Boston Scientific

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LATITUDE™

Programming System, Model 3300

WORKBOOK

TABLE OF CONTENTS

LATITUDE™ Programming System, Model 3300

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

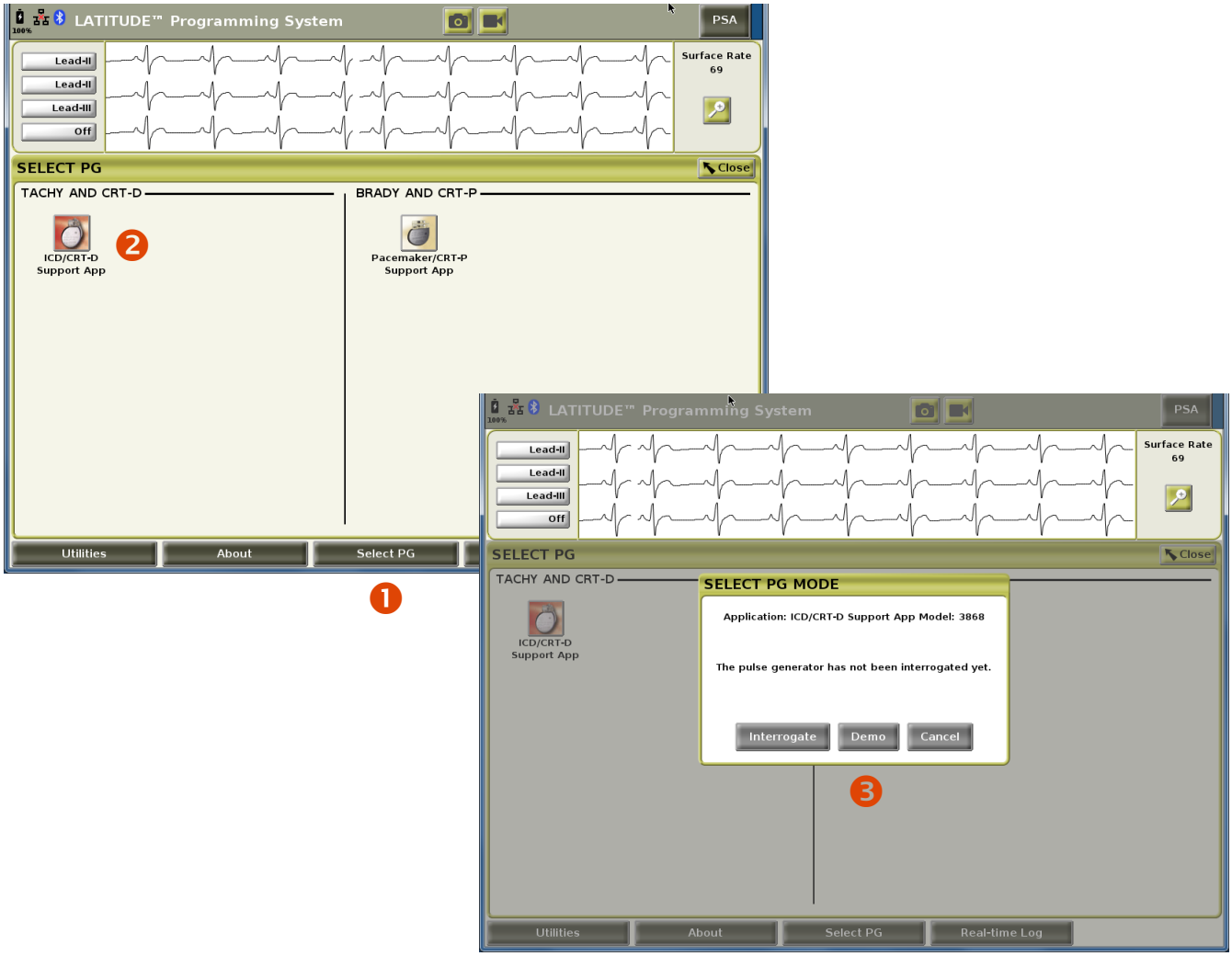
This hands-on guide will familiarize you with the software screens encountered during navigation of a typical follow-up for BSC devices. It is designed to be used with the Brady and Tachy demo mode on the programmer and with de-identified patient case studies which can be provided by your local BSC representative.

- 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.

Using Demo Mode

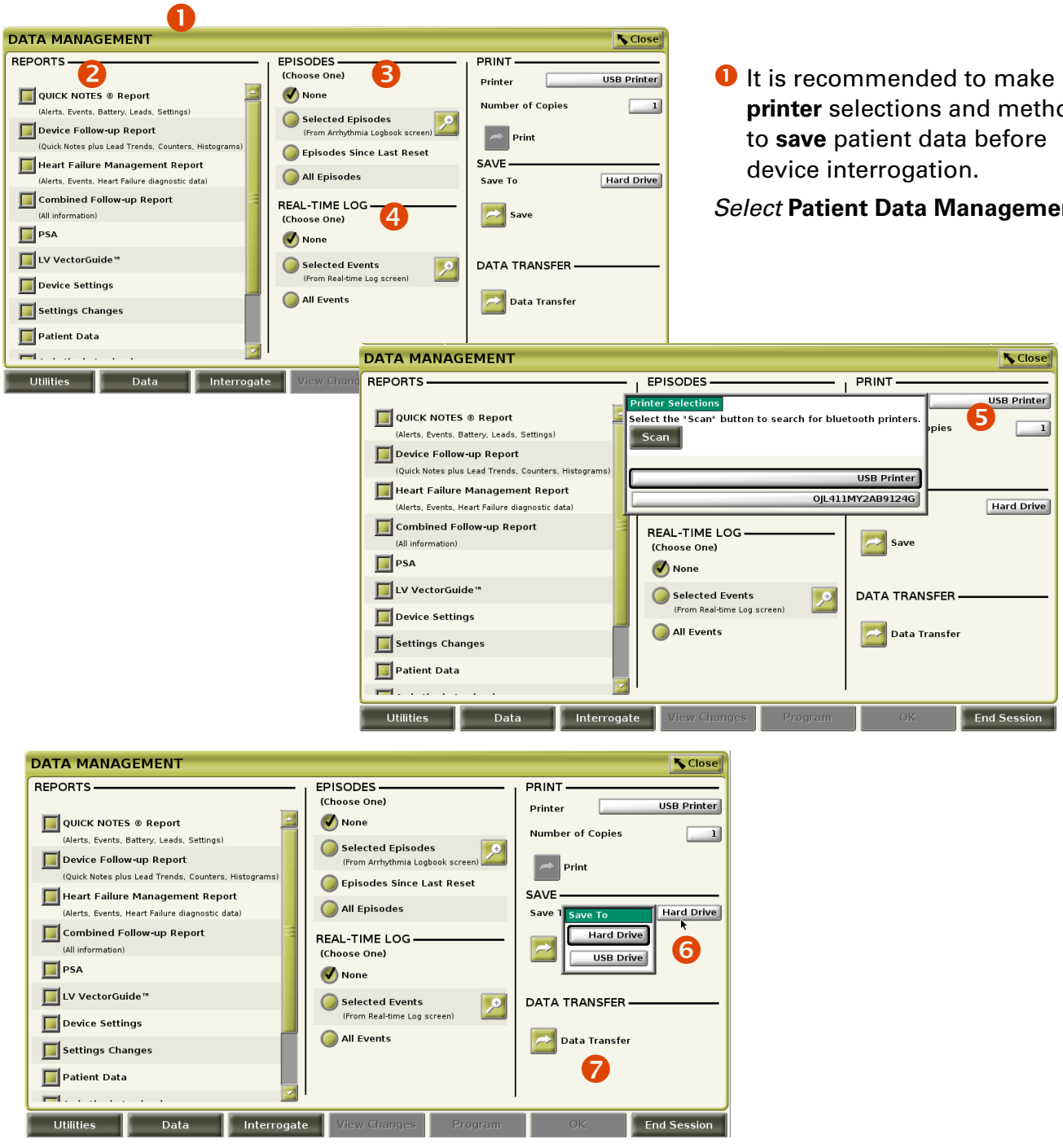


Turn on the programmer.
Select PG ❶.

Select **ICD/CRT-D Support App** ❷.

Then *Select* **Demo** ❸.

Printing and Saving



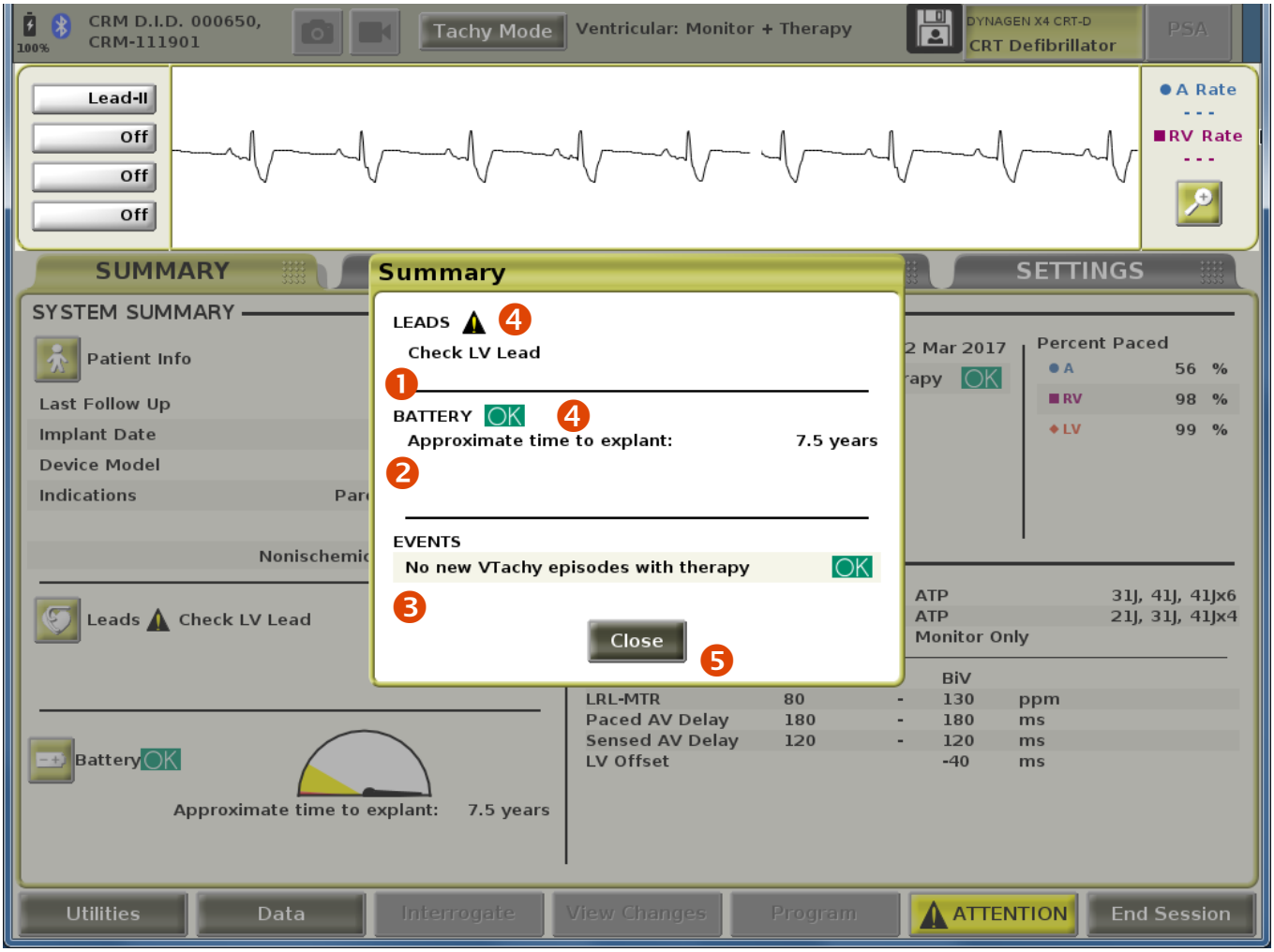
❶ It is recommended to make **printer** selections and method to **save** patient data before device interrogation.

Select **Patient Data Management**.

❷ Clinician selects desired Reports, ❸ Episodes, and ❹ Events, ❺ Options to Print, ❻ Save and ❼ Transfer Data can be selected.

