



LATITUDE™

Programming System, Model 3300

**Boston
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WORKBOOK

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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.

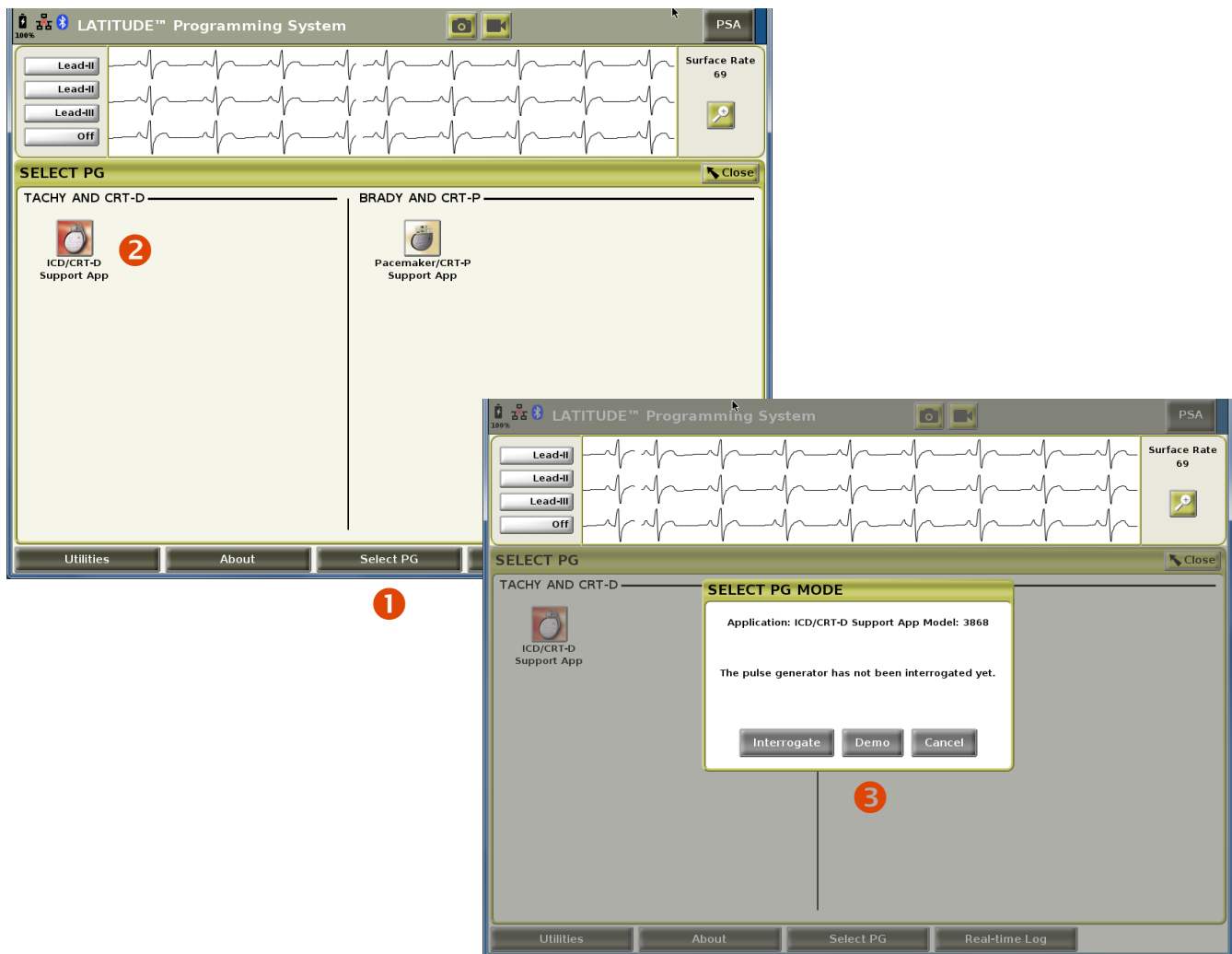
Use the Table of Contents to quickly locate specific information or to gain an overall understanding of the topics/screens contained in the workbook. Note that the topics have been assigned different colors and are organized by these colors throughout the guide.

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.

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Using Demo Mode



Turn on the programmer.

Select PG 1.

Select ICD/CRT-D Support App 2.

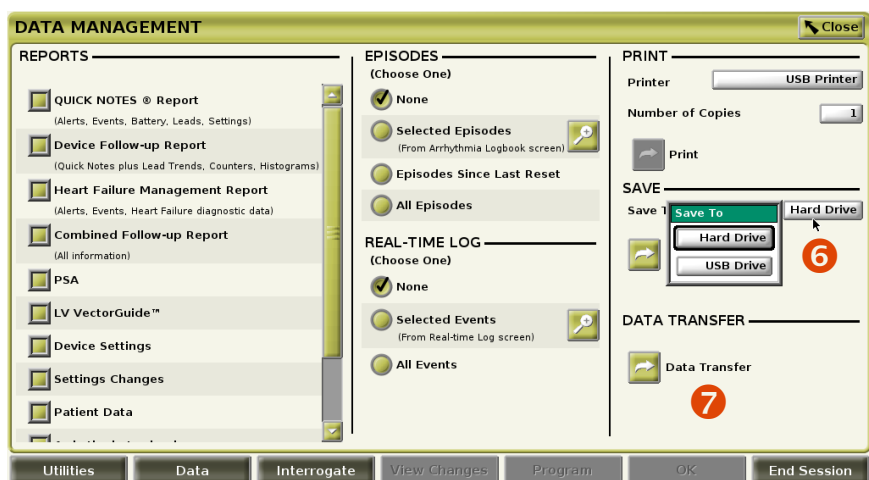
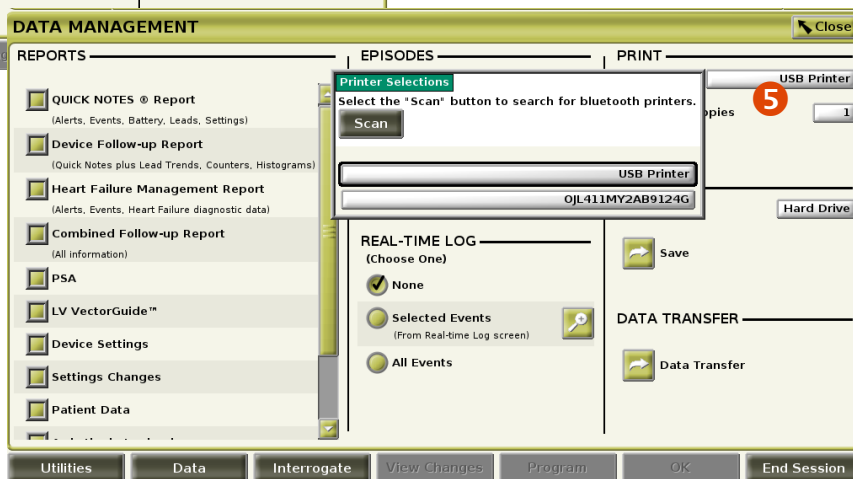
Then Select Demo 3.

Printing and Saving



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

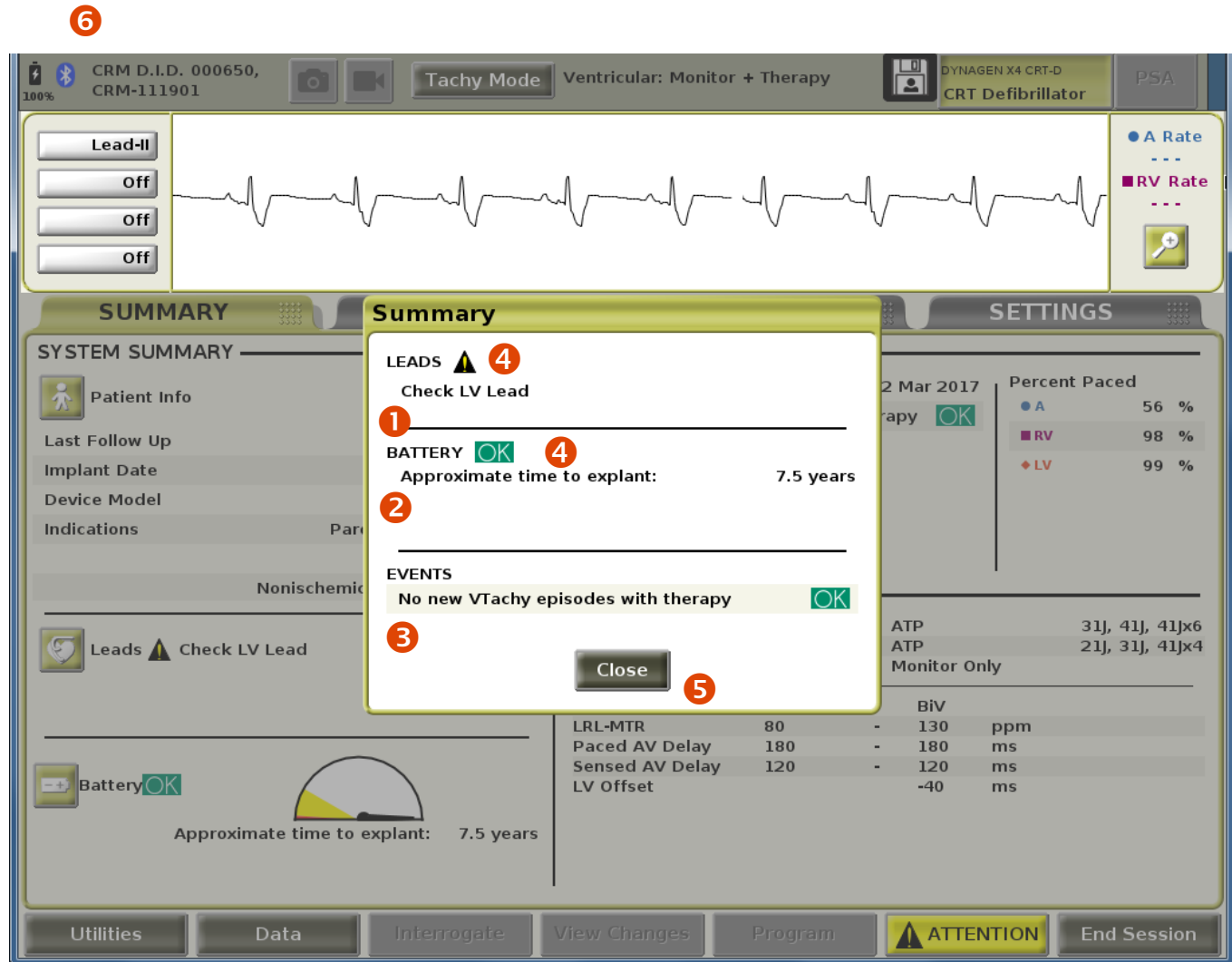
Select Patient Data Management.



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

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Summary Pop-up Screen



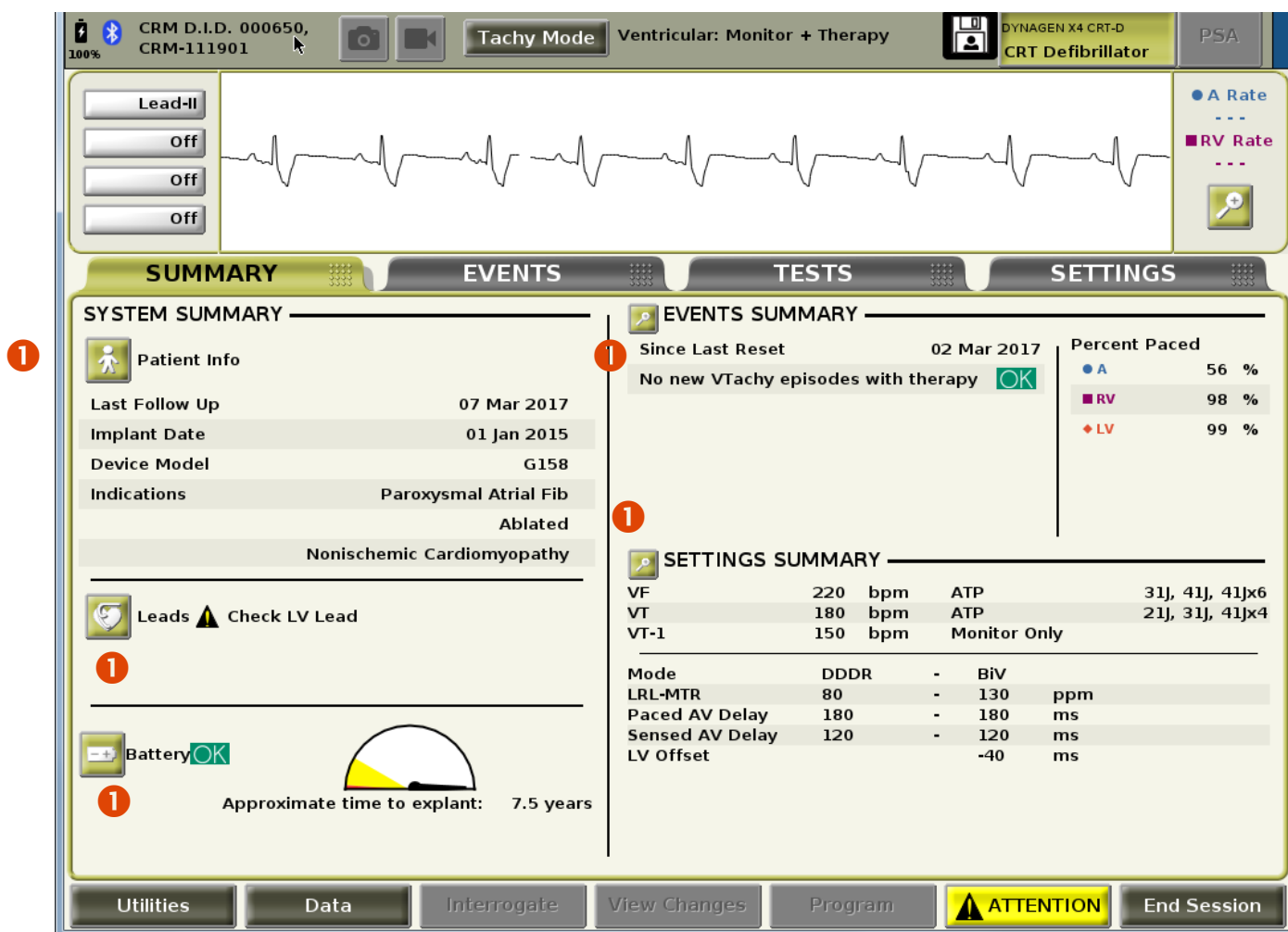
Upon interrogation, a **Summary** pop-up screen will give you the status of:

- 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.

