

# LATITUDE™

PROGRAMMING SYSTEM, MODEL 3300



## WORKBOOK

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LATITUDE™ Programming System, Model 3300

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## Programmer Interface Enhancements

The user interface of the LATITUDE™ Programming System, Model 3300 balances familiarity with workflow-enhancing updates. Physicians and allied health professionals provided input to the design of this interface to help busy clinicians be more efficient at implant and follow-up.

## Workbook Layout

This hands-on guide will familiarize you with the software screens encountered during navigation of a typical follow-up for BSC devices. It is designed to be used with the Brady and Tachy demo mode on the programmer and with de-identified patient case studies which can be provided by your local BSC representative.

- If the demo mode is used no data will be present.
- De-identified patient case studies consist of stored EGMs, diagnostic data, and up to one year of trending information.

Use the Table of Contents to quickly locate specific information or to gain an overall understanding of the topics/screens contained in the workbook. Note that the topics have been assigned different colors and are organized by these colors throughout the guide.

Below each software illustration is a brief description of what is being displayed on screen and/or steps for you to follow.

*The Information contained here is not intended to replace the Instruction (or other) manual. Please refer to the manual for the full instructions for use including the contraindications, warnings, precautions, and adverse events.*

## LATITUDE™ Programming System, Model 3300

## Using Demo Mode



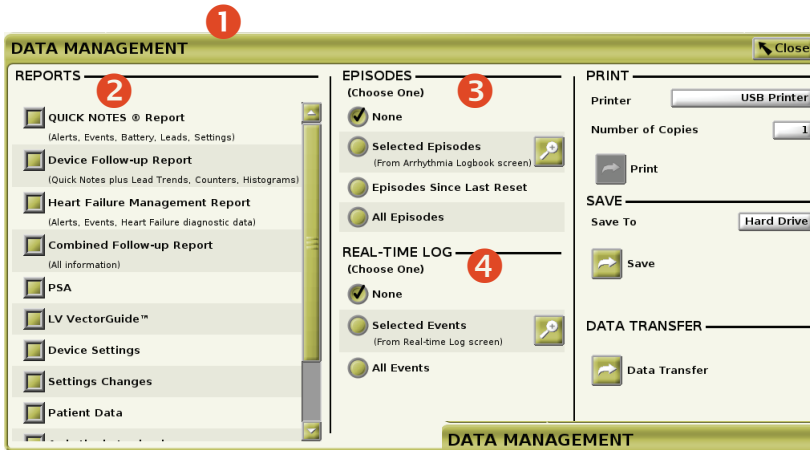
Turn on the programmer.

**Select PG** 1.

**Select ICD/CRT-D Support App** 2.

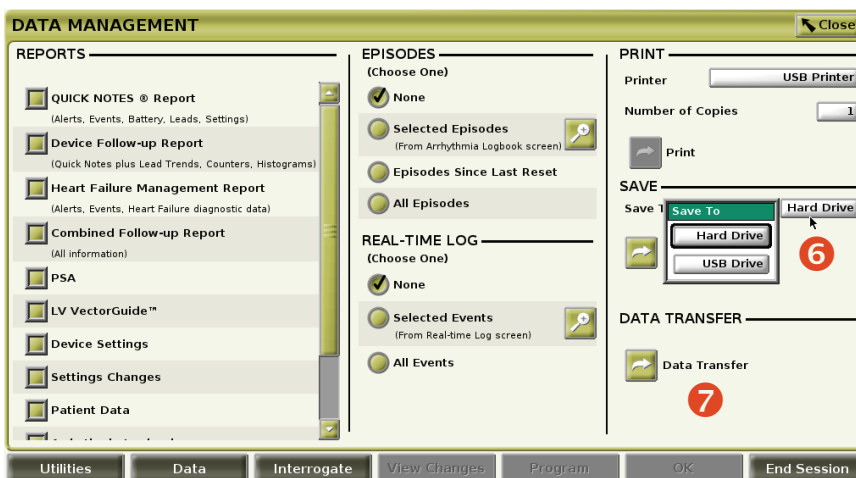
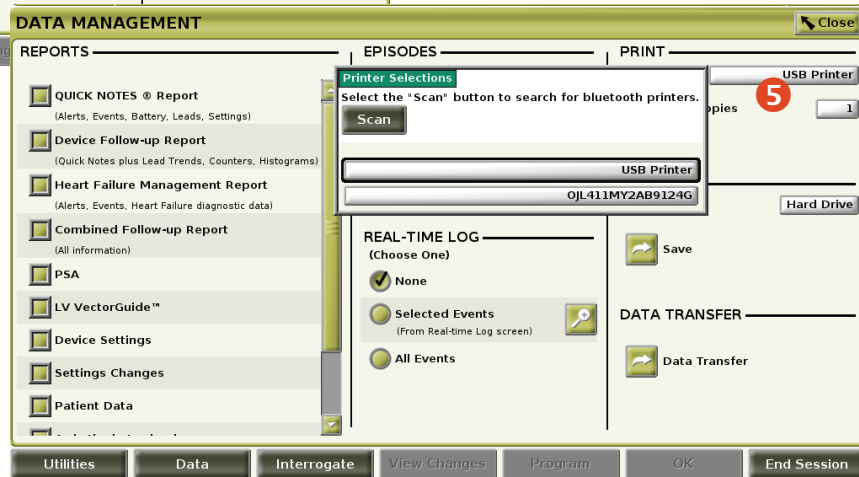
Then **Select Demo** 3.

## Printing and Saving



1 It is recommended to make **printer** selections and method to **save** patient data before device interrogation.

**Select Patient Data Management.**



2 Clinician selects desired Reports, 3 Episodes, and 4 Events,  
5 Options to Print, 6 Save and 7 Transfer Data can be selected.

## LATITUDE™ Programming System, Model 3300

## Summary Pop-up Screen

6

The screenshot displays the LATITUDE™ Programming System interface. At the top, there is a status bar with patient information (CRM D.I.D. 000650, CRM-111901), device mode (Tachy Mode), and device type (DYNAGEN X4 CRT-D CRT Defibrillator). The main screen is divided into several sections: a top section with a heart rate monitor and lead status (Lead-II, Off, Off, Off); a middle section with a 'Summary' pop-up window; and a bottom section with 'SYSTEM SUMMARY' and 'SETTINGS' tabs. The 'Summary' pop-up window is the focus, showing the following information:

- LEADS** (Warning icon): Check LV Lead (1)
- BATTERY** (OK icon): Approximate time to explant: 7.5 years (2)
- EVENTS** (OK icon): No new VTachy episodes with therapy (3)
- Close** button (5)

The background 'SYSTEM SUMMARY' section includes patient info, last follow up, implant date, device model, indications, and a battery status indicator showing an approximate time to explant of 7.5 years. The 'SETTINGS' section shows percent paced for A (56%), RV (98%), and LV (99%) leads, and ATP settings for Monitor Only.

Upon interrogation, a **Summary** pop-up screen will give you the status of:

- 1 **Leads**
- 2 **Battery**
- 3 **Events**
- 4 **Issue Status**

Select **Close** 5 on the Summary pop-up screen to continue with the follow-up.

- 6 Note: The following screens are shown using stored de-identified patient data from Patient Data Management. The information is representative only.

## Summary Screen

CRM D.I.D. 000650, CRM-111901

Tachy Mode Ventricular: Monitor + Therapy

DYNAGEN X4 CRT-D CRT Defibrillator

PSA

Lead-II

Off

Off

Off

100%

• A Rate

• RV Rate

SUMMARY EVENTS TESTS SETTINGS

SYSTEM SUMMARY

1 Patient Info

Last Follow Up 07 Mar 2017

Implant Date 01 Jan 2015

Device Model G158

Indications Paroxysmal Atrial Fib Ablated

Nonischemic Cardiomyopathy

Leads 1 Check LV Lead

Battery OK

1

Approximate time to explant: 7.5 years

EVENTS SUMMARY

1 Since Last Reset 02 Mar 2017

No new VTachy episodes with therapy OK

Percent Paced

• A 56 %

• RV 98 %

• LV 99 %

SETTINGS SUMMARY

VF	220 bpm	ATP	31J, 41J, 41Jx6
VT	180 bpm	ATP	21J, 31J, 41Jx4
VT-1	150 bpm	Monitor Only	

Mode	DDDR	-	BiV
LRL-MTR	80	-	130 ppm
Paced AV Delay	180	-	180 ms
Sensed AV Delay	120	-	120 ms
LV Offset		-	40 ms