Summary Pop-up Screen

❻



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

❶ **Leads**

❷ **Battery**

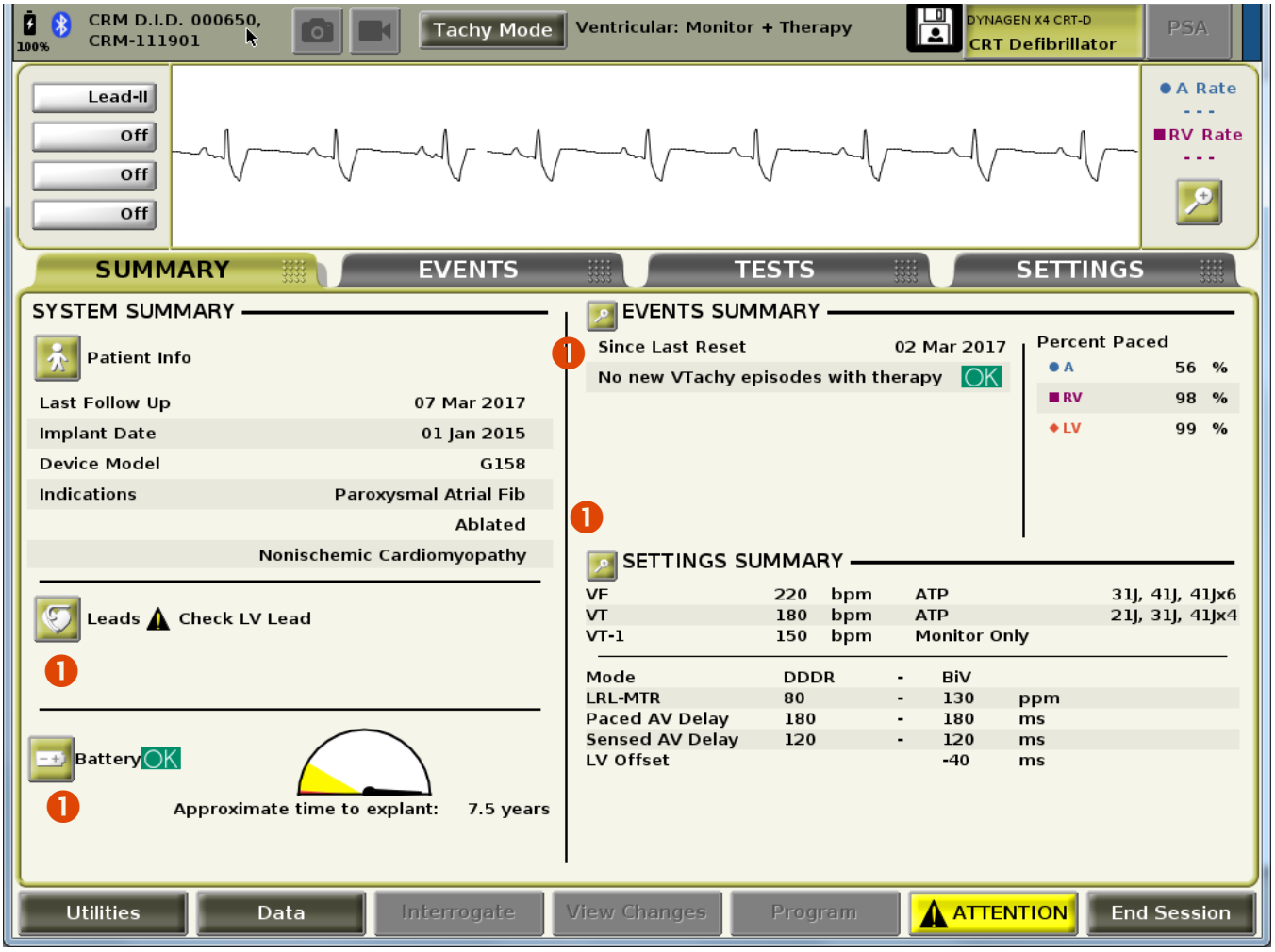
❸ **Events**

❹ **Issue Status**

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

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

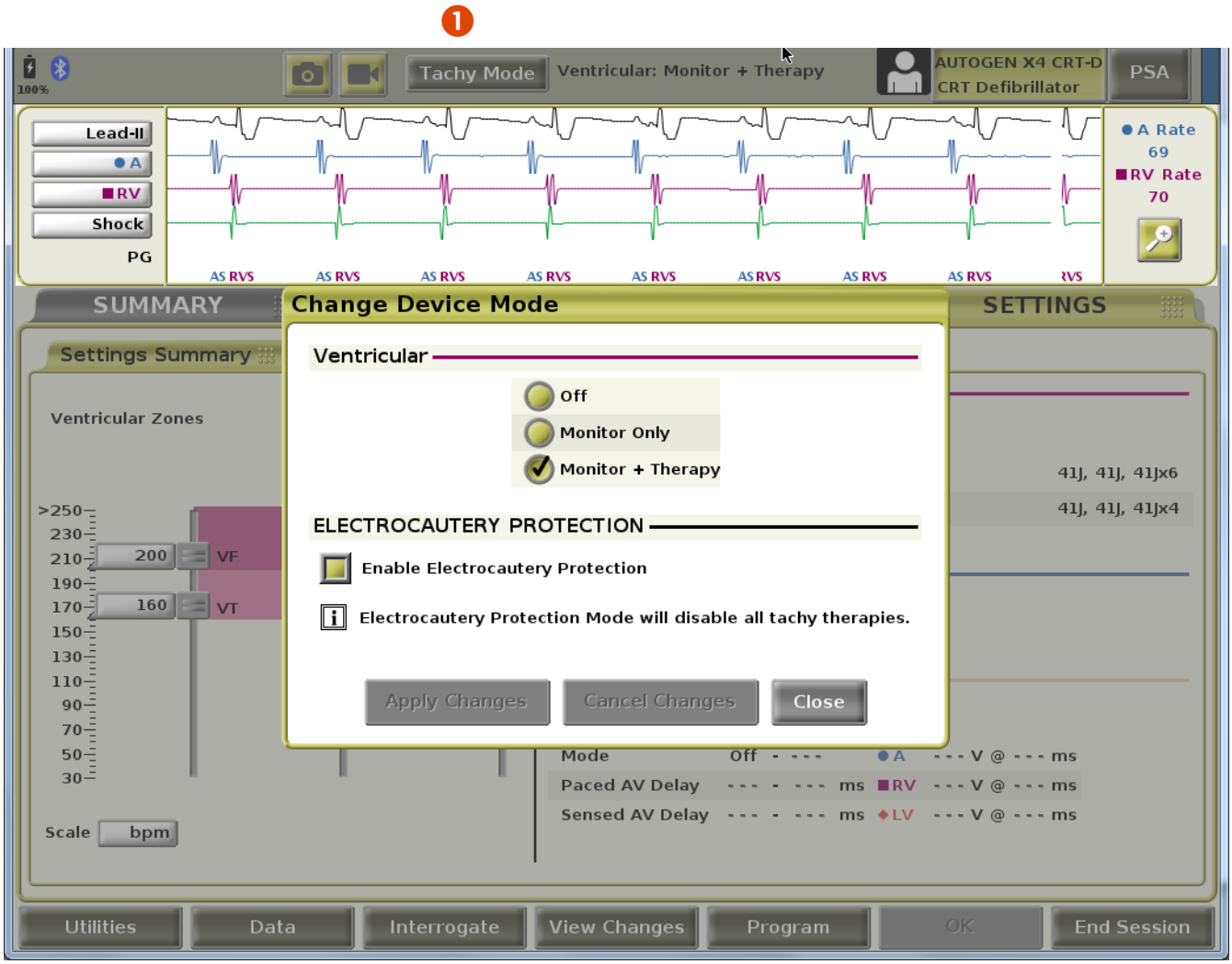
Summary Screen



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

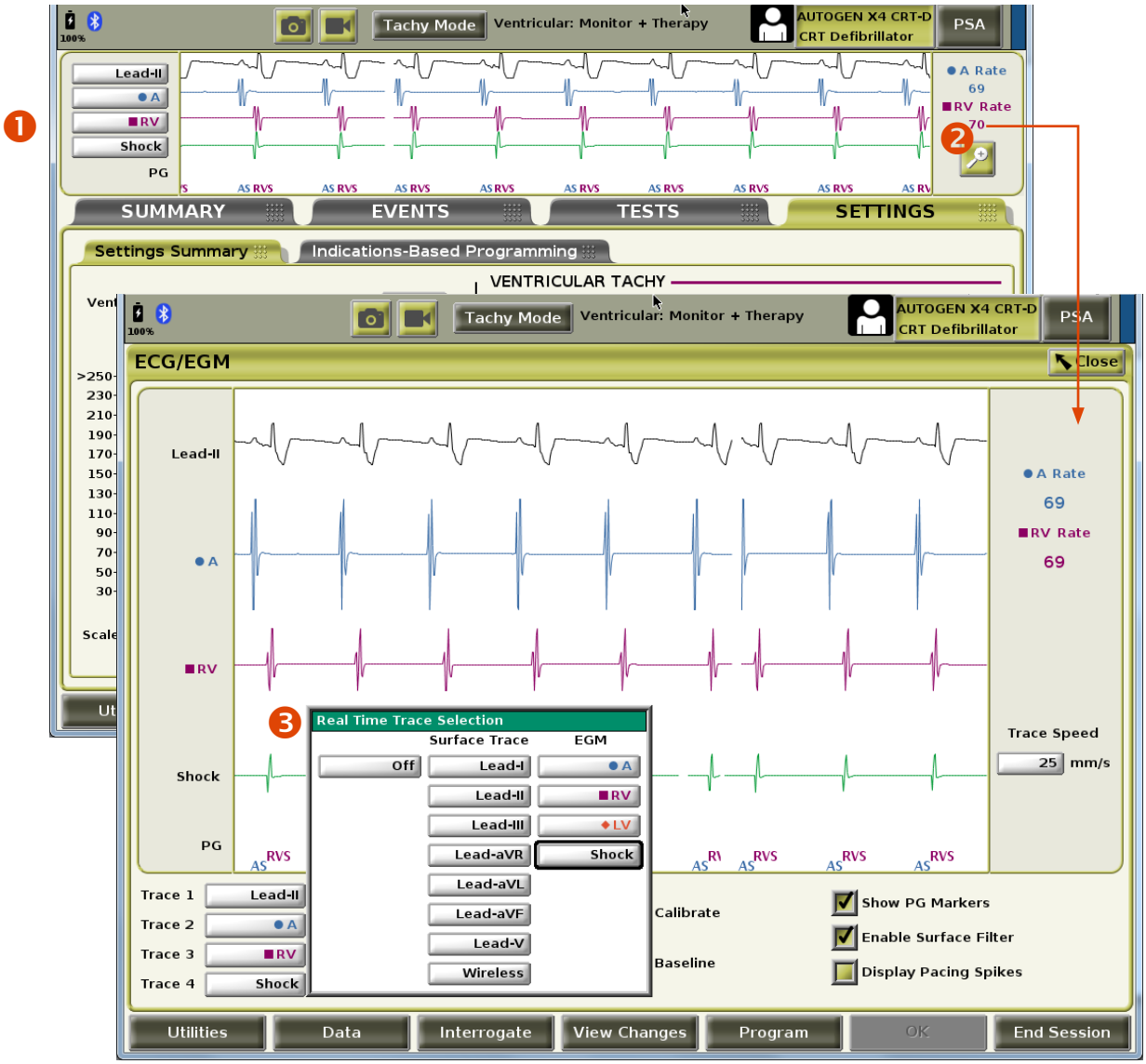
Select the relevant icon ❶ for more detailed information.

Tachy Mode



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

Enhanced EGM Functionality

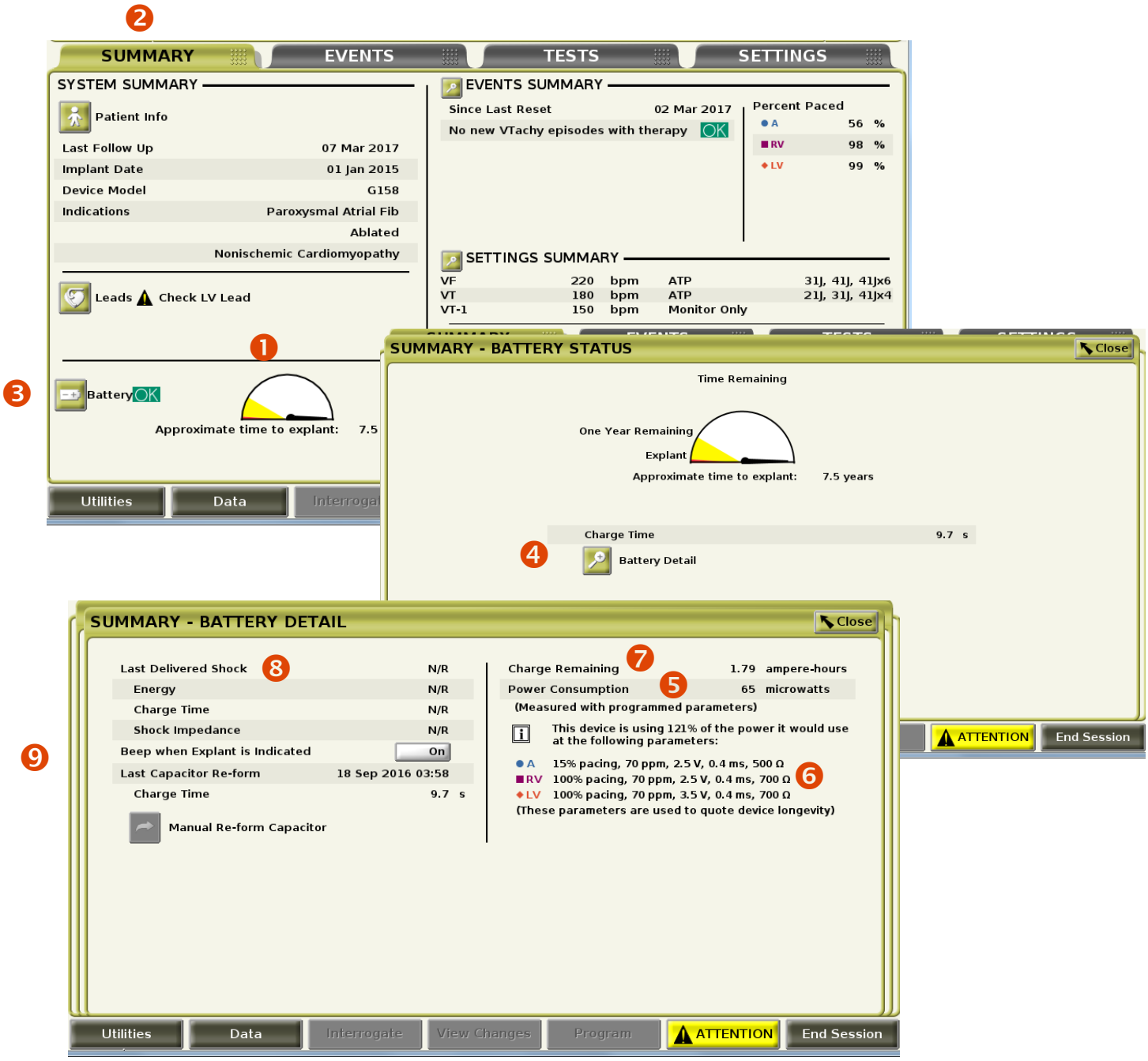


The nominal display setting is surface and three EGMs ❶.

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

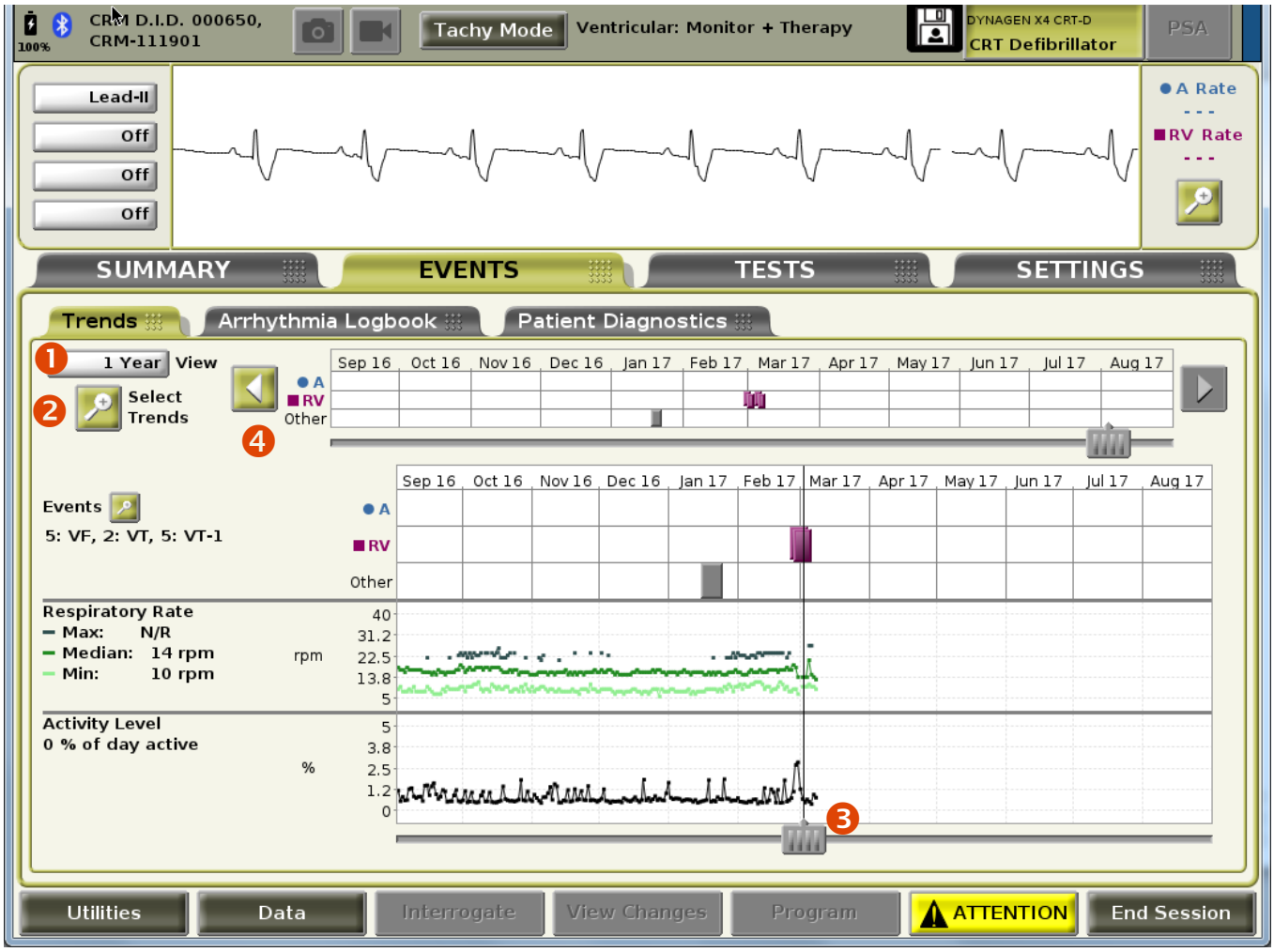
Select **Details button** ❷ to enlarge the four lead channels.