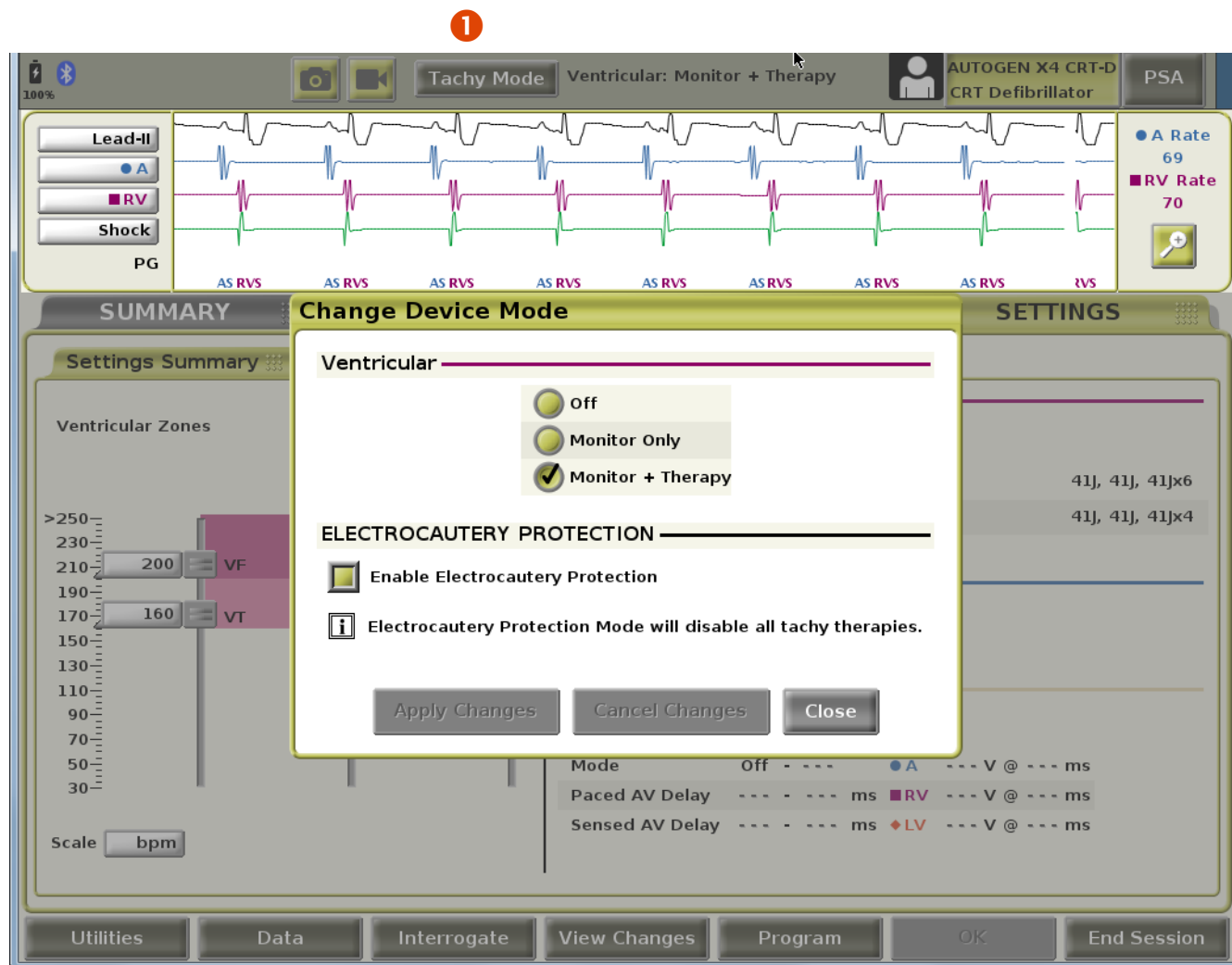
Summary Screen



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

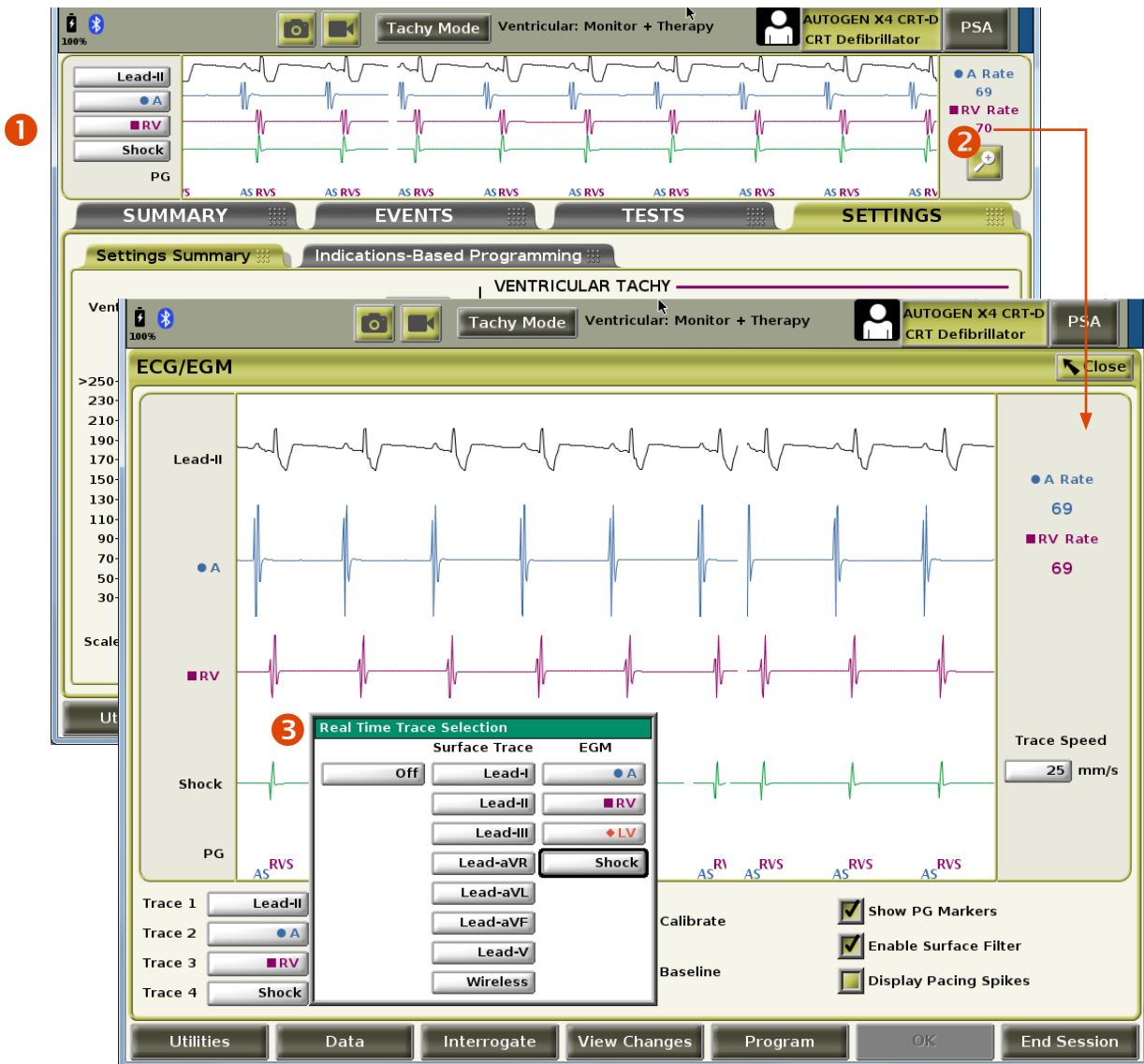
Select the relevant icon **1** for more detailed information.

Tachy Mode



As with previous devices, **Tachy Mode** ① can be changed from the top of the screen.

Enhanced EGM Functionality



The nominal display setting is surface and three EGMs ①.

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

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

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Battery

2

1

3

4

5

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8

9

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

SYSTEM SUMMARY

Patient Info

Last Follow Up: 07 Mar 2017
 Implant Date: 01 Jan 2015
 Device Model: G158
 Indications: Paroxysmal Atrial Fib
 Ablated
 Nonischemic Cardiomyopathy

Leads **Check LV Lead**

Battery **OK**

Approximate time to explant: 7.5

EVENTS SUMMARY

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	

SUMMARY - BATTERY STATUS **Close**

Time Remaining

One Year Remaining

Explant

Approximate time to explant: 7.5 years

Charge Time: 9.7 s

Battery Detail

SUMMARY - BATTERY DETAIL **Close**

Last Delivered Shock	N/R	Charge Remaining	1.79 ampere-hours
Energy	N/R	Power Consumption	65 microwatts
Charge Time	N/R	(Measured with programmed parameters)	
Shock Impedance	N/R	<p>i This device is using 121% of the power it would use at the following parameters:</p> <p>• A 15% pacing, 70 ppm, 2.5 V, 0.4 ms, 500 Ω</p> <p>• RV 100% pacing, 70 ppm, 2.5 V, 0.4 ms, 700 Ω</p> <p>• LV 100% pacing, 70 ppm, 3.5 V, 0.4 ms, 700 Ω</p> <p>(These parameters are used to quote device longevity)</p>	
Beep when Explant is Indicated	<input checked="" type="checkbox"/> On		
Last Capacitor Re-form	18 Sep 2016 03:58		
Charge Time	9.7 s		
<p>Manual Re-form Capacitor</p>			

ATTENTION **End Session**

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

- 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

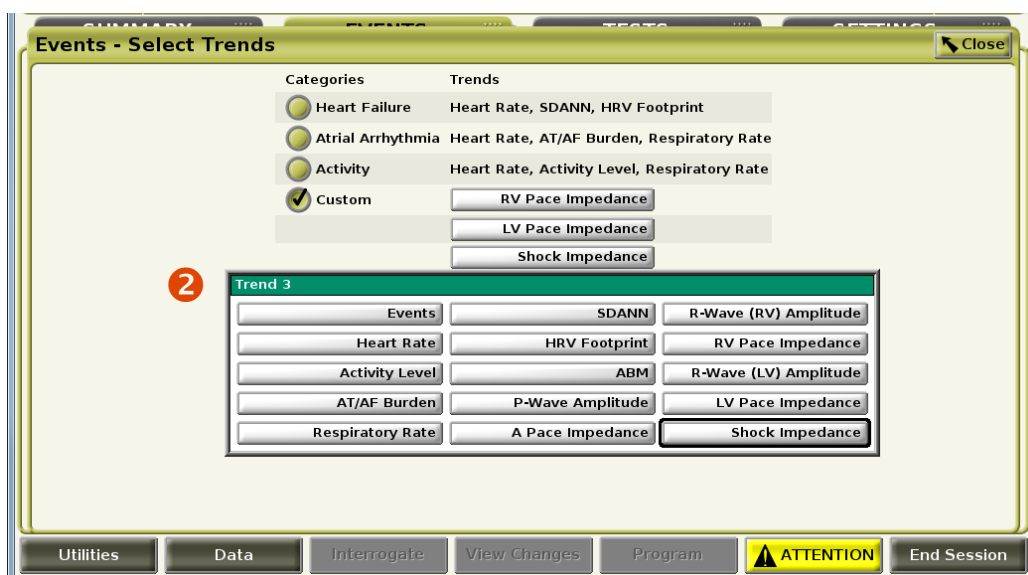


From the **EVENTS** tab, select the **Trends** tab.

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.

