDD(R) or DDI(R).
 - Ten consecutive slow V cycles occur while BTR is in the active stage.

Notes/Additional Information

In previous ICD and CRT-D pulse generators, the PRM displayed an interactive limit (yellow) whenever the device was programmed to a dual-chamber pacing mode and: lowest tachy rate cut-off interval \geq fastest pacing rate – AV Delay for fastest pacing rate. For ICDs and CRT-Ds described in

this primer, this attention (yellow) is calculated/displayed only if: LRL (normal, post-shock, or ATR) satisfies the equation – regardless of whether the fastest pacing rate satisfies the equation.

- If LRL satisfies the equation, then BTR is not applicable (i.e., will never be activated) while that LRL is active (e.g., while post-shock is active) – so the undersensing conditions could occur during that time.
- The AV Delay for AV Search is used (when programmed on) for determining the attention (yellow) and therefore also for determining whether or not BTR is applicable. AV search is not used in combination with the ATR LRL.
- CRT-Ds only: If the device is pacing BiV with a negative LV offset, LV offset will be 0 while Brady-Tachy Response is active to avoid interactions.



Electrocautery Protection Mode

Physicians may consider programming when pacemaker-dependent patients undergo a surgical procedure where electrocautery will be used. Electrocautery Protection mode disables tachy therapy to prevent device from responding to EMI generated by electrocautery, but also provides asynchronous pacing, to prevent pacing inhibition.

Programmable Values

- Tachy mode: OFF
- Monitor Only
- Monitor + Therapy
- Electrocautery Protection

Navigation

To access Electrocautery Protection:

1. At the top of the screen select **Tachy Mode**
2. On the Change Device Mode dialog select **Enable Electrocautery Protection**
3. Select **Apply Changes**

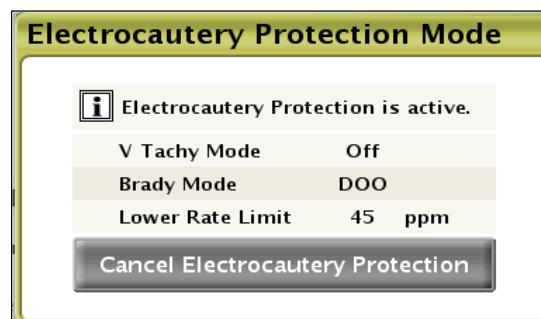


Clinical Application

Electrocautery Protection does not require constant telemetry; it is a programmed command. When Electrocautery Protection is selected:

- Tachy mode is immediately programmed OFF
- Normal Brady pacing mode is immediately programmed to asynchronous pacing in chamber(s) for which normal pacing is enabled
 - VOO if normal Brady pacing mode was programmed VVI(R) or VDD(R)
 - DOO if normal Brady pacing mode was programmed DDD(R) or DDI(R)
 - AOO if normal Brady pacing mode was programmed AAI(R)
 - Rate is the programmed LRL
 - Output is normal pacing amplitude and pulse width (post-shock parameters have no effect on this mode)
- If Brady mode is OFF, pacing will remain OFF if Electrocautery Protection is enabled.
- Only programmer functions available during Electrocautery Protection are STAT SHOCK, STAT PACE and ECG recorder.
- Application of a magnet while device is in the Electrocautery mode has no effect on the Tachy mode, regardless of how it is programmed.
- A constant tone will be emitted from the device if a magnet is applied if Tachy mode was OFF/Monitor Only before Electrocautery Protection was started; if Tachy mode was Monitor + Therapy before Electrocautery Protection was started, one beep per second will occur.

This screen will be displayed anytime a device is interrogated with Electrocautery Protection ON:



Special Situations	
Brady mode = OFF	<ul style="list-style-type: none"> • Only Tachy mode is affected • No change to Brady pacing status.
Tachy episode in progress when Electrocautery Protection mode is selected	<ul style="list-style-type: none"> • Programming not allowed. • Programmer displays message indicating episode is in progress.
ATR episode in progress	<ul style="list-style-type: none"> • Programming <i>is</i> allowed. Asynchronous pacing mode will be based on Normal Brady parameters, <i>not</i> Fallback mode.

Special Situations	
STAT SHOCK or STAT PACE	<ul style="list-style-type: none">If either STAT SHOCK or STAT PACE is selected, the Electrosurgery Protection is immediately exited and Tachy mode restored to previous settingIf STAT SHOCK is selected, pacing will return to Normal Brady settingsIf STAT PACE is selected, pacing will begin at STAT pacing parameters

How to Exit Electrosurgery Protection

- The only way to exit Electrosurgery Protection is to select Cancel Electrosurgery Protection on programmer message window.
- The device will return to settings prior to selection of Electrosurgery Protection.
- If ICD was programmed to Monitor Only, the device will be returned to Monitor Only not Monitor + Therapy.
- Previous settings are stored in the device and not programmer – any programmer can be used to cancel Electrosurgery Protection (even if programmer had been turned OFF or a different programmer was used, message will still appear).

Notes/Additional Information

- To document programming of Electrosurgery Protection mode, print real-time ECG while programming Electrosurgery Protection. Tracing will include a label *Electrosurgery Protection Enabled*. As with all tracings, time and date are printed at top.
- Use of MRI, although described in the system guides as a warning (see below), is sometimes deemed necessary by a physician. Electrosurgery Protection mode is the appropriate mode to use to suppress tachy detection and maintain asynchronous pacing; however, use of Electrosurgery mode in no way guarantees normal device operation during MRI.

WARNING: Magnetic Resonance Imaging (MRI) exposure.

Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

Monitor Only



A Monitor Only zone allows the physician to set up a detection zone to record rhythms that occur outside a therapy zone. For example, a Tachy Therapy zone may be set to 180 bpm, but the physician may wish to monitor rates from 150 to 180 for any possible arrhythmias. ICD and CRT-D devices described in the primer may be programmed with one monitoring zone, in either a two-zone or three-zone set-up. Previous families of devices allowed a Monitor Only zone in a three-zone set-up. When a Monitor Only Zone is programmed in a three-zone device, detection enhancements are available in

the VT zone. In previous families, detection enhancements that inhibited therapy (i.e., Onset) were not available when a Monitor Only zone was programmed.

Availability

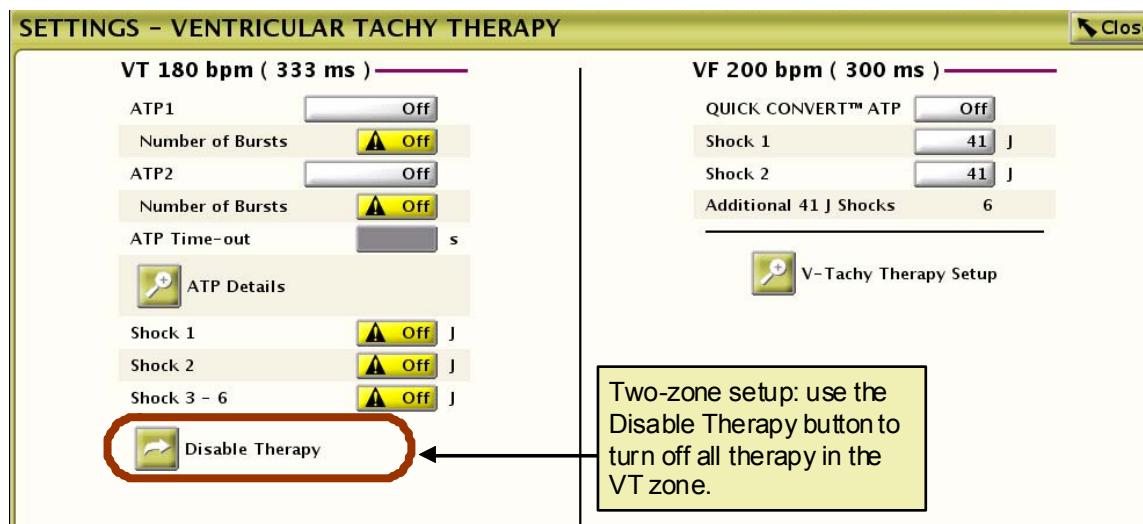
- Available only in a multiple zone setup.
- Only one zone may be set as monitor only (therapy disabled in that zone); either the VT or the VT-1 zone may be programmed with therapy disabled.
- From the Setting Summary screen, select  to select/view tachy therapy.

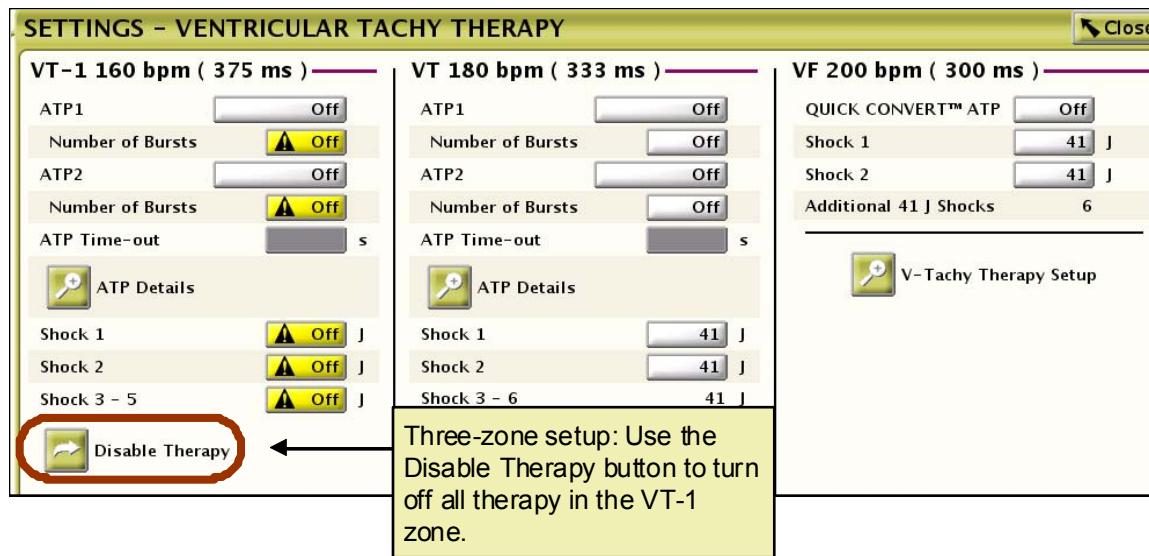
Programmable Values

In the VT or VT-1 zones, use the Disable Therapy button to turn off all therapy in that zone.

Algorithm

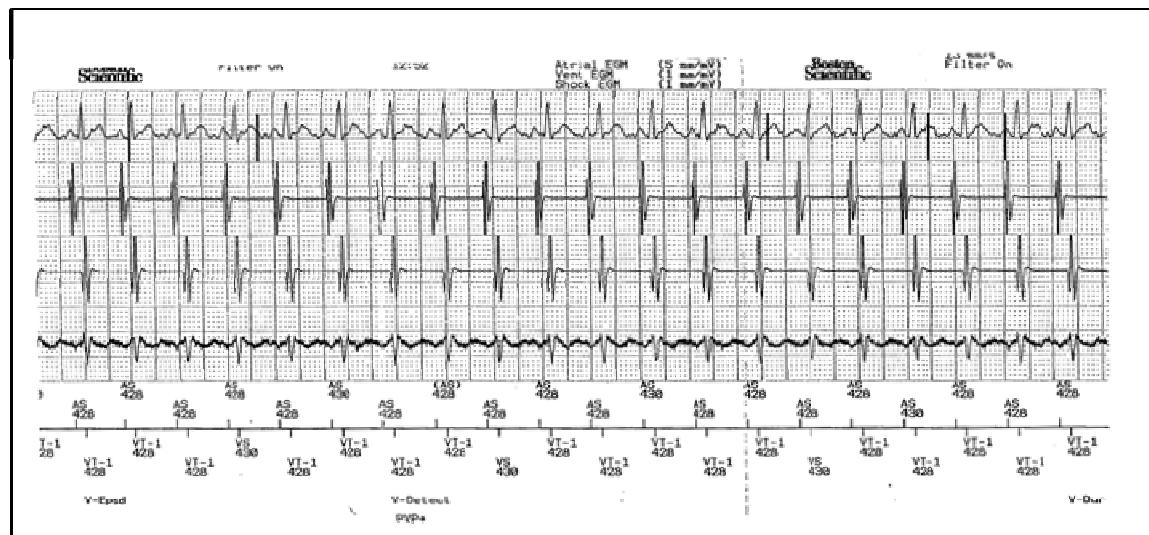
If a monitoring zone is used, the device will apply all detection criteria and detection enhancements to the monitoring zone, without applying any tachy therapy (ATP or shocks).

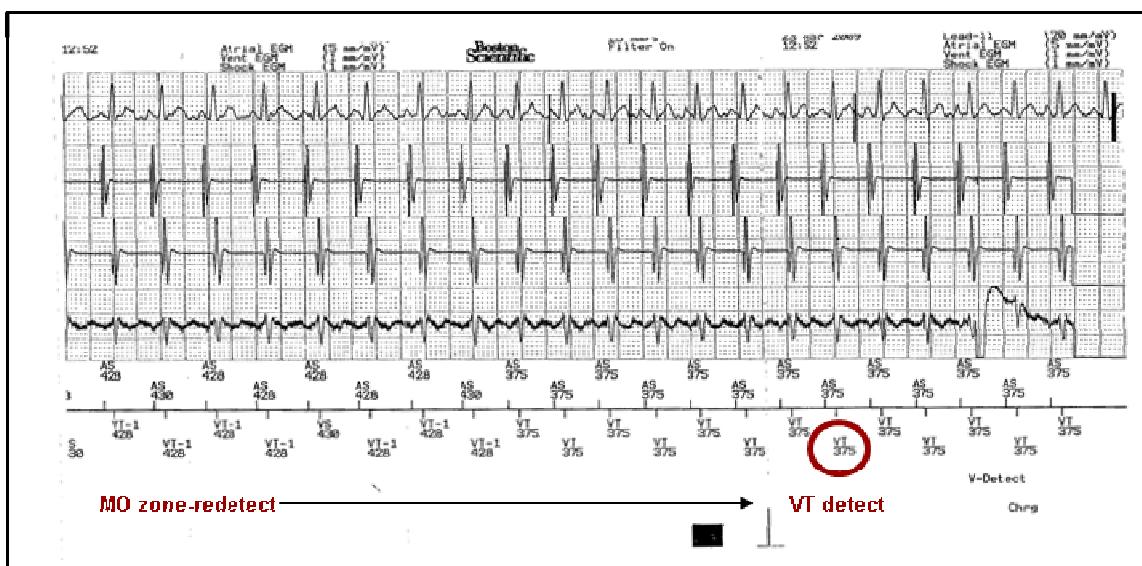




Notes/Additional Information

- Monitor Only events will appear in the Arrhythmia Logbook like any other event, but with the notation *No Therapy*.
- If all therapy is to be disabled in the device, use the Tachy mode to either turn tachy functions OFF or to Monitor Only. For either of these Tachy modes, tachy therapy would not be available.
- If programmed to a three-zone configuration with VT-1 programmed to Monitor Only and detection enhancements ON in the VT zone, rhythm discrimination will be applied when a tachycardia meets initial detection in the Monitor Only zone and the rate subsequently accelerates to the VT zone.
 - For INCEPTA, ENERGEN, and PUNCTUA devices, initial detection is restarted and detection enhancements are available in the VT zone.
 - For COGNIS and TELIGEN devices, detection enhancements are not available during Redetection if therapy was unavailable during initial detection (see example below).





TACHYARRHYTHMIA THERAPY



Shock Therapy

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Shock therapy may be customized to treat specific arrhythmias and maximize patient safety. The following table compares shock therapy features from previous products to COGNIS and TELIGEN. The features will also be described in detail in this section.

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
# of shocks: VT-1 Zone	<ul style="list-style-type: none"> • Maximum of 5 shocks. • Number of shocks programmable. • May disable all therapy in VT-1 zone. 	No change from previous devices.
# of shocks: VT Zone	<ul style="list-style-type: none"> • Maximum of 5 shocks. • Number of shocks is nonprogrammable. • May not disable therapy in VT zone. 	<ul style="list-style-type: none"> • Maximum of 6 shocks. • TWO-ZONE SETUP: • Number of shocks is programmable. • May disable all therapy in VT zone. • THREE-ZONE SETUP: • Number of shocks is nonprogrammable. • May not disable therapy in VT zone.

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
# of Shocks: VF Zone	Five plus up to 3 additional max energy shocks.	<ul style="list-style-type: none"> Nonprogrammable, 8 shocks are always available in the VF zone
Shock Energy	<ul style="list-style-type: none"> Shock energy for shocks 1 and 2 is programmable. Shocks 3-5 are max energy. Additional shocks VF zone are max energy. 	<ul style="list-style-type: none"> Shock energy for shocks 1 and 2 are programmable. Shocks 3-8 are max energy.
Constant Energy	Pulse width adjusted to accommodate differences in lead impedance to deliver constant energy.	<ul style="list-style-type: none"> No change from previous devices
Shock Delivery	Shock is delivered synchronous to sensed event, per rules of detection	<ul style="list-style-type: none"> No change from previous devices
Charge Time	<ul style="list-style-type: none"> Typical charge times at BOL: High Energy device: 7-8 secs 	<ul style="list-style-type: none"> Typical charge times at BOL: High Energy device: 8.8 secs
Shock Waveform	Biphasic or monophasic, programmable	<ul style="list-style-type: none"> Biphasic, nonprogrammable
Vector/Polarity	<ul style="list-style-type: none"> Vector is non-programmable, may be changed only through physical lead connection. Polarity is programmable 	<ul style="list-style-type: none"> Vector is programmable Polarity is programmable (Refer to Shock Vector and Polarity section for details.)
Committed/Noncommitted	Shocks may be programmed as committed or noncommitted; Noncommitted shocks are subject to reconfirmation during and post charge	No change from previous devices
Invert Last Shock Polarity	Available in VITALITY 2 as a programmable feature; not available in other devices	Nonprogrammable, polarity of last shock in a zone is usually inverted – see exception below

Shock Therapy – General Rules

- Detection rules must be followed for each zone in order to deliver therapy in that zone. Once therapy has been delivered, redetection rules determine if any further therapy will be delivered.

See the Initial Detection and Detection Enhancement topics for more details.

- Therapy delivered must always be of \geq strength of any previously delivered therapy.
- Therapy may be disabled in the lowest zone of a two- or three-zone setup. Therapy only may be disabled in a single zone.

- The maximum number of shocks delivered in any one episode is:
 - 5 if the rate stays in the VT-1 zone
 - 6 if the rate stays in the VT zone
 - 8 if the rate increases up into the VF zone.
- Once all available therapy has been delivered for an episode, no further therapy will be delivered during that episode; if the episode ends and a new episode begins, all therapy will again be available for the new episode.
- If the device is programmed for non-committed shocks, the device will not allow two consecutive diverted shocks; the shock following any diverted shock will be committed.

See the Reconfirmation topic for more details.

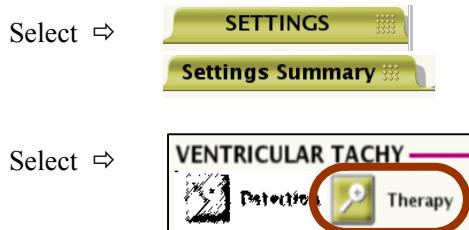
- Diverted shocks do not count against available shocks for an episode.
- STAT shocks do not count against available shocks for an episode.

Detection parameters and therapies in a three-zone configuration

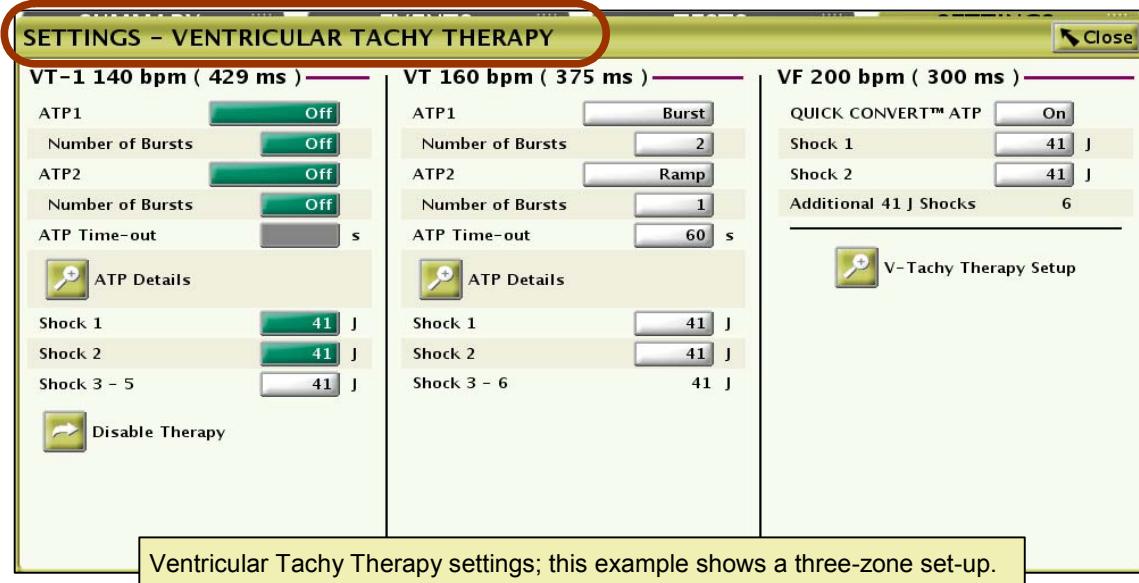
	Detection/ Duration		ATP Therapy	Redetection	Shock Therapy	Post-shock Redetection
VF zone	Rate/Duration		Quick Convert™ ATP	Redetect Duration	Up to 8 Shocks	Redetect Duration Post-shock Duration
VT zone	Rate/Duration	Polymorphic VT accelerator or Rhythm ID SRD	ATP1 ATP2	Redetect Duration Polymorphic VT accelerator	Up to 6 shocks	Redetect Duration Post-shock Duration Post- shock Detection Enhancement Post-shock SRD
VT-1 zone	Rate/Duration	OBDE or Rhythm ID SRD	ATP1 ATP2	Redetect Duration	Up to 5 shocks No shocks	Redetect Duration Post-shock Duration Enhancement Post-shock SRD
Brady	DDR(R)/SSI(R) Pacing					Post-shock DDD(R) Pacing

Programmable Values

To navigate to shock parameters:

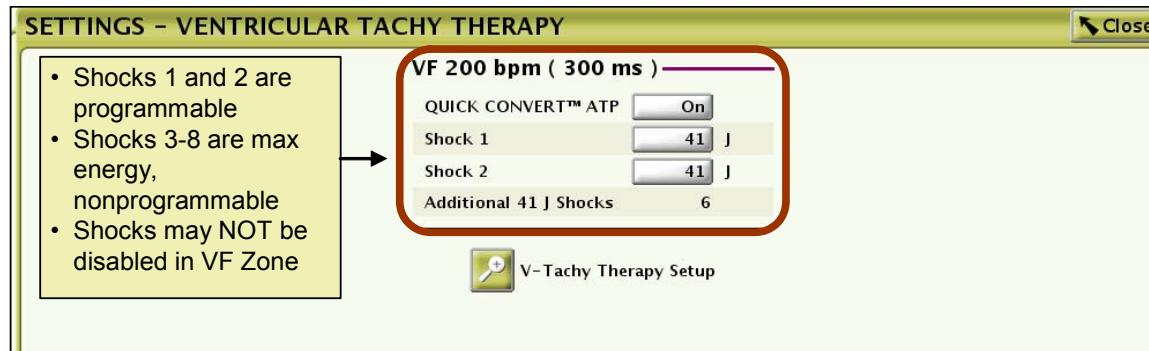


From the Settings Summary screen select:



Number of shocks, One-Zone Setup, VF Zone only – in previous devices, the device delivered five shocks in the VF zone automatically, with the programmable option to add up to three additional shocks. ICD and CRT-D devices described in this primer provide a total of eight shocks automatically in the VF zone; no programming is needed.

NOTE: QUICK CONVERT ATP is available in the VF zone prior to shock delivery.

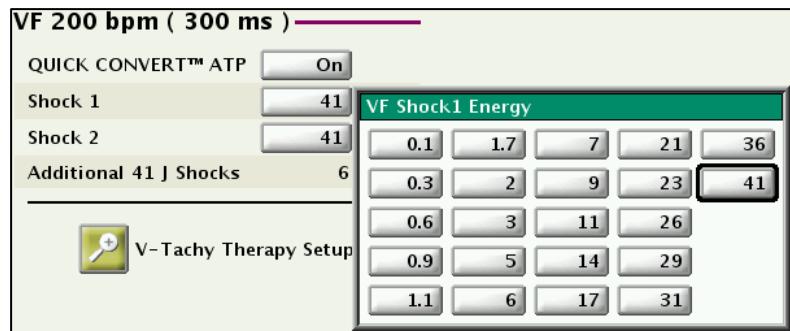


See the *QUICK CONVERT ATP* topic for more information.

One-Zone Setup: VF

Zone Programming

- Shock energy is programmable for shocks 1 and 2, with energies from 0.1 to 41 joules, nominal value = 41 joules.
- Shock therapy may not be disabled in the VF zone.
- Shock energy for Shock 1 must be \leq Shock 2 energy.



SETTINGS – VENTRICULAR TACHY THERAPY

VT 160 bpm (375 ms)

ATP1

Number of Bursts

ATP2

Number of Bursts

ATP Time-out

ATP Details

Shock 1

Shock 2

Shock 3 – 6

Disable Therapy

VF 200 bpm (300 ms)

QUICK CONVERT™ ATP On

Shock 1

Shock 2

Additional 41 J Shocks

V-Tachy Therapy Setup

2-Zone Setup: VT Zone

- Shocks 1 and 2 are programmable
- Shocks 3-6 are max energy or Off
- All shocks may be disabled in VT Zone
- All therapy (ATP and shocks) may be disabled in the VT Zone

2-Zone Setup: VF Zone

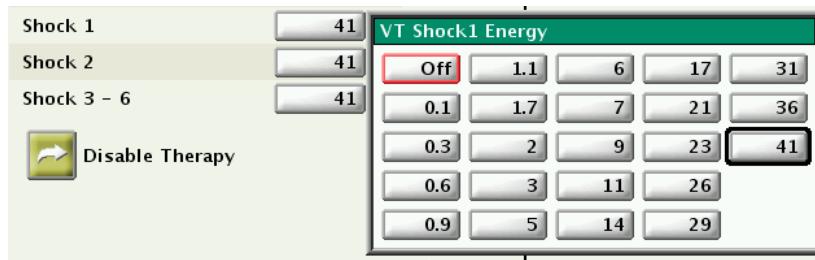
- Shocks 1 and 2 are programmable
- Shocks 3-8 are max energy, nonprogrammable
- Shocks may NOT be disabled in VF Zone

Number of Shocks, Two-Zone Setup: VT and VF Zones – in previous devices, the device delivered five shocks in the VT and VF zones, with the programmable option to add up to three additional shocks in the VF zone. Previous devices did not allow disabling all therapy in a two-zone setup. In a two-zone setup, ICDs and CRT-Ds described in this primer provide:

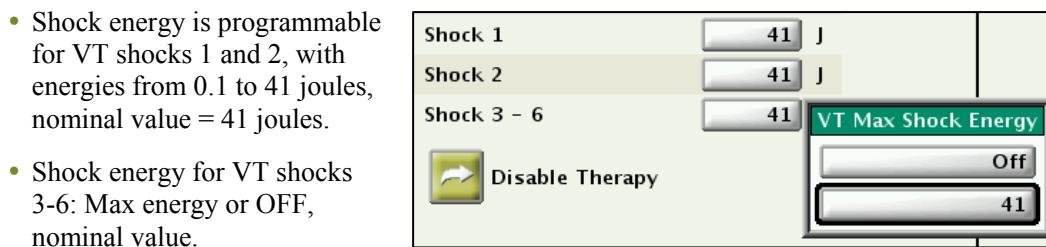
- Up to six shocks in the VT zone
- Up to a total of eight shocks automatically in the VF zone
- Shock therapy may be disabled entirely in the VT zone, allowing The VT zone to be used as a monitoring zone, or to provide ATP only

NOTE: Up to two schemes of ATP therapy are available in the VT zone.

See ATP topic for more information.



Two-Zone Setup: VT and VF Zone Programming



- Shock energy is programmable for VT shocks 1 and 2, with energies from 0.1 to 41 joules, nominal value = 41 joules.
- Shock energy for VT shocks 3-6: Max energy or OFF, nominal value.
- All shock therapy may be disabled in the VT zone.
- All therapy (ATP and shocks) may be disabled in the VT zone.
- Shock energy for VT Shock 1 must be \leq VT Shock 2 energy.
- If Shock 2 is programmed ON, Shock 1 must also be programmed ON.
- If max energy shocks (shocks 3-6) are programmed ON, Shocks 1 and 2 must also be programmed ON.
- Shock energy is programmable for Shocks 1 and 2, with energies from 0.1 to 41 joules, nominal value = 41 joules.
- Shock therapy may not be disabled in the VF zone.
- Shock energy for VF Shock 1 must be \leq VF Shock 2 energy.

SETTINGS – VENTRICULAR TACHY THERAPY

VT-1 140 bpm (429 ms)	VT 160 bpm (375 ms)	VF 200 bpm (300 ms)
ATP1 Off	ATP1 Burst	QUICK CONVERT™ ATP On
Number of Bursts Off	Number of Bursts 2	Shock 1 41 J
ATP2 Off	ATP2 Ramp	Shock 2 41 J
Number of Bursts Off	Number of Bursts 1	Additional 41 J Shocks 6
ATP Time-out 60 s	ATP Time-out 60 s	
ATP Details Shock 1 41 J Shock 2 41 J Shock 3 – 5 41 J Disable Therapy		
ATP Details Shock 1 41 J Shock 2 41 J Shock 3 – 6 41 J		

3-Zone Setup: VT-1 Zone

- Shocks 1 and 2 are programmable
- Shocks 3-5 are max energy or Off
- All shocks may be disabled in VT-1 Zone
- All therapy (ATP and shocks) may be disabled in the VT -1 Zone

3-Zone Setup: VT Zone

- Shocks 1 and 2 are programmable
- Shocks 3-6 are max energy
- Shocks may NOT be disabled in the VT zone

3-Zone Setup: VF Zone:

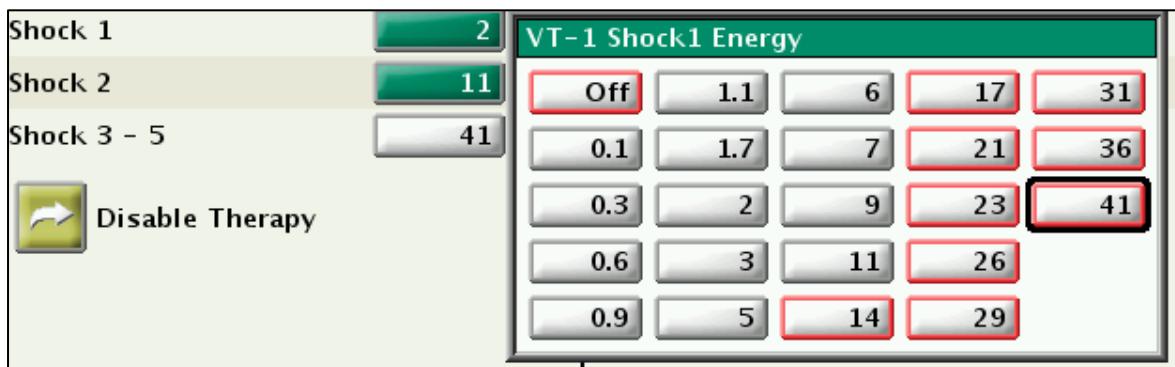
- Shocks 1 and 2 are programmable
- Shocks 3-8 are max energy, nonprogrammable
- Shocks may NOT be disabled in VF Zone

Number of shocks, Three-Zone Setup: VT-1, VT and VF Zones – in previous devices, the device delivered up to five shocks in the VT-1, VT, or VF zones with the programmable option to add up to three additional shocks in the VF zone. In a three-zone setup, ICD and CRT-D devices described in this primer provide:

- Up to five shocks in the VT-1 zone
- Up to six shocks in the VT zone
- Up to a total of eight shocks automatically in the VF zone
- Shock therapy may be disabled entirely in the VT-1 zone, allowing The VT-1 zone to be used as a monitoring zone, or to provide ATP only

NOTE: Up to two schemes of ATP therapy are available in the VT-1 and VT zones.

See ATP topic for more information.



Three-Zone Setup: VT-1, VT and VF Zone Programming

- Shock energy is programmable for VT-1 Shocks 1 and 2, with energies from 0.1 to 41 joules, nominal value = 41 joules.
- All shock therapy may be disabled in the VT-1 zone.
- Shock energy for VT-1 Shocks 3-5: Max energy or OFF, nominal value.
- All therapy (ATP and shocks) may be disabled in the VT-1 zone.
- Shock energy for VT-1 Shock 1 must be \leq VT-1 Shock 2 energy.
- If Shock 2 in the VT-1 zone is programmed ON, Shock 1 must also be programmed ON.
- If VT-1 max energy shocks (shocks 3-5) are programmed ON, Shocks 1 and 2 must also be programmed ON.
- Shock energy is programmable for VT Shocks 1 and 2, with energies from 0.1 to 41 joules, nominal value = 41 joules.
- Shock energy for VT shocks 3-6: Max energy or OFF, nominal value.
- Shock energy for VT Shock 1 must be \leq VT Shock 2 energy.
- Shock energy is programmable for VF Shocks 1 and 2, with energies from 0.1 to 41 joules, nominal value = 41 joules.
- Shock energy for VF Shock 1 must be \leq VF Shock 2 energy.
- Shock therapy may not be disabled in the VF zone.

Constant Energy

Shock energy output levels remain constant over the lifetime of the device, unaffected by lead impedance or battery voltage. Since the point where the pulse width is truncated is tied to a specific decrease in voltage and not a fixed-pulse width, the pulse width is automatically varied to handle changes in system impedances; the higher the shocking impedance, the longer the pulse width. Battery voltage does not affect energy delivery since the internal voltage regulation makes the amplitude independent of the battery voltage.

Shock Delivery

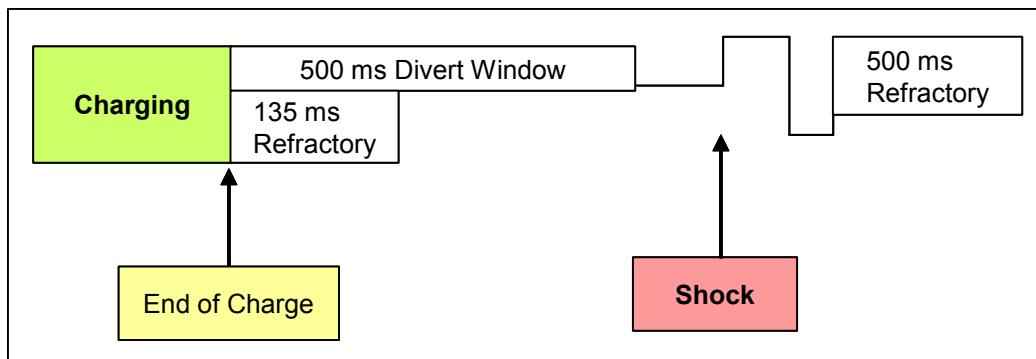
Shocks are delivered synchronously to a sensed R-wave, unless there are no events to be sensed. In that case, the shock is delivered asynchronously after no device has been sensed for two seconds. If the shock is non-committed, then the device will start pacing at the lower rate limit and the shock will be internally diverted.

Once all programmed shocks have been delivered for an episode, no further therapy can be delivered for that episode (except STAT shocks). Only shocks that have actually been delivered count against total shocks for an episode. If a shock is diverted, through reconfirmation, or manually diverted via the programmer or magnet, the diverted shock does not count toward total shocks available for that episode.

The device determines which shock to deliver based on the detected rate prior to the capacitors charging. At the end of charging, the following are in effect:

- Non-programmable 500 ms divert window at the end of charge
- Non-programmable 135 ms refractory period at end of charge
- Non-programmable 500 ms post shock refractory period (was 250 ms in previous device families)

NOTE: The first sensed event after shock delivery will be unclassified, i.e., marked as “- -”. A paced event following shock delivery will always be classified with a pace marker.



Charge Time

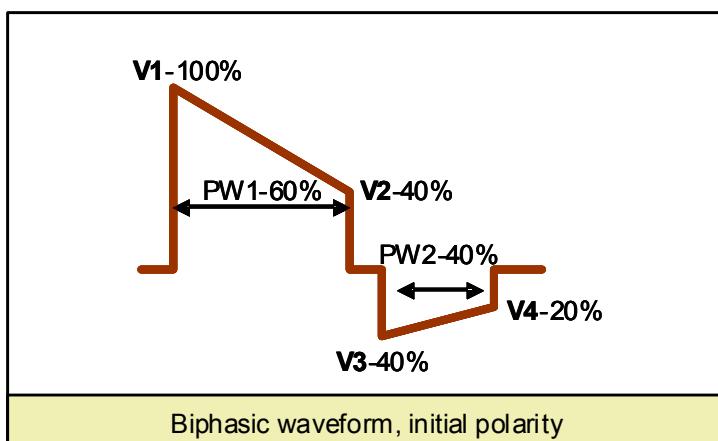
- ICDs and CRT-Ds described in this primer operate on a one-cell battery and their charge times are similar to VITALITY 2 family of devices.
- Charge time is assessed automatically whenever an automatic capacitor reform or therapy shock is performed.

See the Battery Status Assessment topic for more details on Charge Time.

Shock Waveform

Previous devices delivered energy through biphasic waveform with the option to program the waveform to monophasic. Based on Guidant and industry experience with biphasic waveforms, and

their proven effectiveness, ICDs and CRT-Ds described in this primer deliver energy via a biphasic waveform only, with no programmable options. With biphasic waveforms, current delivery begins in one direction from the shock electrodes and then after a portion of the energy is delivered, the current is delivered in the reversed.



This biphasic waveform in BSC CRM devices is referred to as having an *80% tilt*. This means the trailing edge voltage of the shock waveform is 20% of the leading edge voltage. The difference between the leading and trailing edge is an 80% drop (tilt) in voltage. This is accomplished in the following manner:

- Phase 1 is truncated after the Phase 1 leading edge voltage (V1) has dropped by 60% ($100\% - 60\% = 40\%$).
- The trailing edge voltage of Phase 1 (V2) equals the leading edge voltage of Phase 2 (V3).
- Phase 2 is truncated after the Phase 2 leading edge voltage (V3) has dropped by 50% ($50\% \times 40\% = 20\%$).

Vector/Polarity

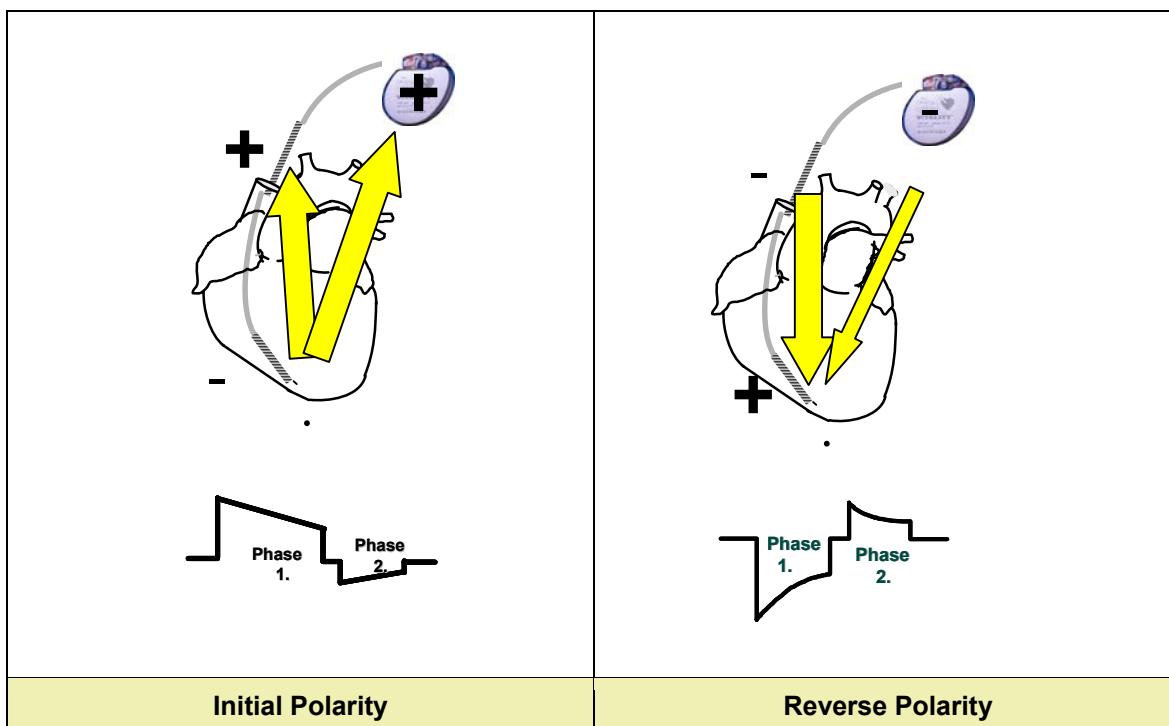
See the Shock Vectors section for more details.

Committed/Noncommitted

See the Reconfirmation topic for more details.

Invert Last Shock

If all the shocks available in an episode are delivered, the polarity of the last shock for each zone will be the reverse of the programmed polarity. Some physicians believe that delivering the last shock in a therapy zone with inverted polarity (compared to the previous shocks) is appropriate if a patient has not converted following the previous shocks in that zone. Shock Polarity refers to the direction of shock energy delivery.



In VITALITY 2 Invert Last Shock Polarity is programmable; this feature was not available in other device families. For ICDs and CRT-Ds described in this primer, the last shock delivered in any zone will have a polarity opposite that of the previous shocks delivered. The ability to reverse the polarity of the last shock is automatic (not programmable).

The device will reverse polarity for a shock if:

- The shock is the last shock available in that zone.
- The previous shock did not have reversed polarity.

Example 1: The patient has VF appropriately detected in the VF zone and does not convert after the first seven shocks. The eighth and final shock in the VF zone would be delivered with inverted polarity.

Example 2: A device has three zones programmed. The patient has an arrhythmia that is treated with shocks in the VT-1 zone. The rhythm did not convert after the first four shocks; the fifth and final shock in the VT-1 zone would be delivered with inverted polarity.

Example 3: A device has three zones programmed. The patient has an arrhythmia that is detected and treated in the VT zone. Five shocks are delivered, and the patient's rhythm is not converted. The sixth shock in the VT zone is delivered with inverted polarity. Then the rhythm accelerates to the VF zone, and one more shock is delivered using the programmed polarity. The patient's rhythm is still not converted. The last shock (eighth over all) also has inverted polarity.

Example 4: A device has three zones programmed. The arrhythmia is detected and shocks are delivered as follows:

- Detected in the VT-1 zone

- VT-1 shocks 1–4 delivered with programmed polarity, redetection met
- VT-1 shock five delivered with reversed polarity
- Rhythm accelerates to VT zone
- VT shock delivered with programmed polarity – not reversed because previous shock was reversed
- Rhythm accelerates to the VF zone
- VF shock seven delivered with programmed polarity, redetection met
- VF shock eight delivered with reversed polarity

Notes/Additional Information

- All programmed displayed, or reported values for shock energy are stored energy values. In general, stored energy values are approximately 14% higher than delivered energy.
- Parameter interactions (*red warning bar* on bottom of screen) will occur if an attempt is made to program values that are not allowed. Any warnings on the bottom of the screen must be resolved by entering the acceptable value before the device may be programmed. Refer to the Parameter Interactions section for details.
- During DFT Testing, if after induction a patient's rhythm spontaneously breaks after device begins to charge, the device will divert. Unlike PRIZM-based devices, the charge after the divert is held on the capacitors and will bleed off slowly. If another induction is attempted, the charge on a subsequent shock might be noticeably shorter, but the programmed energy will be accurate. If it is desired to not have *this short charge time* occur, a Manual Capacitor Reform can be commanded. This will cause the device to dump whatever charge it has stored and the next induction sequence will exhibit normal time to charge for the desired shock energy.

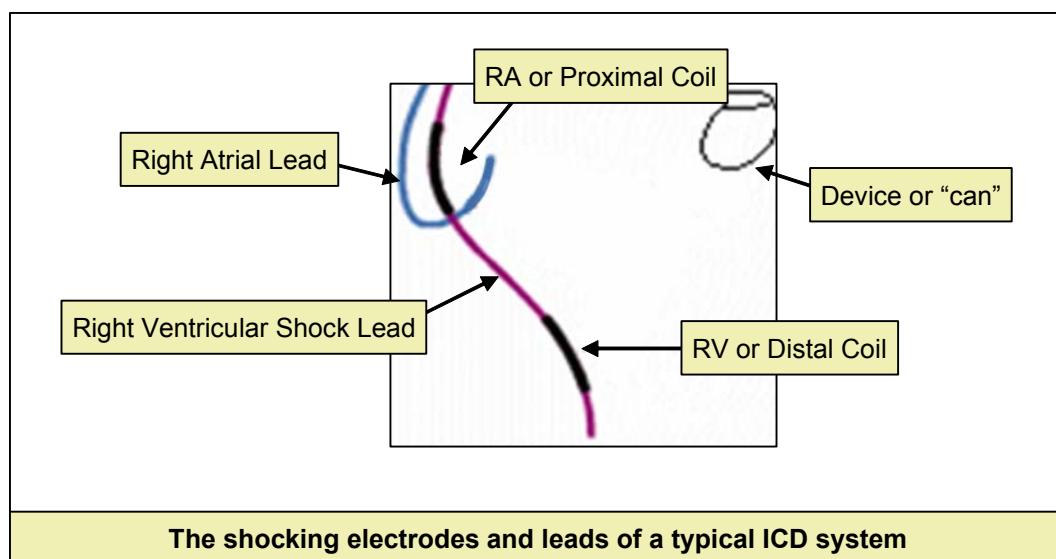
Shock Vectors



Shock vector and polarity define the shock energy delivery pathway within the patient's body. Shock vector refers to which shock electrodes are used to deliver the shock energy; and shock polarity refers to the direction of the current during shock energy delivery.

NOTE: For the purposes of describing shock energy delivery, we describe current as flowing from positive (anode) to negative (cathode).

In previous BSC CRM device systems, the only way to change shock energy delivery vectors was to physically change how leads were connected to the device (e.g., unplug the proximal coil to achieve the RV Coil-to-Can vector). Additionally, in previous devices, the Can always served as a shock electrode (i.e., the Can was always *hot*).



For an individual patient, a change to the direction of current flowing during energy delivery could affect the amount of energy needed to convert an arrhythmia. For the ICDs and CRT-Ds described in this primer shock vectors are programmable, which means that shock vectors can be changed non-invasively via the programmer. The shock vector uses three possible shocking electrodes:

1. RV or distal coil
2. RA or proximal coil
3. Device or Can itself.

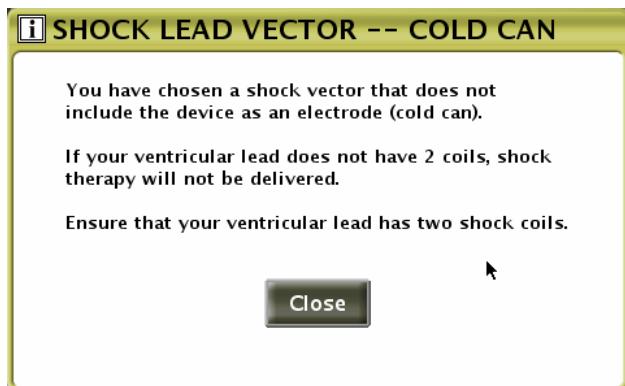
NOTE: When the Can is not chosen as an electrode, it is considered to be *cold*.

When the three shock vectors are combined with programmable shock polarity (positive or negative), there are six shock therapy delivery options.

Availability

- When a dual shock electrode lead is used with the device, all shock lead vectors may be used.
- If a single shock electrode lead is present, RV Coil to RA Coil should not be used as a shock will not be delivered.
- Every shock circuit requires at least one positive and at least one negative pole. It is very important to check whether the shock lead has dual or single shock electrodes when programming shock lead vectors.

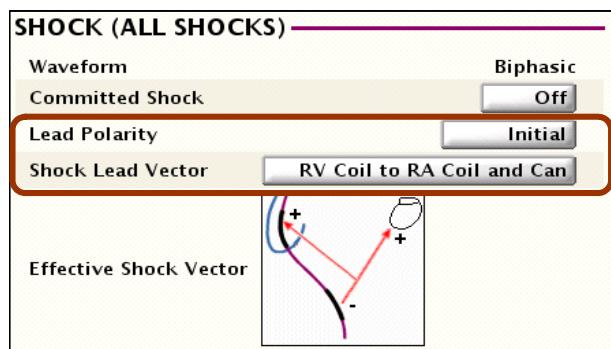
NOTE: If RV-coil to RA-Coil is chosen, an alert window will provide a reminder to verify that a dual electrode lead is required.



Programmable Values

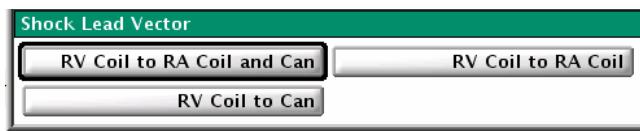
Shock Therapy parameters may be programmed on the Ventricular Tachy Therapy Setup screen:

- From the Settings Summary screen select
- From the Ventricular Tachy Therapy screen select
- Select Polarity or Shock Lead Vector on the Ventricular Tachy Therapy Setup screen:



Shock Lead Vector

- Nominal: RV-Coil to RA-Coil and Can.
- Shock Lead Vectors and Polarity combinations; arrows indicate shock delivery pathway.



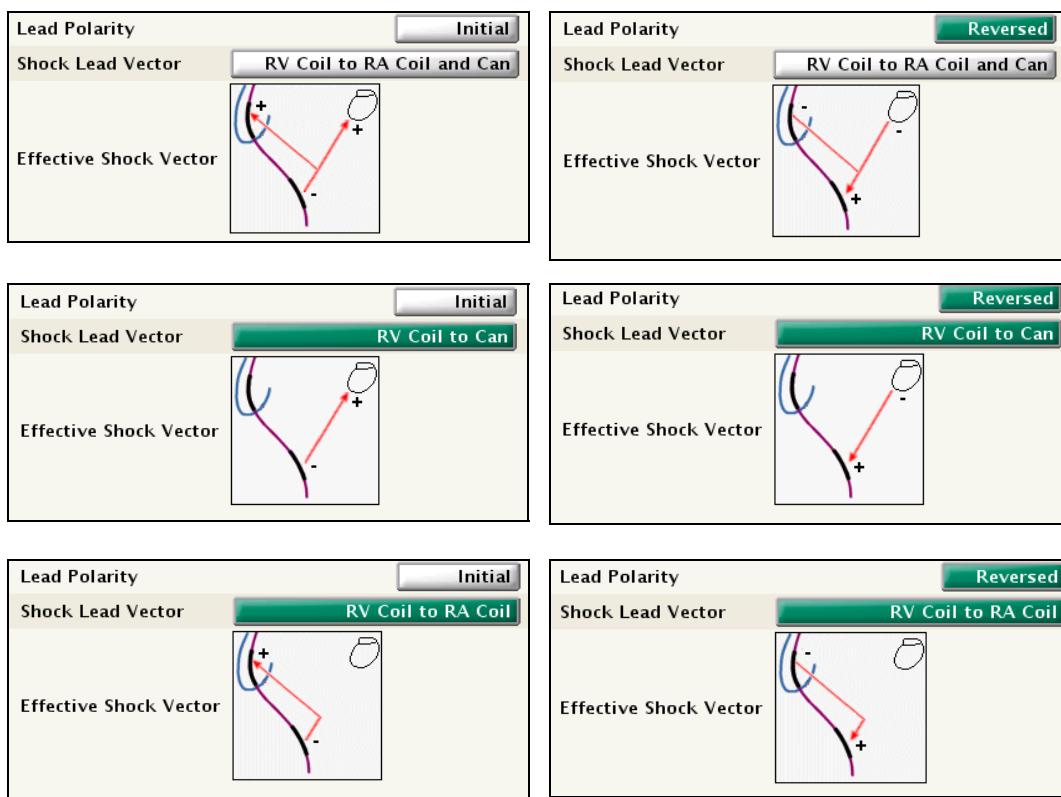
Lead Polarity

- Nominal Initial.
- Initial Polarity:
- RV Coil is negative for first phase.
- RA Coil is positive for first phase.
- Can is positive for first phase.



- Reverse Polarity:
- RV Coil is positive for first phase.
- RA Coil is negative for first phase.
- Can is negative for first phase.

Shock Lead Vectors and Polarity Combinations; arrows indicate shock delivery pathway



Reports

Shock vector and polarity programmed values are shown on the Device Settings Report.

Interpreting/Clinical Applications

- The shock EGM is always collected through the RV (Distal) Coil-to-Can vector, regardless of the programmed Shock Vector.
- If Rhythm ID is programmed ON, the device will use the RV (Distal) Coil-to-Can vector, to collect morphology signals for vector timing correlation, regardless of the programmed Shock Vector.

- The shock lead integrity test is performed using the programmed Shock Vector and Polarity, i.e., it uses the same pathway that a delivered therapy shock would use.

Notes/Additional Information

- Changes to shock polarity should only be done through programming. Always place the RV or distal coil terminal pin in the negative DF-1 port, and the RA or proximal coil in the positive DF-1 port.
- If a 4-SITE²⁵ lead is used, the only way to change the shock vector is through reprogramming.
- There is no connection between the lead information entered on the Patient Data screen and the shock lead configuration. The user must verify shock lead type (i.e., dual or single shock electrode) to be sure that the shock vector is programmed appropriately.
- If an IS-1/DF-1 lead is used, the proximal coil may still be capped at implant; however, if this is done it is good practice to document this condition in the Notes section of the Patient Data screen for future reference/reprogramming.
- If the RA or proximal coil is capped, RV Coil-to-RA Coil should not be used. Also, ensure that the device is placed in the pectoral/abdominal pocket before proceeding with any testing.

Ventricular Antitachycardia Pacing (ATP) Therapy

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Antitachycardia Pacing (ATP) therapy and parameters enable the pulse generator to interrupt the following fast rhythms by delivering a series of critically timed pacing pulses:

- Monomorphic ventricular tachycardia
- Supraventricular tachycardias

An ATP scheme consists of one or more bursts. Each burst is typically made up of several pacing pulses. The basic timing of these pacing pulses is controlled by:

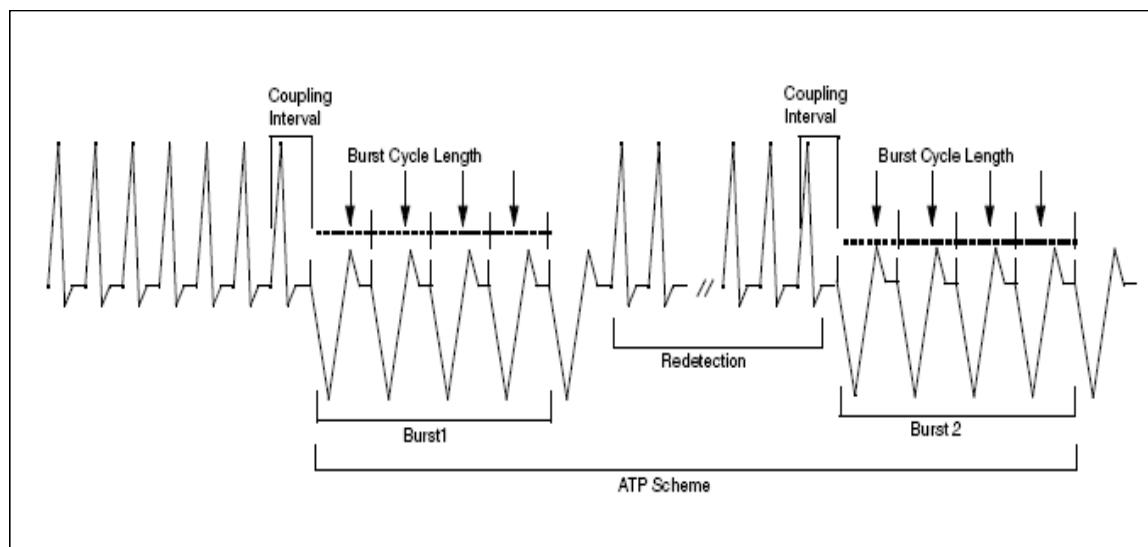
- The **Coupling Interval**, which controls how closely the first pulse in the burst will follow the sensed R-wave (i.e., time between last sensed event and first pace pulse in the burst)
- The **Burst Cycle Length**, which controls the timing of the remaining pulses within the burst

Up to two ATP schemes may be programmed in each of the lower zones in a multi-zone configuration. An ATP scheme may be customized with the following parameters:

- Number of bursts delivered
- Number of pulses within each burst

²⁵ May not be available in all geographies

- Coupling Interval
- Burst Cycle Length
- Minimum pacing interval



In CRT-D devices ATP is delivered Bi-V (i.e., to both the RV and LV) with the equivalent of zero LV Offset and uses the programmed LV lead configuration. Output (amplitude and pulse width) for RV and LV are separately programmable.

Availability

- Available in both the VT-1 and VT zones. Two ATP schemes are programmable in each zone.
- Programmable ATP schemes are not available in a one-zone configuration.
- ATP is available in the VF zone as QUICK CONVERT ATP (fixed parameters) only.

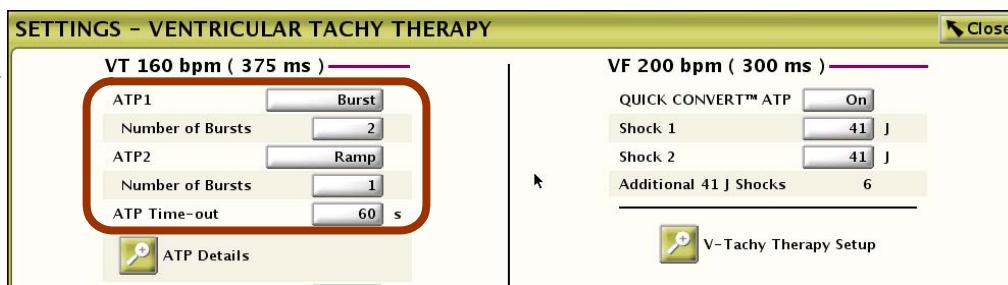
See the QUICK CONVERT topic for more details.

Navigation to ATP Parameters

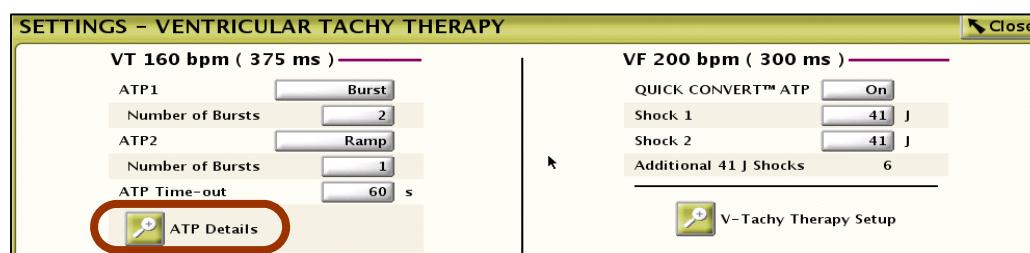
From the Settings Summary screen select ⇒



From the Ventricular Tachy Therapy screen select \Rightarrow ATP Details to program parameters relating to scheme and number of bursts.



From the Ventricular Tachy Therapy screen select \Rightarrow ATP Details to program parameters relating to decrements, intervals within the burst.



Programmable Values

ATP Type – the following ATP types are available:

- **Burst** pacing scheme is clinically defined as three or more pacing pulses delivered in the same attempt. This type of scheme is probably the most commonly used. (Single pulses and doubles are also considered *bursts* by the system.) A burst scheme on the menu is the simplest type and least aggressive ATP scheme, with no changes from one delivered burst of ATP to the next.
- **Ramp** is a burst scheme that shortens the intervals between pulses within the burst. A ramp pacing scheme is programmed by using a ramp decrement. The principles of Ramp Decremental pacing, also known as *auto decremental pacing*, are the same as for all burst techniques: to penetrate the intervening tissue and provide a critically timed pacing pulse to

break the reentry circuit. The shortening of each subsequent pacing interval *peels back* the refractory periods of the intervening tissue allowing subsequent pacing intervals to be faster (shorter).

Example: CI = 300 ms, BCL = 300 ms, Ramp = 10, CI Decrement = 0 ms

All bursts = 300, 300, 290, 280, 270, 260

Scan is a sequence of related bursts that systematically shortens the interval from one burst to the next. A scan can be programmed by using:

- **Scan Decrement** which designates the interval decrease between bursts.
- **Coupling Interval Decrement** which shortens the time between the last sensed R-wave and the first pacing from one burst to the next.

Example: CI = 300 ms, BCL = 300 ms, Scan Decrement = 10, CI Decrement = 0 ms

1st burst = 300, 300, 300, 300, 300

2nd burst = 300, 290, 290, 290, 290

Ramp/Scan applies both a decrement between pulses and a decrement between bursts. This is the most aggressive ATP scheme (i.e., may possibly be pro-arrhythmic).

Example: Initial CI/BCL = 300 ms, Ramp = 10, Scan = 10, CI Decrement = 0 ms, Minimum Interval = 250 ms

1st burst = 300, 300, 290, 280, 270, 260

2nd burst = 300, 290, 280, 270, 260, 250

3rd burst = 300, 280, 270, 260, 250, 250

In all ATP schemes, the burst is delivered in VOO mode. The normal paced ventricular refractory period is applied following the last pulse of a burst after which the ventricular sensing window is available for detection.

Number of Bursts - Nominal: 4.

- Number of pacing attempts, or bursts included in each ATP scheme.
- Programmable from OFF, 1-30. If OFF is chosen, the ATP scheme will not be used.
- If programmed to 1, Coupling Interval Decrement and Scan Decrement are not applicable because there are no further bursts.
- Each burst is followed by redetection sequence (i.e., 8/10, 6 /10 maintained during Duration, Last interval is in the zone at the end of Duration). Redetection must be met to deliver the next ATP burst.

VT ATP1 Number of Bursts					
Off	6	12	18	24	30
1	7	13	19	25	
2	8	14	20	26	
3	9	15	21	27	
4	10	16	22	28	
5	11	17	23	29	

- If the rhythm remains in the same zone once the programmed number of bursts has been delivered, the next therapy delivered is either the second programmed ATP scheme or shock therapy (if shocks are programmed ON in that zone).

Pulses per Burst, Increment, Maximum Number of Pulses

Three parameters determine how many pulses will be delivered in a burst:

- Initial Pulses per Burst
- Increment
- Maximum number of pulses

VT ATP1 Initial Pulses per Burst				
1	7	13	19	25
2	8	14	20	26
3	9	15	21	27
4	10	16	22	28
5	11	17	23	29
6	12	18	24	30

Pulses per Burst Nominal: 10

Increment Nominal: 0

VT ATP1 Pulse Increment per Burst		
0		3
1		4
2		5

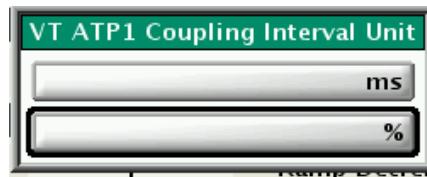
Maximum Nominal: None

VT ATP1 Maximum Pulses per Burst				
1	7	13	19	25
2	8	14	20	26
3	9	15	21	27
4	10	16	22	28
5	11	17	23	29
6	12	18	24	30

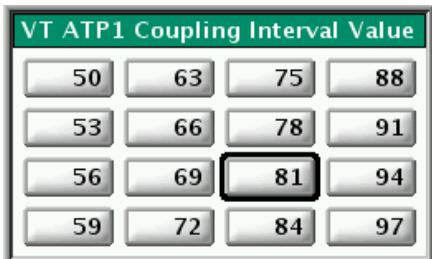
- All bursts deliver the same number of pulses when Pulse Count Increment is programmed to 0.
- Successive bursts have an increasing number of pulses if the Pulse Count Increment is > 0 and Maximum Number of Pulses is greater than the Initial Pulse Count.
- The device automatically adds the specific number of pulses to each subsequent burst until the Maximum Number of Pulses or the Number of Bursts is reached. If the Maximum Number of Pulses is reached first, each subsequent burst has the same (maximum) number of pulses.
- Pulse Count Increment can be programmed to more than one pulse.
- Several pulses (> 10) may increase chance of re-inducing arrhythmia.

Coupling Interval (CI) and Coupling Interval Decrement

Coupling Interval may be expressed as a percentage (adaptive) or a fixed interval.

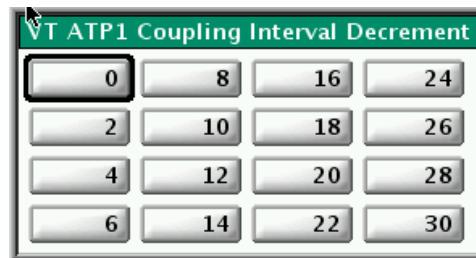


Nominal Coupling Interval: 81%



VT ATP1 Coupling Interval Value							
120	200	280	360	440	520	600	680
130	210	290	370	450	530	610	690
140	220	300	380	460	540	620	700
150	230	310	390	470	550	630	710
160	240	320	400	480	560	640	720
170	250	330	410	490	570	650	730
180	260	340	420	500	580	660	740
190	270	350	430	510	590	670	750

Nominal Coupling Interval Decrement: 0



- Delay between last sensed ventricular event and delivery of first pulse of ATP burst.
- Can be programmed as a percentage or a fixed interval (ms). Coupling Interval programmed as a percentage will adapt to the patient's rhythm, Fixed interval coupling interval will always follow the patient's intrinsic at the same interval.
- Examples of common values include: 81%, 84%, 88%.
- The lower the percentage, the shorter the interval and the more aggressive the therapy.
- Percentage is applied to average of last four R-R intervals prior to therapy. The adaptive (i.e., CI is programmed to a percentage) Coupling Interval readapts between each burst in a

scheme only if there is no Coupling Interval Decrement or Scan Decrement programmed. With the Coupling Interval Decrement programmed to a value greater than zero, the Coupling Interval only adapts for the first burst because the decrement value determines the timing of the first pulse in subsequent bursts.

- CI Decrement decreases Coupling Interval from one burst to next.

Burst Cycle Length (BCL)

- Burst Cycle Length may be expressed as a percentage (adaptive) or a fixed interval.

VT ATP1 Burst Cycle Length			
50	63	75	88
53	66	78	91
56	69	81	94
59	72	84	97

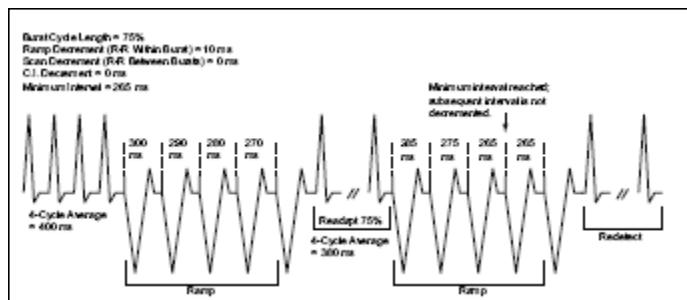
VT ATP1 Burst Cycle Length							
120	200	280	360	440	520	600	680
130	210	290	370	450	530	610	690
140	220	300	380	460	540	620	700
150	230	310	390	470	550	630	710
160	240	320	400	480	560	640	720
170	250	330	410	490	570	650	730
180	260	340	420	500	580	660	740
190	270	350	430	510	590	670	750

- Nominal: 81%.
- Interval between pulses in a burst, beginning with the time between the first and second pulse.
- Can be programmed as a percentage (adaptive) or a fixed interval (ms).
- Percentage is applied to average of last four R-R intervals prior to therapy.
- BSC has observed that this interval is typically programmed 15-30% faster than MVT rate.
- An adaptive BCL readapts between each burst in a scheme only if there is no Scan Decrement or Coupling Interval Decrement programmed. If a Scan Decrement is programmed, the BCL only adapts for the first burst. Decrements associated with the BCL can be used to create Ramp, Scan and Ramp/Scan pacing schemes.

Ramp Decrement

- Nominal: none.
- Shortens the interval between each pacing pulse within a burst.

VT ATP1 Burst Cycle Ramp Decrement			
0	8	16	24
2	10	18	26
4	12	20	28
6	14	22	30

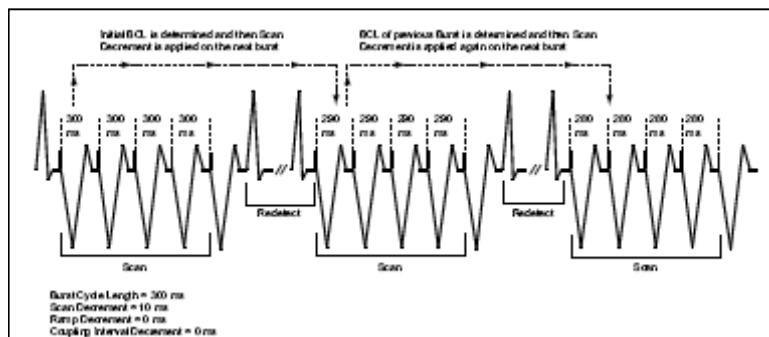


Scan Decrement

- Nominal: none.
- Shortens the time between each successive burst in an ATP scheme. Scan Decrement determines how much to decrement the BCL from burst to burst.
- Each Scan burst is followed by redetection; redetection must be met to deliver further bursts in the scheme.

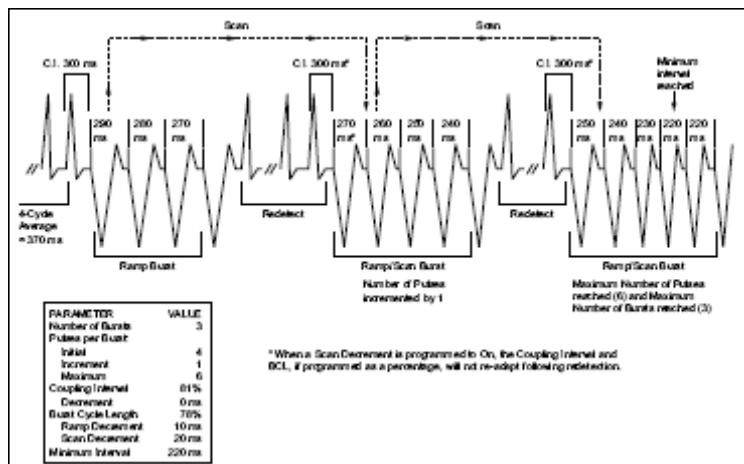
VT ATP1 Burst Cycle Scan Decrement

0	8	16	24
2	10	18	26
4	12	20	28
6	14	22	30



Ramp/Scan

- Nominal: none.
- Programming both the Ramp and Scan decrements creates a pacing scheme where the BCL shortens both within and between bursts.
- Ramp/Scan is the most aggressive type of ATP.



Minimum Interval

- Nominal: 220
- Shortest Coupling Interval and Burst Cycle Length allowed.
- Not recommended to go below 200 ms (risk of re-inducing arrhythmia).
- The Minimum Interval allows the physician to decrement the interval yet retain control of the minimum cycle length in a burst to avoid accelerating the patient's arrhythmia.
- Minimum Interval applies to the whole scheme, not just for the Burst Cycle Length (BCL) or Coupling Interval.

VT ATP1 Minimum Interval					
120	180	240	300	360	
130	190	250	310	370	
140	200	260	320	380	
150	210	270	330	390	
160	220	280	340	400	
170	230	290	350		

ATP Time-out

- Nominal: 60 seconds.
- Determines how long a patient will receive ATP therapy before shock therapy is initiated. When the ATP Time-out expires and if the arrhythmia persists in the same zone, shock therapy is initiated.
- Programmable values: OFF, 10 seconds to 3600 seconds.