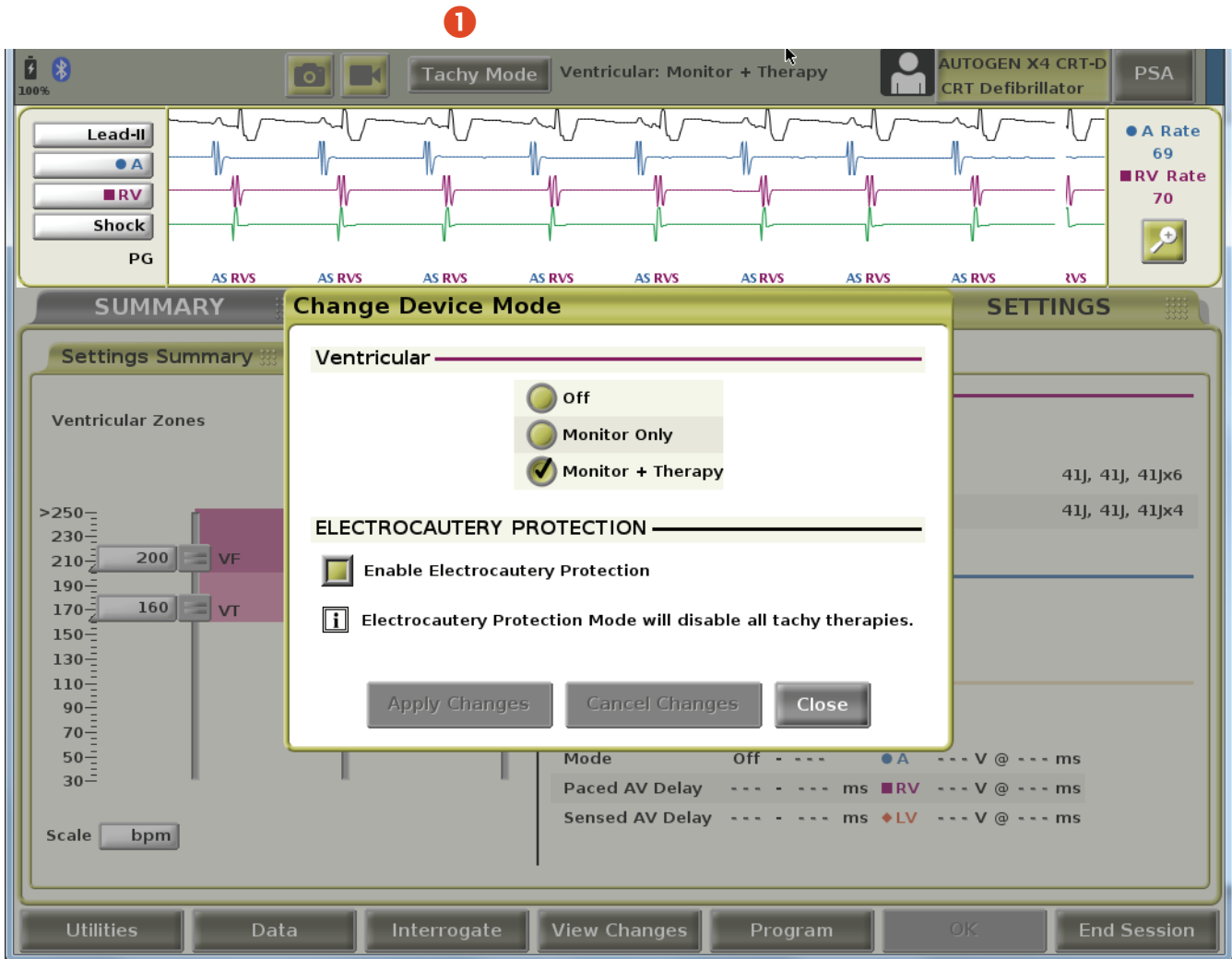
Utilities Data Interrogate View Changes Program ATTENTION End Session

The **Summary** screen provides an overview of device and patient data.

Select the relevant icon 1 for more detailed information.

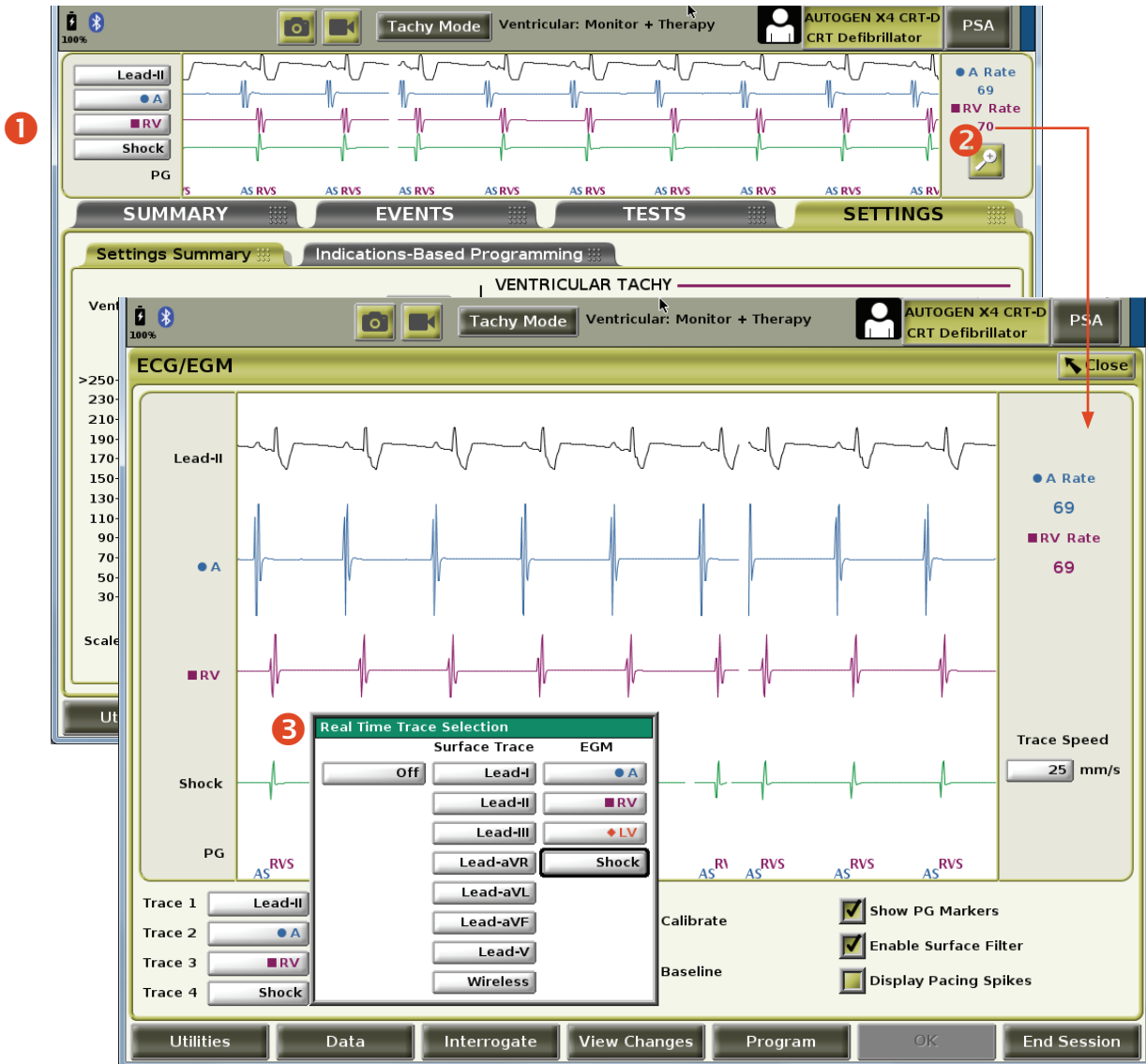


Tachy Mode



As with previous devices, **Tachy Mode** ❶ can be changed from the top of the screen.

## Enhanced EGM Functionality



The nominal display setting is surface and three EGMs **1**.

An LV EGM is available under Real Time Trace Selection **3**.

Select **Details** button **2** to enlarge the four lead channels.

Battery

**2**

**1**

**3**

**4**

**5**

**6**

**7**

**8**

**9**

- 1 Review the **Time to Explant Gauge** on the **SUMMARY** 2 tab upon device interrogation.
- 3 Select **Battery Icon** for more detail.
- 4 Select **Battery Detail** button for information 5 of power consumption, 6 percent of power used vs. nominal settings, 7 charge remaining, and last 8 delivered shock information.
- 9 This is where the **Beep when Explant** can be reprogrammed.

## Trends



From the **EVENTS** tab, *select* the **Trends** tab.

*Customize* the display by:

- 1 **View**
- 2 **Select Trends**
- 3 *Move* the scroll bar to highlight information displayed on left panel.
- 4 *Use* the macro view to scroll back in time to find earlier episodes.