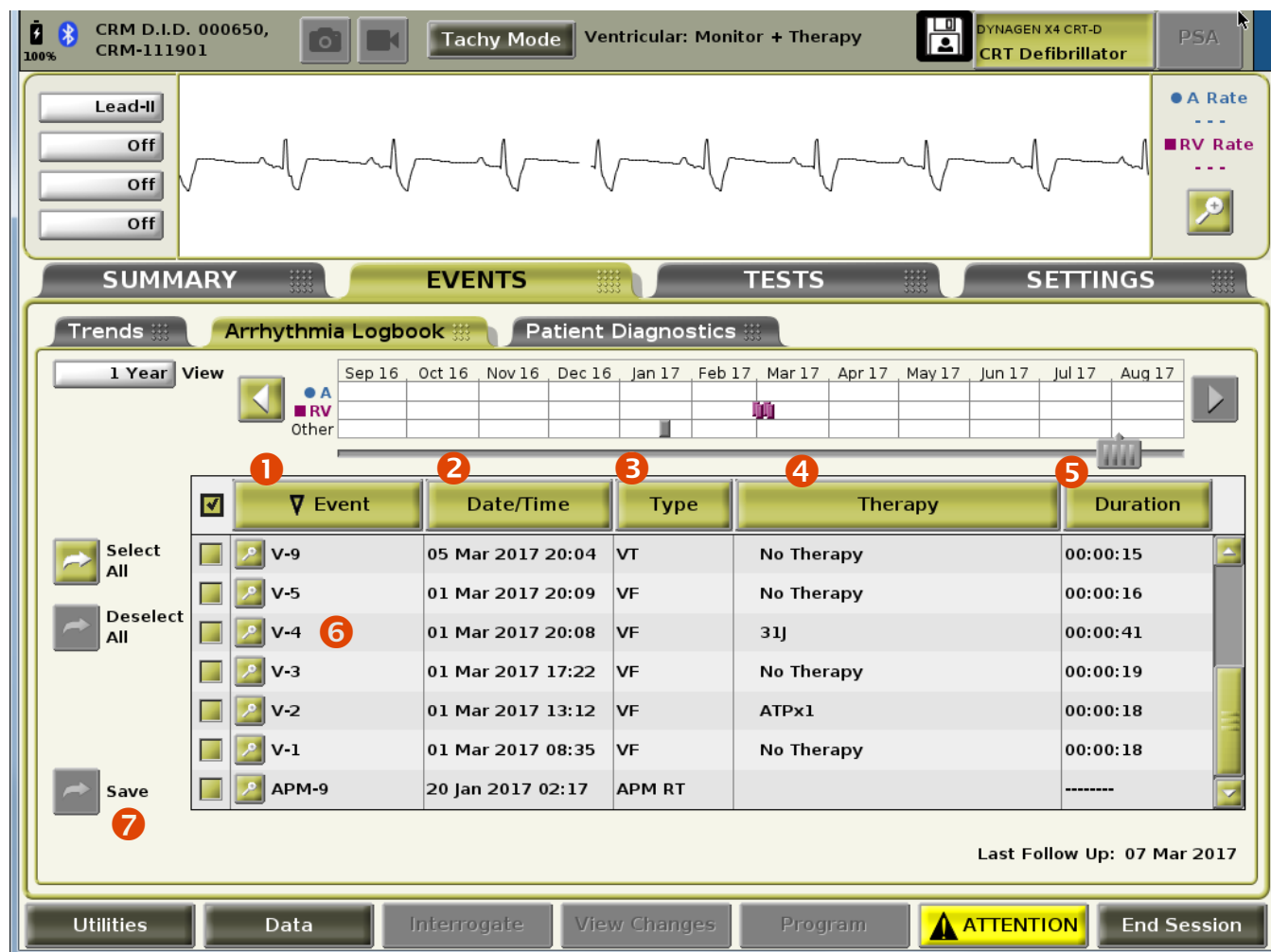
Trends (continued)



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



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



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Patient Diagnostics

1

2

3

4

EVENTS - HISTOGRAMS

Data Type: ☒ Atrial and Ventricular ☐ Ventricular Response

Time Period: ☒ Since Last Reset 09 Feb 2017 to Today ☐ Reset Before Last 26 Feb 2016 to 09 Feb 2017

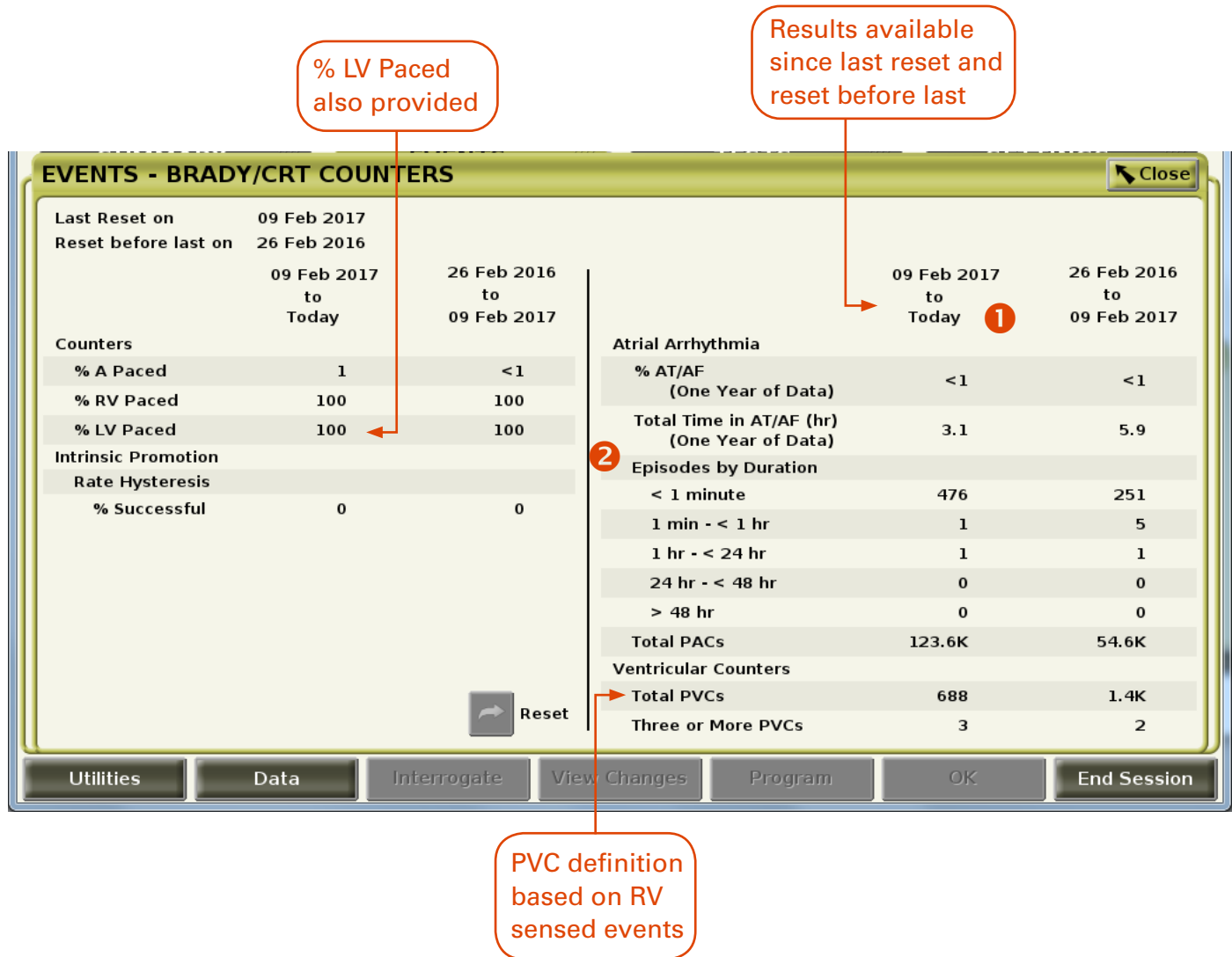
Rate Counts: ☒ Rate Counts ☐ Reset

EVENTS - RATE COUNTS

Chamber	Rate (bpm)	09 Feb 2017 to Today	26 Feb 2016 to 09 Feb 2017	Rate (bpm)	09 Feb 2017 to Today	26 Feb 2016 to 09 Feb 2017
Atrial						
Right Ventricular						
Left Ventricular						
	0-29	0	0	0	0	0
	30-39	0	0	0	0	0
	40-49	0	0	11	0	0
	50-59	405	0	191	0	0
	60-69	428.1K	81	2.2M	28	0
	70-79	2.9M	722	13.9M	706	0
	80-89	4.7M	2.3K	10.9M	3.7K	0
	90-99	2.9M	11.5K	6.5M	16.4K	0
	100-109	2.0M	17.8K	5.1M	23.8K	0
	110-119	1.5M	21.3K	2.9M	20.1K	0
	120-129	764.2K	6.8K	971.8K	6.9K	0
	130-139	248.2K	480	161.5K	1.4K	0
	140-149	0	244	0	633	0
	150-159	0	240	0	595	0
	160-169	0	199	0	455	0
	170-179	0	125	0	132	0
	180-189	0	63	0	35	0
	190-199	0	24	0	18	0
	200-209	0	5	0	7	0
	210-219	0	2	0	3	0
	220-229	0	2	0	1	0
	230-239	0	4	0	0	0
	240-249	0	0	0	0	0
	≥250	0	0	0	2	0

- 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

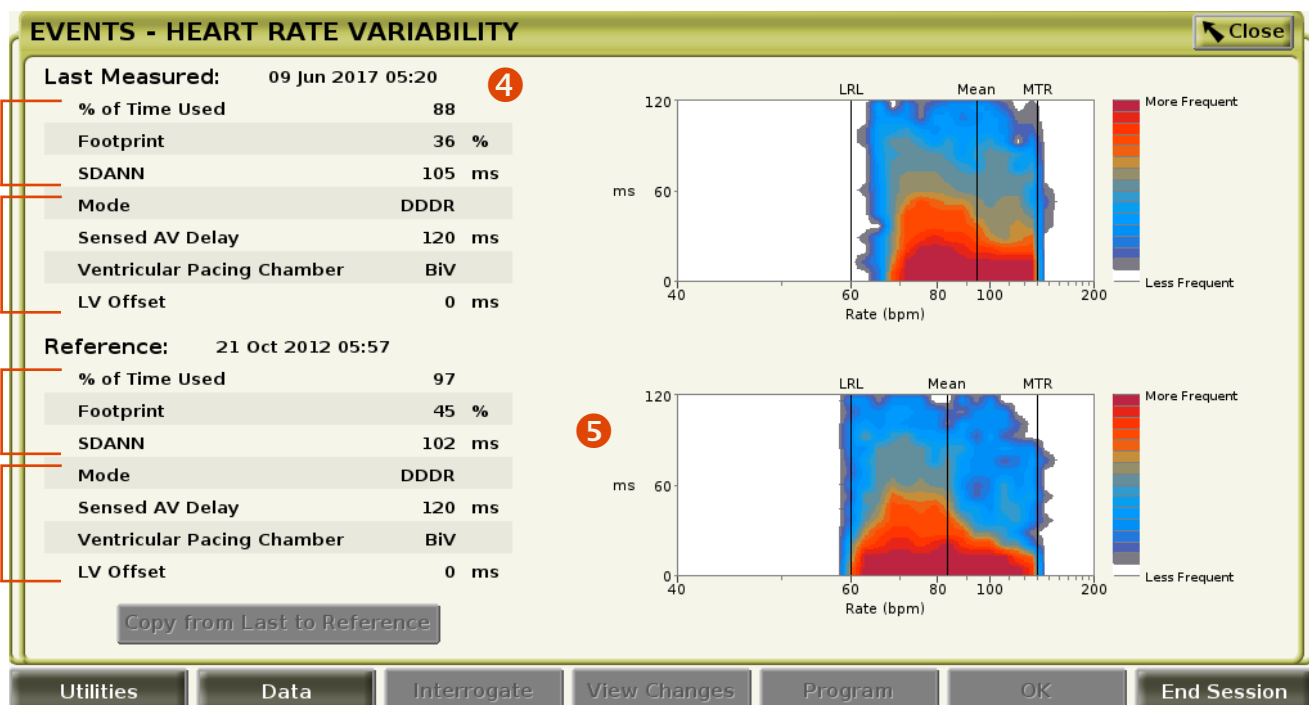
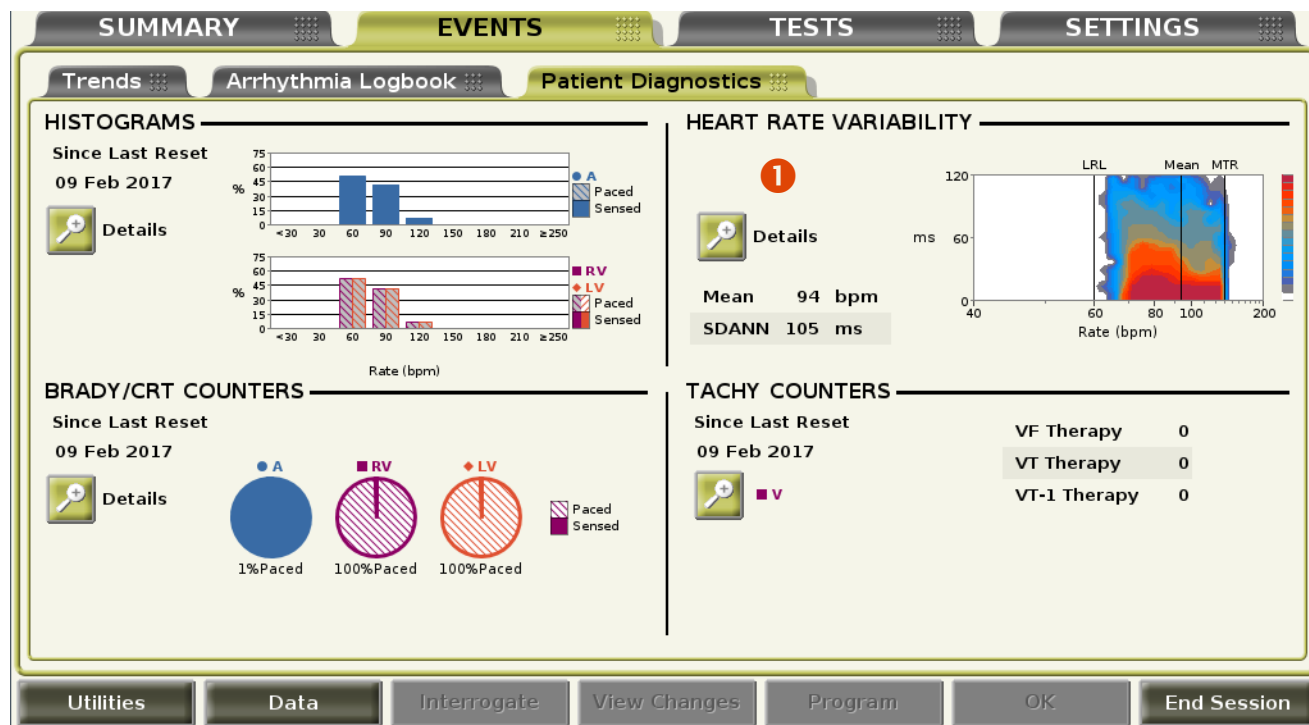