VT ATP Time-out						
Off	40	105	300	510	1800	
10	45	120	330	540	2100	
15	50	150	360	570	2400	
20	55	180	390	600	2700	
25	60	210	420	900	3000	
30	75	240	450	1200	3300	
35	90	270	480	1500	3600	

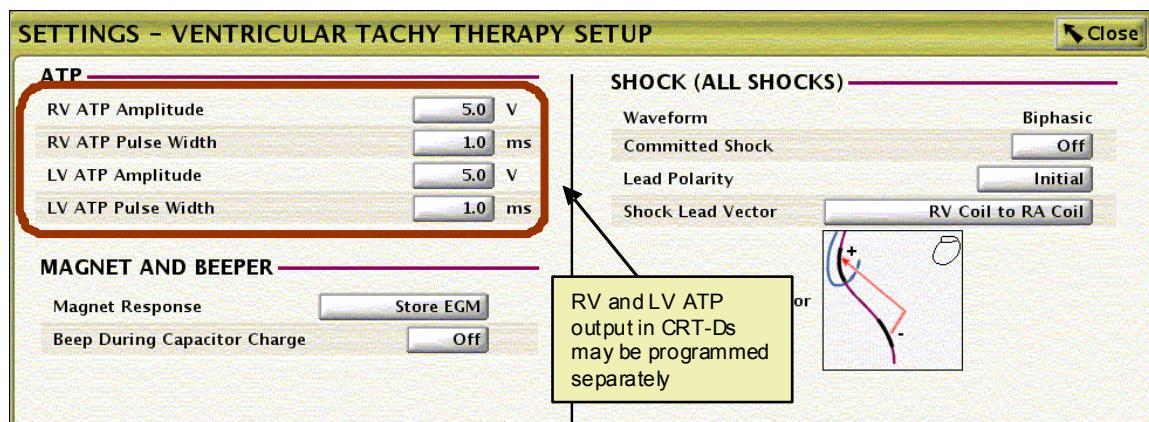
- Timer starts when ATP therapy is initiated.
- ATP Time-out will not terminate ATP burst in process. If the Time-out elapses during the middle of a burst, the burst is completed before any shock therapy is begun.
- ATP Time-out can be separately programmed in the VT-1 and VT zones.
- The ATP Time-out does not directly initiate therapy; rate and Redetection Duration for a particular zone must still be satisfied for shock therapy to be initiated. The ATP Time-out only directs therapy selection to skip over any remaining ATP therapy.
- VT time-out takes precedence over the VT-1 Time-out.
- The VT-1 ATP Time-out must be > the VT ATP Time-out.
- When two zones are programmed, the ATP Time-out functions as one timer with two endpoints. The timer starts running when the first ATP scheme (in either zone) is selected. When redetection is met in a zone, the device checks to see if the ATP Time-out for that zone has expired. If it has not, ATP therapy continues. If it has, programmed shock therapy for that zone is initiated.

ATP Output (V-Tachy Therapy Setup)

- Nominal: 5 V @ 1 ms.
- ATP output may be programmed to different values than normal brady and post-shock pacing to ensure capture of every pacing pulse during ATP.

NOTE: ATP for CRT-Ds described in this primer is delivered Bi-V (i.e., to both the RV and LV) and uses the programmed LV lead configuration. Output (amplitude and pulse width) for RV and LV are separately programmable.

Access to the ATP output parameters is through the V-Tachy Therapy Setup.



Terminating ATP Schemes

Any one of the following conditions may terminate ATP therapy (during a burst or between bursts of a scheme) in an episode:

- The rhythm no longer meets detection and end-of-event timer times out.
- The programmed Number of Bursts is exhausted.
- The rhythm is redetected in another zone.
- Shock if Unstable is satisfied, and therapy bypasses remaining ATP and proceeds to shock therapy.
- ATP Time-out is reached and therapy advances to shocks.
- DIVERT THERAPY, EP induction, Commanded therapy (including STAT Shocks), or Temporary Brady Pacing, are commanded from the programmer.
- A magnet is applied to the device (if magnet function is programmed to Inhibit Therapy).

NOTE: Pressing the DIVERT THERAPY or applying a magnet will abort the ATP burst in process. ATP therapy can only be diverted during a burst, not between bursts of a scheme. Another ATP scheme can be initiated by redetection (once the magnet is removed if diversion is due to magnet placement).

Clinical Considerations for ATP Programming

The following should be kept in mind for programming ATP schemes:

- Non-scanning ATP schemes (Scan Decrement=0, Coupling Interval Decrement=0) readapt between bursts (if programmed to adaptive values).
- Redetection Duration between bursts is programmable.
- Detection windows allow a minimum time of eight intervals plus 1 second for VT to break cleanly.
- ATP Time-out has two programmable time-outs (VT-1 and VT) allowing ATP for a longer period of time in the VT-1 zone.
- ATP-Only therapy is available in the VT-1 zone of a three-zone setup, or in the VT zone of a two-zone setup.
- Tachy detection is not available during delivery of ATP pulses; the pulses are delivered in VOO mode.
- If Shock if Unstable is programmed ON, ATP therapy will be skipped or interrupted in favor of shock therapy if a fast rhythm in the VT zone becomes unstable.
- Detection enhancements are not available during redetection between ATP bursts.

There is no particular ATP scheme recommended for programming BSC CRM devices. ATP parameters listed above represent some commonly programmed parameters.

Notes/Additional Information

- If a ramp or scan decrement are used, the coupling interval and Burst Cycle Length will use the decrement rules to determine when the next burst starts and the time between pulses in the burst rather than the percentage programmed.

- The time resolution of the PG is 2.5 ms and intervals are always displayed as integer values. Therefore, the intervals displayed for coupling intervals or burst cycle intervals may not always match what is calculated by hand.
- 20,000 ATP pulses at 5 V, 1.0 ms, and 500 ohms equals 1J shock (31J shock = 620K ATP pulses).
- Atrial ATP is not available, either as therapy or on the EP Test screen.



QUICK CONVERT ATP

QUICK CONVERT ATP provides you with an additional option to treat fast, monomorphic VT that is detected in the VF zone. When QUICK CONVERT ATP is programmed to ON, the pulse generator delivers one burst of ATP for an episode detected in the VF zone in an attempt to avoid an otherwise scheduled charge and painful shock for a pace-terminable fast VT.

Availability

- Available in the VF zone; applied to rates ≤ 250 bpm.
- Available in one-, two-, or three-zone configurations.

QUICK CONVERT ATP is delivered only once per episode, and only as the first attempt. For example, the detection rate in the VF zone was initially > 250 bpm, the device charges, but diverts the shock. Redetection is satisfied after the diverted shock. The next therapy available would be a shock; QUICK CONVERT ATP can only be applied as the initial attempt.

Programmable Values

- ON or OFF (nominally ON).
- ATP parameters are fixed as follows:

Number of Bursts	1
Pulses per Burst	8
Coupling Interval	88%
Burst Cycle Length	88%
Minimum Interval	220ms
Increments or Decrements	None

- ATP output is programmable.

See the ATP topic for more details.

QUICK CONVERT ATP may be programmed from the Ventricular Tachy Therapy Setup screen:

- From the Settings Summary screen select
- From the Ventricular Tachy Therapy screen select QUICK CONVERT ATP:



Algorithm

- Detection is met in the VF zone, i.e., 8/10 beats are faster than the VF rate zone cutoff.
- VF Duration times out and 6/10 beats are still in the VF zone.
- The average rate of the last four beats of Duration is ≤ 250 bpm.
- ATP burst is delivered, with fixed values:

Number of Bursts	1
Pulses per Burst	8
Coupling Interval	88%
Burst Cycle Length	88%
Minimum Interval	220ms
Increments or Decrements	None

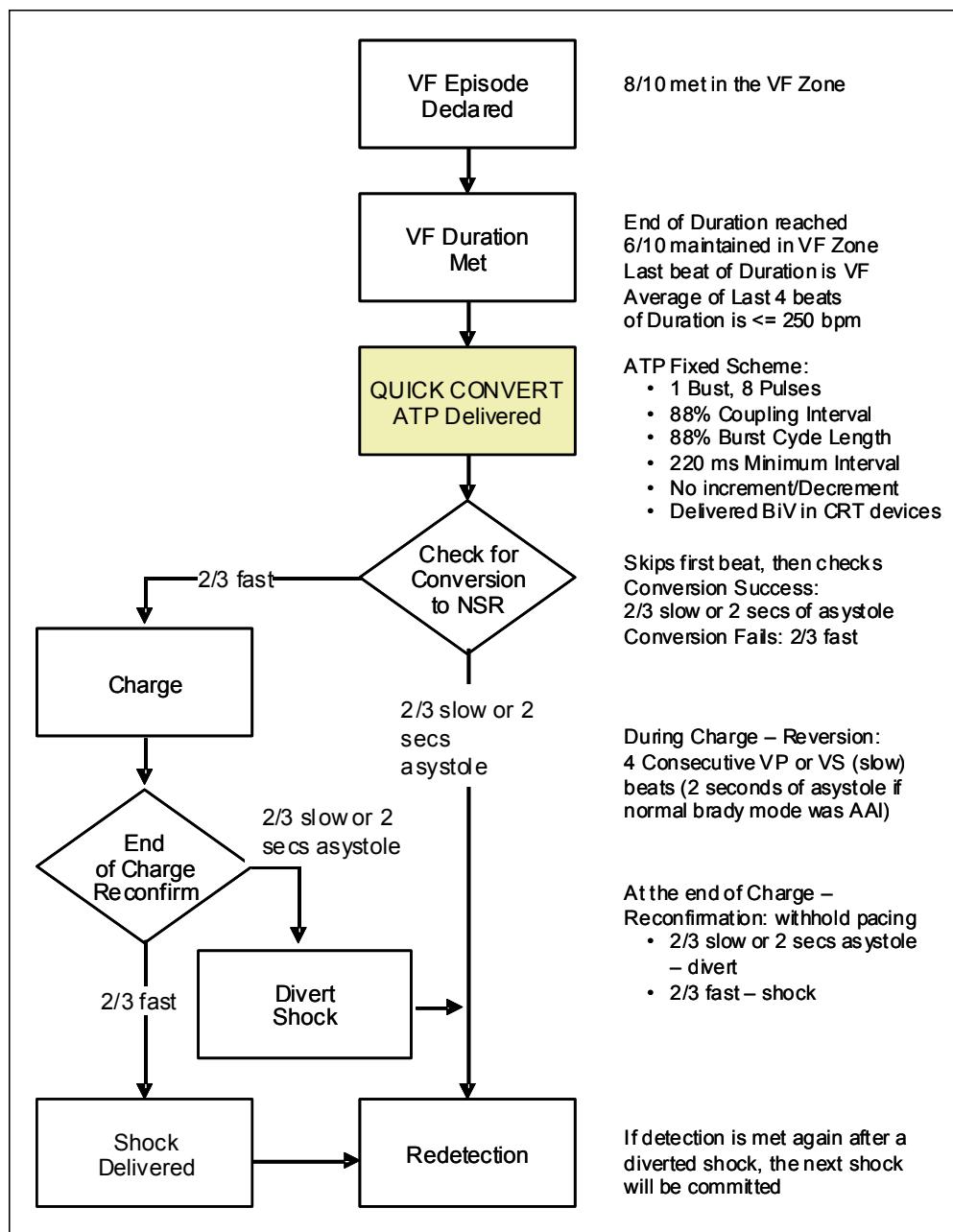
- After QUICK CONVERT ATP is delivered, device confirms whether rhythm remains fast:
 - Skip the first beat after the last ATP pulse, and then evaluate the rate. If asystole (2 seconds with no sensed ventricular events) is seen at this point the device will go immediately to redetection without waiting to evaluate the next 2/3 beats.
 - If 2/3 beats are slow (or there is 2 seconds of asystole in devices programmed AAI); the rhythm is converted and the device goes into redetection, returns to normal brady pacing and starts end-of episode timer.
 - If programmed DDD and asystole occurs, device uses VTR pacing. Will see three VP events before switching back to normal brady (first is skipped, 2/3 slow).
 - If programmed AAI and asystole occurs, device will wait 2 seconds (no pacing) plus 1 LRL before returning to AAI.

- If 2/3 beats are fast, charging will begin. Device will reconfirm rate during charge, but because delivery of ATP cleared the detection counters, the device looks for four consecutive slow beats (i.e., VP or VS), (or up to 2 seconds of asystole for devices programmed AAI) to divert. Once the end of charge is reached, the usual reconfirmation algorithm is applied.

See the flowchart on next page.

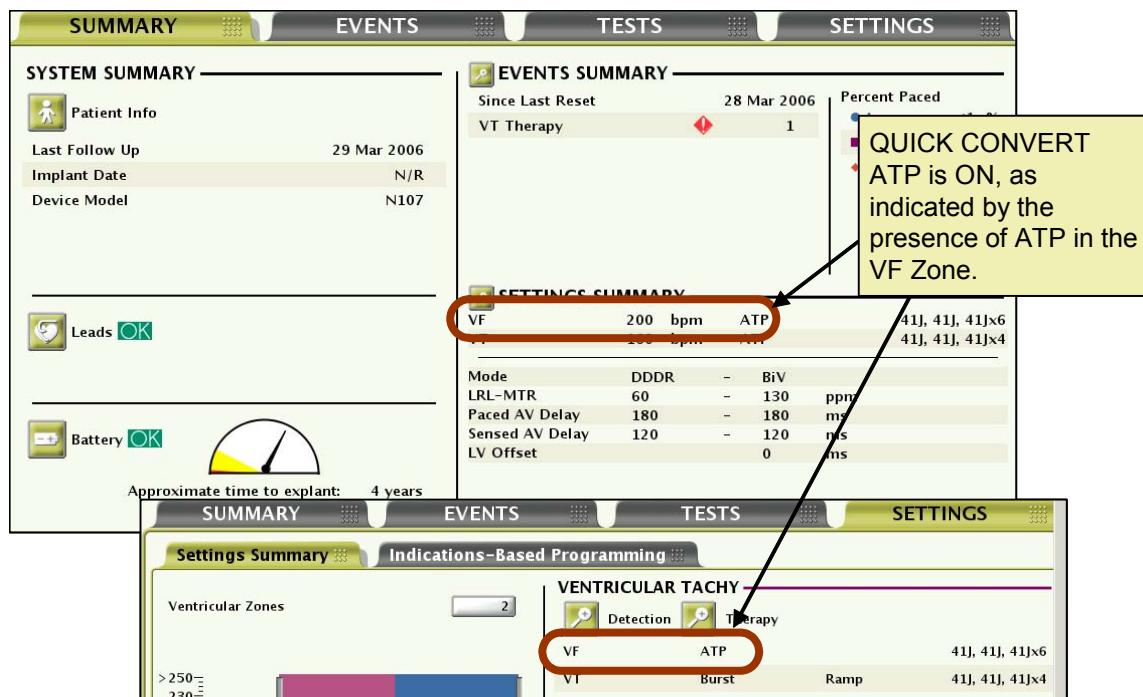
NOTE: The *beginning of charge* marker is delayed 300 ms from when charging actually starts.

- Charging starts on the second fast beat.
- Charge start marker may appear aligned with next beat if the next beat is ~ 300 ms.



Reporting QUICK CONVERT ATP Information Settings

To determine if QUICK CONVERT ATP is ON, check screens or reports that show device settings:



Episodes

To determine if QUICK CONVERT ATP was applied in a particular episode, check the following:

<input checked="" type="checkbox"/>	Event	Date/Time	Type	Therapy	Duration
<input type="checkbox"/>	V - 19	28 Mar 2006 16:22	VT	ATPx2	00:00:21
<input type="checkbox"/>	V - 18	28 Mar 2006 14:51	VF	ATPx1, 41J	00:00:45

Events - Stored Event

Event V - 18 VF 28 Mar 2006 14:51

- Average Rate 70 bpm
- Average Rate 228 bpm

Attempt	Elapsed Time(s)	
1	00:00:03	41J V Shock

VF ATP delivered prior to shock
Charge Time: 6.3 s
Lead Impedance: 41Ω

Event Ended 00:00:45

Screen or reports that list episodes (e.g., Arrhythmia Log book or Quick Notes) will show that ATP was delivered in the VF Zone

Notes/Clinical Applications

- If 2/3 slow beats are observed post QUICK CONVERT, the device enters into redetection. If the device then begins to charge the shock is committed.

- Turning on QUICK CONVERT ATP will delay charge in the VF zone by approximately 1.5-2.5 seconds—exact timing depends on ATP cycle length and intrinsic rate during 2/3 evaluation.
- If QUICK CONVERT ATP is delivered and the rhythm slows to a lower zone where other ATP schemes are programmed, those schemes may be used to treat the rhythm.
- QUICK CONVERT ATP may only be used as the first attempt in an episode. If ATP is delivered in a lower zone, and the rate accelerates to the VF zone, QUICK CONVERT ATP will not be used; the device will use shock therapy.
- QUICK CONVERT ATP will be delivered BiV in CRT-D devices.
- The 2/3 confirmation of rhythm after QUICK CONVERT ATP is delivered will occur regardless of how the Committed/Noncommitted parameter (i.e., shock Reconfirmation) is programmed.



STAT Shock

STAT shock allows a clinician to deliver emergency, max-energy shocks any time during a communication session regardless of programmed parameters or detection status.

Availability

- Available at any time during a communication session (with wand and/or RF).
- Available in any Tachy mode (in Storage, once STAT SHOCK is commanded, mode automatically changes from Storage to OFF).
- When a STAT SHOCK is delivered, therapy counters will increment and a “Commanded” episode will be stored (even if Tachy mode is OFF). The episode will look identical to a Commanded Shock both on the EP test screen (during the episode) and in the Logbook (after the episode). Additionally, under Battery Status information, Last Delivered Shock will reflect data from STAT SHOCK.
- Does not count as a shock in a therapy sequence for a given episode.
- STAT SHOCK uses the programmed shock vector and polarity.
- STAT SHOCK is not available when the device is in Safety Core mode.

Output

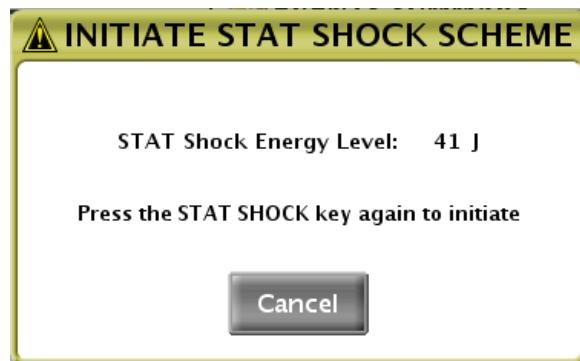
- Maximum available output energy at the programmed polarity and waveform.
- Shock is ALWAYS committed, but can be manually diverted.
- Shocks are delivered R-wave synchronously *unless* an R-wave is not sensed for two seconds then shock is delivered asynchronously.
- Post shock pacing will be initiated and pacing will occur at the post-shock values as needed.

To perform STAT SHOCK:

1. Position wand within range of pulse generator to begin interrogation session; for RF devices, a wand does not need to be kept over the device in order to initiate STAT SHOCK after initial interrogation.

NOTE: All telemetry activity, including STAT PACE, STAT SHOCK, and DIVERT THERAPY commands, is disabled while the Patient Confirmation window is displayed.

2. Press the Yellow STAT SHOCK key located on programmer key pad. A message will appear:



3. To initiate shock, press the Yellow STAT SHOCK key again. A message will now appear indicating that STAT SHOCK is in process.
 4. When shock has been delivered, message window will disappear.
 5. If Tachy mode is Monitor Only or Monitor + Therapy, post-shock redetection will be initiated (no detection enhancements will be used). If the device deems therapy is necessary, the programmed sequence of therapy will be initiated or resumed, including ATP and/or low energy shocks.
- There is a 500 ms Divert Window at the end of charge and a 500 ms post shock refractory period.



EP Test Screen Introduction

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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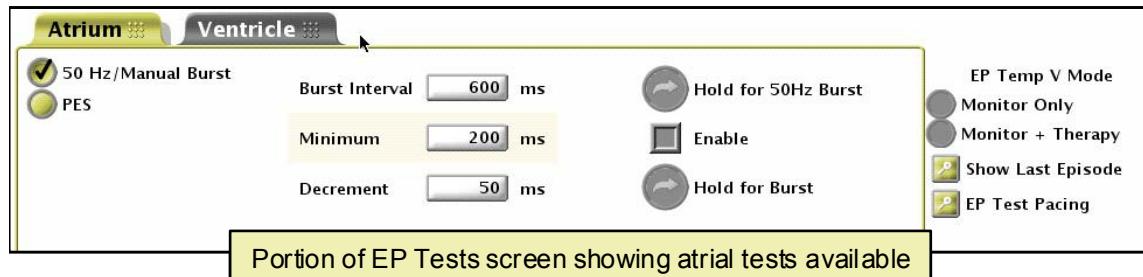
The EP Tests screen is used to monitor event activity, induce arrhythmias in the atrium or ventricle, and command therapy in the atrium or ventricle.

WARNING: 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.

Navigation

1. From the System Summary screen, select TESTS
2. Select EP Tests



Portion of EP Tests screen showing atrial tests available

Device status area shows:

- Heart rate
- Whether there is an episode in progress
- Type of episode
- Episode elapsed time
- Stage of episode (e.g., Attempt 1, redetection)
- Time since therapy

SUMMARY EVENTS TESTS SE

Lead Tests EP Tests Temp Brady Manual Rhythm ID

DDD
40 bpm
V: No Episode

Normal Pacing

Atrium Ventricle

50 Hz/Manual Burst S1 Pulses 8
PES S1 Interval 400 ms
V Fib Shock on T Shock Coupling 310 ms
Commanded ATP Energy 1.1 J
Commanded Shock

Use the tabs to select tests for the Atrium or Ventricle

ATP 41J 41J Max
100% 100%
2x Burst 1x Ramp 41J 41J Max

Enable Induce

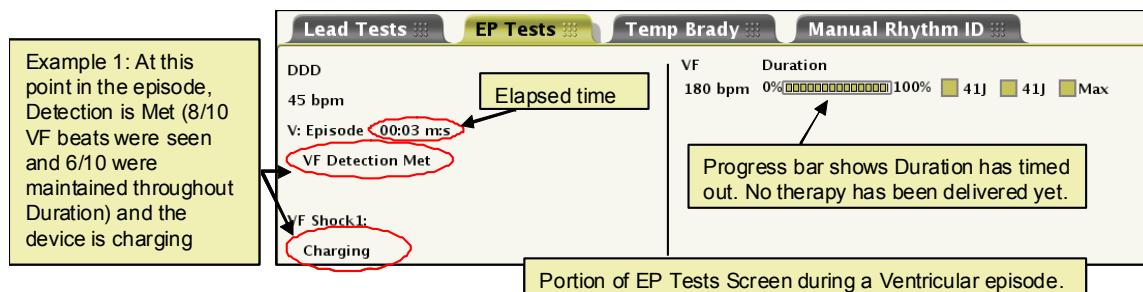
EP Tests Screen, showing Ventricular tests available

For ventricular episodes in progress, this area shows:

- Detection progress for each programmed zone
- Rate
- Which therapy has been delivered

Device/Episode Status

The top half of the EP Tests screen gives information on the patient's current status, and the status of any ongoing episode. During an induction sequence, the detection process and therapy delivery is indicated.



Example 1: At this point in the episode, Detection is Met (8/10 VF beats were seen and 6/10 were maintained throughout Duration) and the device is charging

Lead Tests EP Tests Temp Brady Manual Rhythm ID

DDD
45 bpm
V: Episode 00:03 ms

VF Duration
180 bpm 0% 100% 41J 41J Max

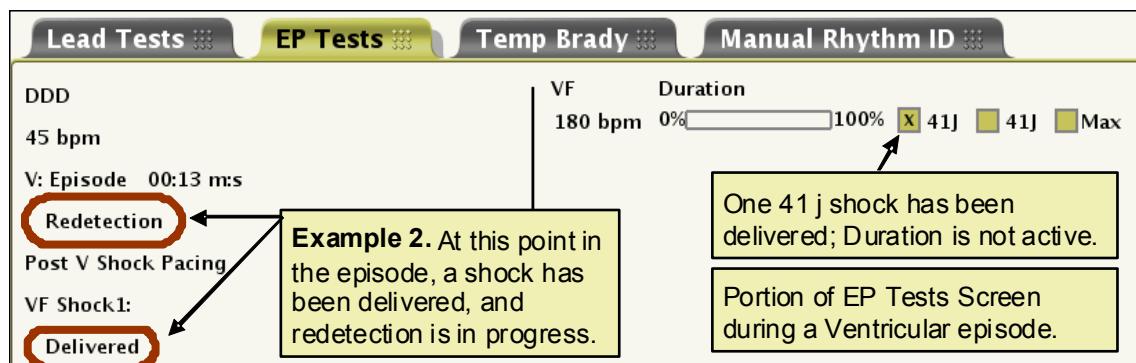
Elapsed time

VF Detection Met

VF Shock1: Charging

Progress bar shows Duration has timed out. No therapy has been delivered yet.

Portion of EP Tests Screen during a Ventricular episode.



EP Tests/Commanded Therapy

The bottom half of the screen provides the opportunity to do device-based EP testing, inductions, and commanded therapy. The tabbed pane separates the features available for the atrium and ventricle.

On the right, the user can temporarily set the ventricular tachy mode, as appropriate for each function.

NOTE: EP Temp V Mode is only in use for the tests on this screen.
Changing this mode does not permanently reprogram Tachy mode.



A button gives quick access to the detail for the last episode, which is convenient for viewing the results of an induction or commanded therapy.

EP Test Pacing Screen

Clicking EP Test Pacing opens a sub-window which gives the user access to EP Test pacing parameters.

Backup Pacing – parameters are applied only when an atrial test (PES or Manual Burst) is selected on the EP Tests screen. These parameters control backup ventricular pacing during the test. When ON is selected for this mode, backup pacing will be VOO.

NOTE: In CRT-Ds, backup pacing will be BiV.

EP Test Pacing Outputs – allow the user to select amplitude and pulse width for atrial and ventricular pacing that will be used during EP Tests (i.e., Commanded ATP, Manual Burst, or PES).

See the individual EP topics in this manual for detailed descriptions of each test.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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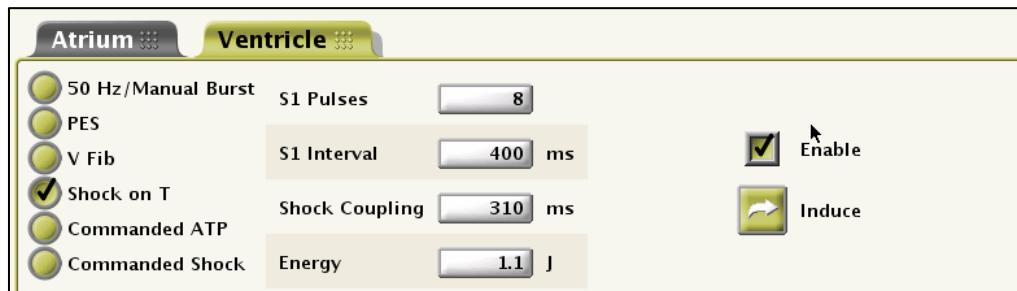
EP Test Shock on T

Shock on T is used to induce ventricular fibrillation by delivering a pacing drive train (up to 30 equally-timed pacing pulses, or S1 pulses) through right ventricular rate-sensing electrodes, followed by a properly timed shock from shock electrodes into T-wave.

Availability

Available under EP Tests, ventricular tests only; not available for the atrium.

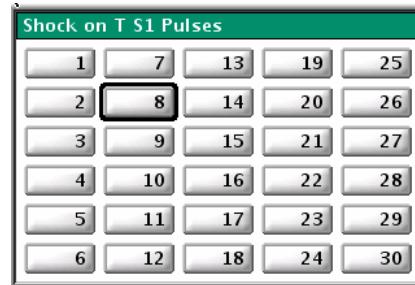
Device Tachy mode must be Monitor+ Therapy.



Programmable Values

S1 Pulses

- Nominal = 8.
- Number of pulses in the pacing train that will precede the shock.



S1 Interval

- Nominal = 400 ms.
- Interval used for all pulses in the pacing train. S1 interval is coupled to last sensed or paced event.



Shock Coupling Interval

- Nominal = 310 ms.
- Interval from the last delivered pacing pulse where shock will be delivered.

Energy

- Nominal = 1.1 joule.
- Energy that will be delivered to the T-wave to induce the patient.
- High energy devices max energy = 41 joules.

Shock on T Shock Coupling Interval						
SYNC	80	160	240	320	400	480
10	90	170	250	330	410	490
20	100	180	260	340	420	500
30	110	190	270	350	430	
40	120	200	280	360	440	
50	130	210	290	370	450	
60	140	220	300	380	460	
70	150	230	310	390	470	

Shock on T Energy				
0.1	1.7	7	21	36
0.3	2	9	23	41
0.6	3	11	26	
0.9	5	14	29	
1.1	6	17	31	

Algorithm

1. From the EP Tests screen select 
2. Check  
3. Verify that the device is programmed to *Monitor + Therapy* mode.
4. Select desired value for each parameter.
5. Select  
6. Press   (do not hold). Pulses are delivered in sequence followed by the shock.
7. Once induction is initiated, only the Divert key will stop the induction.

Notes/Additional Information

- Pace train is delivered at amplitude and pulse width programmed on the EP Test Pacing screen.
- Shock configuration is the same as programmed shock vector and polarity.
- In CRT-Ds, the pacing train is delivered BiV with 0 ms LV offset regardless of permanent programmed value.
- Post-Shock Delay and Post-Shock Pacing will be enabled after Shock On T for PUNCTUA, ENERGEN, INCEPTA.

WARNING: 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.

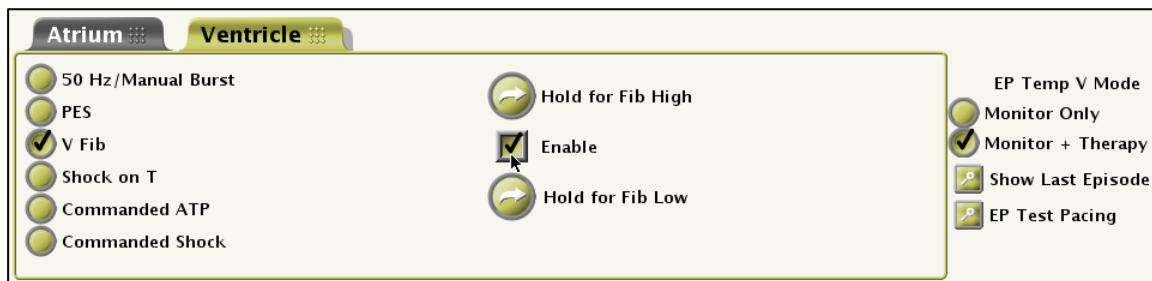
ICD	INCEPTA	INCEPTA
CRT-D	ENERGEN	ENERGEN
	PUNCTUA	PUNCTUA
	COGNIS	

EP Test Fibrillation Introduction

Uses shocking electrodes (and normal charging/shock delivery circuits) to stimulate right ventricle at very fast rates and high outputs to induce ventricular fibrillation. Fibrillation Induction is not as effective in inducing VT.

Availability

- Available under EP Tests, ventricular tests only; not available for the atrium.
- Device Tachy mode must be Monitor + Therapy.



Programmable Values



delivers pulses at an interval of 50 ms (20 Hz) at 15 V at 1.1 ms.



delivers pulses at an interval of 50 ms (20 Hz) at 9 V at 1.1 ms.

Algorithm

- From the EP Tests screen select **Ventricle**
- Check the V Fib **V Fib** radio button.
- Verify that the device is programmed to *Monitor + Therapy* mode.
- Select **Enable** to highlight the fib induction options.
- Select and hold desired induction option (Hold for Fib High or Hold for Fib Low).
- Fibrillation induction train is delivered as long as Hold for Fib High/Fib Low button is held and telemetry is maintained. Fib induction train will stop about 0.5 seconds after button is released.

Fib induction train is delivered through the shocking electrodes, using the programmed shock lead configuration.

Notes/Additional Information

- Fib High/Low will self terminate after 15 seconds of continuous delivery.
- Fib train pulses are delivered in alternating polarity; this minimizes residual voltage build-up on leads and improves post induction sensing.
- It is normal for sensing to be disturbed for up to 2 seconds after Fib Induction; this may result in an extraneous brady paced pulse during the induced VF.
- Very successful for inducing VF, but causes dramatic muscle contractions – patient should be sedated.
- Atrial fibrillation may occasionally be seen as a result of induction but is often self-terminating or converted back to sinus by the delivered ventricular shock.
- If using Fib High or Fib Low and induction is interrupted, there may be a telemetry problem:
 - For induction telemetry sessions, consider repositioning the wand and change the distance of the wand from the pulse generator to not more than 2.4 inches.
 - For RF telemetry, there may be interference; locate source of interference.
 - If Fib induction is being performed and telemetry is lost (*out of range/telemetry noise* message) arrhythmia is detected and the device starts charging, then telemetry is reestablished while Fib button is still being held and a Manual Divert occurs and is noted on Event data.
- Post-Shock Delay and Post-Shock Pacing will be enabled after V Fib Low/High for PUNCTUA, ENERGEN, INCEPTA.
- Reports last few pulses delivered during V Fib induction as extremely short VF intervals (30 or 50 ms) in Intervals Report and on stored EGM.

Differences between 50 HZ and Fib High/Fib Low

	50 HZ	Fib Low	Fib High
Amplitude	EP Test values	9 V	15 V
Pulse Width	EP Test values	1.1ms	1.1 ms
Interval	20 ms	50 ms	50 ms
Duration	As long as the hold button is pressed. Pressing the hold button for one screen typically induces VF		As long as the hold button is pressed. Pressing the hold button for half a screen typically induces VF
Electrodes	Pace/Sense (tip-coil)	Shock electrodes (normally V-triad)	

	50 HZ	Fib Low	Fib High
Comments	By using pace/sense electrodes, pectoral stimulation is avoided. Less harmful for the patient.	Alternating polarity to minimize post-induction sensing problems	

WARNING: 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.

EP Test Programmed Electrical Stimulation (PES)



Programmed electrical stimulation (PES) allows the electrophysiologist to deliver a premature impulse to the patient's reentrant circuit at just the right moment to induce arrhythmias. PES delivers up to 30 equally-timed pacing pulses (S1) followed by up to four premature stimuli (S2 – S5).

PES is commonly used to induce monomorphic VT or A Fib. Programmed stimulation protocols vary from institution to institution.

Availability

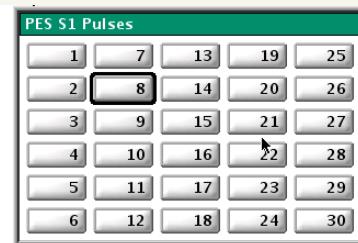
- Device must be in *Monitor + Therapy* mode.
- PES may be delivered to the Atrium or Ventricles (CRT-Ds pace BiV in ventricle).



Programmable Values

S1 pulses

- Nominal = 8.
- Number of pulses to be used as the S1 pacing train.



S1 interval

- Nominal = 600 ms.
- Interval used for all the S1 pulses in the train. S1 interval is coupled to last sensed or paced event.

S2, S3, S4, S5 intervals

- S2 Nominal = 600 ms.
- S3, S4, S5 Nominal = OFF.
- Interval used for the premature stimuli that will follow the pacing train. S2-S5 are independent from drive cycle and have no interactive limits.

PES S1 Interval									
120	200	280	360	440	520	600	680		
130	210	290	370	450	530	610	690		
140	220	300	380	460	540	620	700		
150	230	310	390	470	550	630	710		
160	240	320	400	480	560	640	720		
170	250	330	410	490	570	650	730		
180	260	340	420	500	580	660	740		
190	270	350	430	510	590	670	750		

S# Decrement (where # is the last pulse in the PES train)

Nominal = 0 ms.

Decrement that will be subtracted from the last S pulse automatically, each time the INDUCE button is pressed.

PES Auto Decrement			
0	30		
10	40		
20	50		

Algorithm

1. From the EP Tests screen select or
2. Check
3. Verify that the Tachy mode is *Monitor + Therapy*.
4. Select the number of S1 Pulses to be delivered as the pacing train.
5. Select the S1 interval (S1 pulses should capture the heart at a rate slightly faster than the intrinsic rate).
6. Select the S2-S5 intervals (typically at a shorter interval than the S1 interval by 10 – 20 ms).
7. Select S# decrement if desired (where # is the last pulse in the PES train).

8. Select

9. Press (do not hold). Pulses are delivered in sequence.

10. The decrement value is automatically subtracted from the last S pulse in the scheme and applied the next time the *Induce* button is pressed.

Auto Decrement

- A PES scheme is set up, and an auto (S#) decrement entered. When the INDUCE button is pressed for the first induction, the PES pulses are applied.
- If additional PES attempts are made, the auto decrement is applied to the last S pulse in the scheme each time the INDUCE button is pressed.

Notes/Additional Information

- All pulses except the first are delivered in VOO or AOO and amplitude and pulse width are programmed on the EP Test Pacing screen.
- Once PES is initiated, only the Divert key will stop the induction.
- Delivery of PES will terminate any episode in progress.
- PES is not recorded in therapy history.
- Markers are available throughout PES delivery except during telemetry command.
- In CRT-Ds, the pacing train is delivered BiV with 0 ms LV offset regardless of permanent programmed value.

WARNING: 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.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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EP Test Manual Burst Pacing

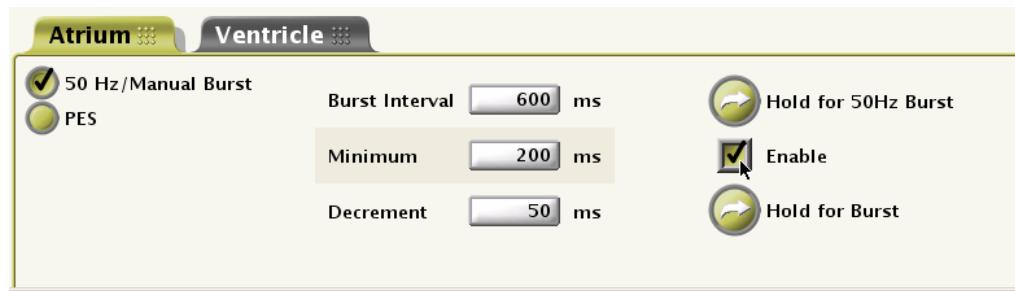
Manual burst pacing is commonly used to induce monomorphic VT or atrial fibrillation, or to noninvasively terminate arrhythmias.

NOTE Manual burst pacing allows physician to deliver eight pulses as a pace train which can then be followed by a ramp scheme. Ramp schemes are more likely to induce VF than fixed-rate bursts.

Availability

- Available via EP Test screen for either Atrium or Ventricule.
- Only available if Tachy mode = Monitor + Therapy.

- Backup EP Pacing is available for Atrial Manual burst only.
- In CRT-Ds, manual burst is delivered to the right ventricle only.



Programmable Values

Burst Interval

- Nominal = 600 ms.
- Cycle length of the first 8 pulses in the burst.

Manual Burst Pacing Burst Interval							
20	110	200	290	380	470	560	650
30	120	210	300	390	480	570	660
40	130	220	310	400	490	580	670
50	140	230	320	410	500	590	680
60	150	240	330	420	510	600	690
70	160	250	340	430	520	610	700
80	170	260	350	440	530	620	710
90	180	270	360	450	540	630	720
100	190	280	370	460	550	640	730

Minimum

- Nominal = 200 ms.
- Shortest interval the device will allow if a decrement is programmed.

Manual Burst Pacing Minimum Interval							
20	110	200	290	380	470	560	650
30	120	210	300	390	480	570	660
40	130	220	310	400	490	580	670
50	140	230	320	410	500	590	680
60	150	240	330	420	510	600	690
70	160	250	340	430	520	610	700
80	170	260	350	440	530	620	710
90	180	270	360	450	540	630	720
100	190	280	370	460	550	640	730

Decrement

- Nominal = 50 ms.
- Interval decrement that will applied after the first eight pulses are delivered.
- The decrement is used if the physician wishes to create a ramp scheme.
- Pacing pulses use the amplitude and pulse width values from the EP Test Backup Pacing screen.

Manual Burst Pacing Decrement	
0	30
10	40
20	50

Algorithm

1. From the EP Tests screen select **Atrium** or **Ventricle**

NOTE: When Atrium is selected, backup VOO pacing is available (programmable) via the EP Test Pacing button.

2. Verify that the Tachy mode = Monitor + Therapy.

3. Select **Enable** to ready device to deliver burst.

4. Select  **Hold for Burst** to deliver burst.
5. First eight pulses are delivered at the programmed burst interval.
6. If a decrement is programmed, each subsequent burst interval will be decremented until the Minimum is reached. Any further pulses will be delivered at the Minimum interval.
7. Manual Burst will be delivered as long as button is pressed.

NOTE: Any of following will terminate Manual Burst:

- Release of Hold for Burst button
- Interruption of telemetry
- Pressing the Divert button
- Initiating a STAT Shock
- Initiating PES, Commanded ATP, Commanded Shock

Notes/Additional Information

- Atrial Manual Burst/50 Hz pacing will self terminate after 45 seconds of continuous pacing.
- Ventricular Manual Burst/50 Hz pacing will self terminate after 30 seconds of continuous pacing.
- In the event a magnet to the device during delivery of burst interrupts device detection and any episode in progress is terminated, detection is automatically re-initiated after burst is ended.
- Event markers and EGMs will be interrupted during burst delivery, and will resume when burst is ended.
- Back-up VOO pacing available during 50 Hz Burst in atrium via the EP Test Pacing button.
- Tachy Detection is automatically disabled during Manual Burst Pacing and re-enabled after burst is completed.
- If RF telemetry is in effect, the burst may only be terminated by releasing the Hold for Burst button.
- Delivery of a burst will terminate any episode in progress.

WARNING: 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.

EP Test 50Hz Burst

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Manual burst pacing is commonly used to induce monomorphic VT or atrial fibrillation, or to noninvasively terminate arrhythmias. 50 Hz pacing is a special feature of Manual Burst Pacing,

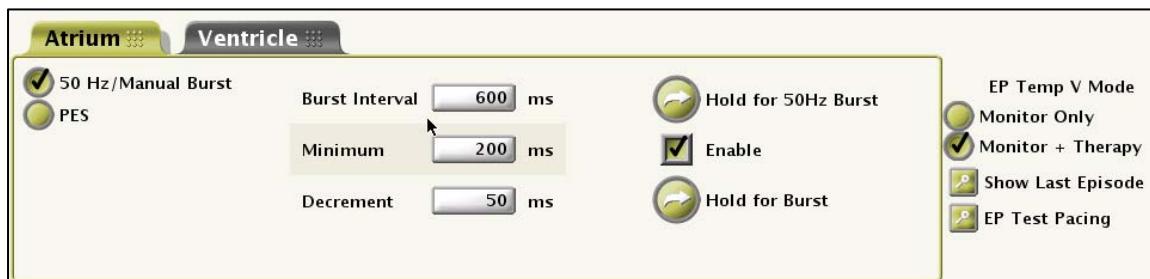
allowing the physician to deliver a burst of pacing pulses at fixed frequency of 50 Hz (50 pulses per second).

- Hertz = measure of frequency in cycles per second. 1 Hertz (Hz) = 1 cycle per second.
- 50 Hz pulses are delivered 1 pulse every 20 ms.

Availability

Available via EP Test screen for either Atrium or Ventricles.

Only available if Tachy mode = Monitor + Therapy.



Programmable Values

None – Burst parameters are fixed and are not programmable if Hold for 50 Hz Burst button is selected (these values will **not** appear on screen):

- Burst Interval = 20 ms.
- Minimum Interval = 20 ms.
- Decrement fixed at 0.

Pulses are delivered at programmed EP Test amplitude and pulse width (accessed via EP Test Pacing button). In CRT-Ds, a 50 Hertz burst to the ventricle is delivered RV only. Pulses are delivered in AOO or VOO mode, based on the chamber selected.

Algorithm

1. From the EP Tests screen select **Atrium** or **Ventricle**

NOTE: When Atrium is selected, backup VOO pacing is available (programmable) via the EP Test Pacing button. Since backup pacing is VOO, the RV rate channel EGM is not displayed during this time.

2. Select **Enable** to ready device to deliver burst.
3. Select **Hold for 50Hz Burst** to deliver burst at one pulse every 20 ms (50 Hz). Burst will be delivered for as long as button is held.

Any of following will terminate 50 Hz Burst:

- Release of Hold for 50 Hz Burst button
- Interruption of telemetry
- Pressing the Divert button
- Initiating a STAT Shock
- Initiating PES, Commanded ATP, Commanded Shock

Interpreting/Clinical Applications

- Applying a magnet to the device during delivery of burst, interrupts device detection and any episode in progress is terminated. Detection is automatically re-initiated after burst is ended.
- Event markers and EGMs will be interrupted during burst delivery, and will resume when burst is ended.
- Back-up VOO pacing available during 50 Hz burst in atrium via the EP Test Pacing button.
- Tachy Detection is automatically disabled during Manual Burst Pacing and re-enabled after burst is completed.
- If RF telemetry is in effect, the burst may only be terminated by releasing the HOLD button.
- Delivery of a burst will terminate any episode in progress.

WARNING: 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.



EP Test Commanded Shock

Allows the physician to deliver shocks with programmable coupling interval and energy.

- Commonly used to shock patient at any time when STAT shock at maximum output is not desired (e.g., to cardiovert Atrial Fibrillation, to treat ventricular arrhythmias below the lowest cut-off rate, or to deliver 1.1J shock to test lead connections in clinical situations a painless Shock Lead Integrity Test is not selected).
- Can be used to convert induced arrhythmias.
- May be used to induce VF when coupled correctly.

See the following section: Programmable Values Coupling Interval.

Availability

- Available under EP Tests, ventricular tests only; not available for the atrium.

- Device Tachy mode must be Monitor + Therapy or Monitor Only.



Programmable Values

Coupling Interval

- Nominal = SYNC.
- Interval from the last ventricular sensed event until shock delivery.
- SYNC indicates the shock will be delivered with a sensed R-wave.
- SYNC is the most commonly used value.

Commanded Shock Coupling Interval						
SYNC	110	180	250	320	390	460
50	120	190	260	330	400	470
60	130	200	270	340	410	480
70	140	210	280	350	420	490
80	150	220	290	360	430	500
90	160	230	300	370	440	
100	170	240	310	380	450	

Commanded Shock Energy						
0.1	1.7	7	21	36		
0.3	2	9	23	41		
0.6	3	11	26			
0.9	5	14	29			
1.1	6	17	31			

Shock Energy

- Nominal = 41 joules for high energy.
- 31 joules for standard energy.
- Amount of energy that will be delivered with the commanded shock.

Algorithm

- From the EP Tests screen select **Ventricle**
- Check the **Commanded Shock** button.

Commanded Shock may be used for cardioversion or to induce an arrhythmia.

Procedure to shock (cardioversion)

- Select SYNC (committed and delivered R-wave synchronously) for the **Coupling Interval**.
- Select **Shock Energy** (0.1 J to maximum output of device).
- Select **Enable**
- Press **Deliver Shock** to initiate shock delivery.

Procedure to Induce

1. Determine and select the Coupling Interval.
 - In NSR, run paper at 50 mm/sec.
 - Measure QRS from sensed marker to upslope of T-wave – the aim is to deliver a shock into the T-wave.
2. Select Shock Energy (0.1 J to maximum output of device).
3. Select **Enable**
4. Press **Deliver Shock**
to
initiate shock delivery.

Notes/Additional Information

- Following any Commanded Shock, re-detection duration is used and post-therapy pacing is activated if programmed.
- All Commanded Shocks are committed and delivered R-wave synchronously or as programmed with coupling interval. (If no R-waves are sensed for 2 seconds, shock is delivered asynchronously).
- Commanded Shocks will be recorded in Events as a V-event – Commanded.
- Breaking telemetry (RF or wand) will not terminate test; use Divert Therapy button to terminate shock delivery.
- Commanded Shock delivery is inhibited when magnet is positioned over pulse generator, if the Magnet Response = Inhibit Therapy.

WARNING: 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.

ICD	INCEPTA	INCEPTA
	ENERGEN	ENERGEN
	PUNCTUA	PUNCTUA
	TELIGEN	COGNIS

EP Test Commanded ATP

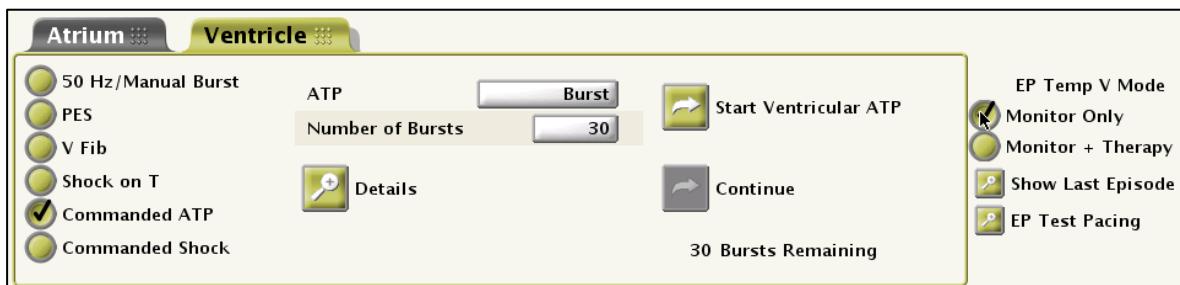
Commanded ATP allows the physician to manually test ATP therapy schemes.

- All detection is manually performed by the physician.
- Paced pulses are delivered at programmed ATP amplitude and pulse width in AOO or VOO mode through right ventricular pace-sense lead.

Availability

- Available under EP Tests, ventricular tests only; not available for the atrium.

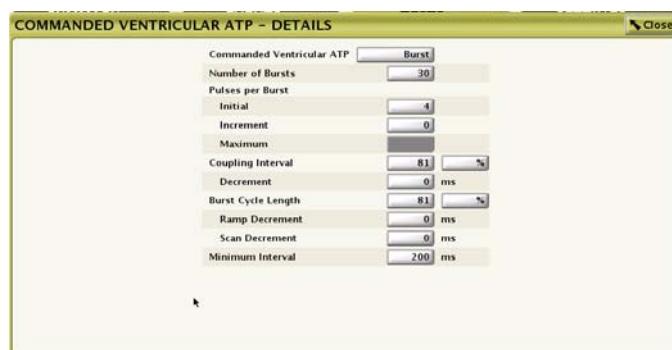
- For CRT-Ds only, ATP is delivered BiV.
- Must be done in Monitor Only mode to prevent interaction between detection-initiated therapy and commanded manual therapy.



Programmable Values

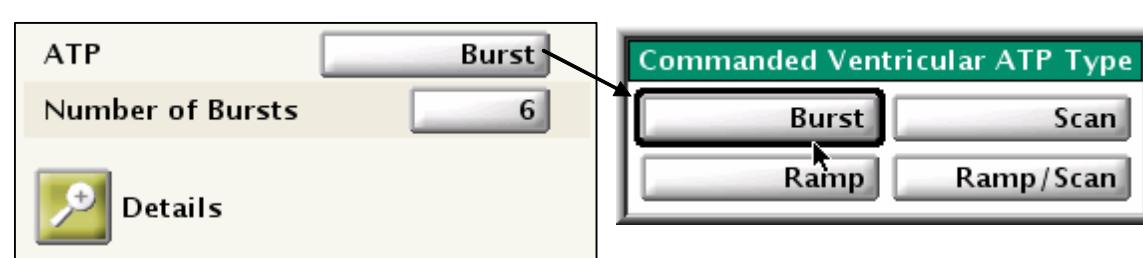
All ATP parameters may be used in Commanded ATP.

See the ATP section for descriptions of parameters.



Algorithm

- From the EP Tests screen select **Ventricle**
- Program EP Temp V mode to Monitor Only mode.
- Check **Commanded ATP**



- Use the ATP and Number of Bursts fields to select the type of ATP that will be used.



5. Use the to program ATP parameters. For descriptions of parameters.

See the ATP topic.



6. Press to initiate 1st burst – number of programmed bursts will be displayed as Bursts Remaining.



7. Press to initiate delivery of 2nd burst (and any remaining bursts).

8. Other ATP schemes may be selected at any time; select desired scheme and repeat above sequence.

Notes/Additional Information

- If Continue is pressed after 10 seconds have passed, a new episode will be declared.
- Once all bursts are delivered, another ATP scheme may be selected or Start Ventricular ATP button may be pressed to repeat schemes already programmed.
- If programmed values are changed between bursts, Start Ventricular ATP must be re-initiated.
- Commanded ATP is recorded as a physician-commanded therapy counter and displayed on Counters screen.
- ATP outputs (amplitude and pulse width) are programmed on the V-Tachy Therapy Setup screen.

WARNING: 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.

PACING THERAPIES



Brady Parameters

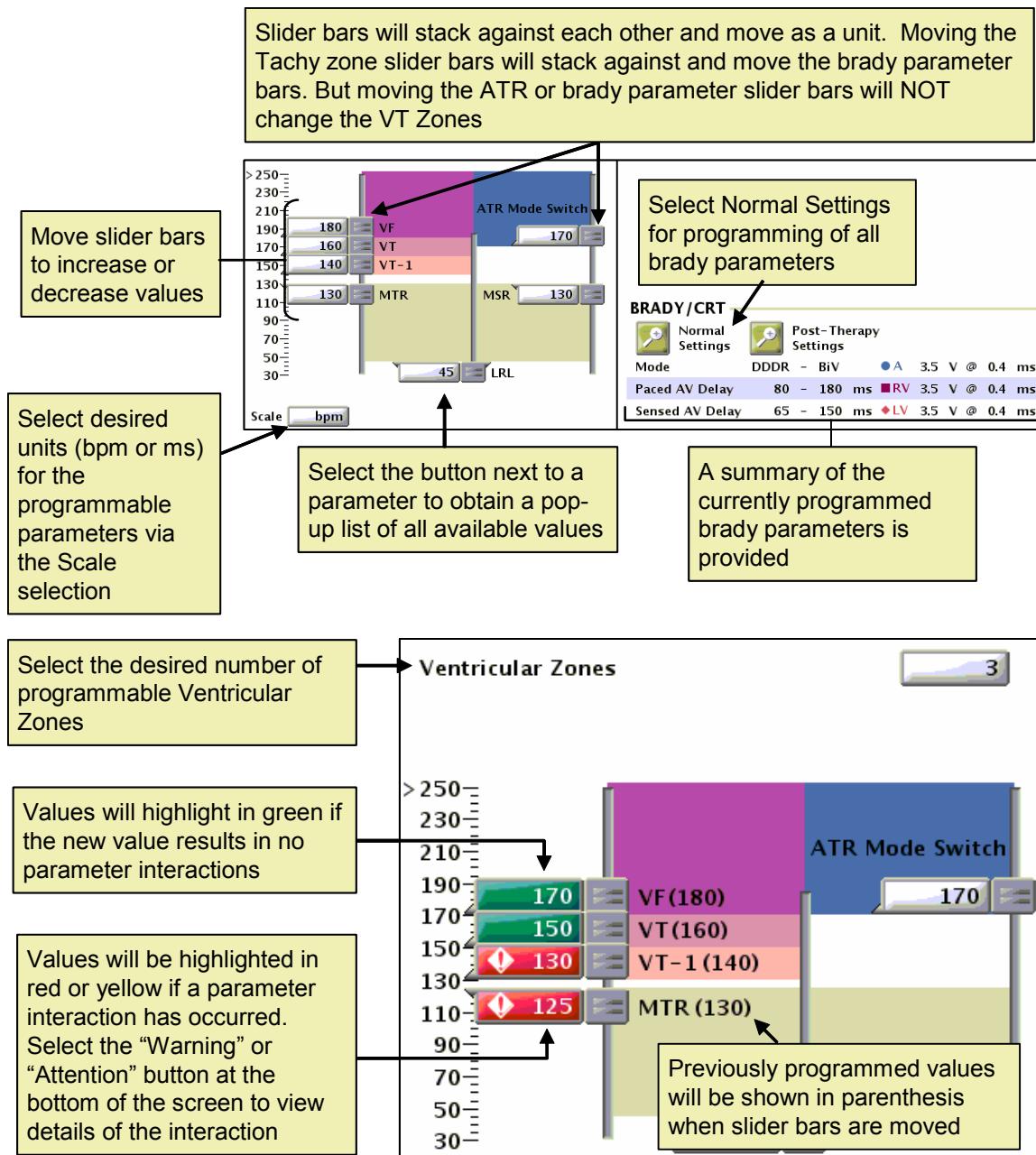
ICD	INCEPTA	INCEPTA
	ENERGEN	ENERGEN
	PUNCTUA	PUNCTUA
	TELIGEN	COGNIS

Individually programming brady parameters allows the clinician to provide programmable options to individualize patient therapy. A summary of brady parameters is available on the Summary screen and programming of all brady parameters is available on the Settings Summary screen.

See the Post-Shock and Temporary Parameters topics for further details on other brady parameter programming options.

Navigation

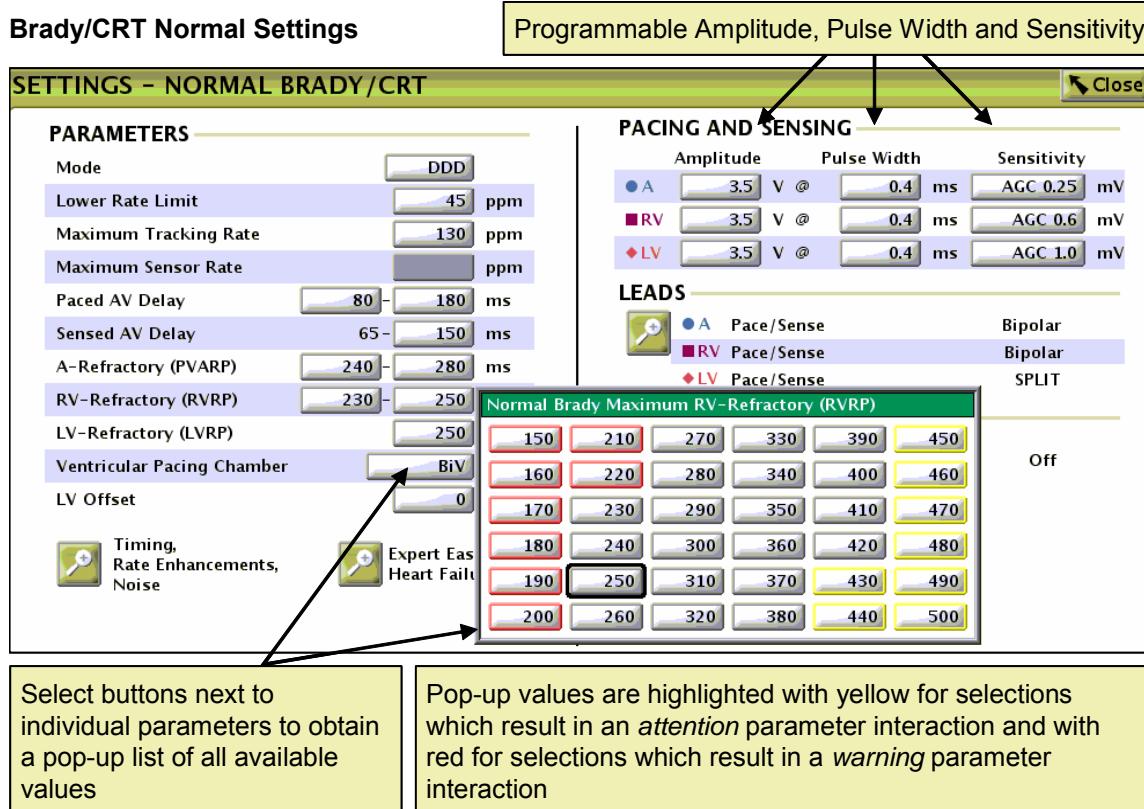
From the Settings screen select ⇨ **Settings Summary**



Brady and Brady/Tachy Interactive Limits

- LRL must be > 10 bpm below than the MSR, MTR and MPR
- The MTR interval must be \geq the TARP interval (Minimum AV Delay + Minimum PVARP = TARP); otherwise upper rate behavior would occur at rates below the MTR
- The lowest Tachy rate zone must be > 5 bpm above the MTR, MSR and MPR

- The lowest Tachy rate zone must be > 15 bpm above the LRL.
- Adjacent Tachy rate zones must differ by at least 20 bpm.



Notes/Additional Information

- The *Program* button must be selected to permanently program any changes to the device.
- As values are changed on the Settings Summary screen using the slider bars, values will automatically change on the Normal Brady/CRT screen and Ventricular Tachy Detection screen as well. Likewise, values changed under Normal Brady/CRT and Ventricular Tachy Detection will automatically be represented on the Settings Summary screen.
- The MSR is independently programmable from the MTR (i.e., the MSR may be above, below, or equal to the MTR).
- The ATR slider bar on the Settings Summary screen is not available when ATR Mode Switch is OFF. If ATR Mode Switch is OFF, V Tachy A-Fib Rate Threshold in Tachy Detection may still be programmed ON.
- Brady Parameters may be printed via the Reports Tab and is found within the “Device Follow-up Report”, “Combined Follow-up Report” and “QUICK NOTES Report.”

See the AV Delay topics for details on the programming of Paced and Sensed AV Delay as well as Dynamic AV Delay.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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STAT Pace

Brady parameters intended to confirm capture and keep the patient stable.

Programmed Parameters

- Indicated on PRM screen when STAT Pace is selected (see below for details for each setting).



- Additionally, the following changes are made to programmed parameters (if applicable) when STAT Pace is initiated:
 - Rate Smoothing Up/Down
 - VRR: OFF
 - CRT-Ds: Pacing Chamber: BiV
 - LV Offset: 0 ms
 - LVPP: 400 ms
- The first STAT Pace key brings up the STAT Pace screen and as soon as the second STAT Pace Key depression, outputs are changed to STAT Pace Parameters.
- To cancel STAT Pace changes and revert to previously programmed values, select View Changes – Load Initials – Program.

Notes/Additional Information

- Available in Storage, OFF, Monitor Only, Monitor and Therapy.
- By activating STAT Pace in Storage mode, device automatically programs from Storage to OFF.
- If feature is activated and current session is ended, STAT Pace window pops up to alert user that feature is active.
- Feature not available at EOL.

NOTE: Feature not available in Safety Core.

ICD	INCEPTA	CRT-D	INCEPTA
	ENERGEN		ENERGEN
	PUNCTUA		PUNCTUA
	TELIGEN		COGNIS

Post-shock Parameters

- Provides separately programmable pacing output parameters that can be applied during a programmable period of time following shock delivery.
- Previous devices provided a duplication of Normal Brady pacing parameters post-shock; devices described in this primer provide the following parameters only, to simplify programming:
 - Lower Rate Limit
 - Atrial amplitude and pulse width
 - Right ventricular amplitude and pulse width
 - Left ventricular amplitude and pulse width (CRT-Ds only)
 - Post Therapy Period

For any other parameters, (e.g., pacing mode, LV lead configuration, adaptive rate pacing, etc.) the device will apply the programmed normal brady parameters post shock.

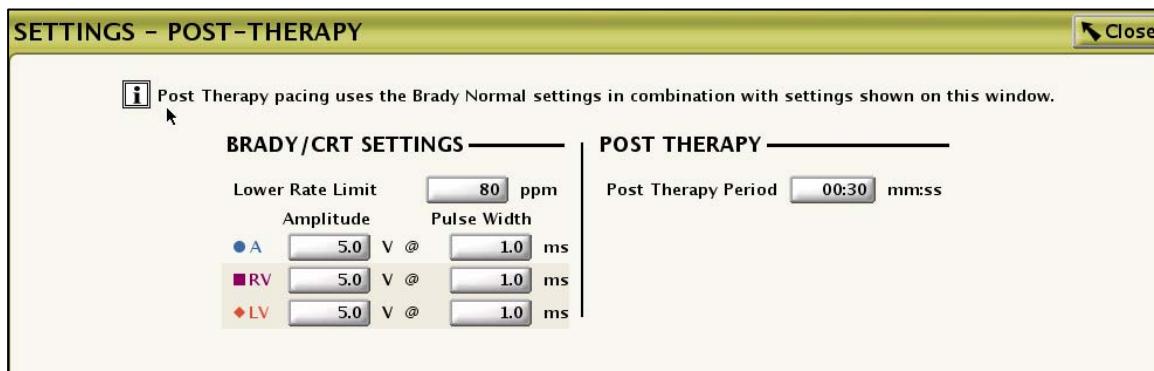
NOTE: Post-Shock pacing delay is fixed at 2.25 seconds and is non-programmable. However, if a COGNIS/TELIGEN device was interrogated with a software version earlier than model 2868 v1.03, it may exhibit a 3 second post-shock delay instead. In this case, the post-shock delay will be permanently fixed at 3 seconds. All programmers were updated to model 2868 v1.04 in the first half of 2009.

Availability

- Not available if Normal Brady Pacing mode = OFF or if device is at EOL.
- Post-Therapy brady is automatically ON if Normal Brady Pacing is in use.
- Post-Therapy brady pacing is not applied after ATP and diverted shock. Instead, the device returns to and applies normal brady parameters and outputs.

- Post-Therapy brady pacing will be suspended during the following, and resumed when these function are completed:
 - Temporary Brady
 - Pacing threshold tests
 - Impedance tests
 - ATP

From the Setting Summary screen, choose to select/view Post-Shock Brady settings.



Programmable Values

Post-Therapy Lower Rate Limit – pacing rate that will be applied during post-therapy pacing.

- 30 – 185 (Nominal = 80 bpm)
- ICDs (Nominal = 60 bpm)
- CRT-Ds (Nominal = 45 bpm)

Atrial Amplitude and Pulse Width – Atrial output values that will be applied during the post-therapy pacing period.

Post Therapy Lower Rate Limit					
30	60	90	120	150	180
35	65	95	125	155	185
40	70	100	130	160	
45	75	105	135	165	
50	80	110	140	170	
55	85	115	145	175	

- Nominal amplitude = 5.0 V
- Nominal pulse width = 1 ms

Post Therapy Atrial Pace Pulse Width				Post Therapy Atrial Pace Amplitude					
0.1	0.6	1.1	1.6	0.1	0.8	1.5	2.2	2.9	4.0
0.2	0.7	1.2	1.7	0.2	0.9	1.6	2.3	3.0	4.5
0.3	0.8	1.3	1.8	0.3	1.0	1.7	2.4	3.1	5.0
0.4	0.9	1.4	1.9	0.4	1.1	1.8	2.5	3.2	
0.5	1.0	1.5	2.0	0.5	1.2	1.9	2.6	3.3	
				0.6	1.3	2.0	2.7	3.4	
				0.7	1.4	2.1	2.8	3.5	

RV Amplitude and Pulse Width – pacing output values that will be applied to the right ventricle during the post-therapy pacing period. These output values are also used for ventricular ATP.

- Nominal amplitude = 5.0 V
- Nominal pulse width = 1 ms

Post Therapy Right Ventricle Pace Amplitude						Post Therapy Right Ventricle Pace Pulse Width			
This setting is used for multiple features. Programming this value affects: <ul style="list-style-type: none"> • Ventricular ATP • Post Therapy Brady 						This setting is used for multiple features. Programming this value affects: <ul style="list-style-type: none"> • Ventricular ATP • Post Therapy Brady 			
0.1	0.8	1.5	2.2	2.9	4.0	0.1	0.6	1.1	1.6
0.2	0.9	1.6	2.3	3.0	4.5	0.2	0.7	1.2	1.7
0.3	1.0	1.7	2.4	3.1	5.0	0.3	0.8	1.3	1.8
0.4	1.1	1.8	2.5	3.2	5.5	0.4	0.9	1.4	1.9
0.5	1.2	1.9	2.6	3.3	6.0	0.5	1.0	1.5	2.0
0.6	1.3	2.0	2.7	3.4	6.5				
0.7	1.4	2.1	2.8	3.5	7.0				

LV Amplitude and Pulse Width – pacing output values that will be applied to the left ventricle during the post-therapy pacing period. These output values are also used for ventricular ATP.

- Nominal amplitude = 5.0 V

- Nominal pulse width = 1 ms

Post Therapy Left Ventricle Pace Amplitude	Post Therapy Left Ventricle Pace Pulse Width																																																	
<p>This setting is used for multiple features. Programming this value affects:</p> <ul style="list-style-type: none"> • Ventricular ATP • Post Therapy Brady <table border="1"> <tr><td>0.1</td><td>0.8</td><td>1.5</td><td>2.2</td><td>2.9</td><td>4.0</td><td>7.5</td></tr> <tr><td>0.2</td><td>0.9</td><td>1.6</td><td>2.3</td><td>3.0</td><td>4.5</td><td></td></tr> <tr><td>0.3</td><td>1.0</td><td>1.7</td><td>2.4</td><td>3.1</td><td>5.0</td><td></td></tr> <tr><td>0.4</td><td>1.1</td><td>1.8</td><td>2.5</td><td>3.2</td><td>5.5</td><td></td></tr> <tr><td>0.5</td><td>1.2</td><td>1.9</td><td>2.6</td><td>3.3</td><td>6.0</td><td></td></tr> <tr><td>0.6</td><td>1.3</td><td>2.0</td><td>2.7</td><td>3.4</td><td>6.5</td><td></td></tr> <tr><td>0.7</td><td>1.4</td><td>2.1</td><td>2.8</td><td>3.5</td><td>7.0</td><td></td></tr> </table>		0.1	0.8	1.5	2.2	2.9	4.0	7.5	0.2	0.9	1.6	2.3	3.0	4.5		0.3	1.0	1.7	2.4	3.1	5.0		0.4	1.1	1.8	2.5	3.2	5.5		0.5	1.2	1.9	2.6	3.3	6.0		0.6	1.3	2.0	2.7	3.4	6.5		0.7	1.4	2.1	2.8	3.5	7.0	
0.1	0.8	1.5	2.2	2.9	4.0	7.5																																												
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<p>This setting is used for multiple features. Programming this value affects:</p> <ul style="list-style-type: none"> • Ventricular ATP • Post Therapy Brady <table border="1"> <tr><td>0.1</td><td>0.6</td><td>1.1</td><td>1.6</td></tr> <tr><td>0.2</td><td>0.7</td><td>1.2</td><td>1.7</td></tr> <tr><td>0.3</td><td>0.8</td><td>1.3</td><td>1.8</td></tr> <tr><td>0.4</td><td>0.9</td><td>1.4</td><td>1.9</td></tr> <tr><td>0.5</td><td>1.0</td><td>1.5</td><td>2.0</td></tr> </table>		0.1	0.6	1.1	1.6	0.2	0.7	1.2	1.7	0.3	0.8	1.3	1.8	0.4	0.9	1.4	1.9	0.5	1.0	1.5	2.0																													
0.1	0.6	1.1	1.6																																															
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Post Therapy Pacing Period																																																		
<table border="1"> <tr><td>00:15</td><td>01:30</td><td>05:00</td><td>45:00</td></tr> <tr><td>00:30</td><td>02:00</td><td>10:00</td><td>60:00</td></tr> <tr><td>00:45</td><td>03:00</td><td>15:00</td><td></td></tr> <tr><td>01:00</td><td>04:00</td><td>30:00</td><td></td></tr> </table>		00:15	01:30	05:00	45:00	00:30	02:00	10:00	60:00	00:45	03:00	15:00		01:00	04:00	30:00																																		
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01:00	04:00	30:00																																																

Post Therapy Period – determines how long the device will operate using post-shock parameters. At the end of the Post-Shock Therapy Period, the device returns to the programmed Normal Brady Parameters. Nominal = 30 seconds.

Algorithm

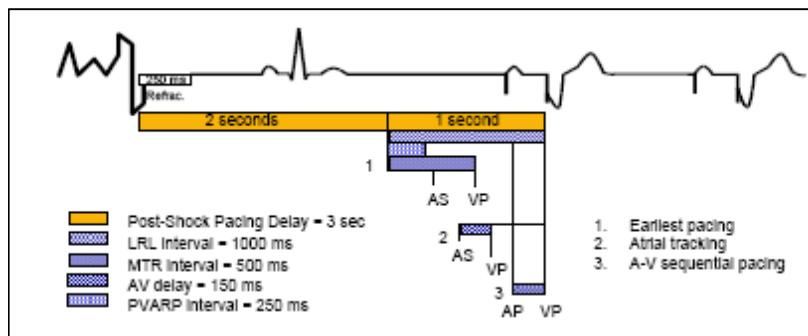
Post-therapy pacing is activated following ANY shock delivery including:

- Shocks delivered due to detection
- Commanded shocks
- Shocks from induction
- STAT shocks

Post-therapy pacing is not applied after a diverted shock or ATP delivery.