## Trends (continued)



Events - Select Trends | Close

Categories	Trends
<input type="radio"/> Heart Failure	Heart Rate, SDANN, HRV Footprint
<input type="radio"/> Atrial Arrhythmia	Heart Rate, AT/AF Burden, Respiratory Rate
<input type="radio"/> Activity	Heart Rate, Activity Level, Respiratory Rate
<input checked="" type="radio"/> Custom	RV Pace Impedance LV Pace Impedance Shock Impedance

**2** Trend 3

Events	SDANN	R-Wave (RV) Amplitude
Heart Rate	HRV Footprint	RV Pace Impedance
Activity Level	ABM	R-Wave (LV) Amplitude
AT/AF Burden	P-Wave Amplitude	LV Pace Impedance
Respiratory Rate	A Pace Impedance	Shock Impedance

Utilities | Data | Interrogate | View Changes | Program | **ATTENTION** | End Session

**1** Trend data are recorded daily. Up to one year of data is stored.

**2** Select **Custom** to display any three Trends at one time.

## Arrhythmia Logbook

CRM D.I.D. 000650, CRM-111901

Tachy Mode Ventricular: Monitor + Therapy

DYNAGEN X4 CRT-D CRT Defibrillator

PSA

Lead-II

Off

Off

Off

A Rate

RV Rate

SUMMARY EVENTS TESTS SETTINGS

Trends Arrhythmia Logbook Patient Diagnostics

1 Year View

Sep 16 Oct 16 Nov 16 Dec 16 Jan 17 Feb 17 Mar 17 Apr 17 May 17 Jun 17 Jul 17 Aug 17

Event	Date/Time	Type	Therapy	Duration
V-9	05 Mar 2017 20:04	VT	No Therapy	00:00:15
V-5	01 Mar 2017 20:09	VF	No Therapy	00:00:16
V-4	01 Mar 2017 20:08	VF	31J	00:00:41
V-3	01 Mar 2017 17:22	VF	No Therapy	00:00:19
V-2	01 Mar 2017 13:12	VF	ATPx1	00:00:18
V-1	01 Mar 2017 08:35	VF	No Therapy	00:00:18
APM-9	20 Jan 2017 02:17	APM RT		-----

Select All

Deselect All

Save

Last Follow Up: 07 Mar 2017

Utilities Data Interrogate View Changes Program ATTENTION End Session

Select the column headings to sort by:

- 1 Event
- 2 Date/Time
- 3 Type
- 4 Therapy
- 5 Duration

Choose an event by selecting the respective icon for more details.

In this example, we are going to look at **V-4**.

Check which episodes you want to **Save** to Hard Drive or USB.

## Stored VF Event EGM



- 1 A 31J shock was delivered after a charge time 2 of 6.0 sec. with successful conversion of the rhythm. The intervals 3 present a visual representation of the rates measured during the episode.
- 2
- 3
- 4 Note: the zones are indicated by horizontal lines.

## LATITUDE™ Programming System, Model 3300

### Patient Diagnostics

**1**

**2**

**3**

**4**

**EVENTS - HISTOGRAMS**

**EVENTS - RATE COUNTS**

Chamber	Rate (bpm)	09 Feb 2017 to Today		26 Feb 2016 to 09 Feb 2017		09 Feb 2017 to Today		26 Feb 2016 to 09 Feb 2017	
		Paced	Sensed	Paced	Sensed	Paced	Sensed	Paced	Sensed
Atrial	0-29	0	0	0	0	0	0	0	0
Right Ventricular	30-39	0	0	0	0	0	0	0	0
Left Ventricular	40-49	0	0	11	0	0	0	0	0
	50-59	405	0	191	0	0	0	132	0
	60-69	428.1K	81	2.2M	28	0	0	35	0
	70-79	2.9M	722	13.9M	706	0	0	18	0
	80-89	4.7M	2.3K	10.9M	3.7K	0	0	7	0
	90-99	2.9M	11.5K	6.5M	16.4K	0	0	3	0
	100-109	2.0M	17.8K	5.1M	23.8K	0	0	1	0
	110-119	1.5M	21.3K	2.9M	20.1K	0	0	0	0
	120-129	764.2K	6.8K	971.8K	6.9K	0	0	0	0
	130-139	248.2K	480	161.5K	1.4K	0	0	0	2
	≥250	0	0	0	0	0	0	0	2

- 1** From the EVENTS tab, *select* the **Patient Diagnostics** tab.
- 2** To see Histogram activity *select* the **Details** button.
- 3** *Select* the **Rate Counts Details** button for information of all chambers.
- 4** *See* **Rate Counts** for chamber selected.



## Brady/CRT Counters

**EVENTS - BRADY/CRT COUNTERS** Close

	09 Feb 2017 to Today	26 Feb 2016 to 09 Feb 2017		09 Feb 2017 to Today	26 Feb 2016 to 09 Feb 2017
Last Reset on		09 Feb 2017			
Reset before last on		26 Feb 2016			
<b>Counters</b>					
% A Paced	1	<1			
% RV Paced	100	100			
% LV Paced	100	100			
<b>Intrinsic Promotion</b>					
Rate Hysteresis					
% Successful	0	0			
<b>Atrial Arrhythmia</b>					
% AT/AF (One Year of Data)	<1	<1			
Total Time in AT/AF (hr) (One Year of Data)	3.1	5.9			
<b>Episodes by Duration</b>					
< 1 minute	476	251			
1 min - < 1 hr	1	5			
1 hr - < 24 hr	1	1			
24 hr - < 48 hr	0	0			
> 48 hr	0	0			
Total PACs	123.6K	54.6K			
<b>Ventricular Counters</b>					
Total PVCs	688	1.4K			
Three or More PVCs	3	2			

Utilities Data Interrogate View Changes Program OK End Session

Reset

1 Results available since last reset and reset before last

2 PVC definition based on RV sensed events

% LV Paced also provided

Select the **Brady/CRT Counters Details** button to see additional information since last reset and reset before last. ①

② Note: Atrial arrhythmias are segmented in percentage and total time in hours, as well as by Duration.

Heart Rate Variability

**SUMMARY**   **EVENTS**   **TESTS**   **SETTINGS**

Trends   Arrhythmia Logbook   Patient Diagnostics

**HISTOGRAMS**  
Since Last Reset  
09 Feb 2017  
Details

**HEART RATE VARIABILITY**  
1 Details  
Mean 94 bpm  
SDANN 105 ms

**BRADY/CRT COUNTERS**  
Since Last Reset  
09 Feb 2017  
Details

**TACHY COUNTERS**  
Since Last Reset  
09 Feb 2017  
VF Therapy 0  
VT Therapy 0  
VT-1 Therapy 0

Utilities   Data   Interrogate   View Changes   Program   OK   End Session

**EVENTS - HEART RATE VARIABILITY**   Close

Last Measured: 09 Jun 2017 05:20 4

3 % of Time Used 88  
Footprint 36 %  
SDANN 105 ms  
2 Mode DDDR  
Sensed AV Delay 120 ms  
Ventricular Pacing Chamber BiV  
LV Offset 0 ms

Reference: 21 Oct 2012 05:57

3 % of Time Used 97  
Footprint 45 %  
SDANN 102 ms  
2 Mode DDDR  
Sensed AV Delay 120 ms  
Ventricular Pacing Chamber BiV  
LV Offset 0 ms

Copy from Last to Reference

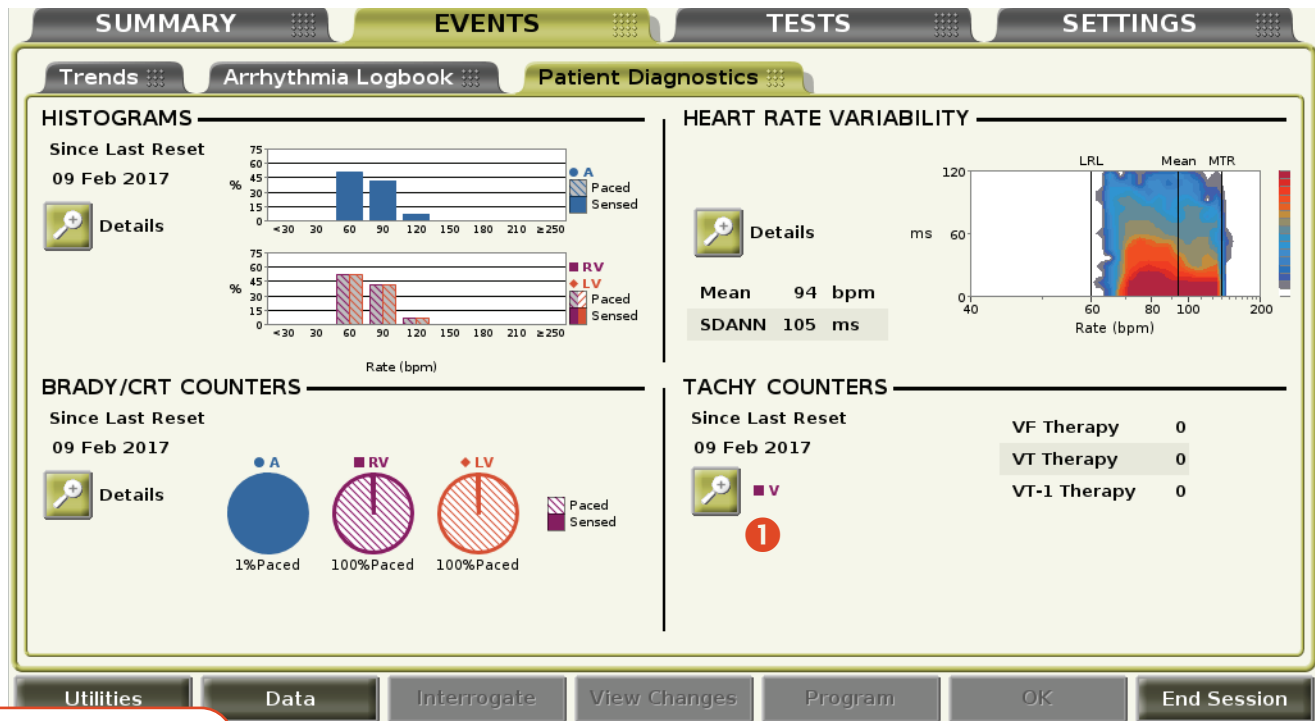
Utilities   Data   Interrogate   View Changes   Program   OK   End Session