Select the **Brady/CRT Counters Details** button to see additional information since last reset and reset before last. ①

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

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Heart Rate Variability

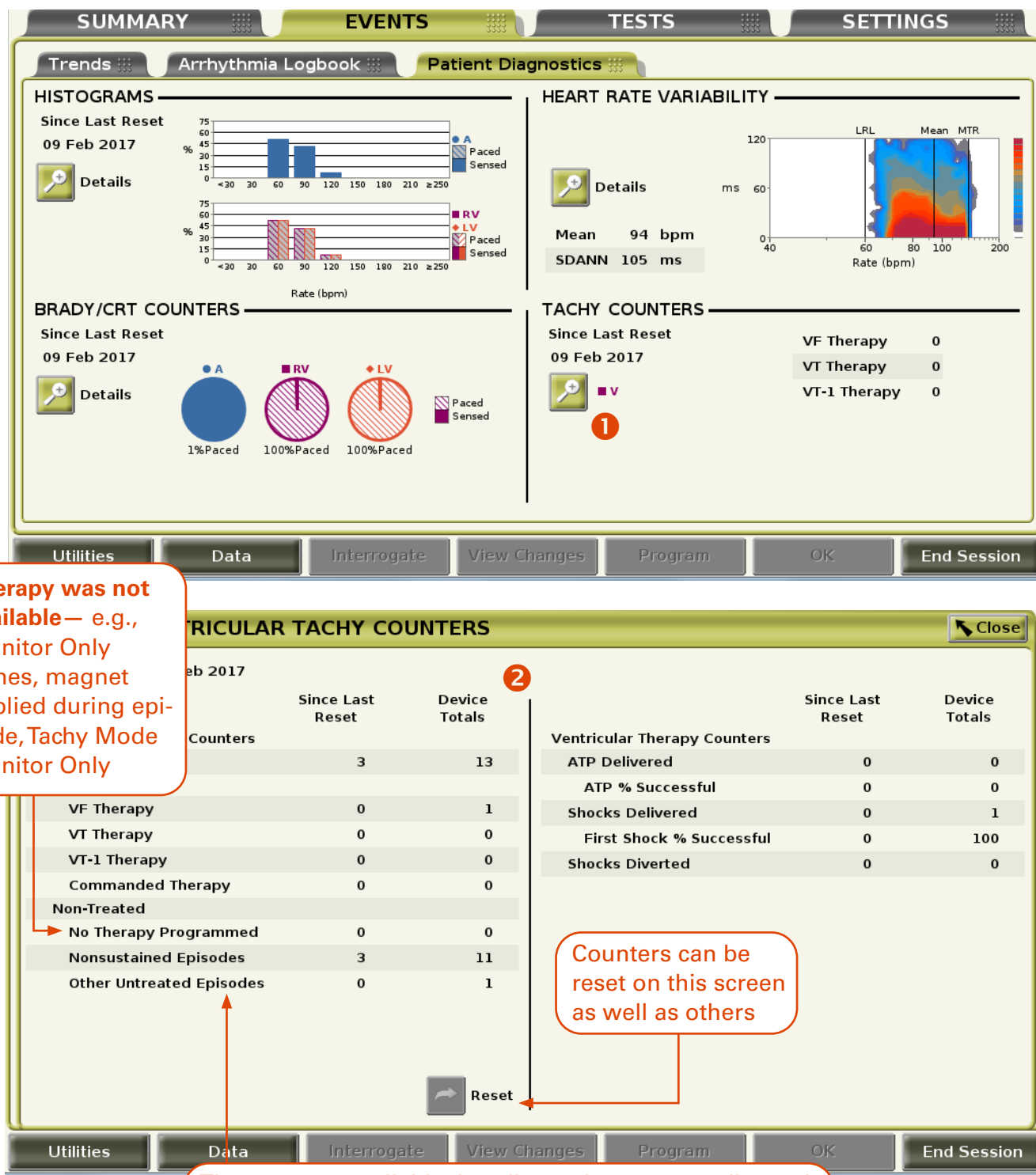


Select the **Details** ① button for **Heart Rate Variability** to view pacing parameters ② and specific heart failure diagnostic information. ③

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

⑤ The Reference plot is stored underneath for comparison.

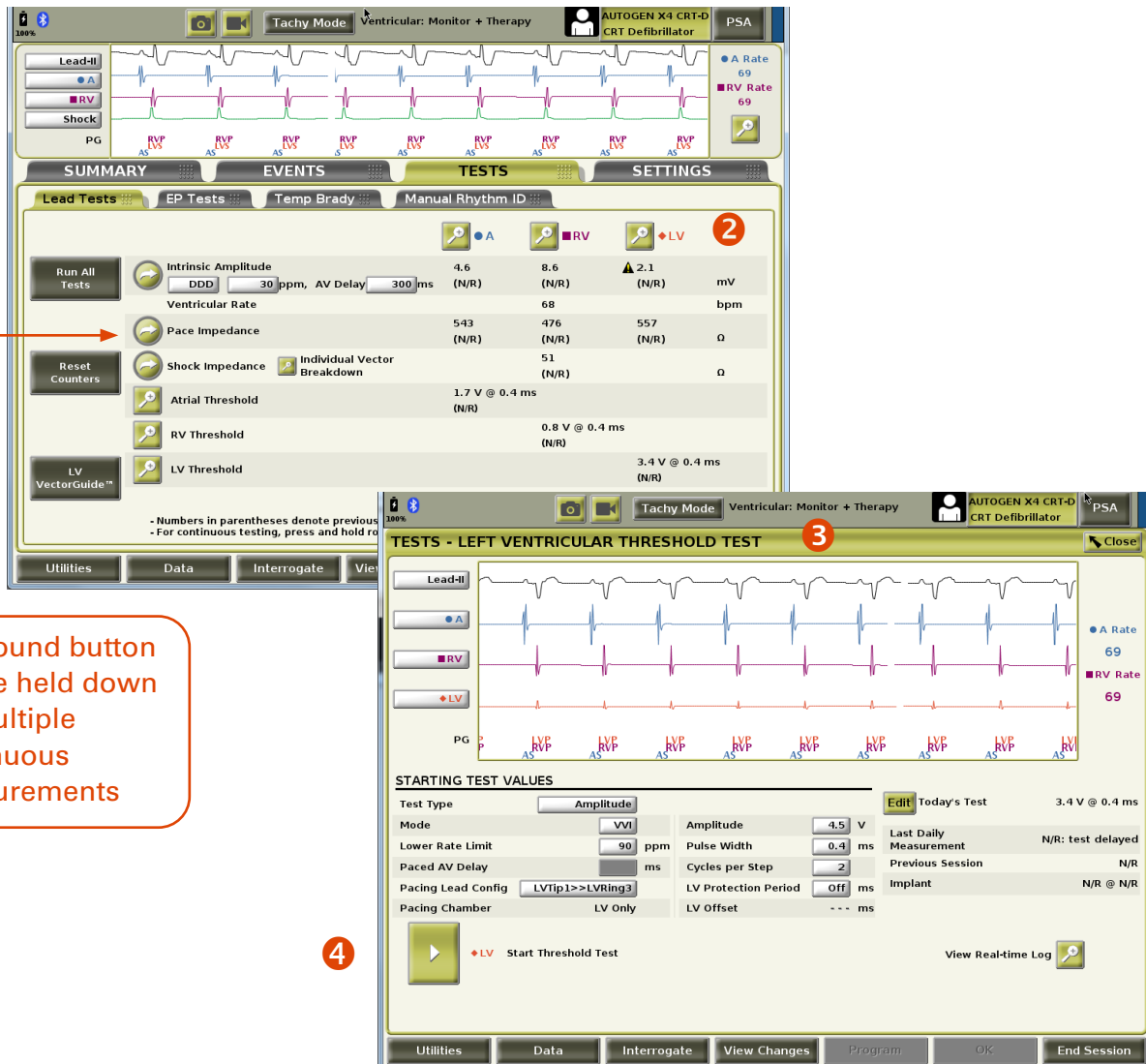
Tachy Counters



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

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Lead Tests



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 LVThresholdTest 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

1 Pacing Lead Config

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

2 Real-time Log

LV Threshold-8
Date/Time: 03 Aug 2017 20:21:38
Duration: 00:00:12
Notes: 3.4 V @ 0.4 ms LVTip1>LVRing3

3 Information

Update Threshold Test Result Value

Current Chamber: Left Ventricle
Current Amplitude: 4.0 V
Current Pulse Width: 0.4 ms

Update Cancel

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™

LV VectorGuide™ Close

1. Select Vectors:

☐ LVTip1 ☐ LVRing3
☐ LVRing2 ☐ LVRing4 ☐ Unipolar

2. Run Tests:

<input checked="" type="checkbox"/>	Pace Vector	RVS-LVS Delay	Imp. Ω	PNS	Δ LV Threshold
<input checked="" type="checkbox"/>	LVRing3>>LVRing4	77 ms	547 Ω	No PNS 7.5V @ 0.4 ms	2.2 V @ 0.4 ms
<input checked="" type="checkbox"/>	LVRing3>>Can	77 ms	558 Ω	No PNS 7.5V @ 0.4 ms	1.7 V @ 0.4 ms
<input checked="" type="checkbox"/>	LVRing3>>LVRing2	77 ms	924 Ω	No PNS 7.5V @ 0.4 ms	1.7 V @ 0.4 ms
<input type="checkbox"/>	LVRing3>>RV	77 ms	600 Ω	PNS 7.5V @ 0.4 ms	
<input type="checkbox"/>	LVRing2>>Can	73 ms	559 Ω	No PNS 7.5V @ 0.4 ms	
<input type="checkbox"/>	LVRing2>>LVRing3	73 ms	925 Ω	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% ATP 31J 41J Max
VT 0% 100% 1x Burst 1x Ramp 21J 31J Max
VT-1 0% 100% Stable AFib Sudden V>A

Atrium Ventricle

50 Hz/Manual Burst S1 Pulses 8
PES S1 Interval 400 ms Enable
V Fib Shock Coupling 310 ms Induce
✓ Shock on T Energy 1.1 J