- Once a shock is delivered, post-therapy brady timing is activated one post-therapy LRL escape interval before 2.25 seconds expires. Prior to this point, intrinsic activity can be sensed and counted toward tachy detection and/or ATR criteria but do not initiate any pacing timing.
- Once brady timing is activated, the device initiates timing intervals that are typically started with a ventricular event (for ventricular modes). These timing intervals include the VA interval, PVARP, and MTR interval.
 - If PVARP After PVC is programmed ON, that value will be used; if not, the device will use normal brady PVARP.
 - PVARP After PVC marker (PVP→) will be applied, indicating the return to dual chamber pacing (device was in VTR mode switch during event).

- The actual delivery of the first pacing pulse post-shock depends on the cardiac activity that occurs after the brady timing is activated. The example below shows the various timing windows that would be in effect for a device programmed DDDR with AV Delay of 150 and a post-therapy LRL rate of 60 bpm.



Examples: DDD Post-shock Pacing examples

Earliest Pacing – the earliest that a p-wave can be sensed and tracked is following the PVARP that is set up when brady timing is activated. If a p-wave is sensed, the earliest a V-pace can be delivered is at the end of the MTR interval that was initiated with brady timing activation. AV Delay may be prolonged to avoid violating the MTR.

Atrial Tracking – a V-pace may be delivered at the programmed AV Delay when the sensed p-wave occurs late enough that the end of the AV Delay is not within the MTR interval.

A-V sequential pacing – if no p-wave or R-waves are sensed, the first ventricular pacing pulse is delivered after 2.25 seconds, with an atrial pacing pulse preceding the programmed AV Delay interval.

- Application of the Post-Shock parameters is terminated if:

- Post-Shock period times out
- Post-Shock pacing is reprogrammed to a value less than the elapsed time
- Post-Therapy Period can only be re-started by another shock

Notes/Additional Information

- Post Shock Pacing Delay applies to all pacing after a shock is delivered.
- Any normal brady programming changes to LRL, amplitude, or pulse width that are programmed while Post-Shock parameters are in effect will be applied after the Post-Therapy Period has ended.
- During the Post Therapy Period, if Cross Blanking is programmed to SMART in RA, RV, or LV, the Cross Chamber value is temporarily changed to a fixed period of 85 ms in each chamber SMART is active. At the end of the Post Therapy Period, the Cross Chamber Value reverts back to SMART (RA 15 ms, RV/LV 37.5 ms).
- If the Post Therapy Period is programmed initially to a longer time period, and then while the Post Therapy period is in effect, reprogrammed to a time period that is shorter than the elapsed time, the Post Therapy Pacing will end immediately. The Post-Therapy Period can only be re-started by another shock.

- For devices programmed to a rate response mode (e.g., DDDR), any sensor data accumulated for modulating the pacing rate is cleared with shock delivery. Sensor data collection resumes immediately following shock delivery and continues during Post-Therapy Pacing. The first interval post-shock is always at the Post Therapy LRL. Adaptive-rate pacing can begin as soon as there is ample sensing data (about 5 seconds). Therefore, there may be a few paced intervals at the LRL before the pacing rate begins to increase to respond to the sensor.
- CRT-Ds:
 - If programmed to a dual-chamber mode, RV-only (regardless of LV pacing configuration), device will pace RV-only post shock unless an ATR mode switch occurs during the post shock pacing period or after the post shock pacing period ends. Pacing would then switch from RV-only to BiV during the mode switch.
 - If programmed to VVI(R) mode, RV-only (regardless of LV pacing configuration), devices will pace RV-only. Post Shock LV pacing output and pulse width will be grayed out.

Temporary Brady/ CRT Parameters



Temporarily programming brady parameters allows the user to temporarily assess brady therapy settings while maintaining the permanently programmed parameters during a clinic follow-up. As opposed to devices prior to TELIGEN/COGNIS, the Temporary Parameters screen for devices described in this primer increase ease of use by eliminating non-essential temporary brady options. Please refer to the Normal Brady Parameters and Post-Shock Parameters sections for further details on other brady programming options.

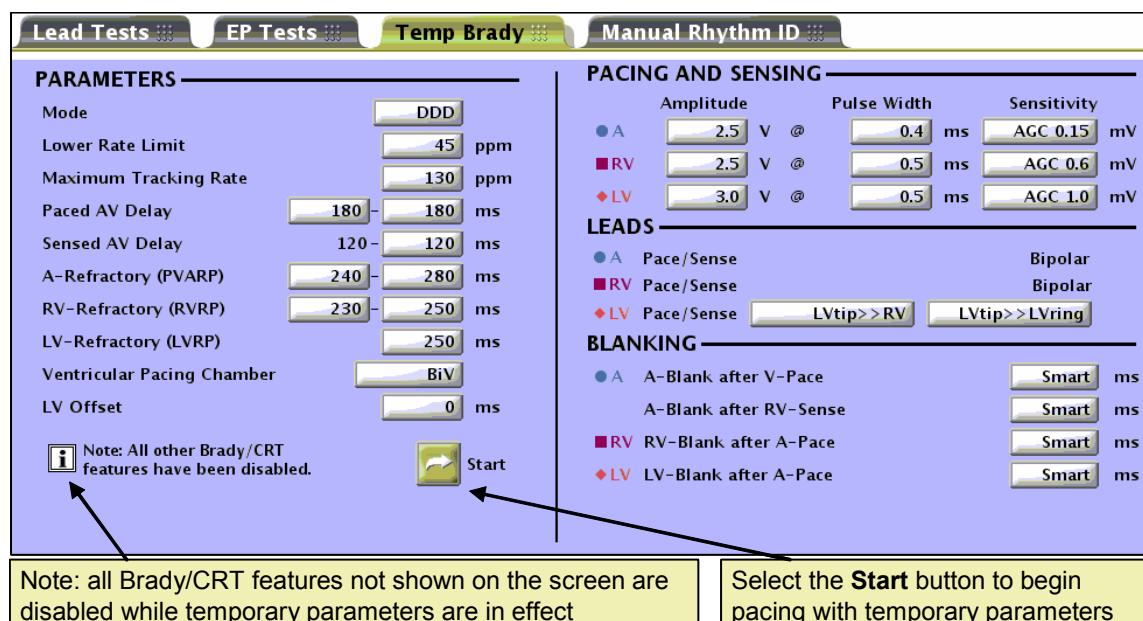
Navigation

From the Tests screen select ⇨

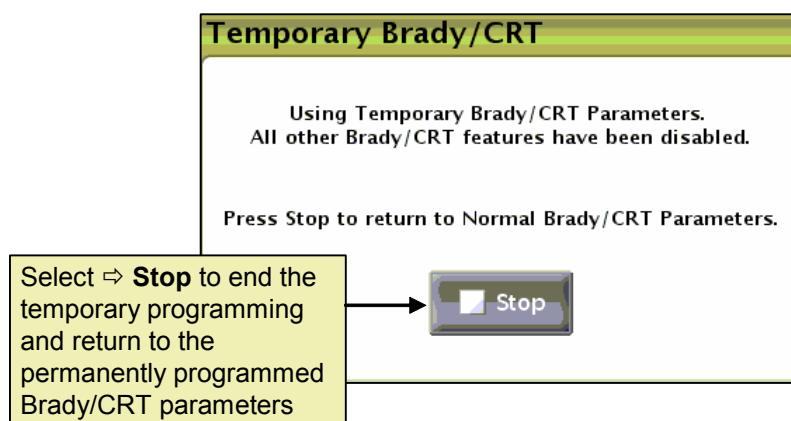


Available Parameters

The following parameters are available for temporary programming (note the blue background of the Temporary Brady screen as opposed to the white background of the Normal Brady screen):



After the *Start* button is selected, the following pop-up screen will be present indicating temporary parameters are in effect:



Notes/Additional Information

- The Start button must be selected to enact temporary parameters.
- Parameters not viewable on the main Temporary Brady Parameters screen are not available for temporary programming and will be disabled while temporary parameters are in effect with the exception of temporary LV-only pacing which is not available in device models distributed in the U.S.
- An active ATR episode will end if the temporary mode selected is a non-tracking mode.

Warning: 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.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Accelerometer

Adaptive Rate Pacing with Accelerometer Sensor provides an increase in heart rate by detecting body movement associated with physical activity. By increasing a patient's heart rate, those with chronotropic incompetence can benefit from a more physiologic response to movement and have a decrease in symptoms associated with low heart rates during activity.

Availability

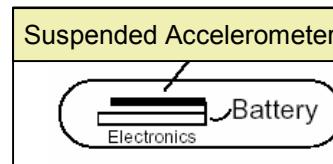
- Available in all permanent and/or ATR modes which are rate responsive (DDD, DDIR, VDDR, VVIR and AAIR)
- Navigation:

1. From the Settings screen select 
2. Select 
3. Select 

Accelerometer Operation

The accelerometer is a mass suspended from the integrated circuit in a *diving board* orientation along the X-axis. The X-axis records forward and backward motion: the advantages of using this axis are:

- It demonstrates a more uniform response to different types of activity (cycling versus walking) but with sufficient signal amplitude to reflect changes in the intensity of work.
- The orientation (header up/down or serial number facing/away from ribs) of the pulse generator does not affect the accelerometer response.



The accelerometer sensor measures the amplitude (force of motion) and frequency of body motion. The movement of the accelerometer within the Can is then converted to an electrical signal which is used by the sensor circuitry to determine rate changes above the LRL. The sensor responds to activity in the frequency range of 1-10 Hz where physiologic activity signals predominantly occur.

Programmable Values

Max Sensor Rate (MSR)	30-185 bpm	Nominal: 130 bpm
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- Maximum rate the device will pace in response to sensor input.
- Independently programmable from the MTR
- Must be at least 5 bpm lower than the lowest Ventricular Tachy Detection Rate and ATR Trigger Rate.
- Must be at least 10 bpm higher than the Normal Brady LRL, ATR/VTR Fallback LRL and Post-Therapy LRL.

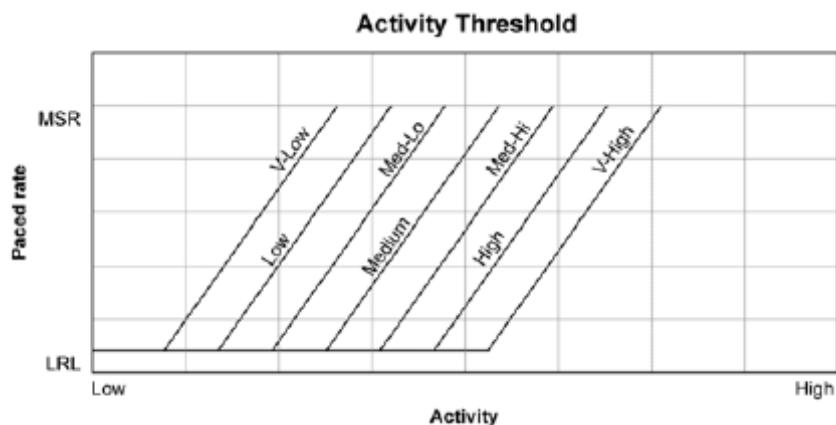
Accelerometer	ON/OFF/ATR Only (non-programmable)
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- The XL automatically turns ON when the device is programmed to a permanent and/or ATR rate responsive mode.

Activity Threshold	Very Low to Very High	Nominal: Medium
Reaction Time	10-50 seconds	Nominal: 30 secs
Response Factor	1-16	Nominal: 8
Recover Time	2-16 minutes	Nominal: 5 mins

Activity Threshold

Determines the minimum amount of activity needed to cause an increase in the sensor-driven pacing rate. A *lower setting* requires *less motion* to increase the pacing rate and a *higher setting* requires *more motion* to increase the pacing rate. For example, programming from the Medium setting to the Low setting would allow a lower amount of activity to cause a sensor-driven rate increase. The Activity Threshold should be set low enough to allow a rate increase with minor activity such as walking but be high enough to prevent rate increases due to lower intensity motion.

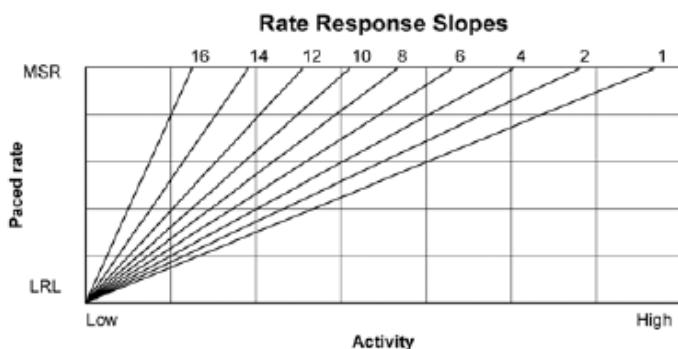


Reaction Time

Determines how quickly the pacing rate will rise to a new level once an increase in activity is detected. The value selected indicates the time required to increase the pacing rate from the LRL to the MSR at a maximum level of activity. The rate will increase in steps and the device will pace for multiple cycles at each step before increasing to the next higher rate to avoid abrupt increases in the pacing rate. Shorter reaction times result in faster increases in the pacing rate and may be beneficial for younger/more active patients, patients with deconditioned hearts that require rapid elevation, or for reducing symptoms in patients with orthostatic hypotension. Longer reaction times result in slower increases in the pacing rate and may be needed for patients who can tolerate only small rate changes.

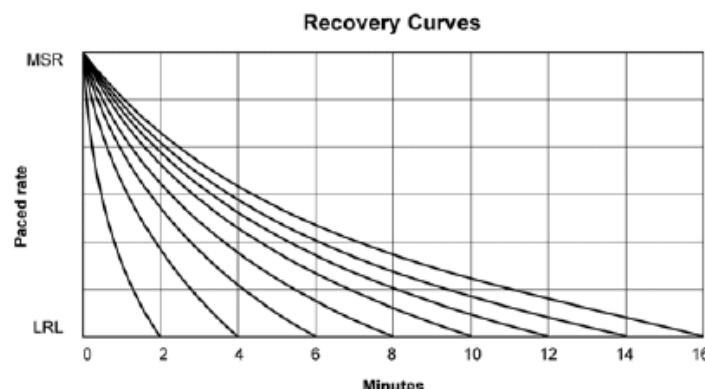
Response Factor

Determines the aggressiveness of the sensor at all levels of activity and functions independently from the reaction time and recovery time parameters. A high response factor setting will require less activity to reach the MSR and a low response factor setting will require more activity to reach the MSR. Each value increase in the response factor setting will result in a 10-15 beat per minute increase in heart rate at a given activity level. If programmed *too low*, there will be an insufficient increase in heart rate with activity. If programmed *too high*, the patient may reach the MSR at moderate levels of activity. Reprogramming the MSR or LRL does not change the slope (overall aggressiveness) of the response factor.



Recovery Time

Determines how quickly the pacing rate will decrease to a new level once a decrease in activity is detected. The value selected indicates the time required to decrease the pacing rate from the MSR to the LRL in the absence of activity. The rate will decrease in steps and the device will pace for multiple cycles at each step before decreasing to the next lower rate to avoid abrupt decreases in the pacing rate. Shorter recovery times result in faster decreases in pacing rate and longer recovery times result in slower decreases in the pacing rate. The recovery time is also applied when returning to the LRL after temporarily pacing at a higher temporary LRL.



Notes/Additional Information

- The Accelerometer is suspended when temporary parameters are in effect since all temporary modes are non-rate responsive.
- The Accelerometer functions the same in Post-Therapy Settings as in normal pacing.

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Sensor Trending

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

The pulse generator collects and stores rate and sensor data.

- The rate data represents the programmed parameters.
- The Sensor Replay option allows you to adjust the parameter values and view the result without having to repeat an exercise test.

Availability

- Trending is available in any mode; the device does not need to be in a rate responsive mode.
- Although the *Reset and Start Trending* selection is available, no data will be recorded if the Normal Brady/CRT pacing mode is OFF.
- Navigation:

- From the Settings screen select
- Select
- Select

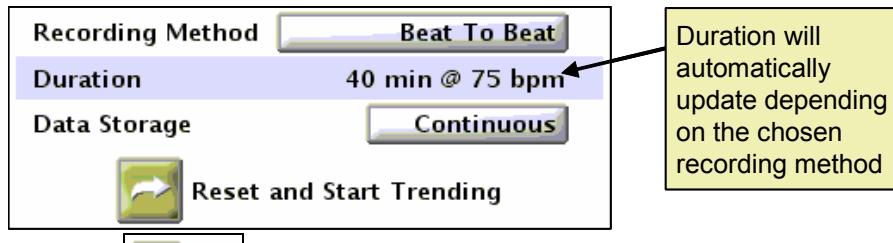
Programmable Values

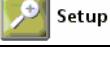
To obtain programmable parameters on the Sensor Trending screen, select  **Setup**

Recording Method	<ul style="list-style-type: none"> • 30 Seconds Average • Beat-to-Beat • OFF 	Nominal: 30 second Average
Data Storage	Continuous or Fixed	Nominal: Continuous
Duration	Non-programmable	

- 40 min @ 75 bpm with Beat-to-Beat
- 25 hours with 30 Second Average
- Unlike previous devices, duration will not vary based on programmed mode

Steps to perform a new trend:



1. Select  **Setup** from the Sensor Trending screen
2. Select a Recording Method:
 - Beat-to-Beat records and plots the rate of every ventricular beat (or every atrial beat in AAI(R) mode).
 - Consider for hall walks or shorter periods of activity.
 - While the Insignia Trending feature does not include sensor data for Beat-to-Beat mode, the Trending feature for devices described in this primer does include sensor data in this mode.
 - 30-Second Average records the rate of every beat and plots the average rate of each 30-second period.
 - Consider for sustained activity or to view an entire day of trending results.
 - PVC/PAC intervals are included both recording methods.
 - If the Recording Method is OFF, no trending data will be recorded.
3. Select Data Storage:
 - Continuous storage will continuously record the latest information and once the Duration time is reached, newer data will begin to over-write older data.
 - This option allows viewing of data immediately prior to data retrieval.

- Fixed storage will begin recording from the time the trend is reset and stops recording once the Duration time is reached.
 - This option allows viewing of data immediately following initial set-up for a fixed amount of time.
- If the Recording Method is OFF, no trending data will be recorded regardless of the selected Data Storage.

4. Select  **Reset and Start Trending** to clear past results and begin a new trend.
5. Physician administers instructions to patient to perform an exercise test (i.e., hall walk) and re-interrogates the device when the exercise test is complete.

Trend Results

Trending results will be blank on initial interrogation. Once in the Sensor Trending screen, select either the Interrogation *hard key* or the Interrogation *touch screen* button to obtain updated results. Likewise, if the trend is reset during the currently active telemetry session prior to the patient performing a hall walk, the device must be reinterrogated when the patient returns to obtain updated data.

NOTE: As opposed to previous devices, results may be obtained in any tachy mode and trending is not suspended during temporary brady, diagnostic tests, or ventricular tachy episodes.

Displayed data represents the heart rate recorded from the atrial channel if in AAI(R) mode or from the ventricular channel in all other modes. Combined atrial/ventricular information is no longer available as in previous devices.

- The actual rate is displayed in *black*.
- The sensor indicated rate is displayed in *orange*.

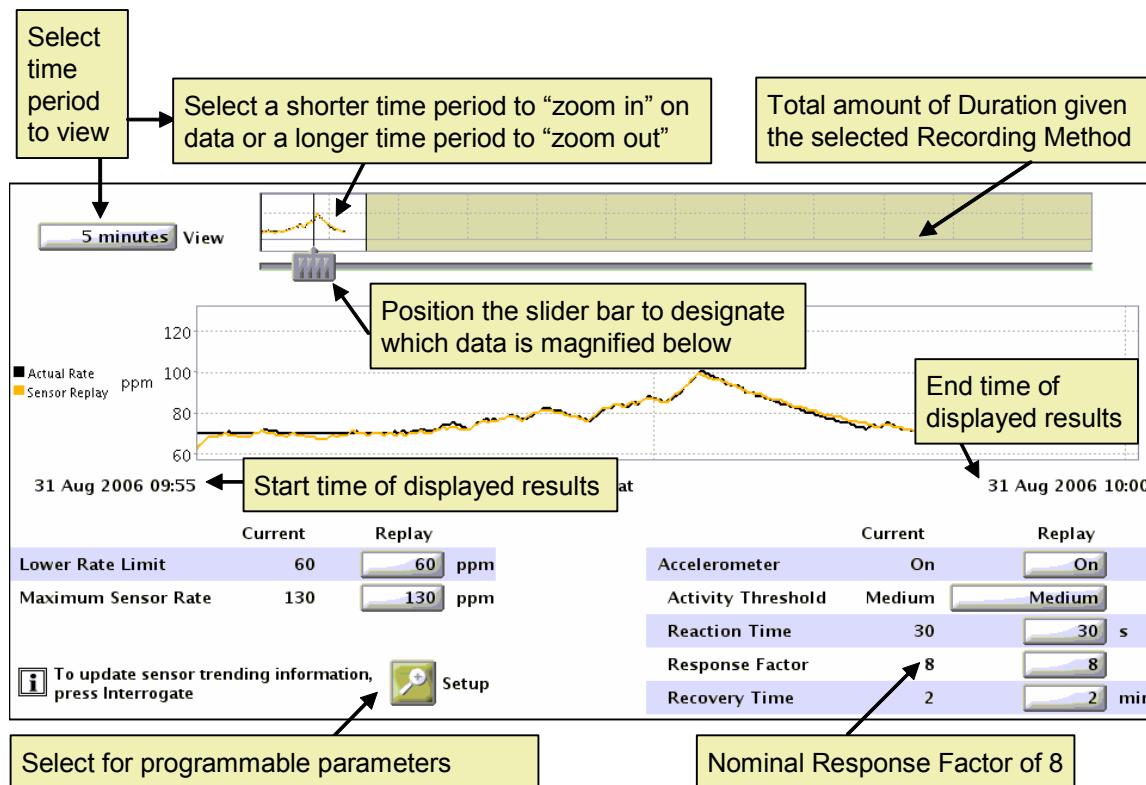
Using the Replay Function

The *Current* columns on the lower half of the screen will show the LRL, MSR and sensor values which were in place when results were recorded. The *Replay* columns may be used to adjust the sensor parameter values to obtain new results without having the patient repeat an activity session. When changes are input to the Replay columns, the *orange sensor replay line* will automatically adjust to show what the sensor would have done at the same activity level if the new Replay parameters had been present at the time of recording.

If the device is in a non-rate responsive mode, results will continue to be collected and stored although the graph will not show an orange sensor line and the current parameters will show Accelerometer OFF. To obtain the sensor's response, turn the Accelerometer ON via the Replay function. The Sensor Reply line will appear and demonstrate how the sensor would have responded if it had been turned ON during the recording period.

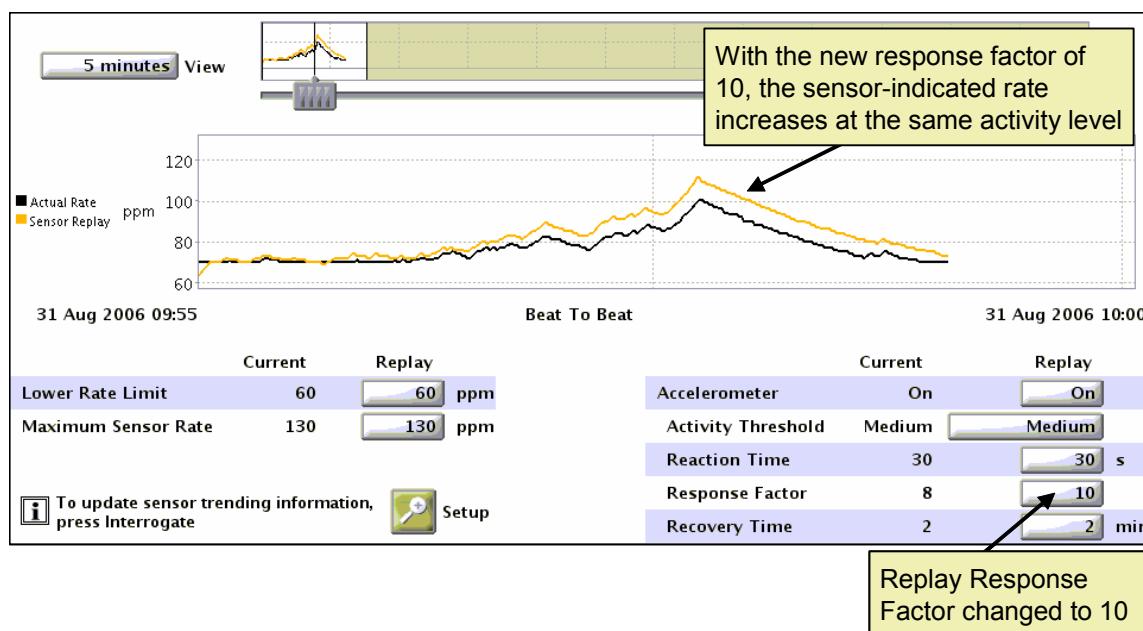
Example: Trend Example:

In this example, the trend was reset and started with a Beat-to-Beat Recording Method and a Continuous Data Storage. The patient then performed a short walk at nominal Accelerometer parameters. When the patient returned, the device was re-interrogated with the following results:



The available selections for the time period *View* will vary due to the different Durations of the two Recording Methods.

- Selections when the Beat-to-Beat Recording Method is used range from 5 minutes to 40 minutes.
- Selections when the 30-Second Average Recording Method is used range from 1 hour to 25 hours.



- To assess the sensor's response when new parameters are applied, a response factor of 10 is placed in the Replay column. The sensor line automatically increases to indicate what the sensor would have done at a response factor of 10 given the same activity.

Notes/Additional Information

- Trending is nominally ON and will begin storing results as soon as the device is programmed out of Storage mode.
- Trend results cannot be printed.
- The Trending function does not affect device longevity.

Atrial Tachy Response (ATR)



The Atrial Tachy Response feature (ATR mode switch) is designed to limit tracking of atrial arrhythmias by automatically mode switching to a non-tracking mode when programmed ATR criteria are met. ATR limits the amount of time that the ventricular-paced rate is at the MTR or exhibits upper-rate behavior (2:1 block or Wenckebach) in response to a pathological atrial arrhythmia. ATR also limits the amount of time that CRT is inhibited due to pathological atrial tachycardia.

Availability

- Available in DDD(R) and VDD(R) modes
- Navigation:

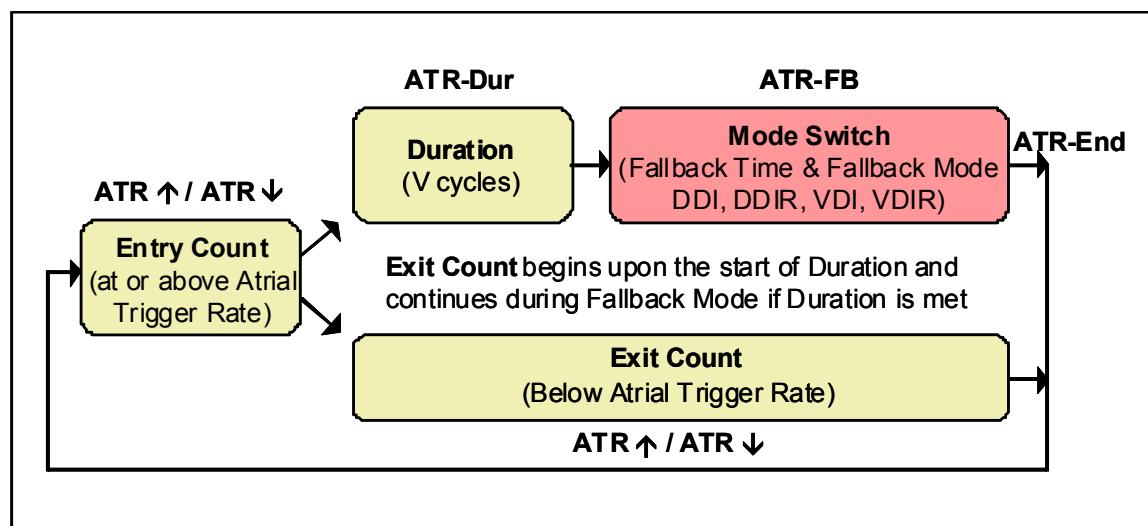
- From the Settings screen select 
- Select  **ATRIAL TACHY**

Programmable Values

	Range Of Values	Nominal Value
ATR Mode Switch	ON/OFF	ON
Trigger Rate	<ul style="list-style-type: none"> • 100-300 bpm, • must exceed the programmed MTR and MSR by ≥ 5 bpm 	170 bpm
Duration	0-2048 ventricular cycles	8 cycles
Entry Count	1-8 atrial cycles	8 cycles
Exit Count	1-8 atrial cycles	8 cycles
Fallback Mode	<ul style="list-style-type: none"> • ICD: VDI(R), DDI(R) • CRT-D: VDI(R), DDI(R) • DDI(R) fallback modes are available only in normal DDD(R) mode 	DDI DDI
Fallback Time	00:00 to 02:00 mins	00:30 sec
ATR/VTR Fallback LRL	<ul style="list-style-type: none"> • 30-185 ppm, • may be greater or less than the normal brady LRL; must be ≤ 10 bpm less than the MTR/MSR 	70 ppm
Ventricular Rate Regulation (VRR)	<ul style="list-style-type: none"> • ICD: ON/OFF • CRT-D: OFF, Min, Med, Max 	ON Min
BiV Trigger (CRT-Ds only)	ON/OFF	ON
Maximum Pacing Rate	30-185 bpm	130 bpm

Algorithm

Schematic of ATR algorithm



Step 1: ATR Trigger Rate is exceeded

The ATR algorithm continually monitors for sensed atrial events which are equal to or above the programmed Trigger Rate. All refractory (i.e., PVARP) and non-refractory atrial events are included while atrial events within the blanking period or noise windows are not counted.

NOTE: The ATR Trigger Rate slider bar on the Settings Summary screen is not available when ATR Mode Switch is OFF. If ATR Mode Switch is OFF, the Ventricular Tachy A-Fib Rate Threshold is programmable on the Ventricular Tachy Detection Enhancements screen.

NOTE: The ATR Trigger Rate is linked to the AFR Trigger Rate and Vent Tachy A-Fib Rate Threshold. If one of the three rates is reprogrammed, the others will automatically change to the same value.

Step 2: Entry Count is met

The Entry Count is a count of atrial events that occur above the Trigger Rate and determines how quickly the atrial arrhythmia is initially detected. The Entry Counter increments (+1) for each sensed atrial event *equal to or above* the Trigger Rate and decrements (-1) for:

- Each sensed or paced atrial event below the Trigger Rate.
- Each sensed or paced ventricular event in which there has not been an atrial event within the last 2 seconds.

Once the counter reaches the programmed Entry Count, Duration begins. A lower programmed Entry Count requires fewer fast atrial events to fulfill this initial detection and begin Duration.

Step 3: Duration criteria is met and the Exit Count begins

Duration determines the number of ventricular cycles during which the atrial arrhythmia will be monitored prior to mode switching. Programming a short Duration causes the device to mode switch more quickly whereas a long Duration prevents mode switching due to shorter, non-sustained atrial arrhythmia episodes. During Duration, the Exit Count increments and decrements to ensure the count remains above zero for the programmed amount of ventricular cycles.

See Step 7: Exit Count Description below.

In the event of a short, non-sustained episode of atrial tachycardia, the Exit Count will reach zero prior to the end of Duration and no mode switch will occur. If the Exit Count is above zero at the end of Duration, the Fallback Time and Fallback mode will begin.

CAUTION: Entry Count and Duration

Use caution when programming both the Entry Count and Duration to low values as this will result in a mode switch after only a few fast atrial beats.

Step 4: Fallback Mode is initiated

The Fallback mode is the non-tracking pacing mode which is initiated once Duration is met and remains in effect until the Exit Count is reaches zero.

- If both permanent and ATR Fallback modes are rate responsive, the device will use the permanent sensor parameters. If the permanent mode is non rate responsive, the ATR Fallback mode may be programmed rate responsive using the Accelerometer sensor.
- A dual-chamber pacing Fallback mode is only available if the permanent Brady pacing mode is dual chamber (i.e., DDI(R) is not available as a Fallback mode in permanent VDD(R) mode).
- In CRT-Ds, the pacing chamber is BiV while in Fallback mode regardless of the permanently programmed pacing chamber.

Step 5: Ventricular paced rate decreases during Fallback Time

Fallback Time determines how quickly the ventricular-paced rate will decrease to the ATR/VTR Fallback LRL, sensor-indicated rate or VRR-indicated rate (whichever is faster). Programming a shorter Fallback Time will result in a faster decrease of the ventricular-paced rate which physicians may consider for patients who are symptomatic at higher ventricular rates. If Exit count is met while device is falling back to Fallback LRL, it is possible for the rate to drop to normal Brady LRL. The physician may consider programming a Rate Smoothing to avert this type of sudden rate drop.

Step 6: Ventricular paced rate decreases to the ATR/VTR Fallback LRL

The ATR/VTR Fallback LRL is the separately programmable lower rate which the ventricular paced rate will decrease to during Fallback Time. The device will remain at the fastest of the Fallback LRL, sensor-indicated rate, VRR- indicated rate, or Max Pacing Rate until the end of the

mode switch episode. ATR/VTR Fallback LRL may be *greater than or less than* the normal brady LRL.

The ATR/VTR Fallback LRL is also the rate used for back-up VVI pacing in the presence of detected ventricular arrhythmias. This Fallback LRL is available for tachy detection programming even if ATR is programmed OFF.

Step 7: Exit Count is met

The Exit Count is a count of atrial events that occur below the Trigger Rate and determines if the device will enter a mode switch following Duration or if the device will exit an active mode switch once the atrial arrhythmia ends. The Exit Counter increments (+1) for each sensed atrial event *equal to or above* the Trigger Rate and decrements (-1) for:

- Each sensed or paced atrial event below the Trigger Rate.
- Each sensed or paced ventricular event in which there has not been an atrial event in the last two seconds.

The lower the programmed Exit Count, the faster the device will return to a tracking mode once the atrial arrhythmia ends. All refractory and non-refractory atrial events are included while atrial events within the blanking period or noise windows are not counted. If the Exit Count reaches zero during Duration, no mode switch will occur. If the count reaches zero during an active ATR episode, the mode switch will end and the device returns to normal programmed settings.

CAUTION: Entry count and duration

Use caution when programming the Exit Count to a low value as a few cycles of atrial undersensing could cause an exit of the mode switch.

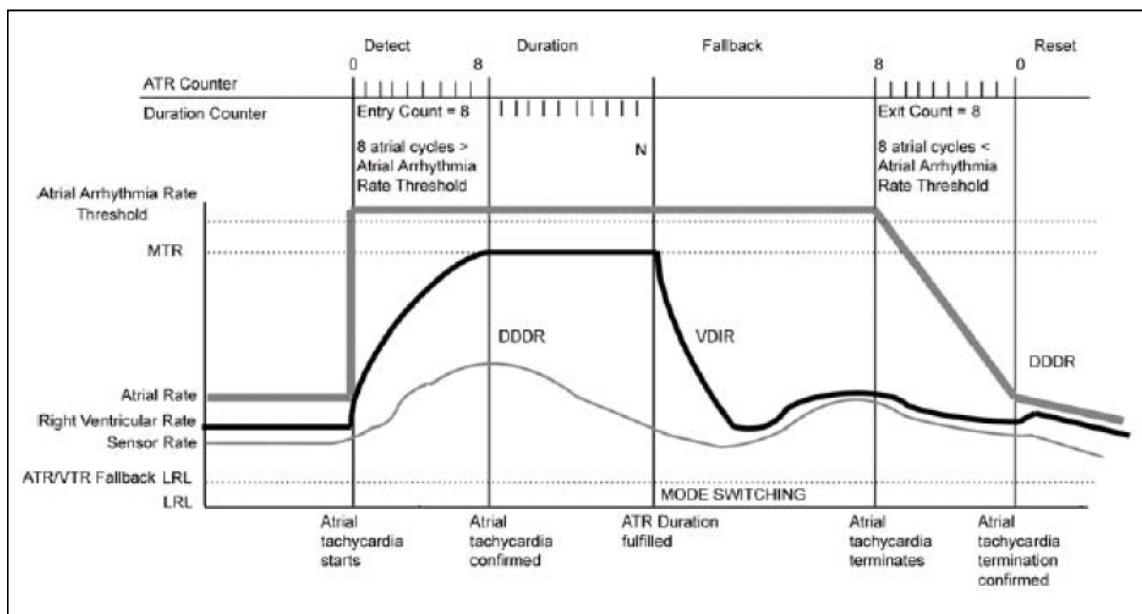
ATR will immediately be terminated if a ventricular tachy detection window becomes satisfied (8/10 fast intervals). The ATR episode is immediately terminated and the device performs a VTR mode switch.

Ventricular Rate Regulation/BiV Trigger/Maximum Pacing Rate

The VRR algorithm reduces the V-V cycle length variability during conducted atrial arrhythmias while not exceeding the programmed Maximum Pacing Rate. If VRR is ON, it is active once the ATR mode switch criteria are met.

In CRT-Ds, a Min, Med or Max VRR setting may be programmed with a fallback mode of VDI(R) and a Min setting may be programmed with a DDI(R) fallback mode. BiV trigger promotes synchronized RV and LV pacing in a non-tracking mode.

See the VRR and BiV Trigger topics for further details.



Sample of ATR function

Arrhythmia Logbook Storage

An event is stored in the Arrhythmia Logbook at the end of duration.

See the Arrhythmia Logbook topic for further details on event storage.

- Up to three detailed episodes may be stored with associated EGMs; up to 10 total ATR events may be listed.
- If *In Progress* is displayed for duration, the ATR episode is still in progress; the associated stored EGM is available while the episode is in progress.
- Stored EGM Event markers:

ATR-Dur	Marks the start of duration
ATR-FB	Marks the beginning of fallback mode
VP-FB	Marks each ventricular paced event during fallback
ATR-End	Marks the end of the ATR episode
↑ ATR	Indicates an atrial event above the trigger rate
↓ ATR	Indicates an atrial event below the trigger rate

- For each event, 10 seconds EGM prior to and 10 seconds EGM after the start of the ATR mode switch are stored.
- The interval graph will show each of the intervals which are stored on the EGM.

Episode Report Details

- Event Number (e.g., ATR-7), event date, and event time are provided.
- ATR Event Onset
 - Average A-rate: average A-rate at time the ATR mode switch was triggered.
 - × Calculated from the four-interval average preceding point of mode switch
 - Average V-rate: average V-rate at time the ATR mode switch was triggered.
 - × Calculated from four-interval average preceding point of mode switch
- Event Ended
 - Total duration of the ATR mode switch episode.
 - × If the ATR episode duration exceeds 48 hours, the programmer will display > 48hours

Notes/Additional Information

- In CRT-Ds, the pacing chamber is BiV while in Fallback mode regardless of the permanently programmed pacing chamber.

See the Lead Configuration topic if no LV lead is implanted (CRT-Ds.)

- ATR functions the same in Post-Therapy as in normal brady pacing.
- AV Search Plus, Rate Hysteresis, and PVARP extension are suspended during an ATR mode switch while AFR, Dynamic AVD, PVARP and VRP are not suspended.
- The Atrial Burden counter is incremented in the appropriate duration bin when the ATR mode switch ends. If an ATR mode switch occurs during ventricular redetection, the device will increment the Atrial Burden counter and an ATR EGM will be stored.
- Temporary parameters may be used and lead measurements may be obtained during an ATR episode. Temporary parameters and intrinsic lead measurements will terminate an active ATR episode if the temporary mode is a non-tracking mode. Following a return to permanent programming, the ATR algorithm must fulfill entry criteria to reenter a mode switch.
- VRR and Rate Smoothing function during an ATR mode switch:
 - If both are ON; Rate Smoothing is suspended while VRR is active during ATR (VRR is active once Duration is met and disabled once the mode switch is exited).
 - If VRR is OFF and Rate Smoothing is ON; Rate Smoothing is suspended during the ATR Fallback Time and is re-enabled once the device reaches the greater of the ATR/VTR fallback LRL or sensor-indicated rate.
- When using ATR with Rate Smoothing and/or AFR, consider Duration=0 since those algorithms will result in slower ventricular pacing rates and thus the time for a mode switch to occur may be extended.

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Atrial Flutter Response (AFR)

Atrial Flutter Response provides immediate dissociation of the atrium and ventricle for atrial rates faster than the programmed AFR Trigger Rate. While AFR immediately prevents tracking of atrial arrhythmias and is sometimes referred to as a *one beat mode switch*, a true mode switch will not occur until ATR criteria are met.

AFR will help to prevent symptoms during short atrial arrhythmia episodes or during the time period while ATR mode switch criteria are being fulfilled. Additionally, AFR prevents pacing into the atrial vulnerable period (period following an action potential, where the membrane is *hyper-excitable* to stimulus) by inhibiting scheduled atrial pacing until all AFR windows have expired. Pacing into the atrial vulnerable period could occur if an atrial pace is scheduled soon after a refractory atrial sense.

Availability

- Available in DDD(R) and DDI(R) pacing modes.
- Not available in VDD(R) mode as the AFR algorithm requires atrial pacing.
- Navigation:

1. From the Settings screen select 
2. select 

Programmable Values

Atrial Flutter Response	ON/OFF	Nominal: OFF
Trigger Rate	100-300 bpm	Nominal: 170 bpm

The AFR Trigger Rate is linked to the ATR Trigger Rate and Vent Tachy A-Fib Rate Threshold. If one of the three rates is reprogrammed, the others will automatically change to the same value. The Trigger Rate must be ≥ 5 bpm above MTR/MSR. If ATR and/or AFR are programmed OFF, the Ventricular Tachy A-Fib Rate Threshold is programmable on the Ventricular Tachy Detection Enhancements screen.

Algorithm

A single atrial sensed event occurring in PVARP triggers an AFR window equal to the programmed Trigger Rate (e.g., Trigger Rate of 230 bpm = AFR window of 260 ms). If an atrial-sensed event occurs within that AFR window (above the AFR trigger rate), it triggers another AFR window. As

atrial-sensed events continue to occur within AFR windows, they are classified as AS in refractory, are not tracked, and retrigger additional AFR windows.

See the AFR function example below.

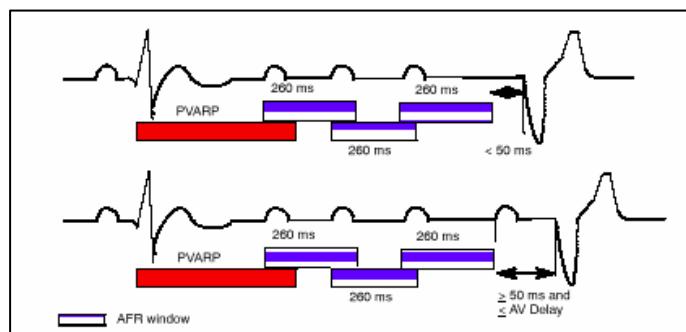
- Dual-chamber operation (i.e., tracking) resumes when both PVARP and the AFR window have expired without an atrial sense occurring within them.
- Ventricular pacing is not affected by AFR and will always take place as scheduled.

Atrial pacing is inhibited during AFR windows.

- Atrial pacing that was withheld during PVARP or the AFR window is delivered as soon as these windows expire, providing there is at least 50 ms but no more than the programmed AV Delay before the next scheduled ventricular pace.

See the AFR function example below.

- If there is more than the programmed AV Delay before the next scheduled VP, the AP will occur at the end of the VA interval as expected.
- This change in AV Delay may alter the effectiveness of CRT delivery if the AFR Trigger Rate is programmed to a value that is less than the patient's sinus rate.



AFR function

Notes/Additional Information

- There are no AFR counters and AFR is not a storage trigger for the Arrhythmia Logbook; an EGM will be stored when ATR Mode Switch criteria are met.
- AFR events are identified with *AS-FI* on EGMs.
- AFR is still available in DDI(R) mode to prevent pacing into the atrial vulnerable period.

See introductory paragraph above.

- AFR may slightly lengthen the time it takes to fulfill ATR Mode Switch criteria. By preventing the tracking of atrial arrhythmias, AFR results in a slower ventricular pacing rate which may extend the time required to fulfill the ventricular cycles of ATR Duration.
- AFR will continue to operate during temporary pacing functions as long as the temporary pacing mode retains atrial tracking.
- AFR and Rate Smoothing:

- If Rate Smoothing is programmed on with AFR, it may control changes in the ventricular pacing rate at the onset and end of an atrial arrhythmia.
- Down Rate Smoothing will gradually decrease the ventricular pacing rate to the sensor-indicated rate or the LRL.
- Up Rate Smoothing will gradually increase the ventricular pacing rate to resynchronize with the p-waves if the atrial rate is faster than the SIR or LRL.



Ventricular Rate Regulation (VRR)

VRR is designed to reduce the V–V cycle length variability during partially conducted atrial arrhythmias by modestly increasing the ventricular pacing rate. VRR may dampen or eliminate rapid changes in the paced ventricular rate caused by sensed atrial rates above the MTR. In CRT-D devices, VRR may help promote CRT by increasing the percent of ventricular pacing during conducted atrial arrhythmias.

Availability

- DDD(R) and VDD(R) modes: Available only during an ATR mode switch.
- DDI(R), AAI(R) and VVI(R) modes: Available at all times.
- Navigation:

1. From the Settings screen select ⇨



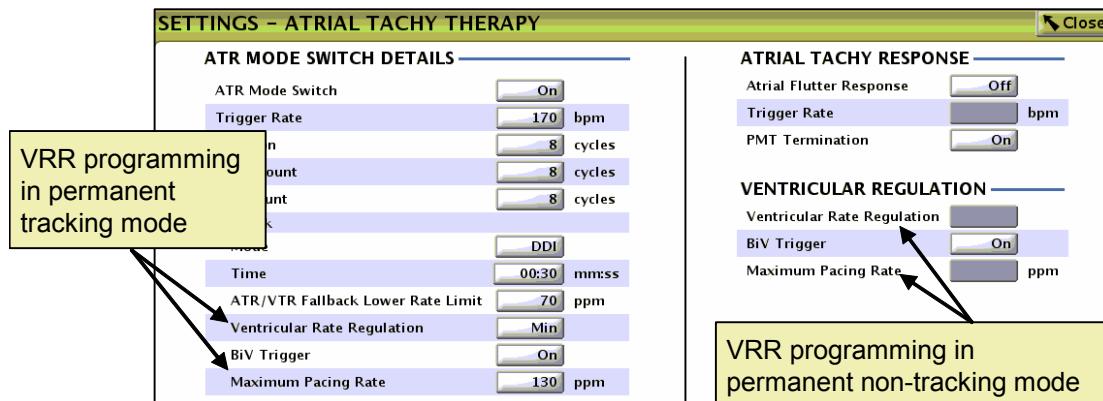
2. Select ⇨



Programmable Values

	Range Of Values	Nominal Value
ICD: Tracking modes	ON/OFF	ON
ICD: Non-tracking modes	ON/OFF	OFF
CRT-D: Tracking modes	OFF, Min, Med, Max	Min
CRT-D: Non-tracking modes	OFF, Min, Med, Max While Med and Max are available as selections in DDI(R) they will result in a parameter interaction (see Notes below)	OFF OFF
Max Pacing Rate (MPR)	30-185 ppm	130 ppm

- When programming from a permanent tracking to a non-tracking mode, VRR will be nominally ON if it had previously been programmed ON in a non-tracking mode.
- The VRR programming location will vary depending on the permanently programmed mode. Only one of the two VRR locations will be available at a time and the other location will be dimmed.



- For CRT-Ds, if the pacing chamber is programmed to BiV, VRR pacing will be delivered BiV at the programmed LV Offset interval. During a mode switch, this BiV pacing behavior will occur in a tracking (i.e., DDD or VDD) mode or a non-tracking (i.e., VVI or DDI) mode.
- For CRT-Ds, if the pacing chamber is programmed to RV-Only, in a non-tracking mode, VRR pacing will be delivered only to the RV. But, if in a tracking mode and in an ATR mode switch even with RV-Only selected, pacing will still be BiV at an LV Offset of 0 ms. If the physician does not desire any LV pacing they may consider programming the LV output sub-threshold.

Algorithm

The device calculates a VRR-indicated pacing interval based on a weighted average of the current V-V cycle length and previous VRR-indicated pacing intervals. The amount of pacing observed will increase with more irregularly conducted rhythms (such as atrial fibrillation) and will decrease with more regularly conducted rhythms (such as atrial flutter). The programmed Max Pacing Rate dictates the maximum possible VRR-indicated rate.

VRR Calculation

The weighted average is approximately equivalent to the average of the last 16 right-ventricular cycles. This weighted average is used as the new rate for the next ventricular paced interval:

$$\left(\begin{array}{c} \text{VRR Venricular} \\ \text{Pacing Interval} \end{array} \right) = \frac{1}{16} \times \left(\begin{array}{c} \text{Most Recent} \\ \text{V - V Interval} \end{array} \right) \times \left(\begin{array}{c} \text{Intrinsic or} \\ \text{Paced Weight} \end{array} \right) + \frac{15}{16} \times \left(\begin{array}{c} \text{Previous VRR} \\ \text{Pacing Interval} \end{array} \right)$$

Programmed VRR value	Intrinsic weight	Paced weight
MIN	$1.1 \pm 1\%$	$1.2 \pm 1\%$
MED	$0.6 \pm 1\%$	$1.2 \pm 1\%$
MAX	$0.6 \pm 1\%$	$1.1 \pm 1\%$

- Ventricular paced intervals cause a decrease in VRR-indicated rate.
- Ventricular sensed intervals cause an increase in VRR-indicated rate.
- The Min value of 1.1 will cause the paced rate to be slightly below the intrinsic rate whereas the Med/Max values of 0.6 will cause the paced rate to be faster than the intrinsic rate.
- The VRR-indicated rate is bound by the LRL and the programmed MPR.
- In CRT-Ds, if a BiV Trigger beat is included in the weighted average, the timing of the triggered pace will be used for the V-V interval, but it will be weighted as a sensed beat.

When VRR is first activated (beginning of ATR fallback mode or first programmed ON in a non-tracking mode), the calculation is *seeded* with a pre-determined value initially since no previous intervals are available. Therefore, it may take multiple cycles before pacing above the LRL is observed. The predetermined value is dependent upon device programming:

- In tracking modes, the programmed ATR/VTR LRL interval is used as the seeded interval.
- In non-tracking modes, the programmed normal brady LRL interval is used as the seeded interval.
- If hysteresis is active, the hysteresis interval is used as the seeded interval.

While in ATR Fallback, the pacing rate will be the fastest of:

1. ATR LRL
2. ATR fallback pacing rate
3. VRR-indicated rate
4. Sensor-indicated rate interval

Sample Calculation (MIN Setting)

If the VRR interval calculation after the previous ventricular event was 800 ms and next ventricular event is sensed at 700 ms, what would be the calculated VRR paced interval at that point?

$$\text{(VRR Pacing Interval)} = \frac{1}{16} \times (700 \text{ ms}) \times (1.1) + \frac{15}{16} \times (800 \text{ ms}) = 798 \text{ ms}$$

Using data from the example above, (MIN Setting) and the fact that the patient's next V-V interval was paced (i.e., 798 ms), what would be the calculated VRR pacing interval at that point?

$$\text{(VRR Pacing Interval)} = \frac{1}{16} \times (798 \text{ ms}) \times (1.1) + \frac{15}{16} \times (798 \text{ ms}) = 808 \text{ ms}$$

NOTE: In both examples the calculated VRR interval does not vary a great deal from one beat to the next.

In CRT-Ds, the degree of rate increase with sensed intervals is determined by the programmed setting (MIN, MED, MAX).

The programmable values (MIN, MED, MAX) affect the degree of rate regulation:

- A higher setting will increase CRT pacing more than a lower setting (i.e., MAX vs. MED).
- A higher setting will decrease V-V variability more than a lower setting.
- In ICDs, this calculation is fixed to be equivalent to the MIN setting.

Notes/Additional Information

- VRR and Rate Smoothing:
 - If both are ON; Rate Smoothing is suspended when VRR is active during ATR (VRR is active once Duration is met and is suspended once the mode switch is exited).
 - If VRR is ON in a permanent non-tracking mode, Rate Smoothing is suspended (although Rate Smoothing is able to be programmed ON, it is suspended in this scenario).
 - If VRR is OFF and Rate Smoothing is ON, Rate Smoothing is suspended during the ATR Fallback Time and is re-enabled once the device reaches the greater of the ATR/VTR fallback LRL or sensor-indicated rate.
- VRR is not active above the lowest rate cutoff in the lowest tachy detection zone.
- VRR is active below the LRL (i.e., Hysteresis rate).
- MIN is the only setting allowed in DDI(R) mode. Since MED and MAX for VRR provide more aggressive pacing than MIN, VRR can force atrial pacing in DDI(R) mode, thereby creating a positive feedback loop if the atrial pace conducts to the ventricle.

Example: If an AP-VS occurs, VS events shorten the VRR interval which will shorten the VA time. This allows for a subsequent AP-VS event, which continues to shorten the VRR interval. If MED and MAX were allowed, the device could reach the MPR sooner and would cause the patient to spend more time at the MPR, which is undesirable.



BiV Trigger (CRT-D Only)

BiV Trigger is designed to promote synchronized RV and LV pacing after an RV-sensed event in order to increase contractile function for heart failure patients.

Availability

- BiV Trigger is available at all times in any ventricular pacing mode (other than asynchronous modes). The feature may be programmed to operate during an ATR mode switch, independent of an ATR mode switch, or both
- Navigation:

1. From the Settings screen select 

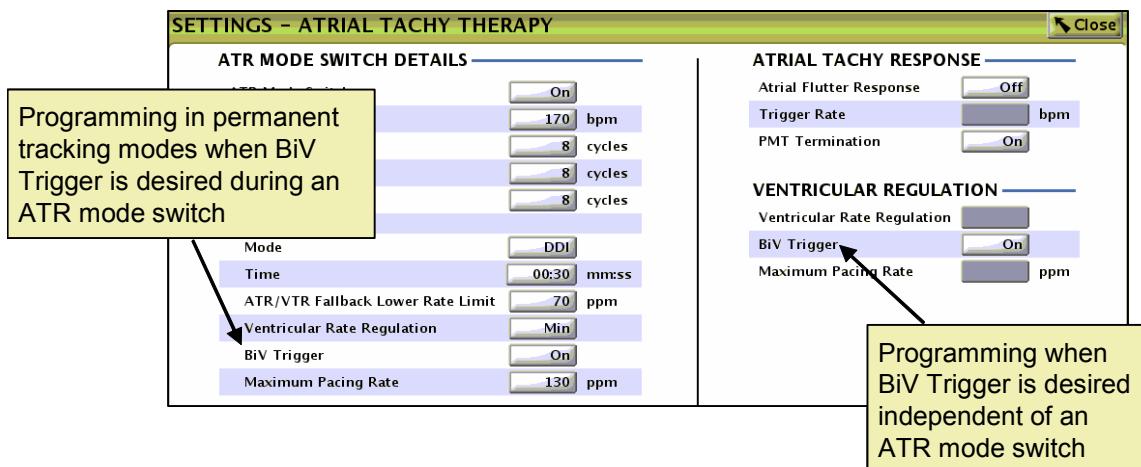
2. Select ⇒



Programmable Values

BiV Trigger (ATR)	ON/OFF	Nominal: ON
BiV Trigger (independent of ATR)	ON/OFF	Nominal: OFF
Max Pacing Rate (MPR)	30-185 ppm	Nominal: 130 bpm

- The BiV Trigger programming location will depend on if the feature is desired to operate during an ATR mode switch, independent of an ATR mode switch, or both.

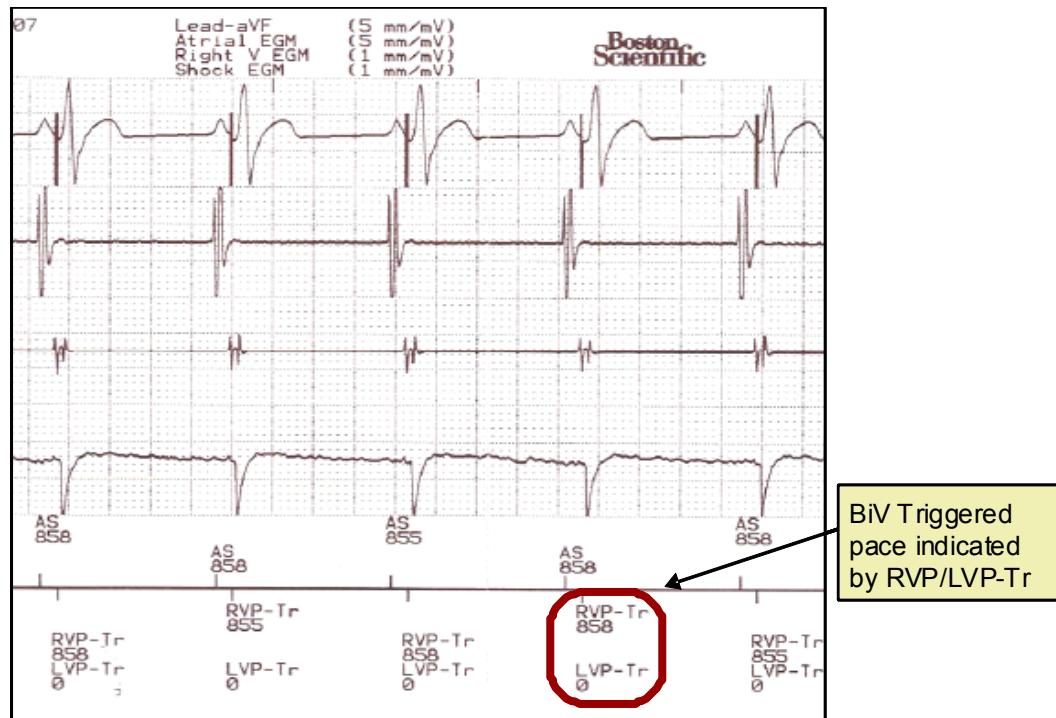


Algorithm

A BiV pace is triggered within 8-10 ms after an RV-sensed event between the LRL and MPR. The feature functions the same during post-shock pacing as in normal pacing and can be used in conjunction with VRR. BiV Trigger in conjunction with VRR is designed to provide additional CRT support during atrial arrhythmias.

- In LV-Only pacing²⁶, BiV trigger is still active and RV pacing will occur (timing is still RV based).
- In RV only pacing, LV pacing will still occur due to BiV trigger.
 - LV output must be reduced to the minimum if LV pace/capture is not desired.
- LV Offset is not applied to a BiV trigger pace.
- BiV Trigger is not active during A/RV/LV intrinsic amplitude or threshold testing.
- Paced events occurring due to BiV Trigger are identified with *-Tr* on EGMs.

²⁶ LV-Only pacing is not available in CRT-D models distributed in all geographies

Sample of BiV Trigger:**Notes/Additional Information**

- If the normal parameters are temporarily programmed to allow intrinsic conduction, BiV Trigger will still cause ventricular pacing. If the ventricular pacing chamber is set to LV-only²⁷ or RV-only, BiV Trigger will still cause Bi-Ventricular pacing.
- If BiV trigger is programmed ON in Atrial Tachy, BiV will be available in Temp Brady.

PVARP After PVC

PVARP after PVC is designed to help prevent Pacemaker Mediated Tachycardia (PMT) which may be caused by the tracking of a retrograde conducted atrial event by automatically extending PVARP for one cardiac cycle following a PVC. This algorithm attempts to place retrograde atrial events within PVARP thereby preventing retrograde atrial events from being tracked.

Availability

- Available in DDD(R), DDI(R) and VDD(R) modes.

²⁷ Not available in CRT-D models distributed in all geographies.

▪ Navigation:

1. From the Settings screen, select  **Settings Summary**

2. Select  **Normal Settings**

3. Select  **Timing, Rate Enhancements, Noise**

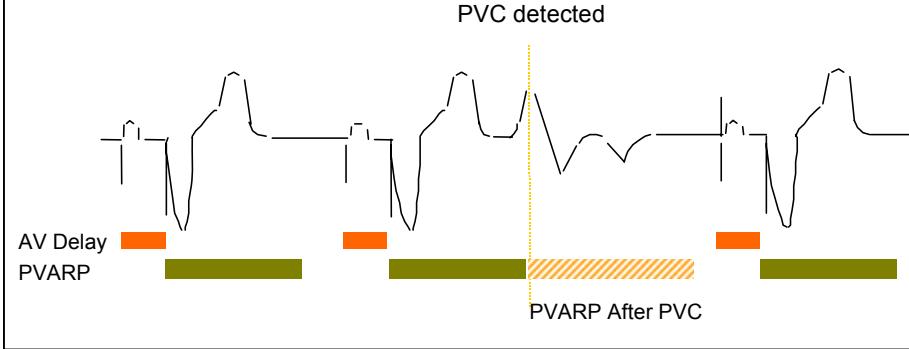
Programmable Values

PVARP after PVC	Off, 150-500 (50 ms increments)	Nominal: 400 ms
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- PVARP after PVC is completely independent of the permanently programmed PVARP value.

Algorithm

PVARP after PVC automatically extends the programmed PVARP for one cardiac cycle following a PVC. Atrial sensed events occurring during this PVARP will be sensed but will not initiate a timing cycle or inhibit atrial pacing.



The diagram illustrates the timing of events following a PVC. It shows three EGMs. The first EGM has an AV Delay marker (orange bar) followed by a PVARP marker (green bar). The second EGM has an AV Delay marker (orange bar) followed by a PVARP marker (green bar). A vertical dashed line labeled "PVC detected" marks the transition from the second EGM to the third. The third EGM has an AV Delay marker (orange bar) followed by a PVARP After PVC marker (orange hatched bar).

Following this cycle, PVARP returns to the permanently programmed value.

- PVC is defined as an RV-sensed event which follows an RV paced or sensed event with no intervening atrial event. Sensed and paced atrial events as well as refractory atrial events are accepted as an intervening atrial event.
- PVARP after PVC will not occur more frequently than every other cardiac cycle since timing cycles are reset following a PVC.
- If the permanently programmed PVARP is longer than PVARP after PVC, the longer PVARP will be used.
- The PVARP after PVC marker is designated on EGMs as *PVP→*

Other scenarios which trigger PVARP after PVC

- Programming or automatically transitioning from a non-tracking to a tracking mode (such as transitioning from an ATR or VTR mode switch back to normal brady; the *PVP*→ marker signals the return to a dual-chamber tracking mode).
- If a VP in VDD(R) mode is not preceded by an atrial sense.
- If AP is inhibited due to AFR,
- Following Noise Response events (VP-Ns, RVP-Ns),

Notes/Additional Information

PVARP after PVC may cause inhibition of CRT therapy in heart failure patients who have intact AV conduction since atrial events in PVARP will not be tracked. If this occurs, program the Tracking Preference feature ON in conjunction with PVARP after PVC.

PMT Termination



Pacemaker mediated tachycardia may occur in dual-chamber tracking modes when AV synchrony is lost and retrograde conduction occurs which is longer than the programmed PVARP. The PMT Termination algorithm breaks active PMT episodes by extending PVARP for one ventricular cycle to cause one atrial-sensed event to occur in PVARP and break the AS-VP cycle.

While this algorithm will terminate active episodes of PMT, if the underlying cause for the loss of AV synchrony is not addressed the PMT may recur. Additionally, while intended to break PMT, the PMT algorithm may also occur in response to normal tracking of intrinsic atrial events at the MTR.

Availability

- Available in DDD(R) and VDD(R) modes
- Navigation:

1. From the Settings screen select ⇒ **Settings Summary**
2. Select ⇒ **ATRIAL TACHY**

Programmable Values

PMT Termination	ON/OFF	Nominal: ON
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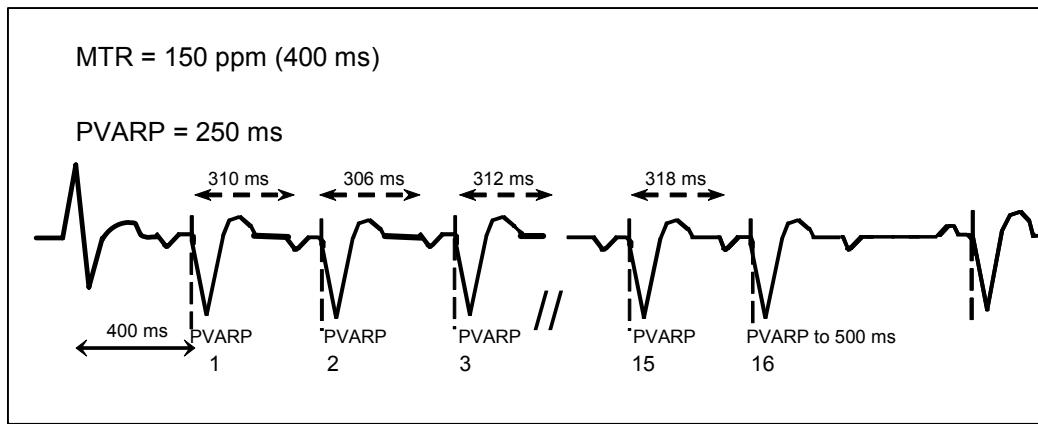
Pacemaker Mediated Tachycardia Review²⁸

- Triggered by a loss of A-V synchrony (triggers may include, PVCs, atrial fib, atrial oversensing/atrial undersensing, loss of atrial capture).
- Subsequent ventricular events result in retrograde conduction to atrium (in patients with an intact retrograde pathway).
- The retrograde p-wave is sensed by the device, which tracks the p-wave and triggers a ventricular pace. This ventricular pace may cause another retrograde event and the cycle is continuously repeated.
- This *endless loop* tachycardia most often occurs at URL or MTR, but may occur at slower rates.

Algorithm

The PMT algorithm is applied if 16 consecutive AS-VP cycles occur at the maximum tracking rate and the associated V-A intervals do not vary by more than 32 ms. When PMT is declared, PVARP is extended to 500ms for one cycle following the 16th ventricular pace to mimic VA block.

- The V-A interval of each event is compared to the first V-A interval of 16 intervals.
- If any one of next 15 V-A intervals is more than 32 ms different than the first V-A interval, the device resets the count to zero and continues to monitor for PMT.



Arrhythmia Logbook Storage

An EGM is stored in the Arrhythmia Logbook when a PMT episode is declared. While there is no true PMT counter, the number of PMT events can be assessed by the number associated with the PMT episodes in the Arrhythmia Logbook. The event numbers continuously increment even though events may not remain in memory.

See the *Arrhythmia Logbook* topic for further details on event storage.

²⁸ Cardiac Pacing, 2nd Edition, by Kenneth Ellenbogen

- The PMT termination algorithm must be turned ON for PMT EGMs to be stored.
- Up to three detailed episodes may be stored with associated EGMs; up to five total PMT events may be listed.
- Stored EGM Event markers:
 - PMT-B: marks the PMT break using the PVARP extension

Episode Report Details

- Event number (e.g., PMT-7), event date, and event time are provided,
- Event Onset
 - Average A rate: average A rate at time PMT termination feature was triggered
 - Average V rate: average V rate at time PMT termination feature was triggered
- Calculated from the four atrial and ventricular interval averages prior to triggering PMT Termination algorithm.
- Event Ended
 - Since there is no exit criteria for the PMT Termination algorithm, this selection will be blank.

Notes/Additional Information

- The PVARP after PVC and Rate Smoothing algorithms may also be useful in preventing and controlling the device's response to retrograde conduction.
- Rate Smoothing is not applied on the interval where PVARP is extended.
- PMT could result from the shortening of PVARP by the Tracking Preference feature on CRT devices. If a retrograde conduction occurs on the same VS where Tracking Preference applies the shortened PVARP, a PMT could occur.

Retrograde conduction test

False PMTs are possible when the device is AS-VP at the MTR for 16 cycles, particularly when a low MTR has been programmed. The following steps can help determine if the patient's episode was a PMT due to retrograde conduction or simply normal atrial tracking (exercise response):

How to verify appropriate atrial sensing and capture for evidence of situations that may have led to the PMT (for example, loss of A-V synchrony):

1. Check intrinsic amplitude measurement and observe the real-time ECG for appropriate sensing.
2. Perform a threshold test to make sure there is atrial capture with an adequate safety margin.

See [A Closer Look](#) for steps on performing a manual retrograde conduction test.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Rate Hysteresis

Rate Hysteresis is designed to promote longer periods of intrinsic activity by allowing the patient's intrinsic rate to decrease below the LRL. Rate Hysteresis benefits patients who are sensitive to pacing stimuli as well as increases battery longevity by reducing the pacing percentage. The additional Search Hysteresis option periodically lowers the LRL to actively search for and promote intrinsic activity.

Availability

- CRT-Ds available in DDD and AAI; ICDs available in DDD, DDI, VVI, AAI.
- Not available in rate responsive or VDD mode.
- Navigation:

1. From the Settings screen select ⇒



2. Select ⇒



3. Select ⇒



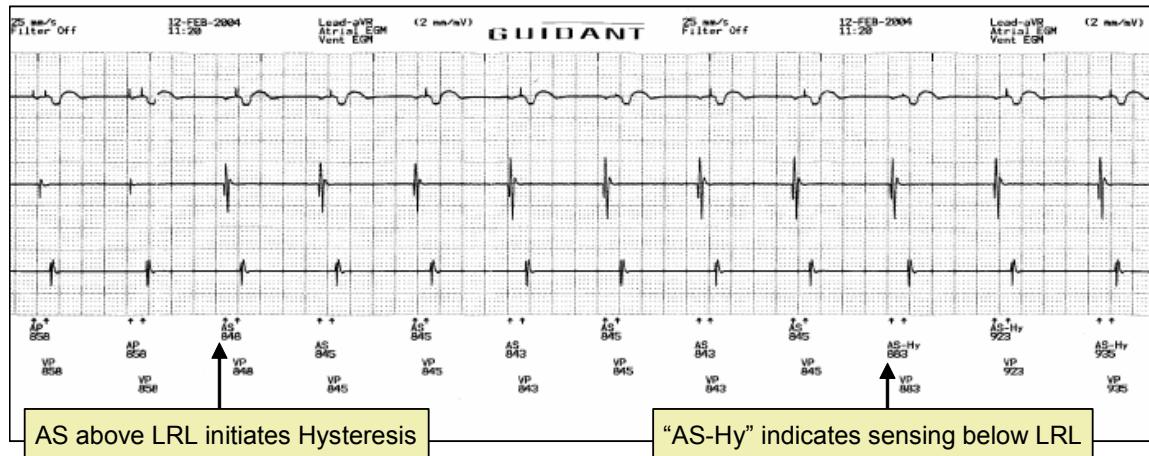
Programmable Values

PMT Termination	OFF, 5-80 bpm	Nominal: OFF
Search Hysteresis	OFF, 256-4096 cycles	Nominal: OFF

Algorithm

Rate Hysteresis – activated by a single non-refractory atrial-sensed event in DDD, DDI and AAI mode and by a single non-refractory ventricular sensed event in VVI mode. When Rate Hysteresis is activated, the permanent LRL value is temporarily lowered by the programmed Hysteresis Offset amount to allow intrinsic activity below the LRL. When Hysteresis is deactivated, the device returns to the Normal Brady/CRT LRL.

- Hysteresis is deactivated by single non-refractory atrial paced event at the Hysteresis rate in DDD, DDI and AAI mode and by a single non-refractory ventricular paced event at the Hysteresis rate in VVI mode.
- EGM displays *AS-Hy* when events occur between the LRL and Hysteresis rate.



Real-time strip demonstrating Rate Hysteresis

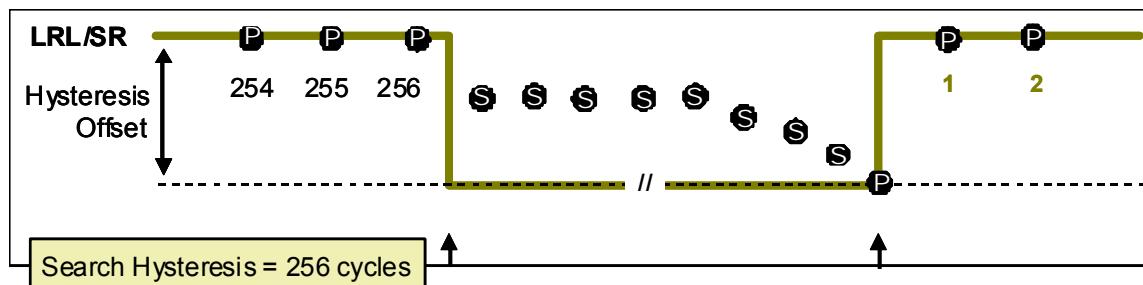
Search Hysteresis – Rate Hysteresis requires intrinsic sensed events for activation. To promote intrinsic activity in patients who are paced, Search Hysteresis periodically searches for intrinsic events below the LRL once the programmed number of search cycles is reached.