Select the **Details** 1 button for **Heart Rate Variability** to view pacing parameters 2 and specific heart failure diagnostic information. 3

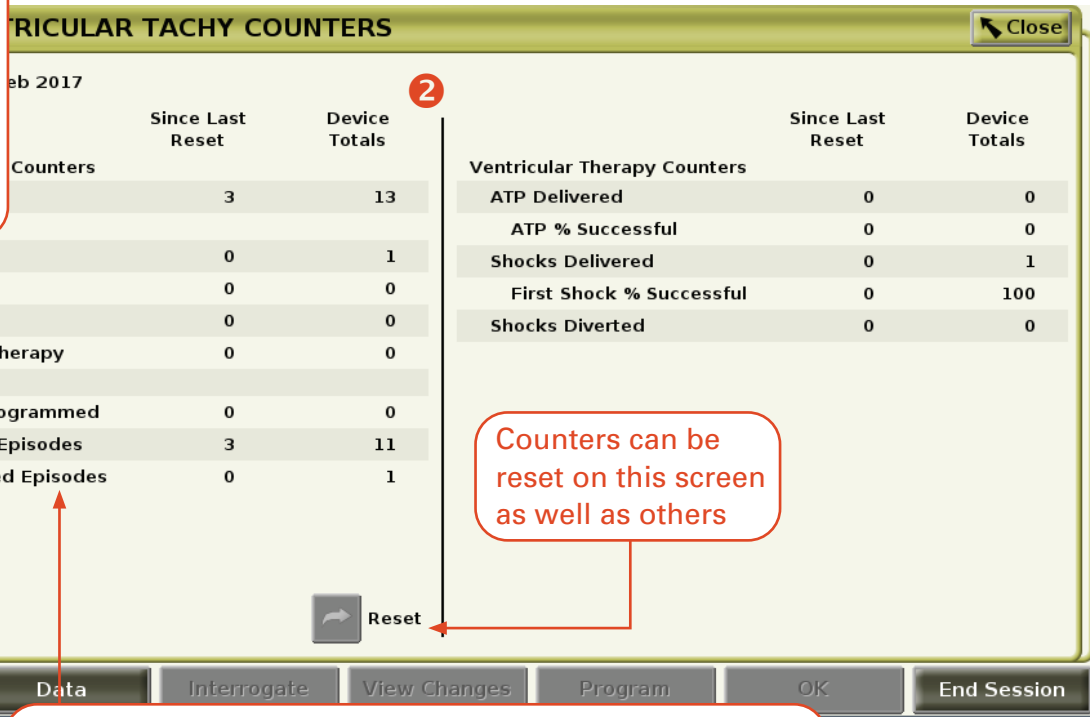
4 Note: Last measured includes a 24 hour period of averaged “5-minute” intervals.

5 The Reference plot is stored underneath for comparison.

## Tachy Counters



Therapy was not available— e.g., Monitor Only Zones, magnet applied during episode, Tachy Mode Monitor Only



Counters can be reset on this screen as well as others

Therapy was available, but diverted—e.g., user diverted, changed tachy therapy mode, divert reconfirm, etc.

- ① Select the **Tachy Counter Detail** button to view specific information regarding treated and non-treated episodes. ②

## LATITUDE™ Programming System, Model 3300

## Lead Tests

The screenshot displays the LATITUDE™ Programming System interface. The top section shows the patient's status: Tachy Mode, Ventricular: Monitor + Therapy, AUTOGEN X4 CRT-D CRT Defibrillator, and PSA. The main screen is divided into several tabs: SUMMARY, EVENTS, TESTS, and SETTINGS. The TESTS tab is active, showing a table of test results for Intrinsic Amplitude, Ventricular Rate, Pace Impedance, Shock Impedance, Atrial Threshold, RV Threshold, and LV Threshold. A red circle '1' highlights the 'Run All Tests' button. A red circle '2' highlights the 'Run' buttons for A, RV, and LV. A red circle '3' highlights the 'TESTS - LEFT VENTRICULAR THRESHOLD TEST' screen, which shows the test configuration and a 'Start Threshold Test' button. A red circle '4' highlights the 'Start Threshold Test' button. A red callout box on the left contains the text: 'Any round button can be held down for multiple continuous measurements'.

Parameter	Value	Unit
Intrinsic Amplitude	4.6, 8.6, 2.1	mV
Ventricular Rate	68	bpm
Pace Impedance	543, 476, 557	$\Omega$
Shock Impedance	51	$\Omega$
Atrial Threshold	1.7 V @ 0.4 ms	(N/R)
RV Threshold	0.8 V @ 0.4 ms	(N/R)
LV Threshold	3.4 V @ 0.4 ms	(N/R)

**TESTS - LEFT VENTRICULAR THRESHOLD TEST**

STARTING TEST VALUES

Parameter	Value	Unit
Test Type	Amplitude	
Mode	VVI	
Lower Rate Limit	90	ppm
Paced AV Delay		ms
Pacing Lead Config	LVTip1>>LVRing3	
Pacing Chamber	LV Only	
Amplitude	4.5	V
Pulse Width	0.4	ms
Cycles per Step	2	
LV Protection Period	Off	ms
LV Offset	---	ms

All lead tests may be performed from this screen.

Select **Run All Tests** ① for automatic intrinsic amplitude and pacing impedance measurements.

Each test can also be run independently for manual tests ②.

In this example, the LV Threshold Test ③, has been selected.

Select **Start Threshold Test** ④.

Note: Screens depicted are now using a live device demo on a simulator.

## LV Threshold Test Options

The figure consists of three screenshots from the LATITUDE™ Programming System interface, illustrating the steps for performing and reviewing an LV Threshold Test.

**Screenshot 1: Pacing Lead Config**  
 This window shows the configuration for the LV Threshold Test. The "Pacing Lead Config" section allows selecting a pace vector from a table. The table below shows the configuration for the LV lead (LVTip1) and other leads (LVRing2, LVRing3, LVRing4, RV, Can). The LV lead is selected with a checkmark in the "Anode (+)" column.

Vectors	LVRing2	LVRing3	LVRing4	RV	Can
LVTip1	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LVRing2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LVRing3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
LVRing4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The "Pacing Chamber" is set to "LV Only". The "Start Threshold Test" button is visible.

**Screenshot 2: Real-time Log**  
 This window displays the real-time log of the LV Threshold Test. The "Notes" section shows the test results: "3.4 V @ 0.4 ms LVTip1>>LVRing3". The "Real-time Log" section shows the test waveform with a speed of 25 mm/s. The "LOC" (Lower Rate Limit) is set to 3.5 V. The "Speed" is 25 mm/s. The "Lead-II" section shows the test waveform with a speed of 2 mm/mV. The "RV" section shows the test waveform with a speed of 1 mm/mV. The "LV" section shows the test waveform with a speed of 2 mm/mV. The "PG" section shows the test waveform with a speed of 0.5 mm/mV. The "AS" section shows the test waveform with a speed of 0.01 mV. The "LOC" section shows the test waveform with a speed of 0.01 mV.

**Screenshot 3: Information Dialog**  
 This window shows the "Information" dialog box for updating the threshold test result value. The "Current Chamber" is set to "Left Ventricle". The "Current Amplitude" is 3.0 V. The "Current Pulse Width" is 0.4 ms. The "Update" button is visible.

LV lead configuration can be temporarily changed during threshold testing ①.

Review the threshold test results on Real-time Log ②.

Pacing Threshold Test results can be edited before printing for accurate documentation ③.

## LV VectorGuide™

**1. Select Vectors:**

LVTip1  LVRing3  
 LVRing2  LVRing4  Unipolar

**2. Run Tests:**

<input checked="" type="checkbox"/>	Pace Vector	RVS-LVS Delay	Imp. $\Omega$	PNS	$\Delta$ LV Threshold
<input checked="" type="checkbox"/>	LVRing3>>LVRing4	77 ms	547 $\Omega$	No PNS 7.5V @ 0.4 ms	2.2 V @ 0.4 ms
<input checked="" type="checkbox"/>	LVRing3>>Can	77 ms	558 $\Omega$	No PNS 7.5V @ 0.4 ms	1.7 V @ 0.4 ms
<input checked="" type="checkbox"/>	LVRing3>>LVRing2	77 ms	924 $\Omega$	No PNS 7.5V @ 0.4 ms	1.7 V @ 0.4 ms
<input type="checkbox"/>	LVRing3>>RV	77 ms	600 $\Omega$	PNS 7.5V @ 0.4 ms	
<input type="checkbox"/>	LVRing2>>Can	73 ms	559 $\Omega$	No PNS 7.5V @ 0.4 ms	
<input type="checkbox"/>	LVRing2>>LVRing3	73 ms	925 $\Omega$	No PNS 7.5V @ 0.4 ms	

**3. Program Normal Brady/CRT Settings:**

Pacing Lead Config:  Amplitude:  V Pulse Width:  ms

Utilities Reports Interrogate View Changes Program OK End Session

LV VectorGuide™ streamlines LV quadripolar testing to determine the optimal LV Pacing Lead configuration for each individual patient. One screen is used for initiating tests, sorting results, and programming the selected Pace Vector.

Run **RVS-LVS Delay** ❶ and **Impedence** ❷ on all.