Battery



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

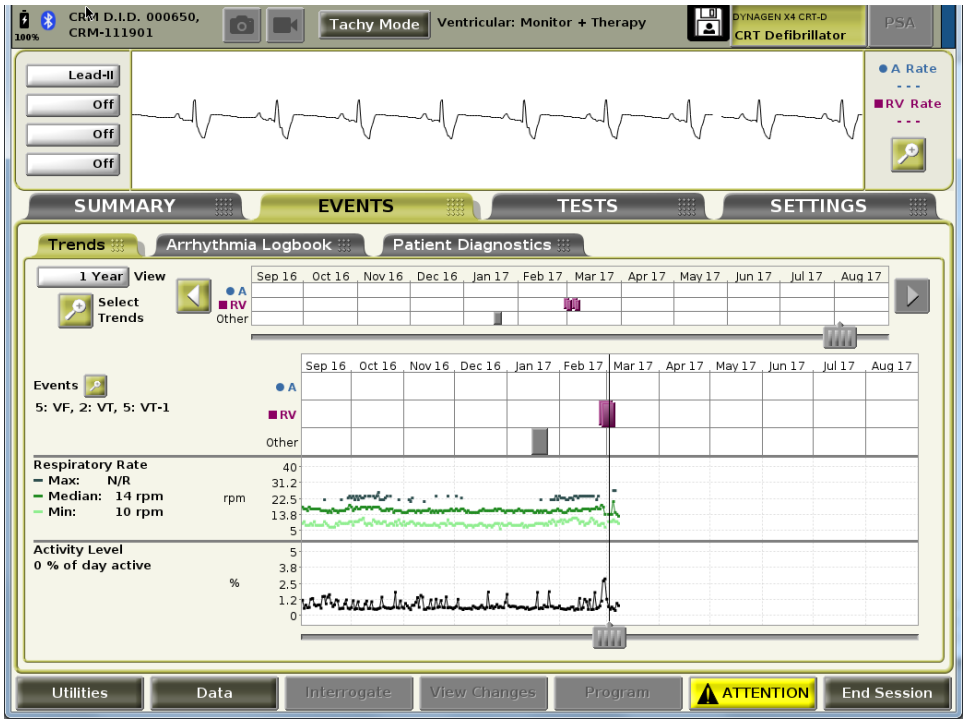


From the **EVENTS** tab, *select* the **Trends** tab.

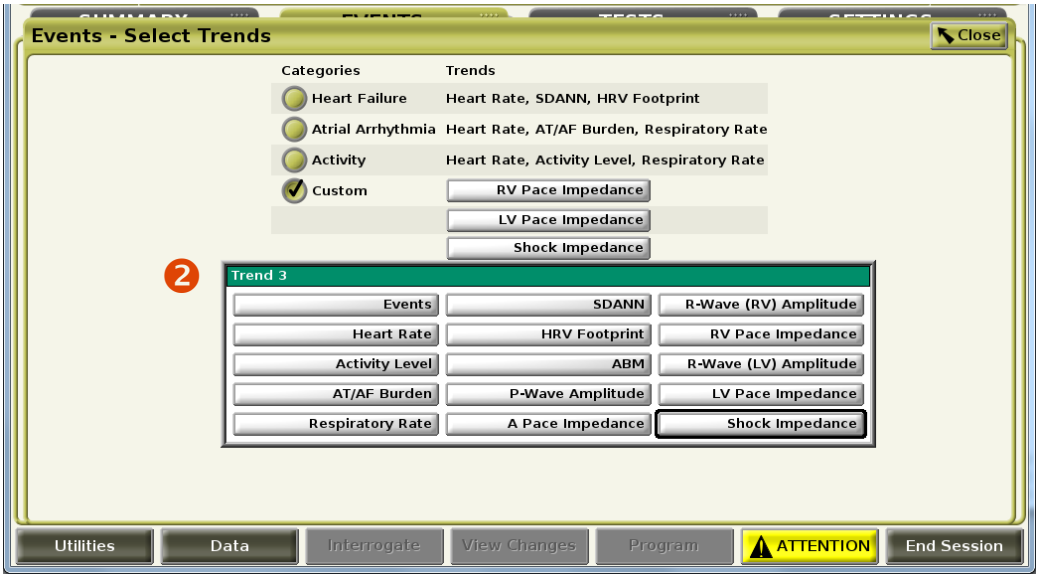
Customize the display by:

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

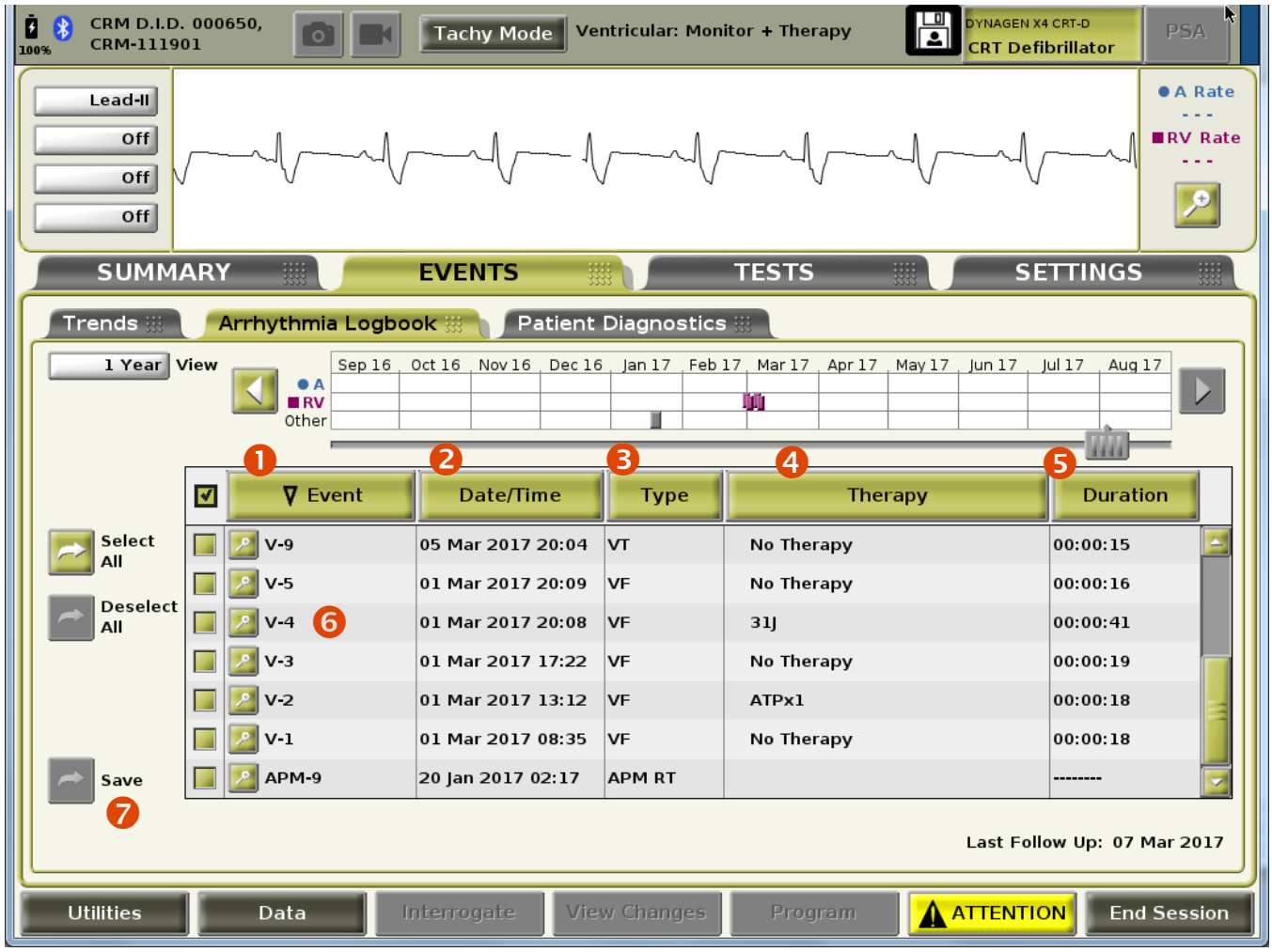


2

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:

❶ **Event**

❷ **Date/Time**

❸ **Type**

❹ **Therapy**

❺ **Duration**

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

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

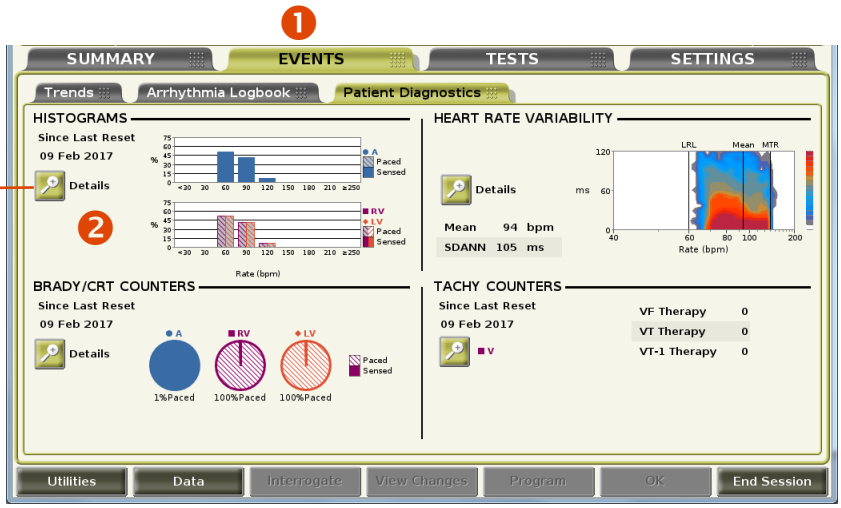
Check which episodes you want to **Save** ❼ to Hard Drive or USB.

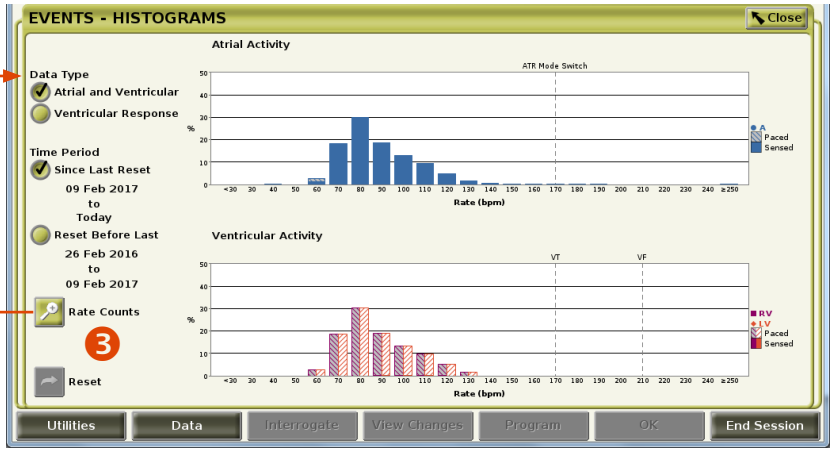
Stored VF Event EGM

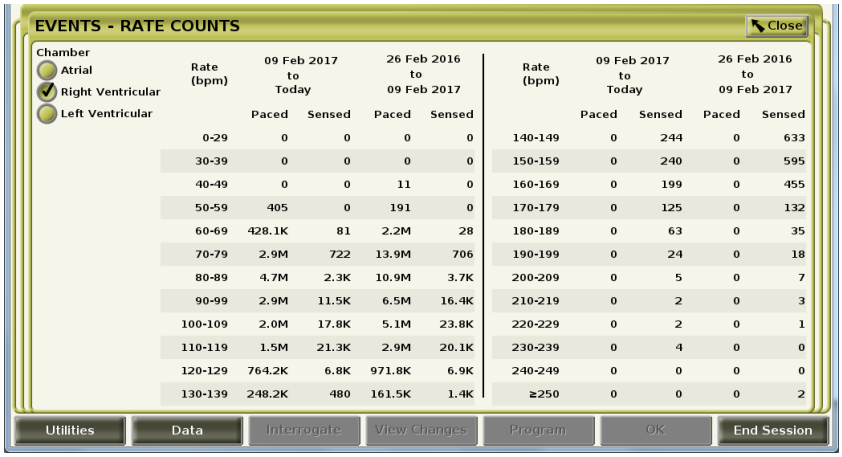
❶ A 31J **shock** was delivered after a charge time ❷ of 6.0 sec. with successful conversion of the rhythm. The **intervals** ❸ present a visual representation of the rates measured during the episode.

❹ Note: the zones are indicated by horizontal lines.