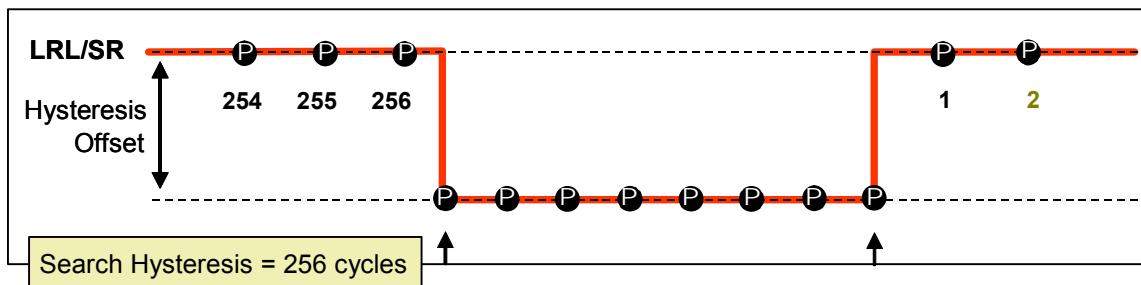
The programmed amount of search cycles must be consecutively atrial paced (ventricular paced in VVI) for a search to occur. If no intrinsic activity is sensed during the programmed number of search cycles, the LRL is abruptly decreased by the Hysteresis Offset amount for up to eight cardiac cycles. During these eight cycles, the device searches for intrinsic activity.

- If intrinsic activity is sensed during the search cycles, Hysteresis will remain active until an atrial pace (ventricular pace in VVI) occurs at the Hysteresis Offset rate.
- If intrinsic activity is not sensed during the search, pacing will resume at the LRL following the eight ventricular cycles.

Examples: Successful Search – intrinsic activity is found below the LRL but above the Hysteresis Offset rate. The device will continue at this LRL until one pace occurs at the Offset rate. The device then returns to the permanently programmed LRL.

Unsuccessful Search – the device paces for 8 cycles at the Hysteresis Offset rate and then returns to the permanently programmed LRL.





Notes/Additional Information

- Hysteresis is suspended during ATR mode switch episodes.
- Rate Smoothing and Hysteresis:
 - Rate Smoothing Up/Down remains active during Rate Hysteresis.
 - During Search Hysteresis, Rate Smoothing Down is suspended from the LRL to the Hysteresis rate but Rate Smoothing Up will smooth the rate from the Hysteresis rate back to the LRL.
- In CRT-Ds, Hysteresis is not available in VVI mode since this would promote intrinsic ventricular activity and prevent the delivery of CRT.

ICD	INCEPTA	INCEPTA
	ENERGEN	ENERGEN
	PUNCTUA	PUNCTUA
	TELIGEN	COGNIS

Rate Smoothing

Large fluctuations in heart rate may cause a patient to feel symptoms of dizziness, shortness of breath and/or palpitations. Rate Smoothing eliminates large cycle-to-cycle variations in rate by preventing paced intervals (A and/or V) from changing by more than a programmed percentage from one cycle to next. Rate Smoothing controls the device's response to sudden changes in rate caused by:

- Sinus arrest, SA blocks, brady-tachy syndrome
- PAC/PVC's
- Brief, self-terminating SVT's or Atrial Fib/Flutter
- P -waves initiated via retrograde conduction
- Pacemaker Wenckebach
- Pulse generator sensing of myopotentials, EMI and cross-talk
- Retrograde conducted p-waves

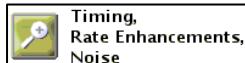
Availability

- Rate Smoothing Down is available in all pacing modes. Rate Smoothing Up is available in DDD(R), VDD(R), DDIR, VVIR and AAIR modes.

▪ Navigation:

1. From the Settings screen select 

2. Select 

3. Select 

Programmable Values

Rate Smoothing Up	OFF, 3-25% (3% increments)	Nominal: OFF
Rate Smoothing Down	OFF, 3-25% (3% increments)	Nominal: OFF
MPR (DDI, SSI only)	30-185 bpm	Nominal: 130 bpm

Algorithm

Rate Smoothing Up controls the *largest increase allowed* in the pacing rate and Rate Smoothing Down controls the *largest decrease allowed* in the pacing rate. The calculation limits pacing intervals on a beat-to-beat basis by the programmed percentage. The current R-R interval (paced or sensed) is assessed and the next paced interval is calculated based on the programmed Up/Down Rate Smoothing percentage. If intrinsic events occur faster than the Rate Smoothing interval, the device will be inhibited as expected.

NOTE: In CRT-Ds, Rate Smoothing intervals are based on RV events unless the pacing chamber is programmed in Temporary to LV Only²⁹, in which case RVS and LVP events are used to calculate intervals.

Rate Smoothing Application

Mode	Rate Smoothing applied between (bpm)
DDD/VDD	LRL and the MTR
DDD(R)/VDD(R)	LRL and the greater of the MSR or MTR
DDI(R)/SSI(R)	LRL and the MSR
DDI/SSI	Up: Hysteresis rate and LRL Down: LRL and the MPR

DDI/SSI modes

In DDI and SSI modes, a MTR and MSR are not applicable and the device will not increase the pacing rate through the tracking of atrial arrhythmias or through rate response. Thus, Rate

²⁹ LV-Only pacing is not available in CRT-D models distributed in all geographies.

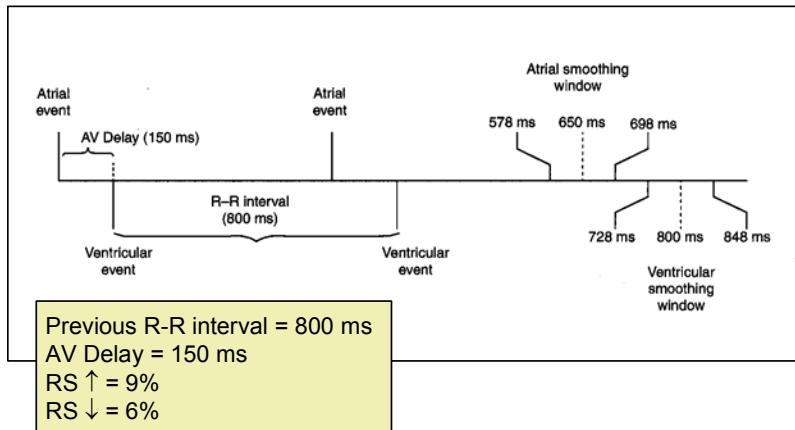
Smoothing Up is not programmable unless Hysteresis is ON. If Hysteresis is ON, Rate Smoothing Up is applied between the Hysteresis rate and LRL.

Rate Smoothing Down is available in DDI/SSI modes to smoothly decrease the patient's heart rate following a sudden intrinsic drop in rate. Since a MTR and MSR are not available, a Max Pacing Rate (MPR) is required. The MPR acts as a *pseudo* upper rate limit which the Rate Smoothing algorithm uses to calculate paced intervals. In these modes, Rate Smoothing is applied between the LRL and the MPR.

Rate Smoothing Sample Calculation (non-PVC)

The Rate Smoothing interval is based on the most recent R-R interval and the Up/Down Rate Smoothing percentage. This creates two synchronization windows for the next cycle; one for the A and one for the V:

- Atrial Sync Window = [(previous R-R) ± (Rate Smoothing Value)] – (AV Delay)
- Ventricular Sync Window = (previous R-R) ± (Rate Smoothing Value)



Example of Non-PVC Rate Smoothing Calculation

Ventricular Sync Window ↑	Ventricular Sync Window ↓	Atrial Sync Window ↑	Atrial Sync Window ↓
$800 - 9\% =$ $800 - 0.09(800) =$ $800 - 72 =$ 728 ms	$800 + 6\% =$ $800 + 0.06(800) =$ $800 + 48 =$ 848 ms	V Sync Window – AVD= $728 \text{ ms} - 150 \text{ ms} =$ 578 ms	V Sync Window – AVD= $848 \text{ ms} - 150 \text{ ms} =$ 698 ms

Rate Smoothing Sample Calculation (Post-PVC)

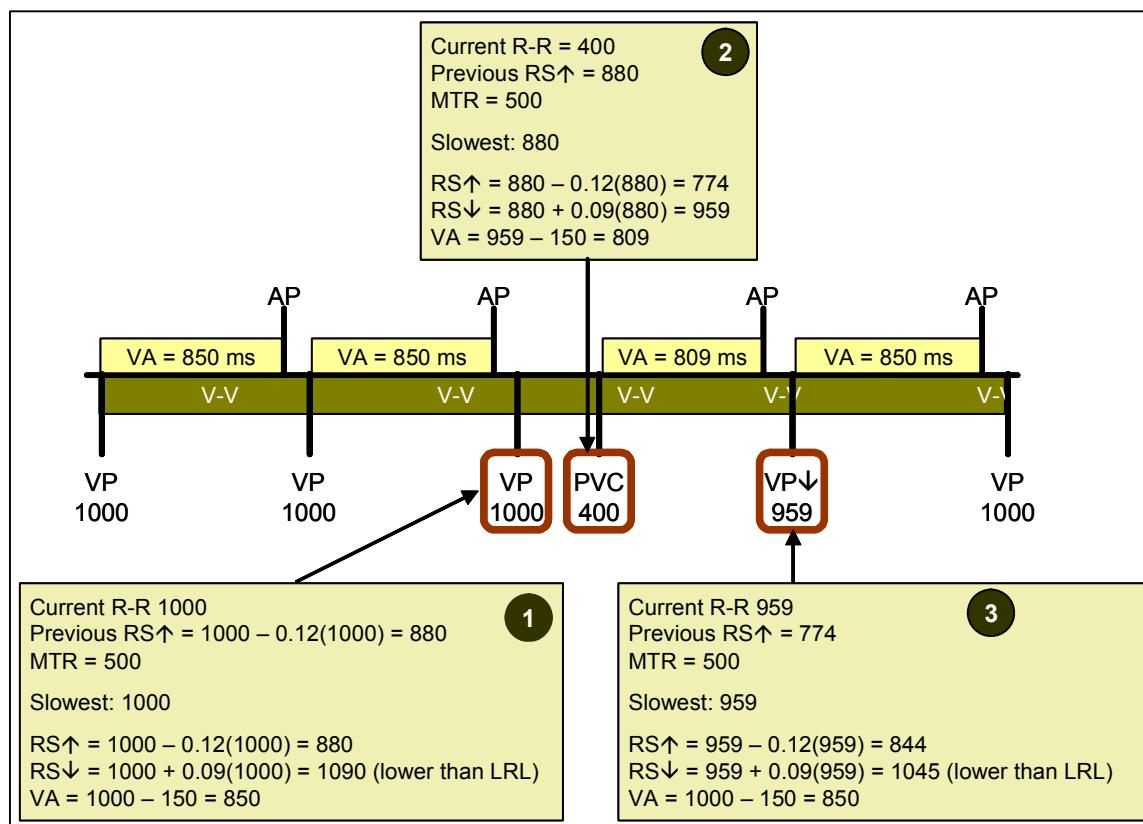
Following a PVC, additional intervals are evaluated to calculate the subsequent paced interval:

1. Determine the slowest of the following three intervals:
 - Current V-V interval
 - Previous RS ↑ interval (if RS ↑ is programmed OFF, a default value = 12%)
 - MTR or MPR
2. Calculate both RS ↑ and RS ↓ windows (still bounded by LRL/Hysteresis and URL)
 - VA = RS window - AV Delay

Example: Rate Smoothing Calculation Post-PVC

Programmed Values:

- LRL/MTR = 60/120 bpm (1000/500 ms)
- AV Delay = 150 ms (fixed)
- RS↑ = 12%, RS↓ = 9%



Increasing RS↑ percentage will allow greater changes in RS↓ interval. In the example above, if RS↑ = 25%, the following changes would occur, affecting the next RS↓ interval:

- Box 1: $RS\uparrow = 1000 - 0.25(1000) = 750 \text{ ms}$
- Box 2: Previous $RS\uparrow = 750 \text{ ms}$ and $RS\downarrow = 750 + 0.09(750) = 818 \text{ ms}$

Notes/Additional Information

- When $RS\downarrow$ is programmed ON and $RS\uparrow$ is programmed OFF, the pacemaker will automatically prevent fast intrinsic beats (e.g., PVCs) from resetting the $RS\downarrow$ escape rate any faster than 12% per cycle. (This is designed to prevent the device from pacing near the MTR following a single PVC).
- Rate Smoothing and Hysteresis:
 - Rate Smoothing Up/Down remains active during Rate Hysteresis.
 - During Search Hysteresis, Rate Smoothing Down is suspended from the LRL to the Hysteresis rate but Rate Smoothing Up will smooth the rate from the Hysteresis rate back to the LRL.
- Rate Smoothing Up may extend AV Delay in heart failure patients when the intrinsic atrial rate increases exceed the increases in the ventricular pacing rate from Rate Smoothing calculations. This may result in prolonged AV Delays in patients with AV block and inhibition of ventricular pacing in patients with intact AV conduction.
- Rate Smoothing is suspended in the following situations:
 - During the eight cycles of Search Hysteresis (see note above)
 - Upon triggering PMT Termination algorithm
 - Immediately following programmed increases in the LRL
 - At intrinsic rates above the MTR
 - After Duration during an ATR Mode Switch when VRR is programmed
 - When VRR is programmed permanently in a non-tracking mode, Rate Smoothing can be programmed ON, but it will be suspended
 - If VRR is OFF and Rate Smoothing is ON; Rate Smoothing is suspended during the ATR Fallback Time and is re-enabled once the device reaches the greater of the ATR/VTR fallback LRL or sensor-indicated rate

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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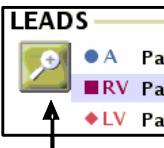
Lead Configuration

To provide multiple independent LV pacing and sensing configuration options in order to allow the clinician to tailor programming for each individual patient. Electronic repositioning utilizes different LV lead configurations to improve LV sensing and thresholds as well as to enable programming around extra cardiac stimulation. Unipolar LV pacing and sensing configurations were not available in devices prior to COGNIS, but for CRT-Ds described in this primer these LV lead configurations are available. RV oversensing of the LV unipolar signal is not a concern due to RV blanking and refractory periods following an LV pace. Likewise, LV oversensing of the RV signal is not a concern due to LV blanking and refractory periods following an RV pace.

See the Refractory Periods topic for further information on blanking and refractory.

Availability

Navigation:

- From the Settings screen select 
- Select 
- Select 

LV will be labeled as SPLIT if Pace/Sense configurations differ from each other

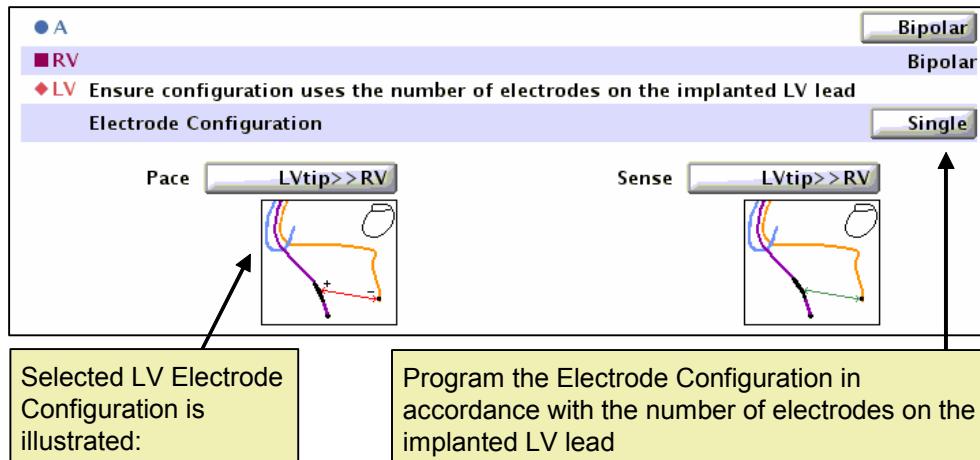
Select square button to obtain CRT-D Electrode Configurations (see below). ICD Electrode Configurations are programmed

Programmable Values

Atrial	Bipolar/OFF	Nominal: Bipolar
Right Ventricular	Bipolar (non-programmable)	Nominal: Bipolar
Left Ventricular (CRT-D)	Single/Dual/None	Nominal: None

- Single: LV lead with single electrode is implanted
- Dual: LV lead with dual electrodes is implanted

- None: No LV lead is implanted



- Programming an Electrode Configuration which does not represent the number of electrodes on the LV Lead may result in unpredictable LV sensing and pacing.
- When None is selected for the LV Electrode Configuration, the programmed Pacing Chamber must be RV only.

See the Notes/Additional Information section below for programming considerations when an LV lead is not used.

NOTE: The nominal LV Electrode Configuration of None, combined with the nominal pacing chamber of BiV will automatically result in an *interactive limit warning message*. This is intentional to ensure that the LV Electrode Configuration and/or pacing chamber is appropriately programmed at implant.

Any time an Electrode Configuration is reprogrammed, it is important to perform baseline lead measurements to ensure optimal performance.

- The LV Electrode Configuration must be Single or Dual in permanent Brady/CRT mode in order to have LV programming options and LV EGMs in Temp Brady mode.
- LV EGMs are available in all LV Sense configurations, if LV Sense is OFF, the LV EGM will be a flat line.
- Available LV lead configurations:

	Single Electrode		Dual Electrode	
Pace/Sense Selection	Pace	Sense	Pace	Sense
LVtip >> Can 	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	Single Electrode		Dual Electrode	
Pace/Sense Selection	Pace	Sense	Pace	Sense
 <p>Nominal Sense Configuration if Single is selected Nominal Pace Configuration if Single is selected</p>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	N/A	N/A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	N/A	N/A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
 <p>Nominal Sense Configuration if Dual is selected Nominal Pace Configuration if Dual is selected</p>	N/A	N/A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	N/A	N/A	<input checked="" type="checkbox"/>	N/A
Off	N/A	<input checked="" type="checkbox"/>	N/A	<input checked="" type="checkbox"/>

Notes/Additional Information

When programmed to AAI mode

- The LV Sense option is not available and although LV EGMs are still displayed, no LV sensed events will be detected.
- The LV Pace option is still available and there is LV pacing during ATP regardless of the LV Electrode Configuration.
- In clinical situations where an atrial or LV lead are not used, contact Technical Services for programming considerations.



AV Delay

Individualizing the programmed AV Delay helps preserve A-V synchrony and CRT effectiveness. Previous devices offered the programming of a Paced AV Delay with additional programming of a Sensed AV Offset. Additionally, Dynamic AV Delay was separately programmable with a minimum and maximum AV Delay value. Devices described in this primer provide the following programmable values all within two selections:

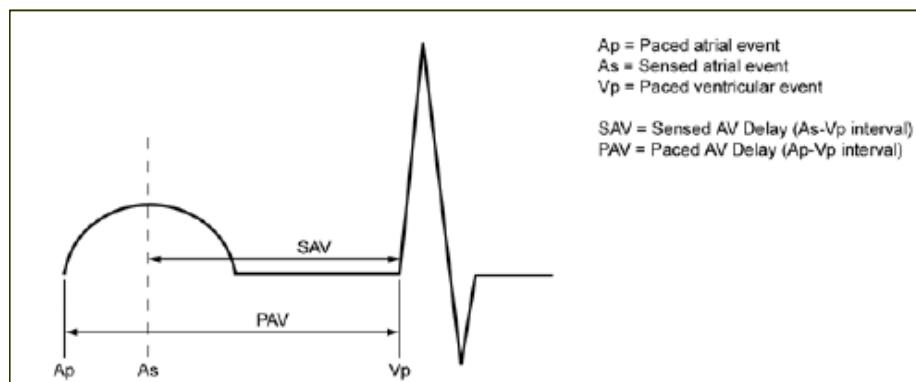
- Paced AV Delay (dynamic or fixed)
- Sensed AV Delay (dynamic or fixed)

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	Devices described in this Primer
Paced and Sensed AV Delay	Paced AVD is programmable along with a Sensed AV Offset. The Sensed AVD is calculated by taking the Paced AVD minus the Sensed AV Offset	<ul style="list-style-type: none">• Paced AVD and Sensed AVD are separately programmable.• Although the programming has been simplified, the function of AVD is similar to previous devices.
Dynamic AV Delay	Dynamic AVD is separately programmable from Paced AVD with a minimum and maximum value and an optional Sensed AV Offset	<ul style="list-style-type: none">• Dynamic or fixed Paced AVD are programmed by setting a minimum and maximum Paced AVD.• Sensed AVD will automatically be dynamic if the Paced AVD is dynamic
Fixed AV Delay	Paced AVD is programmable with an optional Sensed AV Offset	<ul style="list-style-type: none">• Programming the minimum and maximum Paced AVD to the same value provides a fixed paced AVD;• Sensed AVD will automatically be fixed if the Paced AVD is fixed

Paced and Sensed AV Delays are applied to intervals initiated by an atrial pace or atrial sense respectively. A separately programmable Sensed and Paced AVD is intended to account for the

difference in timing between atrial sensed and atrial paced events. A shorter value for the Sensed AVD will compensate for the short time delay required for the device to sense an intrinsic p-wave (see following diagram). In CRT-Ds, it may be necessary to program different Sensed and Paced AVDs to optimize CRT delivery during atrial sensing and atrial pacing.



Sensed vs. Paced AVD

Dynamic AV Delay provides a more physiologic response to rate changes by mimicking the shortening of the intrinsic PR interval with increases in heart rate. Both the Sensed and Paced AVD will automatically shorten in a linear fashion between the maximum value and the minimum value. Dynamic AV Delay will also assist in decreasing upper rate behavior by increasing the rate at which 2:1 block occurs (TARP interval).

Availability

- Available in DDD(R), DDI(R) and VDD(R) modes
- Navigation:

1. From the Settings screen select **Settings Summary**

2. Select **Normal Settings**

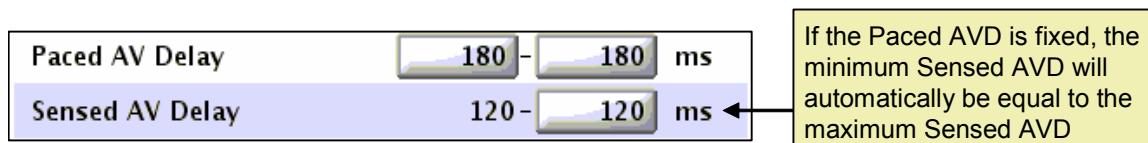
Programmable Values

Paced AV Delay	Minimum: 30-400 ms	Nominal: CRT-D 180 MS Nominal: ICD 80ms
	Maximum: 30-400ms	Nominal: 180 ms

- Maximum value for ICDs is 400 ms; CRT-Ds is 300 ms.
- The minimum Paced AVD must be \leq to the maximum Paced AVD.

Sensed AV Delay	Minimum: non-programmable	Nominal: 65 ms
	Maximum: 30-400ms	Nominal: 150 ms

- Maximum value for ICDs is 400 ms; CRT-Ds is 300 ms.
- The maximum Sensed AVD must be \leq to the maximum Paced AVD.
 - The maximum Sensed AVD may be no more than 100 ms less than the maximum Paced AVD.
- The minimum Sensed AVD is non-programmable in all modes other than VDD(R). The minimum value will automatically adjust when any of the other three programmable AV Delay parameters are changed.
 - To calculate the minimum Sensed AVD, the ratio of the minimum and maximum Paced AVD is calculated and this same ratio is applied to the Sensed AVD parameters.
 - The minimum Sensed AVD will always be \leq to the minimum Paced AVD.
 - The minimum Paced AVD minus the Minimum Sensed AVD will always be less than the maximum Paced AVD minus the Maximum Sensed AVD (i.e., with Dynamic AVD, a smaller offset is used at faster rates).
- Sensed AV Delay (sensed AV offset) is not applied during AV Search Plus.



Fixed AV Delay

Programming a fixed AV Delay will provide a static AV Delay at all heart rates. To program a fixed AV Delay, set the minimum and maximum Paced AVD to the same value. The Sensed AVD will automatically be fixed if the Paced AVD is fixed.

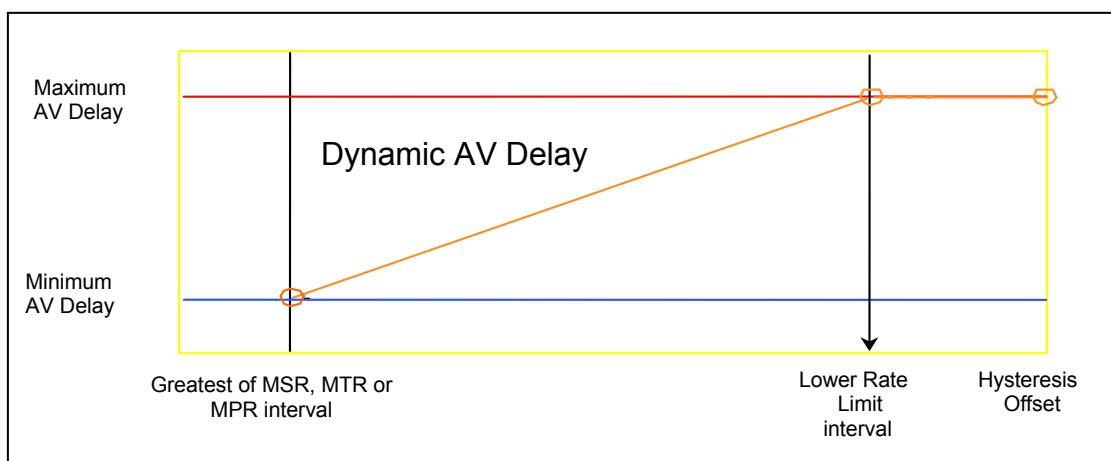
Dynamic AV Delay

Dynamic AV Delay automatically shortens the Sensed and Paced AVD in a linear fashion between the maximum value (applied at the LRL) and the minimum value (applied at the greatest of the MSR, MTR or MPR).

The AV Delay will automatically be dynamic if the minimum Paced AVD is less than the maximum Paced AVD. The Sensed AVD will automatically be dynamic if the Paced AVD is dynamic.

The value for the current cycle's AV Delay is based on the previous A-A or V-V interval. If the previous cardiac cycle contained an AP, the AV Delay is based on the previous scheduled V-V interval. If the previous cardiac cycle contained an AS, the AV Delay is based on the previous non-refractory A-A interval (if there is one; otherwise the V-V will be used). This calculated interval is applied to both atrial sensed and paced beats. The Dynamic AV Delay value is not adjusted following a PVC or if the previous cardiac cycle was limited by the MTR.

When programming a Dynamic AV Delay, the maximum value will be applied at the LRL and the minimum value will be applied at the greatest of the MSR, MTR or MPR with a linear change between the two (see below). If Rate Hysteresis is programmed ON, the maximum AV Delay will be applied at both the LRL and the Hysteresis offset rate. Dynamic AV Delay is suspended during AV Search Hysteresis.



Dynamic AV Delay

AV Search Plus



AV Search Plus elicits and promotes intrinsic AV conduction and minimizes right ventricular pacing by periodically extending the AV Delay to a programmed length. AV Search Plus can also increase device longevity by decreasing the amount of right ventricular pacing.

Availability

- Available in DDD(R), DDI(R) and VDD(R) modes.

▪ Navigation:

1. From the Settings screen select ⇒



2. Select ⇒



3. Select ⇒



Programmable Values

AV Search Plus	ON/OFF	Nominal: OFF
----------------	--------	--------------

- Search AV Delay: 30-400 ms
- Search Interval: 32-1024 intervals

Algorithm

The search begins every 32-1024 ventricular cycles (programmed Search Interval). All paced and sensed ventricular cycles are counted other than those which are contained in the search interval. The AV Delay is then extended for up to eight cycles to promote intrinsic conduction. If intrinsic conduction occurs during any of these eight cycles, the Search AV Delay remains in effect until 2/10 cycles no longer have intrinsic conduction and ventricular pacing occurs at this extended AV Delay. If eight consecutive cycles occur at the Search AV Delay without intrinsic breakthrough, the AV Delay returns to programmed value.

- The programmed Search AV Delay is applied to both the programmed Sensed AV Delay and Paced AV Delay.
- Dynamic AV Delay and Sensed AV Delay (sensed AV offset) are suspended during the search and while the extended AV Delay is in effect.
- The Search AV Delay must be set longer than the maximum Paced AV Delay.
- Intrinsic conduction and PVC's will not restart the Search Interval.
- AV Search Plus % Successful is provided in Events → Patient Diagnostics → Brady Counter Details.

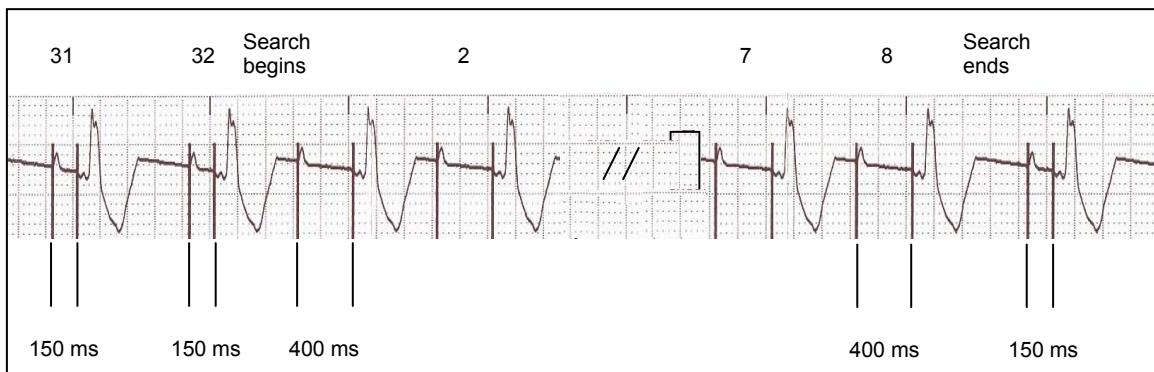
Example: Successful search example

- Paced AV Delay: 150 ms
- Search AV Delay: 400 ms
- Intrinsic PR Interval: 250 ms
- Search Interval: 32 cycles
- The increased AV Delay remains in effect until 2/10 cycles have no conduction and ventricular pacing occurs at the Search AV Delay.



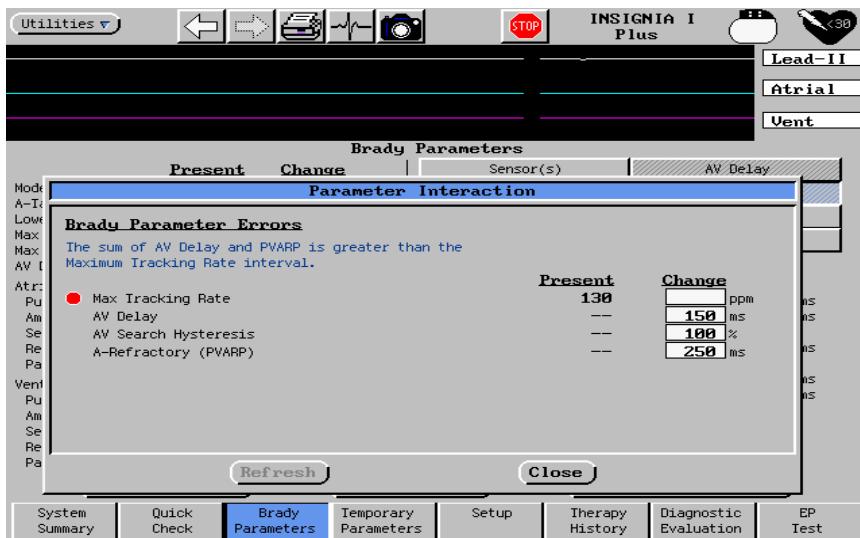
Example: Unsuccessful search example

- Paced AV Delay: 150 ms
- Search AV Delay: 400 ms
- Intrinsic PR Interval: 500 ms
- Search Interval: 32 cycles
- After eight intervals at the Search AV Delay without intrinsic breakthrough, the AV Delay returns to programmed value.



Notes/Additional Information

- The results of the DAVID Trial demonstrated a relationship between unnecessary right ventricular pacing and an increased incidence of heart failure; thus it may be desirable to minimize RV pacing.
- With the previous AV Search Hysteresis algorithm, programming an AV Delay increase which would create a total atrial refractory period (TARP) interval longer than the MTR interval would result in a parameter interaction (see below). Although ICDs described in this primer will still display this interaction, it was removed for the specific scenario where the extended AV Delay programmed for AV Search Plus creates a long TARP interval. This is to allow a longer AV Delay to be programmed in patients who have intact intrinsic conduction; therefore paced upper rate behavior would be avoided.



RYTHMIQ



- RYTHMIQ is designed to eliminate unnecessary ventricular pacing for patients who appear to have normal AV conduction, and to prevent clinically significant pauses as defined by the 2008 ACC/AHA/HRS guidelines.³⁰
 - Provides AAI(R) pacing, with back-up VVI pacing at the LRL of 15 bpm slower than the LRL.
 - Monitors for loss of conduction, and switches to DDD(R) to restore AV synchrony if conduction is lost.
 - While pacing in DDD(R) mode, use AV Search + to periodically check for return of intrinsic conduction. If normal conduction returns, switches back to AAI(R).
 - Allows direct mode switch to ATR from Primary AAI(R) if atrial arrhythmias are detected; the device does not have to be in DDD(R) mode to detect an atrial arrhythmia.
 - RYTHMIQ does not require dropped ventricular beats (long pauses) to switch to DDD(R) pacing.
- A RYTHMIQ event is recorded in the Arrhythmia Logbook when loss of conduction is detected and the mode switches to DDD(R).

³⁰ ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. Journal of the American College of Cardiology, Vol. 51(21), May 27, 2008.

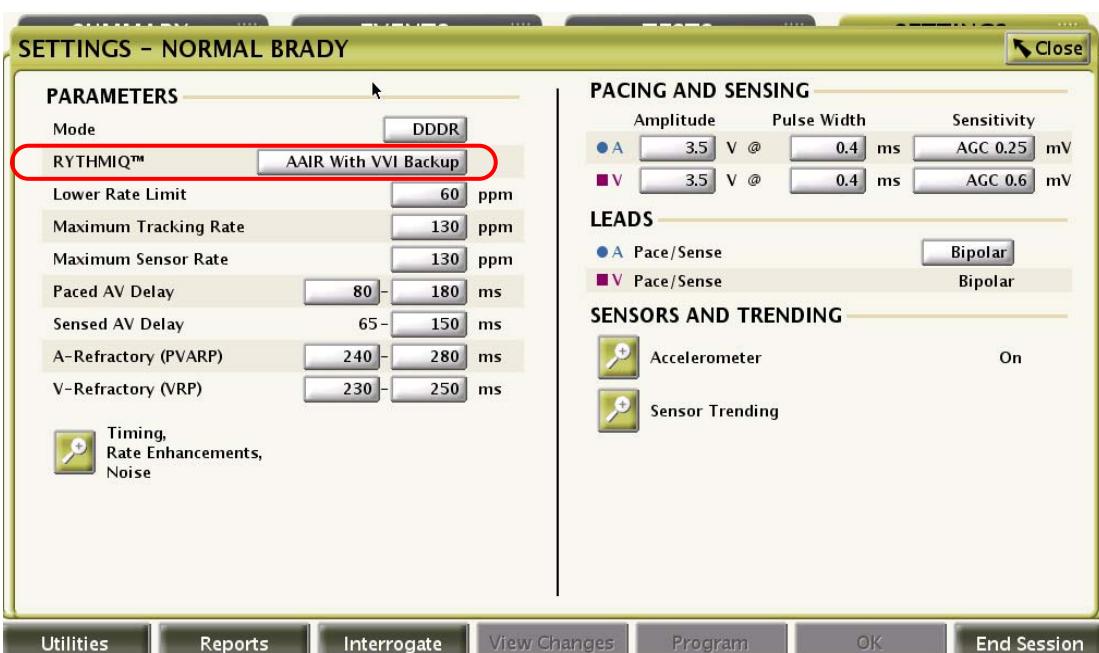
Availability

- DDD or DDD(R) modes only.
- Normal Brady only; not active in Temporary Brady, Post-Therapy Brady, or Electrocautery modes.

Navigation

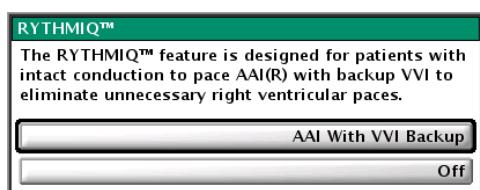
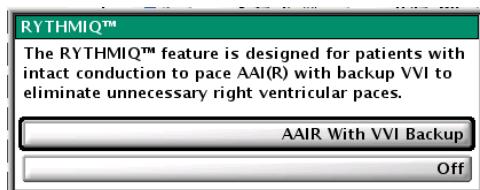
1. From the Settings Screen, Select 

2. Select  **Normal Settings**



Programmable Values

- RYTHMIQ: OFF, AAI(R) with VVI Back-up.
- Nominal: OFF.
- If the Normal Brady mode is DDDR, RYTHMIQ may be programmed AAIR with VVI Backup, or OFF.
- If the Normal Brady mode is DDD, RYTHMIQ may be programmed AAI with VVI Backup, or OFF.

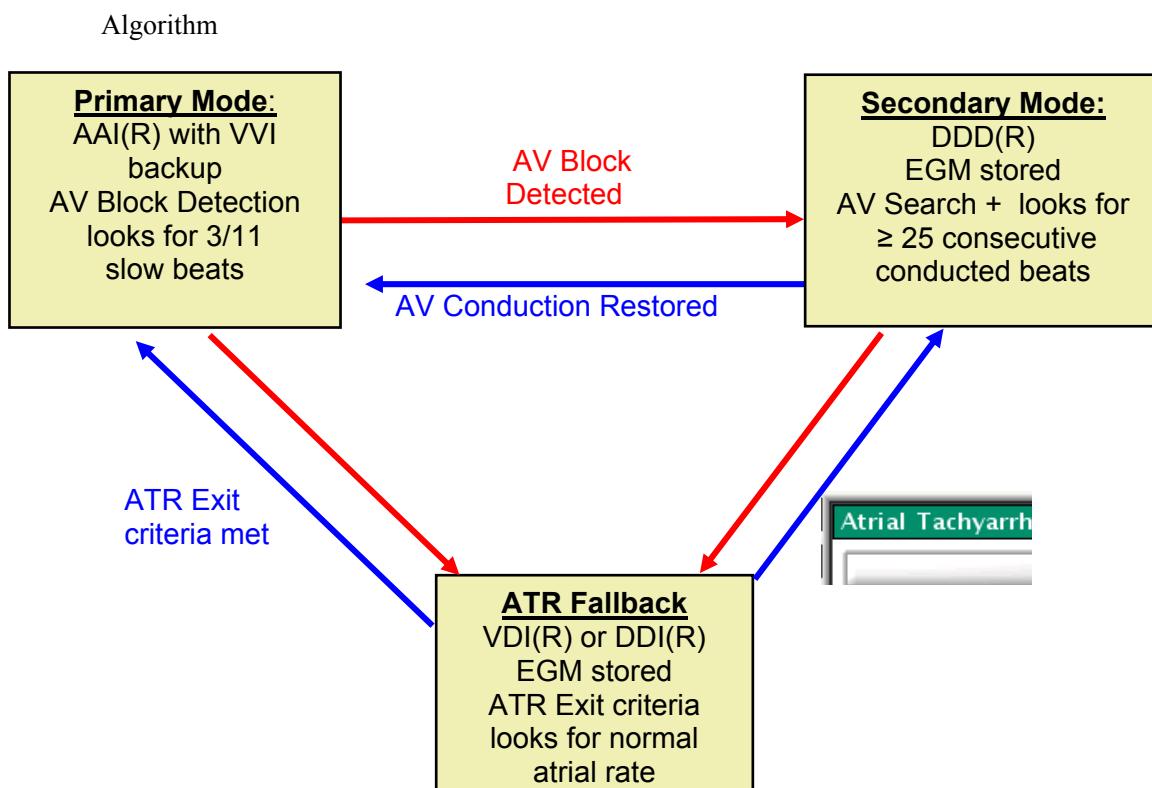


Related Parameters

- Lower Rate Limit (LRL): 30-185 bpm Nominal: 60 bpm for ICDs, 45 for CRT-D.
 - VVI Back-up: non-programmable; automatically set to 15 bpm below the programmed LRL; limited to min of 30 and max of 60 bpm.
 - For an LRL < 45 bpm, the VVI Back-up LRL will be 30 bpm.
 - For an LRL is > 75 bpm, the VVI Back-up LRL will be 60 bpm.

NOTE: To ensure the VVI back-up pacing rate is slower than the LRL, a *red Warning Interactive limit* will be displayed if the Normal Brady LRL is set to 30 bpm.

- During VVI Back-Up, rate modifiers such as rate smoothing are not available.
- AV Search Plus: OFF, 32-1024 cycles Nominal: OFF
 - Search AV delay: 10-400 ms
 - Search Interval: 32-1024 intervals.
 - If RYTHMIQ is ON, AV Search Plus will be automatically be ON with a search AV delay of 400 ms and a search interval of 32 cycles.
 - If AV Search Plus is already enabled prior to enabling RYTHMIQ, the AV Search Plus parameters are unchanged.
 - If RYTHMIQ is ON and AV Search is programmed OFF, the device will pace in AAI(R) until AV block is detected, then switch to DDD(R) and remain in DDD(R) until reprogrammed.



Primary Pacing Mode: AAI(R) with VVI back-up

When RYTHMIQ is ON, the device paces in AAI(R) mode at the LRL or the sensor indicated rate, with VVI Back-up pacing.

- AAI(R) and VVI Back-up operate independently of each other.
 - If complete AV block occurs, ventricular paces will be delivered at the backup VVI rate asynchronous to the AAI(R) mode.
 - If partial AV block occurs, ventricular pacing may occur and will be dependent on the degree of AV block (4:3, 3:1, etc.).
- VVI backup pacing rate is the LRL minus 15 bpm, with Min rate of 30 bpm and Max rate of 60 bpm (nonprogrammable).
- As long as AV conduction continues, AAI(R) pacing continues. AV Block Detection monitors for loss of conduction.

During RYTHMIQ Primary AAI(R) pacing, all AAI(R) pacing features are available except Rate Hysteresis, since it could decrease the rate below the VVI Backup LRL.

NOTE: During AAI(R) pacing, the device will not mark early ventricular events as PVCs; the device must be in a tracking mode to label an early ventricular beat as a PVC.

AV Block Detection

During Primary AAI(R) pacing, if three slow ventricular beats are detected in a window of 11, AV conduction is considered blocked, and the pacing mode will switch to DDD(R).

Slow ventricular beats are any of the following:

- V paced event
- V pace or V-inhibit due to noise response
- V sensed event > AAI LRL + 150 ms
- V sensed event > AAI(R) sensor indicated rate + 150 ms

NOTE: The 3/11 block counter will be reset to 0/11 and will no longer count blocked events when:

- The device switches to the Secondary DDD(R) mode
- The device enters Temporary Brady
- A Tachy episode is declared and the device mode switches to VTR
- The device enters Post-Shock Brady
- An ATR mode switch occurs
- RYTHMIQ is programmed OFF

Secondary Pacing Mode: DDD(R)

When sustained AV block is detected (i.e. 3/11 slow ventricular beats), the device reverts to secondary DDD(R) mode to ensure ventricular pacing support.

- All of the parameters programmed ON in the primary AAI mode will be applied in the secondary DDD(R) mode: LRL, amplitudes, pulse widths, PVARP.
- Parameters required for dual chamber pacing will be applied: Paced and Sensed AV Delay and ventricular refractory.
- AV Search Plus may be programmed ON to search for restored AV conduction *See AV Conduction Detection below*. If sustained AV conduction is detected, the device will return to the Primary AAI(R) with VVI Back-Up mode.

NOTE: If AV Search Plus is programmed OFF and the AV block is detected, the device will switch to DDD(R) mode permanently, and would require manual reprogramming to return to Primary AAI(R).

- The mode switch to DDD(R) will be recorded in the Arrhythmia Logbook as a RYTHMIQ event, and an EGM will be stored. *See the Arrhythmia Logbook section below*.
- During RYTHMIQ Secondary DDD(R) pacing, all DDD(R) pacing features are available except Rate Hysteresis, since it could decrease the rate below the VVI Backup LRL.

AV Conduction Detection

During secondary DDD(R) pacing, the AV Conduction Detector uses AV Search Plus to search for restored AV conduction:

- When the AV Search Interval is reached, the AV delay is extended to the programmed AV Search Plus value.
- Failed Search: If either of the following occur, the device will maintain secondary DDD(R) pacing and the AV Search Plus interval will be restarted.
 - AV Search Interval is reached and no AV conduction is detected.
 - AV Search Interval is reached and the AV delay is extended to the programmed AV Search Plus value and no AV conduction is detected.

- No intrinsic conduction is detected within the 8 cycle search period
- two out of the last 10 ventricular events are paced (rolling window)
- Successful Search: If a V-sense is detected within the 8 cycle period of AV search hysteresis, hysteresis continues:
 - AV Conduction Detector Counter is initialized at “0”
 - Each ventricular sensed event will be marked as VS-Hy (Hysteresis)
 - AV Conduction Counter is incremented with each VS-Hy beat, VS-Hy need not be consecutive
 - When the AV Conduction Counter is ≥ 25 , sustained conduction is detected and the device switches back to the primary AAI(R) mode with VVI back-up

NOTE: The AV conduction counter will be reset to 0 and will no longer count conducted events when:

- The device switches to the Primary AAI(R) mode
- The device enters Temporary Brady
- A Tachy episode is declared and the device mode switches to VTR
- The device enters Post-Shock Brady
- An ATR mode switch occurs
- RYTHMIQ is programmed OFF

Atrial Arrhythmia Detection: ATR Entry Criteria Met

See ATR section for more details.

ATR detection is active during RYTHMIQ. If an atrial arrhythmia occurs, the device can mode switch from either Primary AAI(R) or Secondary DDD(R) directly to ATR.

ATR Detection Summary:

- Atrial rate exceeds the ATR trigger.
- ATR Entry count is met.
- ATR Duration counts ventricular events during Primary AAI(R) or Secondary DDD(R) modes.
- Exit Counter begins to decrement/increment.
- When Duration counter is met and if Exit Counter is >0 , the device mode switches to ATR fallback mode.

NOTE: ATR detection is not available in Temporary Brady or Post Shock Brady modes.

ATR Fallback

The transition from AAI(R) or DDD(R) to ATR fallback occurs on the next ventricular event after ATR Duration is met. RYTHMIQ is suspended during ATR fallback.

- Fallback Pacing mode starts, and ventricular pacing rate decreases toward the ATR/VTR LRL during Fallback Time.

- Exit Counter continues to increment/decrement.
- Once Fallback Time has expired, device paces as required at the ATR/VTR LRL. Fallback Pacing will remain in effect until the Exit Count reaches zero.

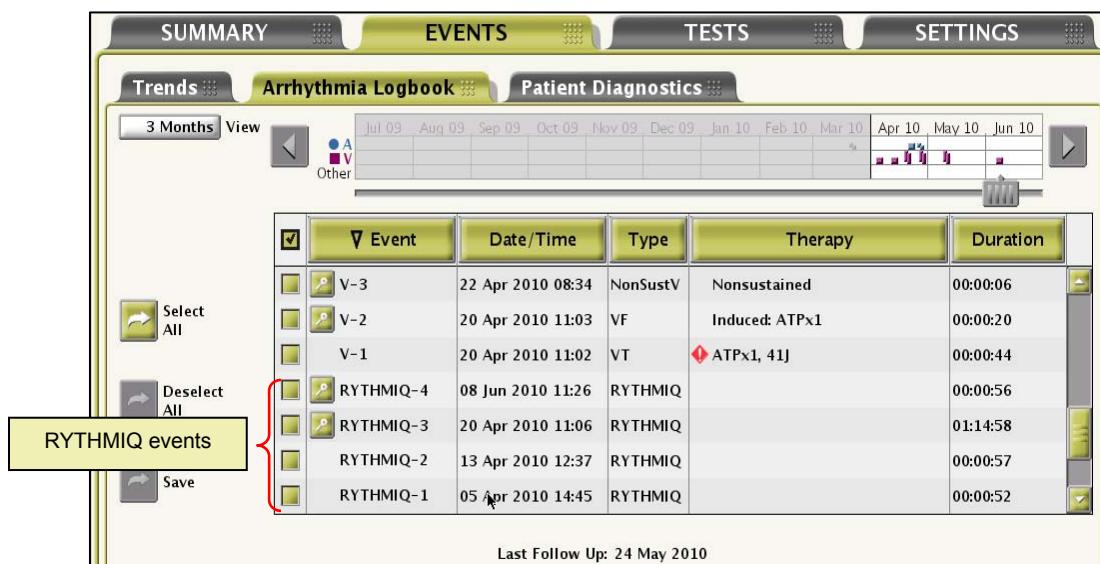
NOTE: RYTHMIQ's 3/11 AV block counter will be reset to 0/11 and will no longer count blocked events during ATR.

ATR Exit Criteria Met

When the ATR Exit Count =0, the device switches from ATR to back to the RYTHMIQ pacing mode:

- If the device was pacing in Primary AAI(R) mode when ATR mode switch occurred, it will return to Primary AAI(R) mode.
- If the device was pacing in Secondary DDD(R) mode when ATR mode switch occurred, it will return to Secondary DDD(R) mode.

Arrhythmia Logbook



An event is stored in the Arrhythmia Logbook when the RYTHMIQ algorithm switches to the secondary DDD(R) mode.

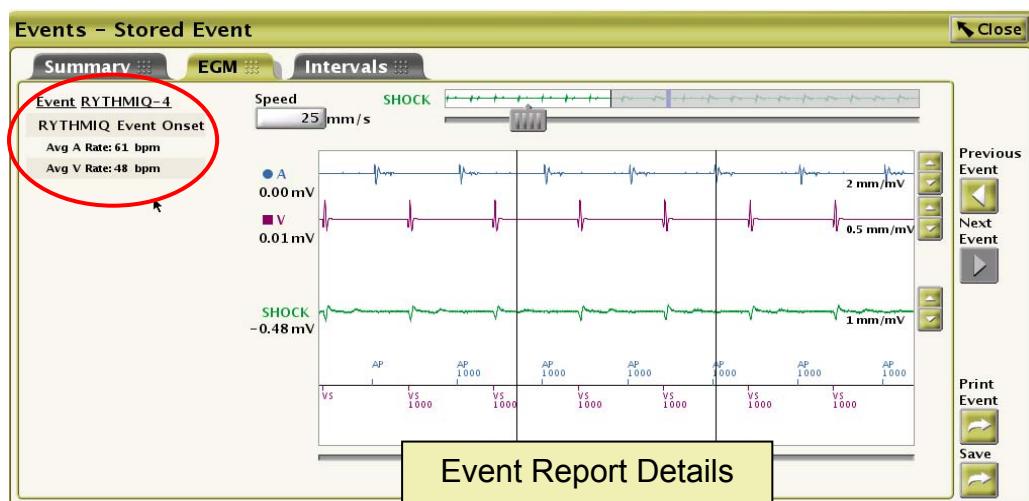
- Up to three events (minimum of one) with EGM details may be stored. Up to 10 total RYTHMIQ events (three with details, seven without) may be listed in the logbook. RYTHMIQ events are priority four in the logbook, which is the lowest event priority; any higher priority events may overwrite RYTHMIQ events. *See the Arrhythmia Logbook, Memory Allocation Table for more details.*
- Duration indicates the total time spent in Secondary DDD(R) mode. Duration is provided once the device returns to the Primary AAI(R) with VVI Back-up mode.

- *In Progress* indicates, the RYTHMIQ algorithm is currently in the secondary DDD(R) mode and has not yet returned to Primary AAI(R). The associated stored EGM is available for viewing while the episode is in progress.

Stored Event Report

RYTHMIQ stored events include:

- Event detail page
- 20 seconds of EGMs: 10 seconds before the switch to Secondary DDD and ten seconds after
- Interval graph, showing each of the intervals on the EGM



Event Details

- Event number (e.g., RYTHMIQ-5) identifies the event and acts a counter for how many total RYTHMIQ events have occurred.
- Event date and event time provide a time stamp of when the mode switched to Secondary DDD.

RYTHMIQ Event Onset

- Average A-rate: average of the four atrial intervals preceding the mode switch.
- Average V-rate: average of the four ventricular intervals preceding the mode switch.
- Event Ended Duration of the RYTHMIQ event, starting when the device switches to Secondary DDD(R) and ends when the device switches back to Primary AAI(R) with VVI Backup.

NOTE: The Average A- and V-rates do not appear on the printed report.

EGM markers:

- RYTHMIQ appears at the 10-second mark in the EGM, indicating the start of Secondary DDD(R) mode. This marker will also appear at the end of a RYTHMIQ event, when the mode switches back to Primary AAI(R) plus VVI Backup.

- PVP→ PVARP extension, indicating the device is switching to a tracking mode (e.g., Secondary DDD(R)) from a non-tracking mode (AAI(R) with VVI Backup).

To help determine which mode switch occurred:

- RYTHMIQ with PVP→ indicates Primary AAI(R) switching to Secondary DDD(R).
- RYTHMIQ without PVP→ indicates Secondary DDD(R) switching back to Primary AAI(R).

Notes/Additional Information

Tachy events/Post Therapy

- If a Tachy episode is declared while RYTHMIQ is programmed ON (i.e. 8/10 fast beats > the lowest Tachy rate zone cutoff), VTR pacing mode will be VVI.
- During Post-Therapy Brady pacing, RYTHMIQ is suspended. The device will use the programmed Normal Brady mode (i.e., DDD(R)) and this mode will be in effect throughout the programmable Post-Therapy Pacing period; nominally 30 seconds (range: 15 seconds to 1 hour). When the Post Therapy Pacing period ends, the device will return to the RYTHMIQ Primary AAI(R) or Secondary DDD(R) mode, whichever was active prior to declaring the episode (i.e. 8/10 fast beats).

Temp Brady

- During Temporary Brady pacing, RYTHMIQ is suspended. When exiting the Temporary mode, the device will return to the RYTHMIQ Primary AAI(R) or Secondary DDD(R) mode, whichever was active prior to the change to Temporary mode.

Electrocautery Protection

- If Electrocautery Protection is enabled while RYTHMIQ is ON, the Brady mode will be DOO as long as Electrocautery Protection is ON. When Electrocautery Protection is disabled, the device will return to either the RYTHMIQ Primary AAI(R) or Secondary DDD(R) mode, whichever was active when Electrocautery Protection was enabled.

Daily Measurements

- Daily Measurements are available for both chambers when the Reverse Mode Switch feature is enabled.

Brady Features

- Rate Hysteresis and Rate Hysteresis with Search are not allowed when RYTHMIQ is enabled (*a Warning interactive limit* will occur to ensure the RYTHMIQ back-up pacing rate is maintained).
- Rate Smoothing is active during RYTHMIQ but only will be applied during Primary AAI(R) and Secondary DDD(R). Rate smoothing is not applied during the back-up VVI pacing.
- Counters: the AV Search % successful counter be incremented if it is extended during a RYTHMIQ mode switch.

Indications-Based Programming (IBP)

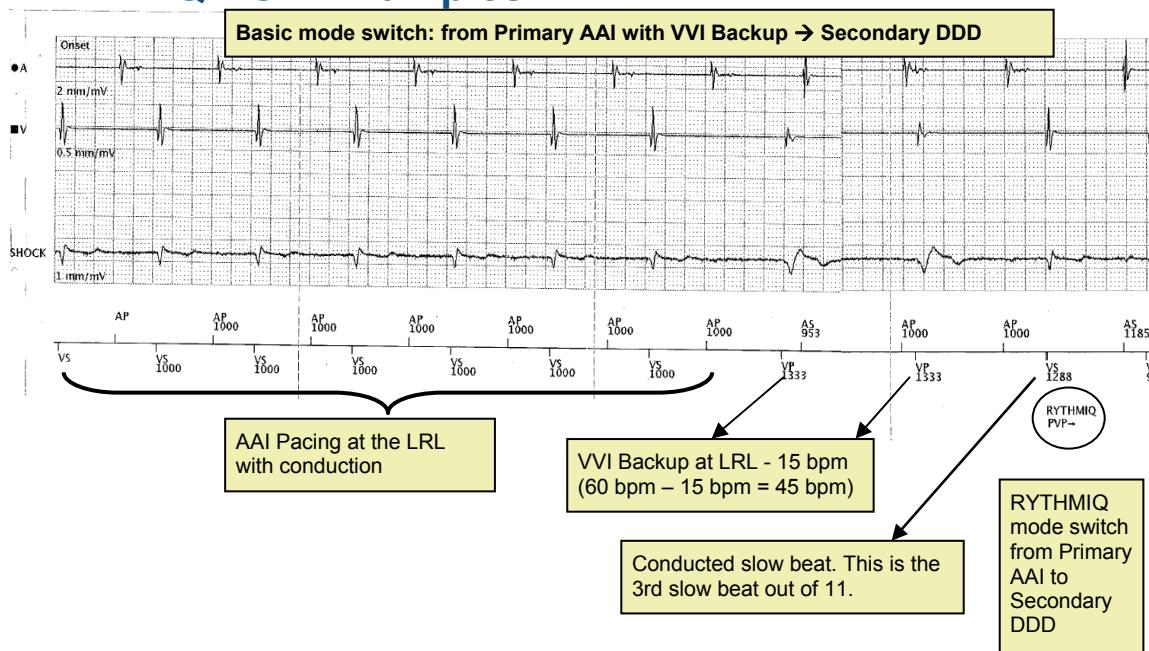
RYTHMIQ will be part of the recommended (IBP) programming for any patients with:

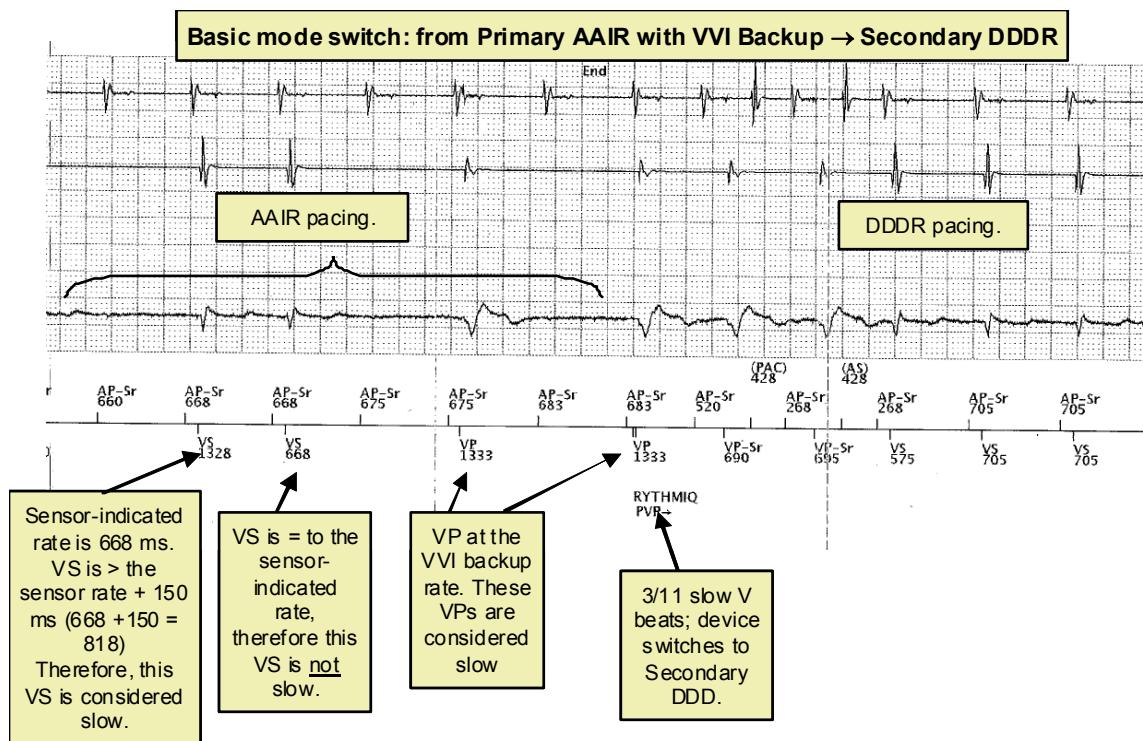
- AV Node Normal or with 1st degree block, and
- Atrial Arrhythmias = None or Paroxysmal/Persistent Atrial Arrhythmias.

RYTHMIQ will not be part of the recommended (IBP) programming for patients with:

- Second degree block
- Complete Heart Block
- Permanent/Chronic AF

RYTHMIQ EGM Examples





Not available for TELIGEN models distributed in U.S.

Reverse Mode Switch (RMS)

Reverse Mode Switch (RMS) is designed to eliminate unnecessary ventricular pacing for patients who appear to have normal AV conduction. RMS operates in an AAI(R) pacing mode with VVI backup during times of normal conduction.

Availability

- RMS is available in Normal Brady, DDD and DDD(R) modes. RMS is not available in Temporary Brady or Post-Shock Brady modes.
- Navigation:

- From the Settings screen select
- Select

Programmable Values

DDR(R) LRL	30-185 bpm	Nominal: 60 bpm
Reverse Mode Switch	OFF, AAIR with VVI Back-up	Nominal: 60 bpm
Reverse Mode Switch	OFF, AAIR with VVI Back-up	Nominal: OFF

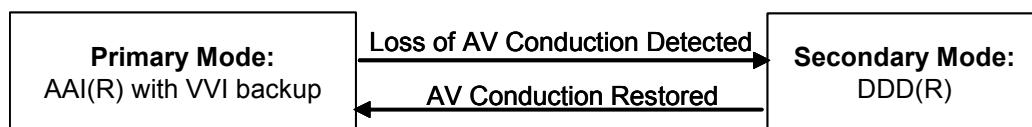
- VVI Back-up: 30-60 bpm (non-programmable)
 - The VVI Back-up mode is automatically set by the programmer to be 15 bpm below the DDD(R) LRL (and also AAI(R) LRL).
 - The VVI Back-up LRL is limited to a range of 30-60 bpm. If the DDD(R) LRL is less than 45 bpm, the VVI Back-up LRL is still set to a minimum of 30 bpm. Likewise, if the DDD(R) LRL is greater than 75 bpm, the VVI Back-up LRL is set to a maximum of 60 bpm.
 - × To ensure the RMS back-up pacing rate is slower than the DDD(R)/AAI(R) LRL, a red warning *Interactive limit* will be displayed if the Normal Brady LRL is set to 30 bpm

AV Search Plus	OFF, 32-1024 cycles	Nominal: OFF
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- Search AV Delay: 10-400 ms
- Search Interval: 32-1024 intervals
 - Once Reverse Mode Switch is enabled, AV Search Plus will be ON with a seeded search AV Delay of 400 ms and a search interval of 32 cycles. If AV Search Plus is already enabled prior to enabling RMS, the AV Search Plus parameters are unchanged.

Algorithm

Reverse Mode Switch (RMS) uses a primary mode of AAI(R) with VVI backup pacing which is utilized when RMS is enabled. When a loss of conduction is detected, the device reverts to the secondary mode of DDD(R) to ensure ventricular pacing support. AV Search Plus searches for restored AV conduction while in secondary mode and once AV conduction is restored, the device returns to the primary AAI(R) mode with VVI back-up pacing.



Primary AAI(R) with VVI Back-up Mode

When programmed to a DDD(R) mode with Reverse Mode Switch enabled, the device will function in AAI(R) mode with VVI back-up. The AAI(R) and back-up VVI mode operate independently. The VVI LRL is non-programmable and the algorithm sets the LRL to 15 bpm less than AAI(R) LRL, if possible. The AAI(R) mode is the primary pacing mode and features such as Rate Hysteresis will operate from this mode while the VVI mode is simply a back-up mode.

- If sustained AV conduction occurs the VVI timing cycle will be reset to the VVI back-up rate and ventricular pacing inhibition will occur (VVI LRL is less than AAI(R) LRL).

See the following AV Conduction Counter below.

- VS events will be marked as VS-Hy (Hysteresis) until sustained AV conduction is confirmed.
- The start and end of an RMS episode is marked on EGMs as *RMS-Epsd*.
- If loss of AV conduction occurs, ventricular paces will be delivered at the VVI LRL asynchronous to the AAI(R) mode.
- If partial loss of AV conduction occurs, ventricular pacing may occur and will be dependent on the degree of conduction loss.

AV Conduction Loss Detected

To assess loss of AV conduction, the Reverse Mode Switch algorithm uses a non-programmable AV conduction assessment scheme. During normal AV conduction, the atrial and ventricular intervals should be similar and the ventricular interval should never be significantly slower than the atrial interval (with the exception of PVCs and PACs). Each time a blocked ventricular event occurs, the Block Detector Counter is incremented. A blocked ventricular event is defined as:

- A VP or noise reversion VP (VVI interval timeout)
- The V-V interval is longer than the AAI LRL interval +150 ms. (V-V interval is slower than the atrial rate but not slow enough to cause a VP)
- The V-V interval is longer than the AAI(R) sensor indicated rate interval +150 ms. (V-V interval is slower than the sensor indicated rate but not slow enough to cause a VP)

AV Conduction Loss Declaration

- Three blocked ventricular events in a window of 11 beats causes the transition to DDD(R)
- The RMS episode will be logged in the Arrhythmia Logbook along with a stored EGM

Secondary DDD(R) Mode

When the device switches to a DDD(R) mode, all of the parameters used in the primary mode will be applied (amplitudes, pulse widths, etc.) as well as the programmed DDD(R) LRL. A programmed AV Delay and AV Search Plus are required for appropriate DDD(R) functionality as well as to assess for a restoration of intrinsic AV conduction.

AV Conduction Detected

The RMS AV conduction assessment scheme utilizes AV Search Plus to assess for intrinsic AV conduction. Once the AV Search Interval is reached, the AV Delay is extended to the programmed AV Search Plus value. Each time an intrinsic ventricular sensed event occurs, the AV Conduction Counter is incremented.

- In the backup DDD(R) mode when the AV Search Interval is reached, the AVD is extended to 400 ms and AV Search Hysteresis (AVSH) starts
- If a V-sense is detected within the eight cycle period of AVSH, then apply AV Hysteresis. The AV Conduction Detector Counter is initialized at “0”
- If no intrinsic conduction is detected within the eight cycle search period, the programmed DDD(R) AV Delay is resumed and the search interval is restarted (failed search)

Conduction Declaration

- If 2 out of the last 10 ventricular events are paced (rolling window), the programmed DDD(R) AV Delay is resumed.
- If the AV Conduction Counter is ≥ 25 (to ensure sustained AV conduction), the device will revert back to the primary AAI(R) mode with VVI back-up

NOTE: The AV Search Plus feature can be turned OFF in order to remain in the secondary DDD(R) mode until the next follow-up.

Arrhythmia Logbook Storage

An event is stored in the Arrhythmia Logbook at the beginning of an RMS event (when the RMS algorithm enters the secondary DDD(R) mode).

See the Arrhythmia Logbook topic for further details on event storage.

- Up to three detailed episodes may be stored with associated EGMs; up to 10 total RMS events may be listed
- If *In Progress* is displayed for duration, the RMS algorithm is currently in the secondary DDD(R) mode; the associated stored EGM is available while the episode is in progress
- Stored EGM Event markers
- RMS-Epsd: marks the start of the RMS event and secondary DDD(R) mode
- PVP→: marks the PVARP extension at end of RMS event
- For each event, 10 seconds prior to and 10 seconds after the end of the RMS event are stored
- The interval graph will show each of the intervals which are stored on the EGM

Episode Report Details

- Event number (e.g., RMS-5), event date, and event time are provided.
- RMS Event Onset:
 - Average A-rate: average A-rate at time the RMS mode switch is triggered and calculated from the four-interval average preceding the point of the mode switch
 - Average V-rate: average V-rate at time the RMS mode switch is triggered and calculated from four-interval average preceding the point of the mode switch

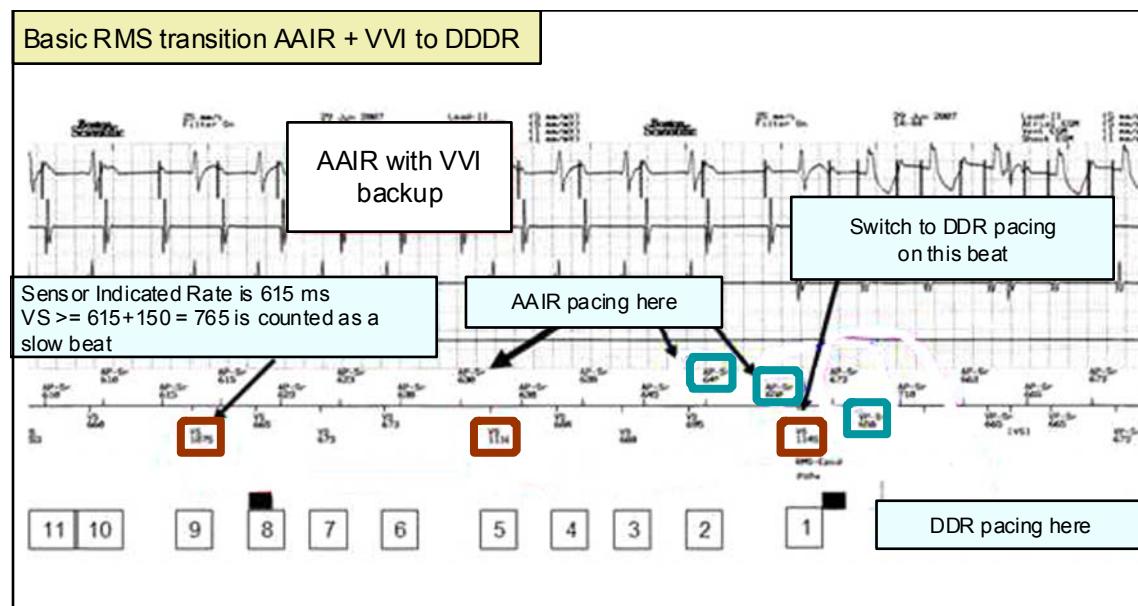
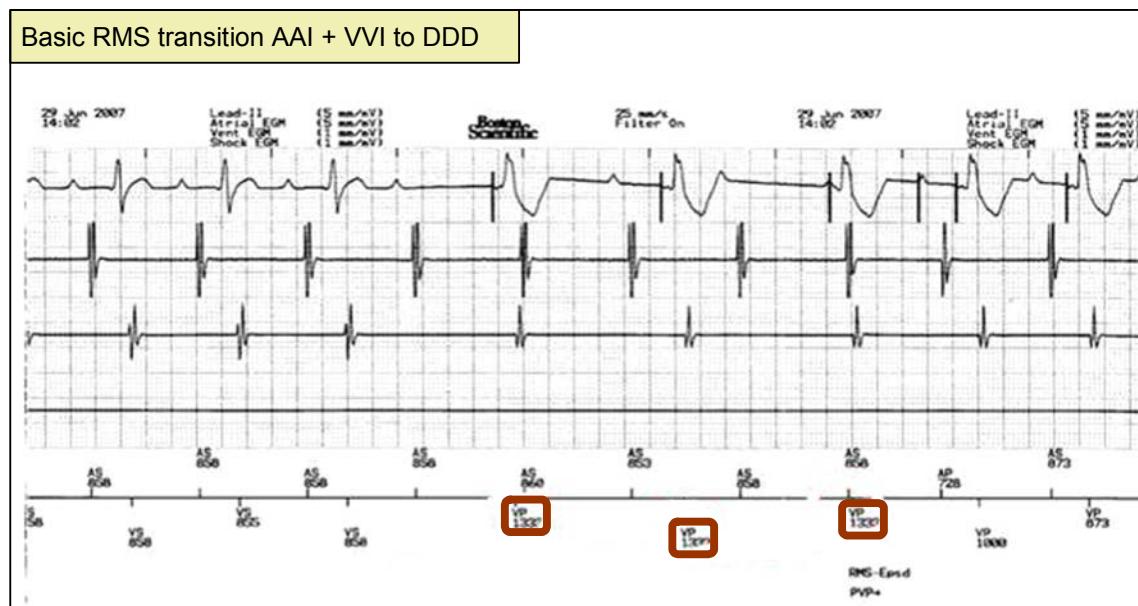
- Event Ended
 - Total Duration that the RMS algorithm was in the secondary DDD(R) mode
 - A Duration is provided once the device returns to the primary AAI(R) with VVI Back-up mode

Notes/Additional Information

RMS interaction with other features

- ATR mode switch is not possible during RMS primary mode (AAIR). ATR mode switch can only occur from the secondary mode (DDDR). RMS was the predicate algorithm to RHYTHMIQ. RHYTHMIQ was enhanced to allow ATR mode switch from AAIR.
- As a general rule, the Reverse Mode Switch feature should be treated as a dual chamber mode when considering feature interactions.
- When exiting the temporary mode, the device will revert back to whichever mode (primary or secondary) was present prior to the temporary change.
- If a ventricular arrhythmia is detected and the VTR state is entered, the VVI mode will be applied.
- During Post-Shock Brady pacing, the Reverse Mode Switch feature is suspended. The device uses the secondary pacing mode during the Post-Shock Pacing period which is nominally 30 seconds and could be programmed up to one hour (range: 15 seconds to 1 hour). At the expiration of the Post Shock Pacing period, the PG will return to Normal Brady parameters and apply the RMS primary or secondary mode, whichever was active prior to declaring the episode (i.e., when brady transitions to VTR).
- Daily Measurements are available for both chambers when the Reverse Mode Switch feature is enabled.
- Rate Hysteresis and Search Hysteresis are not allowed when RMS is enabled (a *warning interactive limit* will occur to ensure the RMS back-up pacing rate is maintained).
- Rate Smoothing is active during RMS but will only be applied during AAI(R) function and is not applied to the back-up pacing.
- Magnet mode will be DOO regardless if the device is presently using the primary or secondary mode.