Then **Select Pace Vectors** with the longest **RVS-LVS Delay**. (Note: > 70 ms if possible)

Then **Perform PNS** test ❸ on those pace vectors.

Next, for those vectors with no **PNS**, **perform LV Threshold** ❹.

Last, **program** to optimal **Pace Vector** ❺.

## EP Tests

CRM D.I.D. 000650, CRM-111901

Tachy Mode Ventricular: Monitor + Therapy

DYNAGEN X4 CRT-D CRT Defibrillator

PSA

Lead-II

Off

Off

Off

• A Rate

•••

■ RV Rate

•••

SUMMARY EVENTS TESTS SETTINGS

Lead Tests EP Tests Temp Brady Manual Rhythm ID

DDDR

80-130 bpm

V: No Episode

No Therapy:

VF Duration 0% 100%

220 bpm

VT 0% 100%

180 bpm

VT-1 0% 100%

150 bpm

ATP

31J 41J Max

1x Burst

1x Ramp

21J 31J Max

Stable AFib

Sudden V>A

Atrium Ventricle

50 Hz/Manual Burst

PES

V Fib

Shock on T

Commanded ATP

Commanded Shock

S1 Pulses 8

S1 Interval 400 ms

Shock Coupling 310 ms

Energy 1.1 J

Enable

Induce

EP Temp V Mode

Monitor Only

Monitor + Therapy

Show Last Episode

EP Test Pacing

Utilities Data Interrogate View Changes Program ATTENTION End Session

This screen provides the options for induction and termination of arrhythmias.

## Temporary Brady Screen

CRM D.I.D. 000650, CRM-111901

Tachy Mode Ventricular: Monitor + Therapy

DYNAGEN X4 CRT-D CRT Defibrillator

PSA

Lead-II Off Off Off

A Rate RV Rate

SUMMARY EVENTS TESTS SETTINGS

Lead Tests EP Tests Temp Brady Manual Rhythm ID

PARAMETERS

Mode DDD

Lower Rate Limit 80 ppm

Maximum Tracking Rate 130 ppm

Paced AV Delay 180-180 ms

Sensed AV Delay 120-120 ms

A-Refractory (PVARP) 280-280 ms

RV-Refractory (RVRP) 230-250 ms

LV-Refractory (LVRP) 250 ms

Ventricular Pacing Chamber BiV

LV Offset -40 ms

Note: All other Brady/CRT features have been disabled.

Start

PACING AND SENSING

	Amplitude	Pulse Width	Sensitivity
A	2.0 V @	0.4 ms	AGC 0.25 mV
RV	2.0 V @	0.4 ms	AGC 0.6 mV
LV	2.0 V @	0.8 ms	AGC 1.0 mV

LEADS

A Pace/Sense Bipolar

RV Pace/Sense Bipolar

LV Pace/Sense LVRing4>>RV LVTip1>>LVRing2

BLANKING

A	A-Blank after V-Pace	Smart ms
A	A-Blank after RV-Sense	Smart ms
RV	RV-Blank after A-Pace	65 ms
LV	LV-Blank after A-Pace	Smart ms

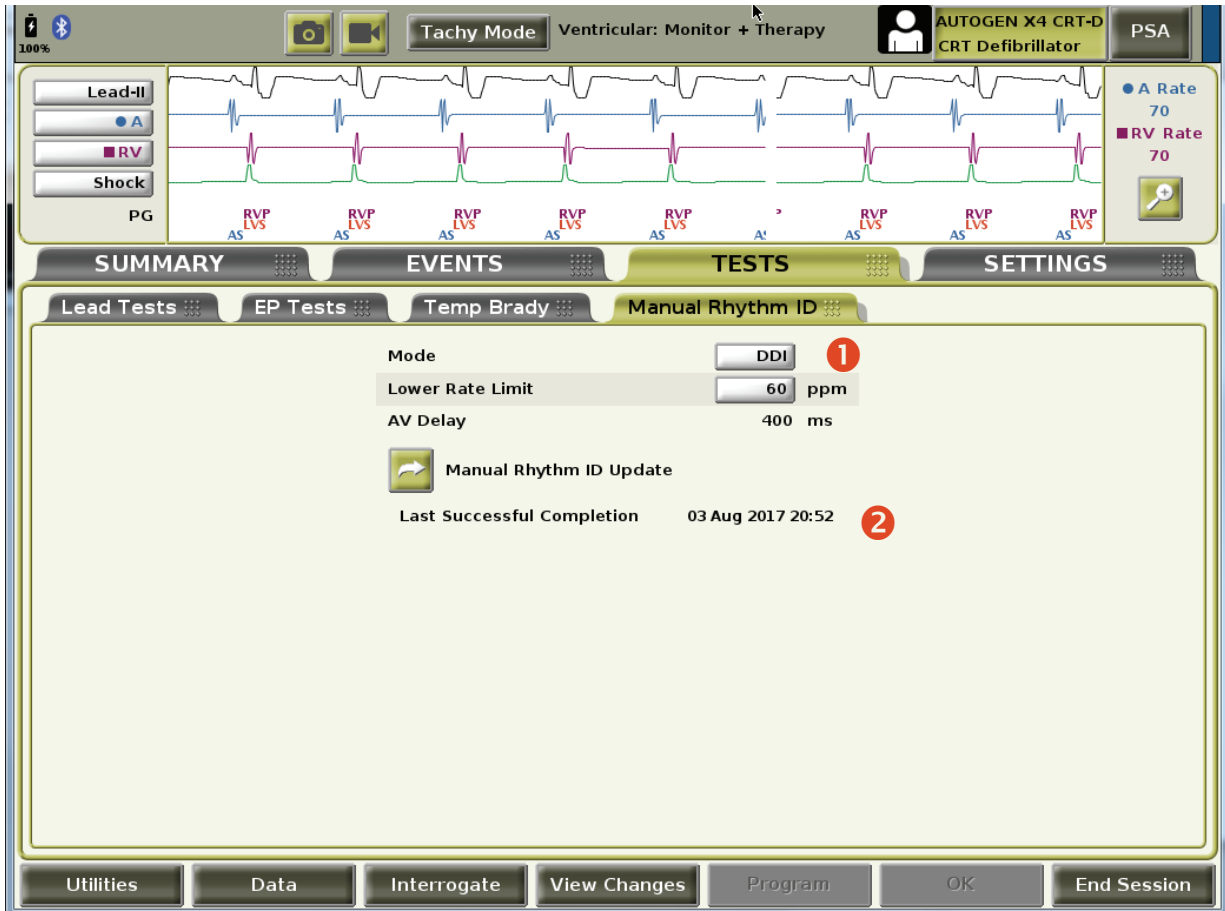
Utilities Data Interrogate View Changes Program ATTENTION End Session

These parameters are activated with Start button ①.

Temp Brady includes only the features shown on the screen, e.g., Rate Smoothing automatically disabled during Temp Brady. ②



## Manual Rhythm ID



When selected, programmable pacing parameters ❶ temporarily change to update the Rhythm ID Template.

Last successful update is available on this screen. ❷

## Settings Summary

CRM D.I.D. 000650, CRM-111901

Tachy Mode Ventricular: Monitor + Therapy

DYNAGEN X4 CRT-D CRT Defibrillator

PSA

Lead-II

Off

Off

Off

A Rate

RV Rate

SUMMARY EVENTS TESTS SETTINGS

Settings Summary Indications-Based Programming

Ventricular Zones 3

>250

230 220 VF

210 180 VT

190 150 VT-1

170 170 Atrial Trigger

150

130 130 MTR MSR

110 80 LRL

90

70

50

30

Scale bpm

VENTRICULAR TACHY

Detection Therapy

VF ATP 31J, 41J, 41Jx6

VT Burst Ramp 21J, 31J, 41Jx4

VT-1 Monitor Only

ATRIAL TACHY

Therapy

BRADY/CRT

Normal Settings Post-Therapy Settings

Mode DDDR - BiV A 2.0 V @ 0.4 ms

Paced AV Delay 180 - 180 ms RV 2.0 V @ 0.4 ms

Sensed AV Delay 120 - 120 ms LV 2.0 V @ 0.8 ms

Utilities Data Interrogate View Changes Program ATTENTION End Session

Increase or decrease rate zone cut-offs by:

- ① Move the slider bar grips up and down to propose zone change.
- ② Select number to view a list of available values.
- ③ Review summary of currently programmed parameters.

Select relevant icon to review and modify brady and other tachy settings.

## Ventricular Detection Enhancements

CRM D.I.D. 000650, CRM-111901

Tachy Mode Ventricular: Monitor + Therapy

DYNAGEN X4 CRT-D CRT Defibrillator

PSA

Lead-II

Off

Off

Off

● A Rate

■ RV Rate

SETTINGS - VENTRICULAR TACHY DETECTION

VT-1 150 bpm ( 400 ms ) VT 180 bpm ( 333 ms ) VF 220 bpm ( 273 ms )

Parameter	VT-1 150 bpm ( 400 ms )	VT 180 bpm ( 333 ms )	VF 220 bpm ( 273 ms )
Rate	150 bpm	180 bpm	220 bpm
Interval	400 ms	333 ms	273 ms
Initial Duration	2.5 s	2.5 s	1.0 s
Redetection Duration	1.0 s	1.0 s	1.0 s
Post-shock Duration	1.0 s	1.0 s	1.0 s

Detection Enhancement Type Onset/Stability

VT Detection Enhancement On

VT-1 Detection Enhancement

Detection Enhancement Type

Off Onset/Stability Rhythm ID

Utilities Data Interrogate View Changes Program ATTENTION End Session

- ① Clinician has 2 options of ventricular detection enhancement type: **Rhythm ID** or **Onset/Stability**.