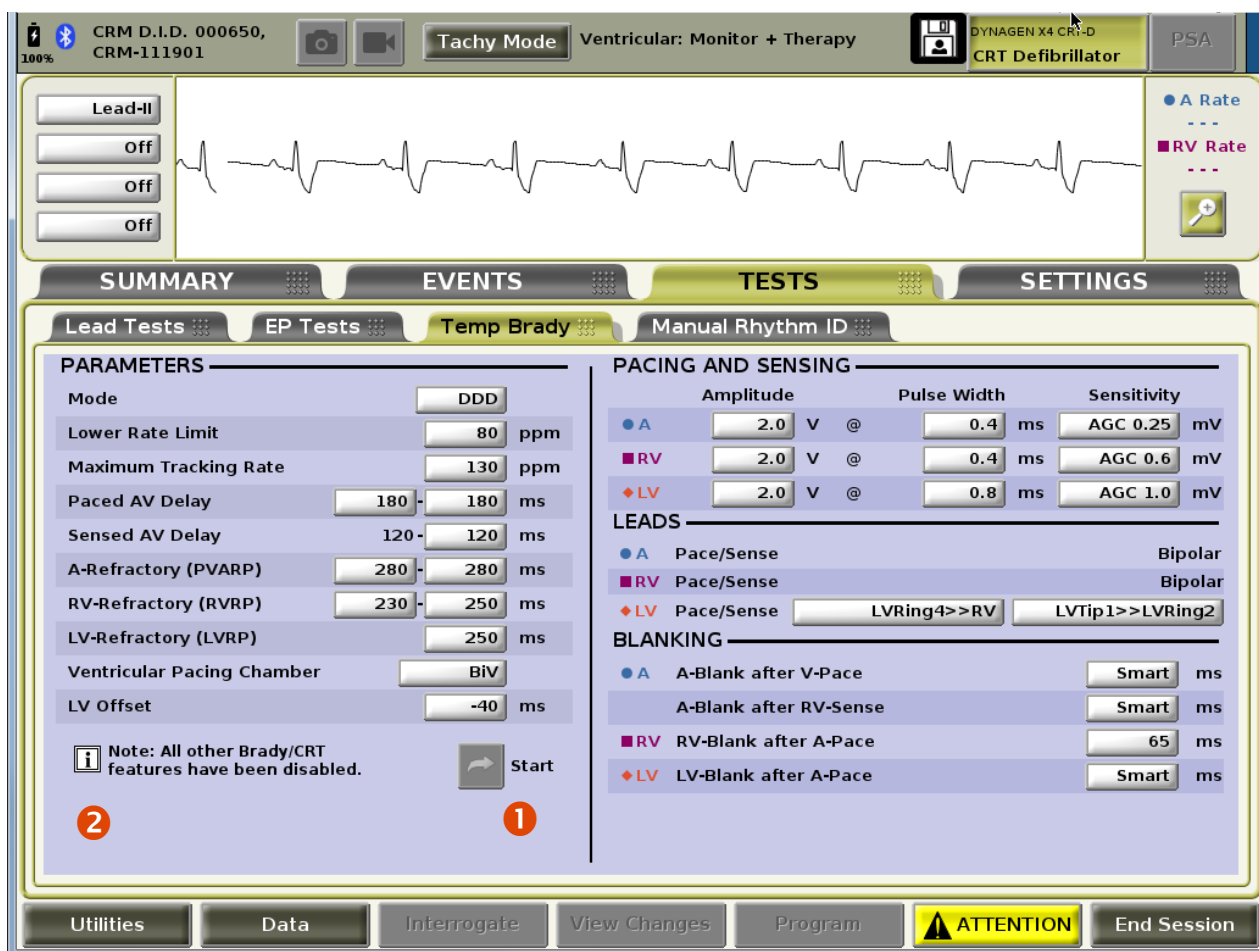
Commanded ATP
Commanded Shock

EP Temp V Mode
Monitor Only
Monitor + Therapy
Show Last Episode
EP Test Pacing

Utilities Data Interrogate View Changes Program ATTENTION End Session

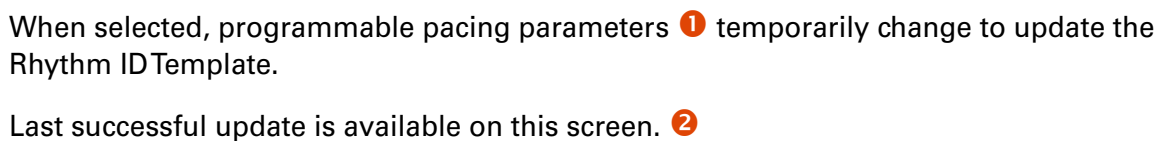
This screen provides the options for induction and termination of arrhythmias.

Temporary Brady Screen



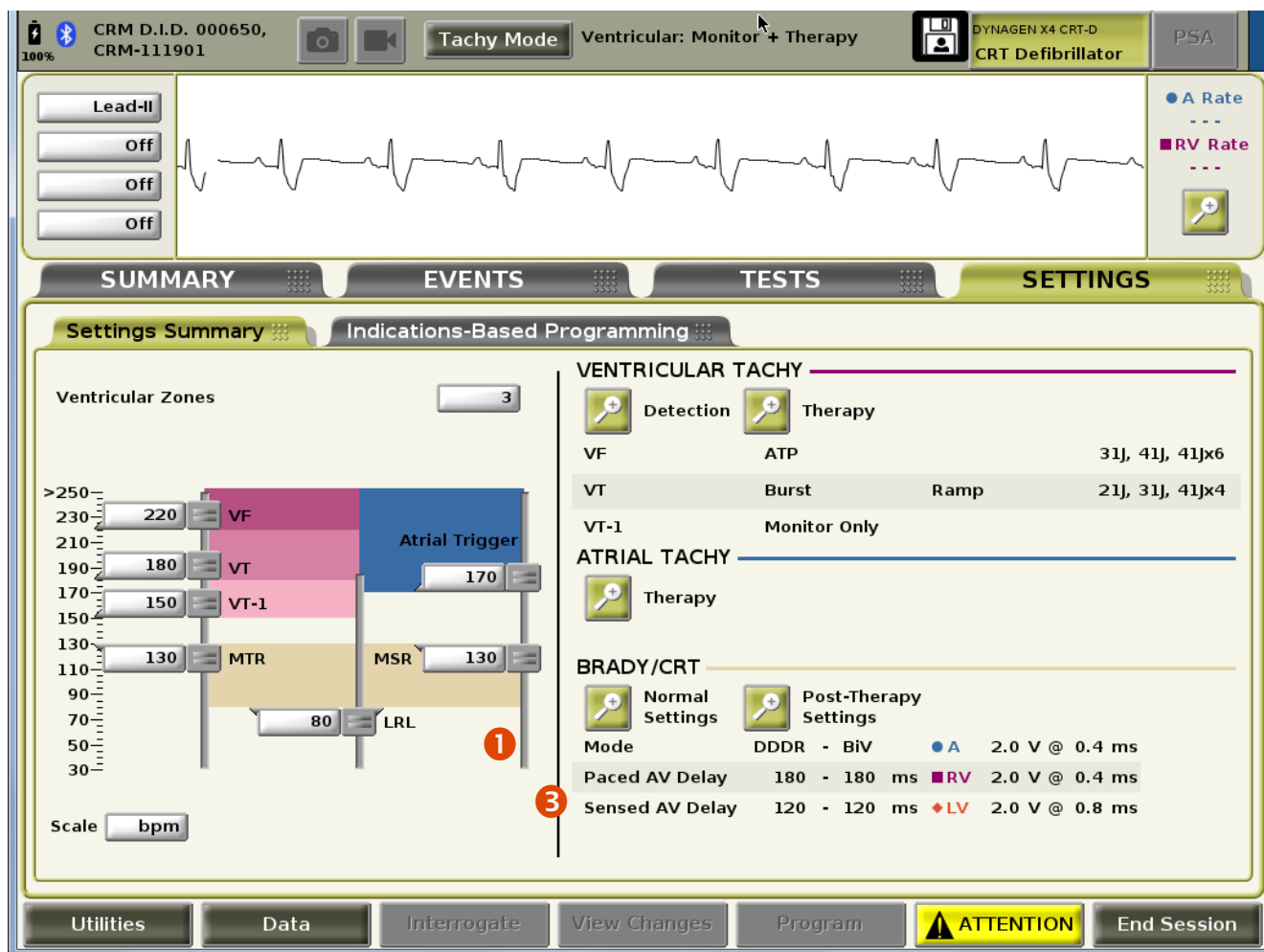
These parameters are activated with Start button ①.

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



Last successful update is available on this screen. 2

Settings Summary

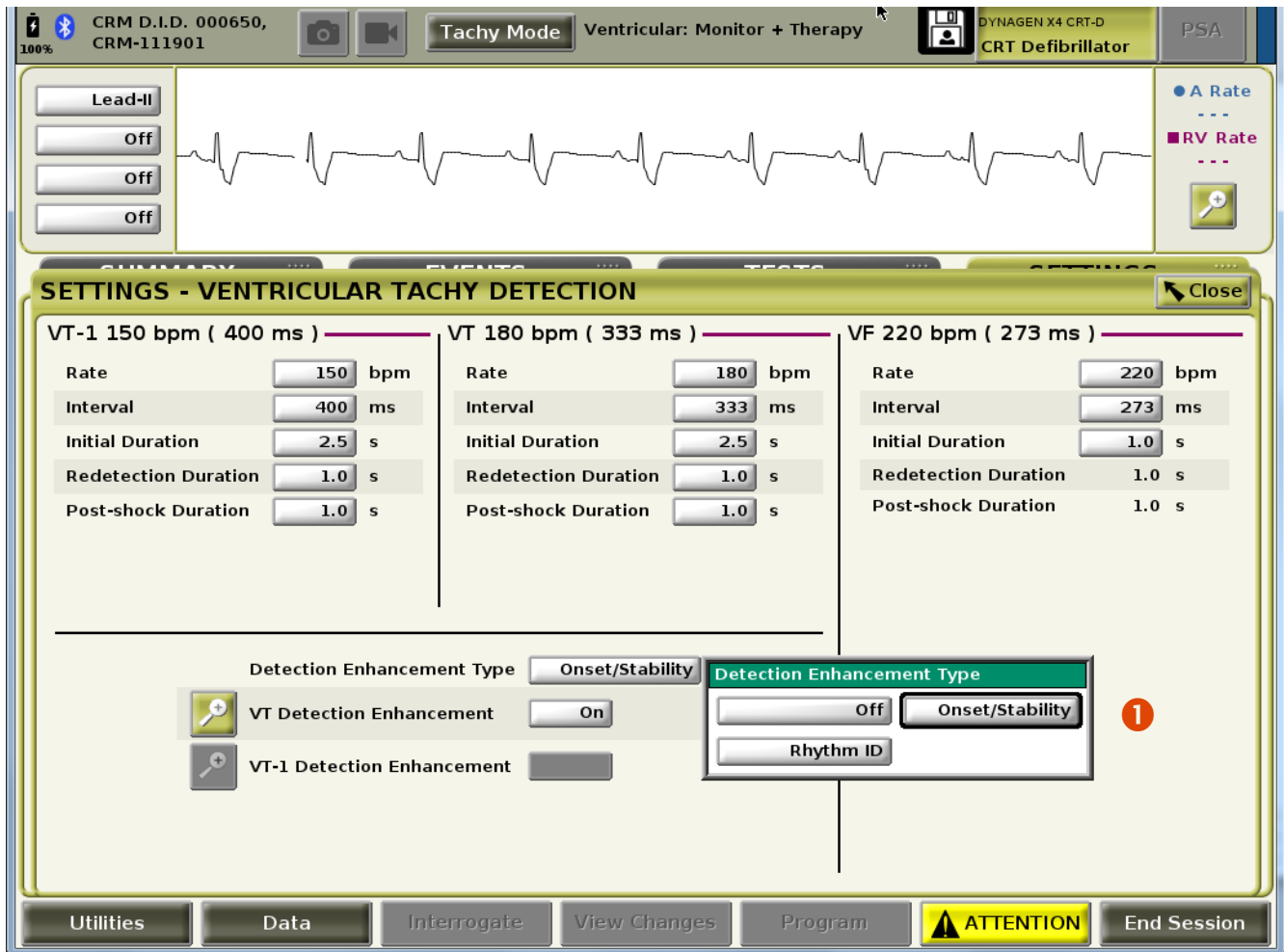


Increase or decrease rate zone cut-offs by:

- 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.

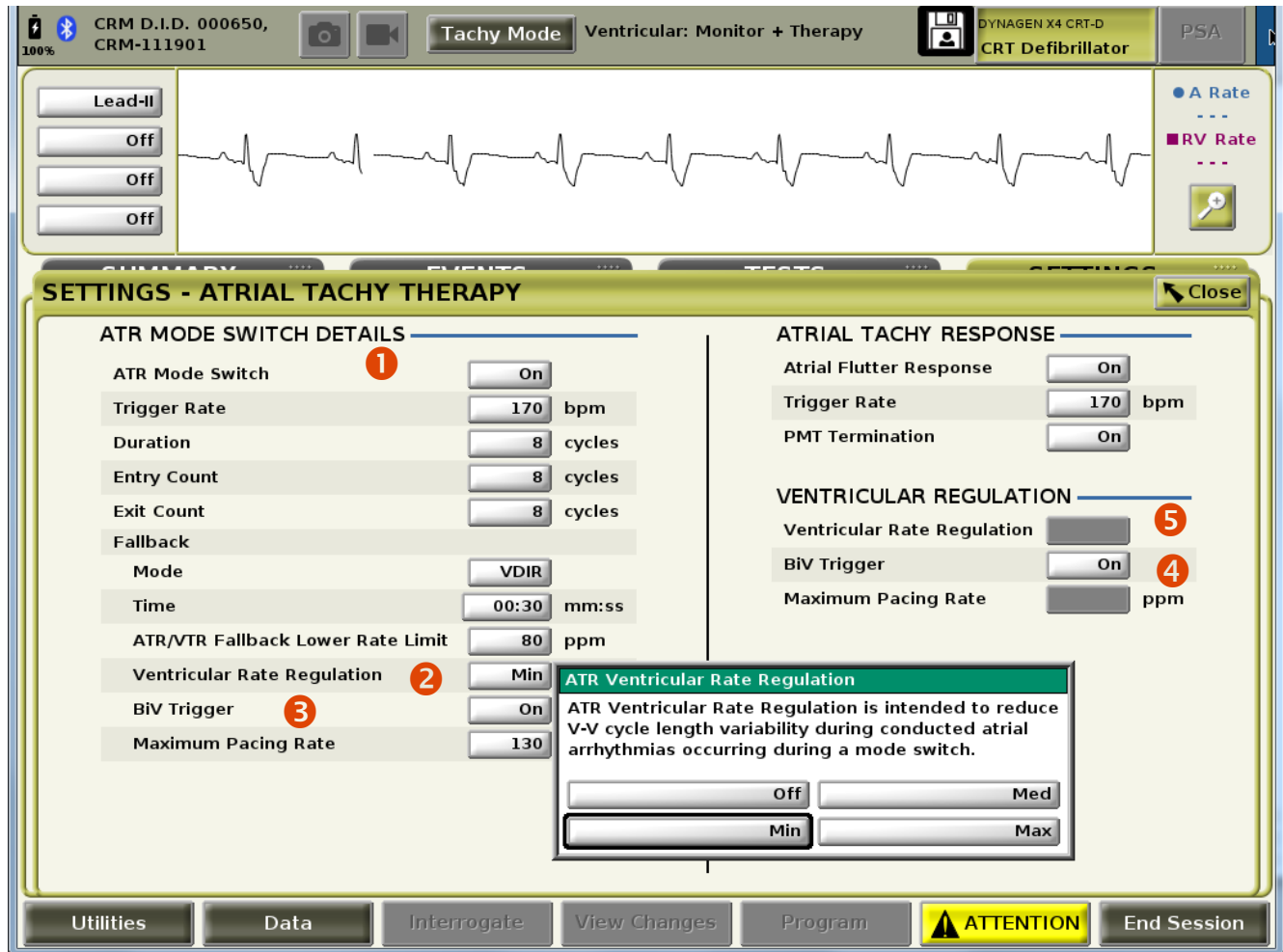
Select relevant icon to review and modify brady and other tachy settings.