Patient Diagnostics







4

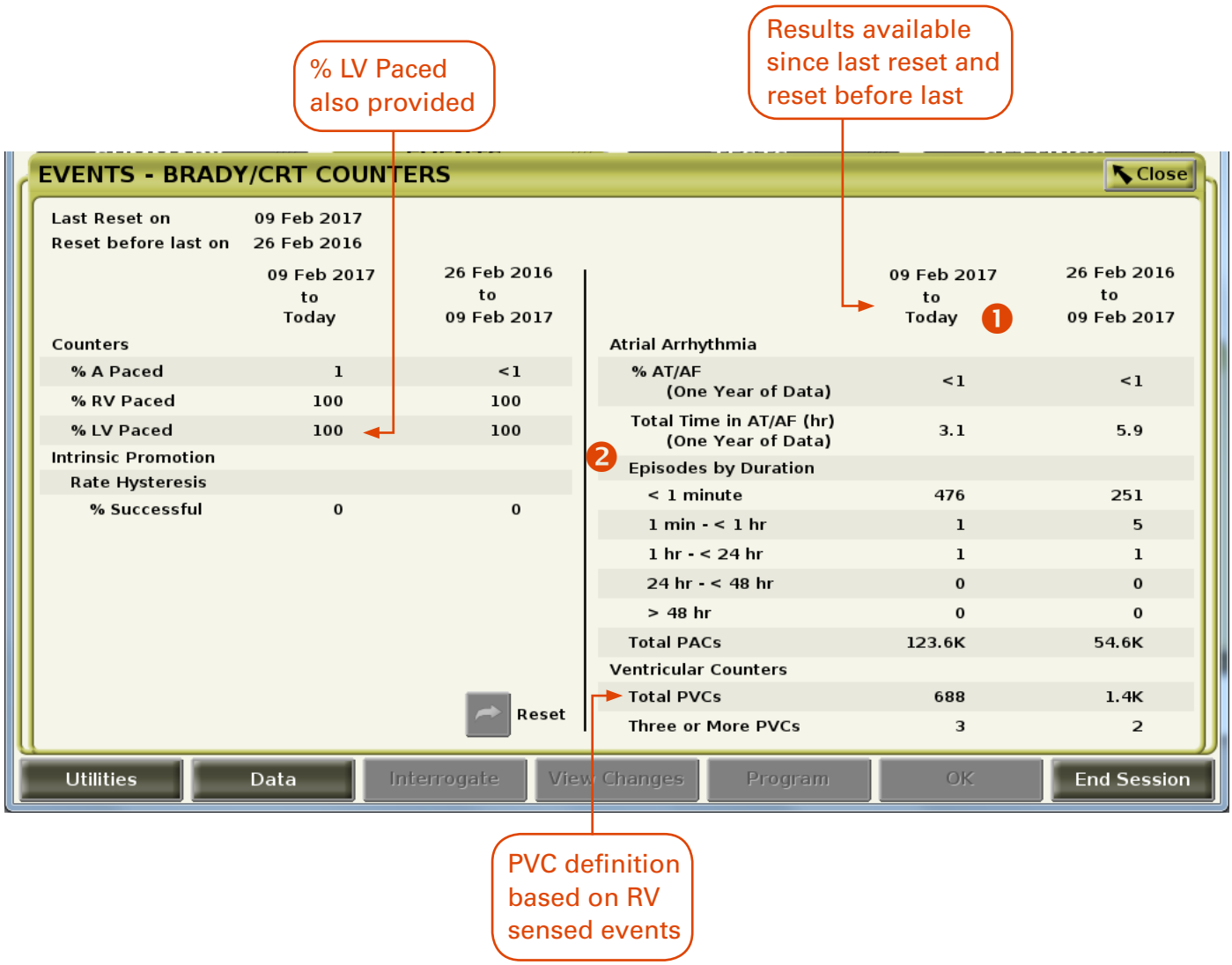
❶ From the EVENTS tab, *select* the **Patient Diagnostics** tab.

❷ To see Histogram activity *select* the **Details** button.

❸ *Select* the **Rate Counts Details** button for information of all chambers.

❹ *See* **Rate Counts** for chamber selected.

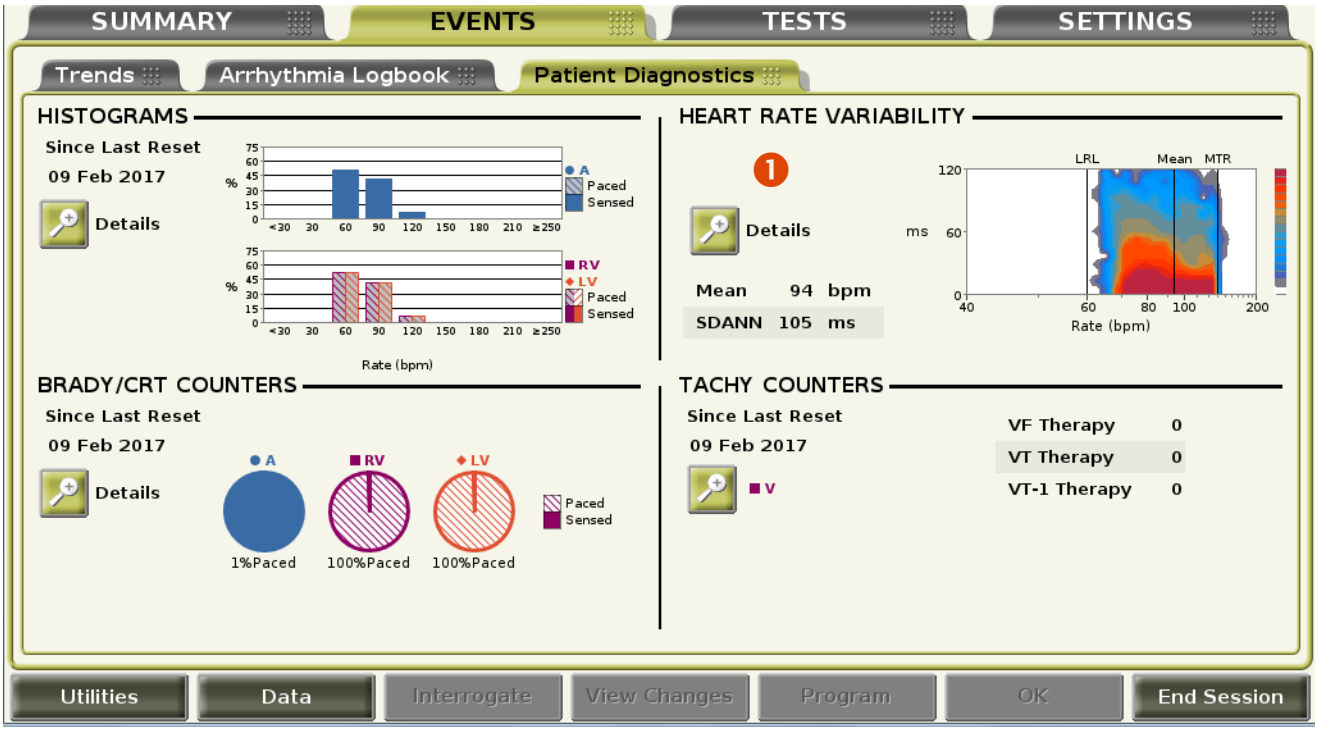
Brady/CRT Counters

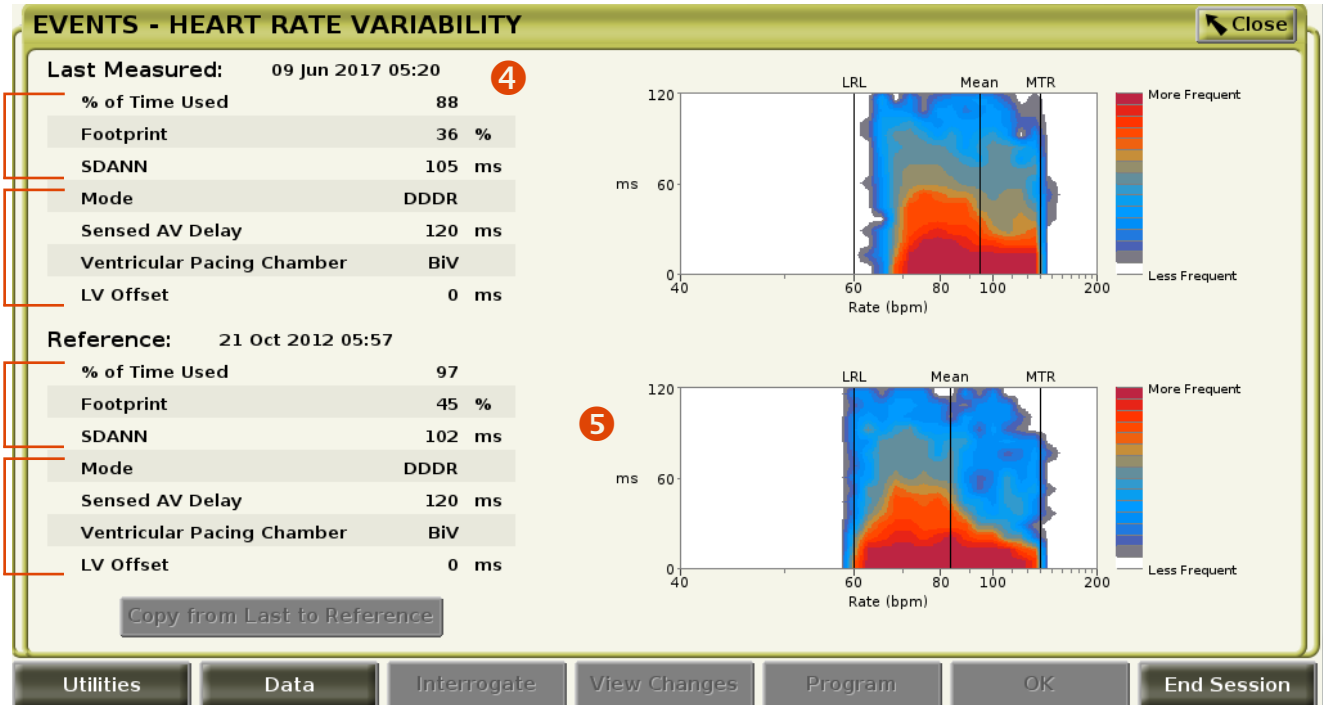


Select the **Brady/CRT Counters Details** button to see additional information since last reset and reset before last. ❶

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

Heart Rate Variability



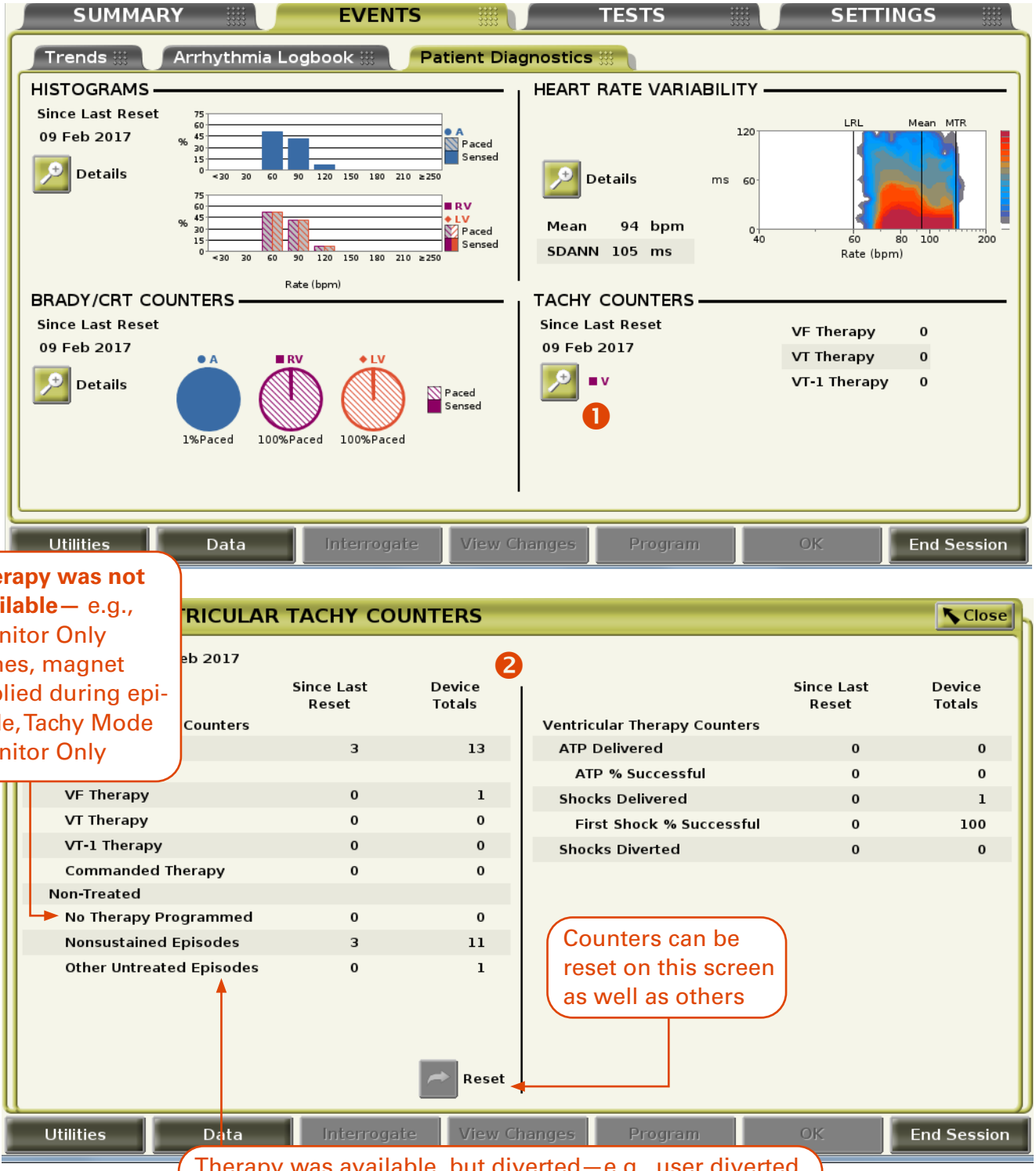


Select the **Details** ❶ button for **Heart Rate Variability** to view pacing parameters ❷ and specific heart failure diagnostic information. ❸

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

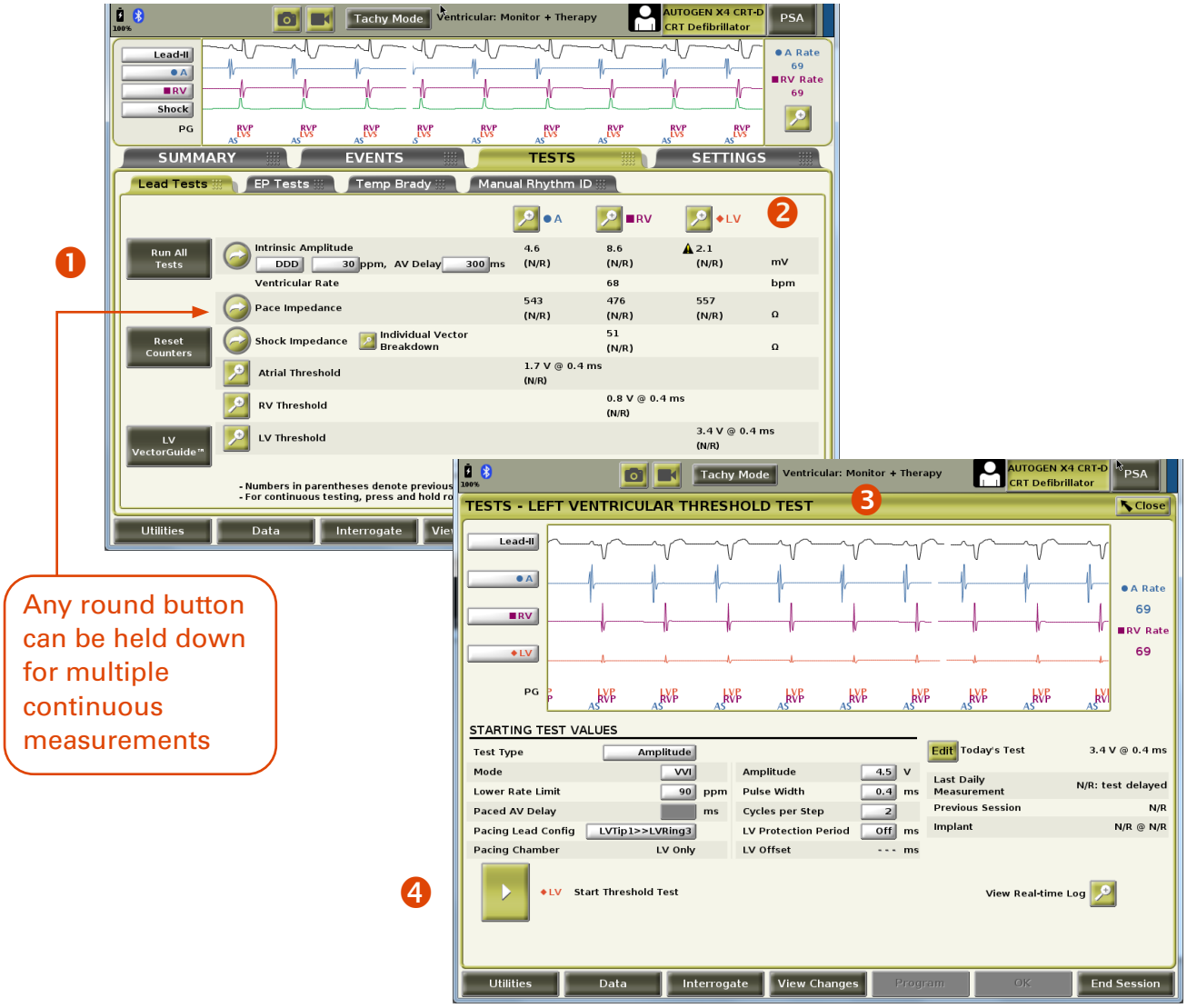
❺ The Reference plot is stored underneath for comparison.