## Atrial Tachy Therapy

**SETTINGS - ATRIAL TACHY THERAPY**

**ATR MODE SWITCH DETAILS**

- ATR Mode Switch **1**
- Trigger Rate  bpm
- Duration  cycles
- Entry Count  cycles
- Exit Count  cycles
- Fallback
  - Mode
  - Time  mm:ss
  - ATR/VTR Fallback Lower Rate Limit  ppm
- Ventricular Rate Regulation **2**
- BiV Trigger **3**
- Maximum Pacing Rate

**ATRIAL TACHY RESPONSE**

- Atrial Flutter Response
- Trigger Rate  bpm
- PMT Termination

**VENTRICULAR REGULATION**

- Ventricular Rate Regulation  **5**
- BiV Trigger  **4**
- Maximum Pacing Rate

**ATR Ventricular Rate Regulation**

ATR Ventricular Rate Regulation is intended to reduce V-V cycle length variability during conducted atrial arrhythmias occurring during a mode switch.

Utilities Data Interrogate View Changes Program **ATTENTION** End Session

- 1** These parameters are designed to tailor **ATR mode switch** to the patient's needs.
- 2** Notice that **Ventricular Rate Regulation (VRR)** and **BiV Trigger** **3** can be programmed to be active only during an ATR mode switch, or
- 4** BiV Trigger can also be programmed on independently.
- 5** If the device is programmed to VVI or VVI(R), **VRR** can be active at all times.

## Brady/CRT Parameters

**SETTINGS - NORMAL BRADY/CRT**

**PARAMETERS**

- Mode: DDD
- Lower Rate Limit: 45 ppm
- Maximum Tracking Rate: 130 ppm
- Maximum Sensor Rate: ppm
- Paced AV Delay: 160 - 160 ms
- Sensed AV Delay: 100 - 100 ms
- A-Refractory (PVARP): 280 - 280 ms
- RV-Refractory (RVRP): 230 - 250 ms
- LV-Refractory (LVRP): 250 ms
- Ventricular Pacing Chamber: BiV
- LV Offset: 0 ms
- Timing, Rate Enhancements, Noise
- SmartDelay™ optimization

**PACING AND SENSING**

	Amplitude	Pulse Width	Sensitivity
A	3.5 V@	0.4 ms	AGC 0.25 mV
RV	3.5 V@	0.4 ms	AGC 0.6 mV
LV	3.5 V@	0.4 ms	AGC 1.0 mV

**LEADS**

Lead	Pace/Sense	Configuration
A	Pace/Sense	Bipolar
RV	Pace/Sense	Bipolar
LV	Pace/Sense	SPLIT

**RATE ADAPTIVE PACING**

Feature	Setting
Accelerometer	Passive

Brady parameters to tailor to meet patient's needs.

RYTHMIQ™

**Device Mode** Brady Therapy Enabled ACCOLADE MRI EL Dual Chamber Pacemaker PSA

100% Lead-II A V Off PG

A Rate 69 V Rate 70

**SETTINGS - BRADY** [Close]

**PARAMETERS**

Mode: **DDDR**

RYTHMIQ™: **Off**

Lower Rate Limit: **60**

Maximum Tracking Rate: **120**

Maximum Sensor Rate: **120**

Paced AV Delay: **150 - 250**

Sensed AV Delay: **150 - 250**

A-Refractory (PVARP): **260 - 260 ms**

V-Refractory (VRP): **240 - 250 ms**

Timing, Rate Enhancements, Magnet, Noise

**PACING AND SENSING**

Amplitude: **5.0 V**

Pulse Width: **0.2 ms**

Sensitivity: **Fixed 0.75 mV**

**AAIR With VVI Backup**

**Off**

**RATE ADAPTIVE PACING**

Minute Ventilation: **On**

Accelerometer: **Passive**

Utilities Data Interrogate View Changes Program OK End Session

**RYTHMIQ™**  
The RYTHMIQ™ feature is designed for patients with intact conduction to pace AAI(R) with backup VVI to eliminate unnecessary right ventricular paces.

## Parameter Interactions

The image shows two overlapping screenshots from the LATITUDE™ Programming System. The top screenshot displays the 'SETTINGS - BRADY' window for an ACCOLADE MRI EL Dual Chamber Pacemaker. The 'PARAMETERS' section includes:

- Mode: DDDR
- RYTHMIQ™: Off
- Lower Rate Limit: 60 ppm
- Maximum Tracking Rate: 150 ppm (red diamond icon)
- Maximum Sensor Rate: 120 ppm
- Paced AV Delay: 150 ms (red diamond icon)
- Sensed AV Delay: 150 - 250 ms
- A-Refractory (PVARP): 260 ms (red diamond icon)
- V-Refractory (VRP): 240 ms (yellow triangle icon)

The 'PACING AND SENSING' section shows Amplitude (5.0 V), Pulse Width (0.4 ms), and Sensitivity (Fixed 0.75 mV for A, Fixed 2.5 mV for V). The 'LEADS' section shows Pace/Sense for both A and V set to Bipolar. The 'RATE ADAPTIVE PACING' section shows Minute Ventilation set to On and Accelerometer set to Passive.

The bottom screenshot displays the 'PARAMETER INTERACTIONS' window. It shows the following errors:

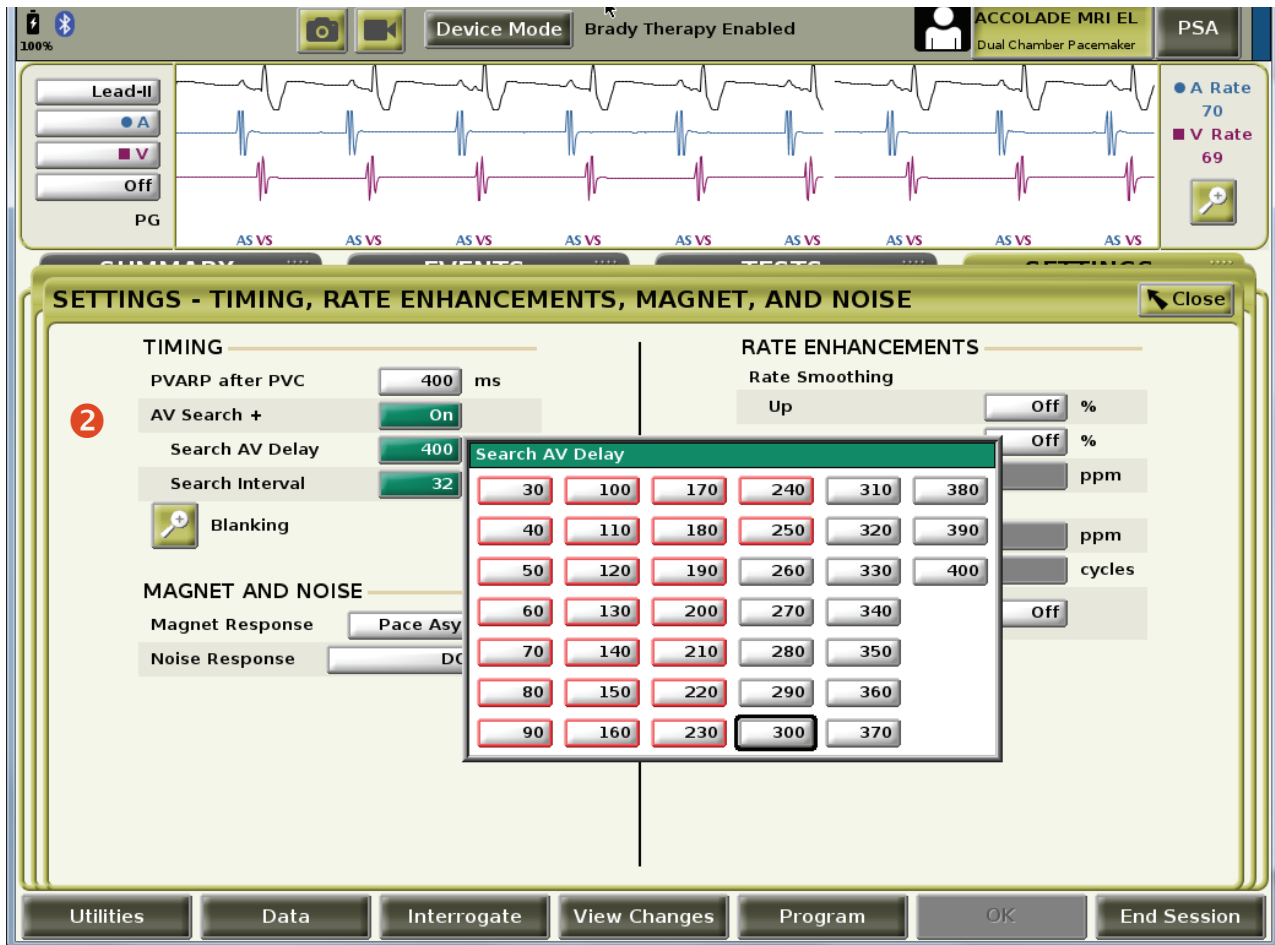
- Normal Brady Maximum Tracking Rate:** 150 ppm (red diamond icon). Error: The selected MTR cannot be reached. AV Delay + PVARP must be ≤ Maximum Tracking Rate (ms). Button: Fix Others.
- Normal Brady Minimum Paced AV Delay:** 150 ms (red diamond icon). Button: Fix Others.
- Normal Brady Minimum A-Refractory (PVARP):** 260 ms (red diamond icon). Button: Fix Others.
- Normal Brady Minimum V-Refractory (VRP):** 240 ms (yellow triangle icon). Error: To improve ventricular sensing, Right Ventricular Refractory Period should be < one-half of Upper Rate Limit (ms). Button: Fix Others.
- Normal Brady Maximum Tracking Rate:** 150 ppm (red diamond icon). Button: Fix Others.