RMS Samples



SmartDelay (CRT-D Only)

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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SmartDelay recommends customized AV delays to maximize each patient's hemodynamic response to CRT. The algorithm quickly (< 2.5 minutes) provides recommended settings for programming paced-and sensed-AV Delay based on the measurement of intrinsic AV intervals, interventricular timing, and

LV lead location. The objective of SmartDelay is to recommend AV Delays that provide optimally timed fusion of the intrinsic activation and the pacing stimuli; resulting in a more synchronous ventricular contraction and improved peak rate of ventricular pressure change during systole (LV dP/dtmax). LV dP/dtmax is considered an index for global ventricular contractile function and pumping efficiency.

SmartDelay is a new device feature, but the concept is not new to CRT patients. Boston Scientific's approach to optimization has evolved over the last decade, and some basic elements of the formula upon which the feature was designed were used to recommend AV delays in clinical trials. Specific trials that used these elements are COMPANION, DECREASE HF, and RENEWAL 3 AVT Trial. Clinical data from CRT-AVO regarding hemodynamic performance of this feature relative to other AV Delay optimization methods shows that the SmartDelay optimization algorithm recommended AV Delays that maximized global contractile function as measured by LV dP/dtmax.

The SmartDelay optimization test evaluates right and left ventricular response to both atrial sensed-and paced-events to determine suggested settings for the following:

- Paced AV Delay
- Sensed AV Delay

These suggested settings can be used when programming the pulse generator for CRT.

NOTE: When collecting atrial paced and sensed events, backup DDD pacing is provided at the temporary LRL. Increase temporary paced LRL 10-15 bpm over NSR, which can be selected from the SmartDelay Optimization screen. This temporary LRL is nominally set to 80 ppm.

Availability

- Available in VDD(R) and DDD(R) modes while in a normal operating state.
- The SmartDelay optimization test will not run under the following conditions:
 - LV electrode configuration is programmed to None
 - Tachy episode or ATR mode switch in progress
 - During the post-therapy period
 - During a tachycardia episode as determined by the pulse generator detection criteria
- Other scenarios where testing is allowed but will be unsuccessful are:
 - Battery Status at EOL
 - Magnet application
 - Storage mode
 - EP Test is active
- Because the test measures A-V conduction times, physicians may elect not to test patients with complete AV block.

- SmartDelay is available and can be performed during ZIP or inductive telemetry.

NOTE: Tachy Therapy is disabled while SmartDelay testing is in progress

- Navigation

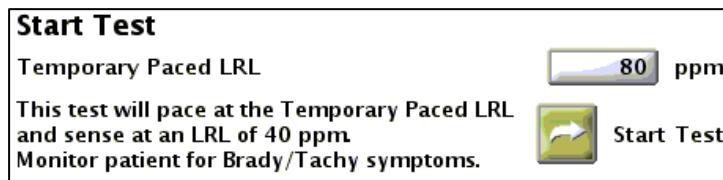
- From the Settings screen select 



- When changing modes from DDD(R) to VDD(R) or vice versa, it is important to rerun the SmartDelay optimization test.
- Maintain telemetry throughout the test.

Programmable Values

- The Temporary Paced LRL is adjustable from 30-185 bpm (nominally 80bpm) to pace above the patient's intrinsic atrial rate while SmartDelay testing is performed. In order to achieve a successful test, this value should be 10-15 beats faster than the patient's sinus rate. A warning message will be provided if the temporary LRL is not at least 10 ppm less than the programmed MTR.
- Programming a temporary LRL to > 100 ppm will prevent an atrial paced measurement from occurring, but the sensed measurements will be conducted.



NOTE: Previous devices offered either a manual mode in which entry of QRS needed to be entered or auto mode. CRT-Ds described in this primer have what is similar to auto mode as QRS duration no longer needs to be entered, because they temporarily change the LV sensing configuration to unipolar (Tip-to-Can) to collect LV sense intervals.

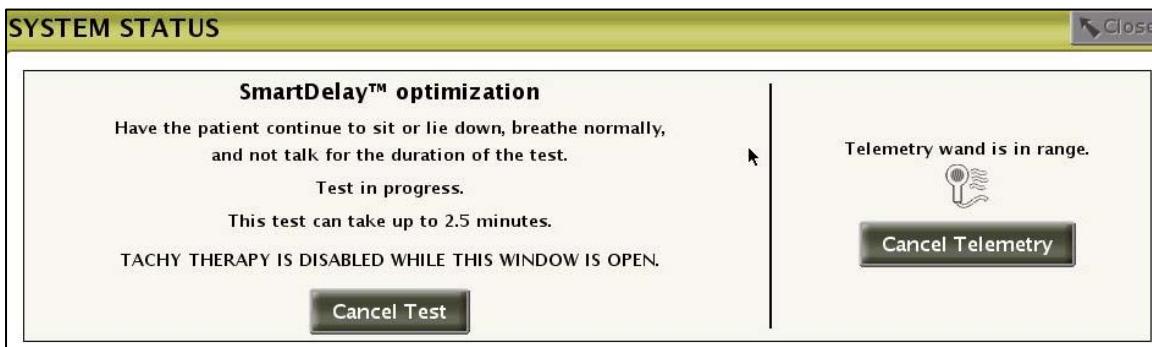
Algorithm

SmartDelay Optimization operates in three phases:

- Measurement phase
- Calculation phase
- Results phase

Before beginning the test, advise the patient to remain still and to avoid talking during the test. The test runs automatically once *Start Test* is selected and uses a bipolar sensing configuration for the RV lead and a Tip-to-Can sensing configuration for the LV lead.

The following screen will be shown during testing:



- Maintain telemetry throughout the test.
- Testing may take up to 2.5 minutes.
- Select *Cancel Test* or *Cancel Telemetry* to terminate testing.
- The test is automatically cancelled if STAT Pace, STAT Shock, or DIVERT Therapy command is selected.

1. Measurement Phase

The device will attempt to measure 15 valid intervals for Atrial sensed AV intervals (As-RVs to As-LVs) and Atrial paced AV intervals (Ap-RVs to Ap-LVs).

To be considered as a valid interval, all of the atrial and ventricular (RV and LV) events for both the current and previous interval must be valid.

See the table titled *Definition of Valid Events*.

These 15 intervals may be based on consecutive or non-consecutive intervals.

- Current Brady/CRT parameters remain in effect other than those listed below which are OFF during the course of testing:
 - Rate Smoothing
 - Dynamic AV Delay
 - Tracking Preference
 - ATR/AFR
 - LV Offset 0 ms
 - Tachy Detection/therapy is disabled

Atrial sensed AV interval measurement

The device first enters a temporary DDD mode with a LRL of 40 bpm and a fixed AV Delay of 400 ms. Following 10 warm-up cycles, 15 intervals are obtained to measure the sensed A to sensed RV (AV_R) and sensed A to sensed LV (AV_L) intervals.

- If the atrial sensed measurement succeeds, the algorithm will proceed to the atrial paced AV interval measurement.
- If the atrial sensed measurement fails solely due to atrial pacing, the algorithm will proceed to the atrial paced AV interval measurement (15 valid sensed intervals are not collected within 70 seconds).
- If the atrial sensed measurement fails for any reason other than atrial pacing, the algorithm will proceed directly to the calculation phase without performing an atrial paced measurement (15 valid sensed intervals are not collected within 70 seconds).
- If the temporary LRL is > 100 ppm, the algorithm will proceed directly to the calculation phase without performing an atrial paced measurement.

Atrial paced AV interval measurement

The device enters a temporary DDD mode at the Programmed Temporary Paced LRL with an extended AV Delay of 450 ms. Following 10 warm-up cycles, 15 intervals are obtained to measure the paced A to sensed RV (AV_R) and paced A to sensed LV (AV_L) intervals.

- If this measurement succeeds, or if 15 valid paced intervals are not collected within 70 seconds, the algorithm will proceed to the calculation phase.

Definition of Valid Events

Measurement	Interval is considered valid if NONE of the following occur
Atrial sensed measurement	A-pace, A-pace inhibited by noise, PAC, A-sense above the MTR or within the refractory period, consecutive A-Senses or A-Noise was detected
Atrial paced measurement	A-pace inhibited by noise, normal A-sense, PAC, A-sense above the MTR or within the refractory period, consecutive A-senses or A-Noise was detected
RV/LV events for both atrial sensed and atrial paced measurement	<ul style="list-style-type: none"> • <u>RV event:</u> RV-pace, RV-pace inhibited by noise, PRVC, and fast RV sense causing RV-RV interval above the MTR or RV-Noise was detected • <u>LV event:</u> LV-pace, LV-pace inhibited by noise, PLVC, and fast LV sense causing LV-LV interval above the MTR or LV-Noise was detected

4. Calculation Phase

During this phase the following calculations are performed:

- Average atrial sensed and paced AV intervals
- LV lead location
- Suggested Pacing Chamber (INTL Only)
- Suggested LV Offset (INTL Only)
- Suggested Paced and Sensed AV Delay

Average atrial sensed and paced AV interval calculation:

If an adequate number of valid sensed AVR and AVL intervals are obtained in the Measurement Phase, intervals within one standard deviation (SD) of the mean are averaged. If the averaged sensed AV interval values are within normal limits and stable, the measurement is considered successful. The sensed AV interval calculation will be considered unsuccessful if any of the following conditions occur:

- The sensed AVR or AVL intervals are too variable ($SD/\text{mean} > 0.25$).
- The average sensed AVR or AVL interval is ≤ 100 ms.
- The average sensed AVL minus AVR value is ≤ -100 ms (such as in a wide RBBB as the LV activates prior to the RV).
- The average sensed AVL minus AVR value is ≥ 200 ms (such as in a wide LBBB as LV activates after the RV).

These same conditions are then applied to the paced AV interval calculation to determine if a successful paced measurement was achieved.

LV lead location analysis:

LV lead location may be manually entered under System Summary \Rightarrow Patient Info \Rightarrow Leads. If the location is entered, SmartDelay will determine LV lead location based on the following table:

Lead Position Selections under Patient Info	SmartDelay LV Lead Location
N/R	Unknown
Right Atrium	Unknown
Right Ventricle	Unknown
Superior Vena Cava	Unknown
Coronary Sinus	Unknown
Epicardial	Unknown

Lead Position Selections under Patient Info	SmartDelay LV Lead Location
LV Base (anterior)	Anterior
LV Base (posterior)	Free Wall
LV Base (lateral)	Free Wall
LV Mid (anterior)	Anterior
LV Mid (lateral)	Free Wall
LV Mid (posterior)	Free Wall

When multiple LV lead locations are entered (i.e. two Y-adapted unipolar leads):

- If at least one of the locations is Anterior and the rest are Unknown, the location will be Anterior.
- If at least one of the locations is Free Wall and the rest are Unknown, the location will be Free Wall.
- If all locations are Unknown, the location will be Unknown.
- If at least one of the locations is Anterior and at least one is Free Wall, the location will be Unknown.

If the LV lead location is not manually entered, or if the location is Unknown via the above table, SmartDelay will calculate the LV lead location by assessing the sensed AVL – AVR value. If these values differ by > 40 ms, the LV lead is more likely to be in the Free Wall. If the values differ by < 40 ms, the LV lead is more likely to be Anterior. If the sensed AV interval measurement is unsuccessful, the paced measurement will be used.

If the LV lead location is entered incorrectly (i.e., an LV Free Wall location is entered as an LV Anterior location), the AV Delay recommendations may be less than optimal.

Suggested Pacing Chamber

For U.S. models, the suggested pacing chamber will be always be BiV.

Suggested LV Offset

For U.S. models, LV Offset is a separately programmable feature and can be manually entered by the physician. SmartDelay takes the LV Offset into account as follows.

SmartDelay uses simple arithmetic to account for the programmed LV Offset in the paced and sensed AV Delay recommendation it provides.

Example: If the SmartDelay suggested AV Delay (which starts at the atrial event and ends at the left ventricular pace) is 150 ms and the programmed LV Offset is -20 ms, then the SmartDelay feature will adjust its recommendation to 170 ms, since the AV Delay feature is programmed from atrial event to right ventricular pace.

SmartDelay maintains the currently programmed LV Offset with the following exceptions:

- If SmartDelay cannot collect sufficient intrinsic events, nominal settings that include LV Offset of zero are suggested.
- If SmartDelay recommended AV Delay and LV Offset together exceed the maximum programmable AV Delay of 300 ms, SmartDelay will suggest a reduced LV Offset.

If you manually adjust LV Offset after running SmartDelay optimization, you will need to adjust the AV delay either by running SmartDelay optimization again or manually reprogramming the AV Delay.

Suggested Paced and Sensed AV Delay (PAVD and SAVD)

A PAVD and SAVD are then calculated based on equations and coefficients developed in clinical trials using the average measured AVL and AVR intervals and LV lead location. These calculated AV Delays are then further refined based on the LV Offset to develop the final Suggested PAVD and SAVD.

- Calculated PAVD and SAVD –SAVD and PAVD values are calculated using the average AVL and AVR intervals. The coefficients of the equations are determined by the LV lead location. If the sensed measurement is unsuccessful, the algorithm will proceed directly to the PAVD calculation.
 - If the average sensed AVL – AVR \leq 0 ms (such as RBBB),
 - × Calculated SAVD: $k1 * \text{average SAVL}$
 - If the average sensed AVL – AVR $>$ 0 ms (such as LBBB)
 - × Calculated SAVD: $(k2 * \text{SAVL}) + (k3 * \text{SAVR}) + k4$
 - The calculated SAVD will always be a minimum of 50 ms and a maximum of the shorter of 240 ms OR [either (70% * sensed AVR) or (70% * sensed AVL)]

These same equations and coefficients are then applied to determine the calculated PAVD if the PAVD measurements were successful.

- The calculated PAVD will always be a minimum of 50 ms and a maximum of the shorter of 300 ms OR [either (70% * paced AVR) or (70% * paced AVL)]

If only one of the two AV interval measurements is successful, the calculated AV Delay for the unsuccessful measure will be based on the successful measurement: i.e., depending on the patient's conduction characteristics, an AV offset of 45 or 60 ms will be added or subtracted to the successfully customized AV Delay to obtain the other value.

- Suggested PAVD and SAVD—finally, the suggested SAVD and PAVD are determined by further refining the calculated SAVD and PAVD using LV offset (as described in Section B.4):
 - LV Offset adjustments:
 - × Suggested PAVD: calculated PAVD + the absolute (positive) of the suggested LV Offset (ex. -50 ms is +50 ms)
 - × Suggested SAVD: calculated SAVD + the absolute (positive) of the suggested LV Offset (ex. -50 ms is +50 ms)

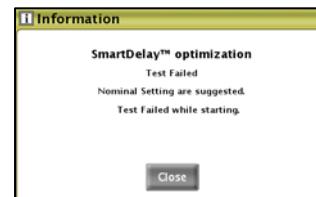
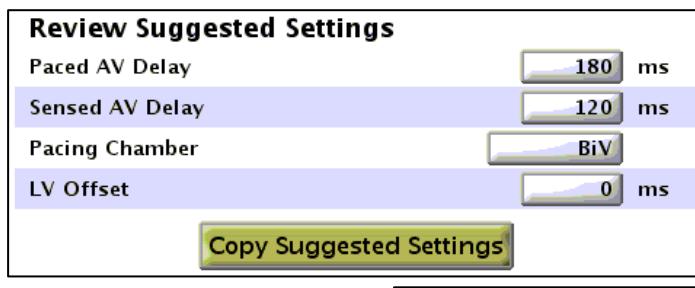
- If both sensed and paced AV interval measurements are successful:
 - × If the calculated PAVD is < calculated SAVD:
 - × Calculated PAVD = calculated SAVD
 - × The SAVD will be a maximum of 100 ms less than PAVD
- If both the sensed and paced AV interval measurements are unsuccessful nominal AV Delay settings will be suggested:
 - × Suggested PAVD = 180 ms
 - × Suggested SAVD = 120 ms
- For all scenarios, the suggested PAVD and SAVD can never exceed 300 ms

5. Results Phase

If testing succeeds, suggested settings will be provided. If both sensed and paced measurements are unsuccessful, an Information screen providing the reason for test failure is displayed and a set of nominal parameters is suggested.

See table titled *Test Failed Message*.

- Suggested settings are individually modifiable as desired.
- Select *Copy Suggested Settings* to transfer suggestions to Brady/CRT Normal Settings.



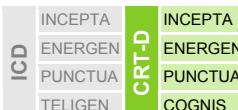
NOTE: Suggested Settings are not stored when the SmartDelay screen is closed and another test must be performed to obtain results if this screen is exited.

- In DDDI mode, both a paced and sensed AV Delay will be suggested.
- In VDDI mode, paced AV Delay does not apply and will not be suggested.
- When changing modes from DDDI to VDDI or vice versa, it is important to rerun the SmartDelay optimization test.
- If testing is unsuccessful, the following Information screen is displayed with a message indicating the reason for test failure. Nominal Settings (values shown above under *Review Suggested Settings*) are provided.

Test Failed Messages

Messages	Reason for Failed Test
Test canceled	Cancel Telemetry, Cancel Test, Divert Therapy, Stat Shock, Stat Pace selected or Telemetry Lost
Test failed while starting	Active V-tachy or ATR episode Post-therapy parameters are in effect, EOL, Magnet application, Storage mode, EP Test is active

Messages	Reason for Failed Test
Test stopped due to insufficient intrinsic events	RV/LV pacing A pacing during atrial sensed measurement if no paced measurement is performed (i.e., temporary LRL > 100 ppm)
Test stopped due to rates above MTR	A, RV or LV sensing above MTR
Test stopped due to Noise	A, RV, or LV noise
Test stopped due to insufficient paced events	A sensing during atrial paced measurement
Test stopped due to PACs	PAC's or consecutive A senses without an RV/LV sense
Test stopped due to PVCs	RV/LV PVCs
Test stopped due to atrial senses occurring during refractory	A senses falling into refractory period
Test was unable to use the Patient's P-R interval	Sensed or paced mean PR interval was </= 100 ms
Patient's P-R interval has too much variability	Sensed or paced mean PR interval was </+ 100ms
Unknown	Other than above



Models distributed in the U.S.
have the negative range
of LV Offsets

LV Offset

LV Offset is designed to enhance programming flexibility in order to coordinate the mechanical response of the right and left ventricle. This feature enables the physician to adjust the delay between delivery of the right and left ventricular pacing pulse. The FDA submission for LV Offset was supported by the DECREASE trial which did not study patients programmed to +LV Offsets and for this reason **+LV Offsets are not available in CRT-D devices distributed in the U.S.**

NOTE: Activating this feature requires individual patient evaluation by a physician.

Availability

- LV Offset is available when the Ventricular Pacing Chamber is set to BiV.
- Navigation:

1. From the Settings screen select 

2. Select 

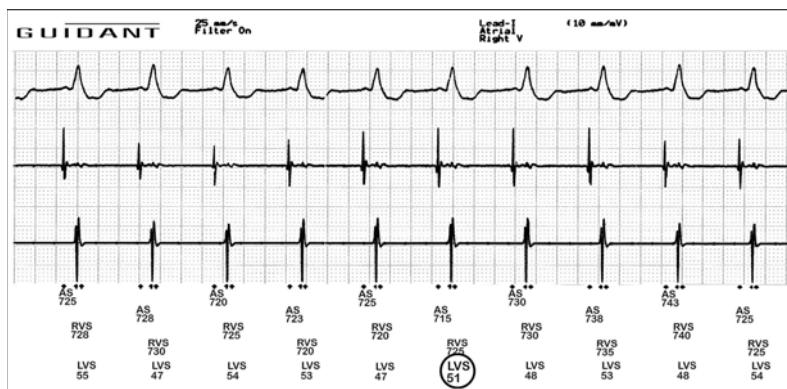
Programmable Values

LV pace prior to RV pace	100 ms to 0 ms (10 ms increments)	Nominal: 0 ms
LV pace after RV pace	0 ms to + 100 ms (10 ms increments) ³¹	Nominal: 0 ms

To determine the LV Offset value, follow these steps:

NOTE: The LV Offset selection is available only if the Pacing chamber option is programmed to BiV.

1. Identify the interval. Program the device to temporary pacing mode ODO. Obtain and print real-time electrocardiogram (EGM) with approximately ten intervals. Identify a representative (averaged) RVS to LVS interval.



2. Check table. Using the average RVS to LVS interval, select the recommended LV Offset from the Table. If the LVS precedes the RVS on the EGM, program the LV Offset to Zero.
3. Select the recommended LV Offset from the choices provided by the programmer. Lengthen the AV delay by the absolute value of the LV Offset (for example, AV Delay = 70 + |-40| = 70 + 40 = 110). Program the device.

NOTE: If subsequently using SmartDelay to determine optimal AV delay, SmartDelay will automatically adjust for the programmed LV Offset. For a detailed description of LV Offset programming with SmartDelay,

4. Select the recommended LV Offset from the choices provided by the programmer. Modify the AV Delay using the following formula and program the device. AV Delaynew = AV Delaypresent – [LV Offsetrecommended – LV Offsetpresent].

RVS to LVS INTERVAL (ms)	RECOMMENDED LV OFFSET
0–15	-20
16–45	-30
46–75	-40
76–105	-50
106–135	-60
136–165	-70
>166	-80

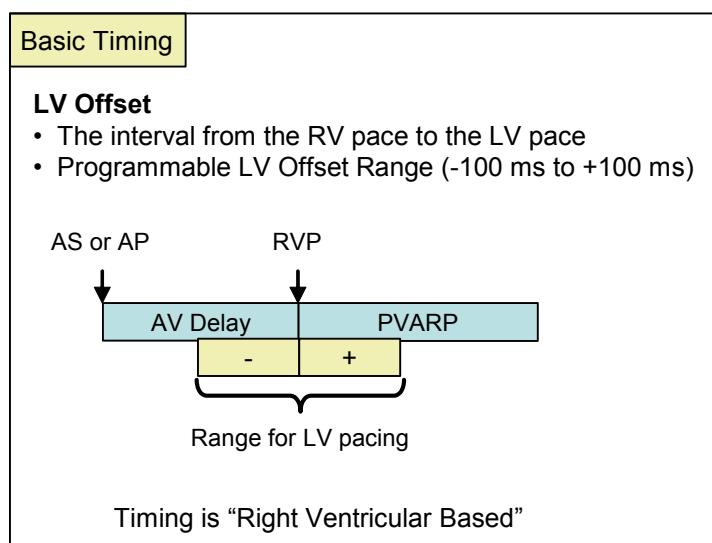
³¹ LV Pace after RV pace (+LV Offset) is unavailable in CRT-D device models distributed in the US

Where:

- AV Delaypresent = currently programmed AV Delay
- LV Offsetpresent = currently programmed LV Offset [nominal value = 0]
- LV Offsetrecommended = recommended LV Offset value from the table based on step 2.

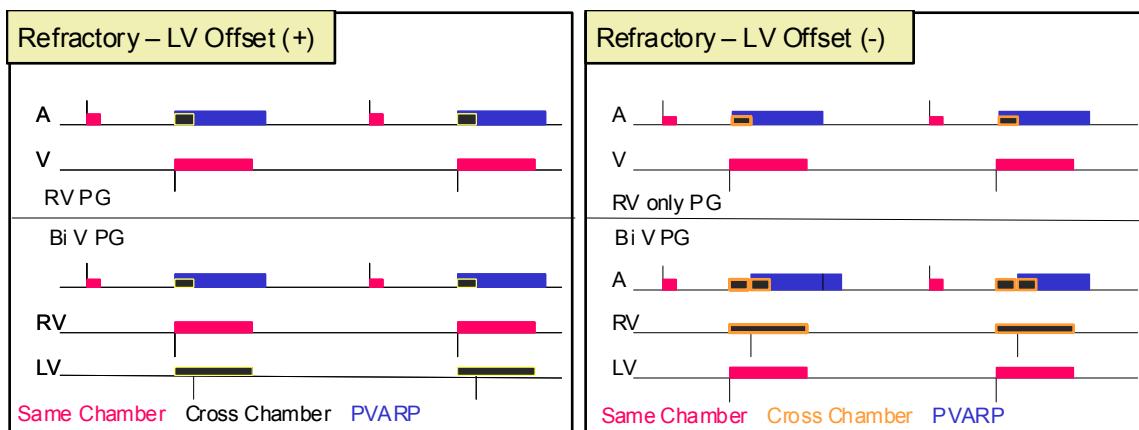
Algorithm

The programmed AVD is always based on RV timing and the PVARP is started by the right ventricular pace:



Considerations from negative LV Offset – with any offset, the atrial cross-chamber blanking increases, which will shorten the atrial sensing window. Smart blanking in CRT-Ds described in this primer help reduce the cross-chamber blanking.

- May inhibit the mode switch from the ATR feature due to p-waves sensed in PVARP ATR mode switch will be inhibited only if the p-waves sensed in PVARP is followed by an RA Pace (This doesn't increment the ATR Up/Down counter). Because the atrial arrhythmia is fast, many p-waves are sensed in PVARP for all devices. The bigger consideration is that with cross-chamber blanking for both RVP and LVP, the p-waves are not sensed during the cross-chamber blank. Since CRT-Ds described in this primer now have SMART sensing after RVP and LVP, the cross-chamber blanking is minimized allowing for more atrial sensing.
- Evaluate the possibility for lowering the ATR trigger rate. With RV-Pacing and LV-Pacing occurring with an offset (both positive and negative), there will be more atrial undersensing than with ventricular sensed events.

Example: Refractory Windows related to LV Offset

The positive and negative LV Offset timing cycle diagrams do not demonstrate all timing cycles; please refer to the dedicated Timing Cycle document for further details.

Explanations to Refractoriness

Intrinsic Events which occur with in absolute refractory or noise window shall not be used as A-senses, RV-senses, or LV-senses for any other features.

RV pace refractory shall be started when the ventricular pacing chamber is set to BiV in combination with an **LV Offset => 0**, RV or LV and a RV pace occurs. The length of the absolute RVpace refractory shall be the length of the effective paced VRP (paced ventricular refractory period). **Result: right V** pace refractory = paced VRP.

LV pace refractory shall be started when the ventricular pacing chamber is set to BiV in combination an **LV Offset < 0** or LV and a left V pace occurs. The length of the absolute left V pace refractory shall be the length of the **LVRP** (left ventricular refractory period).

A (atrial) after RV pace refractory (x chamber refractory) shall be initiated when a RV pace occurs. The length of the absolute A after RVpace refractory is equal to the **A blank after VP**. Refer to *A blank after V pace* in the application. The programming option applies to both, RV and LV pace.

A (atrial) after LV pace refractory shall be initiated when a LV pace occurs. The length of this period is equal to the **A blank after VP**.

RV after LV pace refractory (x chamber refractory) shall be initiated when the V pacing chamber is set to BiV in combination with a LV Offset <0 or LV and a LV pace occurs. The length of the absolute RV pace refractory is equal to the effective **right VRP**.

LV after RV pace refractory (x chamber refractory) shall be initiated when the V pacing chamber is set to BiV in combination with a LV Offset > 0 or RV and a RV pace occurs. The length of the absolute LV pace refractory is equal to the effective **LVRP**.

See the Refractory Period topic.

FOLLOW-UP

Leads Daily Measurements

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Daily lead measurements are provided on the atrial, right ventricular and left ventricular leads for diagnostic purposes to assess lead integrity and stability. In addition to the Daily Lead Measurement results viewable under Summary ⇒ Leads, the trending graphs allow the clinician to customize which results are viewed as well as focus on results for specific time periods.

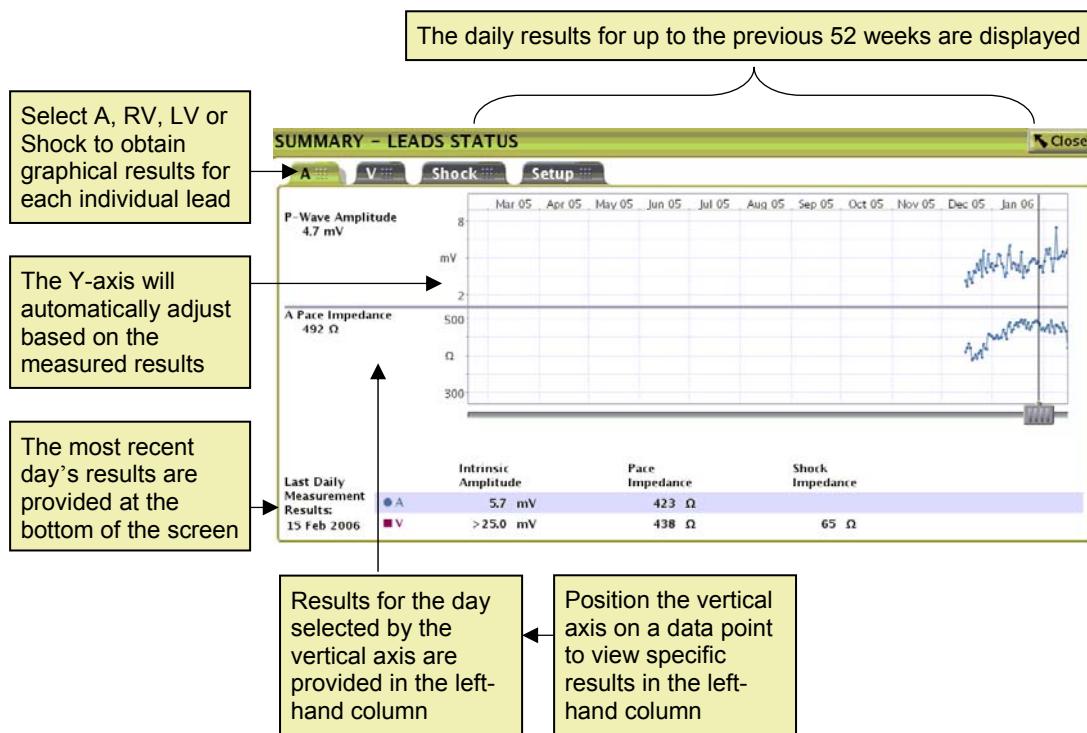
See the Daily Lead Measurements topic for specific information on how lead measurements are recorded and reported.

Availability

- Daily Lead Measures may be turned ON/OFF via Summary → Leads → Setup
 - Nominal: ON.

■ Available Lead Measurement Trends

- P-Wave Amplitude (DR ICDs and CRT-Ds only)
- A-Pace Impedance (DR ICDs and CRT-Ds only)
- R-Wave (RV) Amplitude
- RV Pace Impedance
- Shock Impedance
- R-Wave (LV) Amplitude (CRT-Ds only)
- LV Pace Impedance (CRT-Ds only)



Algorithm

Measurements are collected every 21 hours and reported at the end of a 24-hour time block. The 24-hour internal clock begins at battery connection and the first data collection occurs 21 hours after the device is programmed out of storage mode.

- No data is reported until the device has been out of storage mode for 24 hours.
- The first results will be reported at the next scheduled 24-hour reporting time based on the device's internal clock.

If the device is unable to obtain one or more daily measurements at the scheduled 21-hour time, up to three re-attempts for the unsuccessful measures will be performed at one-hour intervals. Re-attempts do not change the timing of daily measures and the next day's measurement will be scheduled 21 hours from the initial attempt.

- If a valid measure is not recorded after four total attempts (initial plus three re-attempts), the measurement will be reported as Invalid Data or No Data Collected (see the individual test descriptions below for scenarios resulting in an Invalid or No Data Collected result).
- If a valid measure is not collected by the end of a 24-hour time block, the measurement will be reported as Invalid Data or No Data Collected for that day (regardless of the number of re-attempts).
- If no data or an out-of-range measure (see below) is recorded for a particular day, no data point is displayed for that day and therefore blank areas can be observed on the graph.

When the device is programmed out of storage mode, the device notes the date from the PRM (programmed under Utilities → Date and Time). Daily Measurement results are date stamped by the device and this date is shown with the Last Daily Measurement results.

- Since eight measurements will be recorded in seven days, one day will contain two measurements. If one measurement is valid and one invalid that day, the valid measure will be reported. If both measurements are valid, the second measurement will be reported.

Out of Range Measures

A warning message will be provided in the pop-up Summary on initial interrogation as well as on the System screen next to the Leads selection when any daily lead measurement is out of range.

See Reported Values Table below for the range of reported values and out of range limits.

Possible lead messages:

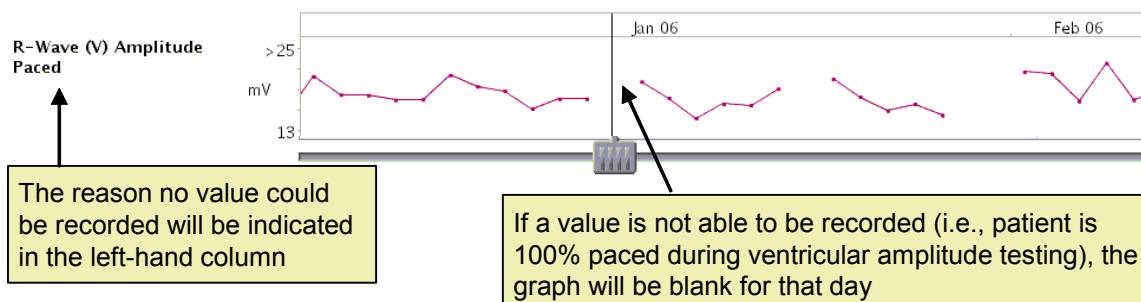
-  **Lead measurements are within range.**
 - Indicates daily lead measurements fall within the “Out of Range Limits” as listed below.
-  **Check RV Lead** (and/or A Lead, LV Lead, Shock Lead)
 - Indicates daily lead measurement(s) fall outside of the “Out of Range Limits” as listed below.

To determine which measurement is out-of-range for the lead listed, evaluate the corresponding lead's daily measurement results. The warning message will automatically clear when the current session is ended. Out-of-range values will not be represented by a dot on the daily measurement trend plot.

NOTE: No out of range measures will cause the device to beep (a daily out of range shock impedance causes the device to beep in previous devices).

The range of reported values and the graphs' Y-axis scale will automatically adjust and vary depending on the trend selected.

If a value is not able to be recorded, the graph will be blank for that day and the reason will be indicated in the left hand column.



Possible Reasons a Value is Not Recorded	
Paced	All events during the testing period are paced
Noise	Noise is detected during the entire testing period
PVC	All sensed events during the testing period are device defined PVCs
PAC	All sensed events during the testing period are device defined PACs
No Data Collected	Test cannot be performed (see below) or measurement is turned OFF
Invalid Data	Test cannot be performed (see below) or measurement is turned OFF

- Situations in which daily measurements cannot be performed
 - Ventricular episode in progress
 - Tachy therapy is active
 - During active telemetry
 - Post-shock delay parameters are in effect
 - EOL
 - LATITUDE³² remote interrogation is in progress

³² LATITUDE Remote Patient Management System is not available in all geographies

Reported Values

Trend	Reported Values	Graph Y-axis Scale Values
P-Wave Amplitude	<ul style="list-style-type: none"> <0.1 to >25.0 mV Paced, Noise, PVC, PAC, No data collected 	<ul style="list-style-type: none"> Min value: <0.1, 0.1, 1-24 mV Max value: 1-25, >25 mV
A-Pace Impedance	<ul style="list-style-type: none"> <200 to >2000 ohms Noise, Invalid data 	<ul style="list-style-type: none"> Min value: 200-2000, <200 Ω Max value: 201-2000, >2000 Ω
R-Wave (RV) Amplitude	<ul style="list-style-type: none"> <0.1 to >25.0 mV Paced, Noise, PVC, PAC, No data collected 	<ul style="list-style-type: none"> Min value: <0.1, 0.1, 1-24 mV Max value: 1-25, >25 mV
RV Pace Impedance	<ul style="list-style-type: none"> <200 to >2000 Ω Noise, Invalid data 	<ul style="list-style-type: none"> Min value: 200-2000, <200 Ω Max value: 201-2000, >2000 Ω
Shock Impedance	<ul style="list-style-type: none"> <20 to >125 Ω Noise, Invalid data 	<ul style="list-style-type: none"> Min value: 20-125, <20 Ω Max value: 20-125, >125 Ω
R-Wave (LV) Amplitude	<ul style="list-style-type: none"> <0.1 to >25.0 mV Paced, Noise, PVC, PAC, No data collected 	<ul style="list-style-type: none"> Min value: <0.1, 0.1, 1-24 mV Max value: 1-25, >25 mV
LV Pace Impedance	<ul style="list-style-type: none"> <200 to >2000 Ω Noise, Invalid data 	<ul style="list-style-type: none"> Min value: 200-2000, <200 Ω Max value: 201-2000, >2000 Ω

Algorithm Intrinsic Amplitude

The device passively attempts to measure an intrinsic P and R wave during one 255 cardiac cycle period. Only one sensed event is required for a measurement.

- Pacing rate is not changed in order to obtain a measurement.
- If a daily measurement is turned ON but sensing is not enabled in that chamber (i.e., atrial intrinsic amplitude in VVI mode), the sense amplifier for that chamber is activated long enough to attempt a measurement. If a daily measurement is turned OFF in the Setup screen, the test will not be performed.
- If a lead port is plugged but that chamber's amplitude test is not deactivated, a low amplitude measured value may be recorded despite the lack of a true input signal.

Displayed Values:

- Successful Measurement Value
- No Data Collected for one of the following reasons:
 - All events during the testing period are paced
 - All sensed events during the testing period are PVCs/PACs
 - Noise is detected during the entire testing period
 - All sensed events are in refractory
 - Measurement turned OFF

- Test cannot be performed (see Notes below for situations in which testing is not performed)
- 21 hour test and 3 re-attempts are unsuccessful

Algorithm Lead Impedance

Unlike lead impedance measurement algorithms for devices prior to TELIGEN/COGNIS, Devices described in this primer *do not utilize a high-output pacing pulse* in order to obtain a measurement. Rather, a *triggered pulse* of 80 μ A amplitude is delivered in the programmed pacing vector, the voltage is measured, and impedance is then calculated using Ohm's Law. The magnitude and frequency of this pulse is not large enough to capture the myocardium and it is timed to occur during blanking periods so that it will not be sensed by the device.

- If a lead is not implanted or not in use (i.e., implanted atrial lead in VVI mode), a lead impedance measure will still be attempted until it is turned OFF in the setup screen. Measures of >2000 ohms will be reported if there is no lead in the port.

Displayed Values

- Successful Measurement Value
- Invalid Data
 - Measurement turned OFF
 - Noise is present in a particular chamber
 - Test cannot be performed (see Notes below for situations in which testing is not performed)
 - 21-hour test and three re-attempts are unsuccessful

Algorithm Shock Lead Impedance

The shock lead impedance measurement algorithms for devices prior to TELIGEN/COGNIS delivered a pulse of 15 mA @ 60 μ s synchronously with a sensed R-wave. ICDs and CRT-Ds described in this primer deliver a smaller, asynchronous pulse of 80 μ A @ 156 μ s in the currently programmed shock lead vector. The voltage is measured in the same vector and impedance is then calculated using Ohm's Law. The magnitude of this pulse is not large enough to capture the myocardium or be sensed by the device.

If there is an out-of-range impedance measurement, testing different shock vectors may indicate which electrode is out of range and whether another shock vector is within normal limits and may be used.

NOTE: When changing shock vectors, perform an induction to verify that the new vector will successfully convert the patient's arrhythmia.

If the currently programmed Shock Lead Vector is RV Coil to RA Coil and Can (Triad), three measurements are performed and then converted into a single result which represents the impedance of the shock vector. If any one of the three measurements are out of range or reports noise, then that out of range measurement or noise will be reported for that day's results.

- If the shock lead impedance measurement is programmed to OFF, the daily measurement will NOT be performed.
- If a device is taken out of storage mode and is not implanted for at least one day, it is possible that an out of range shock lead impedance message could be observed when the device is interrogated prior to actual use

Displayed Values

- Successful Measurement Value
- Invalid Data
 - Measurement turned OFF
 - Noise is present in a particular chamber
 - Test cannot be performed (see Notes below for situations in which testing is not performed)
 - 21 hour test and 3 re-attempts are unsuccessful



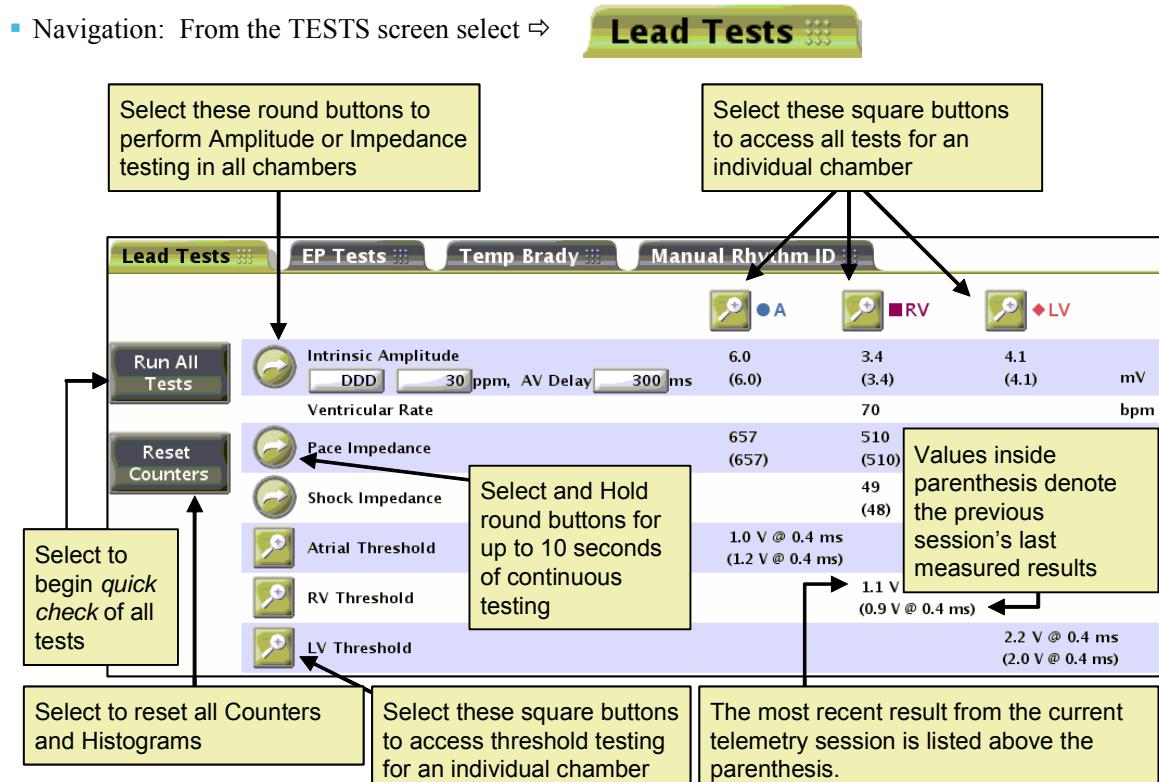
Leads Tests – General Info

Lead tests allow the clinician to perform individualized testing during follow-up to assess lead integrity and lead-tissue interface stability.

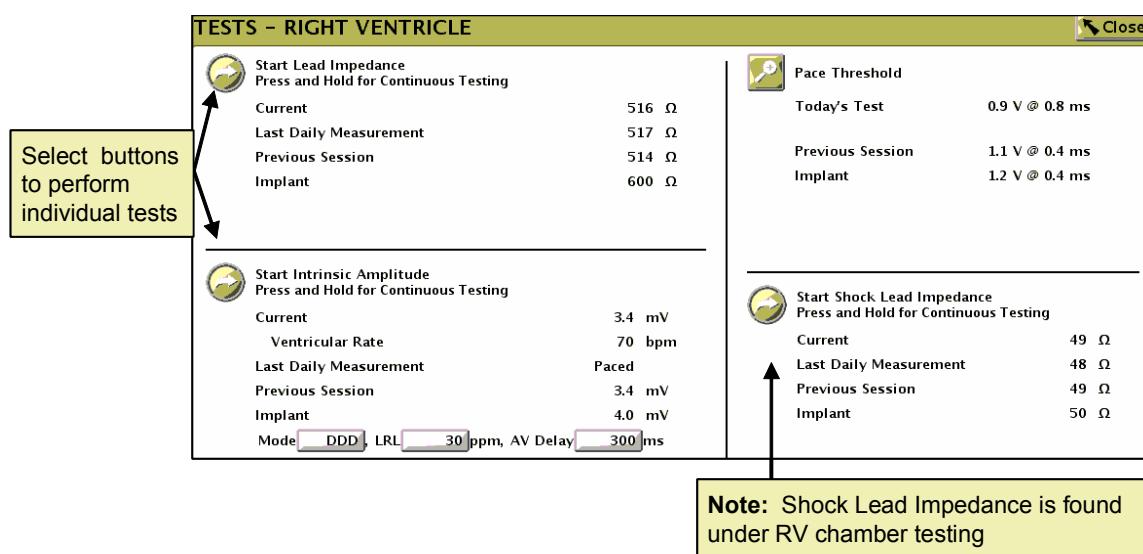
See *Lead Test Detail topic* for specific information on Intrinsic Amplitude, Pace/Shock Impedance and Threshold testing.

Availability

- Navigation: From the TESTS screen select ⇒



- To access an individual chamber testing screen select ⇒
- The Current, Last Daily Measurement, Previous Session and Implant values are provided for comparison
 - Implant values as entered in Summary ⇒ Patient Info ⇒ Implant Data.



Notes/Additional Information

- Additional measured results from automatic Daily Lead Measurements can be viewed via the SUMMARY tab ⇒ Leads or via the EVENTS tab ⇒ Trends.
- Test results may be printed via the Reports Tab and is found within the *Device Follow-up Report*, *Combined Follow-up Report* and *QUICK NOTES Report*.

WARNING: 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.

Auto Lead Detect



Auto Lead Detect sends a signal to measure impedance on the RV lead. A normal impedance (between 200 and 2000 ohms) verifies that there is an RV lead present. An out-of-range impedance (< 200 or > 2000 ohms) may indicate no lead is present.

Availability

- Test starts when the device battery is attached (i.e., in Storage mode) and runs until a normal impedance (from 200 to 2000 ohms) is measured for the RV lead.
- Auto Lead Detect is nonprogrammable.

Algorithm

- The Auto Lead Detect signal is driven between the Can and the RV lead tip, and the impedance is measured Tip-to-Can just like a pacing lead impedance test.

- Signal output: 80 μ A @19.5 μ s, emitted every 2 seconds.
 - Same output as the pacing impedance test except that the signal does not increase in amplitude.
2. The Auto Lead Detect will continue to emit a signal every two seconds until an in-range (200 to 2000 ohm) RV/Can impedance measurement is measured.
 3. Once an in-range impedance measurement is obtained, the Auto Lead Detect signal stops and will not start again.
 - RV lead must be connected properly (i.e., setscrew is not loose) and device must be in the pocket to obtain an in-range impedance.
 - Auto Lead Detect will not restart if the device undergoes a software reset.

Notes/Additional Information

This feature was intended to prevent the Respiratory Rate Trend (RRT) from collecting data during the implantation period after the device is taken out of Storage mode and prior to being connected to the lead system in the first releases of COGNIS/TELIGEN when RRT was nominally ON. RRT was later changed to nominal OFF and removed from COGNIS/TELIGEN making the Auto Lead Detect feature non-value added. Now that the Respiratory Sensor is again available to support RRT and ApneaScan in some models distributed internationally, the labeling cautions to not program the respiratory sensor ON until the system is implanted and tested.

The two-second Auto Lead Detect signal may be seen as artifact on the RV EGM, the Shock EGM, or both EGMs depending on the quality of the lead/Can connection.

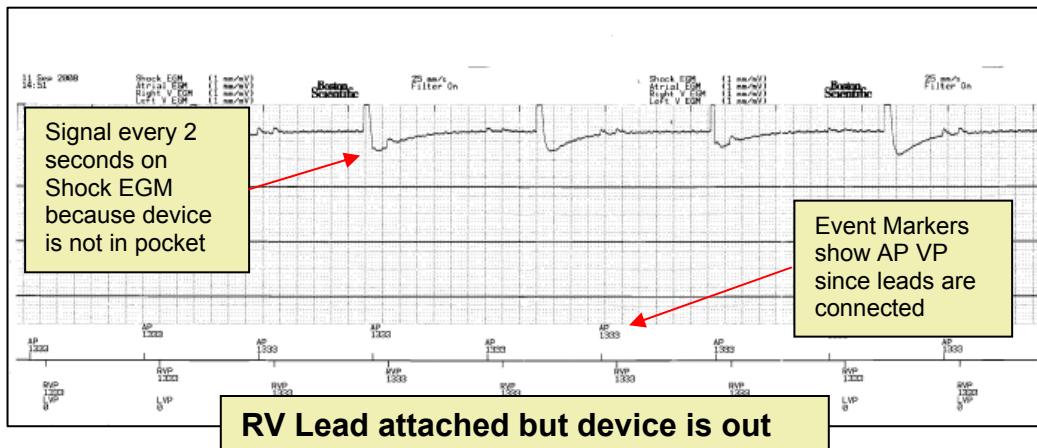
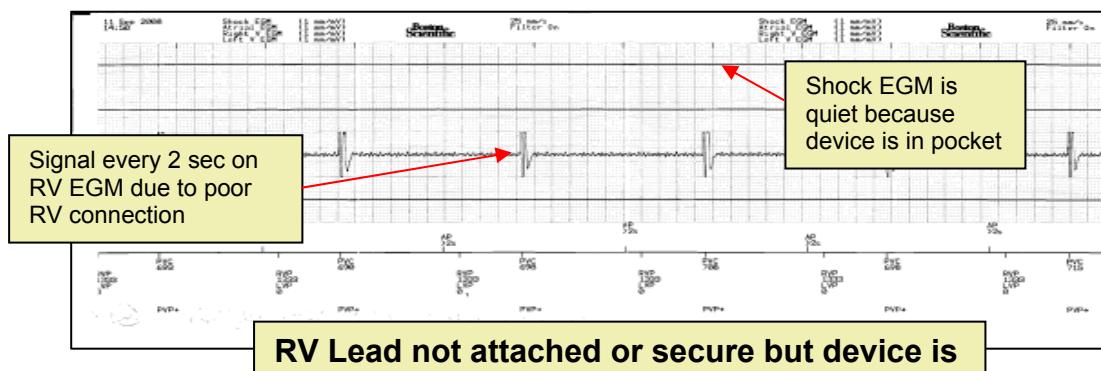
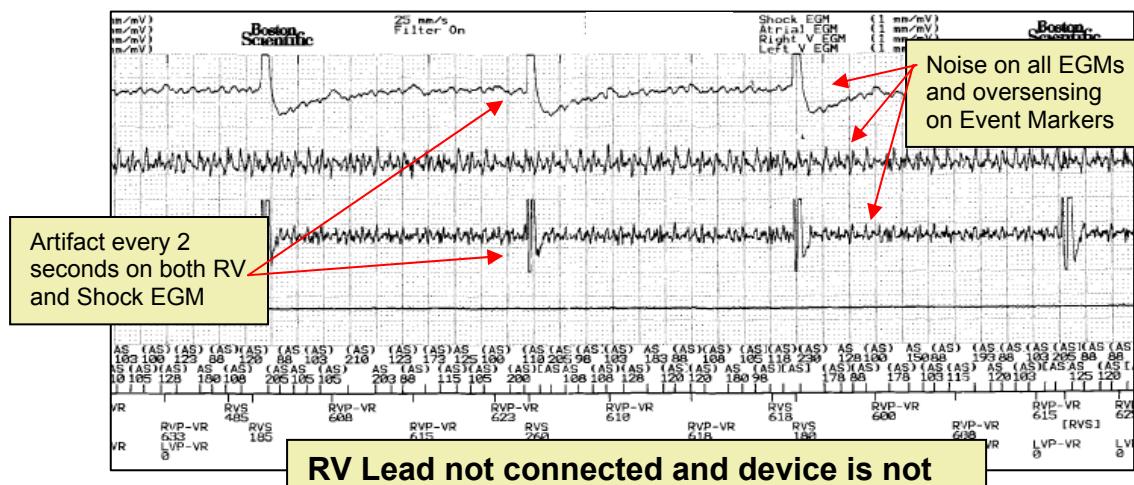
In rare cases, the RV lead may naturally exhibit a high impedance, that is, the lead had a high impedance with the PSA before it was connected to the device, and the impedance measurement with the device was consistently > 2000 ohms, even though the setscrew connection was verified and the lead was properly connected. In this case, the Auto Lead Detect will continue to emit its signal every two seconds. Sensing should be carefully evaluated to be sure that the signal is not sensed by the device.

The examples on the following pages illustrate three different scenarios where artifact may be seen on the RV and/or shock EGMs as well as how it could present in LATITUDE³³:

- RV Lead is not connected and device is not in the pocket
- RV Lead is connected properly but device is not in pocket
- RV lead is not connected properly but device is in the pocket
- ATR is stored in the device during implant and seen in LATITUDE

³³ LATITUDE Remote Patient Management System is not available in all geographies

NOTE: In the first three examples, the Shock EGM is at the top of the strips.



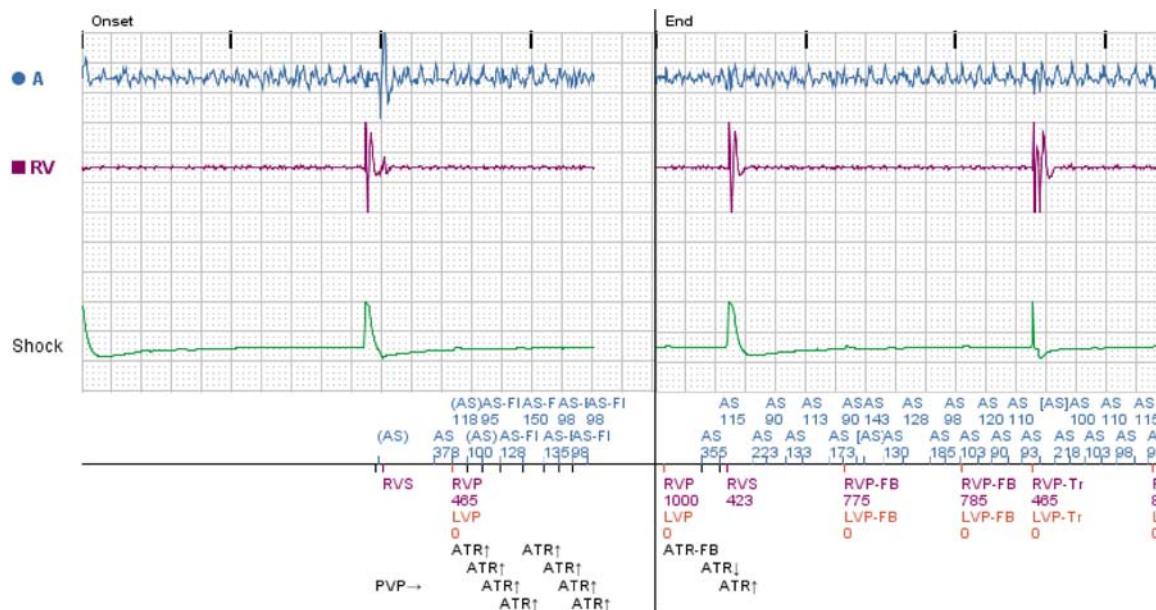
Example of Auto Lead Detect artifact prior to implant as seen on LATITUDE (no RV lead and Can not in pocket)

Event ATR-1 03 Nov 2008 14:32

ATR Event Onset

Avg A Rate bpm Avg V Rate 119 bpm

Event Ended 00:38:52 25 mm/s





Leads Test Details – Amplitude

Lead Test Detail – Amplitude allows the clinician to perform A, RV and LV intrinsic amplitude measurements during follow-up testing.

Programmable Values

Select the round button corresponding to Intrinsic Amplitude to begin testing



- Testing is performed in all chambers, regardless of the temporary programmed mode.
 - Tailor the temporary pacing mode selection as necessary for each individual patient (i.e., ventricular pacing modes for patients with complete heart block, non-tracking modes for patients in atrial fibrillation, etc.).

Mode	DDD/DDI/VDD/VVI/AAI	Nominal: DDD
Rate	30-185 ppm (must be 10 ppm < MTR)	Nominal: 30 ppm
AV Delay	30-300 ms (CRT-Ds)	Nominal: 30 ms
	30-400 ms (ICDs DR)	Nominal: 300 ms

Algorithm

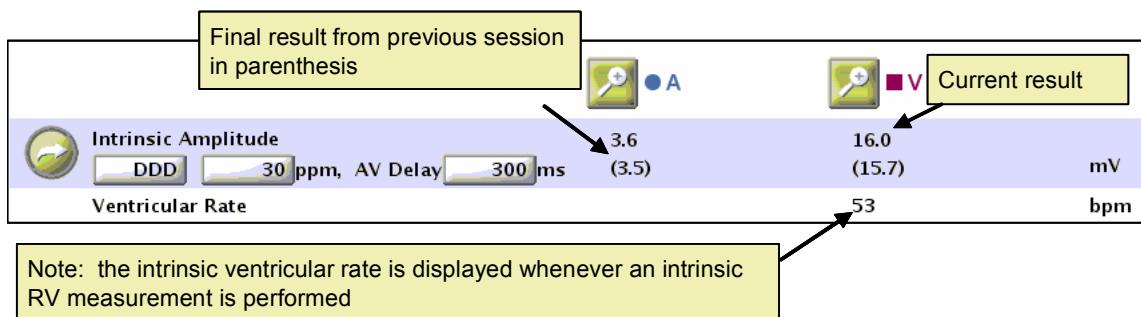
Once the test is begun, a window will display the test's progress.

- The device searches for intrinsic signals in all chambers simultaneously.
 - Testing will automatically terminate once a successful measure has been recorded in each chamber, or when 10 seconds have passed.
- Only one intrinsic beat is needed to obtain a measurement.
 - When multiple chambers are tested, all measurements can be obtained on one cardiac cycle.
- Press and hold the round button for continuous measures.
 - Up to 10 seconds of continuous results are provided.
 - After the button is released, the last measured value will be reported.

- When testing is completed, the current result will be displayed above the final measurement stored from the previous session which will be listed in parenthesis.

- N/R will be displayed in parenthesis if no previous tests have been performed.

- Results display:



Amplitude testing may be terminated via a command from the programmer such as End Test button or Divert Therapy key. Other conditions which will terminate threshold testing include:

- Lowest available setting for amplitude or pulse width is reached without being manually terminated.
- Removing the wand when RF wireless telemetry is disabled.

NOTE: If RF Telemetry is lost, the last measurement performed will be reported once telemetry is restored. The test may continue to decrement; select the End Test button or Divert Therapy to terminate testing.

- Pressing STAT Shock key twice.
- Pressing STAT Pace key twice.

Range of Reported Values

Lead Measurement	Range or Reported Values	Out-of-Range Limits
P-Wave Amplitude (mV)	<0.1 to > 25.0	Min: 0.5 Max: None
R-Wave (RV) Amplitude (mV)	<0.1 to > 25.0	Min: 3.0 Max: None
R-Wave (LV) Amplitude (mV)	<0.1 to > 25.0	Min: 3.0 Max: None

If a result cannot be obtained, one of the following messages will be displayed:

Message	Reason Value Measurement Was Not Obtained
Paced	No events during the testing period are valid and the last event is paced
PVC or PAC	No events during the testing period are valid and the last event is a PVC or PAC
Noise	No events during the testing period are valid and the last event is a noise event

Message	Reason Value Measurement Was Note Obtained
N/R	<ul style="list-style-type: none"> Atrial lead electrode configuration is programmed OFF LV lead electrode configuration is programmed to None Ventricular episode is in progress Tachy therapy is active Post-shock parameters are in effect All sensed events are refractory events

Notes/Additional Information

- Testing cannot be performed in Storage mode or at EOL.
- Intrinsic amplitude testing will terminate an active ATR episode if the temporary mode is a non-tracking mode. Following a return to permanent programming, the ATR algorithm must fulfill entry criteria to re-enter a mode switch.
- In CRT-D, the permanently programmed Ventricular Pacing Chamber does not change during testing.
- If the Atrial or LV Sense Electrode Configuration is programmed to OFF/None, that chamber's results will not be obtained and will indicate *Paced* or *N/R* depending on the temporary mode.
- If the Atrial Electrode Configuration is programmed to OFF and the temporary testing mode is DDD, the RV/LV intrinsic amplitude test will fail since the ventricular sensed beats are defined as PVCs. To obtain ventricular measures if the atrial lead is programmed OFF, the temporary mode must be VVI.

Warning: 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



Leads Test Details – Impedance

Lead Test Detail – Impedance allows the clinician to command A, RV and LV Pace and Shock Lead Impedance measurements during follow-up testing. Measuring lead impedances allows for the accurate assessment of lead integrity.

Programmable Values

Shock and Pace Lead Impedance testing is non-programmable.

- Pace impedance measures are tested in all chambers regardless of the permanent programmed mode or if the Atrial or LV Lead Electrode Configuration is OFF/None.

Algorithm

1. Select the round buttons corresponding to Pace Impedance and Shock Impedance to begin testing.
 - Impedance Testing can be performed in the presence of any intrinsic rhythm.
 - Once the test is begun, a window will display the test's progress.
 - The device performs an impedance measure in all chambers sequentially.
 - Testing will automatically terminate once successful measures have been recorded in all chambers.
2. Press and hold the round button for continuous measures.
 - Up to 10 seconds of continuous results are provided.
 - The last measured value after the button is released will be reported.

Select round buttons from the Lead Tests screen to perform impedance testing



Pace or shock impedance testing may be terminated via a command from the programmer such as End Test button or Divert Therapy key. Other conditions which will terminate threshold testing include:

- Lowest available setting for amplitude or pulse width is reached without being manually terminated.
- Removing the wand when RF wireless telemetry is disabled.

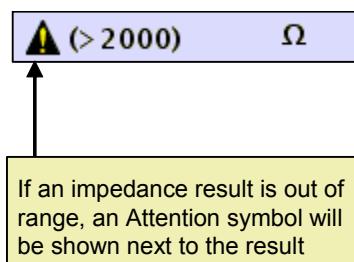
NOTE: If RF Telemetry is lost, the test may continue to decrement; select the End Test button or Divert Therapy to terminate testing.

- Pressing STAT Shock key twice.
- Pressing STAT Pace key twice.

If telemetry is lost during testing, either the measurement will be cancelled or the last measurement performed will be reported once telemetry is restored.

Range of Reported Values

Lead Measurement	Range of Reported Value	Out-of-Range Limits
A Pace Impedance (Ω)	<200 to >2000	<ul style="list-style-type: none"> • Min: 200 • Max: 2000
RV Pace Impedance (Ω)	<200 to >2000	<ul style="list-style-type: none"> • Min: 200 • Max: 2000
Shock Impedance (Ω)	<20 to >125	<ul style="list-style-type: none"> • Min: 20 • Max: 125



Lead Measurement	Range of Reported Value	Out-of-Range Limits
LV Pace Impedance (Ω)	<200 to >2000	<ul style="list-style-type: none"> • Min: 200 • Max: 2000

If a result cannot be obtained, one of the following messages will be displayed:

Message	Reason Value Measurement Was Not Obtained
Noise	Noise is detected during the entire testing period
N/R	<ul style="list-style-type: none"> • Ventricular episode is in progress • Tachy therapy is active • Post-shock parameters are in effect • No measurement is performed

NOTE: Testing cannot be performed in Storage mode or at EOL.

Pace Impedance Detail

Unlike previous lead impedance measurement algorithms, ICDs and CRT-Ds described in this primer *do not utilize a high-output pacing pulse* in order to obtain a measurement. Rather, a *triggered pulse* of 80 μ A amplitude is delivered in the programmed pacing vector, the voltage is measured, and impedance is then calculated using Ohm's Law. The magnitude and frequency of this pulse is not large enough to capture the myocardium and it is timed to occur during blanking periods so that it will not be sensed by the device.

- Significantly increased or high, out-of-range impedances may indicate a lead fracture or setscrew issue.
- Significantly decreased or low, out-of-range impedances may indicate a lead insulation issue.
- Measures of > 2000 ohms will be reported if the port is plugged.

Shock Lead Impedance Detail

For device launched prior to COGNIS/TELIGEN, the shock lead impedance measurement algorithms delivered a pulse of 15 mA @ 60 μ s synchronously with a sensed R-wave. ICDs and CRT-Ds described in this primer deliver a smaller, asynchronous pulse of 80 μ A @ 156 μ s in the currently programmed shock lead vector. The voltage is measured in the same vector and impedance is then calculated using Ohm's Law. The magnitude of this pulse is not large enough to capture the myocardium or be sensed by the device.

If the programmed Shock Lead Vector is RV Coil to RA Coil and Can (Triad):

- COGNIS/TELIGEN perform three measurements and then convert them into a single result which represents the impedance of the shock vector. If any one of the three measurements is out-of-range or reports noise, then that out-of-range measurement or noise will be

reported for that day's results. If Triad shock vector or a cold-can vector is programmed but the proximal coil is absent, the resulting impedance would be > 125 ohms.

- INCEPTA, ENERGEN, and PUNCTUA perform 32 measurements for each vector (96 total measurements for all three vectors) in a round robin sequence in as little as 600ms³⁴. The 32 measurements from each vector are averaged and then converted into a single result which represents the impedance of the shock vector. The design intent of averaging the 32 measurements is that the impedance measurement within the range will be more consistent with each subsequent shock lead impedance test as it will filter noise from third-party monitoring equipment connected to the patient. If any vector has an out-of-range measurement or reports noise, then that out-of-range measurement or noise will be reported for that day's results.

Troubleshooting Out of Range Shock Lead Impedances during implant

See A Closer Look titled, Shock Impedance Testing in COGNIS CRT-Ds and TELIGEN ICDs at Implant Procedures.

Troubleshooting Out of Range Shock Lead Impedances during follow-up

- A normal shocking impedance range is 20-125 ohms
 - If too high ...possible lead conductor fracture or setscrew issue.
 - If too low...possible electrode short or insulation breach.
- If a test is out-of-range or there is a significant change from previous measurement:
 - Evaluate pacing impedance
 - Evaluate pacing thresholds
 - Evaluate R-wave amplitude
 - View shock EGM for noise/artifact
 - Obtain an x-ray and/or view lead under fluoroscopy
 - Perform a max energy shock (best test of entire system)

CAUTION:

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

WARNING: 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.

³⁴ If the measurement doesn't complete within 3 full cardiac cycles the results reported will be "incomplete"

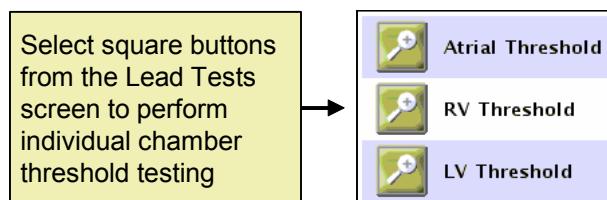


Leads Test Details – Threshold

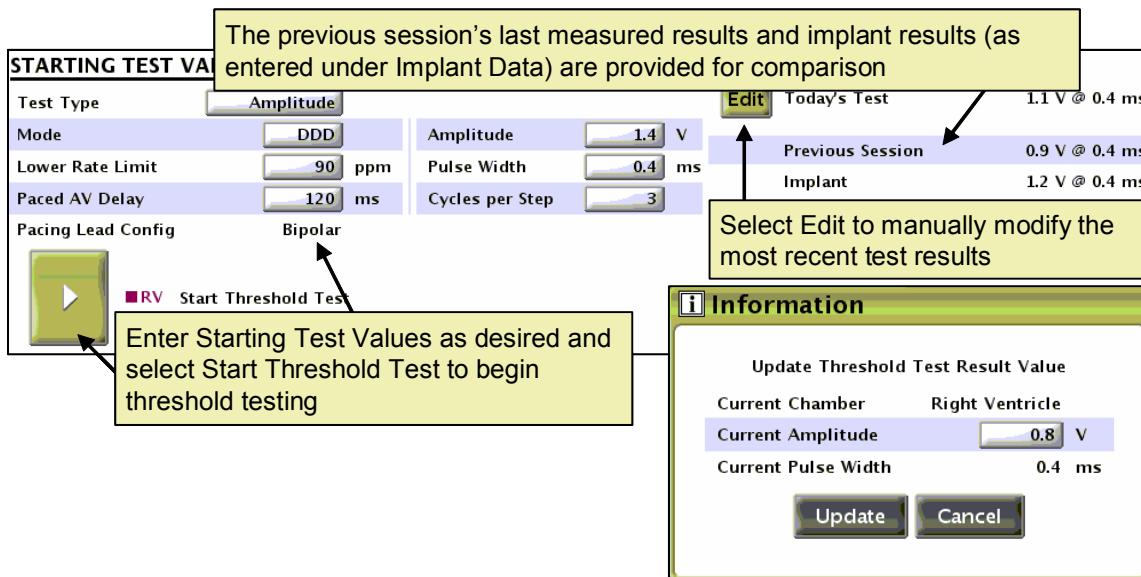
Lead Test Detail – Threshold allows the clinician to perform A, RV and LV pacing threshold measurements to determine the minimum output necessary to maintain capture. Measuring a patient's threshold allows for the appropriate programming of the device's output to obtain an adequate safety margin and preserve battery longevity.

Programmable Values

Select a square button corresponding to A, RV or LV Threshold to begin testing.



Temporary Test Parameters	Range of Values	Nominals
Test Type	Amplitude/Pulse Width	Amplitude
Mode	DDD/VVI (RV/LV) DDD/AAI (Atrial)	DDD
LRL	30 ppm to 10 ppm below programmed MTR	90 ppm
Paced AV Delay	30-300 ms (CRT-Ds) 30-400 ms (ICDs DR)	120 ms
Amplitude	0.1-7.5 V (RV/LV) 0.1-5.0 V (Atrial)	Programmed value on initial interrogation if no previous results are available or 3 V steps above the last measured threshold
Pulse Width	0.1-2.0 ms	Programmed value on initial interrogation
Cycles Per Step	2-5 cycles	3 cycles
LVPP (CRT-Ds)	OFF, 300-500 ms	OFF
Pacing Lead Configuration (CRT-Ds)	Available LV Pace vector options for the currently programmed LV Electrode Configuration (Dual, Single, None)	Programmed value on initial interrogation



- Testing can be performed in any chamber regardless of the currently programmed mode or lead configuration (e.g., RV testing can be performed in permanent AAI mode and LV testing can be performed with an LV Electrode Configuration of None).
- If Amplitude is selected as the Test Type, the amplitude will be seeded with:
 - Three steps (V) above the last measured threshold or
 - The programmed amplitude value on initial interrogation if no previous threshold results are available.
 - The pulse width will be seeded with the programmed value on initial interrogation.
- If Pulse Width is selected as the Test Type, the pulse width will be seeded with:
 - Three steps (ms) above the last measured threshold or
 - The programmed pulse width value on initial interrogation if no previous threshold results are available.
 - × The amplitude will be seeded with the programmed value on initial interrogation.
- For LV threshold testing, the Pacing Lead Configuration will be seeded with:
 - The programmed value on initial interrogation or
 - If the current Normal Brady/CRT LV Electrode Configuration is None, the LV Pacing Lead Configuration for threshold testing is non-programmable and functions in the most recently programmed LV Pace vector.
 - × If the LV Electrode Configuration has never been re-programmed following Storage mode (i.e., has always been None), the LV Testing configuration is non-programmable and functions in an LV Tip to LV Ring configuration.
 - × If the LV pacing configuration is reprogrammed in normal brady, the LV pacing configuration on the Threshold Test screen will not update to match unless device is reinterrogated (*simply pressing interrogate or program button on programmer won't update*).