Tachy Counters



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

Lead Tests



Any round button can be held down for multiple continuous measurements

All lead tests may be performed from this screen.

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

Each test can also be run independently for manual tests ❷.
In this example, the LV Threshold Test ❸, has been slected.

Select **Start Threshold Test** ❹.

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

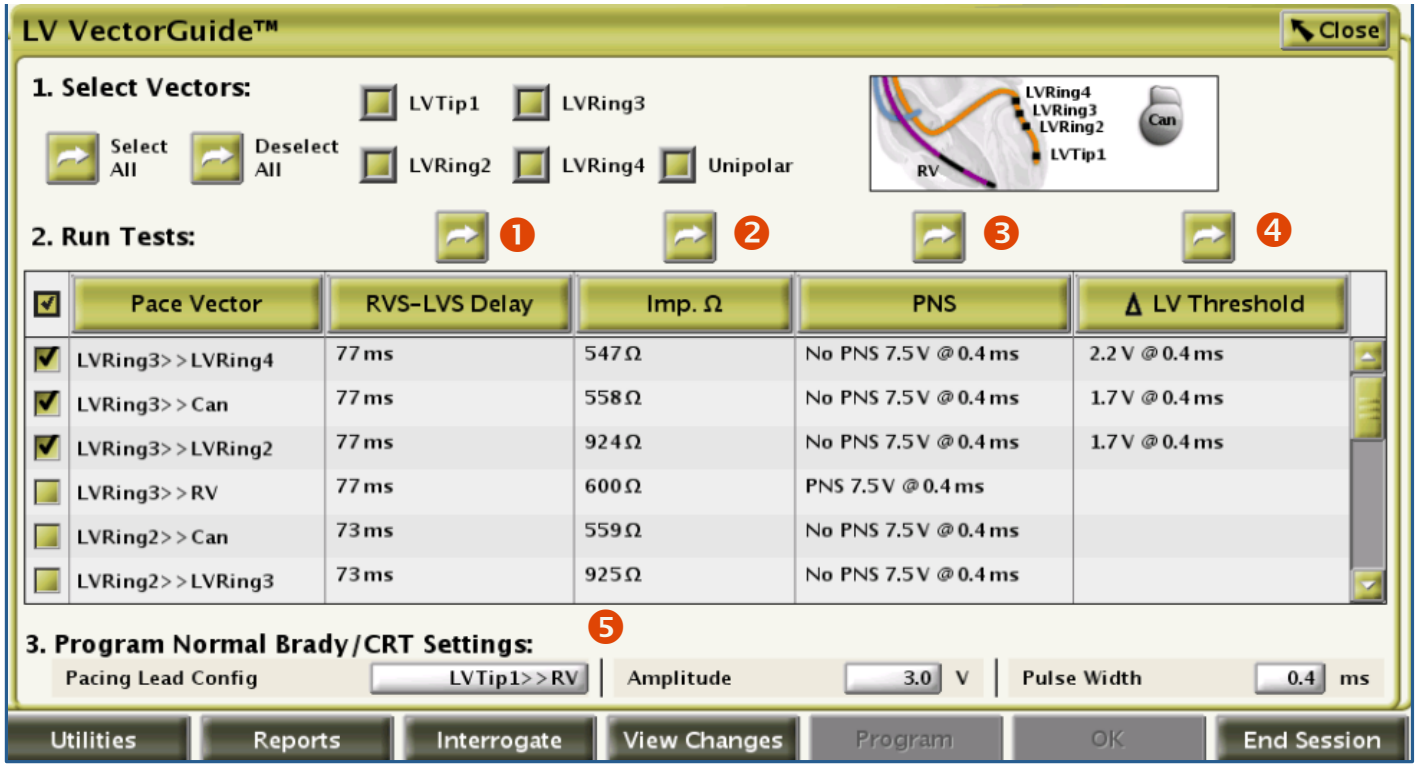
LV Threshold Test Options

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

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

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

LV VectorGuide™



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.

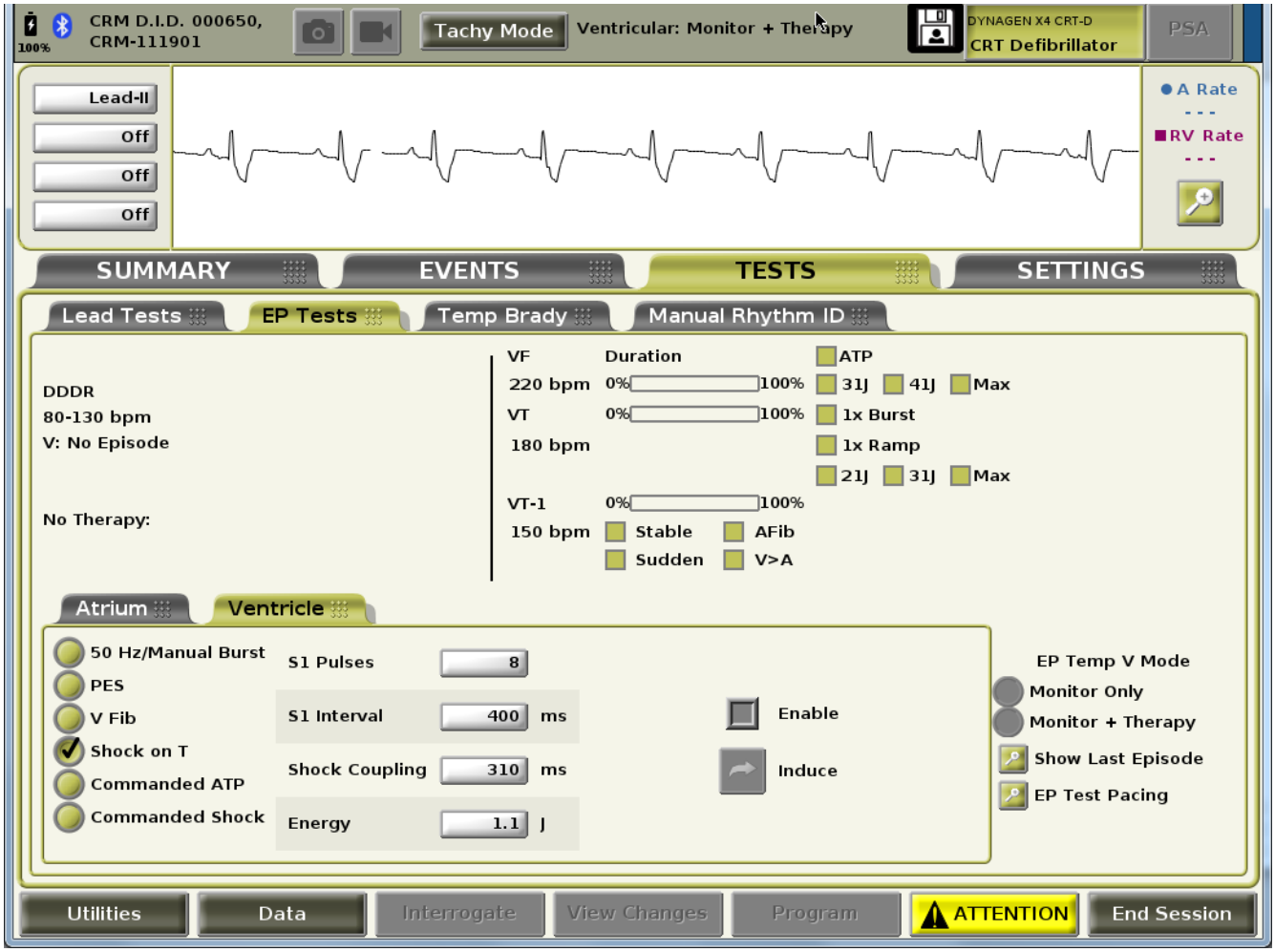
Then *Select* **Pace Vectors** with the longest **RVS-LVS Delay**. *(Note: > 70 ms if possible)*

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

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

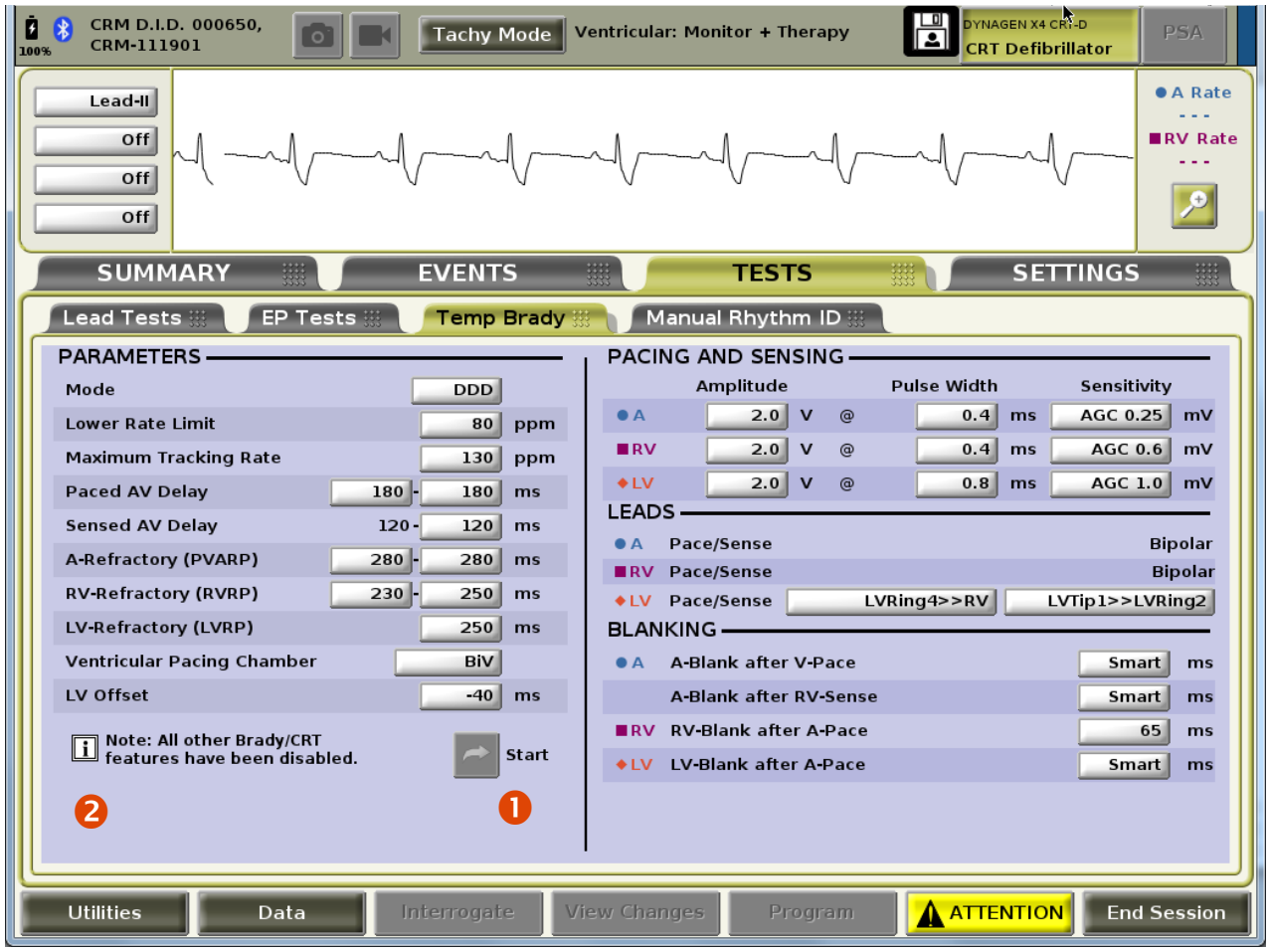
Last, *program* to optimal **Pace Vector** ❺.