A 'WARNING' icon is visible in the bottom right corner of the bottom window.

Color coding identifies interactive limit (red, green, yellow).

**Fix Others** addresses interactive parameters and gives suggested changes to resolve interactions **!**.

AV Search +



- 1 Select Settings tab, then Timing, Rate Enhancements, Magnet and Noise.
- 2 **AV Search +** features an advanced algorithm designed to promote intrinsic ventricular conduction without dropping ventricular beats.



## SmartDelay™ CRT

The screenshot displays the LATITUDE™ Programming System interface for an AUTOGEN X4 CRT-D CRT Defibrillator. The top section shows a patient monitor with ECG waveforms and vital signs (A Rate 69, RV Rate 69). Below the monitor is the 'SETTINGS - NORMAL BRADY/CRT' window, which includes a 'PARAMETERS' section and a 'PACING AND SENSING' section. The 'SmartDelay™ optimization' window is open, showing a 'Start Test' section with a 'Temporary Paced LRL' set to 90 ppm and a 'Start Test' button. Below this is a 'Review Suggested Settings' section with fields for Paced AV Delay (100 ms), Sensed AV Delay (80 ms), Pacing Chamber (BIV), and LV Offset (0 ms). A 'Copy Suggested Settings' button is also present. The 'SYSTEM STATUS' window at the bottom shows the test in progress, with instructions for the patient and a 'Cancel Telemetry' button.

- 1 **SmartDelay** provides recommended settings for programming **PAV** and **SAV Delay** based on measurements of:
- Intrinsic AV intervals
  - Interventricular timing
  - LV lead location

Select **Temporary Paced LRL** 2

Select **Start Test** 3

4 System status as test is running.

## LATITUDE™ Programming System, Model 3300

### Rate Adaptive Sensor Data

The image displays two overlapping screenshots of the LATITUDE™ Programming System interface for an ADVANTIO Dual Chamber Pacemaker. The top screenshot shows the 'SETTINGS - BRADY' screen with various parameters such as Mode (DDDR), Lower Rate Limit (60 ppm), and Pacing and Sensing settings. The bottom screenshot shows the 'SETTINGS - RATE ADAPTIVE PACING' screen, which includes a 'Sensor Trending - 30 Second Average' graph and settings for RightRate™ Pacing and Motion-Based Pacing. A red circle with the number '1' highlights a key icon in the 'RATE ADAPTIVE PACING' settings, indicating that clicking this icon provides access to sensor and trending data.

Sensor and Trending Data are found by selecting relevant icon 1.

## View Changes

**VIEW CHANGES** (Top Screenshot)

1 Status	2 Parameter	3 Old Value	4 New Value
Programmed	Post Therapy Lower Rate Limit	---	45 ppm
Programmed	Post Therapy Pacing Period	---	00:30 mm:ss
Programmed	Post Therapy Right Ventricle Pace Amplitude	---	5.0 V
Programmed	Post Therapy Right Ventricle Pace Pulse Width	---	1.0 ms
Programmed	PVARP after PVC	---	400 ms
Programmed	Rate Hysteresis Offset	---	Off
Programmed	Rate Smoothing Down	---	Off
Programmed	Rate Smoothing Up	---	Off
Programmed	Tracking Preference	---	On
Programmed	V Tachy Mode	Off	Monitor + Therapy

Buttons: Load Initials (5), Cancel Changes (7)

**VIEW CHANGES** (Bottom Screenshot)

Status	Parameter	Old Value	New Value
Pending	PVARP after PVC	---	400 ms
Pending	Rate Hysteresis Offset	---	Off
Pending	Rate Smoothing Down	---	Off
Pending	Rate Smoothing Up	---	Off
Pending	Tracking Preference	---	On
Programmed	Normal Brady A-Blank after RV-Sense	---	Smart
Programmed	Normal Brady A-Sensitivity	---	AGC 0.25 mV
Programmed	Normal Brady LV-Sensitivity	---	AGC 1.0 mV
Programmed	Normal Brady RV-Sensitivity	---	AGC 0.6 mV
Programmed	V Tachy Mode	Off	Monitor + Therapy

Buttons: Load Initials (5), Cancel Changes (6), Program (7)

This screen will be visible if user has *already completed* programming.

This screen will be visible if user has *not yet completed* programming.

The **View Changes** window displays old values and new values during a programming session.

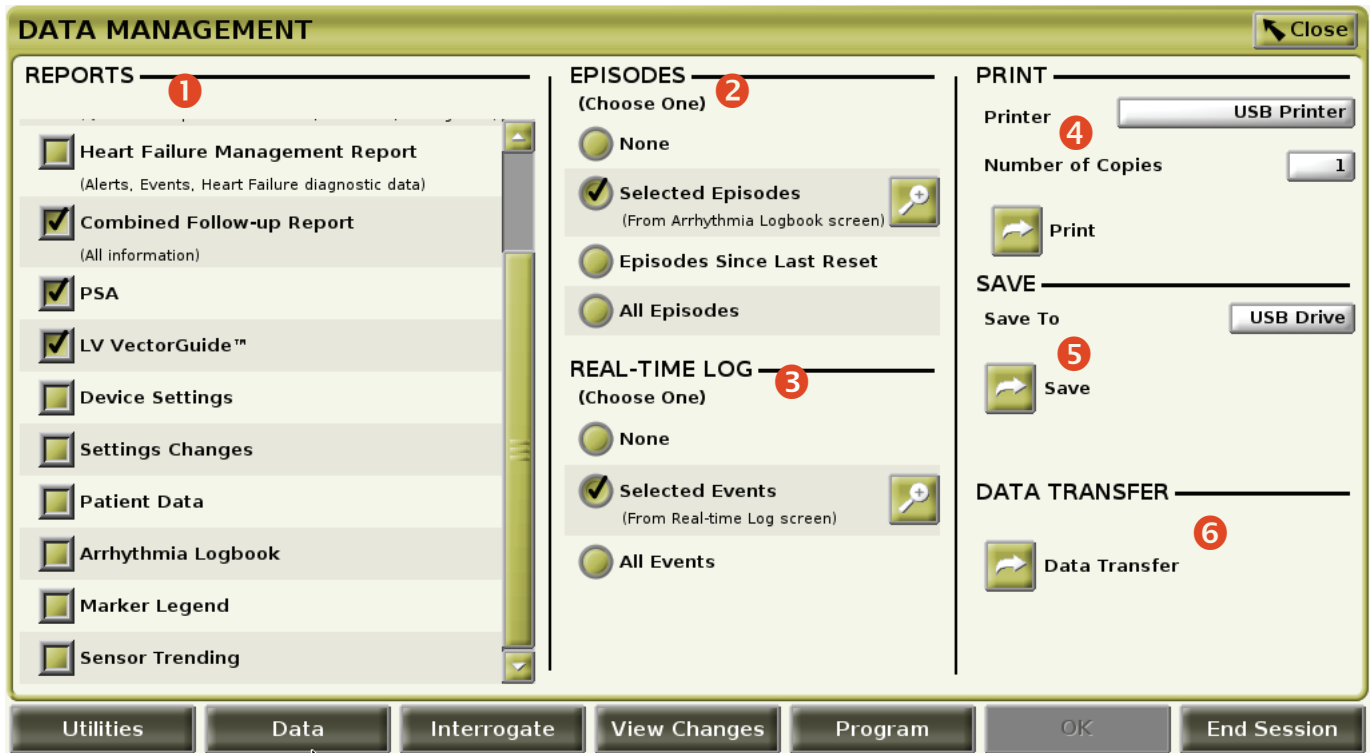
You can sort by:

- 1 **Status**
- 2 **Parameter**
- 3 **Old Value**
- 4 **New Value**
- 5 **Load Initials** will reset all device programming and patient information entered during that interrogation session with the original interrogated values.

6 **Cancel Changes** if proposed programming not desired.

7 **Select Program** on screen or on the programmer itself anytime to apply changes.