Ventricular Detection Enhancements



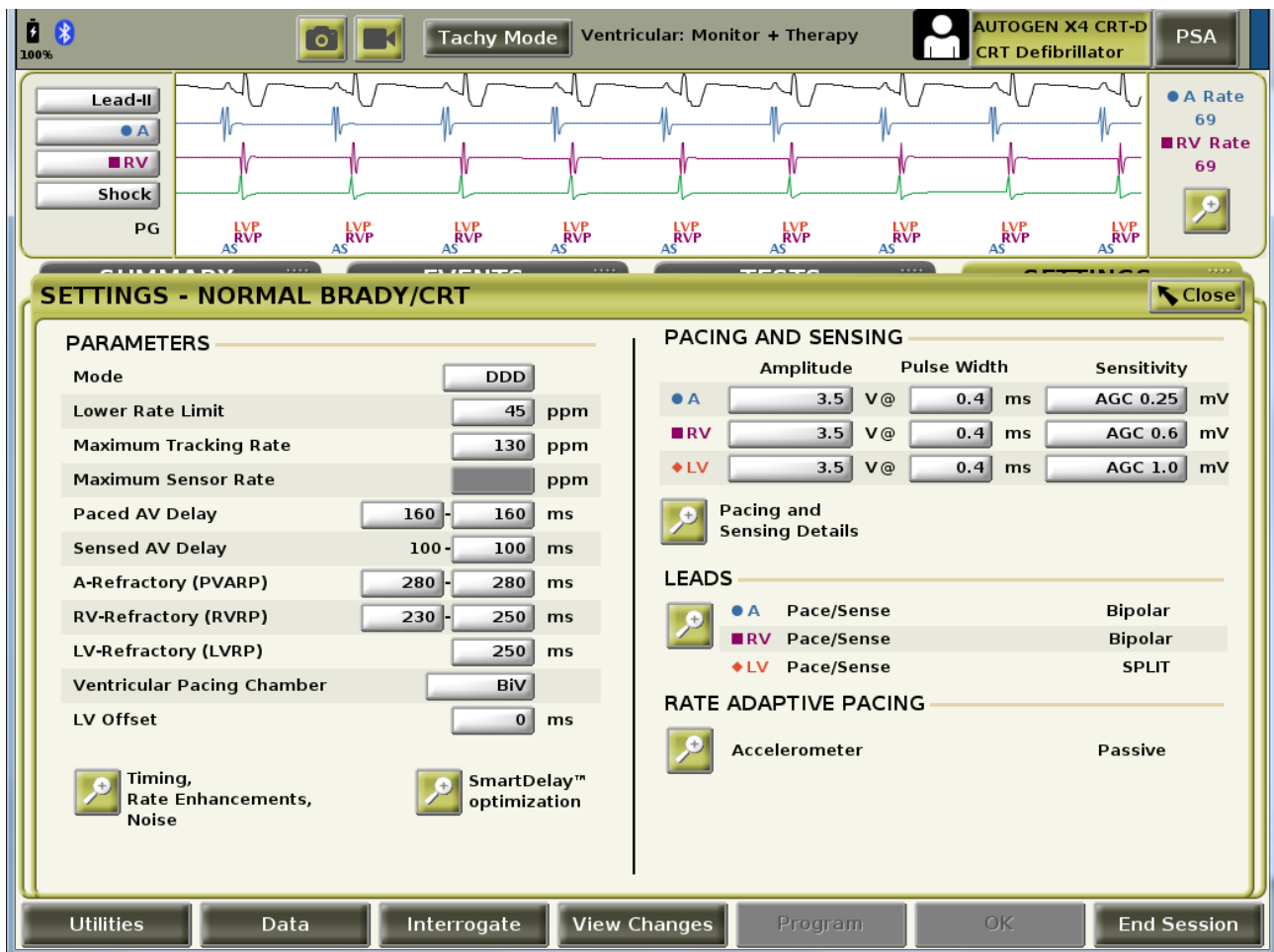
- ① Clinician has 2 options of ventricular detection enhancement type:
Rhythm ID or Onset/Stability.

Atrial Tachy Therapy



- 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



Brady parameters to tailor to meet patient's needs.

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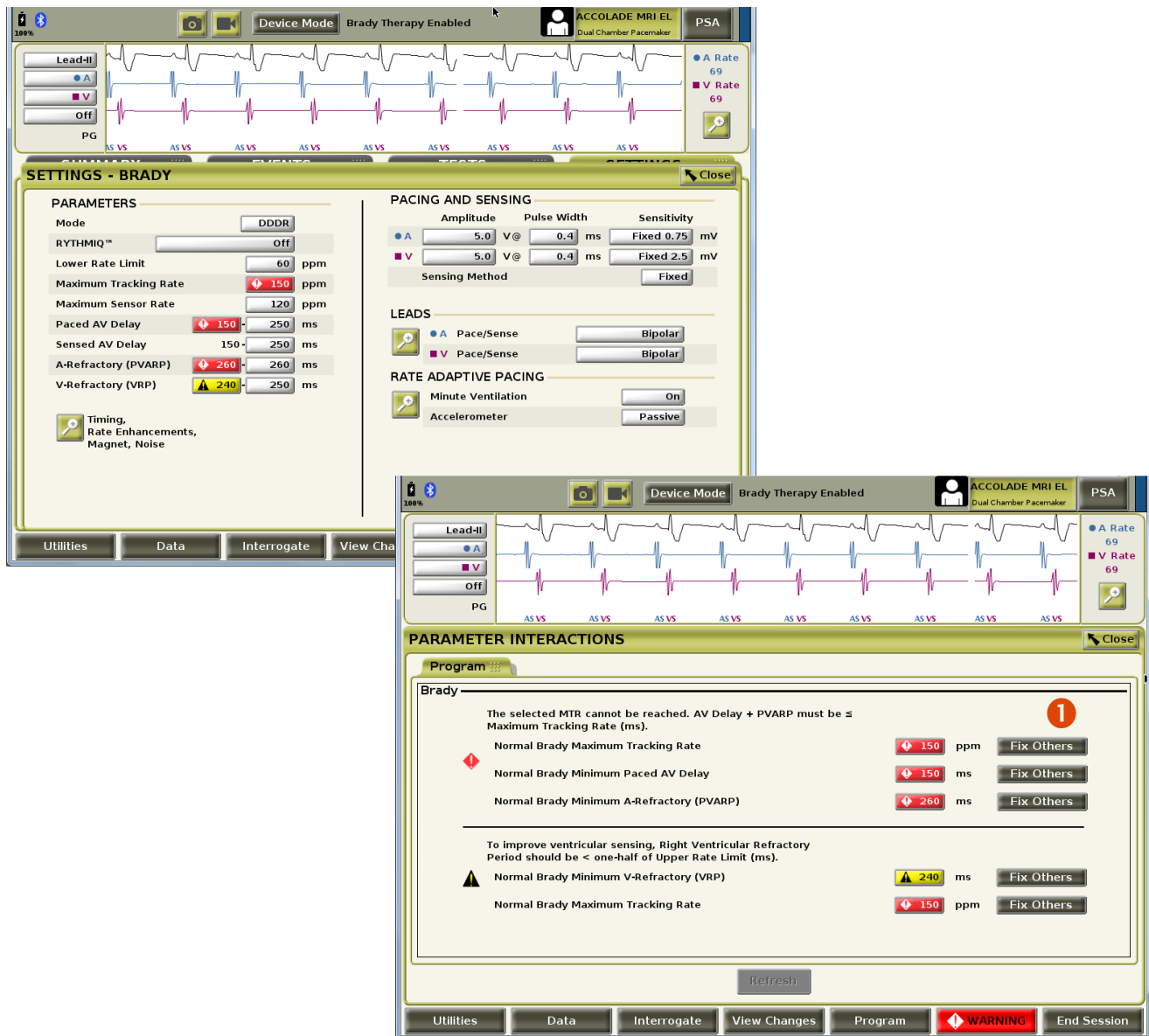
RYTHMIQ™

The screenshot displays the LATITUDE™ Programming System, Model 3300, interface. At the top, the status bar shows "Device Mode", "Brady Therapy Enabled", and "ACCOLADE MRI EL Dual Chamber Pacemaker". The main display area is divided into several sections:

- Lead-II:** Shows three leads (A, V, and PG) with corresponding waveforms. The A Rate is 69 and the V Rate is 70.
- SETTINGS - BRADY:** This section is expanded, showing parameters for the RYTHMIQ™ feature. The Mode is set to "DDDR". The RYTHMIQ™ feature is currently "Off". The Lower Rate Limit is 60, Maximum Tracking Rate is 120, and Maximum Sensor Rate is 120. The Paced AV Delay is 150-250, and the Sensed AV Delay is 150-250. The A-Refractory (PVARP) is 260-260 ms, and the V-Refractory (VRP) is 240-250 ms. A "Timing, Rate Enhancements, Magnet, Noise" icon is present.
- PACING AND SENSING:** This section shows settings for Amplitude, Pulse Width, and Sensitivity. The Sensitivity is set to "Fixed 0.75 mV". The "AAIR With VVI Backup" feature is set to "Off".
- RATE ADAPTIVE PACING:** This section shows settings for Minute Ventilation (set to "On") and Accelerometer (set to "Passive").

A tooltip for the RYTHMIQ™ feature is displayed, stating: "The RYTHMIQ™ feature is designed for patients with intact conduction to pace AAI(R) with backup VVI to eliminate unnecessary right ventricular paces." The bottom of the screen features a navigation bar with buttons for "Utilities", "Data", "Interrogate", "View Changes", "Program", "OK", and "End Session".

Parameter Interactions

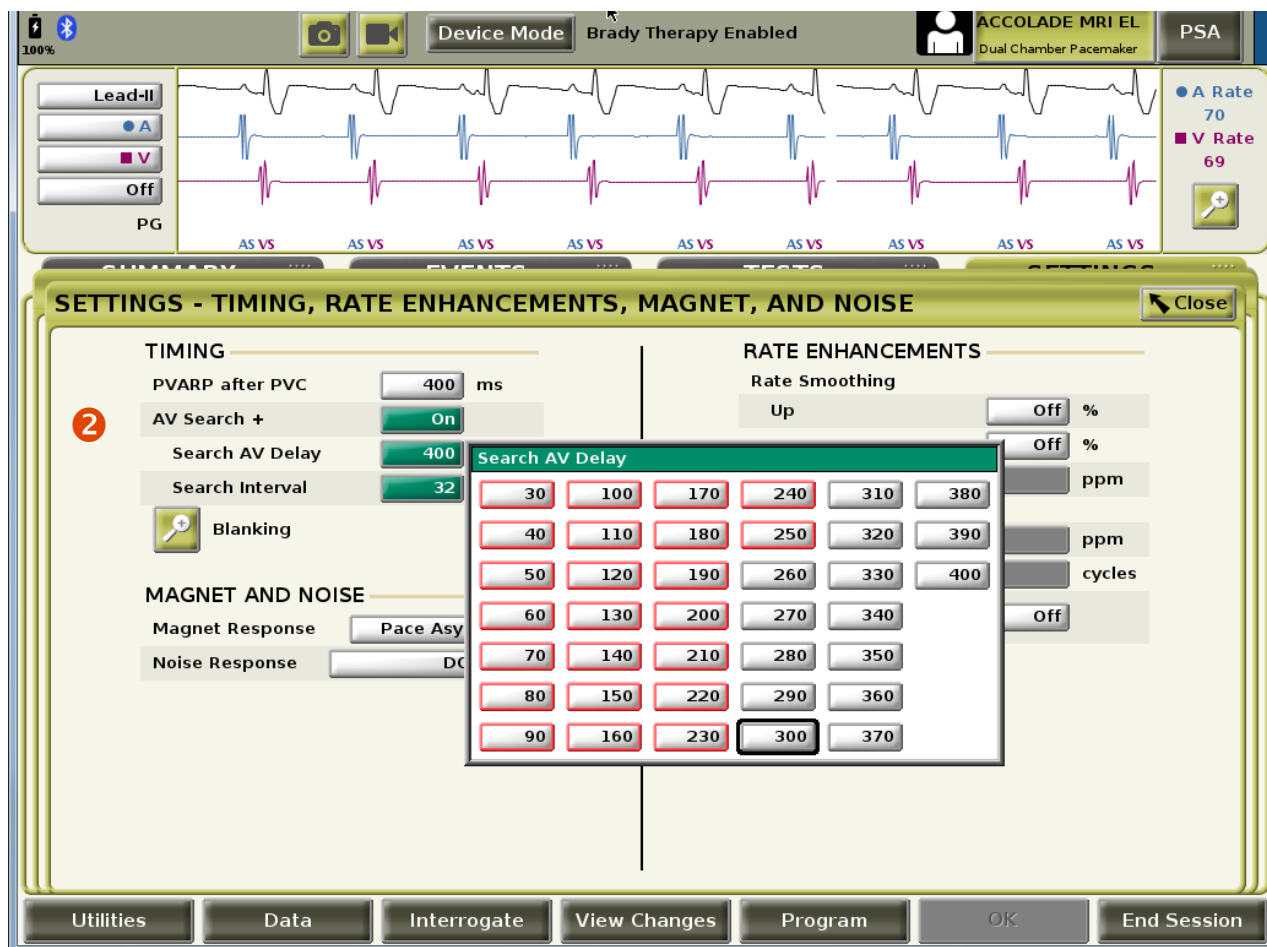


Color coding identifies interactive limit (red, green, yellow).