EP Tests



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

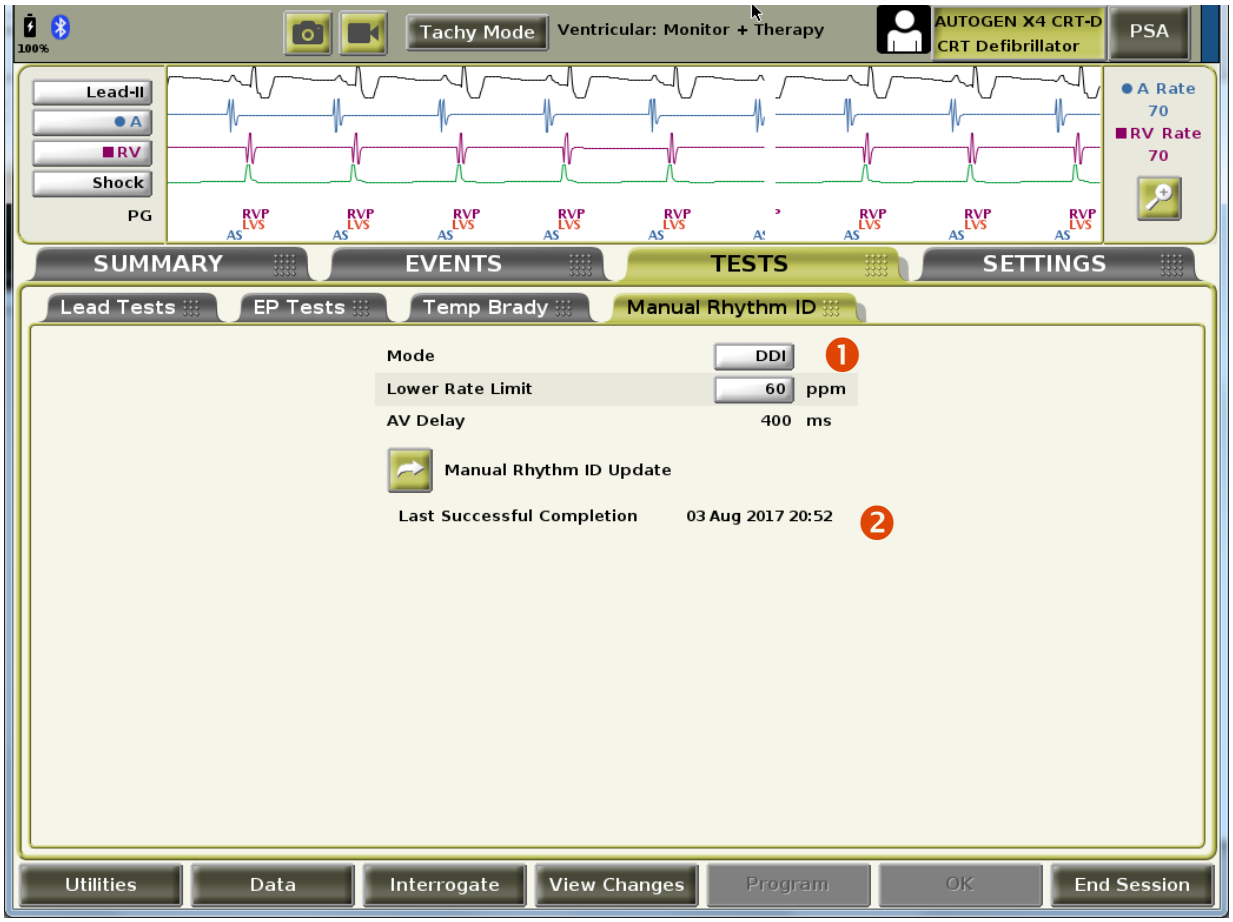
Temporary Brady Screen



These parameters are activated with Start button ❶.

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

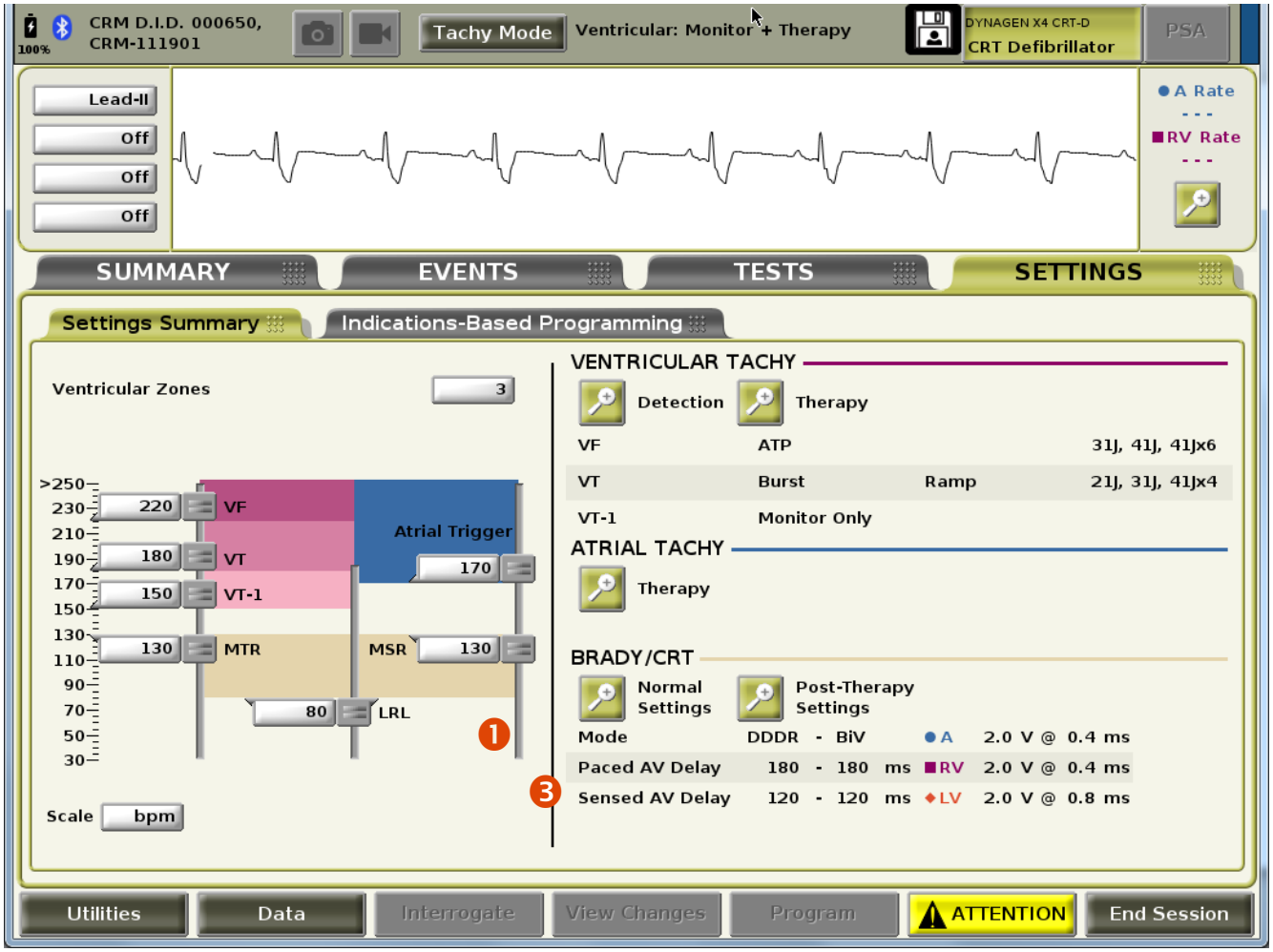
Manual Rhythm ID



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



Increase or decrease rate zone cut-offs by:

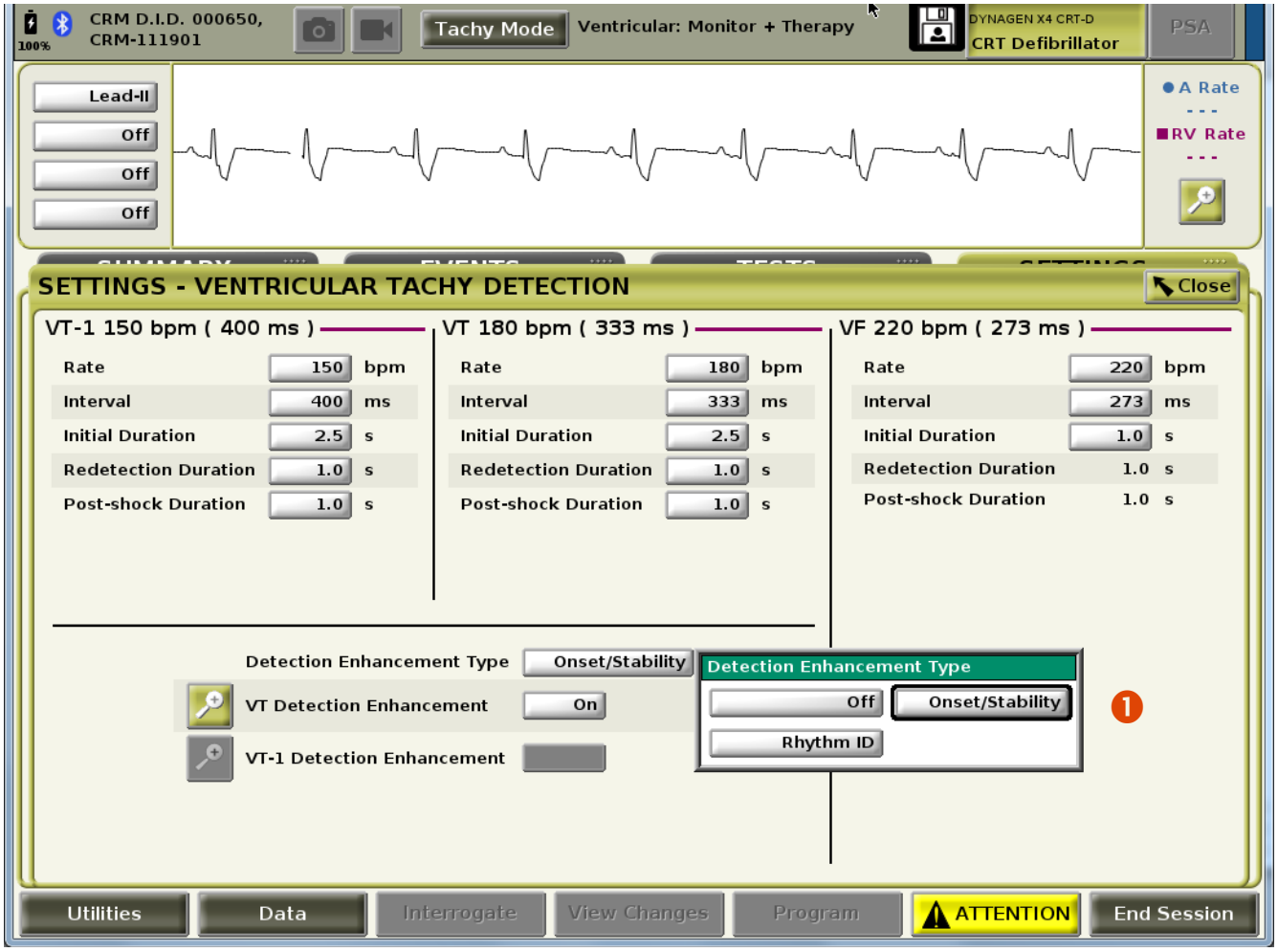
❶ *Move* the slider bar grips up and down to propose zone change.

❷ *Select* number to view a list of available values.

❸ *Review* summary of currently programmed parameters.

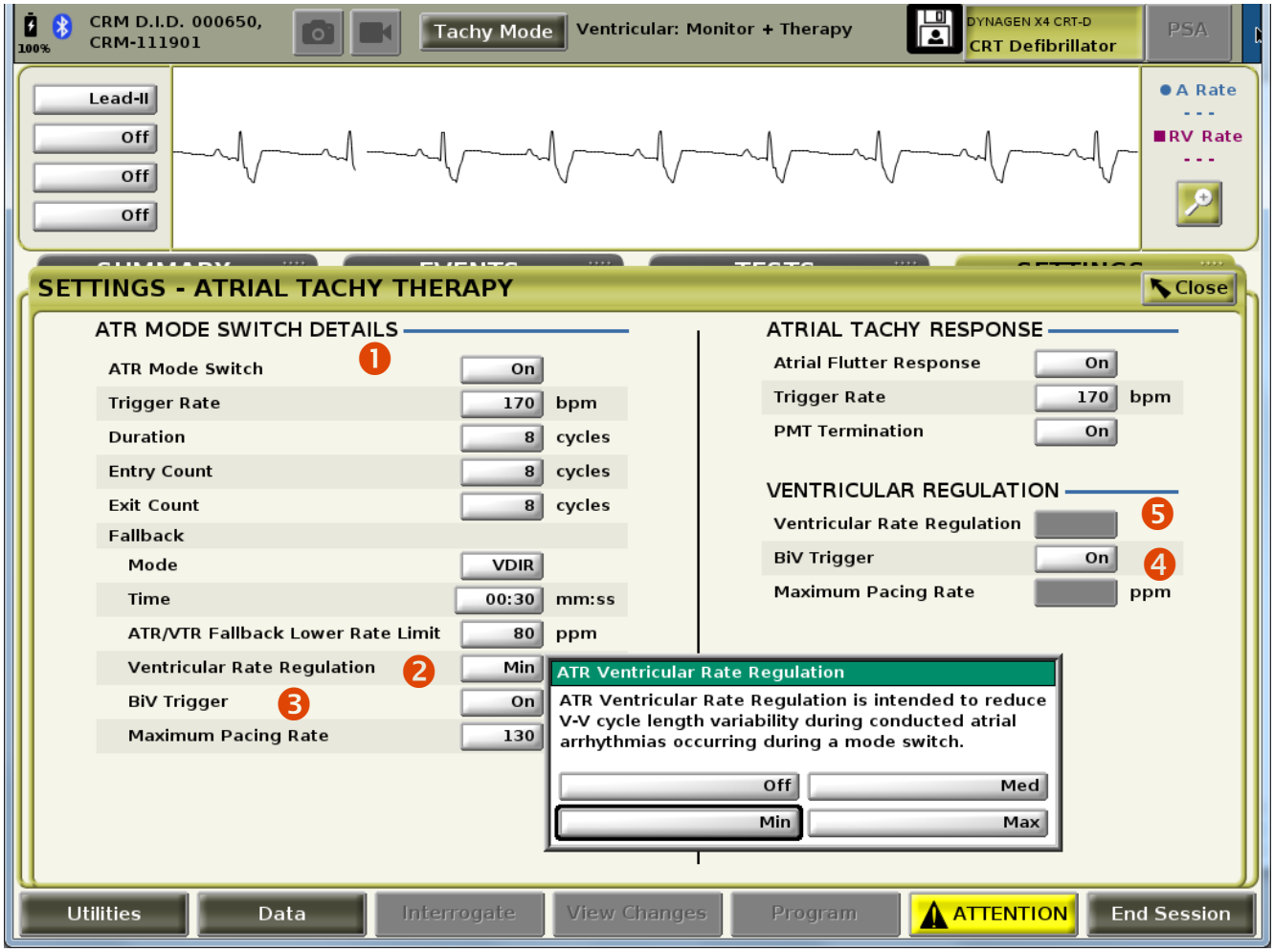
Select relevant icon to review and modify brady and other tachy settings.