## Printing and Saving Reports

**1 Reports:**

- Select desired reports
- Report description included

**2 Episodes:**

- Select desired episodes

**3 Real-time Log:**

- Select events (*snapshot, real-time recorder, automatic*)

**4 Print:**

- USB Printer
- Bluetooth® enabled printer

**5 Save:**

- Hard drive
- USB pen drive

**6 Data transfer:**

- Bluetooth® enabled PC with Latitude Link™ Data Management System

## End Session Confirmation

The screenshot displays the LATITUDE™ Programming System interface. At the top, it shows 'Tachy Mode' and 'Ventricular: Monitor Only'. The main display area shows ECG waveforms for Lead-II, with A and RV rates both set to 69. A dialog box titled 'End Session Confirmation' is overlaid on the screen, listing the following warnings and actions:

- ⚠ Device is in Monitor Only mode. Tachy therapy will not be delivered. **Change Mode**
- ⚠ Settings have NOT been programmed. **View Changes and Program**
- Counters have NOT been reset. **Reset Counters**
- ⚠ Latest Real-time Log data has NOT been saved. **Navigate to Real-time Log Screen**

At the bottom of the dialog are two buttons: **Return to Session** and **End Session**. The background interface includes a 'SETTINGS' panel on the left and a 'Close' button on the right.

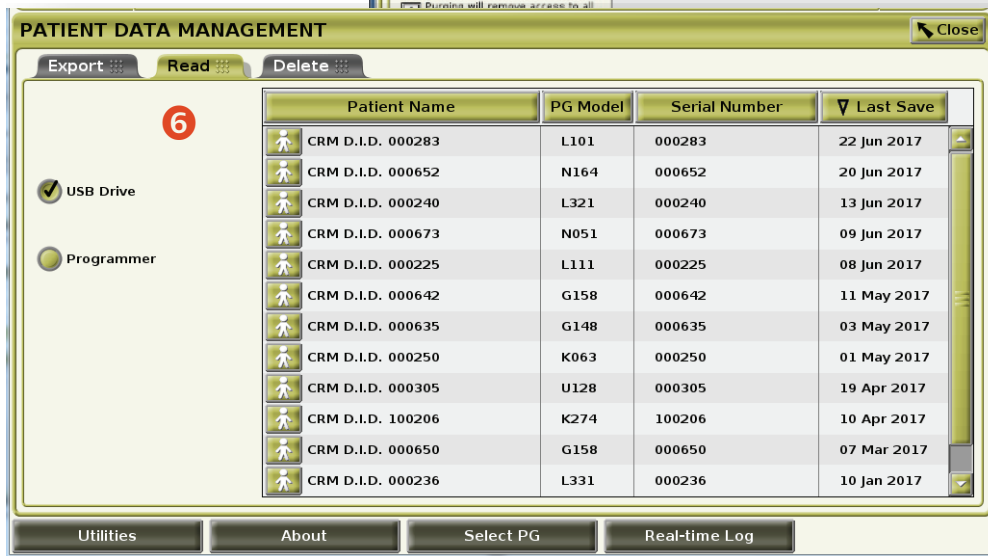
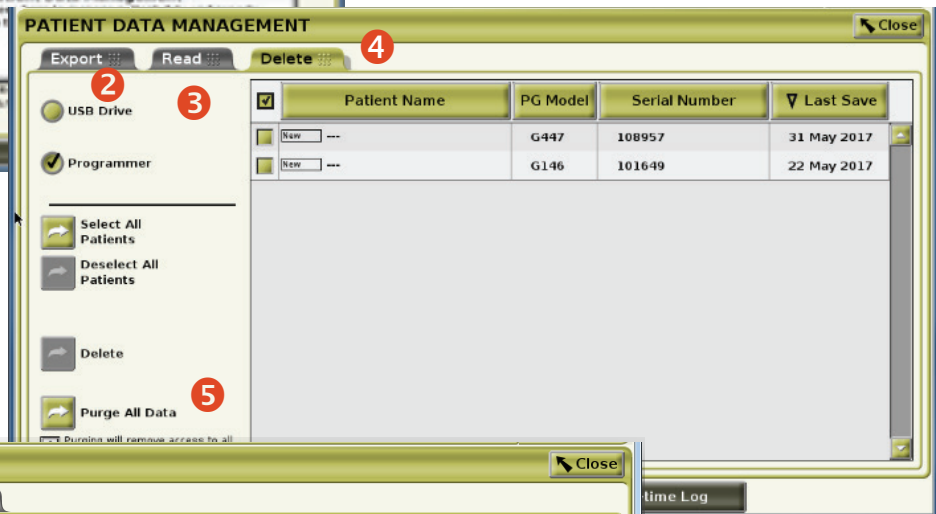
The **End Session** confirmation will alert the user for Tachy Mode, Programming, Counters Reset and Real-time Log saving.

## LATITUDE™ Programming System, Model 3300

## Export, Read, Delete



- 1 Select Patient Data Management when PG is application is closed.
- 2 Export via Data transfer to PC with LATITUDE™ Link.
- 3 Read from USB or Programmer hard drive.
- 4 Delete from Hard Drive or USB.



- 5 Purge All Data – used to cryptologically erase Patient Data from the Programmer.
- 6 Unlike Model 3120 Programmer, cannot print from this screen. Additionally, the programmer limits patient data stored on the hard drive by automatically deleting it after 14 days. There is no notification to the user that the deletion has occurred.

## LATITUDE™ Programming System, Model 3300

**LATITUDE™ PROGRAMMER**

**Intended Use** The LATITUDE Programming System is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. The software in use controls all communication functions for the PG. For detailed software application instructions, refer to the associated product literature for the PG being interrogated.

**Contraindications** The LATITUDE Programming System is contraindicated for use with any PG other than a Boston Scientific PG. For contraindications for use related to the PG, refer to the associated product literature for the PG being interrogated.

The PSA application is contraindicated for use with any programming system other than the Boston Scientific Model 3300 LATITUDE Programming System.

The following uses of the PSA are contraindicated:

- With AV conduction disorders; atrial single-chamber pacing
- With competing intrinsic rhythms; asynchronous modes
- With chronic atrial tachycardia as well as chronic atrial fibrillation or flutter; modes with atrial control (DDD, VDD)
- With poor tolerance of high ventricular rates (e.g., with angina pectoris); tracking modes (i.e., atrial control modes) and propensity for atrial tachycardia
- Use as an external pacemaker

**Warnings** The use of any cables or accessories with the LATITUDE Programming System other than those specified by Boston Scientific could result in increased electromagnetic emissions, decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. Keep all RF communications equipment at least 30 cm (12 in) away from the Model 3300 Programmer. Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor. To avoid the risk of electric shock, only connect the Programmer's Model 6689 Power Adapter to a grounded/earthed power outlet. When accessing the battery, ensure that power to the Programmer is turned off. Do not touch the metal clips on the patient cable or the pacing lead. Discharge any electrical static charge on your person by touching a grounded metal surface before touching the patient, the patient cables, or the device. Unused PSA cable connections contacting conductive surfaces can induce electrical currents into the patient's heart. Electrocautery can induce electrical currents in the PSA cables that can be conducted into the patient's heart. Never stack the Programmer on top of an electrocautery system or associated components. Do not drape electrocautery components or cables on or near the Programmer or associated cables and components. Whenever possible disconnect the PSA cables from the pacing leads when performing an electrocautery procedure. If the Programmer is connected to the patient during an electrocautery procedure, check its operation afterwards. If the Programmer experiences an issue that causes an error condition, the Programmer will need to be power cycled. Use of the Model 3300 Programmer adjacent or stacked with other equipment should be avoided because it could result in improper operation. The Programmer is non-sterile and cannot be sterilized. Operation of the LATITUDE Programming System with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. The LATITUDE Programming System is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. When activating PSA Burst Pacing, which may cause unpredictable arrhythmias, always have cardiac emergency equipment in an operational status available for immediate life support. The LATITUDE Programming System is designed and tested to be defibrillation safe. The PSA cable must be disconnected from the lead(s) before using external defibrillation. If the patient is pacer dependent and the Programmer encounters a fault condition, pacing operation continues unless the fault was in the PSA component itself. For this reason, always have external pacing equipment available for patient back-up. Operating the Programmer with a depleted internal battery or no battery can suspend Programmer function if AC power is temporarily interrupted. Always have external cardiac pacing equipment in an operational status available for immediate life support. Always have external defibrillation equipment and medical personnel skilled in CPR available during implant and follow up testing. If not terminated in a timely fashion, an induced ventricular tachyarrhythmia can result in the patient's death. Single chamber atrial modes are contraindicated for patients with impaired AV conduction. Abruptly terminating pacing may result in extended periods of asystole in some patients. Pacing threshold testing implies loss of capture. Incorrect positioning of the protective silicone rubber sleeves over the PSA cable clip(s) can cause unintended electrical connections that can impair cable function and endanger the patient. Moisture or wet cables can impair cable function and endanger the patient. Before cleaning and disinfecting the Programmer surfaces, power down the device and disconnect the external power supply. If this equipment is used in a residential environment, the equipment might not offer adequate protection to radio-frequency communication services. The Model 6753 Battery is a Lithium-ion battery and as such, is deemed a Dangerous Good in regards to shipping. Do not touch the screen while the Programmer is powering up, as this may cause the area that you touched to become unresponsive when pressed later on.

**Precautions** For specific information on precautions, read the following sections of the product labeling: General, Preparations for Use, Maintenance, Troubleshooting and Handling.

**Adverse Effects** The following list includes the possible adverse effects associated with programming pulse generators described in this information: Asystole, Atrial arrhythmia, Bradycardia, Tachycardia and Ventricular arrhythmia.  
92436264 (Rev. A)

**Caution** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions

**Boston  
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