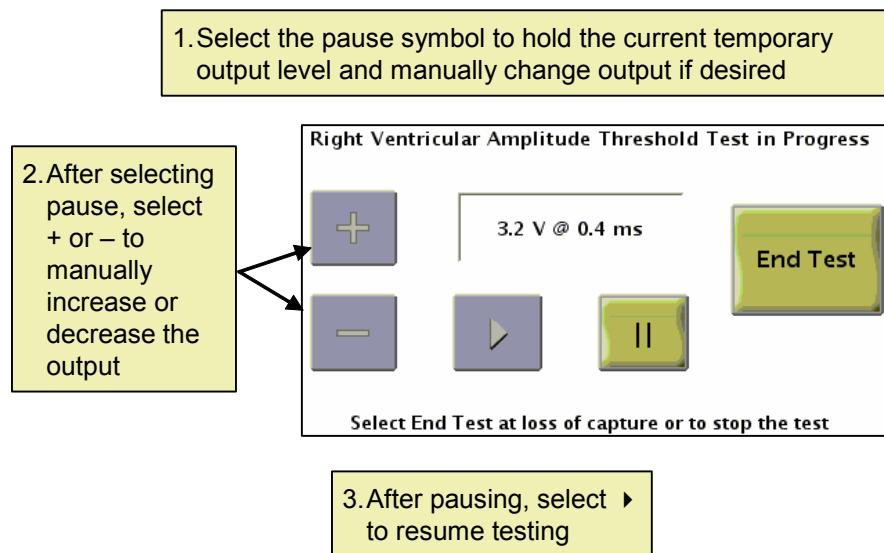
Steps to Perform Threshold Testing

1. **Start Test.** Enter the desired Starting Test Values and begin printing (start printing prior to the test and stop printing after ending the test to obtain notations indicating test initiation as well as the final threshold value).
 - Select the Start Threshold Test button to begin testing. The device enters the temporary state using the Starting Test Values.
 - The ECG/EGM display is enlarged during testing for easier viewing and the current testing output is displayed in the testing window as well as on the print-out.
2. **Verify Capture.** As the output decrements, monitor the ECG to verify capture at each new output level. The programmer will beep to indicate decrements in output.
 - As opposed to previous devices, which decremented on either paced or sensed beats, only paced beats occurring in the chamber being tested are counted to fulfill the programmed Cycles per Step.
 - If Amplitude is selected as the Test Type, the voltage will decrement by 0.5 V between 7.5 V to 3.5 V and 0.1 V thereafter.
 - If Pulse Width is selected as the Test Type, the milliseconds will decrement 0.1 ms throughout testing.
 - If DDD mode is selected, only the output of the selected ventricular chamber is decreased, the atrial output remains unchanged, and the other ventricular chamber is not paced.
 - If VVI mode is selected, only the output of the selected chamber is decreased and the other ventricular chamber is not paced.
 - Back-up RV pacing is not available when measuring LV threshold.

Selecting the pause symbol during the initial cycles in a step will cause the device to hold at the current output.

- If the pause symbol is selected during the last cycles in a step, the output will decrease and then hold at the next output level.

- When testing is resumed, the decrement will continue following 2-5 paces (programmed Cycles per Step) at the current output.



3. **End Test.** When loss of capture is observed, select the End Test button to terminate testing and return to permanently programmed values.

- The final measurement from the previous session (stored in the device memory) as well as the current result will be displayed.
 - The displayed threshold value will be one output step above the level where testing ended (range of 0.1-7.5 V and 0.1-2.0 ms).
 - If no paced beats occur during testing due to inhibition by the patient's intrinsic rhythm, the displayed threshold value will be one output step above the starting test value.

NOTE: Threshold testing may be terminated via a command from the programmer such as End Test button or Divert Therapy key.

Other conditions which will terminate threshold testing include:

- Lowest available setting for amplitude or pulse width is reached without being manually terminated.
- Removing the wand when RF wireless telemetry is disabled.
- Pressing STAT Shock key twice.
- Pressing STAT Pace key twice.

Notes/Additional Information

- Testing cannot be performed in Storage mode, at EOL, or when a ventricular episode is in progress.
- Threshold testing will terminate an active ATR episode if the temporary mode is a non-tracking mode. Following a return to permanent programming, the ATR algorithm must fulfill entry criteria to re-enter a mode switch.
- In CRT-Ds, BiV pacing will be active during an ATR mode switch. If testing occurs during an ATR mode switch, ventricular pacing will only occur in the individual chamber tested.
- If the threshold test was terminated by removing the wand during inductive telemetry, the wand must be repositioned back on the device to record the final output.
- A long LVPP may inhibit left ventricular pacing at higher pacing rates. LVPP may be temporarily programmed to a shorter value or OFF via the LV threshold test screen.
- Manually entering results through the Edit feature will change the currently displayed result. If no further testing is performed, the manually entered value will be the value stored by the device and displayed at the next interrogation.

WARNING: 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.

Arrhythmia Logbook



- Provides a list of the patient's arrhythmic events via a logbook. The Arrhythmia Logbook can be sorted to display recorded events and used to:
 - Evaluate events at follow-up
 - Provide historical list of patient's events
 - Fine-tune the therapy prescription based on information recorded about an arrhythmia
- Provides detailed information for each arrhythmia via event reports and EGMS

See Event – EGM Storage topic for more details.

Feature Comparison to Previous Devices

Feature	Previous Devices (VITALITY and RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Conversion summary	Flowchart summary of all episodes	Conversion summary no longer displayed

Feature	Previous Devices (VITALITY and RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Detection enhancements for an episode on Arrhythmia Logbook	<ul style="list-style-type: none"> Displayed columns for V>A, A-Fib Rate Threshold, Onset, Stability for VITALITY DS and RENEWAL. Displayed column for RID for VITALITY 2 	Detection enhancements are viewed in event detail only, not shown on Arrhythmia Logbook
Events (quantity)	Approx 150 may be listed in Arrhythmia Logbook	Up to 152 events may be listed in Arrhythmia Logbook
Episode types	ATR, PMT, Pt Triggered, V Tachy, Commanded.	ATR, PMT, Reverse Mode Switch ³⁵ , Pt triggered, V Tachy, LATITUDE Communicator (APM), Commanded, Nonsustained
Brady/Tachy episode memory allocation	<ul style="list-style-type: none"> Programmable: 20% brady, 80% tachy nominally Events may be overwritten in a first-in-first-out basis, with optional priority given to VF events. 	Nonprogrammable: Each event type has separate area of memory allocated. Event type priority, memory remaining, and first-in-first-out determine which events overwrite other events.
Reports	<ul style="list-style-type: none"> Reports that show lists of episodes: Arrhythmia Logbook Quick Notes 	Reports that show lists of episodes: <ul style="list-style-type: none"> Arrhythmia Logbook Quick Notes Device Follow-Up Report Combined Follow-Up Report
Query function	Query function may be used to search for certain episodes	View function allows selection of events by calendar periods. Events may be sorted by type, date, etc. on the screen.
Nonsustained events	Programmable; if On, stores events when 8/10 is met. Nonsustained events may write over therapy events.	Nonprogrammable; stores EGM when 3 consecutive fast beats are seen. Nonsustained events are allocated separate memory space and will not write over higher priority events.

Availability

- Available at all times, under the EVENTS tab:
- About 17 minutes of EGMs available.



³⁵ Reverse Mode Switch is available in international models only

- Displays up to 152 lines of event data; number of events with detail data will vary by event type and duration.

The screenshot shows the 'Arrhythmia Logbook' window. At the top, there are tabs for 'SUMMARY', 'EVENTS' (selected), and 'TESTS'. Below the tabs are buttons for 'Trends', 'Arrhythmia Logbook' (highlighted), and 'Patient Diagnostics'. A 'View' dropdown is set to '1 Month'. On the right, a calendar slider shows months from Jan 06 to Mar 06. Below the calendar is a table of events with columns: Event, Date/Time, Type, Therapy, and Duration. The table contains the following data:

Event	Date/Time	Type	Therapy	Duration
V - 14	24 Mar 2006 13:55	NonSustV	Nonsustained	00:00:09
V - 15	24 Mar 2006 14:29	VF	14J, 41J	00:00:52
V - 16	24 Mar 2006 14:33	VF	No Therapy	00:00:18
V - 17	28 Mar 2006 13:44	VT	ATPx2, 41J	00:00:57
V - 18	28 Mar 2006 14:57	VF	ATPx1, 41J	00:00:45
V - 19	28 Mar 2006 16:22	VT	ATPx2	00:00:21
PMT - 2	28 Mar 2006 16:37	PMT		

Annotations provide the following information:

- A yellow box points to the 'View' dropdown with the text: 'View events in time-blocks of 1 week or 1, 3, 6, or 12 months'.
- A yellow box points to the calendar slider with the text: 'Time-blocks with the slider; each bar marked on the calendar indicates events on that date; those events will be displayed in the list below'.
- A yellow box points to the column headers with the text: 'Each column button may be used to sort events'.
- A yellow box points to the magnifying glass icon next to the first event with the text: 'Indicates episode detail available – click to access further detail'.
- A yellow box points to the 'Save to Disk' button with the text: 'Save to Disk'.
- A yellow box points to the bottom of the table with the text: 'Arrhythmia Logbook example shows events sorted by Date/Time, in ascending order, as shown by Δ Date/Time'.

Programmable Values

- Storage of event data is non-programmable.
- May sort recorded events by column headings:
 - Event number
 - Date/Time
 - Therapy
 - Duration
- May adjust *calendar view of events* with the slider, and may narrow the view by choosing 1 week, or 1, 3, 6 months or 1 year.
- The magnifying glass icon indicates the presence of episode detail, stored EGMs, and interval graph reports for a particular episode. Touching the magnifying glass displays those detail reports on the screen. If there is an event listed in the Arrhythmia Logbook but there is no magnifying glass next to the event, there is no more detail in memory for that event.
- Select an event or multiple events for viewing, saving, or printing by using the check box next to the event.

Arrhythmia Logbook Screen Details

View – designates the calendar period that will be listed in the Arrhythmia Logbook Screen.

Moving the slider bar is like applying a date query to the events; only events that occurred in the highlighted portion of the calendar will be displayed on the screen.

- The calendar periods available are: 1 year, 6 months, 3 months, 1 month, and 1 week.

NOTE: Timeframe for forward and backward scrolling is controlled by Implant Date entered under Patient Data. If no Implant Date entered, view will be limited to 12 months of data with no ability to scroll forward or backwards.

NOTE: Adjusting the slider to limit the calendar view will not affect the printed Arrhythmia Logbook Report; the calendar view will be applied to the screen display only.

Event: Number assigned to a particular record in the Arrhythmia Logbook. Each record, or event, provides information about the patient's rhythm at a particular date and time. Events are listed by number within types.

See definition of Type below.

On the Arrhythmia Logbook Screen, touching the *Event* column sorts the events in numeric order within type; types are sorted into alphabetic order.

Date/Time – the date and time the device began recording an event. (For example, the starting time of a ventricular tachy event is the time at which three consecutive fast beats are seen.)

Example of event numbers; numbered consecutively within type					
	Event	Date/Time	Type	Therapy	Duration
<input checked="" type="checkbox"/>	V - 2	10 Apr 2006 12:02	NonSustV	Nonsustained 41J	00:00:27
<input checked="" type="checkbox"/>	V - 1	10 Apr 2006 12:01	VF		00:00:42
<input checked="" type="checkbox"/>	ATR - 3	10 Apr 2006 14:34	ATR		In Progress
<input checked="" type="checkbox"/>	ATR - 2	10 Apr 2006 12:09	ATR		00:59:34
<input checked="" type="checkbox"/>	ATR - 1	10 Apr 2006 12:03	ATR		00:00:27

Therapy delivered during the event

How long the events lasted;
example shows episode in progress

Type – events are classified by type of rhythm or other storage criteria; different types of events have different criteria for storing a record. Each event will be numbered consecutively within type. For example, the Arrhythmia Logbook may list separate events numbered V-17, PMT-17, and ATR-17.

Event #	Type	Event Storage Criteria
V#	Ventricular Events	
	• VF	VF event: Initial detection (8/10) and Duration met in the VF zone
	• VT/VIT-1	VT/VT-1 event: Initial detection 8/10) and Duration met in the VT/VT-1 zone
	• Nonsustained	Nonsustained: 3 consecutive fast beats occurred but Duration was never met
	• Commanded	Commanded: STAT shock or Commanded ATP/shock were manually commanded through the programmer
PTM-#	Patient Triggered Monitor (PTM) Events	Patient applied a magnet and Magnet function is programmed to 'STORE EGM.'
ATR-#	Atrial Tachy Response (ATR)	ATR mode switch occurred.
PMT-#	Pacemaker Mediated Tachycardia (PMT)	PMT Termination was applied
APM-#	Advanced Patient Management (APM) through LATITUDE Communicator	Patient commanded storage of an EGM through the LATITUDE Communicator.
RMS-#	RYTHMIQ / Reverse Mode Switch (RMS)³⁶	Reverse mode switch occurred.

On the Arrhythmia Logbook Screen, touching the Type button sorts the episodes in this order:

1. VF zone episodes (not including nonsustained or commanded)
2. VT zone episodes (not including nonsustained or commanded)
3. VT-1 zone episodes (not including nonsustained or commanded)
4. RHYTHMIQ/RMS reverse mode switch episodes
5. ATR atrial tachy response episodes
6. PMT pacemaker mediated tachycardia episodes
7. PTM – Patient triggered episodes
8. Commanded episodes
9. Nonsustained episodes

³⁶ RHYTHMIQ is not available in all geographies where INCEPTA/ENERGEN ICD/CRT models are distributed. Reverse Mode Switch is not available in all geographies where TELIGEN ICD/DR models are distributed.

10. APM episodes stored as commanded by the LATITUDE communicator

Therapy – description of the therapy delivered:

- ATP x #, where # is number of bursts (e.g., ATP x 3)
- Shocks are listed according to energy delivered and the number of times the therapy was delivered (e.g., 3J, 11J, 41 x 3)
- Induced: therapy delivered after an induction
- Nonsustained: event where three consecutive fast beats were sensed, but the rhythm was not fast at the end of Duration
- No therapy: a ventricular event where 8/10 was satisfied and Duration was met, but no therapy was delivered. The reasons device may not have delivered therapy:
 - No therapy is programmed in that zone (i.e., Monitor Only zone)
 - A magnet was on the device and inhibited therapy
 - The device decided to inhibit and went into Sustained Rate Duration (SRD), but the rhythm broke before SRD timed out

For *no therapy* events, the zone where detection was met will be designated under *Type* in the Arrhythmia logbook.

The alert symbol  will appear in front of the therapy if more than one therapy attempt occurred during this event.

The *Therapy field* will be blank for event types that do not provide therapy: ATR, PMT, APM, Patient Triggered, and RHYTHMIQ/RMS.³⁷

On the Arrhythmia Logbook Screen, touching the *Therapy* button sorts the episodes into two categories:

1. Episodes with a status indicator ! These episodes will be listed first, in event number order.
2. Episodes without a status indicator. These episodes will be listed last, in event number order.

Episode Duration – length of time the event lasted, in hh:mm:ss. If an event lasts longer than 48 hours, it will be designated by > 48 time period.

Duration is measured from the third fast beat (which triggers the beginning of EGM storage) to the end of the episode.

The notation *In Progress* in the Duration column indicates an event is currently being recorded during this interrogation, and has not ended yet.

³⁷ RHYTHMIQ is not available in all geographies where INCEPTA/ENERGEN ICD/CRT models are distributed. Reverse Mode Switch is not available in all geographies where TELIGEN ICD/DR models are distributed.

On the Arrhythmia Logbook Screen, touching the *Duration* button sorts the episodes by the Duration values. When descending sort is chosen, shown by the downward pointing arrow  the sort will first list episodes with completed duration times with longest durations first, followed by In Progress episodes.

Nonsustained Event – an event where the rate becomes slower than the lowest tachy rate zone cutoff before the end of Duration.

- An event will be recorded and EGM will be stored for a nonsustained event as soon as *three consecutive fast beats* occur.
- If 8/10 fast beats occur, an episode will be declared.
- If 8/10 fast beats are not seen, the device will continue to store an EGM until 10 consecutive slow beats occur.
- 10 consecutive slow beats will end a nonsustained event.
- Each nonsustained event EGM will store approximately five seconds marked *Onset* prior to the three consecutive fast beats and a minimum of 10 seconds marked *End* once 10 consecutive slow beats have elapsed.

NOTE: Only the last 9 beats may be displayed on the *End* EGM; storage may truncate the on the 10th beat or at the 10 seconds point.

Memory Allocation – Although devices described in this primer provide more event EGM storage than any previous devices, *memory is still limited*. If many events are recorded, the device will begin to write over older events in memory. The device will prioritize events by type.

Type	Priority 1= highest 4= lowest	Min # of Events with detail reports	Max # of Events with detail reports	# of Events listed in device memory
VF Events: Initial detection is met in the VF zone. Will include spontaneous and induced Events	1	5	30	50
VT-1 or VT Events: Initial detection is met in the VT-1 or VT zones. Will include spontaneous and induced Events	2	3	25	50
Commanded: Therapy was commanded through the programmer without being induced:commanded shock, commanded ATP or STAT shocks	3	0	2	2

Type	Priority 1= highest 4= lowest	Min # of Events with detail reports	Max # of Events with detail reports	# of Events listed in device memory
Nonsustained Events: An event that does not last until the end of Duration (i.e., at least 6/10 beats within the zone at the end of the Duration timer). Three consecutive fast beats trigger storage of an EGM	3	1	2	10
Pt triggered Monitor (PTM): Episode storage was commanded via magnet application	1	1	1	5
Atrial Tachy Response (ATR): Atrial trigger rate was satisfied and device mode-switched	4	1	3	10
Pacemaker Mediated Tachycardia (PMT) PMT termination was activated	4	1	3	5
Advanced Patient Monitoring (APM): Episode triggered by command via LATITUDE Communicator	4	1	1	10
Reverse Mode Switch³⁸ Reverse mode switch occurred.	4	1	3	10

NOTE: For earlier software 2868 version 1.02, a maximum of 10 VF, 5 VT-1/VT and 10 APM were stored with detail reports. Other storage is as listed above.

As new events occur and memory fills up, the device will *write over older events* as follows:

- Events are overwritten on a first-in, first-out basis within type.
- Lower priority data will be overwritten by higher priority data.
- The device will try to preserve the minimum number of events within a type. However, lower-priority events may be overwritten by higher-priority events if enough events occur.
- If one type of event has more events than the minimum, but other types do not, the events that exceed the minimum will be overwritten first, regardless of priority. If all types are at minimum, the oldest of the lowest priority will be overwritten first.
- The device will store no more than the maximum number of events for a particular type. For example, once 30 VF events have been stored, the device will begin overwriting older VF events with newer VF events.

³⁸ RHYTHMIQ is not available in all geographies where INCEPTA/ENERGEN ICD/CRT models are distributed. Reverse Mode Switch is not available in all geographies where TELIGEN ICD/DR models are distributed.

- Ongoing events (events in progress) temporarily have the highest priority. This is because ongoing events are more immediate and until the event is over it will take precedence over any event currently in memory. If some event types have > minimum events stored, the ongoing event may overwrite events with high priority.

See the EGM Event Storage topic for more details on information stored for individual events.

Reports

Several reports list events that occurred since counter were last reset:

- Quick Notes
 - Device Follow-Up Report
 - Combined Follow-Up Report

	ZOOM ® View™	Report Created 29 Mar 2008	
	Arrhythmia Logbook Report	Last Office Interrogation	
Device	COGNIS 100-D N107/ 812095AC0F5A196F057FFFF2	Implant Date	
Tachy Mode	Monitor + Therapy		
Event	Date/Time	Type Therapy	Duration hh:mm:ss
V-2		VF ◆ ATPx1, 36J, 41J	00:01:03
V-1		VT-1 ◆ ATPx2	00:00:30

NOTE: These three reports do not include episode numbers, only that they did occur since the last reset.

The Arrhythmia Logbook Report lists all the events currently in the Arrhythmia Logbook, and provides the same information for events as displayed on the screen.

Notes/Clinical Applications

If an event starts in one zone, then moves to another zone, the event onset (i.e., initial detection) where Duration is first met is used to classify the type of the episode in the Arrhythmia Logbook.

The events listed in the Arrhythmia Logbook are also listed on the Event Trend. If the number of events listed in device memory for a particular type of event exceeds the limit (for example, > 50 VF events), the events will no longer appear in the Arrhythmia Logbook or the Trend bar.

If an event occurs during an active telemetry session and the maximum number of events has already been stored for that type, the new events will be displayed also, more than the maximum number of events will appear. Once the telemetry session ends, the older event will be deleted from memory.

Maximum number of events apply to device memory only; if you are viewing events from a patient data disk, you may see more than the maximum number of events.

Stored Events: Event Details, Electrograms and Interval Graphs



Devices described in this primer record important information about cardiac arrhythmias and other events that the clinician may wish to monitor. Detailed event information is stored for a variety of types of events, and may be viewed on the programmer screen or printed. Stored event information includes event details, electrograms (EGMs) and interval graphs.

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	Devices described in this primer
EGM storage in minutes	6.3 to 19 minutes of memory, depending on which EGM sources programmed ON	About 17 minutes of EGMS in memory; all EGM sources are always ON
EGM storage source	<ul style="list-style-type: none">• A, RV, Shock sources programmable• Markers are always ON• No stored LV EGMS	<ul style="list-style-type: none">• A, RV, Shock sources• Markers are always ON,• LV EGMS stored on pt triggered events
Appearance of therapy on EGM	Shock marker present, actual ATP and shock delivery not displayed on EGM	Will see first three ATP bursts and last ATP burst, shock marker and shock delivery on EGM

Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	Devices described in this primer
EGM scaling	Scaled to fit printout	EGM waveform amplitudes and timing are accurate and measurable on the screen.
Event types	<ul style="list-style-type: none"> • ATR mode switch • PMT (no EGM stored) • Pt Triggered EGM • V Tachy • Commanded • Nonsustained 	<ul style="list-style-type: none"> • ATR mode switch • PMT - EGM stored • Pt Triggered EGM • V Tachy • RMS/RHYTHMIQ³⁹ • Advance Patient Management (LATITUDE) • Commanded • Nonsustained • Each event type has separate priority and area of memory allocated
Event Reports	<ul style="list-style-type: none"> • Three individual episode reports: • Event Detail report • EGM with markers • Interval report 	<ul style="list-style-type: none"> • One event report providing: • Event summary • Summary of each attempt • EGM with all storage sources and markers • Interval graph
Interval graph	Available for VITALITY 2 only	Printed with each event detail report
Pt Triggered Monitor	3 minutes: 1 minute before and 2 minutes after magnet application	No change to EGM from previous devices, but magnet function returns to inhibit therapy after an episode is stored
Nonsustained events	Storage programmable; if ON, stores 10 sec Onset portion of EGM if 8/10 are met. If Off, stores EGM only if Duration is met	<ul style="list-style-type: none"> • Always stores based on 3 consecutive fast beats. • Stored in separate area of memory, so does not impact other event types
LATITUDE Communicator (APM) EGMs	Not available	30 second EGM may be commanded by the patient via the LATITUDE Communicator
Shock EGM auto scale	Used to maximize shock EGM appearance, commanded	Automatic and nonprogrammable
Screen Display	EGMs displayed on screen with caliper	<ul style="list-style-type: none"> • Slider bar and calipers • Clearer display • Complete Markers

³⁹ RMS is not available for TELIGEN DR models distributed in all geographies

Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	Devices described in this primer
EGM paper speed	Paper speed buttons adjust speed for real-time or stored EGMs.	Paper speed buttons active for real-time EGMs only. Stored EGMs may be displayed on the screen at different paper speeds and are always printed at 25 mm/s
Pre-attempt average rates	Average of the last 4 beats of Duration	No change from previous devices
Post attempt average rates	Four-beat average of beats 4-7 after therapy delivered	Minimal clinical value, so no longer reported

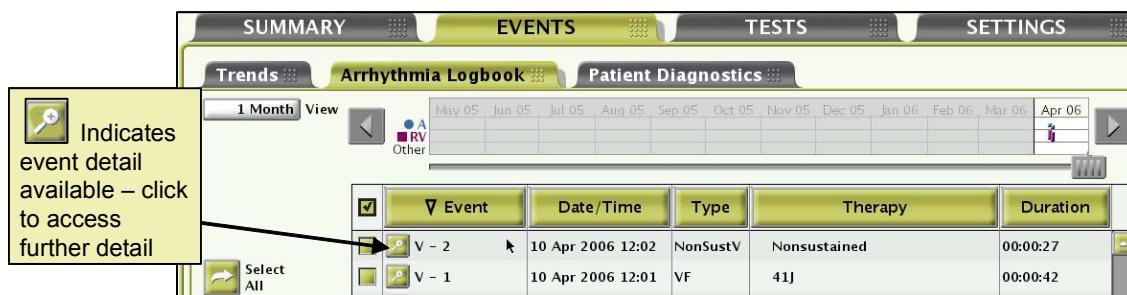
Availability

Available at all times:

- Under the EVENTS tab, select  **Arrhythmia Logbook** 
- The magnifying glass  indicates the presence of episode detail, stored EGMs, and interval graph reports for a particular episode. Touching the magnifying glass displays those detail reports on the screen. If there is an event listed in the Arrhythmia Logbook but there is no magnifying glass next to the event, there is no further detail in memory for that event.

NOTE: Events in progress when the device is interrogated will not have detailed information until the event ends.

- Select an event or multiple events for viewing, saving, or printing one event at a time by using the check box  next to the event.



Event Details

Each event listed in the Arrhythmia Logbook as having details (i.e., there is a  next to the event number), will have summary data, EGMs and Intervals available. Event information may be displayed on the screen or printed.

Individual event information includes the following:

- Date and time of the event
- Average A and V Rate for each attempt
- Attempt details listing therapy delivered and elapsed time for each attempt
- Event Ended (total elapsed time)
- Three-channel EGM (Atrium, Right Ventricle, and Shock) with annotated markers

Events – Stored Event

Summary EGM Intervals

Event V – 18 VF 28 Mar 2006 14:57

- A Average Rate 70 bpm
- V Average Rate 228 bpm

Attempt	Elapsed Time(s)
1	00:00:03 41J V Shock VF ATP delivered prior to shock Charge Time: 6.3s Lead Impedance: 41Ω
Event Ended 00:00:45	

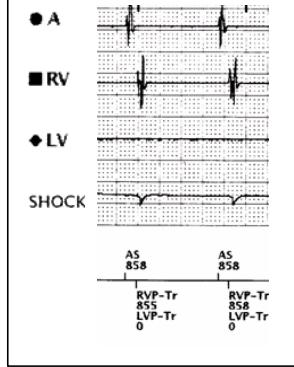
Summary Screen for an individual event provides date/time attempt info, rates, and elapsed time

Previous Event
Next Event

Print Event
Save to Disk

EGM Storage

ICD and CRT-Ds described in this primer provide about 80% more memory for event EGMs than devices launched prior to COGNIS/TELIGEN. EGM storage sources are atrial (A), right ventricular (RV), left ventricular (LV), Shock, and annotated markers; storage sources are all automatically ON and non-programmable. Atrial, RV, Shock, and markers are always stored. LV EGMs are displayed real-time and stored only in Patient Triggered events.



NOTE: If a device is implanted with one of the lead ports plugged, (e.g., the atrial port is plugged because the patient has chronic atrial fibrillation) the EGM source for that for that lead will still be displayed.

EGM Capacity – device has the capability to store about 17 minutes of EGMs. The total amount of EGMs stored in memory depends on the length of the events that have occurred as well as the frequency and number of signals annotated during the event.

When an EGM is stored in memory, the device compresses the EGM data to make more efficient use of memory, in much the same way a Zip file compresses a data file on a computer. EGMs with more frequent intervals, e.g., VF events, or events with noisy signals, have more data to compress and therefore may take up more memory space than EGMs with slower or fewer intervals.

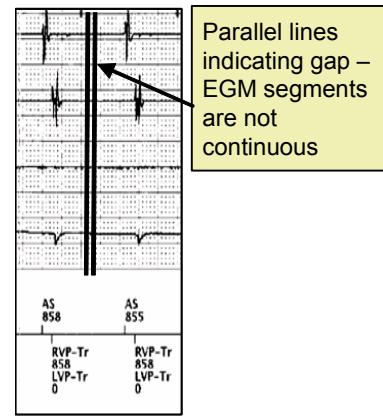
If a large number of events are recorded, the device will begin to write over older events in memory.

See the Arrhythmia Logbook topic for details on memory allocation by event type.

EGM Segment Storage – device stores EGMs in segments; each segment may be from five seconds to two minutes long, depending on the type of event.

EGM segments are triggered by different milestones within the event. The segments may be stored both before and after the milestones, and the length of EGM time stored in any segment depends on when the milestone occurs and how it is programmed.

Example: One event may show a longer segment prior to Duration because Duration is programmed to five seconds in one zone, where a similar event in a different zone may show a shorter segment because the Duration was programmed to one second. In most standard events, the EGM segment time periods will overlap, providing a continuous event EGM.



If the event is particularly long, there may be a gap of time not covered by EGM segments; this gap will be marked on the EGM by two parallel vertical lines.

If the timing of two events allows different events to overlap each other, some EGM data may appear in more than one event.

Example: A group of intervals may appear on an EGM for both an ATR event and a VT event because the ATR event was in progress when the VT event started. The intervals are only stored in the device memory once, but because they apply to both events, they may be printed in both events.

In addition to storing more EGMs per event, the EGM will also show therapy delivery, both ATP and shock.

NOTE: If more than four bursts of ATP are delivered during the event, not all bursts will be stored in EGM memory. The device will only store EGM for burst 1, 2, 3, and the last burst.

This table summarizes the event milestones and EGM segments stored for that milestone.

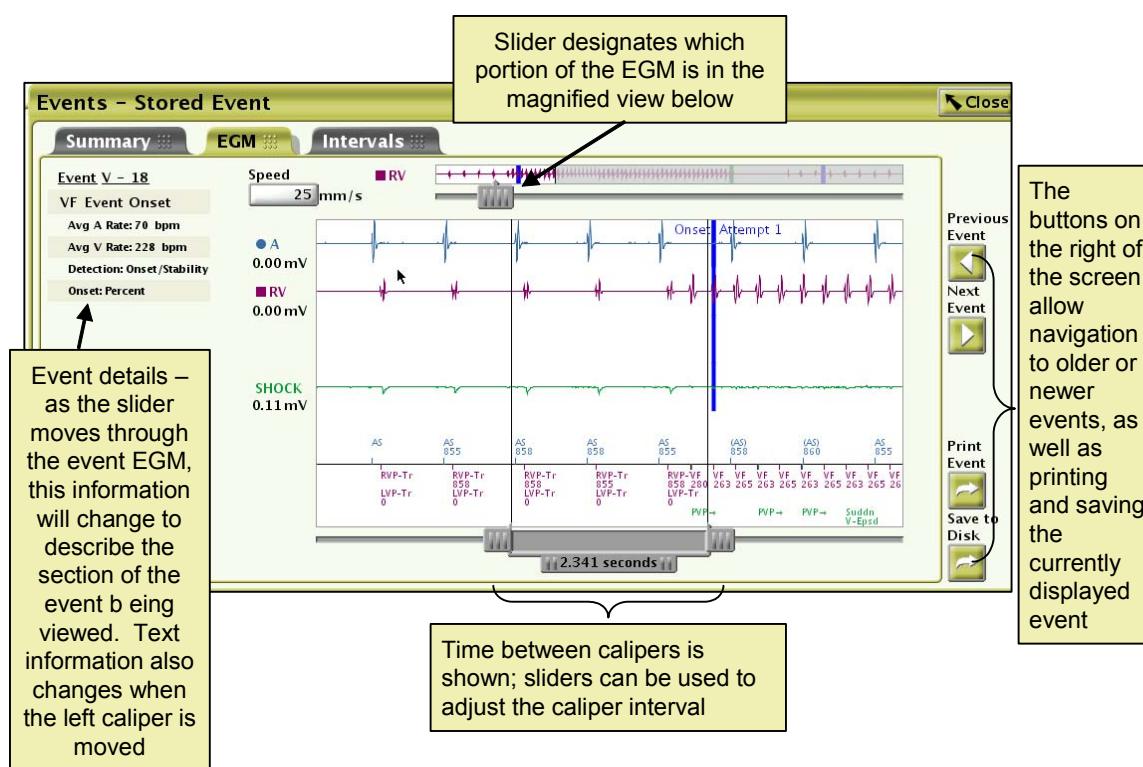
Event Milestone	Amount of EGM stored
3 consecutive fast ventricular intervals (i.e., faster than the lowest tachy rate zone cut-off)	<ul style="list-style-type: none"> • 5 seconds before the 3rd fast interval • 10 seconds after the 3rd fast interval
Duration met, i.e., end of duration was reached and 6/10 beats were still fast	<ul style="list-style-type: none"> • 10 seconds before the end of Duration • 10 seconds after the end of Duration
Start of ATP Therapy delivery for burst 1	<ul style="list-style-type: none"> • 10 seconds before the first pulse of burst 1 • 10 seconds after the first pulse of burst 1

Event Milestone	Amount of EGM stored
End of ATP Therapy delivery for burst 1	<ul style="list-style-type: none">• 10 seconds after the last pulse of burst 1
Start of ATP Therapy delivery for burst 2 and 3	<ul style="list-style-type: none">• 10 seconds after the first pulse of burst
End of ATP Therapy delivery for burst 2 and 3	<ul style="list-style-type: none">• 10 seconds before the last pulse of burst
Start of ATP Therapy delivery for last burst	<ul style="list-style-type: none">• 10 seconds after the first pulse of the last burst
End of ATP Therapy delivery for last burst	<ul style="list-style-type: none">• 10 seconds before the last pulse of the last burst• 10 seconds after the last pulse of the last burst
Start of Charge	<ul style="list-style-type: none">• 10 seconds before the start of charge• 10 seconds after start of charge
Shock therapy delivery/divert	<ul style="list-style-type: none">• 10 seconds before the therapy delivery/divert• 10 seconds after therapy delivery/divert
Application of a magnet for patient-triggered events	<ul style="list-style-type: none">• 2 minutes before the magnet application• 1 minute after magnet application
ATR or RMS ⁴⁰ mode switch	<ul style="list-style-type: none">• 10 seconds before start of mode switch• 10 seconds after start of mode switch
PMT Termination	<ul style="list-style-type: none">• 10 seconds before the PMT is detected• 10 seconds after the PMT is detected
Command to store event via LATITUDE Communicator (APM)	<ul style="list-style-type: none">• 20 seconds before the command• 10 seconds after the command

Event EGM Display

EGMs may be displayed on the programmer screen as well as printed as a report. The following example shows the first section of a VF event.

⁴⁰ RMS is not available for TELIGEN DR models distributed in all geographies



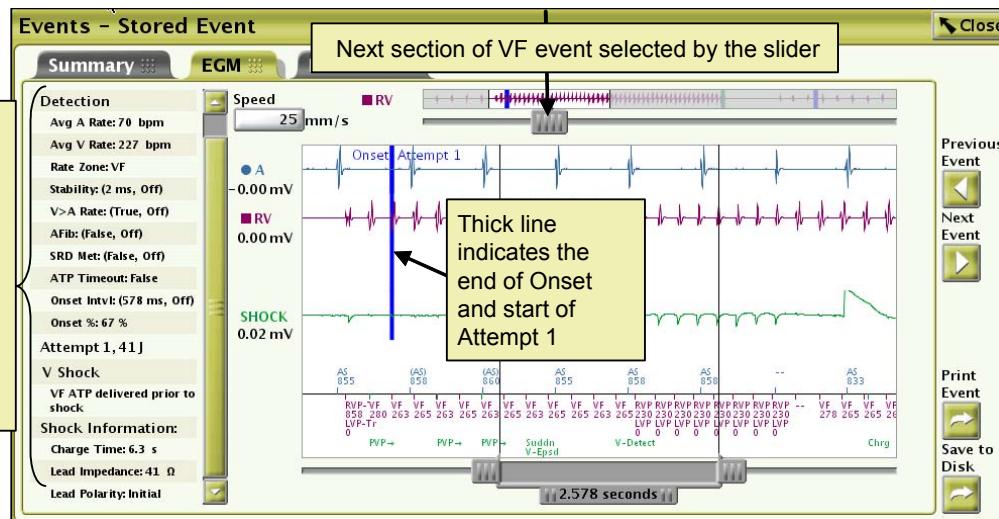
The Speed parameter allows the *paper speed* appearance of the onscreen EGM to be changed.

Nominal speed is 25 mm/s, which corresponds to the standard ECG paper speed when printing an ECG strip. It may be desirable to change the speed to make the EGMs more readable. For example, increasing the speed to 100 mm/s may make an event with very fast signals easier to evaluate.

NOTE: Speed affects screen display only—EGMs will always print at 25 mm/s, regardless of the value chosen as the Speed on this screen.

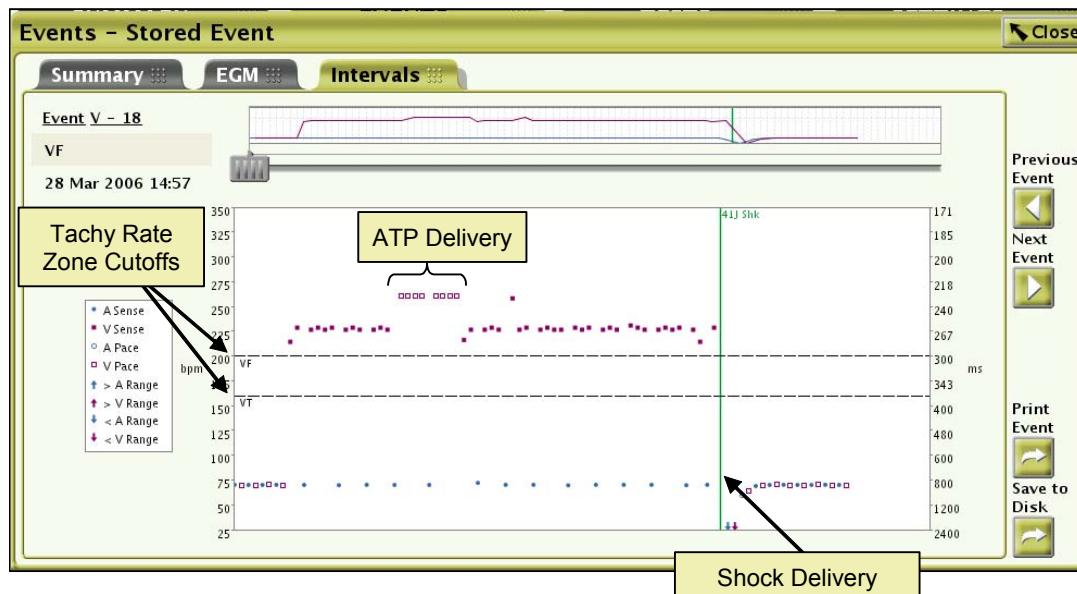
When the top slider is advanced to different parts of the overall event graph, the EGM display changes and detail information associated with that section of the event will be updated on the left of the screen. In the next example, detailed information on the left describes Attempt 1. A scroll bar indicates additional information is available.

Event detail changes to match the portion of the EGM displayed. Note the scroll bar indicating additional information

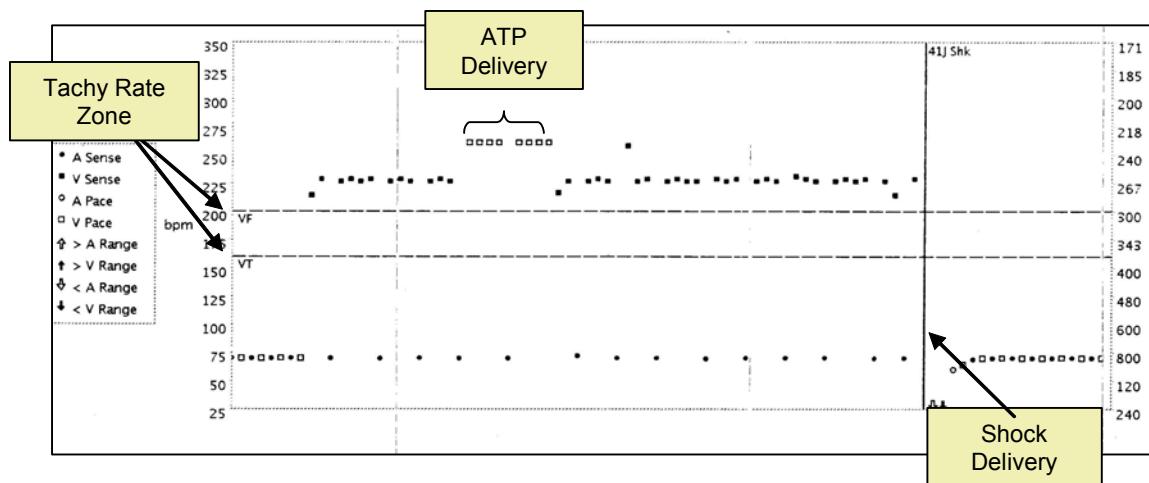


Interval Rate Graph

Each detailed event also provides an interval graph which shows the rate (in ms and bpm) of every interval that occurred in the event. The slider at the top of the screen indicates the portion of the event being displayed.



The interval rate graph prints with the event detail and EGM



End of Event

The following table shows what criteria signal the end of event data storage. EGM storage may end before the event ends.

Event #	Type	Event Storage Criteria
V#	Ventricular Events <ul style="list-style-type: none"> • VF, VT/VT-1, Commanded • Nonsustained 	<ul style="list-style-type: none"> • The VF or VT/VT-1 event ends when the end of episode timer times out: • For events with ATP or diverted shocks, 10 seconds during which redetection (8/10) is not met • For events with shock delivery, 30 seconds during which redetection (8/10) is not met • Note that EGM storage may end before the end of episode timer expires <p>Nonsustained event ends when 10 consecutive slow beats occur or End of Episode Timer ends</p>
PTM-#	Patient Triggered Monitor (PTM) Events	PTM Event ends one minute after magnet application.'
ATR-# or RMS-#	Atrial Tachy Response (ATR)	ATR & RMS events end when the device mode switches back to normal brady mode. EGM storage ends 10 seconds after mode switch occurs.
PMT-#	Pacemaker Mediated Tachycardia (PMT)	PMT event ends 10 seconds after PMT is detected
APM-#	Advanced Patient Management (APM)	APM event ends 10 seconds after the command from the communicator.

Notes/Clinical Applications

- If an ATR event is in progress and a ventricular tachy event begins, the ATR event will end and the ventricular tachy event will take priority for event storage.
- If an event was in progress when the device was interrogated, *In Progress* appears in the Arrhythmia Logbook and event detail may not be available.
- If an interrogation session has started and an event currently in memory is deleted while the interrogation session is running (e.g., another event occurs and writes over it) the Arrhythmia Logbook may still display the episode until the summary information is updated (usually with new session or new interrogation). Detail for the deleted event will not be available.

Printed EGM Examples

The following pages show annotated examples of the EGMs stored for different types of events.

Nonsustained Event – EGM

Storage is triggered by three consecutive fast beats.

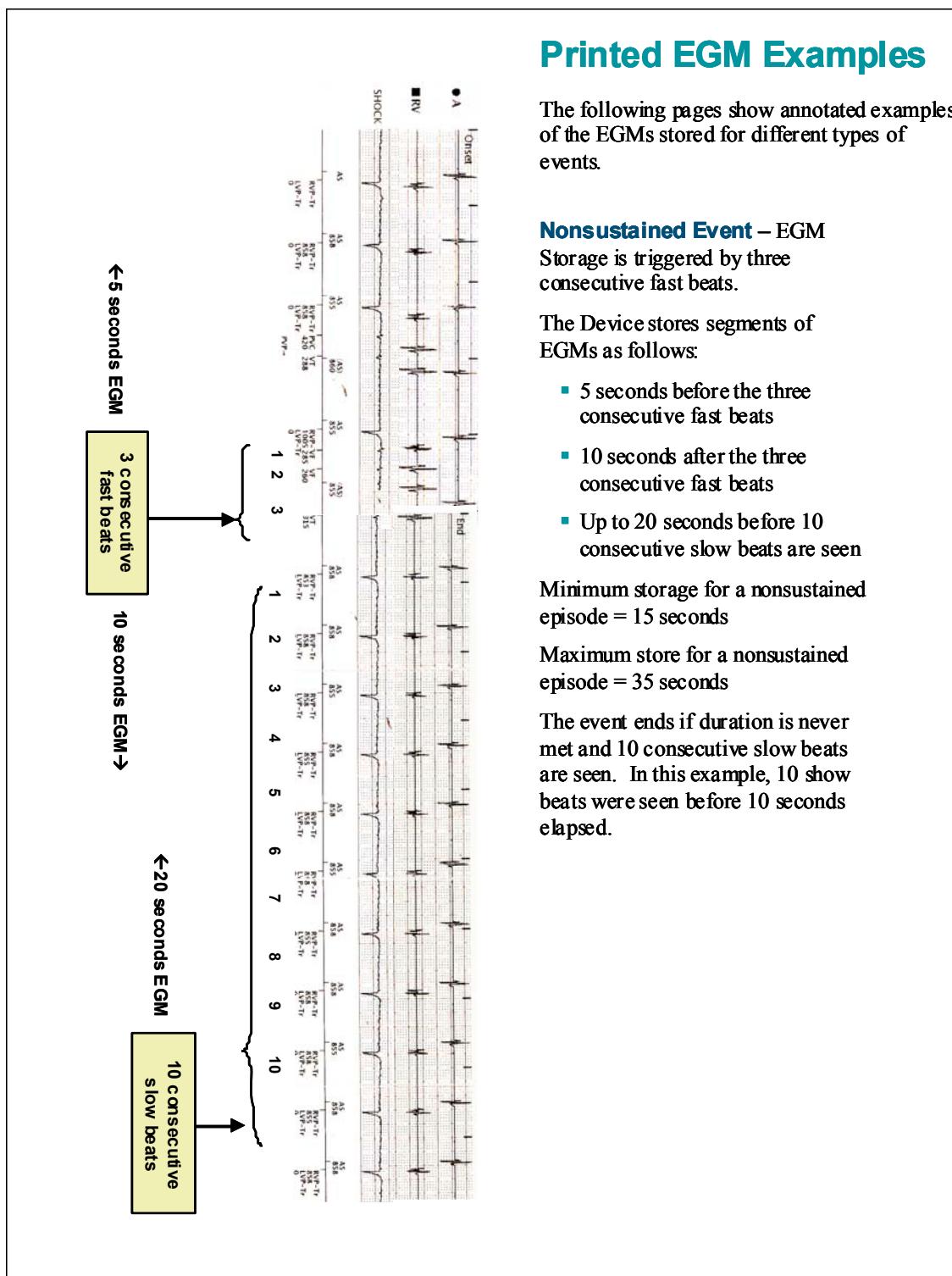
The Device stores segments of EGMs as follows:

- 5 seconds before the three consecutive fast beats
- 10 seconds after the three consecutive fast beats
- Up to 20 seconds before 10 consecutive slow beats are seen

Minimum storage for a nonsustained episode = 15 seconds

Maximum store for a nonsustained episode = 35 seconds

The event ends if duration is never met and 10 consecutive slow beats are seen. In this example, 10 slow beats were seen before 10 seconds elapsed.



Commanded Event – EGM Storage is commanded via the programmer.

- Commanded shock on the EP Test screen
- Commanded ATP on the EP Test screen
- STAT shock

Issuing the command declares an episode (no detection criteria needed).

The device stores segments of EGMs as follows:

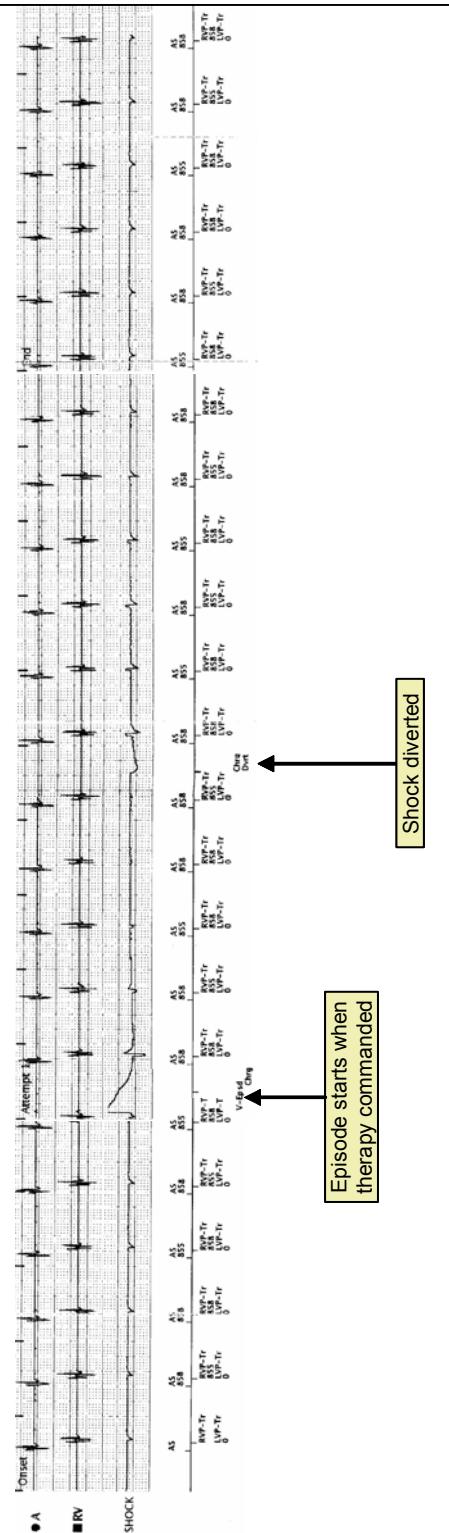
- 5 seconds before from the start of the Episode (when the command is given)
- 10 seconds after the start of the Episode
- Up to 10 seconds before the delivered/diverted therapy
- Up to 10 seconds after the delivered/diverted therapy

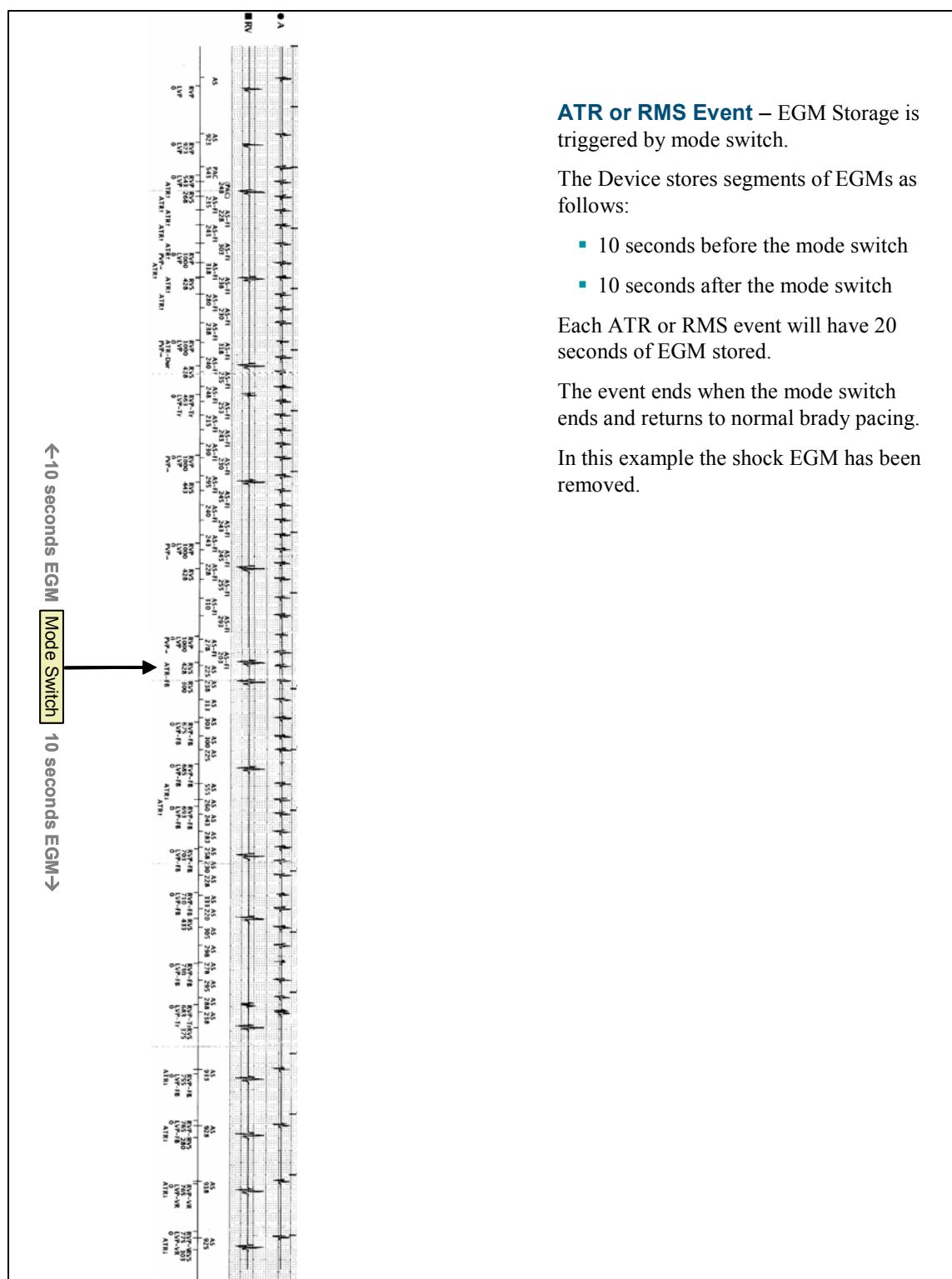
The event ends if redetection is not met and end of episode timer times out.

Minimum storage for a commanded episode = 15 seconds

Maximum storage for a commanded episode = will vary, based on presence of arrhythmia and detection criteria after commanded therapy is given.

In this example, a shock was commanded and then diverted.





VT-1/VT or VF Event – EGM Storage is trigger by:

- Three consecutive fast beats
- Duration is met

The device stores segments of EGMs as follows:

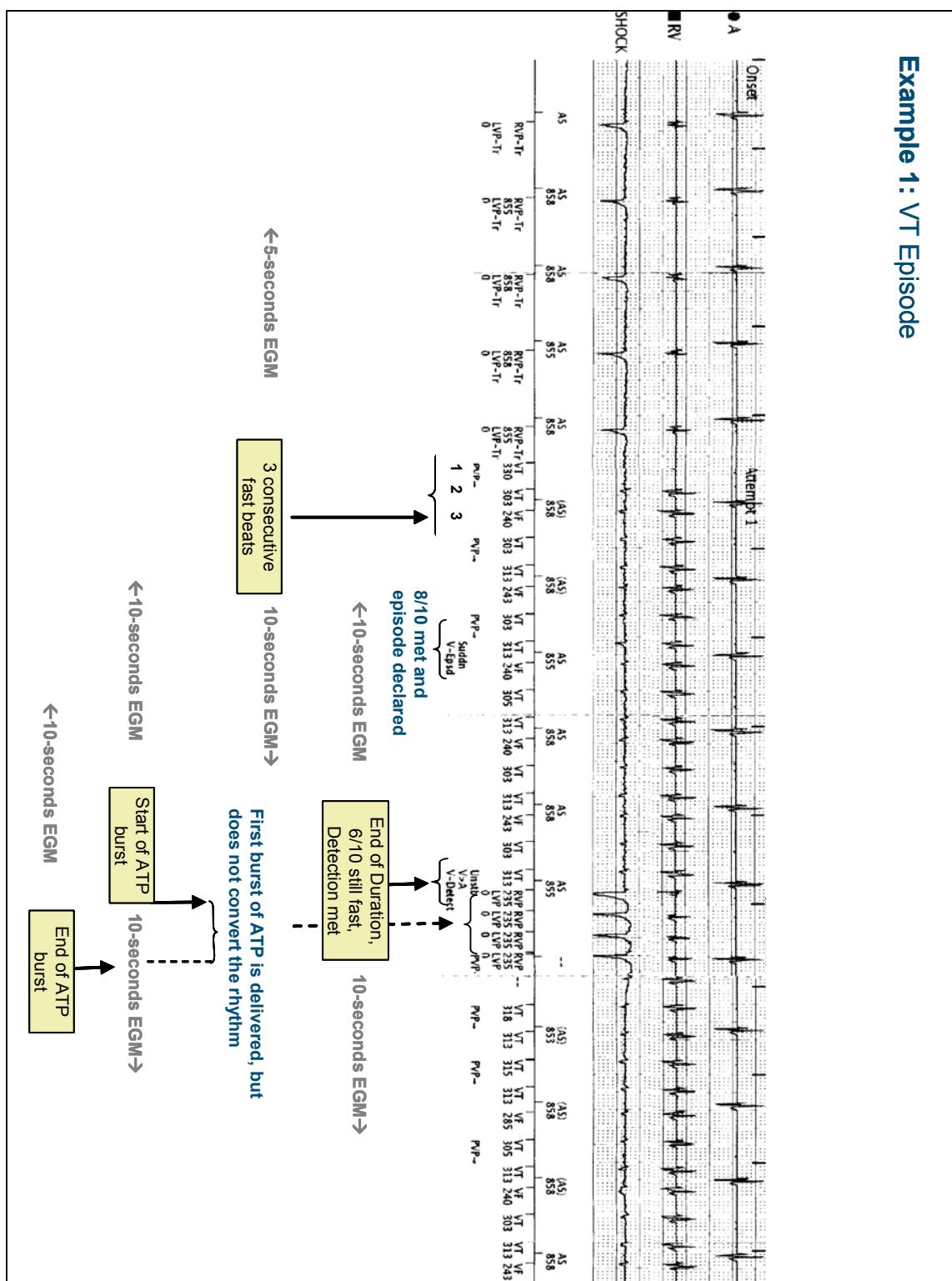
- 5 seconds before and 10 seconds after the three consecutive fast beats
- 10 seconds before and 10 seconds after the end of Duration
- 10 seconds before and after start of first ATP burst
- 10 seconds before end of first ATP burst
- 10 seconds after start and 10 seconds before end of ATP bursts 2, 3, and last burst
- 10 seconds before and after the start of charge for shock therapy
- 10 seconds after the start of the Episode
- 10 seconds before and after the deliver or divert of shock

The event ends when the end of episode timer times out.

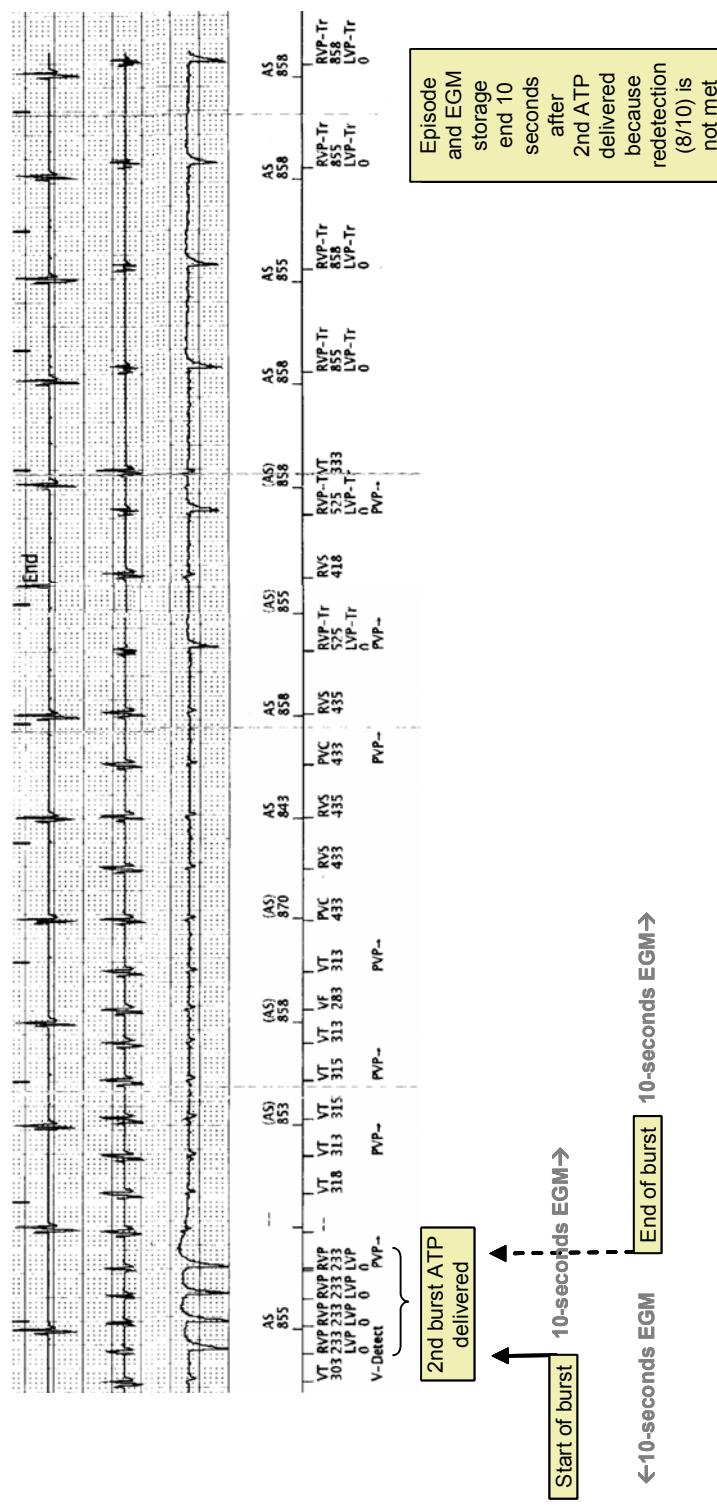
- For events with ATP or diverted shocks, 10 seconds during which redetection (8/10) is not met
- For events with shock deliver, 30 seconds during which redetection (8/10) is not met.

The following two examples illustrate an ATP-only episode (Example 1) and a VF episode with ATP and shock (Example 2)

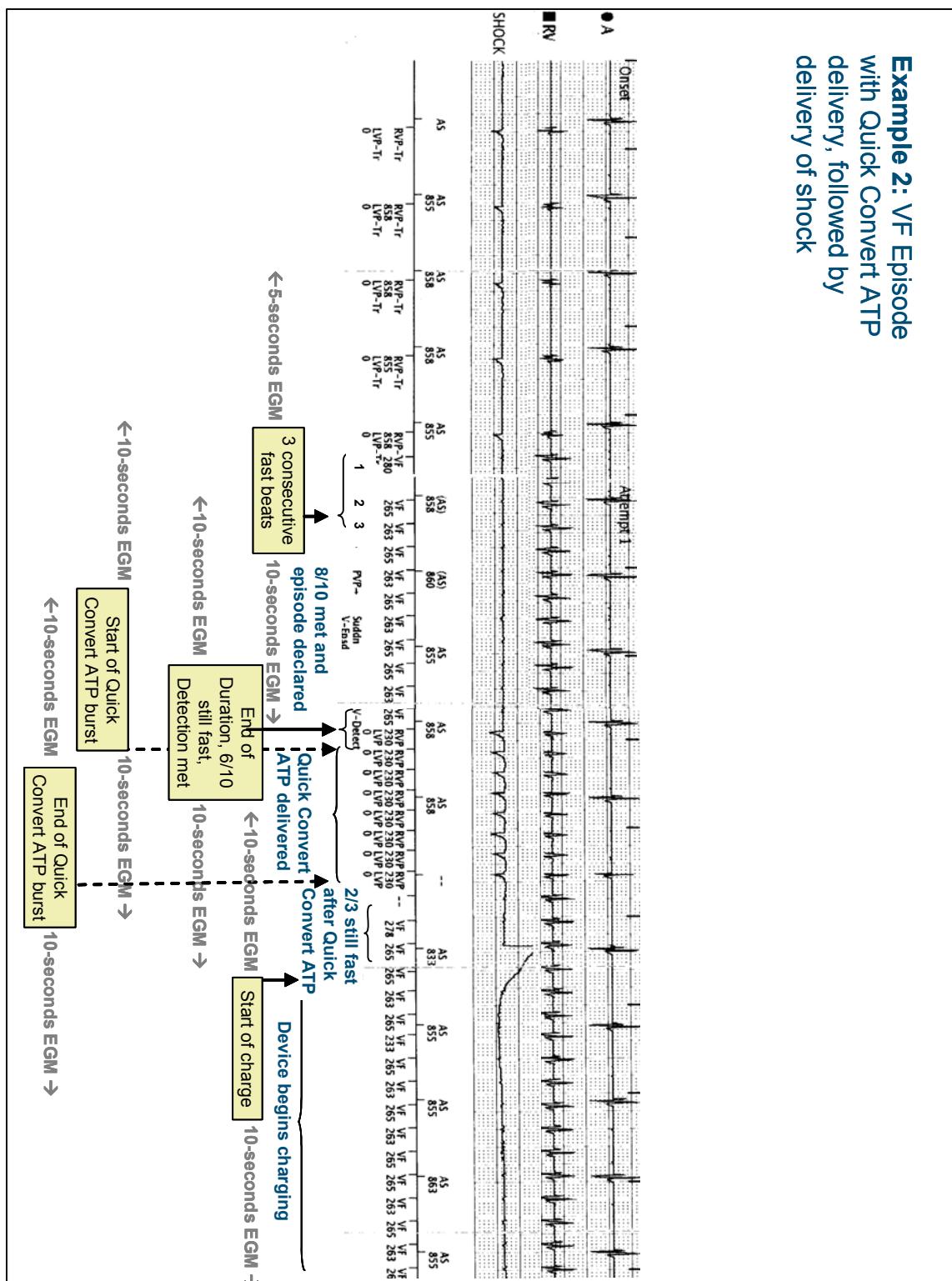
Example 1: VT Episode



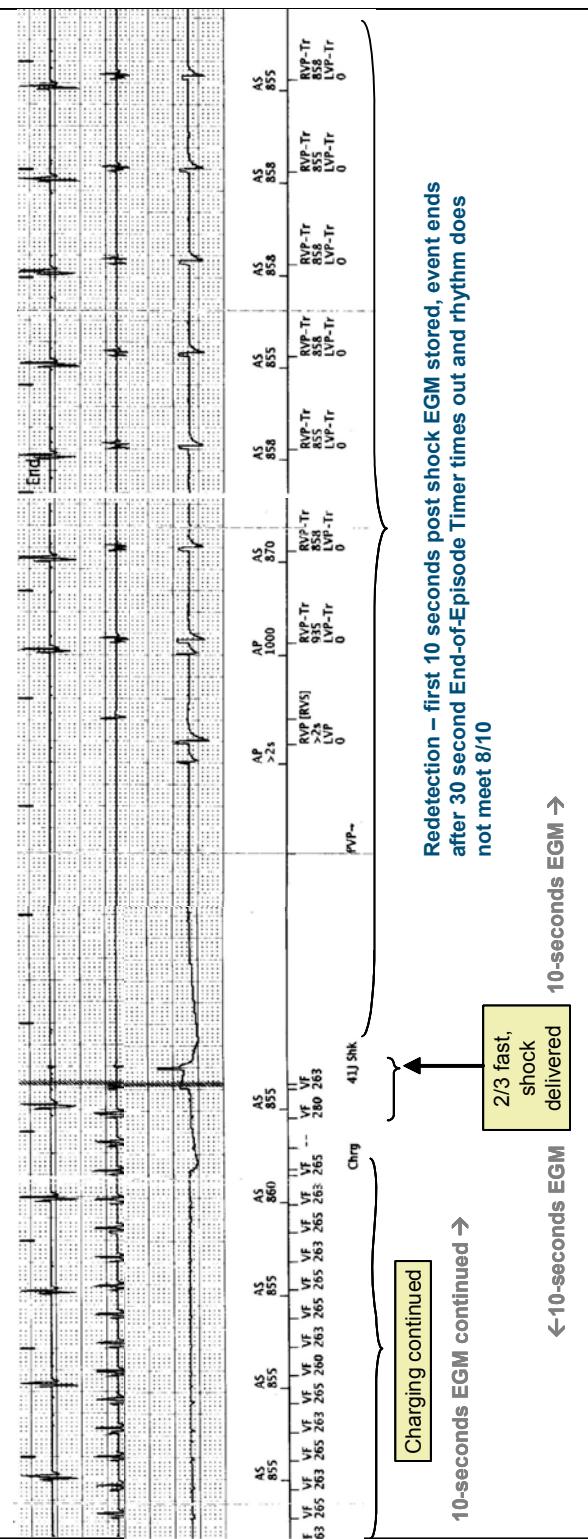
Example 1: *continued*
VT Episode with 2
burst of ATP

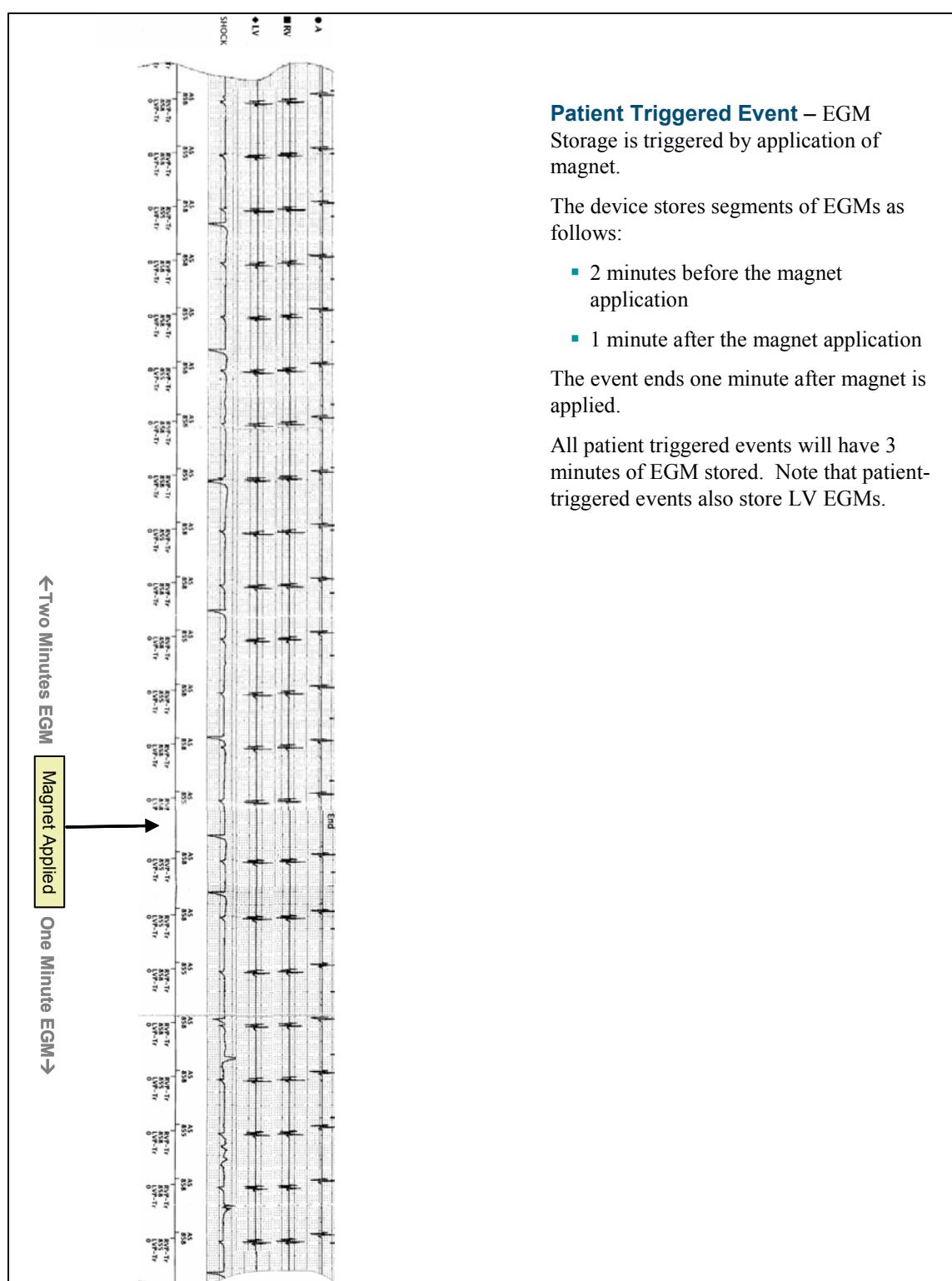


Example 2: VF Episode with Quick Convert AT delivery, followed by delivery of shock



Example 2: continued
VF Episode





PMT Event – EGM Storage is triggered by the PMT termination algorithm:

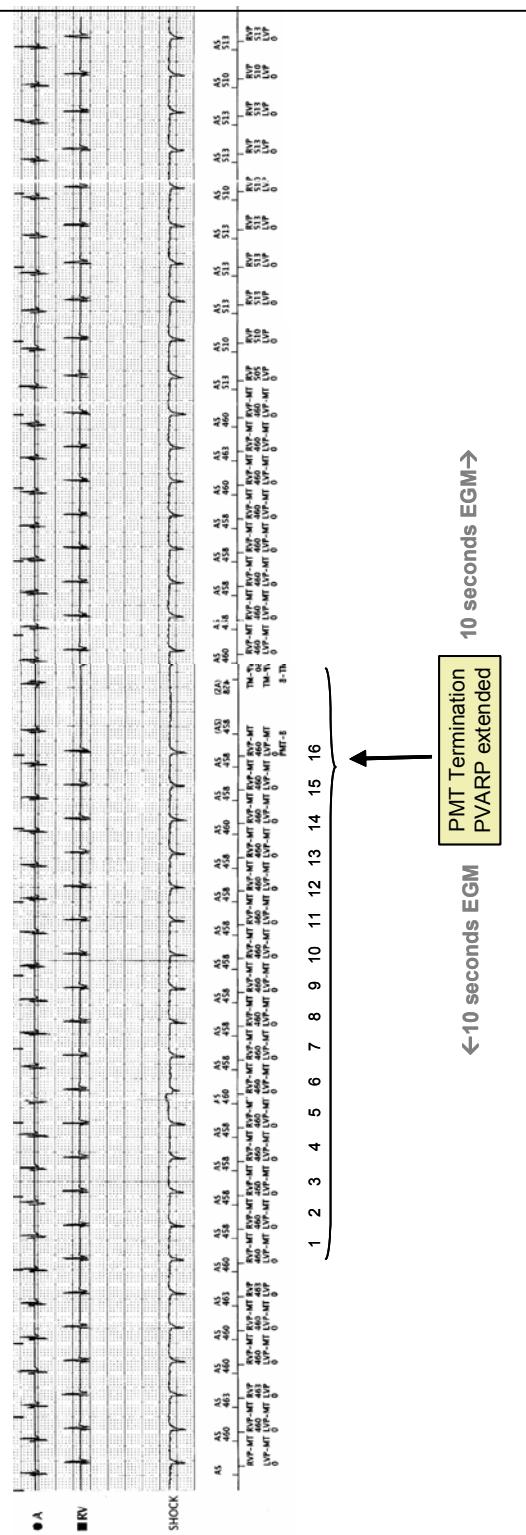
- 16 consecutive beats of AS-VP at the Max Tracking Rate
- V-A intervals for those 16 beats do not vary by > 32 ms

PMT Termination extends PVARP to 500 ms on the 16th beat.