Ventricular Detection Enhancements



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

Atrial Tachy Therapy



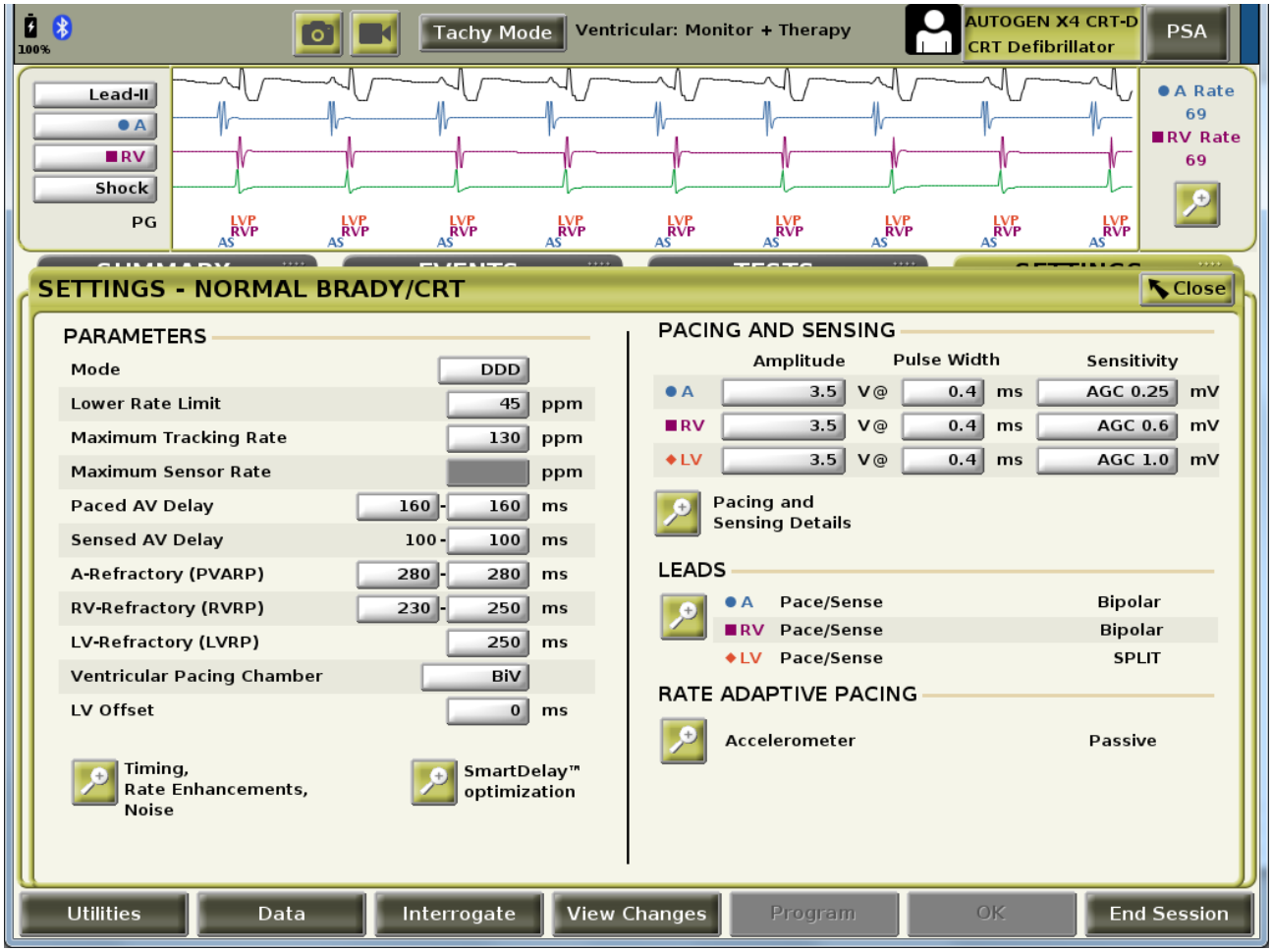
❶ These parameters are designed to tailor **ATR mode switch** to the patient's needs.

❷ Notice that **Ventricular Rate Regulation (VRR)** and **BiV Trigger** ❸ can be programmed to be active only during an ATR mode switch, or

❹ BiV Trigger can also be programmed on independently.

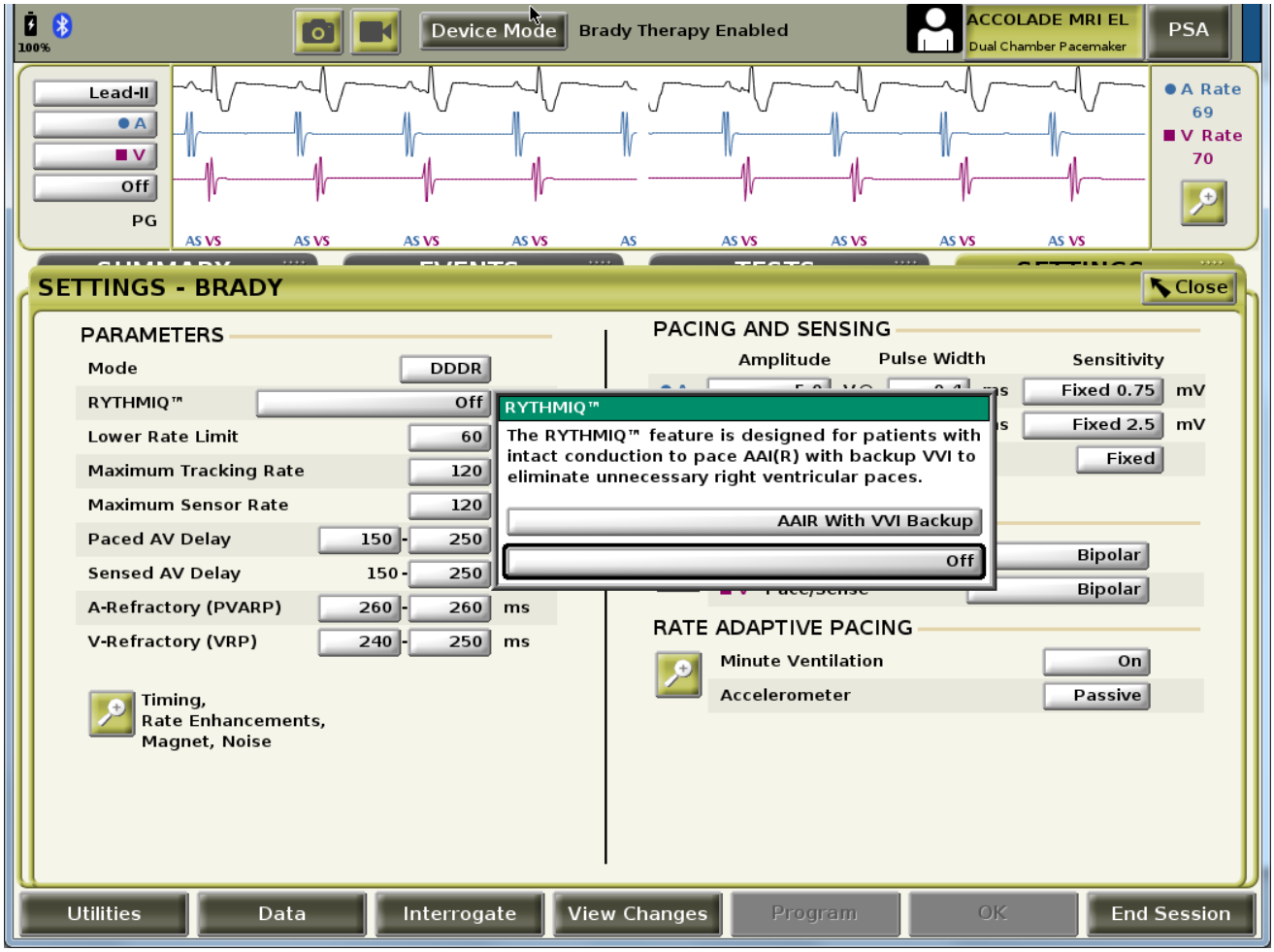
❺ If the device is programmed to VVI or VVI(R), **VRR** can be active at all times.

Brady/CRT Parameters

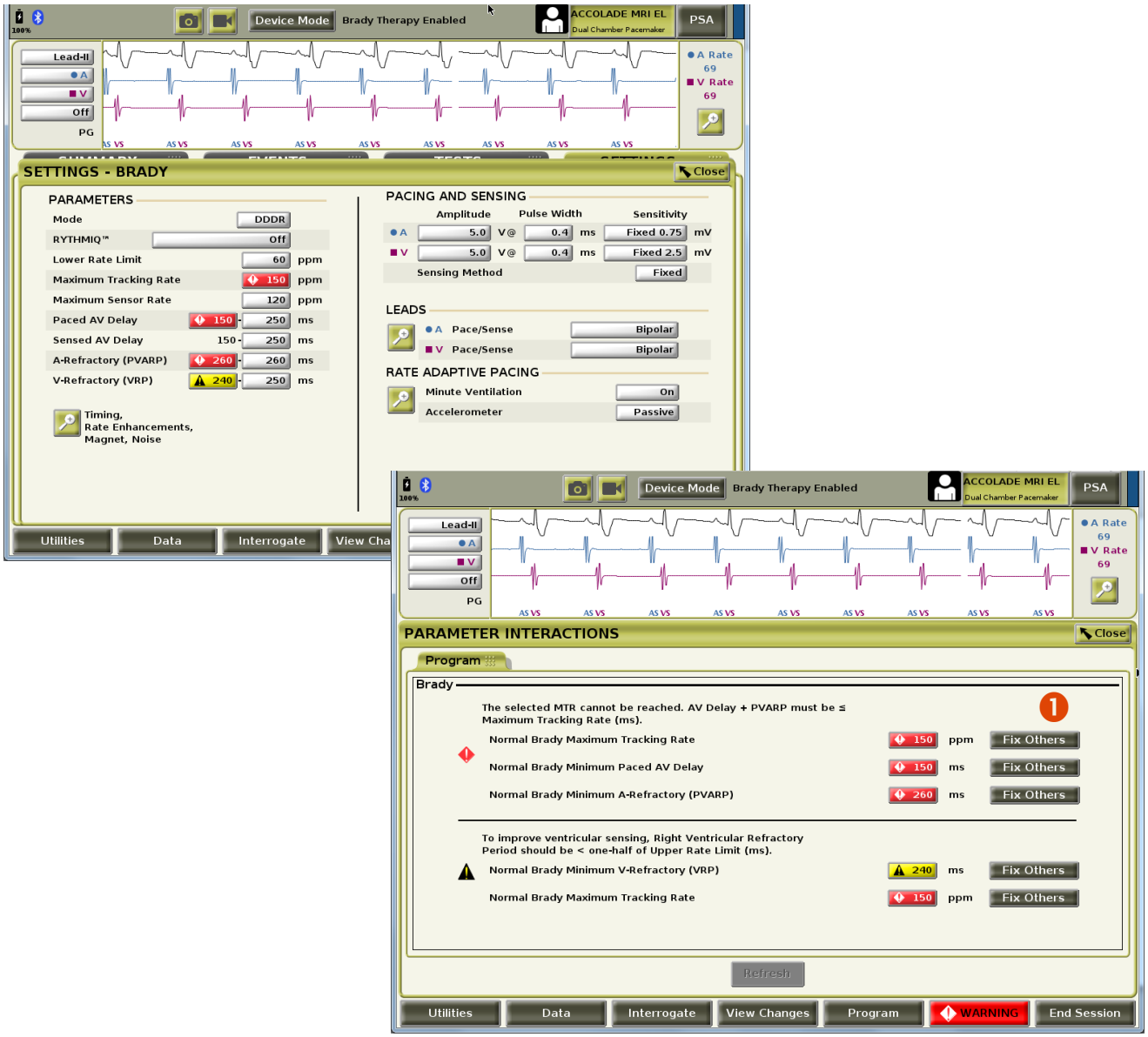


Brady parameters to tailor to meet patient's needs.

RYTHMIQ™


100%
Device Mode
Brady Therapy Enabled
ACCOLADE MRI EL
Dual Chamber Pacemaker
PSA
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
Pulse Width
Sensitivity
Fixed 0.75
mV
Fixed 2.5
mV
Fixed
Bipolar
Bipolar
RATE ADAPTIVE PACING
Minute Ventilation
On
Accelerometer
Passive
RYTHMIQ™
The RYTHMIQ™ feature is designed for patients with intact conduction to pace AAI(R) with backup VVI to eliminate unnecessary right ventricular paces.
AAIR With VVI Backup
Off
Utilities
Data
Interrogate
View Changes
Program
OK
End Session