Fix Others addresses interactive parameters and gives suggested changes to resolve interactions ①.

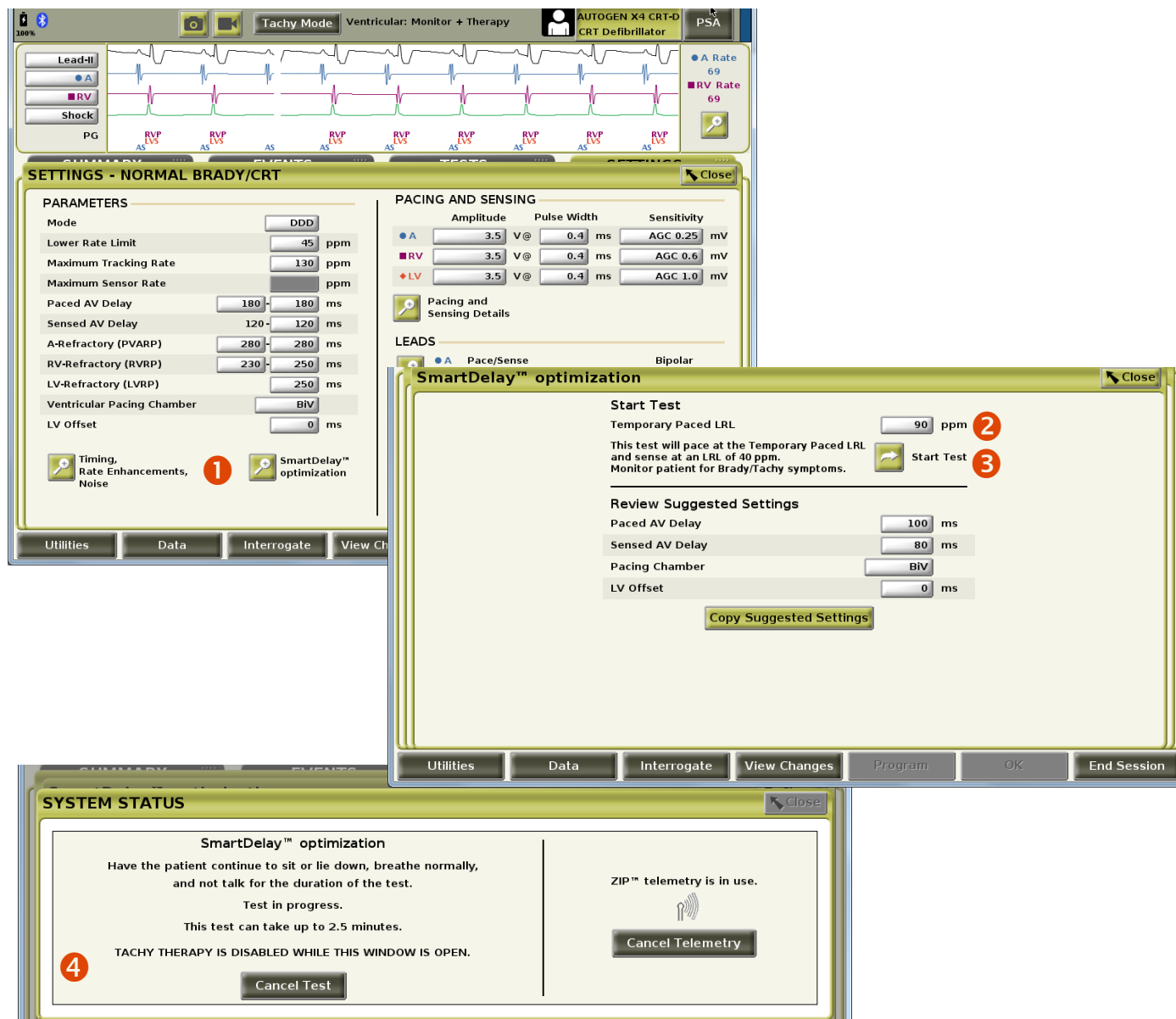
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AV Search +



- 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



- 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.

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Rate Adaptive Sensor Data

The screenshot displays the LATITUDE™ Programming System, Model 3300, interface. The top bar shows the device ID (CRM D.I.D. 000250, CRM-111901), Device Mode, Brady Therapy Enabled, and the device name (ADVANTIO Dual Chamber Pacemaker). The main window is divided into several sections: **SETTINGS - BRADY** and **SETTINGS - RATE ADAPTIVE PACING**.

SETTINGS - BRADY window:

- PARAMETERS:**
 - Mode: DDR
 - Lower Rate Limit: 60 ppm
 - Maximum Tracking Rate: 140 ppm
 - Maximum Sensor Rate: 130 ppm
 - Paced AV Delay: 180 - 280 ms
 - Sensed AV Delay: 180 - 280 ms
 - A-Refractory (PVARP): 240 - 330 ms
 - V-Refractory (VRP): 210 - 250 ms
- PACING AND SENSING:**
 - Amplitude: 2.0 V@
 - Pulse Width: 0.5 ms
 - Sensitivity: Fixed 1.0 mV
 - Sensing Method: Fixed
- LEADS:**
 - A Pace/Sense: Bipolar
 - V Pace/Sense: Bipolar
- RATE ADAPTIVE PACING:**
 - Minute Ventilation: On
 - Accelerometer: On

A red circle with the number 1 is placed over the 'Timing, Rate Enhancements, Magnet, Noise' icon in the 'PARAMETERS' section.

SETTINGS - RATE ADAPTIVE PACING window:

- View:** 1 hour
- Sensor Trending - 30 Second Average:** A graph showing the sensor rate (ppm) over time. The graph is divided into three regions: 'Light to Moderate Exertion' (green), 'Moderate to Vigorous Exertion' (yellow), and 'Vigorous Exertion' (red). The sensor rate is shown as a black line (Actual Rate) and a yellow line (Sensor Replay). The graph shows the sensor rate increasing during the 'Moderate to Vigorous Exertion' and 'Vigorous Exertion' periods.
- RightRate™ Pacing:**
 - Minute Ventilation: On
 - Response Factor: 8
 - Fitness Level: Active
- Motion-Based Pacing:**
 - Accelerometer: On
 - Response Factor: 8
 - Activity Threshold: Medium
- Maximum Sensor Rate:** 130 ppm
- Lower Rate Limit:** 60 ppm
- Legend:**
 - Actual Rate: 86 ppm (Sensed)
 - Sensor Replay: 68 ppm
- Buttons:** More MV Pacing, Less MV Pacing
- Information:** To update sensor trending information, press Interrogate. Telemetry may affect MV sensor status.

Sensor and Trending Data are found by *selecting* relevant icon ❶.

View Changes

VIEW CHANGES Close

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

5 Load Initials Cancel Changes 7

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

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

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

		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	Monitor + Therapy

5 Load Initials Cancel Changes 6

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

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

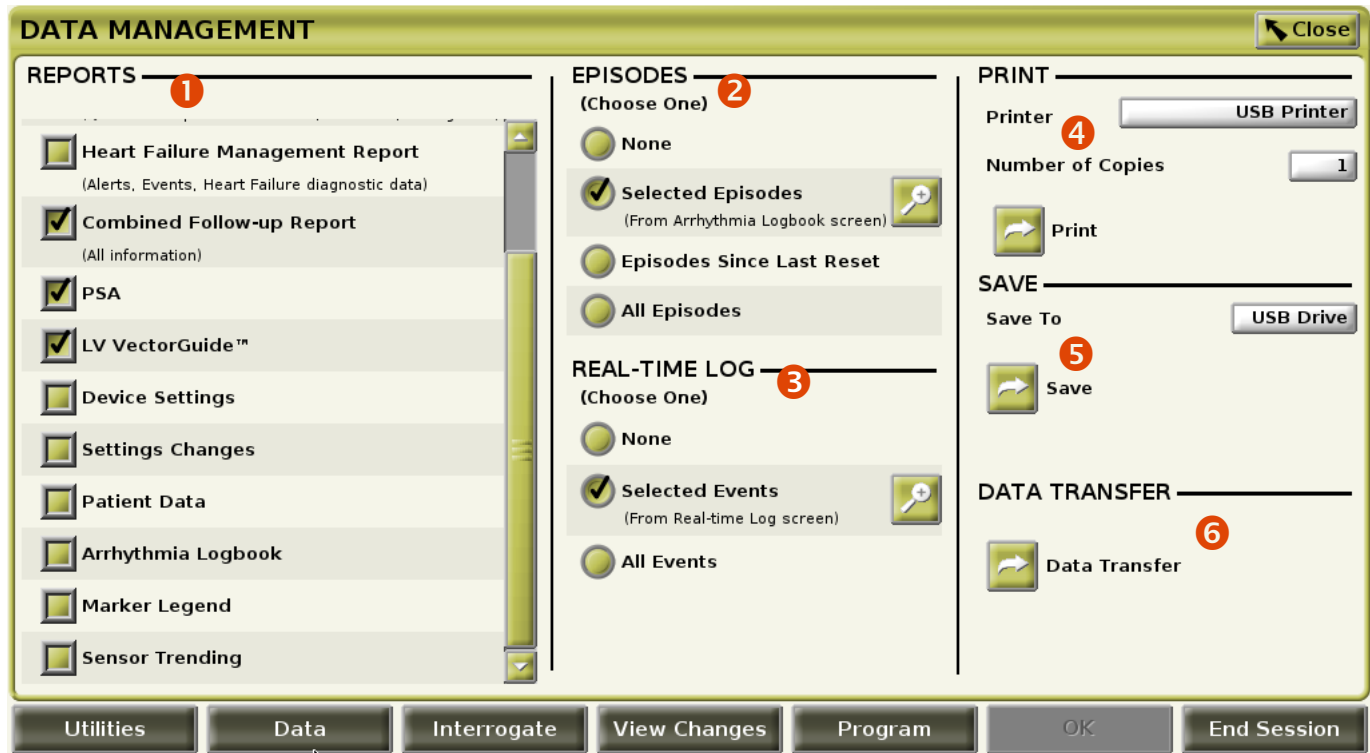
You can sort by:

- 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.

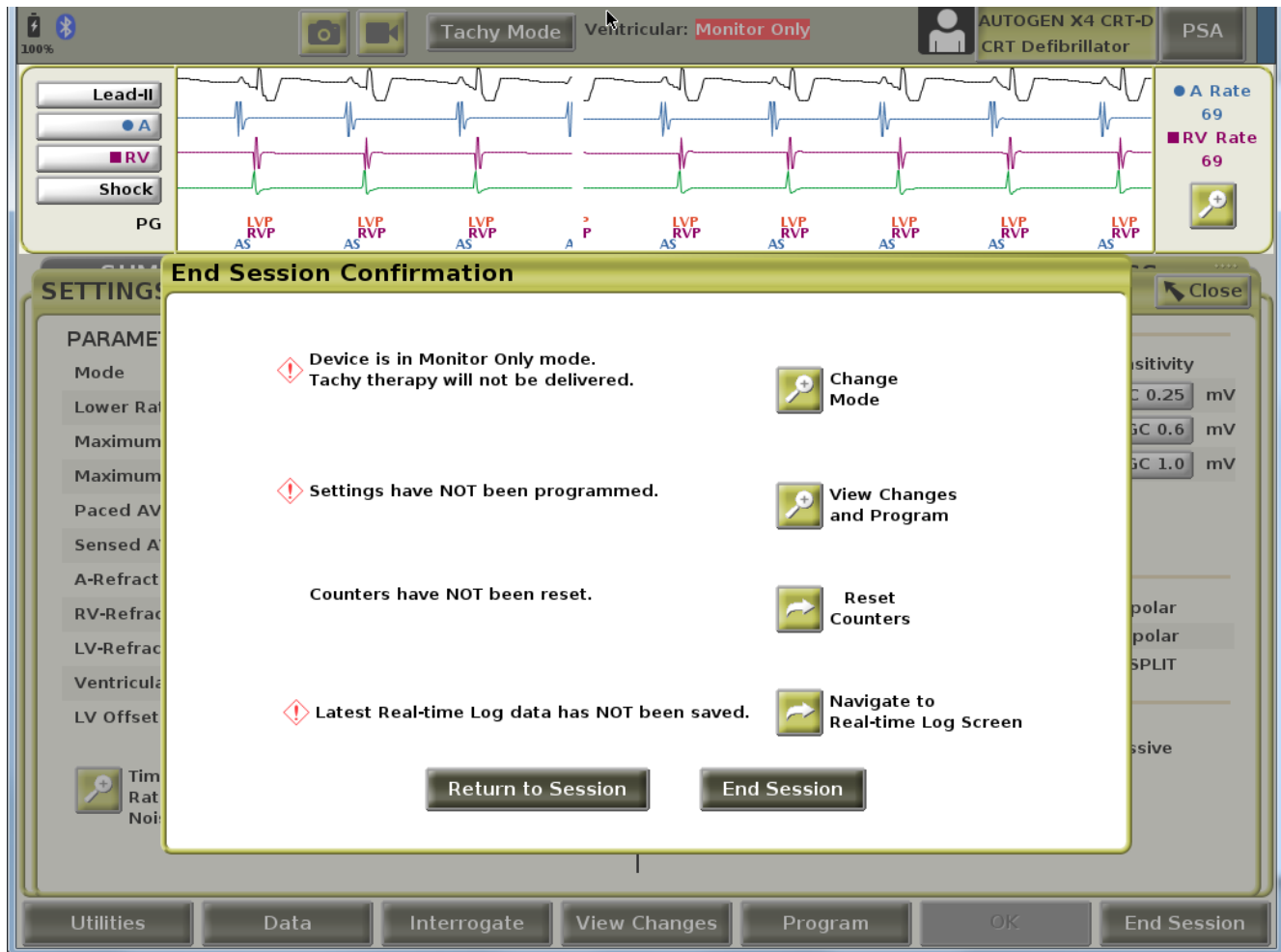
7 **Select Program** on screen or on the programmer itself anytime to apply changes.