The device stores segments of EGMs as follows:

- 10 seconds before the detection of PMT termination
- 10 seconds after the detection of PMT termination
- PMT termination is indicated by PMT-B (PMT-break) marker

PMT events will have up to 20 seconds of EGM stored.





Histogram and Counters

Histograms and counters record cardiac activity including pacing, sensing, and tachy functions which assist the clinician in assessing the appropriateness of individualized patient programming.

- Histograms provide a graph of the total number and total percentage of atrial and ventricular paced and sensed events grouped by rate.
- Brady/CRT Counters provide the percentage of atrial and ventricular paced events, the percentage of successful attempts at intrinsic promotion, and the number of atrial and ventricular ectopic events.
- Tachy Counters provide the Ventricular Tachy Episode and Therapy counts.

Availability

- Available at all times (non-programmable).

Feature Comparison to Previous Devices

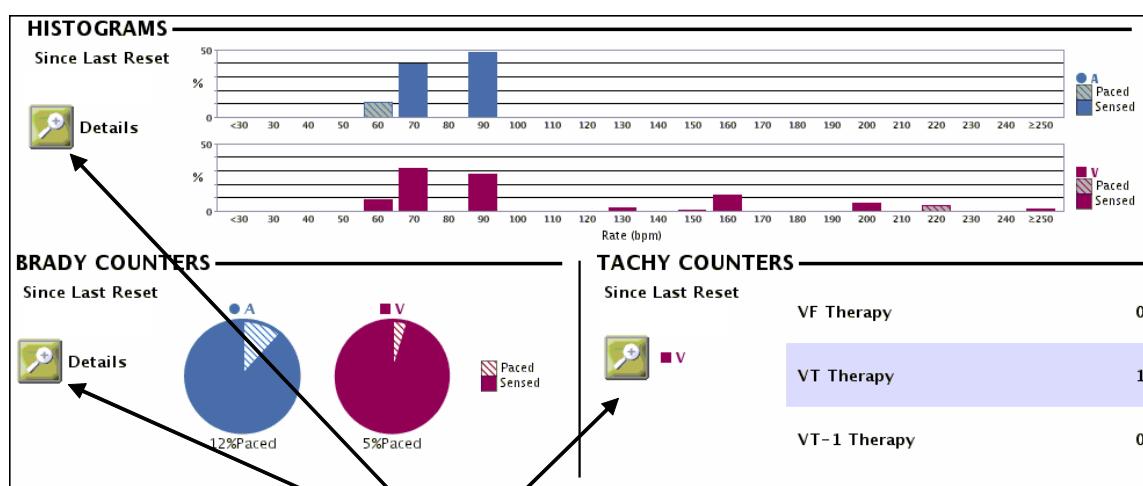
Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	Devices described in this primer
Histograms	Results available <i>Since Last Reset and Device Totals</i>	Results available <i>Since Last Reset and Reset Before Last</i>
	Tabular view of rate counts not available	<i>Rate Counts</i> available providing tabular view of events grouped by rate
	Atrial and ventricular events available separately	Atrial and ventricular events available separately and in combination
Brady Counters	Results available <i>Since Last Reset and Device Totals</i>	Results available <i>Since Last Reset and Reset Before Last</i>
• Atrial and R/L ventricular sensed and paced	Percent of paced and sensed events as well as numeric totals provided	Percent of paced events as well as paced/sensed pie charts provided
• ATR Mode Switches	Total mode switches, min and max duration and mode switch time provided	Atrial Burden with episodes grouped by duration provided. ATR event count found via Arrhythmia Logbook episodes

Feature	Previous devices (VITALITY and RENEWAL CRT-D families)	Devices described in this primer
• PMT	Event count provided	PMT event count found via Arrhythmia Logbook episodes
• R/L ventricular tracked and device determined	Percentages and numeric totals provided	Percent tracked available as a histogram under <i>Ventricular Response</i>
• Single or double PVCs Three or more PVCs	Counts provided	Total PVCs and three or more PVCs provided
• Rate Hysteresis searches and successful searches	Total counts provided	Rate Hysteresis % successful provided
• AV Hysteresis searches and successful searches	Total counts provided	AV Search Plus % successful provided
• Rate Smoothing	Event count provided	Count not available
• Single/Double/Three or more PACs	Counts provided	Total PACs provided
Tachy Counters	Available Since Last Reset and Device Totals	No change from previous devices
• Treated, Non-treated and Total	Episode counts provided	No change from previous devices
• Shocks Attempted	Count provided	First shock % successful provided
• Shocks Delivered	Detection met and physician commanded counts provided	Total shocks delivered count provided
• Shocks Diverted	Reconfirm and physician commanded counts provided	Total shocks diverted count provided
• ATP Schemes Attempted	Count provided	ATP % successful provided
• ATP Delivered	Detection met and physician commanded counts provided	Total ATP delivered counts provided

▪ Navigation:

1. From the EVENTS screen select ⇔





Select the individual Details buttons to access further detailed information including data prior to the last reset

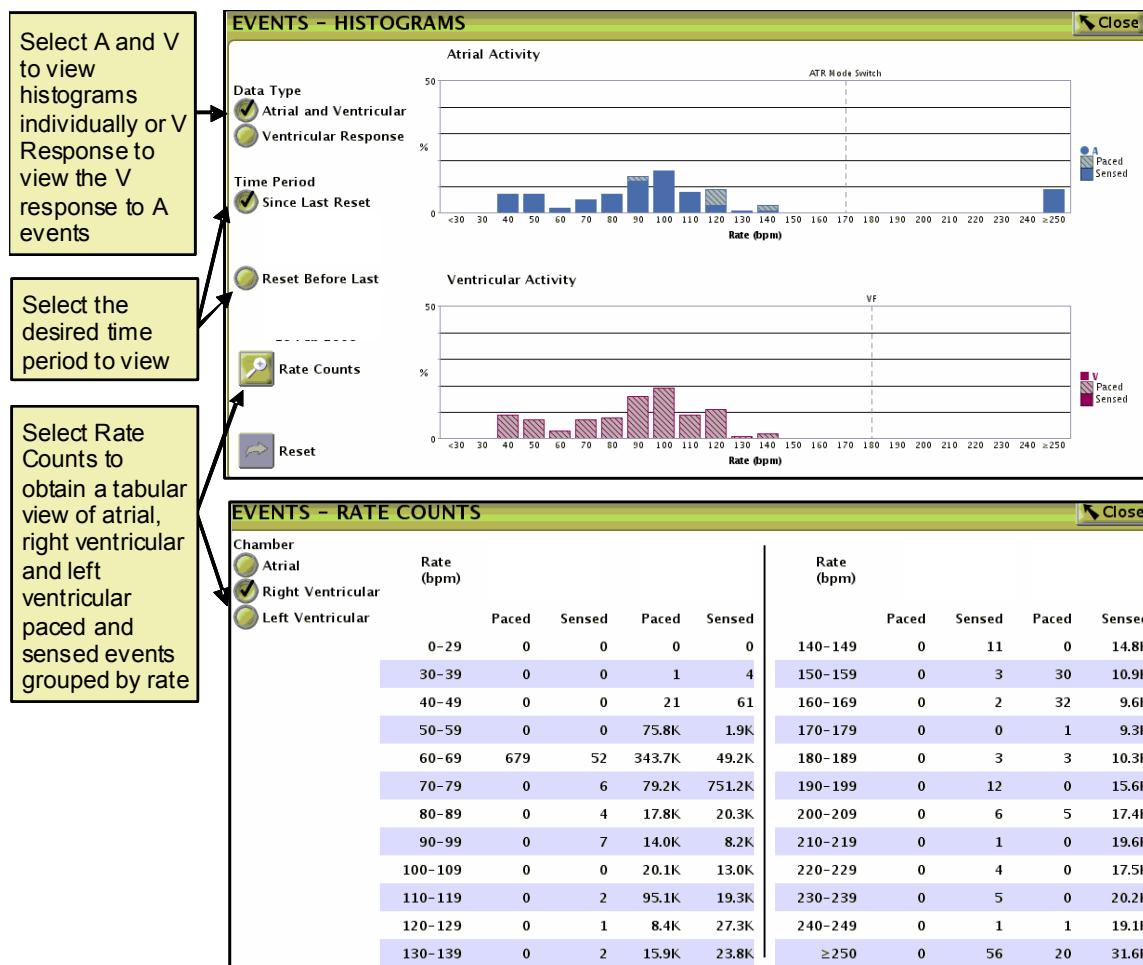
2. Select in any detail screen to reset ALL Brady/CRT Counters, Tachy Counters and Histograms (also can be reset under Lead Tests).

Counters can be reset in 3 locations:

1. Under Histograms, Brady/CRT Counters or Tachy Counters detail screen under the Patient Diagnostics tab
2. Under the Lead Tests tab
3. On the End Session Confirmation box that comes up when pressing End Session if the counters have NOT been reset during the current telemetry session. This is a reminder to reset counters if they have not already done so.

Histogram Detail

Histograms display the distribution of a patient's heart rate, the ratio of paced-to-sensed events at different rates and the ventricular response to sensed- and paced-atrial events at different rates. In devices prior to COGNIS/TELIGEN, data *Since Last Reset* as well as *Device Totals* were available. Devices described in this primer provide data *Since Last Reset* and for the *Reset Before Last* with associated dates to indicate the time period recorded (device totals are not available).



- Vertical lines define tachy rate zones on the ventricular graph and the ATR trigger rate on the atrial graph.
- PES, Manual Burst, ATP events, Temp Brady pacing, diagnostic test events, and PVCs are counted toward histogram totals. PVCs will be tallied in the high rate bins.
- Anytime the device marks an event it will be counted and tallied. This includes counting atrial events in VVI mode or ventricular events in AAI mode if the Tachy mode is not OFF. When the Tachy mode is Monitor + Therapy or Monitor Only the device always senses in the atrium (assuming dual chamber device) and the ventricle regardless of the programmed Brady mode.

Brady/CRT Counters Detail

Brady/CRT Counters provide the percentage of atrial and ventricular paced events, the percentage of successful attempts at intrinsic promotion and the number of atrial and ventricular ectopic events. In devices prior to COGNIS/TELIGEN, data *Since Last Reset* as well as *Device Totals* were available. Devices described in this primer provide data *Since Last Reset* and for the *Reset Before Last* with associated dates to indicate the time period recorded (device totals are not available).

EVENTS - BRADY COUNTERS			
Last Reset on Reset before last on			
Counters			
% A Paced 12 <1			
% V Paced 99 73			
Intrinsic Promotion			
AV Search +			
% Successful 0 0			
Rate Hysteresis			
% Successful 0 0			
Right Side PVCs			
Atrial Burden			
Episodes by Duration			
< 1 minute 0 605			
1 min - < 1 hr 0 11			
1 hr - < 24 hr 0 0			
24 hr - < 48 hr 0 0			
> 48 hr 0 0			
Total PACs 329 65.2K			
Ventricular Counters			
Total PVCs 0 603			
Three or More PVCs 0 0			

Atrial Burden

- The Atrial Burden counter provides the total number of ATR episodes, grouped by duration, which have entered and exited an ATR mode switch.
- Results will not be available if ATR Mode Switch is programmed OFF.
- A PAC is defined as an A-A interval that is < 600 ms and > 25% shorter than the average of the previous four A-A intervals.

Ventricular Counters (Total PVCs, Three or More PVCs)

- A PVC is defined as a sensed ventricular event following another sensed or paced ventricular event without any intervening atrial event inside or outside of refractory.

Tachy Counters Detail

Tachy Counters provide Ventricular Episode and Therapy Counters *Since Last Reset* as well as *Device Totals* which is unchanged from previous devices.

EVENTS - VENTRICULAR TACHY COUNTERS			
Monitor Only Zones, magnet applied during episode	Since Last Reset	Device Totals	
Total Episodes 18 18			
Treated			
VF Therapy 3 3			
VT Therapy 5 5			
VT-1 Therapy 0 0			
Commanded Therapy 2 2			
Non-Treated			
No Therapy Programmed 0 0			
Nonsustained Episodes 6 6			
Other Untreated Episodes 2 2			
Ventricular Therapy Counters			
ATP Delivered 6 6			
ATP % Successful 33 33			
Shocks Delivered 12 12			
First Shock % Successful 33 33			
Shocks Diverted 3 3			
User diverted, changed tachy mode, divert reconfirm, etc.			
3 consecutive fast beats, but duration was not completed			

Ventricular Therapy Counters

ATP Delivered

- ATP Delivered counter is incremented at the start of the first burst of an ATP scheme.
 - Subsequent ATP bursts in the same scheme are not counted individually during the same episode.
 - An ATP scheme is considered diverted only if it is diverted prior to the delivery of the first burst.
- ATP % Successful
 - % of time the arrhythmia is converted without shock delivery.

Shocks Delivered

- First Shock % Successful.
 - % of time the arrhythmia is converted without a second shock.

Notes/Additional Information

- Must have at least one-half of one percent of the total to increment 1%.
- Histograms/Counters are enabled once the device is programmed out of Storage mode and the Detail screens will display N/R for the date the device is programmed out of Storage mode.
- The device counts all paced and sensed events except those immediately following a brady state change or brady programming.
- Paces resulting from the BiV Trigger algorithm increment the RVS counters and not paced counters.
- The first time counters are reset during a programming session, the *Last Reset to Today* values will shift to become the *Reset Before Last* values and the *Last Reset to Today* fields will be zeroed. If the counters are reset again during the same programming session, no values will shift and the *Last Reset to Today* fields will be zeroed again.
- Complete Histogram/Counter results can be printed via the Reports Tab and are found within the Device Follow-up Report and Combined Follow-up Report.

See the Heart Failure Management Report for a summary of Histogram/Counter results.

- It is possible to observe atrial rates below the LRL due to PVCs and ventricular based timing. It is also possible to observe ventricular rates below the LRL due to transition beats between VS and VP events and modified atrial based timing.

See the Timing Cycles topic for further information.

- It is possible that a user may be prompted to reset counters at the end of the session even if they have already done so. This is most likely to happen around the end of Daylight Savings Time. The Reset Counters popup is generated at the end of the session if the timestamp for the last reset precedes the timestamp of initial interrogation (implying that the reset didn't occur during the current session). However, if clocks were synchronized at the start of the session, it is possible for the timestamp of the initial interrogation to appear to be after the reset that happened during the session. This is because the timestamp for the initial interrogation was created before clocks were synchronized.

Heart Rate Variability (HRV) and SDANN

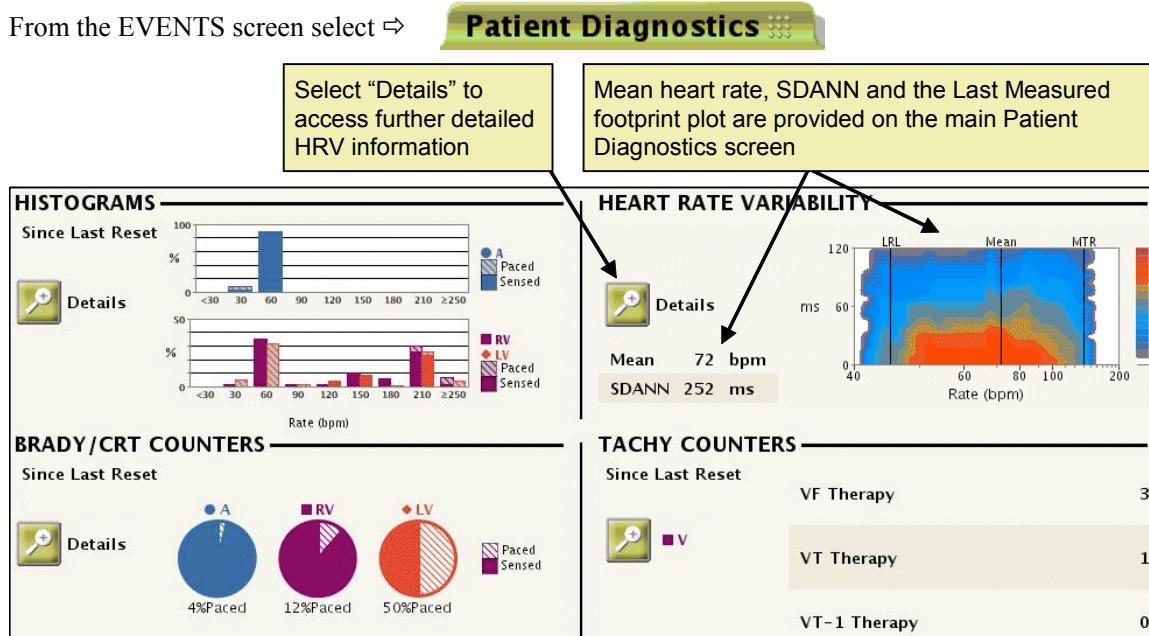
ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Heart Rate Variability (HRV) is a measure of changes in a patient's intrinsic heart rate within a 24-hour collection period. This feature can assist in evaluating the clinical status of heart failure patients.

Availability

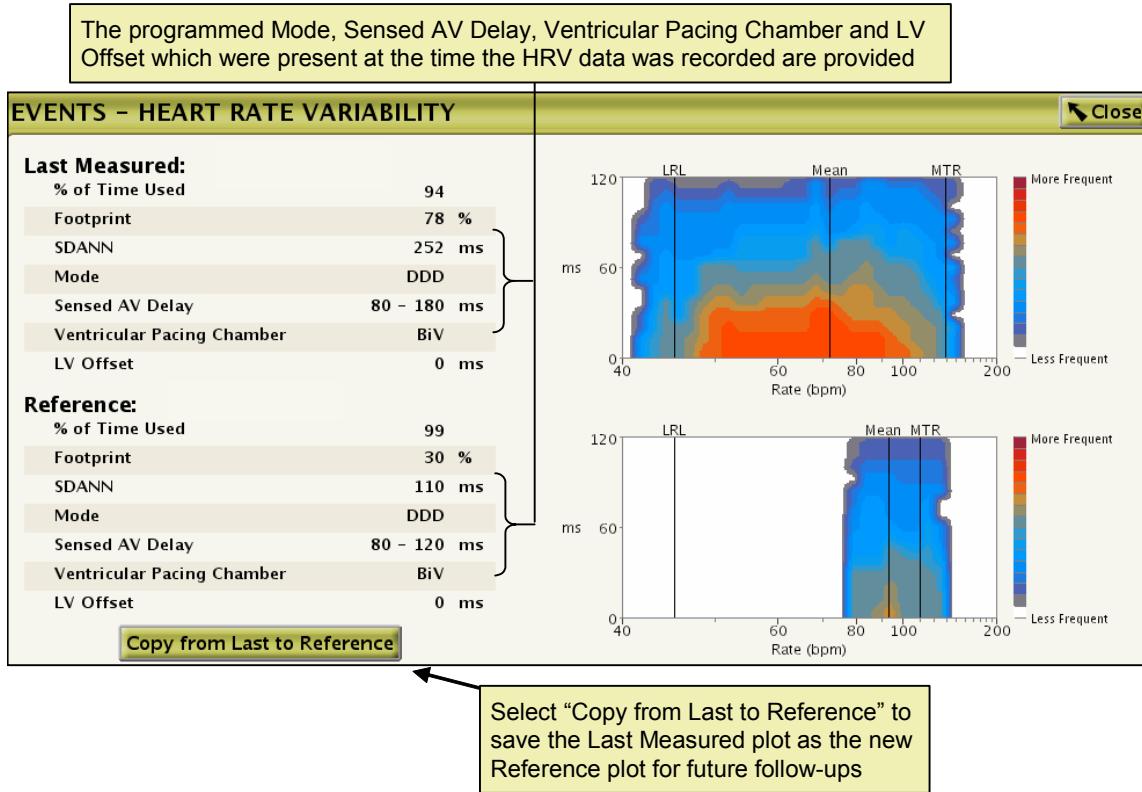
- The HRV monitor collects data when programmed to permanent VDD or DDD mode.
- HRV is not available for rate adaptive or single chamber modes.
- Navigation:

From the EVENTS screen select ⇒



HRV Details

Last Measured and Reference footprint plots and associated data are provided:



Algorithm

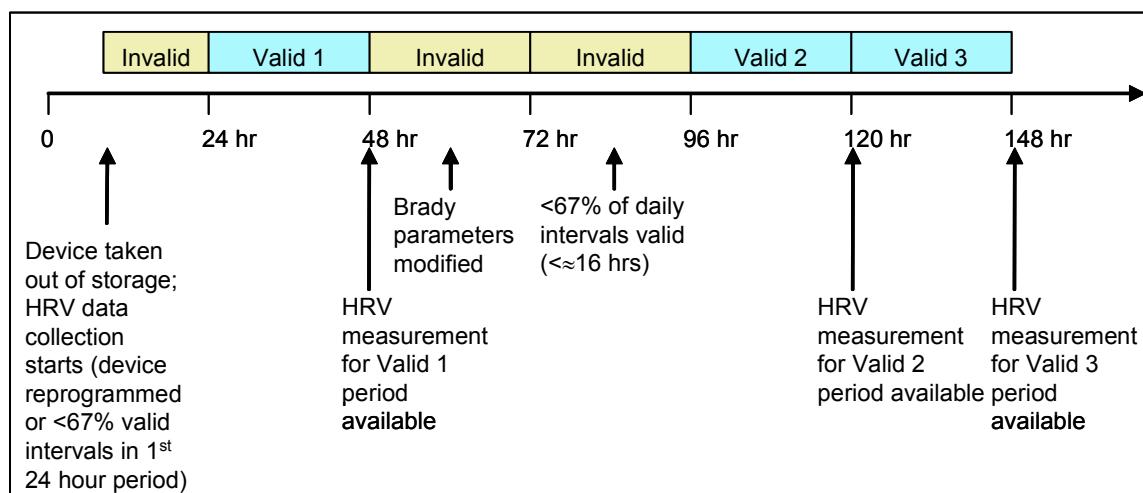
HRV data is collected by measuring the cardiac cycle intervals between RV-paced and -sensed events which follow non-arrhythmic, intrinsic atrial-sensed events. A footprint plot will not be collected if < 67% of the intervals within a 24-hour period are considered valid based on the following criteria:

Intervals included in HRV data collection	Intervals <u>not</u> included in HRV data collection
<ul style="list-style-type: none"> • RVS following sinus AS (below MTR) • RVP following sinus AS (below MTR) • {RVP} (RV pseudo-pace) following sinus AS (below MTR) 	<ul style="list-style-type: none"> • RV event following any AP • RV event occurring after A event above MTR • PVC • Two AS occurring with no intervening V event • RVP-Ns beats • RVP↑ or RVP↓ (Rate Smoothing) • Non-tracked RVP

- The HRV collection period is comprised of 288 five-minute segments (= 24 hours) of intrinsic intervals.
- Data collection starts when device is taken out of Storage mode.

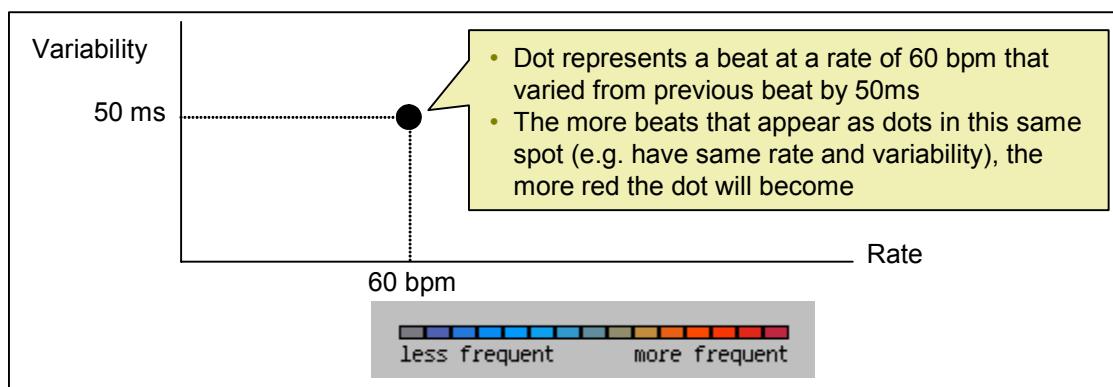
- The plot for the current 24 hours is erased any time the device is reprogrammed.
 - Selecting *Reset* under Histograms or Brady/Tachy Counters will not clear HRV data; HRV data cannot be cleared.
- The device stores the current plot and a reference plot for comparison. The first valid HRV plot will be used for both the Last Measured and Reference.
 - Select *Copy from Last to Reference* to save a new Reference plot.
 - *Copy from Last to Reference* will be grayed-out until at least two separate 24-hour valid plots are available.
- After each 24-hour period is complete, HRV data is reported under Events \Rightarrow Patient Diagnostics as well as under Events \Rightarrow Trends.

Example: HRV measurement periods:



- Graph shows heart rate variability over past 24 hours.
- Vertical lines on graph show LRL, mean heart rate and MTR.
- Horizontal axis (Y) = heart rate range, vertical axis (X) = variability (ms).

X and Y axis are fixed ranges (Y = 0–120 ms; X = 40–200 bpm). If data exceeds upper range, the plot will be clipped.



- Each dot on the plot represents an R-R interval:
 - Interval dot is plotted by its rate value and its change (or variability) from the previous interval
 - Color intensity represents repeated occurrence of point

See the Notes/Additional Information section below for a detailed description of color assignment.

Date/Time

- Date and time the 24-hour period was completed.
- The collection time is fixed when the device is taken out of Storage mode.

% of time used

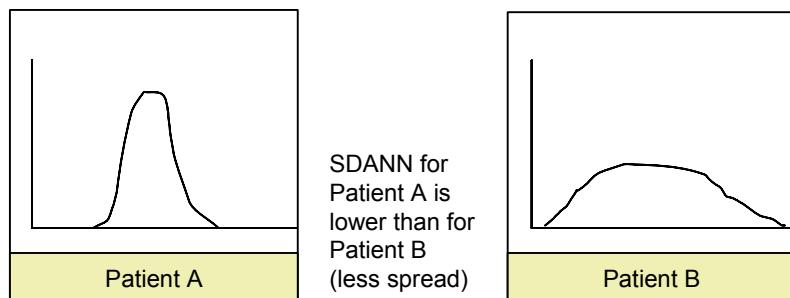
- % of time in 24-hour period that there are valid beats (must be >67%).

Footprint (%)

- Percentage representing area under footprint plot.
- Consider as a *score* for variability over the past 24 hours.
- Footprint value can be from 0% to 100%.

SDANN (Standard Deviation of Averaged Normal-to-Normal R-R intervals)

- Intervals of the 288 five minute collection periods are averaged.
- Values are derived from SDNN (Standard Deviation of all Normal sinus R-R intervals); SDNN is not viewable on programmer screen.



- Normal values⁴¹ for SDANN: 92ms – 162ms.
- Comparison of SDANN given HRV plots for two patients with the same footprint percentage (same area under curve).

⁴¹ Source: Task Force of the European Society of Cardiology the North American Society of Pacing Electrophysiology. "Heart Rate Variability: Standards of Measurement, Physiological Interpretation, and Clinical Use." Circulation 1996;93: 1043-1065.

Mode, Sensed AV Delay, Ventricular Pacing Chamber and LV Offset

- Values which were programmed at the time the HRV data was recorded are provided.

Possible HRV messages

- Messages will be displayed until at least one valid plot is obtained:

Displayed if the device is reprogrammed before one valid plot is obtained

HRV data unavailable because device was reprogrammed in the last 24 hours

Displayed if the currently programmed mode does not support HRV

Programmed Mode **does not** support HRV

Displayed if the Last measured and Reference Data is unavailable for reasons such as an insufficient number of valid beats

Last Measured Data unavailable

Reference Data unavailable

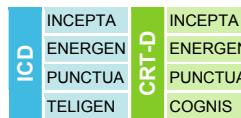
Notes/Additional Information

- Plots are saved as part of Save All to Disk and can be printed with the *Heart Failure Management Report* and *Combined Follow-up Report*.
- The device saves only one set of values for the Last Measured and Reference plot – once data is overwritten by a new plot or copied from Last Measured to Reference, the older data can no longer be retrieved.
- Color mapping scheme for HRV plot:
 - Colors on the footprint are based on quantity of beats at different data points. For example, if one data point occurred 1000 times, it would be assigned the reddest color. The more heartbeats the patient has at the same rate and variability, the more intense (red) the color.
 - The bin count/color mapping on the screen is as follows:

Graduation	Bin Count Range
0	0
1	1
2	2
3	3
4	4 to 7
5	8 to 11
6	12 to 15

Graduation	Bin Count Range
7	16 to 19
8	20 to 51
9	52 to 83
10	84 to 115
11	116 to 147
12	148 to 403
13	404 to 659
14	660 to 915
15	916 and greater

- ✗ Graduation of 0 corresponds to white
- ✗ Graduation of 1 corresponds to gray
- ✗ Graduation of 15 corresponds to red
- ✗ The graduations in the middle correspond to the sliding color scale shown on the HRV screen.



Patient Triggered Monitor

Patient Triggered Monitor is intended for patients who are symptomatic for unknown causes, and no other programmed storage feature documents an episode when the patient's symptoms occur. Patient Triggered Monitor allows the clinician to program the pulse generator to record a three-minute EGM when the patient applies a magnet.

Longevity Impact

- Main reason for longevity impact is technology required to capture two minute pre-trigger portion of EGM. Both storing and accessing two minute loop of EGMs are a significant current draw.
- When Patient Triggered Monitor is programmed to ON for 60 days, longevity is reduced by approximately 5 days.
- To help decrease longevity impact, Patient-Triggered Monitor enforces 60-day timer and only allows storage of one episode.
- Magnet Response is automatically reset to Inhibit Therapy after 60 days if no EGM is stored and Patient Triggered Monitor must be re-enabled to allow storage of an EGM.
- **EGM Channels** RA, RV, LV and shock EGMs as storage sources.

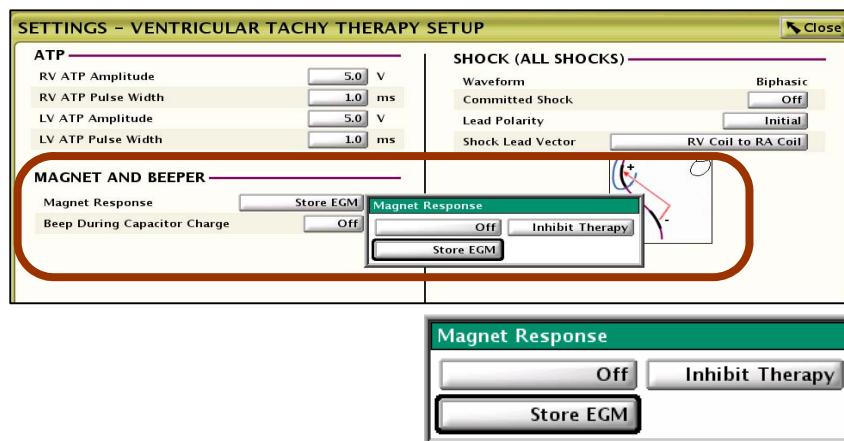
Availability

- One EGM may be stored when the magnet is applied. Once an EGM has been stored, the magnet function will return to Inhibit Therapy. Any additional applications of the magnet will not store an EGM and will inhibit tachy therapy.
- An EGM may be triggered with a magnet regardless of status of brady pacing or Tachy mode (even Electrocautery mode).
- If a tachy episode or EP induction is in progress when the magnet is applied, Patient-Triggered Monitor will still be stored.
- Navigation

- From the Setting Summary screen, select



- From the Settings Ventricular Tachy Therapy screen, select



Patient-triggered Monitor is found under the Magnet Response parameter.

Programmable Values

- Magnet Response:
 - Nominal = Inhibit Therapy.
 - Choose *Store EGM* to allow a magnet to trigger storage of a 3-minute EGM.

Algorithm

- Patient applies the magnet to store an EGM. Magnet must be applied for at least two seconds.
 - Device stores one 3-minute EGM (2 minute pre-magnet/1 minute post-magnet application) plus an interval graph.
- Application of the magnet to store an EGM can be done only once; after the magnet has been applied, Magnet Response will automatically revert to Inhibit. Subsequent applications of the

magnet will inhibit therapy and elicit magnet tones. Magnet Response would need to be reprogrammed to *Store EGM* to allow another EGM to be stored.

- If Magnet Response is set to *Store EGM* but a magnet is not applied for 60 days, the Magnet Response will automatically revert to inhibit.

Notes/Additional Information

- EGM and intervals for one Patient Triggered Monitor will be stored in memory; up to five Patient Triggered episodes (only one with EGM, up to four with date/time but no details) may be listed in the Arrhythmia Logbook.
- Arrhythmia Logbook shows Duration = 1:00 minute, the amount of time that passed since the magnet was applied.
- When Magnet Response = Store EGM, all other magnet features are disabled, including magnet-elicited beeping tones.
- Arrhythmia Logbook will show PT Event as *In Progress* when storing EGM; a clinician may use this notation to demonstrate magnet application and verify that the patient applied the magnet correctly. However, the device allows storage of only one EGM. If an EGM is stored in the clinic as a demonstration, the device must be re-interrogated and the Magnet Response reset to Store EGM before the patient is sent home with the magnet.

Magnet Beeper

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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The presence of a magnet may either inhibit tachy therapy or trigger storage of episodes. The beeper alerts the users or patients to special conditions, such as capacitor charging, explant indicator, or fault conditions.

Availability

Magnet functions are available in non-Storage modes. Differences for Magnet from previous devices

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Inhibit therapy with a magnet	Enable Magnet Use parameter set to ON	Magnet Response parameter set to Inhibit Therapy

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Patient-triggered episode storage	Patient Triggered Monitor parameter set to ON	Magnet Response parameter set to Store EGM
Change tachy mode with magnet	Available in some products	Not available ⁴²

Beeper functions are available. Differences for Beeper from previous devices

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Beeping pattern with magnet application	R-synchronous beeping	1 beep per second
Beep on paced and sensed events	Available	Not available ⁴³
Beep during capacitor charge	Programmable	No change from previous devices
Beep when -Explant is reached	Programmable. When ON, device will beep 16 times every 6 hours once Explant is reached	No change from previous devices
Beep for fault code	Device will beep 16 times every 6 hours for certain faults	No change from previous devices

Programmable Values

Magnet Response

- OFF – device will not respond to a magnet.
- Store EGM – stores a three minute EGM when magnet is applied.

See Patient Triggered Monitor topic.

- Inhibit Therapy (Nominal) – Tachy therapy is inhibited and device beeps while a magnet is in place over the device. Placement of a magnet can divert scheduled therapy or interrupt an induction, as applicable. Brady pacing is not affected by the magnet.

⁴² Continues the practice to simplify use of the magnet and eliminates any possibility that tachy therapy mode could be accidentally changed by a strong magnetic field.

⁴³ For ICDs and CRT-Ds described in this primer, beepers are designed to beep once a second, rather than R-synchronously. If there is a need to demonstrate the tones for a patient, a magnet may be used to trigger beeping.

Beep when Explant is Indicated – ON or OFF

- Nominal: ON

Beep During Capacitor Charge – ON or OFF

- Nominal: OFF

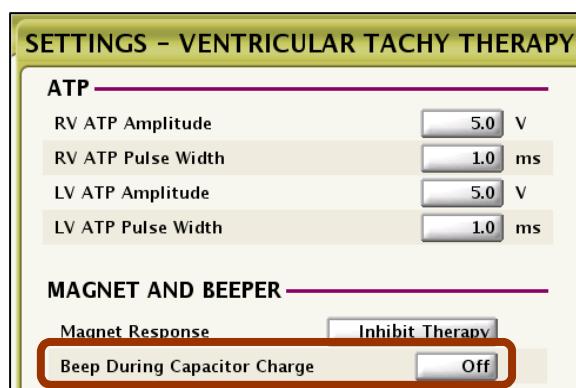
Magnet Navigation – the Magnet Response parameter may be programmed on the Ventricular Tachy Therapy Setup screen:

1. From the Settings Summary screen select ↴
2. From the Ventricular Tachy Therapy screen select ↴  V-Tachy Therapy Setup
3. Select ↴
Magnet Response



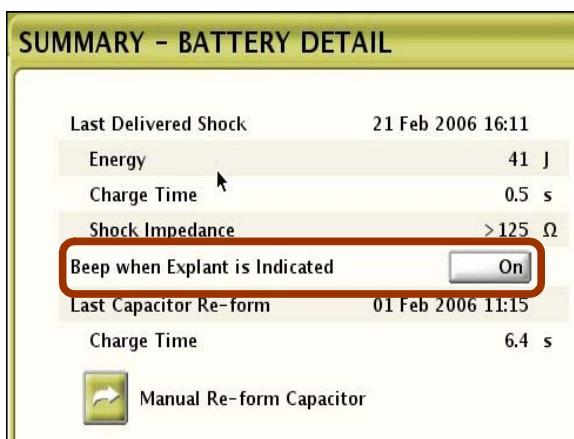
Beeper Navigation – the Beep During Capacitor Charge parameter may be programmed on the Ventricular Tachy Therapy Setup screen:

1. From the Settings Summary screen select ↴
2. From the Ventricular Tachy Therapy screen select ↴  V-Tachy Therapy Setup
3. Select  Beep
During Capacitor Charge:



The Beep when Explant is Indicated parameter can be programmed from the Battery Detail screen:

1. From the Summary screen select ↴
2. From the Battery Status screen select ↴  Battery Detail



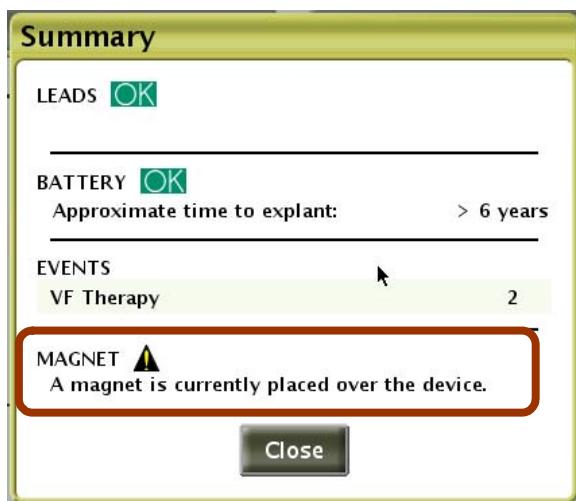
- From the Battery Detail screen select \Rightarrow Beep when Explant is Indicated.

Magnet Notes

- If a magnet is present during a therapy attempt, the Therapy column in the Arrhythmia Logbook will show *No Therapy*.
- The episode detail report could vary for episodes involving a magnet depending on the timing of placement. If a magnet is in place before the first therapy attempt, the detail portion of the Episode Report will show one attempt with No Therapy. If the magnet is placed after an attempt starts—e.g., during charging—two attempts will be displayed in the episode detail. The first will be Diverted, the second will show No Therapy.
- A magnetic field of as much as 10 Gauss may trigger magnet functions.
- If the device is in OFF, Monitor Only, or Electrosurgery mode, and Magnet Response is set to Inhibit Therapy, magnet application will produce a constant tone to indicate that the device is already in a non-therapy mode.
- Tones may continue for up to two seconds after a magnet is removed.
- When a device is in Safety Core, the application of the magnet will inhibit therapy but beeping tones will not be emitted.

See Safety Mode/Core section.

- If a device is interrogated while a magnet is present, the Summary window will indicate it as shown. However, Tachy mode will still show the programmed Tachy mode.



Beep Notes

- The beeper causes a higher drain on the battery when beeping.
- Once the Explant notification has been cleared, consider programming Beep when Explant is Indicated to OFF.
- Beep During Capacitor Charge beeps during therapy charges and manual capacitor reforms, but not during automatic capacitor reforms.
- Beeping tones for magnet application always occur at the same pitch. Tones for a capacitor charge alternate between higher and lower pitched beeps. This alternating pattern is sometimes referred to as *warbling*.

Data Storage

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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- The PRM system allows you to save pulse generator data to the PRM hard drive or a removable floppy data disk. Data saved to the PRM also can be transferred to a removable USB pen drive.
- Version 7.01 or greater of The model 2909 v7.01 software must be installed on the PRM before any USB Pen Drive features can be utilized.

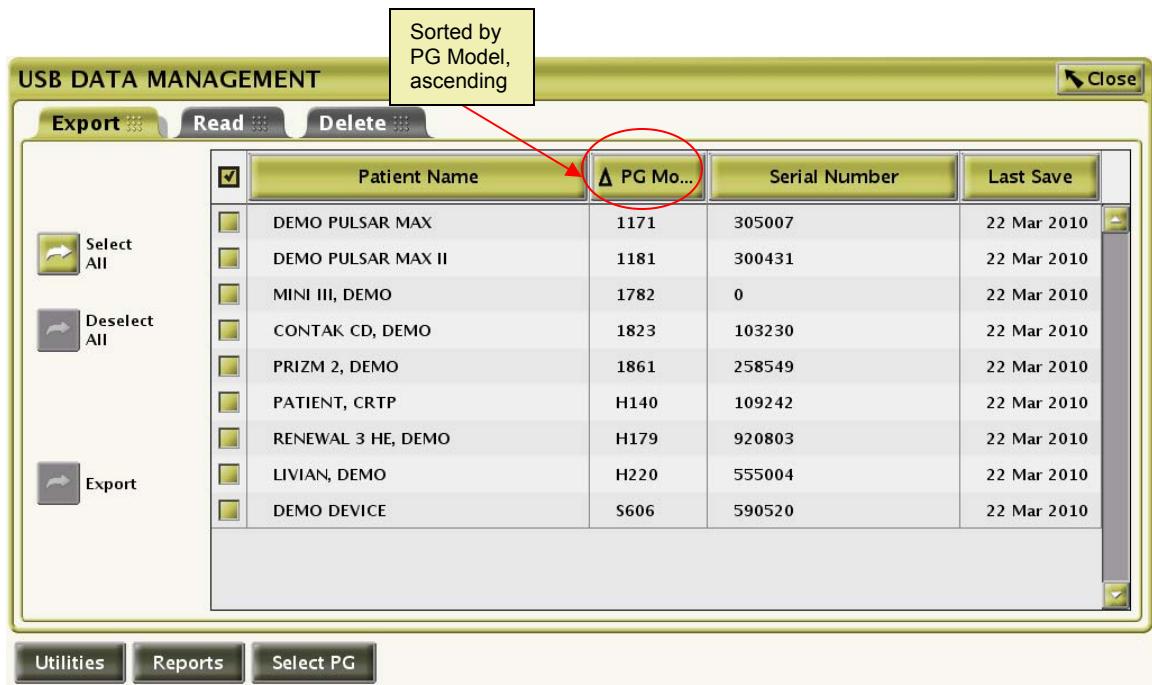
Save to USB Pen Drive

Terminology

- **Patient Record:** an encrypted file identified by the specific device model/serial number that contains device parameter settings, episodes information, stored EGMs (if available) and device memory data (if specifically saved).
- **Save:** the first step in the two-stage process. Patient Records are *Saved* to the PRM hard drive if a floppy disk is not resident in the floppy drive.
- **Export:** the process of moving Patient Records from the PRM hard drive to the USB Pen Drive.
- **Read:** similar to the *Read Disk* feature. Patient Records are *Read* from the PRM Hard drive or the USB Pen Drive and the appropriate PRM Software Application is initiated.
- **Initialize:** the process of creating a password for a specific USB Pen Drive. Patient Records cannot be accessed on non-BSC systems without the password.

Availability

- All devices described in this primer once MAU model 2909 v7.01 AND model 2868 v2.03 has been loaded to a programmer. All PRM Software applications except Delta/Vista.
- Any USB pen drive can be used, any size, any manufacturer.
- USB mass storage devices (e.g., external hard drives) can be used.
- There cannot be any other files on the pen drive. BSC Patient Records are stored in a specific file folder with a specific file naming convention and encryption.
- There is no virus detection program on the programmer or the USB pen drive (even if the USB pen drive is initialized). The integrity of all files are checked prior to the Read function.
- Before returning a PRM to BSC, Be sure to save all Patient Records on the hard drive to a USB Pen Drive before returning a PRM to BSC. All Patient Records will be erased from the PRM hard drive when it is returned.
- If the PRM fails in a manner that renders it completely unusable (touch screen malfunction, black screen on power up, etc.), the Patient Records on that PRM hard drive will be lost.
- Copying USB Pen Drive contents: you can copy patient records from the USB Pen Drive to another USB Pen Drive, but the entire 'bsc' folder on the USB Pen Drive must be copied or it will not be readable on the PRM.
- All columns can be sorted. The default sort is the Last Save column, most recent to oldest until the user selects a sort, which is then persistent for that session.



- COGNIS/TELIGEN will not save any patient records to the PRM hard drive until the Progeny software application is installed (2868 v2.03). Once 2868 v2.03 is installed, any COGNIS/TELIGEN patient record can be saved to the PRM hard drive (it will be backwards compatible).
- Programmer hard drive limitations:
 - Limited to 400 unique patient records, which means 400 files from different device model/serial number combinations.
 - Limited to 300Mb of total hard drive storage space.
 - If either limit is reached, patient records will be deleted on a *first in, first out basis* with no indication to the user.
 - Up to 200 episodes can be saved to the PRM hard drive during a session. Performing the Save All to Disk operation with a patient who has more than 200 episodes will save only the oldest 200 episodes. The system will then notify you that the disk is full and the user will need to restart the session and save only up to 200 selected episodes.



- If a patient has more than 200 episodes, it is recommended that the user perform a selective save operation instead of the Save All to Disk operation.

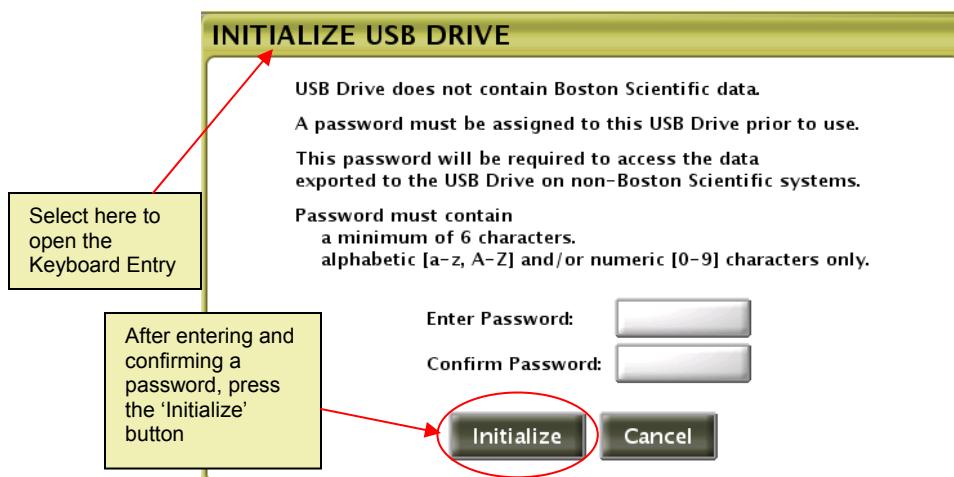
- Pen Drive limitations:

- Limited to 400 unique patient records, which means 400 files from different device model/serial number combinations.
- The amount of data that a pen drive will hold is dictated by the capacity of the pen drive chosen. 100MB of space is reserved on the pen drive at all times.
- When the pen drive is full, a system status dialog box is presented to the user indicating that the *export failed*. This may be confusing to the users. When this dialog is displayed, point the user to the right-hand side, where it explains that the USB Drive capacity has been reached.

Initializing a USB Pen Drive (Create a Password)

The USB Pen Drive must be initialized before patient records can be exported to that USB Pen Drive. The only way to elicit initialization is when attempting an Export for the first time with that specific pen drive. Initialization only needs to be done once.

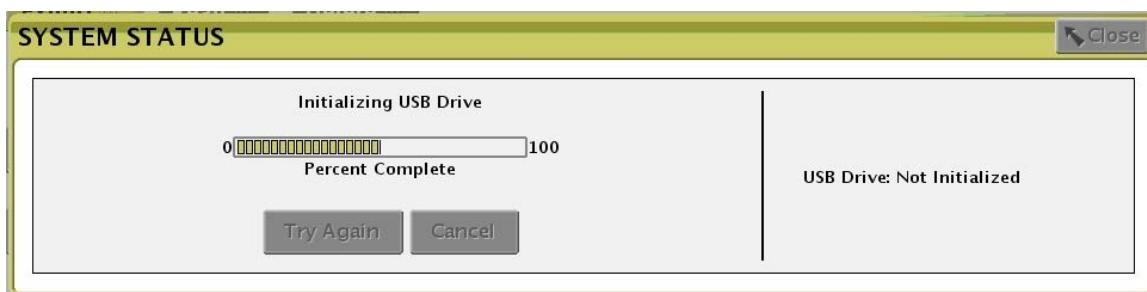
NOTE: If the password is lost and the data is no longer on the PRM hard drive, the data will be lost unless the device is interrogated again. Because of the sensitivity associated with protected health information, there is no password reset process.



- Selecting either the ‘Enter Password:’ or ‘Confirm Password:’ field will open the following Keyboard dialog:



- Choose a password and then select *Accept Changes*. This will close the Keyboard dialog and insert your chosen password into the change field on the Initialize USB Drive dialog.
- After a password is entered and confirmed, select the ‘Initialize’ button. This will begin the initialization process and the following dialog will appear.



Save Patient Records to the PRM Hard Drive

Patient records must first be saved to the PRM hard drive before they can be exported to a USB pen drive. Once patient records have been saved to the PRM hard drive, the user must exit the device application, return to the Multiple Applications Utility and select the *USB Data Management* button to access the data.

- If a Model 6627 Patient Data Disk is not inserted in the PRM disk drive, any disk operations performed from any application will be saved to the PRM hard drive. Data saved to the hard drive can then be Exported to the USB pen drive through the Export feature of the USB Data Management utility, accessible from the PRM startup screen.
- If a Model 6627 Patient Data Disk is inserted in the PRM disk drive, behavior defaults to the Save to Disk behavior (all interaction will be with the floppy and no data will be written to the PRM hard drive).

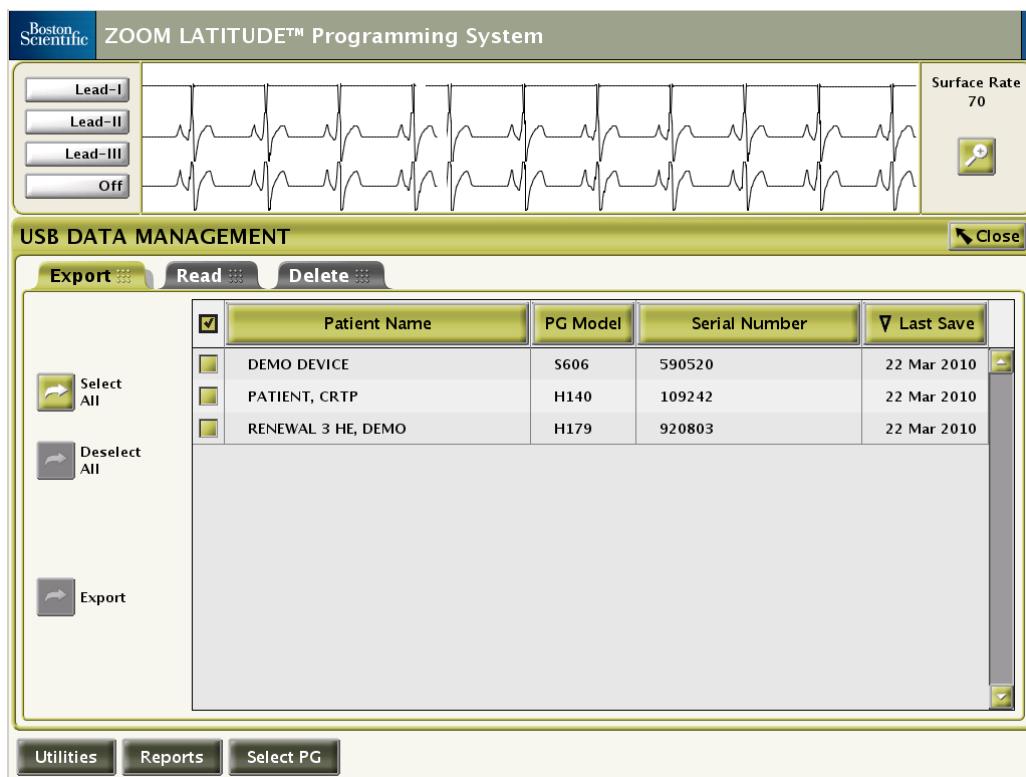
- Saving patient records from within the software applications has not changed. The same terminology is used. Dialogs will still refer to *Disk*.
- If a Save with new data is performed when there is already information for that specific model/serial number, the new data is appended to the existing data.

Exporting from PRM Hard drive to USB Pen Drive

Export refers to moving data from the PRM hard drive to the pen drive. Patient records are available from the PRM hard drive or from the USB Drive if they have previously saved to one of these storage sources.

The *Export* Tab will be the default tab when the user clicks the *USB Data Management* button from the startup screen upon power-up or upon exiting any application

- It will display a list of patient records currently saved on the PRM hard drive.
- Select *Export* tab and a list of the stored patient records which are available is displayed.
- Select the patient record(s) that you want to export to the pen drive (including *Select All*).



- Select the *Export* button to initiate the export operation. If the export can be performed, a dialog will appear indicating that PHI is being exported to the pen drive.



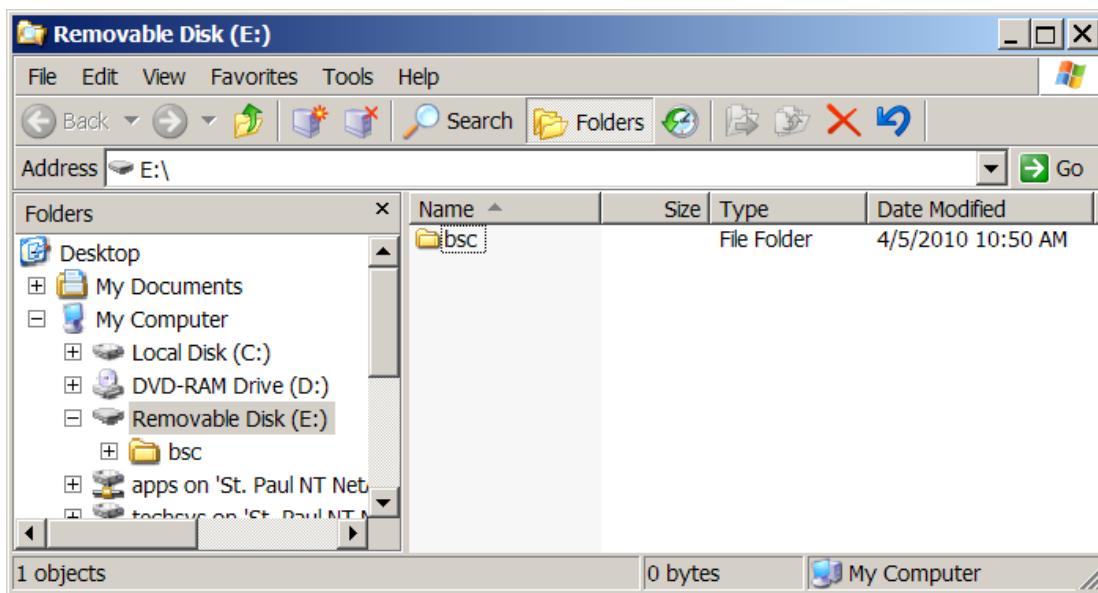
- Do not remove the USB Drive during the export operation.
- If an Export with new data is performed when there is already information for that specific model/serial number on the USB drive, new data will be appended to the existing record.
- If the storage capacity of the USB Drive is reached during the Export operation, the system will display a message stating that the export failed. Perform the following steps:
 1. Remove the first USB Drive
 2. Insert a new USB Drive and select the *Try Again* button to continue with the Export operation
- As many full patient records as possible will be exported to the first USB Drive. Only those patient records that weren't exported to the first USB Drive will be exported to the second USB Drive.

Extracting and Emailing Files

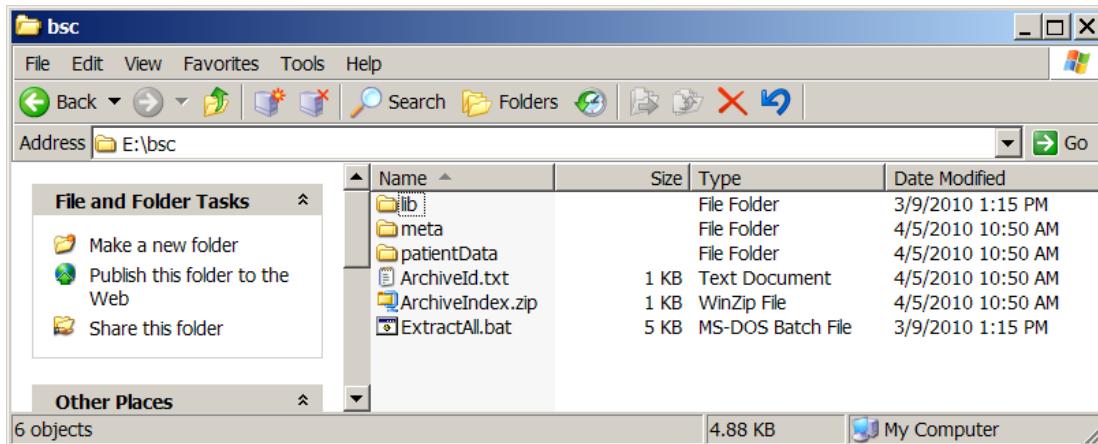
Patient records are encrypted before being written to the pen drive. They are also compressed using the Microsoft Zip utility. The password that the pen drive was initialized with is required to access the individual files from any patient record. The following steps will allow the user access to the individual files from any patient record. This will be useful when it is necessary to e-mail save-to-disk, device memory dumps, or individual episodes for conversion to PDF format (for Contak Renewal TR or Altrua/Insignia).

E-mailing Patient Record Files

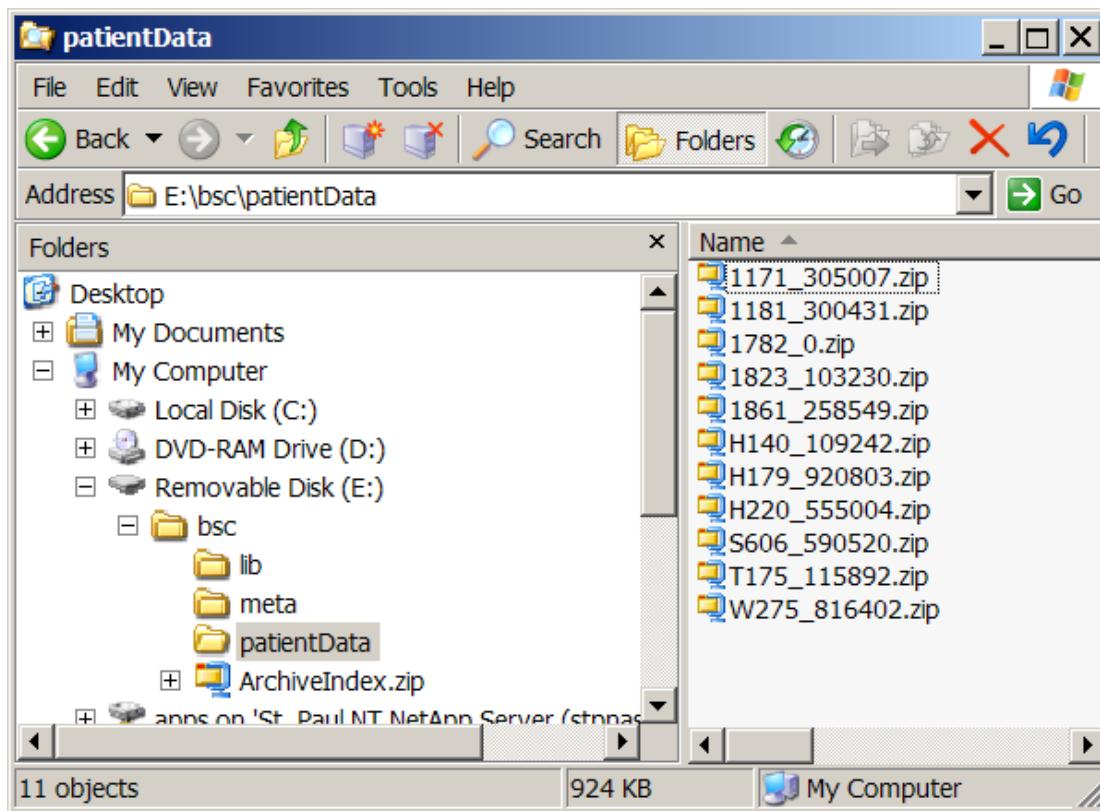
1. On your PC, insert the pen drive into any USB port and open Windows explorer.
2. Navigate to the 'bsc' folder.



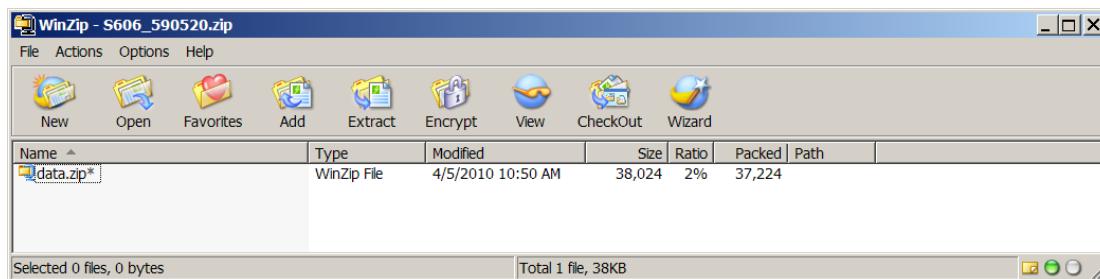
3. Double-click on the 'bsc' folder to access the sub-folders.



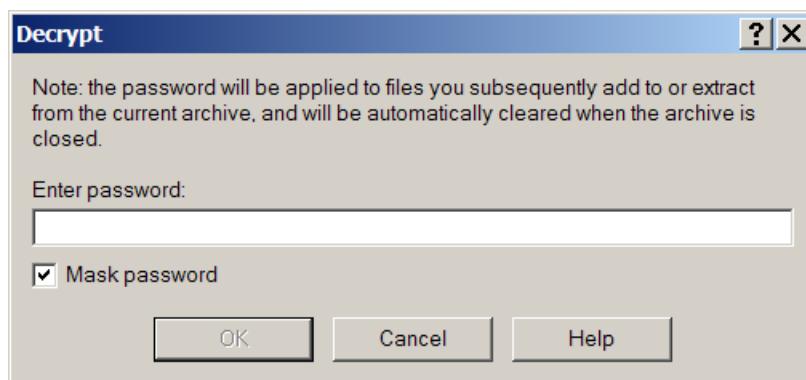
4. Double-click on the *patientData* folder.



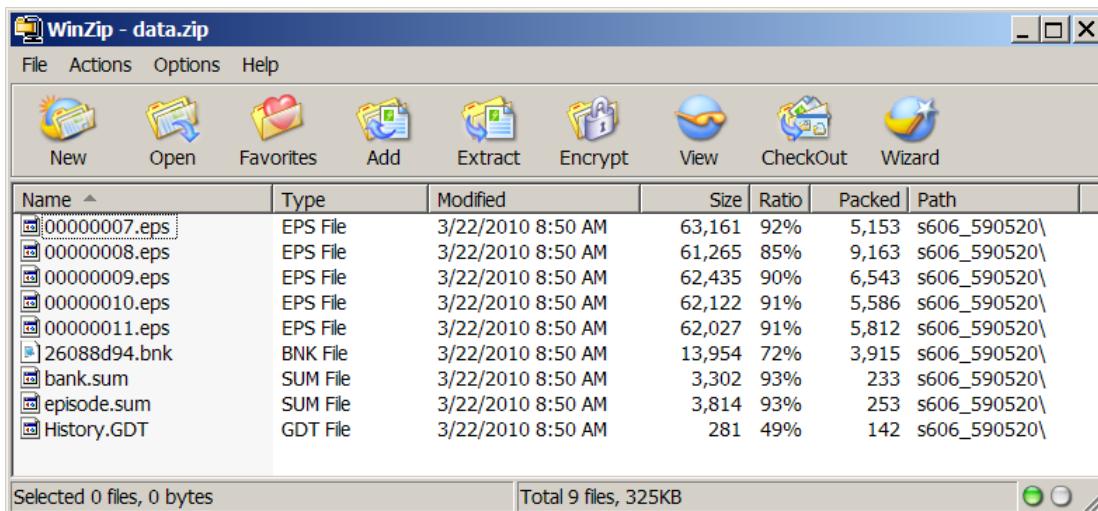
5. Each patient record on the pen drive will be represented as a file in the format *model_serial.zip*.
6. Double click the file that you want to work with, this will open WinZip with one file in it – *data.zip**.



7. Double click the *data.zip** file and the program will ask you for the password of the pen drive.



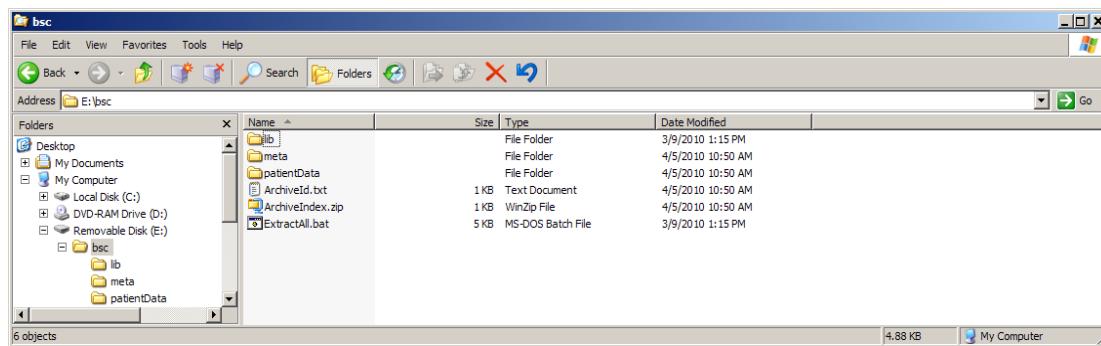
8. Type in the password of the pen drive and WinZip will then display the patient data files.



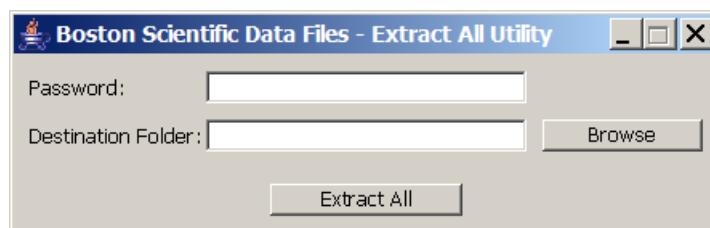
9. These files can now be manipulated individually. They can be copied to your PC hard drive or they can be selected and emailed (e.g., if you were interested in emailing Episode 7 to BSC for conversion to PDF, right-click on the file *00000007.eps*, choose *Extract*, choose a file folder to extract the file to and then email the file from that folder).

Importing Patient Records into an EMR

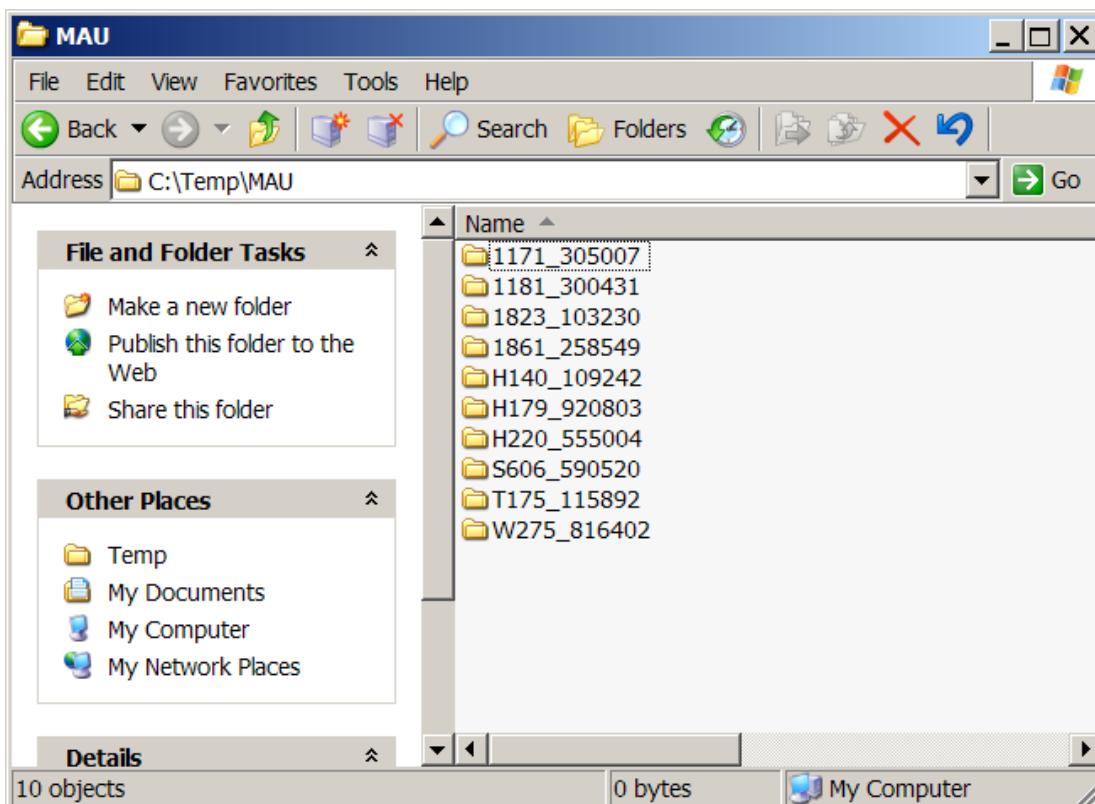
1. Insert the pen drive into the USB port of any computer/laptop and open Windows Explorer.
2. Select the *Removable Disk* (may have automatically opened when the pen drive was inserted and recognized by the computer).
3. Select the *bsc folder*. You will see a file titled *ExtractAll.bat*.