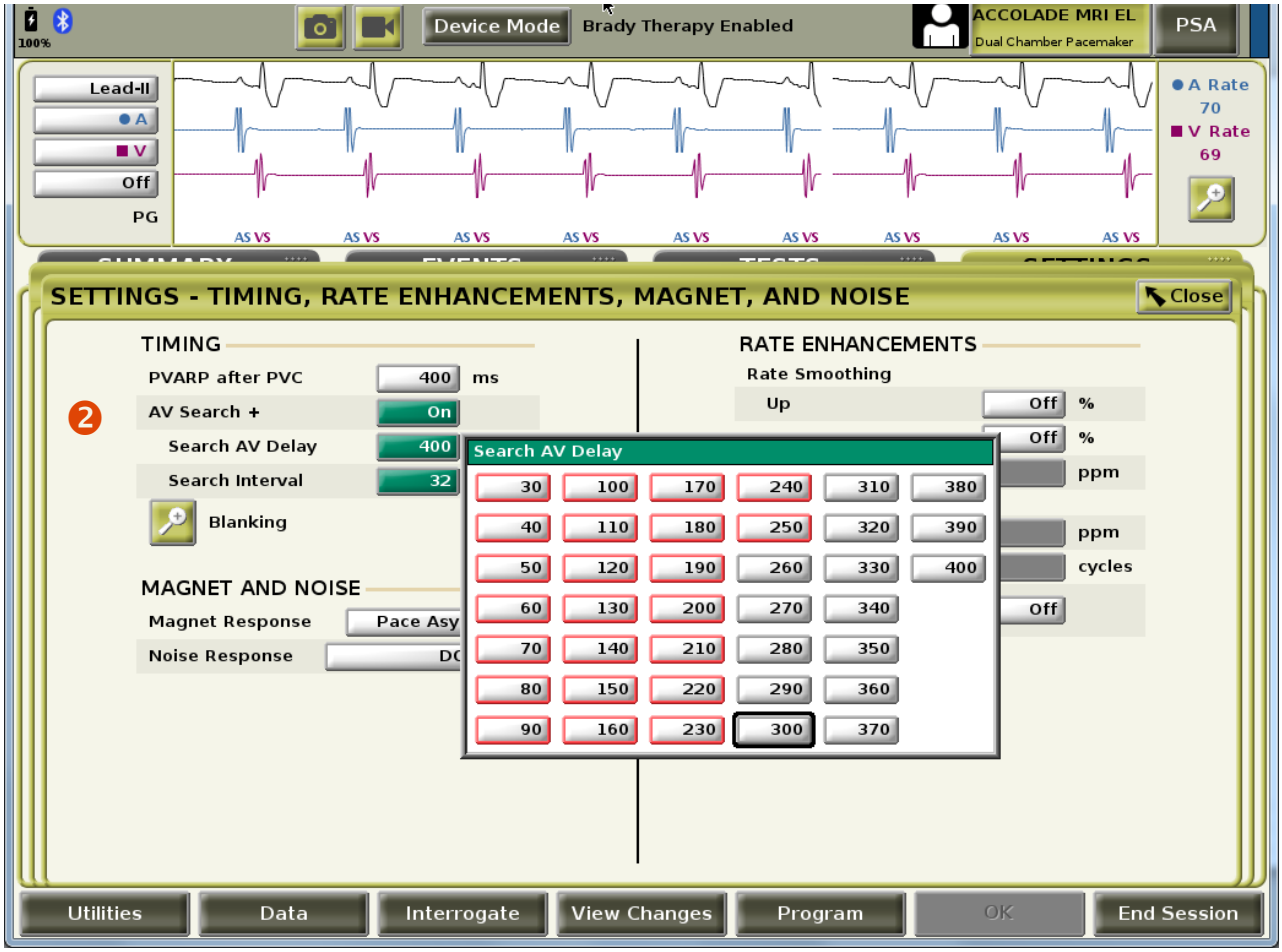
Parameter Interactions



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

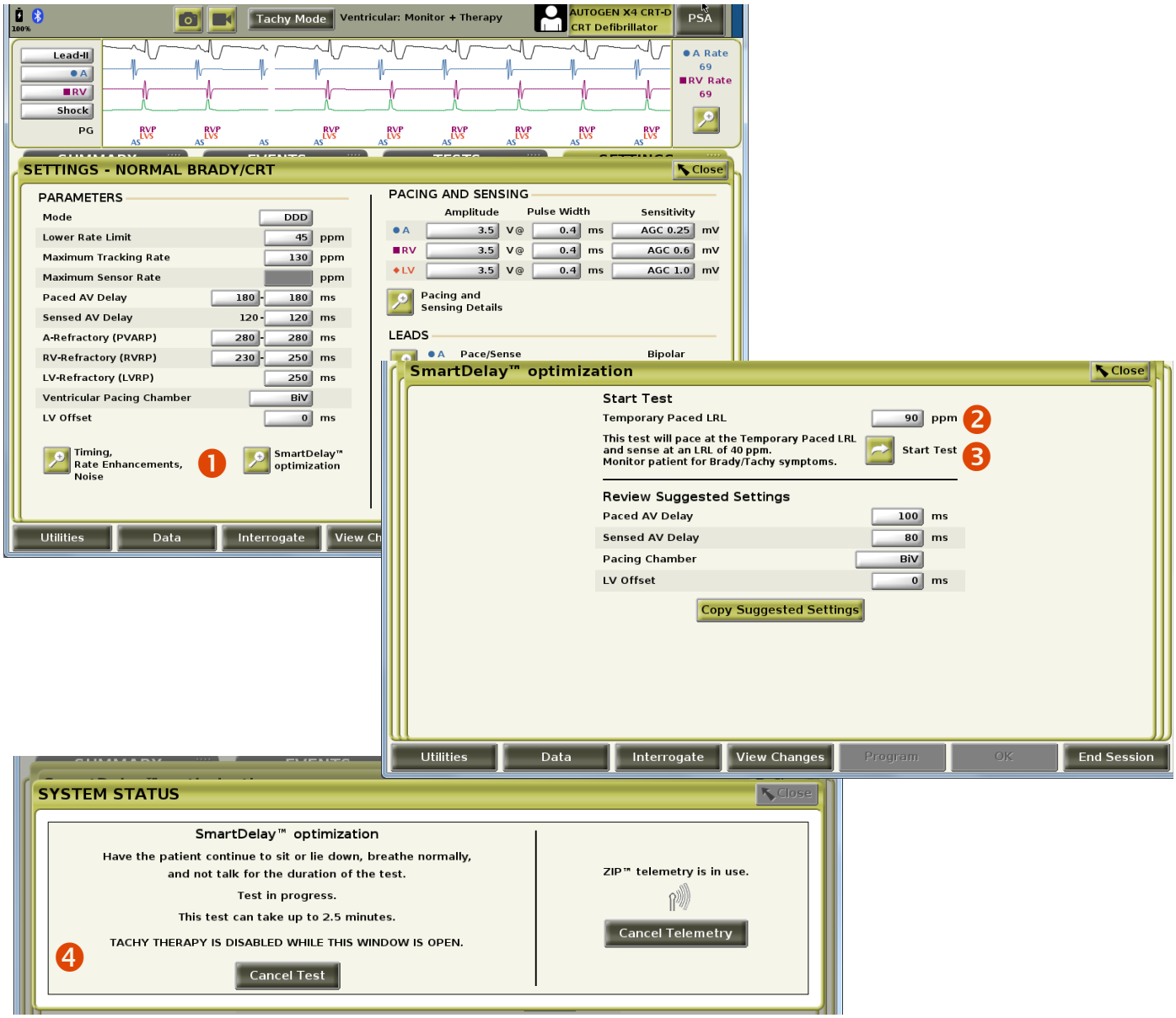
Fix Others addresses interactive parameters and gives suggested changes to resolve interactions ❶.

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



❶ **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** ❷

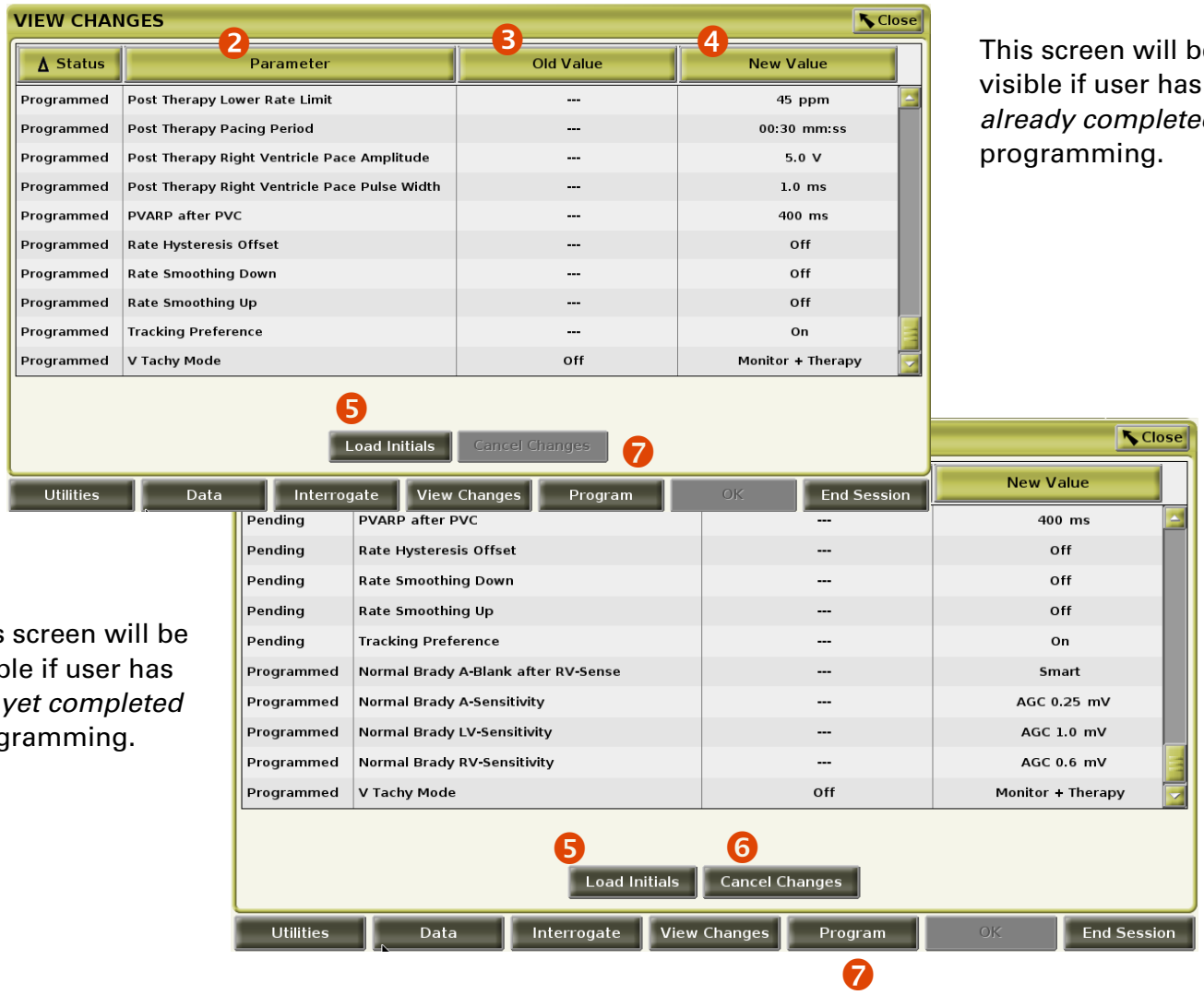
Select **Start Test** ❸

❹ System status as test is running.

Rate Adaptive Sensor Data

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

View Changes



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

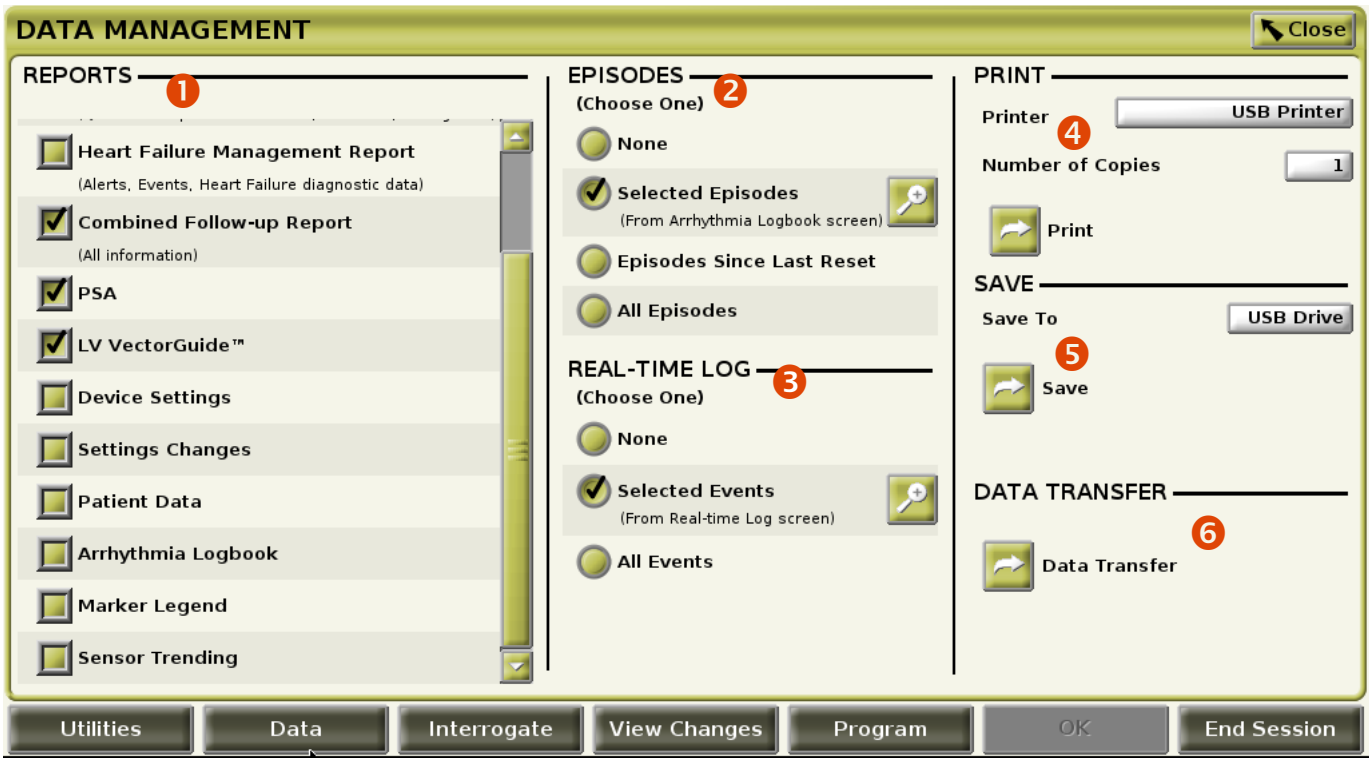
This screen will be visible if user has *not yet completed* programming.

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



❶ **Reports:**
- Select desired reports
- Report description included

❷ **Episodes:**
- Select desired episodes

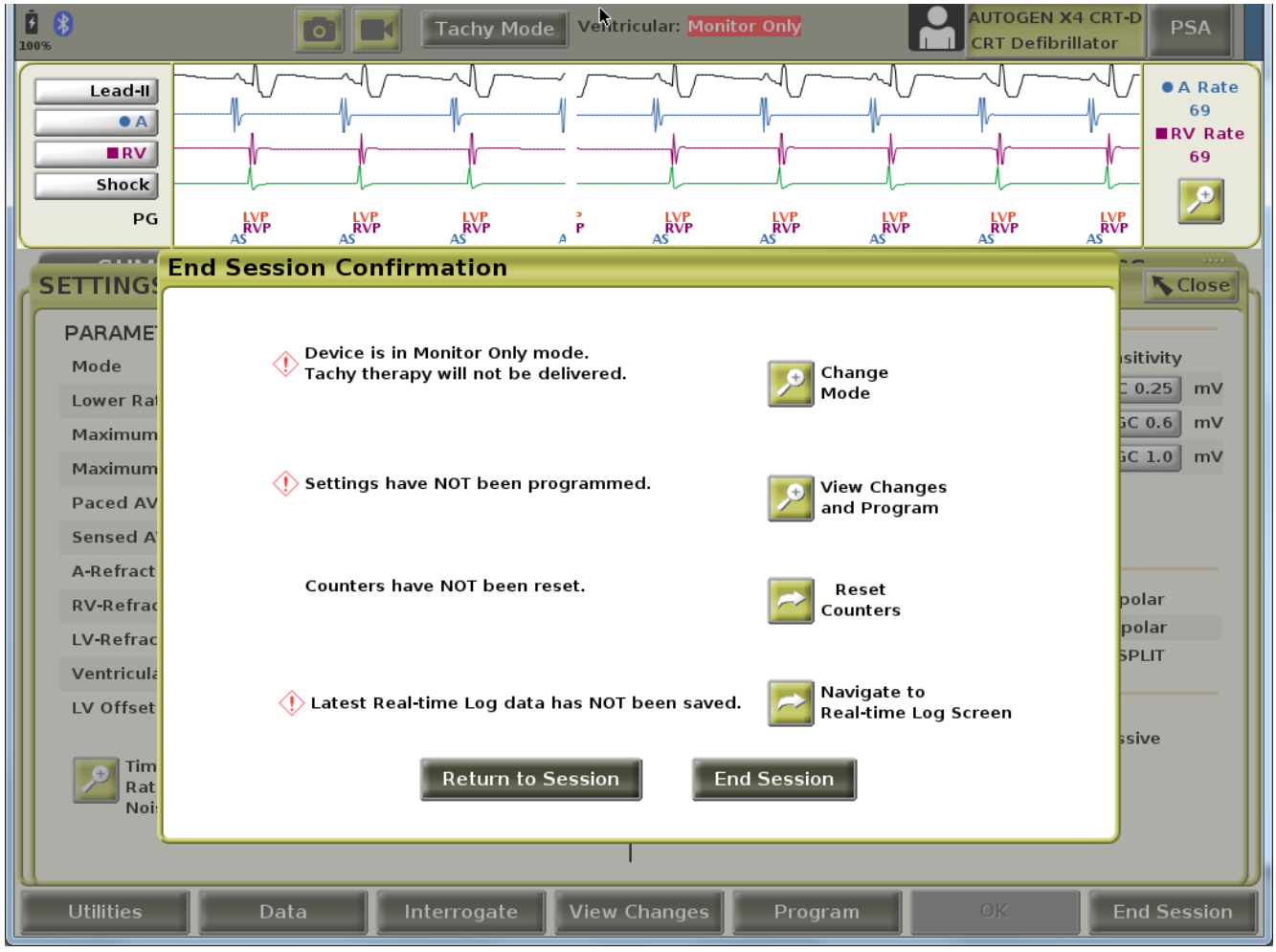
❸ **Real-time Log:**
- Select events *(snapshot, real-time recorder, automatic)*

❹ **Print:**
- USB Printer
- Bluetooth® enabled printer

❺ **Save:**
- Hard drive
- USB pen drive

❻ **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.

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 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/pace 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 magneticfields 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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