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



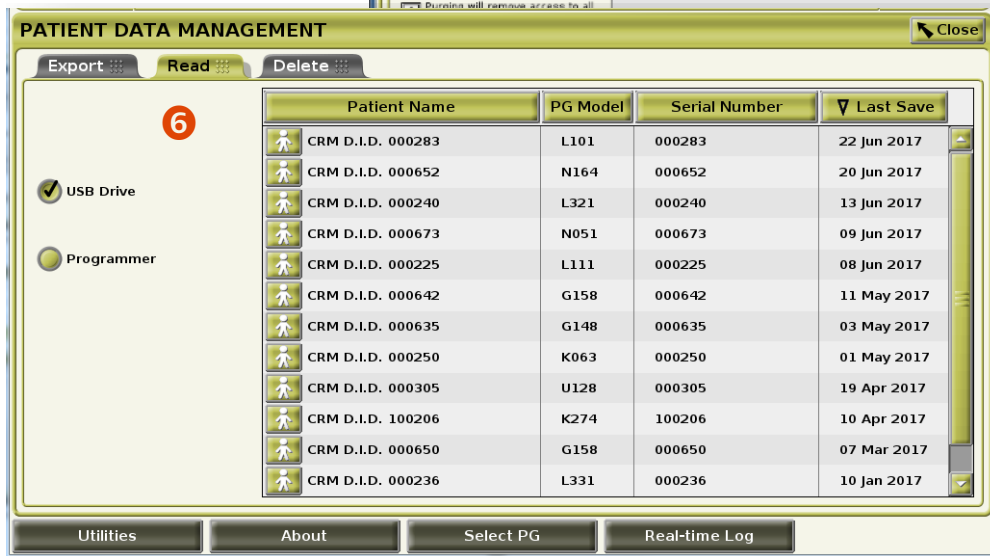
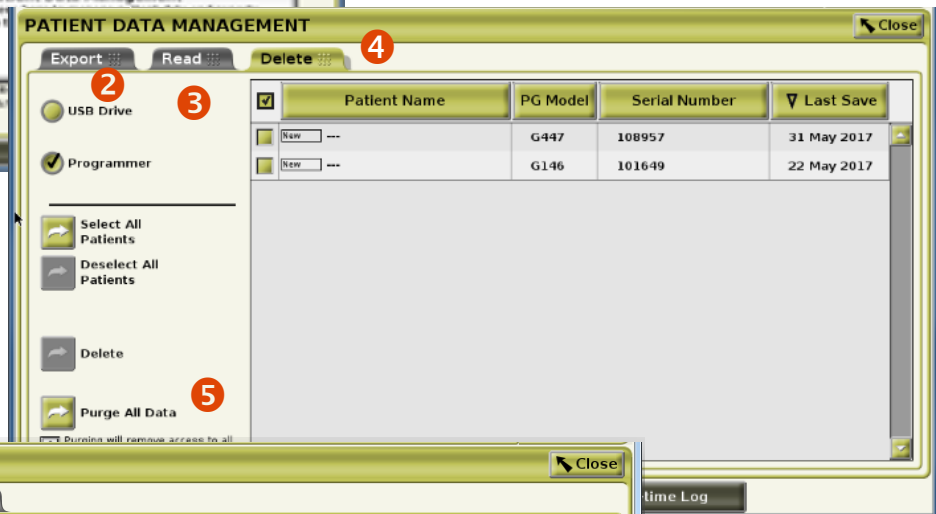
The **End Session** confirmation will alert the user for Tachy Mode, Programming, Counters Reset and Real-time Log saving.

LATITUDE™ Programming System, Model 3300

Export, Read, Delete



- ① Select Patient Data Management when PG 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™ 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 LATITUDE Programming System, Model 3300.

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. During implantation, the PSA application is suitable for temporary external pacing while the patient is being continuously monitored by medical personnel.

WARNINGS

- Use of unspecified cables and accessories. The use of any cables or accessories with the LATITUDE Programming System other than those provided by or specified by Boston Scientific could result in increased electromagnetic emissions, decreased electromagnetic immunity, or electrical shock of the LATITUDE Programming System. Anyone connecting such cables or accessories to the LATITUDE Programming System, including the use of MSOs (Multiple Socket Outlets), may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems. • Equipment modifications. No modification of this equipment is allowed unless approved by Boston Scientific. Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate the equipment. • Radio frequency (RF) communications equipment. Keep all RF communications equipment (including peripherals such as antennas, wands, and cables) at least 30 cm (12 in.) away from the Model 3300 Programmer, including cables specified by Boston Scientific, to avoid degradation of the performance of this equipment. • Connector contacts. Do not simultaneously touch the patient and any accessible LATITUDE Programming System connector or exposed conductor. • Electric shock. To avoid the risk of electric shock, only connect the Programmer's Model 6689 Power Adapter with the appropriate power cord to a grounded/earthed power outlet. • Battery access. When accessing the battery, ensure that power to the Programmer is turned off. Do not touch the connector terminals in the battery compartment while removing or replacing the battery because an electrical charge is present. • Electrostatic charges. The PSA lead system is in electrical contact with the patient's heart and blood. • Do not touch the metal clips on the patient cable or the pacing lead. Electrical currents can be dangerous to the patient and the user. • Discharge any electrical static charge on your person by touching a grounded metal surface before touching the patient, the patient cables, or the device. • Electrical currents. Unused PSA cable connections contacting conductive surfaces can induce electrical currents into the patient's heart. • Attach unused cable connections to surgical draping near the patient or disconnect the unused cables from the system. • Electrocautery. The LATITUDE Programming System is designed and tested to be electrocautery safe. • While the device is designed and tested to be electrocautery safe, electrocautery can induce electrical currents in the PSA cables that can be conducted into the patient's heart. However, Boston Scientific recommends that the Programmer be placed as far from the electrocautery system and associated components as possible to minimize noise being introduced into the LATITUDE Programming System and patient cables. • Electrocautery may also produce unexpected behavior in the Programmer display or operation. If electrocautery is medically necessary, maintain a distance of at least 30 cm (12 inches) between electrocautery equipment and the Programmer and its associated components. Similarly, maintain this distance between the Programmer and its associated components and the patient during these procedures. • 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. During the reset and reboot, which takes up to one minute, there will be no pacing support. For this reason, a backup PSA/pacer resource must be available in case electrocautery is applied. • LATITUDE Programming System location. Use of the Model 3300 Programmer adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. • LATITUDE Programming System must remain outside sterile field. The Programmer is non-sterile and cannot be sterilized. Do not allow the device to enter a sterile zone in an implant environment. • Physiological signals. Operation of the LATITUDE Programming System with physiological signals that are lower than the minimum detectable amplitude may cause inaccurate results. • LATITUDE Programming System is MR unsafe. 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 on MR Safe Practices. Under no circumstances should the LATITUDE Programming System be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas. • Induction. When activating PSA Burst Pacing, which may cause unpredictable arrhythmias, always have cardiac emergency equipment (e.g., external pacemaker, external defibrillator) in an operational status available for immediate life support. • Consider additional preemptive measures in patients where acceleration or a loss of rhythm could cause life-threatening danger. • External defibrillation. The LATITUDE Programming System is designed and tested to be defibrillation safe. • While the Programmer is designed and tested to be defibrillation safe, the patient can be endangered and the Programmer can be damaged. • The PSA cable must be disconnected from the lead(s) before using external defibrillation. • Whenever possible, disconnect all cables from the patient when using external defibrillation equipment. • If the LATITUDE Programming System is connected to the patient during defibrillation, verify that the Programmer is operating as expected after defibrillation. • Loss of power. Operating the Programmer with a depleted internal battery can suspend Programmer function. Operating the Programmer with no battery can suspend Programmer function if AC power is temporarily interrupted. • If the battery has been depleted to 10% or less, the Programmer may need to be powered Off to allow charging to begin and then may be powered back On to continue charging. • If an optional battery is used, do not use a depleted or unapproved battery. For additional patient safety, when the battery level indicator shows 25% or less remaining, connect the AC power to the Programmer. • When operating on battery power, do not attempt to replace the battery. • A yellow attention message displays on the Programmer screen when the battery reaches 25% depletion. When the battery reaches 10% depletion or less, a red warning message displays. At 5%, there is another red warning message followed by a 60-second automatic shutdown. • Loss of pacing support. Always have external cardiac pacing equipment in an operational status available for immediate life support. • Initially, when the Programmer is switched on, the pacing functions of the PSA are switched off while a self-test is conducted. It is not possible to initiate pacing support until after the self-test has completed, which can take up to one minute. • Connecting the PSA cable to the wrong lead may result in ineffective sensing and pacing behavior and loss of pacing support. • If the Programmer encounters a fault condition, pacing operation continues until a restart is initiated unless the fault was in the PSA component itself. • When the user manually restarts the Programmer, pacing support will be lost. The user must manually reinitiate PSA pacing after the system has completed the self-test. The self-test can take up to one minute. • If there is no battery installed or the battery is depleted (5% or less), pacing support will be lost if AC power is lost. • Consider additional preemptive measures in patients where loss of pacing could cause life threatening danger. • Backup defibrillation protection. 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. • Impaired AV conduction. Single chamber atrial modes are contraindicated for patients with impaired AV conduction. • If the patient has impaired AV conduction, AAI programming and antegrade conduction tests must not be performed. • Abruptly terminating pacing. Abruptly terminating pacing may result in extended periods of asystole in some patients. • Gradually decrease the pacing rate until the patient's intrinsic rate is detected for a controlled transition from pace to intrinsic rhythm. • Loss of capture. Pacing threshold testing implies loss of capture. At loss of capture, asystole and pacing during vulnerable periods can occur. • Consider the health of the patient prior to performing a pacing threshold test. • Use of protective sleeves. 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. • Before connecting cables, ensure correct position of protective sleeves. • Do not use wet cables. Moisture on wet cables can impair cable function and endanger the patient. • Exposure to fluids. Before cleaning and disinfecting the Programmer surfaces, power down the device and disconnect the external power supply. Before operating the LATITUDE Programming System, let cleaning and disinfection agents used on the Programmer evaporate. • Emissions and interference. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required), this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment. Other equipment may interfere with the LATITUDE Programming System, even if that equipment complies with the CISPR emission requirements. • Lithium-ion battery. The Model 6753 Battery is a Lithium-ion battery and, as such, is deemed a Dangerous Good in regards to shipping. Do not return the Model 6753 battery to Boston Scientific. Dispose of the battery as required by local regulations. If the battery must be shipped, contact your local shipper for instructions and shipping requirements. • Power up. 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

Electrical and magnetic interference. Electrical interference or "noise" from devices such as electrocautery and monitoring equipment, monitors, or strong magnetic fields may interfere with establishing or maintaining telemetry for interrogating or programming the device and may produce unexpected behavior in the Programmer display or operation. In the presence of such interference, move the Programmer away from electrical devices, and ensure that the wand cord and cables are not crossing one another. Electrical interference or "noise" from concomitant implanted devices such as a ventricular assist device (VAD), drug pump, or insulin pump may interfere with establishing or maintaining telemetry for interrogating or programming the pulse generator. In the presence of such interference, place the wand over the pulse generator and shield both with a radiation-resistant material.

For specific information on precautions, read the following sections of the product labeling: General, Maintenance and Handling, and Radio Frequency (RF) Performance.

ADVERSE EFFECTS

The following list includes the possible adverse effects associated with programming pulse generators described in this manual:

- Asystole • Atrial arrhythmia • Bradycardia • Tachycardia • Ventricular arrhythmia

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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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Effects, and Operator's Instructions.

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