4. Double-click the *ExtractAll.bat* file. You will be prompted to enter the pen drive password and to choose a destination directory.



5. Each patient record on the pen drive will be extracted to a folder that is titled with the device model and serial number.



6. The files within each of these folders (or the folders themselves and their contents) can now be input into any EMR using the same process that was used with floppy disks.

Notes/Additional Information

- Data cannot be read from a pen drive or floppy disk and then saved to the PRM hard drive. If the patient records are still on the PRM, then initialize another pen drive and Export the patient records to the second pen drive.
- There is no way to copy data from a pen drive to another pen drive or to copy data from a floppy disk to a pen drive.
- Patient records are encrypted before being transferred to a pen drive to protect patient privacy.
 - Records are zipped, encrypted (128 bit) and stored in a *bsc/patientData* folder as *model_serialnumber.zip* (USB Drive password is needed to get to the raw data files).
 - Also stores *ArchiveIndex.zip*, which is a password (same) protected file that contains the programmer serial number, MAU version, date/time at time of the latest export and the list of devices/patients on this pen (connects device model/serial number with patient name).

Save to Disk

Save to Disk saves therapy history (event details and Arrhythmia Logbook) and parameter files to external archive disk when a disk is present in the programmer.

Feature Comparison to Previous Devices

Feature	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Saving during an ATR episode	User will get a message stating <i>Episode in progress. Try again when complete.</i> All episodes except the one in progress will successfully save to disk.	No warning message. All episodes except the one in progress will successfully save to disk.
Multiple Save All to Disks in one session	First Save All to Disk will save all episodes. Subsequent saves will only store new episodes since the last save.	Each Save All to Disk saves all episodes stored in the device. Any episodes already on the disk will be kept intact.
Copy Disk function	Available under Utilities menu.	Not available, since Save All to Disk saves all episodes every time.
Format Disk function	Available under Utilities menu.	Not available. Use a new disk or format with a PC.
Paceart Compatible	Yes	No change.
Reading a disk while in Patient mode	Disk episodes must be read in a disk session, separately from an interrogation session.	Episodes can be read from disk to augment device memory during an active interrogation session.
Saving to multiple disks	When the size of the save operation exceeds what can fit on a the disk, after it writes what it can to that disk: <ul style="list-style-type: none"> • The user is prompted to insert another disk • The user must re-initiate the Save-All-to-Disk or Save-to-Disk operation when ready 	When the size of the save operation exceeds what can fit on a the disk, after it writes what it can to that disk: <ul style="list-style-type: none"> • The user is prompted to insert another disk • The user selects Try Again and saving resumes

Availability

Whenever there are episodes stored in device memory, they can be saved to disk. Only one patient's data may be stored on a disk. Multiple follow-ups for a single patient may be saved to a single disk.

There are three ways to save to disk:

1. *Save All to Disk* in the Utilities saves all episodes in device memory.
2. If only a subset is desired, the *Save to Disk* feature on the Arrhythmia Logbook screen can be used. The latter option may be favorable in order to save time or to *weed out* episodes that are not of interest.
3. An individual event may be *Saved to Disk* from the Event Detail screen in the Arrhythmia Logbook.

Save All to Disk function

- Accessed from Disk tab of the Utilities screen.
- The following data will be saved to disk using Save All to Disk function:
 - Therapy history
 - Current programmed parameters
 - Trending values
 - Histogram paced/sensed counters

**Save to Disk from Arrhythmia Logbook**

- Ability to save only selected episodes from Arrhythmia Logbook screen:
 - Check (✓) small box to left of desired episode, or choose Select All button.
 - Select Save to Disk button to save desired episodes (grayed out when no episodes are checked).

Event	Date/Time	Type	Therapy	Duration
V - 3	13 Apr 2006 16:25	VF	2J	00:00:50
V - 1	10 Apr 2006 12:01	VF	41J	00:00:42
V - 5	17 Apr 2006 10:56	VT	No Therapy	00:00:19
ATR - 860	18 Apr 2006 10:39	ATR		01:12:10
ATR - 859	18 Apr 2006 10:38	ATR		00:00:30
ATR - 858	18 Apr 2006 09:47	ATR		00:00:09
ATR - 857	18 Apr 2006 09:44	ATR		00:02:34

Save One Event to disk from the Arrhythmia Logbook

- May save an individual event.
 - Choose an individual event by selecting the magnifying glass next to the event in the Arrhythmia Logbook.
 - From the Event summary, EGM, or Intervals screen, select Save to Disk button.

Attempt	Elapsed Time(s)	
1	00:00:03	41J V Shock Charge Time: 7.5 s Lead Impedance: 41Ω
Event Ended	00:00:43	

Using a Computer to Manage Patient Data Disks

- Contents of a patient data disk can be emailed upon the request of the customer. All files (rather than a subset) saved on disk must be included in the emailed set in order to be successfully read by recipient of email. In addition, files should not be opened on a computer prior to emailing, or data contained on disk may be corrupted.
- Contents of a patient data disk can be copied on a computer and saved to another disk.
- Disks can be formatted (erased) using a PC or using the Format Disk operation in another programmer application (e.g., VITALITY or RENEWAL software).

Reading a Disk on the Programmer

- To begin a programmer session using a patient disk, go to the Select PG screen, and choose TY+. When the Select PG Mode dialog appears, choose Read Disk.

NOTE: QuickStart cannot be used in this case because it requires an actual device to interrogate.

- To determine whether a programmer session is based on a device or a disk, check the session icon in the status bar at the top of the screen.

The **person** image indicates a patient's device has been interrogated.



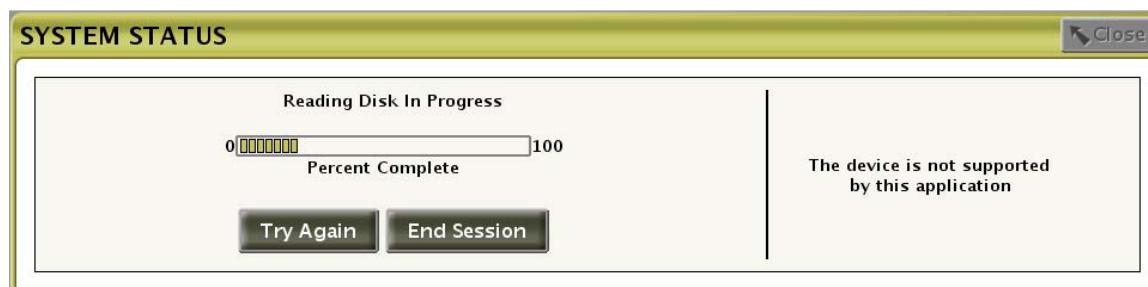
The **disk** image indicates a disk-based session.



- Episodes that are on the disk but no longer in device memory can be displayed in the Arrhythmia Logbook along with all episodes currently stored in the device. This can be accomplished by selecting Read Disk on the Utilities screen during an interrogation session.

Approved Region

When a disk is created for a device, it is encoded with the device's approval region. If the programmer is not configured for that region, it will not read the disk, even if the software key is in place. For instance, a disk from a device in Belgium cannot be read by a programmer configured to work in the U.S. When the user tries to read a disk from a different geography, this screen will appear:



Notes/Additional Information

- Format and copy disk functions are not available for the PRM software associated with devices described in this primer.
- Model 6627 disks are compatible with devices described in this primer; model 6926 disks are formatted in a manner which is not compatible with devices described in this primer.

NOTE: When ordering disks from customer service, customers and reps need to order model 6627 disks, which are DOS formatted. If 6926 disks are ordered, they will need to be reformatted with a PC or with the Format Disk function of another programmer.

application. 6926 disks come pre-formatted for the QNX operating system which is not backwards-compatible with devices described in this primer.

When saving to disk from a previous Save to Disk [Save to Disk #1 see below], the Leads Data from the previous session will not be transferred into the new disk [Save to Disk #2 see below].

Save to Disk #1

ZOOM® View™ QUICK NOTES ® Report				
Leads Data	Implant	Previous Session	Last Daily	
Atrial				
Intrinsic Amplitude	N/R mV	3.0 mV	3.0 mV	
Pace Impedance	N/R Ω	549 Ω	554 Ω	
Pace Threshold	N/R V @ N/R ms	2.7 V @ 0.4 ms		
Right Ventricular				
Intrinsic Amplitude	N/R mV	5.5 mV	5.5 mV	
Pace Impedance	N/R Ω	490 Ω	490 Ω	
Pace Threshold	N/R V @ N/R ms	3.3 V @ 0.4 ms		
Left Ventricular				
Intrinsic Amplitude	N/R mV	5.8 mV	5.8 mV	
Pace Impedance	N/R Ω	>2000 Ω	>2000 Ω	
Pace Threshold	N/R V @ N/R ms	7.5 V @ 0.4 ms		
Shock Vector				
Shock Impedance	N/R Ω	64 Ω	59 Ω	
Brady/CRT Counters Since Last Reset (10 Jun 2003)				
Atrial	19% Paced			
Right Ventricular	30% Paced			
Left Ventricular	30% Paced			

Page 2 of 5

Save to Disk #2

ZOOM® View™ QUICK NOTES® Report				
Leads Data	Implant	Previous Session	Last Daily	...
Intrinsic Amplitude	N/R mV	mV	3.0 mV	
Pace Impedance	N/R Ω	Ω	554 Ω	
Pace Threshold	N/R V @ N/R ms	N/R		
Right Ventricular				
Intrinsic Amplitude	N/R mV	mV	5.5 mV	
Pace Impedance	N/R Ω	Ω	480 Ω	
Pace Threshold	N/R V @ N/R ms	N/R		
Left Ventricular				
Intrinsic Amplitude	N/R mV	mV	5.8 mV	
Pace Impedance	N/R Ω	Ω	>2000 Ω	
Pace Threshold	N/R V @ N/R ms	N/R		
Shock Vector				
Shock Impedance	N/R Ω	Ω	59 Ω	
Brady/CRT Counters Since Last Reset (19 Jun 2009)				
Atrial	19% Paced			
Right Ventricular	30% Paced			
Left Ventricular	30% Paced			

Page 2 of 5

Format and copy disk functions are not available for software associated with devices described in this primer. Legacy device applications do have Save to Disk function but will not allow a complete duplicate of the original disk.



Printed Reports

Provide a hard-copy record of current and historic device settings and data for the patient medical record.

Navigation

The Reports screen is available by clicking the **Reports** button at the bottom of any screen.

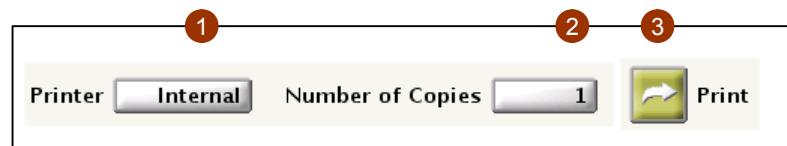
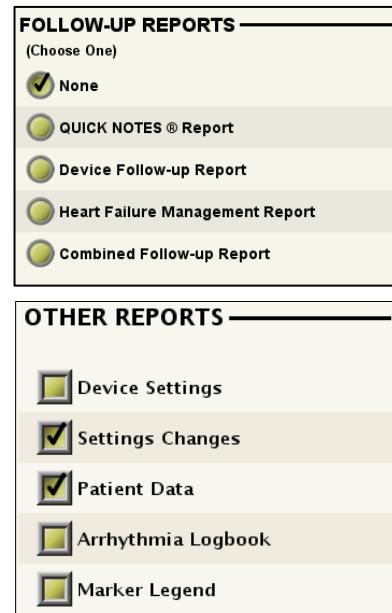


Printing Reports

- Follow-Up Reports are selected by radio button, so only one can be chosen at a time. This is because the reports present similar information in different ways. Similarly, only one Episode Report can be chosen at a time.
- The Other Reports are complementary, so they use check boxes, which allow several to be selected at once.
- To print, check the desired report(s), choose Internal or External printer, and select the number of copies. Then click the Print button.
- After a user chooses to print, the *Processing Report(s)* dialog will appear. It may show a rotating hourglass for several seconds before actual printing begins. The programmer is formatting the entire report and assigning page numbers during this time. The length of delay will vary with the size of the report.
- Printing can only be cancelled by selecting the Cancel button on the *Processing Report(s)* dialog. If this dialog is closed, the report (or reports) will print in its entirety with no other way to cancel.

NOTE: Printing to an External printer can only be accomplished

from the REPORTS screen. For example if an event is selected from the Arrhythmia Logbook, selecting Print will print the selected Episode via the Internal printer (not external printer).



Sample Report Header

Boston Scientific	ZOOM ® View™ QUICK NOTES ® Report Date of Birth Device COGNIS 100-D N107/812085 Tachy Mode Monitor + Therapy	Report Created Last Office Interrogation Implant Date
	Product name Model number Serial number	Date of last programmer-initiated (non-LATITUDE) interrogation.

Sample Report Footer

Software model	Software version
2868 Software Version: 0.26.2 N107 Firmware Version: A_v1.00.0_rc8	Copyright 2006 by Boston Scientific Corporation or its affiliates. All rights reserved. Page 14 of 14
Clinician Signature:	
Firmware version (formerly known as RAM version)	

Comparison of Follow-Up Reports

Information	QUICK NOTES ®	Device Follow-up Report	Heart Failure Management Report	Combined Follow-up
My Alerts	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Most Recent Events	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Battery Status	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Lead Measurements	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Brady/CRT Counters	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Tachy Counters		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Therapy Settings Detail	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Therapy Settings Summary			<input checked="" type="checkbox"/>	
All Events Since Last Reset	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Last Successful Rhythm ID Template		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>

Information	QUICK NOTES ®	Device Follow-up Report	Heart Failure Management Report	Combined Follow-up
Lead Trend Graphs		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Diagnostic Trend Graphs			<input checked="" type="checkbox"/>	
Histograms		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Atrial Burden Counters		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Heart Failure Trend Graphs			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
HRV Data			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

* CRT-D Models Only

Notes on My Alerts	
Tachy Mode other than Monitor + Therapy	Time reported for this alert is the time and date that the report printed, not the date of the mode change.
Check Lead	Time reported for this alert is the time and date that the report printed, not the date of the lead alert occurred.
Battery Status	Time Explant or EOL was tripped, or time report was printed if status is One Year.
Faults	Time reported for this alert is the time and date that the fault was recorded.
ATR > 48 hours	Time reported for this alert is the time and date that the episode started.

Description of Other Reports	
Episode Reports	Episode Detail for a selected episode (from Arrhythmia Logbook), all episodes since last reset, or all episodes.
Device Settings	Shows date of last programming and history of tachy mode changes. Programmed values for all tachyarrhythmia detection and therapy parameter values by zone, HF/Bradycardia parameters, and settings for magnet, beeper, telemetry, sensor trending, and daily measurements.
Settings Changes	Listing of all parameters changed during the current session. Old and new values are given as well as whether changes are pending or have been programmed.
Patient Data	All data from the Patient Data screen.
Arrhythmia Logbook	Lists episode data as seen in the Arrhythmia Logbook.
Marker Legend	Prints definitions of the annotated event markers.

Feature Comparison to Previous Devices

Feature	Previous Devices (VITALITY and RENEWAL CRT-D families)	Devices described in this primer	Rationale for Change
Page orientation	Vertical for all reports except EGMs	All reports horizontal	Based on customer feedback
Clinician signature box	No	Yes	Customers requested a designated place for physician/clinician signature
External printer support	Some models	Yes (see printer requirements in Usage section below)	Customer feedback
Can choose speed of episode EGMs	Yes	No	EGMs can be viewed on screen at different speeds
EGM measurements	EGM amplitude did not correlate to sensing amplitude	Amplitudes of waves in millivolts are accurate	Improved AGC displays and prints measurable sensing amplitudes
Measured Data Report	Yes	No	Replaced with report templates developed with customer input which include measured data
Conversion Summary Report	Yes	No	Customer feedback indicated low utilization
Settings Changes Report	No	Yes	Customers feedback

TRENDS



Trends – General Info

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Trending provides graphical views of specific patient and device data in order to evaluate a patient's condition and/or the effectiveness of programmed parameters. Up to one year of Trend results can be viewed at one time.

See the subsequent Trend Detail topics for specific information on each available trend.

Feature Comparison to Devices Launched Prior to COGNIS/TELIGEN

Trends	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Heart Rate	Provides maximum, average and minimum heart rate for each day of the last week and each week of the last year	Provides the maximum, mean and minimum heart rate for each day starting from the date of implant
Atrial Burden	Counters provide total ATR mode switches and mode switch time percentage	Provides total number of ATR events and ATR total time for each day
Daily Measures	Provides results for each day of the last week and each week of the last year	Provides results for each day starting from the date of implant

Trends	Previous devices (VITALITY or RENEWAL CRT-D families)	ICDs and CRT-Ds described in this primer
Events	Conversion Summary categorizes episodes since last reset and device totals. Arrhythmia Logbook lists all events currently in memory	Organizes events by date and groups by type. Displayed events are the same as those available in the Arrhythmia Logbook
Activity Level	Provides results for each day of the last week and each week of the last year	Provides results for each day starting from the date of implant
HRV Footprint Percentage	Provides results for each day of the last week and each week of the last year	Provides results for each day starting from the date of implant
SDANN	Provides results for each day of the last week and each week of the last year	Provides results for each day starting from the date of implant
ABM	Provides results for each day of the last week and each week of the last year	Provides results for each day starting from the date of implant

Navigation

From the EVENTS screen select  Trends

Algorithm

Trend results are reported every 24 hours.

- The 24-hour clock begins at battery connection.
- Data collection begins when the device is programmed out of Storage mode.
- The first data results will not be reported until the device has been programmed out of Storage mode for 24 hours.
- The timing of first results will be at the next scheduled 24-hour reporting time based on the device's internal clock.
- If a telemetry session is active when results are to be reported, the reporting will be delayed until the telemetry session is ended.
- The Events Trend is linked to the Arrhythmia Logbook and will populate as soon as an episode is completed rather than at the end of a 24-hour time block.

Obtaining data for some trends requires associated programmed features to be adjusted such as turning an atrial lead OFF due to chronic AF and a non-rate responsive mode for HRV Footprint Percentage.

See the Trend Detail topics for information on programmability of individual trends.

- If an associated feature is programmed OFF, the trend graph will be blank for that day and no results are provided.

Selecting Trends

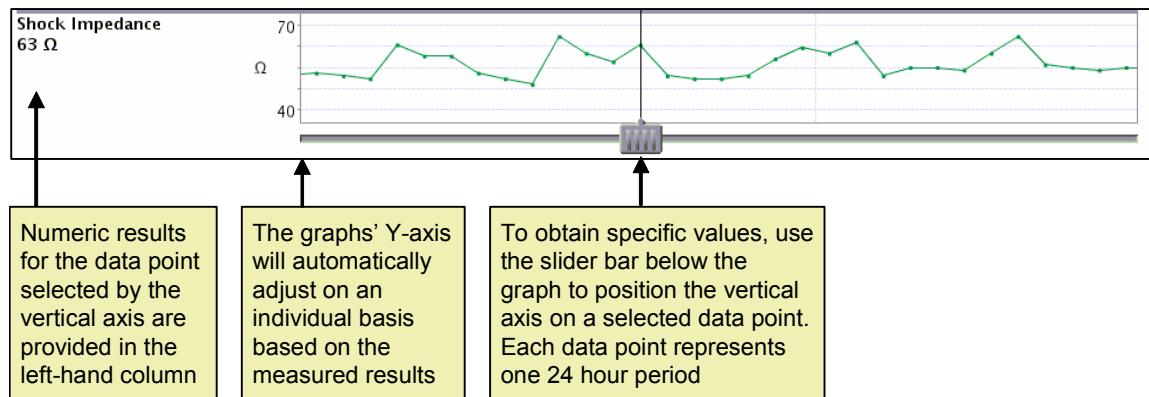
Trends can be viewed as a predetermined category or customized as desired.

To change viewed trends select  Select Trends

NOTE: TELIGEN, PUNCTUA, and ENERGEN do not contain the *Heart Failure* category.

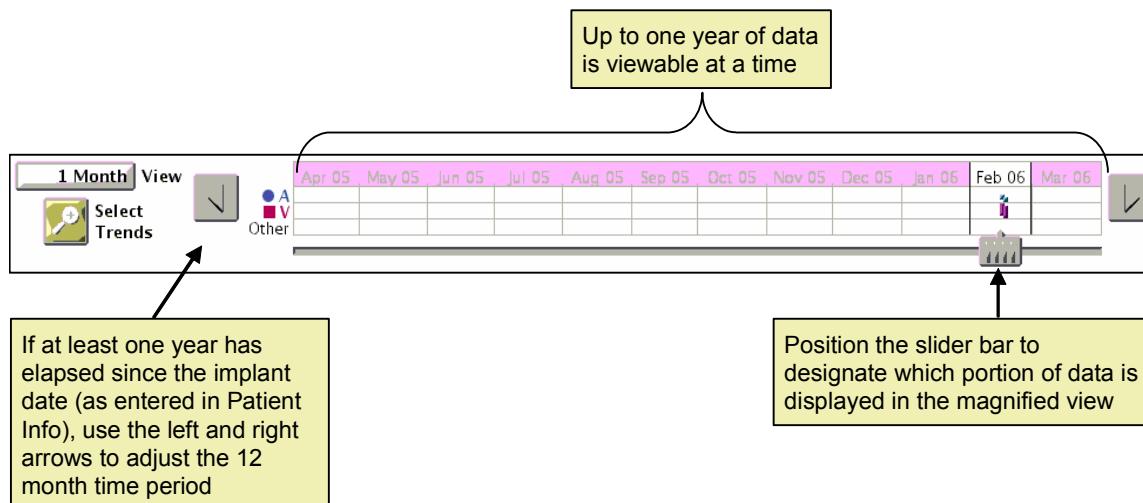
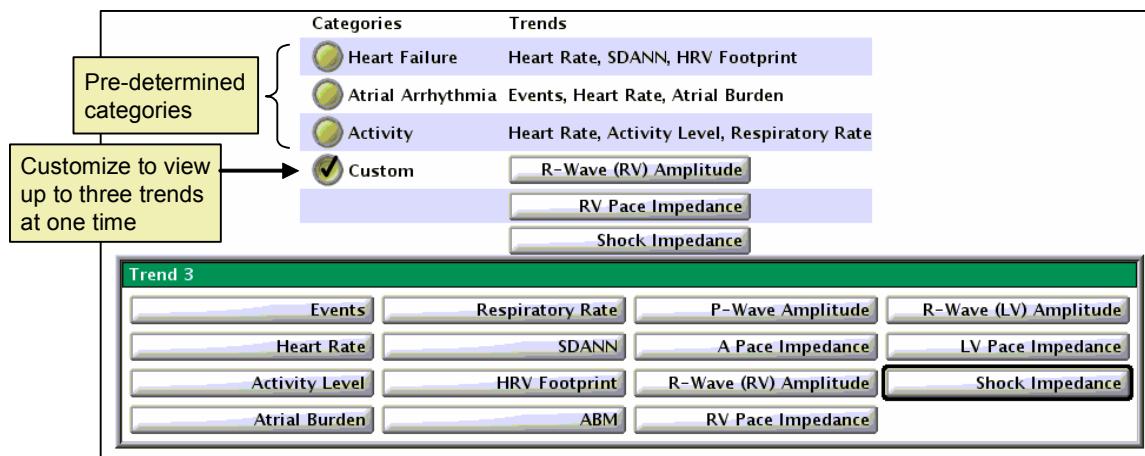
Trend Results

Results for the selected trends are graphed:

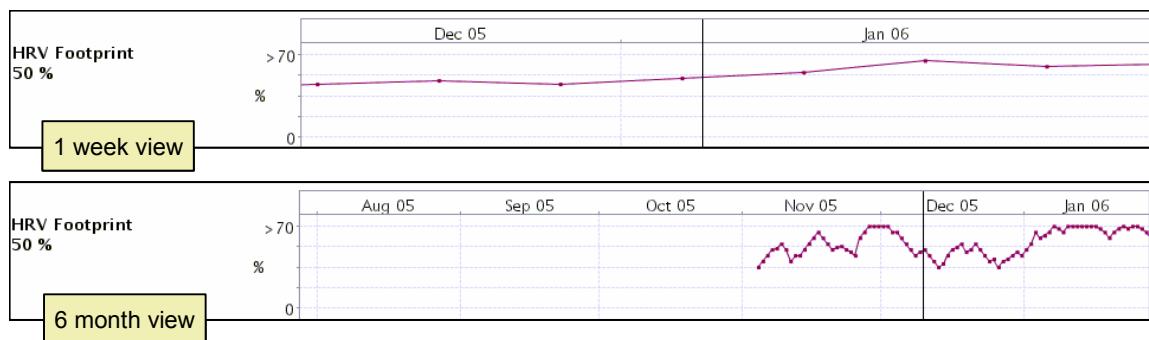


Trends can be viewed in time periods of 1 week, 1, 3 or 6 months and 1 year.

- To change the viewed time period select **1 Month View**
- One year of trend results are available for all trends other than the Events Trend. The Events trend is linked to the Arrhythmia Logbook and therefore may have data available which is older than one year.



As the time period viewed increases (i.e., 1 week to 6 months to 1 year), data will compress.



Notes/Additional Information

- Results graph can be printed via the Reports Tab and is found within the *Heart Failure Management Report* or *Combined Follow-up Report*. The most recent three months of data is available for printing.
- Trending data cannot be cleared/erased.
- To position trend results on appropriate days, the programmer evaluates the date associated with the most recent Daily Measurement results and counts backward to match a data point to a day.

Trends – Heart Rate



The Heart Rate Trend provides a graphical view of a patient's maximum, mean, and minimum right ventricular heart rate each day.

Availability

Always ON (non-programmable) and data will be collected in all pacing modes.

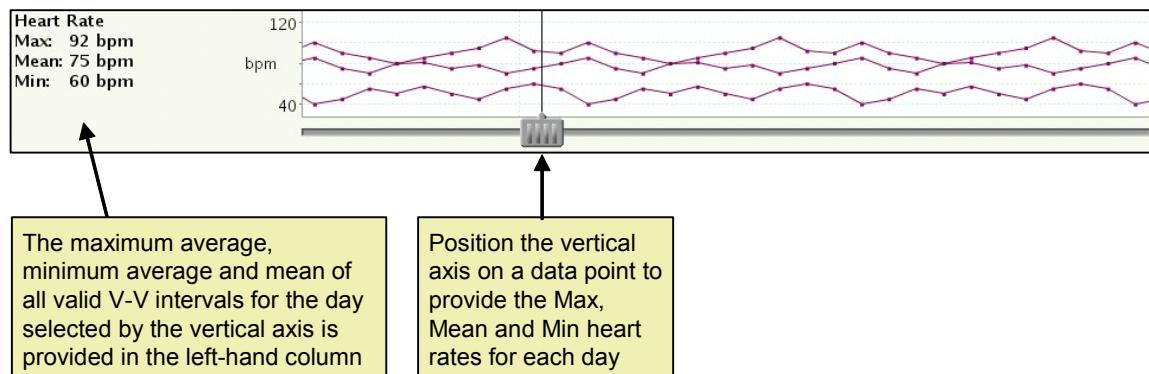
Algorithm

The Heart Rate Trend collects data by averaging the right ventricular rate for each of 288 5-minute segments within a 24 hour period. The trend uses valid V-V intervals for RV paced and sensed events which follow non-arrhythmic, intrinsic atrial events.

Intervals included in trend data collection	Intervals not included in trend data collection
<ul style="list-style-type: none"> RVS following sinus AS (below MTR and above LRL) Tracked RVP following sinus AS (below MTR and above LRL) {RVP} (RV pseudo-pace) following sinus AS (below MTR and above LRL) 	<ul style="list-style-type: none"> RV event following any AP RV event occurring after A event above MTR or at the LRL PVC Two AS occurring with no intervening V event RVP-Ns beats RVP due to Rate Smoothing Non-tracked RVP (CRT-Ds only) Rate-Adaptive RVP (CRT-Ds only)

See *Histograms and Counters under the Events* \Rightarrow *Patient Diagnostics* selection to view further heart rate count details.

Trend Results



- The range of reported values is unlimited.
- The scale next to the graph will automatically adjust with a minimum of <40, 40, 60 or >60 bpm and a maximum of 120, 160, 180 or >180 bpm.

Notes/Additional Information

- N/R will be reported for all values if less than 67% of recorded intervals are considered valid for one 24 hour period.
- Resetting the Histograms and Counters will not erase the Heart Rate Trend data.
- In AAIR mode, the Heart Rate Trend will obtain data as long as the tachy mode is programmed to Monitor or Monitor + Therapy.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Trends – Atrial Burden

The Atrial Burden Trend reports the total number of ATR mode switch events and the total amount of time a patient is in a mode switch each day. The Atrial Burden results found under Brady/CRT Counters provides an additional break-down of total ATR episodes by duration as well as total PACs.

See the Histograms and Counters topic as well as the ATR topic for further details.

Availability

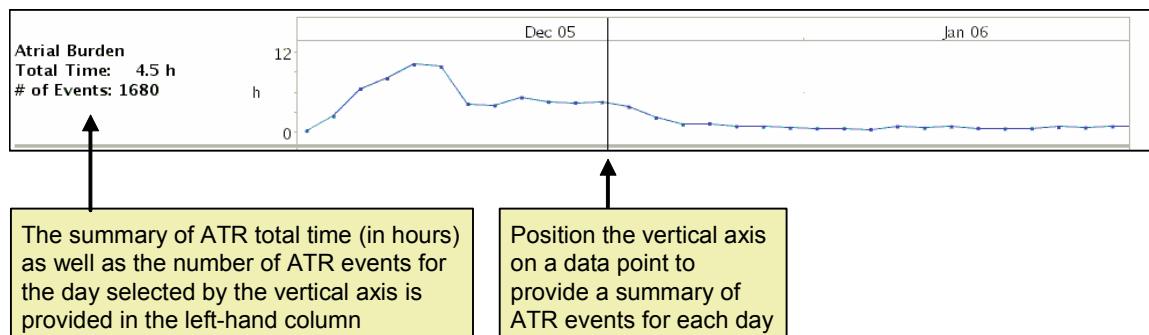
Results are available in DDD(R) and VDD(R) modes when ATR Mode Switch is programmed ON.

Algorithm

The Atrial Burden Trend is updated when an ATR mode switch episode ends and the device returns to a tracking mode. If an ATR episode extends past one day, the total time will be included in that day's results, but the event will not be tallied until the day the episode ends. For example, if an ATR episode begins five hours prior to the end of a 24-hour period and persists continuously for 60 hours:

- Day 1 would report a Total Time of 5 hours and 0 events (an event is not tallied since the ATR was still in progress at the end of the day).
- Day 2 and 3 would report a Total Time of 24 hours each day and 0 events.
- Day 4 would report a Total Time of 7 hours and 1 event (event is tallied on Day 4 since the ATR event ended on that day).

Trend Results



- The range of reported values for Total Time is 0 to 24 hours and Number of Events is unlimited.
- The hours scale next to the graph will automatically adjust with a minimum value of 0 hours with maximum values of 3, 6, 12, 24 or >24 hours.

Notes/Additional Information

- ATR Mode Switch is nominally ON and if the feature is turned OFF, no results will be reported.
- An EGM will be stored in the Arrhythmia Logbook when ATR criteria are met.
- The Atrial Burden Trend cannot be cleared and the resetting of Histograms and Counters will not erase the data.

ICD	INCEPTA ENERGEN PUNCTUA TELIGEN	CRT-D	INCEPTA ENERGEN PUNCTUA COGNIS
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Trends – Daily Measurements

Records up to one year of daily intrinsic amplitude, lead impedance and shock lead impedance measurement. A lead impedance test can be performed and used as a relative measure of lead integrity over time. A shock impedance test is a useful tool in detecting shocking lead integrity changes over time. The intrinsic amplitude test measures the intrinsic P- and R-wave amplitudes for the respective chambers.

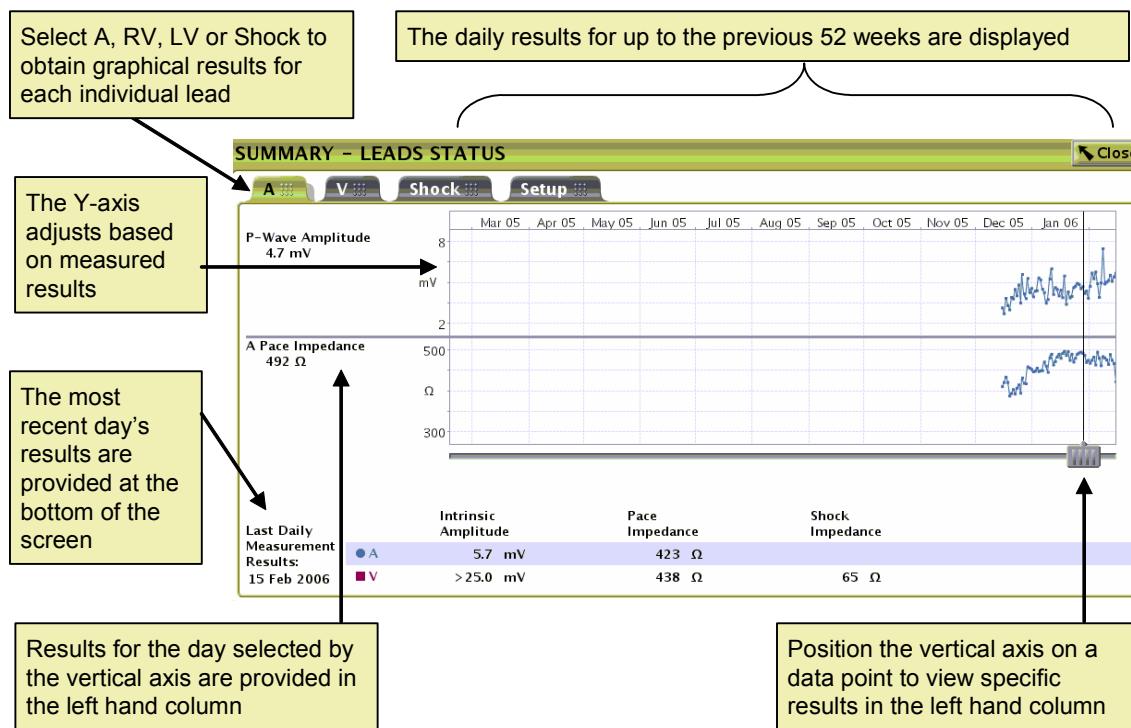
Availability

Navigation: From the Summary screen select



Programmable Values

- Select  to enable or disable lead measurements for A, RV, LV and Shock.
- Individually Programmable ON/OFF.
- Nominal: ON.



Results

Measurements are collected every 21 hours and reported at the end of a 24-hour time block. The 24-hour internal clock begins at battery attach and the first data collection occurs 21 hours after the device is programmed out of Storage mode.

- No data is reported until the device has been out of Storage mode for 24 hours.
- The first results will be reported at the next scheduled 24-hour reporting time based on the device's internal clock.

If the device is unable to obtain one or more daily measurements at the scheduled 21-hour time, up to three re-attempts for the unsuccessful measures will be performed at one-hour intervals. Re-attempts do not change the timing of daily measures and the next day's measurement will be scheduled 21 hours from the initial attempt.

- If a valid measure is not recorded after four total attempts (initial plus three re-attempts), the measurement will be reported as Invalid Data or No Data Collected.
- If a valid measure is not collected by the end of a 24-hour time block, the measurement will be reported as Invalid Data or No Data Collected for that day (regardless of the number of re-attempts).
- If no data or an out-of-range measure is recorded for a particular day, no data point is displayed for that day and therefore gaps can be observed on the graph.

When the device is programmed out of Storage mode, the PG notes the date from the PRM (programmed under Utilities ⇒ Date and Time). Daily Measurement results are date stamped by the PG and this date is shown with the Last Daily Measurement results.

- Since eight measurements will be recorded in seven days, one day will contain two measurements. If one measurement is valid and one invalid that day, the valid measure will be reported. If both measurement are valid, the second measurement will be reported.

Out of Range Measures

A warning message will be provided in the Pop-up Summary on initial interrogation as well as on the System screen next to the Leads selection when any daily lead measurement is out-of-range.

Possible lead messages:

-  Indicates daily lead measurements fall within the *Out Of Range Limits* as listed below.
-  **Check RV Lead** (and/or A Lead, LV Lead, Shock Lead) Indicates daily lead measurement(s) fall outside of the *Out Of Range Limits* as listed below.

To determine which measurement is out-of-range for the lead listed, evaluate the corresponding lead's daily measurement results. The warning message will automatically clear when the current session is ended.

NOTE: No out-of-range measures will cause the device to beep (a daily out-of-range shock impedance causes beeping in devices launched prior to COGNIS/TELIGEN).

Range of reported values

Lead Measurement	Range of Reported Values	Out of Range Limits
P-Wave Amplitude (mV)	<0.1 to >25.0	Min: 0.5
		Max: None
A Pace Impedance (ohms)	<200 to >2000	Min: 200
		Max: 2000
R-Wave (RV) Amplitude (mV)	<0.1 to >25.0	Min: 3.0
		Max: None
RV Pace Impedance (ohms)	<200 to >2000	Min: 200
		Max: 2000
Shock Impedance (ohms)	<20 to >125	Min: 20
		Max: 125

Lead Measurement	Range of Reported Values	Out of Range Limits
R-Wave (LV) Amplitude (mV)	<0.1 to >25.0	Min: 3.0
		Max: None
LV Pace Impedance (ohms)	<200 to >2000	Min: 200

Algorithm

Intrinsic Amplitude

The device passively attempts to measure an intrinsic P- and R-wave during one 255 cardiac cycle period. Only one sensed event is required for a measurement.

- Pacing rate is not changed in order to obtain a measurement.
- If a daily measurement is turned ON but sensing is not enabled in that chamber (i.e., atrial intrinsic amplitude in VVI mode), the sense amplifier for that chamber is activated long enough to attempt a measurement. If a daily measurement is turned OFF in the Setup screen, the test will not be performed.
- If a lead port is plugged but that chamber's amplitude test is not deactivated, a low amplitude measured value may be recorded despite the lack of a true input signal.

Displayed values:

- Successful measurement value
- No Data Collected for one of the following reasons:
 - All events during the testing period are paced
 - All sensed events during the testing period are PVCs/PACs
 - Noise is detected during the entire testing period
 - All sensed events are in refractory
 - Measurement turned OFF
 - Test cannot be performed (see Notes below for situations in which testing is not performed)
 - 21 hour test and three re-attempts are unsuccessful

Lead Impedance

Unlike lead impedance measurement algorithms in devices launched prior to COGNIS/TELIGEN, devices described in this primer *do not utilize a high output pacing pulse* in order to obtain a measurement. Rather, a *triggered pulse* of 80 μ A amplitude is delivered in the programmed pacing vector, the voltage is measured, and impedance is then calculated using Ohm's Law. The magnitude and frequency of this pulse is not large enough to capture the myocardium and it is timed to occur during blanking periods so that it will not be sensed by the device.

- If a lead is not implanted or not in use (i.e., implanted atrial lead in VVI mode), a lead impedance measure will still be attempted until it is turned OFF in the Setup screen. Measures of >2000 ohms will be reported if there is no lead in the port.

Displayed values:

- Successful measurement value
- Invalid Data
 - Measurement turned OFF
 - Noise is present in a particular chamber
 - Test cannot be performed (see Notes below for situations in which testing is not performed)
 - 21 hour test and three re-attempts are unsuccessful

Shock Lead Impedance

In devices launched prior to COGNIS/TELIGEN, shock lead impedance measurement algorithms delivered a pulse of 15 mA @ 60 µs synchronously with a sensed R-wave. ICDs and CRT-Ds described in this primer deliver a smaller, asynchronous pulse of 80 µA @ 156 µs in the currently programmed shock lead vector. The voltage is measured in the same vector and impedance is then calculated using Ohm's Law. The magnitude of this pulse is not large enough to capture the myocardium or be sensed by the device. If there is an out-of-range impedance measurement, testing different shock vectors may indicate which electrode is out-of-range and whether another shock vector is within normal limits and may be used.

NOTE: When changing shock vectors, perform an induction to verify that the new vector will successfully convert the patient's arrhythmia.

- If the shock lead impedance measurement is programmed to OFF, the daily measurement will not be performed.
- If a device is taken out of Storage mode and is not implanted for at least one day, it is possible that an out-of-range shock lead impedance message could be observed when the device is interrogated prior to actual use.
- A normal shocking impedance range is 20-125 ohms.
 - If too high...possible lead conductor fracture.
 - If too low...possible electrode short or insulation breach.

See the Shock Lead Integrity Test topic for further information on the management of out of range shock lead impedances.

Displayed values:

- Successful measurement value
- Invalid Data
 - Measurement turned OFF
 - Noise is present in a particular chamber

- Test cannot be performed (see Notes below for situations in which testing is not performed)
- 21 hour test and 3 re-attempts are unsuccessful

Notes/Additional Information

- Situations in which daily measurements will not be performed:
 - Ventricular episode in progress
 - Tachy therapy is active
 - During active telemetry
 - Post-Therapy Settings are in effect
 - Battery capacity depleted beyond Explant
 - LATITUDE remote interrogation is in progress
- Tests are not performed as a group in one particular order. They are performed individually so that individual re-attempts may be performed if necessary.
- Printing Daily Measurements
 - Implant, previous session and most recent values can be printed via the Reports Tab and found in the *QUICK NOTES Report*.
 - Graphs as well as implant, previous session and most recent values can be printed via the Reports Tab and found in the *Device Follow-up Report* and *Combined Follow-up Report*.
- Differences from previous device families:
 - Tabular view is not available
 - Weekly averages replaced with up to one year of data
 - Daily measurements cannot be cleared
- Rhythm ID template updates and daily measurements will be performed sequentially if they are scheduled to occur at the same time.

Trends – Events

ICD	INCEPTA	INCEPTA
	ENERGEN	ENERGEN
	PUNCTUA	PUNCTUA
	TELIGEN	COGNIS

The Event Trend provides a graphical view of all stored Arrhythmia Logbook events. The Event Trend organizes the events by date and groups by type to provide an overall view of a patient's therapy and non-therapy events. Each marker on the trend graph is a link to reach the Arrhythmia Logbook for further event details.

See Events Arrhythmia Logbook to view the logbook as well as the Arrhythmia Logbook topic for details on the storage of specific events.

Availability

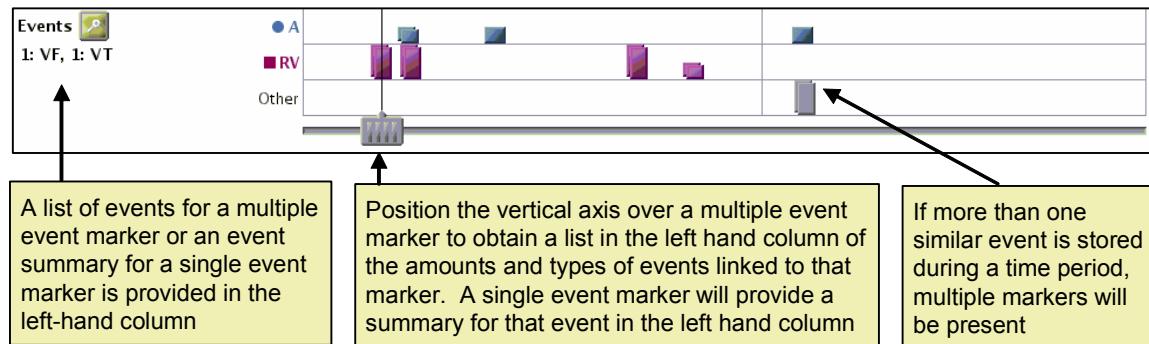
Available at all times (non-programmable).

Algorithm

Arrhythmia Logbook events will also result in a marker on the Event Trend.

- Event markers will populate the trend once an event is declared or in progress; the trend will not wait to update every 24 hours as in other trends.
- When lower priority events are overwritten in the Arrhythmia Logbook, the associated trend event markers will likewise be removed.

Trend Results



The trend will populate with event markers associated with individual or multiple logbook events.

See event marker legend below.

- The summary will show actual numbers of individual events or be labeled as *Multiple Episodes* if numerous different types of events are linked to the markers selected by the vertical axis.
- Selecting a blue, purple or gray event marker will link to Atrial, Ventricular or *Other* events respectively. To view all stored logbook events under the vertical axis, regardless of type, select ⇒
- Selecting a single episode event marker will link to that individual event in the Arrhythmia Logbook. If a multiple episode event marker is selected, a list of events linked to that marker will be shown.
- The number of events linked to an individual marker will vary depending on the time period viewed. As the time period viewed increases (i.e., 1 week to 3 months to 1 year), the time span associated with an individual marker also increases and an increased amount of events will be linked to individual markers.

Example: Event Marker Legend

Event Marker	Event Type
Single Atrial Half (Blue)	ATR Events

Event Marker	Event Type
Multiple Atrial Half (Blue)	Multiple ATR Events
Single Ventricular Full (Purple)	<ul style="list-style-type: none"> • VF Events • VT Events • VT-1 Events • Commanded Ventricular Events
Multiple Ventricular Full (Purple)	Multiple VF, VT, VT-1 and/or Commanded Ventricular Events
Single Ventricular Half (Purple)	Nonsustained Ventricular Events
Multiple Ventricular Half (Purple)	Multiple Nonsustained Ventricular Events
Single Other Full (Gray)	<ul style="list-style-type: none"> • Patient Triggered Monitor Events • Pacemaker Mediated Tachycardia Events • Advanced Patient Monitoring Events
Multiple Other Full (Gray)	Multiple PTM, PMT and/or APM Events



Trends – Activity Level

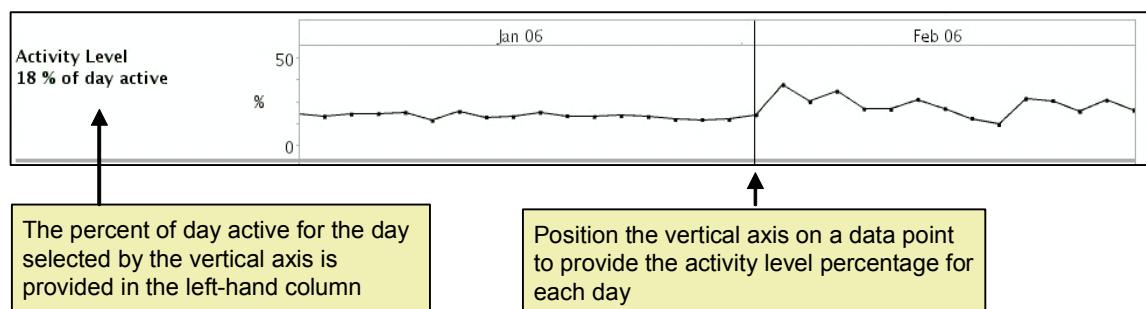
The Activity Level Trend displays a measure of the patient's activity level over time using accelerometer data. This allows the clinician to assess the patient's cardiac status by determining if their activity level is increasing or decreasing over time. Changes in the Activity Level trend may indicate changes in cardiac function as well as compliance with a cardiac rehabilitation program.

Availability

Always ON (non-programmable), brady pacing mode does not need to be programmed to a rate responsive mode.

Algorithm

Each data point represents the percentage of the day in which the accelerometer measured a force of at least 25 milligravities (mGs). This amount of force is approximately equivalent to standing from a seated position.



Trend Results

- The range or reported values is from 0-100%.
- The scale next to the graph will automatically adjust with a minimum of 0% and a maximum of 2.5, 5, 10, 20, 50 or >50%.

Trends – Respiratory Rate Trend (RRT)



Not available for
models distributed in the U.S.

The Respiratory Rate Trend (RRT) displays a graph of the patient's daily minimum, maximum, and median respiratory rate values. These daily values are stored for up to one year to create a longitudinal display of physiological data. The Respiratory Sensor must be programmed to ON for Respiratory Rate trend data to be collected and displayed.

See Respiratory Sensor Section.

The American College of Cardiology (ACC)/American Heart Association (AHA) guidelines recommend the measurement and documentation of physiological vital signs including respiratory rate for cardiac patients.⁴⁴

⁴⁴ ACC/AHA Heart Failure Clinical Data Standards. Circulation, Vol. 112 (12), September 20, 2005.

Availability

- A previous software update disabled the respiratory sensor to mitigate rare cases of oversensing of the respiratory signal resulting in inappropriate therapy⁴⁵. This issue has been rectified and details can be found in the Respiratory Sensor section.
- Available at all times regardless of rate responsiveness.
 - Data will not be collected in Storage, EOL, Temp Brady or if the Respiratory Sensor is in suspension – See the *Respiratory Signal Details* document.
- Navigation – Respiratory Sensor:

1. From the Settings Screen Select:
-  **Settings Summary**
2. Select:  **Normal Settings**
 3. Select:  **Accelerometer**

Programmable Values

- Respiratory Sensor:ON/OFF.
- Nominal = OFF.

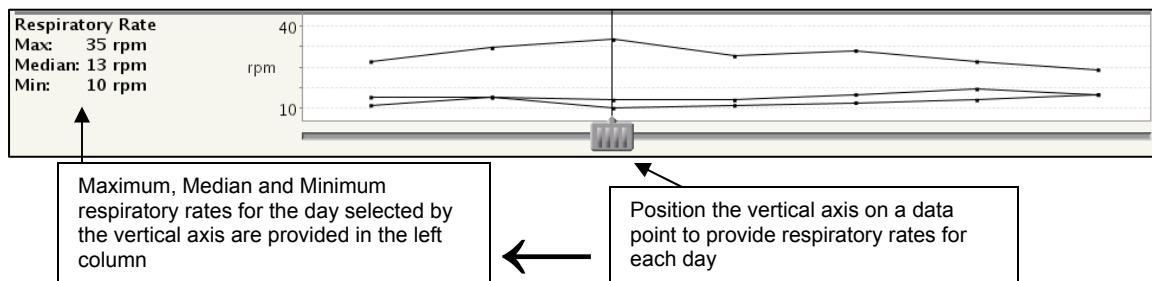
Algorithm

The values reported for RRT are established by arranging the Respiratory Sensor data into time blocks:

Maximum Reported Value	<ul style="list-style-type: none"> • Based on 10 minute time blocks which are used to assess periods of activity which are normally relatively short in duration • The median value for each time block is established and the highest median value from the entire day's 10 minute time blocks is reported • Invalid Measurement, "IM" is reported if less than 1/2 of the 10 min time block results are valid
Median Reported Value	<ul style="list-style-type: none"> • Uses a full 24 hours as its time block and the median value is reported
Minimum Reported Value	<ul style="list-style-type: none"> • Based on 30 minute time blocks which are used to provide stable estimates of long periods of inactivity such as sleep • The median value for each time block is established and the lowest median value from the entire day's 30 minute time blocks is reported • Invalid Measurement, "IM" is reported if less than 2/3 of the 30 min time block results are valid

⁴⁵ Respiratory Sensor Oversensing advisory dated 23 March 2009.

Trend Results



- The range of reported values is unlimited.
- The scale next to the graph will automatically adjust with a minimum of 0, 5 or 10 rpm and a maximum of 40, 50, 60 or >60 rpm.

Maximum rate

- Most specific measure of activity level.
- Should be significantly higher than minimum (up to 3-4 times that of resting) and vary day to day.
- Normal maximum respiratory rate is approximately 30-50 breaths per minute.

Median rate

- Corresponds most closely to resting respiration rate.
- Median is the middle number in a set of numbers in numerical order and is less affected than a mean on extreme values resulting from transient changes in rate such as exercise and deep sleep.
- Normal median respiratory rate is approximately 14-18 breaths per minute.

Minimum rate

- Most specific measure of respiratory distress.
- Minimum ≥ 20 breaths per minute is indicator of rapid, shallow breathing.

Table 1: General Trend Scenarios

Healthy, active patient	<ul style="list-style-type: none"> Low daily min, probably occurring during sleep Slightly higher daily median rate Much higher, more variable daily max rate due to activity, day-to-day variability
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Healthy, sedentary patient	<ul style="list-style-type: none"> • Low min, probably occurring during sleep • Median rate slightly higher than min • Max rate slightly higher than min/median due to limited activity • Less day-to-day variability in max
Heart Failure patient	<ul style="list-style-type: none"> • Somewhat elevated min, median, and max rates chronically • Sharply elevated rates during periods of low exertion associated with developing decompensation episodes

Notes/Additional Information

- During mechanical ventilation, respiration-based trending may be misleading; therefore, the Respiratory Sensor should be programmed to OFF.
- Not Recorded (N/R) is reported if the Respiratory Sensor is turned OFF for an entire day or a partial day where less than the required time blocks are recorded/valid.
- The longevity estimates in the system guide were calculated with the assumption that Respiratory Sensor is programmed ON.
- A device reset will result in a reinitialization of the Respiratory Sensor and that day's data will be lost. Previous data already recorded in the trend will remain.

Trends – HRV, SDANN, ABM



HRV, SDANN, and ABM Trends provide the clinician with historical graphs of daily results for each of the three heart failure measurements:

HRV Footprint percent – the percentage of the total HRV graph which is covered by the footprint plot. Heart Rate Variability (HRV) is a measure of the change in a patient's intrinsic heart rate within a 24-hour collection period.

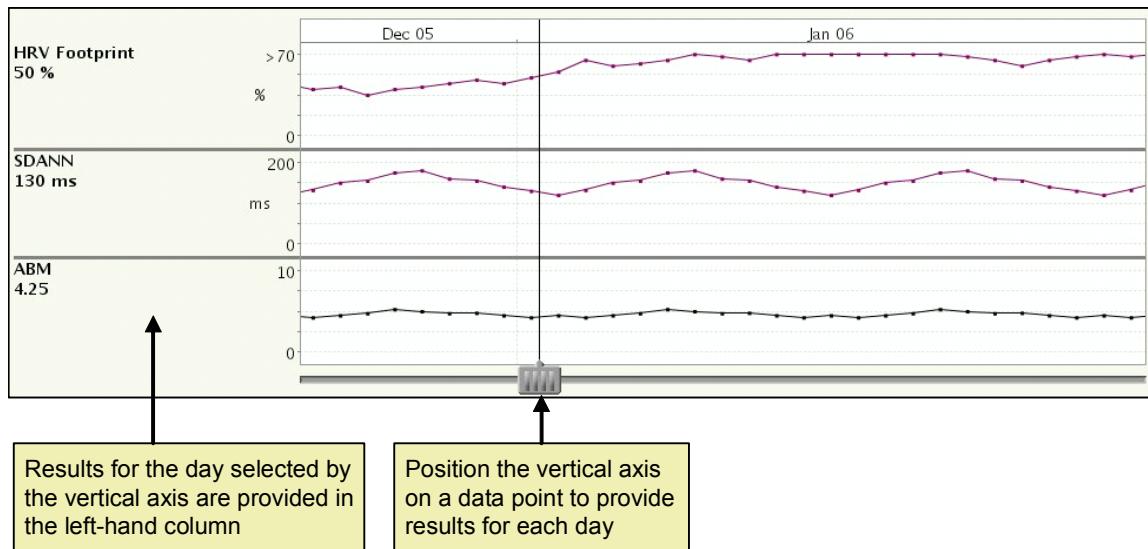
SDANN – (standard deviation of averaged normal-to-normal R-R intervals) is the standard deviation (in ms) of the averaged sinus intervals for 288 5-minute collection periods (24 hours).

ABM – is a surrogate measure of the low-frequency / high-frequency (LF/HF) ratio. Based on R-R interval measurements, this ratio is a measure of sympathovagal balance and reflects sympathetic modulation.

See the Heart Rate Variability topic for specific information on how the HRV Footprint, SDANN and ABM results are developed as well as normal values.

Availability

- Available in VDD or DDD modes.
- Not available in rate responsive modes.
- Not available in non-tracking modes.



Trend Results

HRV

- The range of results for the percentage shown is 0-100%.
- The scale next to the graph will automatically adjust with a minimum of 0 % and a maximum of 20, 30, 40, 50, 60, 70 or >70%.

SDANN

- The range of results for ms shown is unlimited.
- The scale next to the graph will automatically adjust with a minimum of 0 ms and a maximum of 100, 150, 200, 250, 300, 350 or >350 ms.

ABM

- The range of results for the ratio shown is 0 to 200.
- The scale next to the graph will automatically adjust with a minimum of 0 and a maximum of 1, 2, 5, 10, 20 or >20.
- ABM is a surrogate for LF/HF ratio. Based on R-R interval measurements, this ratio is a measure of sympathovagal balance and reflects sympathetic modulation).

See the Heart Rate Variability topic for specific information on how the HRV Footprint, SDANN, and ABM results are developed as well as normal values.

Notes/Additional Information

- Copying last to reference in HRV does not clear the HRV Footprint, SDANN or ABM trends.
- No values for the day will be reported if less than 67% of recorded intervals for the 24-hour period are considered valid, if the device is reprogrammed during the 24-hour period, or if the device is not in VDD or DDD mode.



Trends – ApneaScan

ApneaScan is a trend of the average number of respiratory disturbance events the patient experiences per hour during a programmed sleep period. It is modeled after accepted sleep clinic scoring methodologies for detection of apnea and hypopnea,⁴⁶ and may be used along with other clinical information to identify patients who may be at high risk for sleep-disordered breathing.

The pulse generator considers a respiratory disturbance event to be a 26% or greater reduction in the respiratory signal amplitude, lasting at least 10 seconds. The average is calculated by dividing the total number of respiratory disturbance events observed during a sleep period by the total number of hours in the sleep period. These averages are plotted once a day to the ApneaScan trend.

ApneaScan provides a daily measurement of the apnea-hypopnea index (AHI):

$$\text{Daily Apnea-Hypopnea Index (AHI)} = \frac{\text{apnea events} + \text{hypopnea events}}{\text{Total sleep hours per night}}$$

The AHI is reported each day by counting the number of:

- **apneas** (cessation of breathing)
- **hypopneas** (decrease in breathing)

Availability

- A previous software update disabled the Respiratory Sensor to mitigate rare cases of oversensing the respiratory signal resulting in inappropriate therapy.⁴⁷ This issue has been rectified and details can be found in the Respiratory Sensor section.
- Available at all times regardless of rate responsiveness.
 - Data will not be collected in Storage, EOL, Temp Brady or if the Respiratory Sensor is in suspension.

See the Respiratory Sensor section.

⁴⁶ Meoli et. Al., Sleep, Vol. 24 (4), 2001.

⁴⁷ Respiratory Sensor Oversensing advisory dated 23 March 2009.

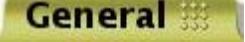
Navigation

Respiratory Sensor

1. From the Settings screen Select  **Normal Settings**
2. Select  **Accelerometer**

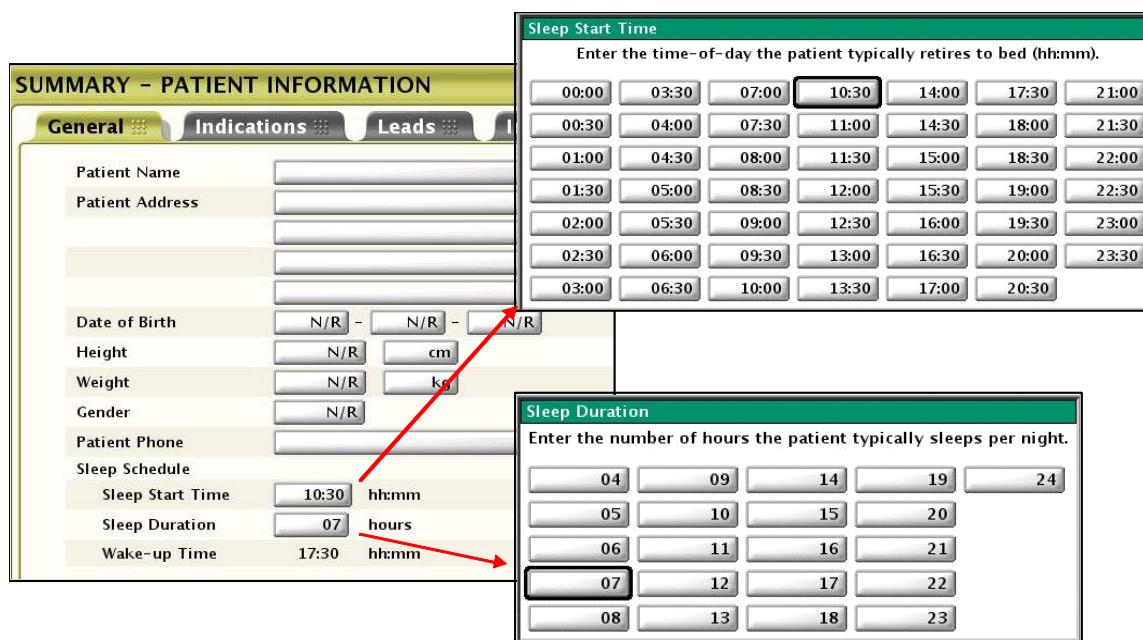
Settings Summary

Sleep Schedule

1. From the Summary screen Select  **Patient Info**
2. Select  **General**

Programmable Values

- Respiratory Sensor: ON/OFF. Nominal = OFF
- Sleep Schedule
 - Sleep Start Time: 00:00 to 23:30 (hh:mm). Nominal = 23:00
 - Sleep Duration: 04 to 24 hours. Nominal = 7 hours



Algorithm

- ApneaScan collects data during a programmable time period when the patient is expected to be sleeping. The Wake-up Time is automatically calculated from the Sleep Start Time and Sleep Duration.

- Apnea and hypopnea events are detected by assessing the amount of time between breaths that exceed a minimum baseline value.

Minimum Baseline Respiration

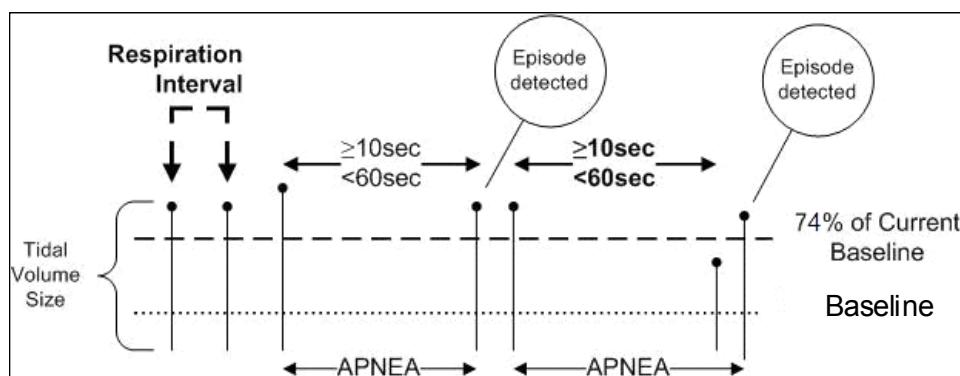
- The baseline is a weighted, 2 minute average which is continually updated using a 15/16 *old* tidal volumes and 1/16 *new* tidal volume equation.
- If small increases or decreases occur or a sudden large decrease in tidal volume occurs, the baseline will adjust gradually to account for these changes. But when a patient moves from a supine to a sitting position, the postural change can result in a significant change to the respiratory sensor signal by changing ventilation and blood flow distribution in the chest.
- To allow for this change in position, if a sudden large change in tidal volume occurs, the algorithm will quickly readjust the baseline:
 - If a large (4X baseline), but transient increase (9 breaths or less) occurs, the baseline will update as usual.
 - If a large (4X baseline), sustained increase (10 breaths) occurs, the baseline will be increased to the new higher value. The new baseline will be held for at least 10 breaths as the baseline can only be reset as often as every 10 breaths.

Apnea

Apnea causes a patient to take large inspirations, separated by periods of no breathing. Thus, ApneaScan defines an apnea episode as:

2 consecutive large (>74% above baseline) breaths, where the time between breaths is > 10 seconds and < 60 seconds

Typical Apnea Event



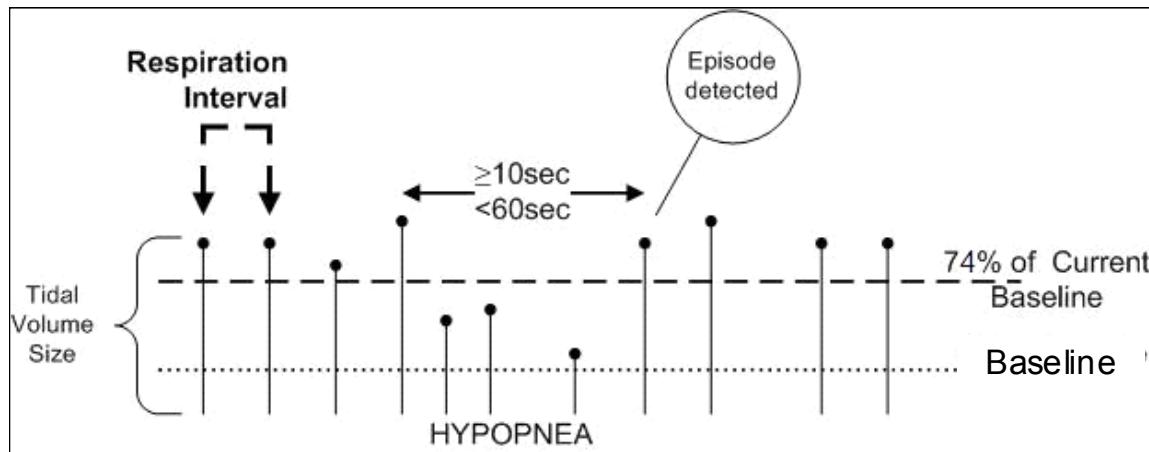
NOTE: As seen in the second episode detection above, an episode will still be defined as apnea if:

- A single small breath occurs between large breaths
- Multiple small breaths occur ≥ 10 seconds after the preceding large breath

Hypopnea:

Hypopnea causes a patient to have an abnormally shallow or slow respiratory rate. Thus, ApneaScan defines a hypopnea episode as:

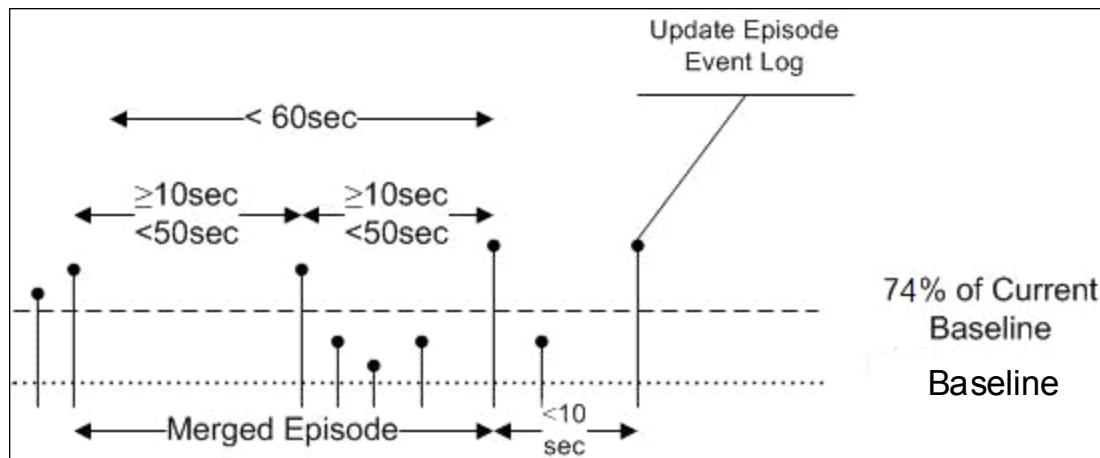
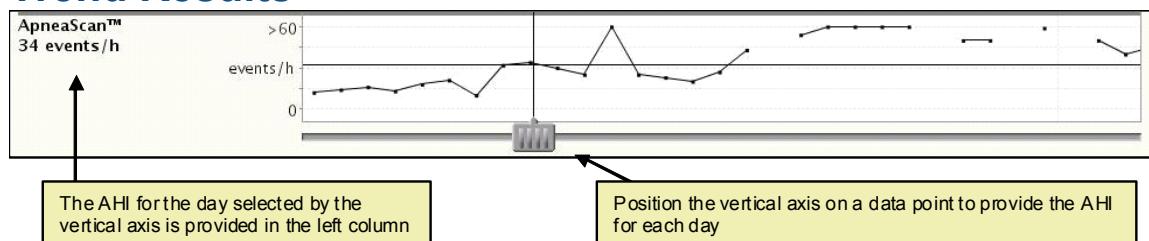
An apnea event (as defined above) which additionally contains consecutive small breaths (<74% above baseline) which occur < 10 seconds after the preceding large breath

Typical Hypopnea Event

- If two apnea/hypopnea episodes are separated by more than 60 seconds, low tidal volume signals that are below the baseline are suspected rather than just a slow breathing rate; these episodes are not counted.
- If an apnea/hypopnea episode crosses over between two hourly intervals, the episode is counted toward the second hour's total.
- AHI measurements will be suspended during:
 - High voltage activity: (charge, shock, cap dump) suspended for one hour
 - Lead impedance measurements
 - Respiratory Sensor transitions or suspensions due to noise
 - Brady Temp mode

Merged Episodes

When any combination of two apnea and/or hypopnea episodes are separated by a single large tidal volume, these episodes will be *merged* and counted as a single episode – see figure below. This is to ensure that a single spurious breath will not cause multiple episodes to be declared.

Merged Episode**Trend Results**

- Range of reported values in left-hand column is 0 to 240 events per hour.
- Y-axis minimum value will always be 0 and the maximum value can be 15, 30, 60 or >60 events/hour.
- A horizontal line corresponding to 32 events/hour is displayed on the graph. Values above this threshold may indicate the presence of sleep-disordered breathing.

The trend data is calculated by tallying the apnea and hypopnea events after every hour of the programmed Sleep Schedule. This total number of events is then divided by the programmed Sleep Duration to result in the average events/hour value.

- Data collection begins one hour after the programmed Start Time and ends one hour prior to the end of the Sleep Duration, so that data is not collected while the patient is falling asleep and waking-up.
- At least two hours of valid data must be obtained to plot a data point; therefore the minimum programmable Sleep Duration is 4 hours.
- As with all daily measures, the 24-hour daily measurement reporting time may not correlate with the wake-up time. Thus, there may be a delay in reporting results from the most recent night.
- If the device's 24-hour reporting time occurs overnight (within a current sleep schedule), data will include both the current night and previous night's data.

Notes/Additional Information

- During mechanical ventilation, respiration-based trending may be misleading; therefore, the Respiratory Sensor should be programmed to OFF.
- If the Start Time, Duration, or device clock are reprogrammed while a current Sleep Schedule is active, the AHI calculation will stop for the night and be rescheduled for the next sleep period.
- The longevity estimates in the system guide were calculated with the assumption that the Respiratory Sensor will be ON.
- A *device reset* will result in a re-initialization of the Respiratory Sensor and that day's data will be lost. Previous data already recorded is available.
- Development of this algorithm is based on data from the Rest studies: [Feasibility of Automated Detection of Advanced Sleep Disordered Breathing Utilizing an Implantable Pacemaker Ventilation Sensor, Shalaby et al, PACE 2006; 29:1036–1043](#)



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