



LATITUDE™

PROGRAMMING SYSTEM
MODEL 3300



Pacing System Analyzer (PSA) Application In-Service



Connections

Patient Connections

Inductive Telemetry Wand
Model 6395

S-ICD Telemetry Wand
Model 3203

Connection Port
(for future use)

Patient ECG Cable
Model 3153

PSA Cable A / RV
Model 6763

PSA Cable LV
Model 6763



Verify proper adapter if
video screen uses VGA or
HDMI connection

Physician Connections



Power (ON / OFF)
Button is green when
the Programmer is ON

USB 2.0 Port (3)

USB 3.0 Port (1)

Ethernet Port

DisplayPort Out

AC Power
Connection

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Connectivity and Power

Verify Desired Power and Connectivity

- **Lightning bolt (a)** appears inside the black battery symbol if the programmer is attached to AC power and battery charge is provided
- When unplugged to AC power, battery icon changes color at different levels of charge:

- 25-100%** charged
- 10-24%** charged
- <10%** charged



- Check for **(b) Bluetooth® connectivity** on the Main Screen prior to selecting Quick Start or the PSA application to ensure **Bluetooth® printing** capability, or connect USB cable to USB printer

Note: When powering ON the LATITUDE™ Programming System, it may take up to one minute for the software to load and during this time the screen may be flashing or blank

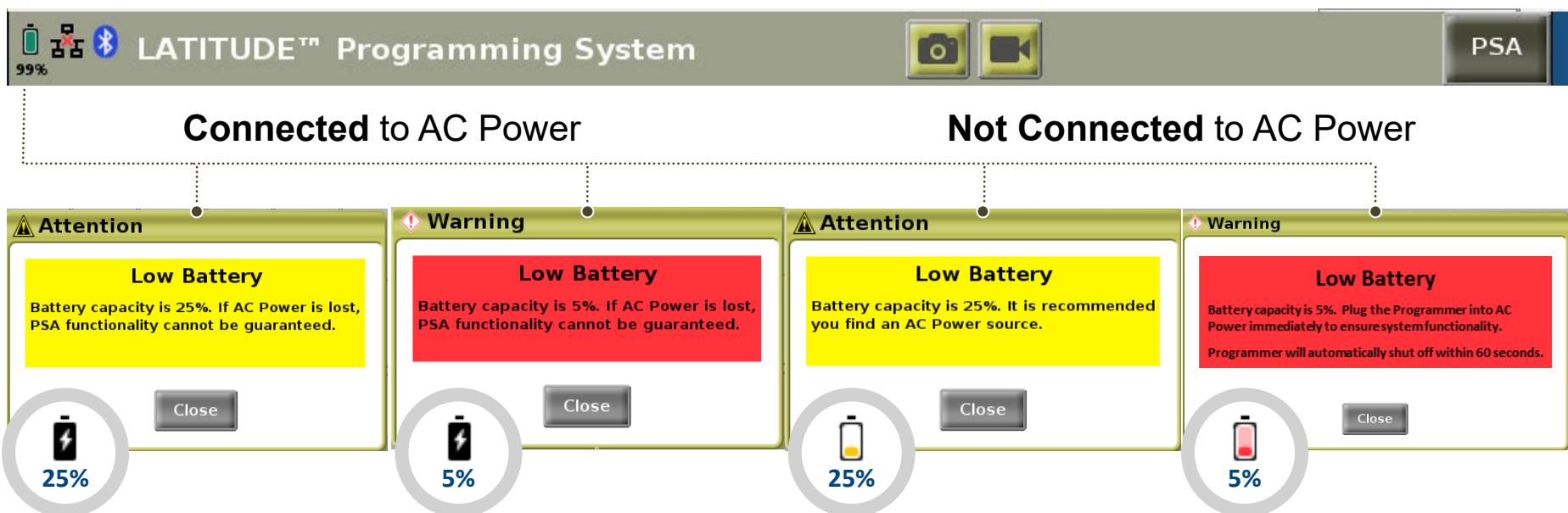


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Main Screen: Power Supply Indicator

- If the Programmer is connected to external AC power, the internal battery (Model 6753) will be charging, whether the Programmer is ON or OFF
- Depending on age of the battery, a full charge should last for approximately 2 hours of normal operation
- Messages will display on the Programmer screen at different levels of battery depletion



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Startup Work Flow



Device Interrogation

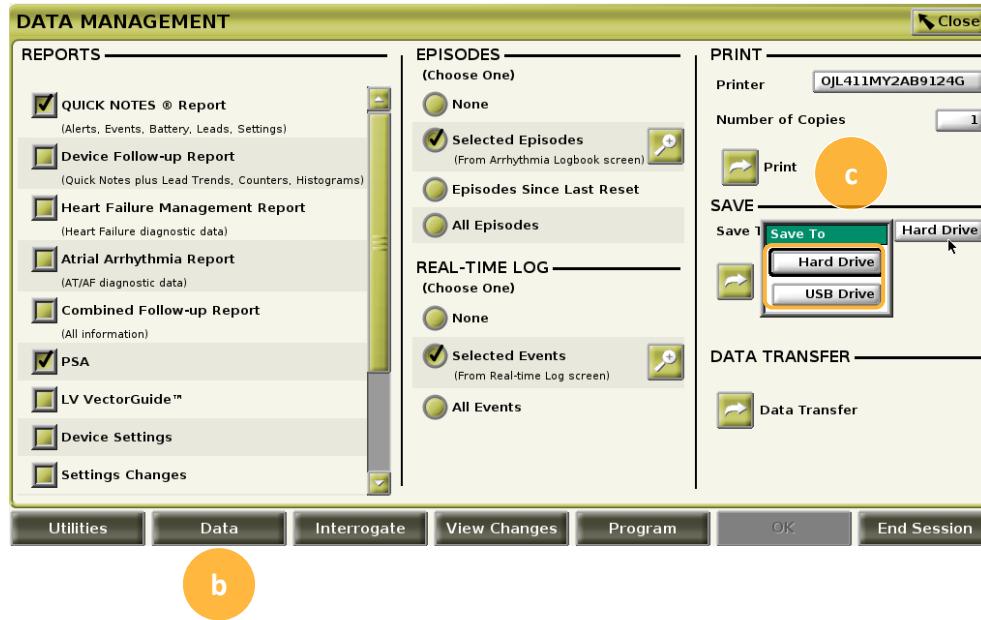
- Interrogate the device via **Quick Start button** before starting the PSA application
- Device application button **(a)** will then be visible at upper right of startup screen next to PSA button
- Saved PSA data will be associated within the device being implanted
- During the implant case, toggle between the PSA and PG application as desired

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Startup Work Flow



Data Management

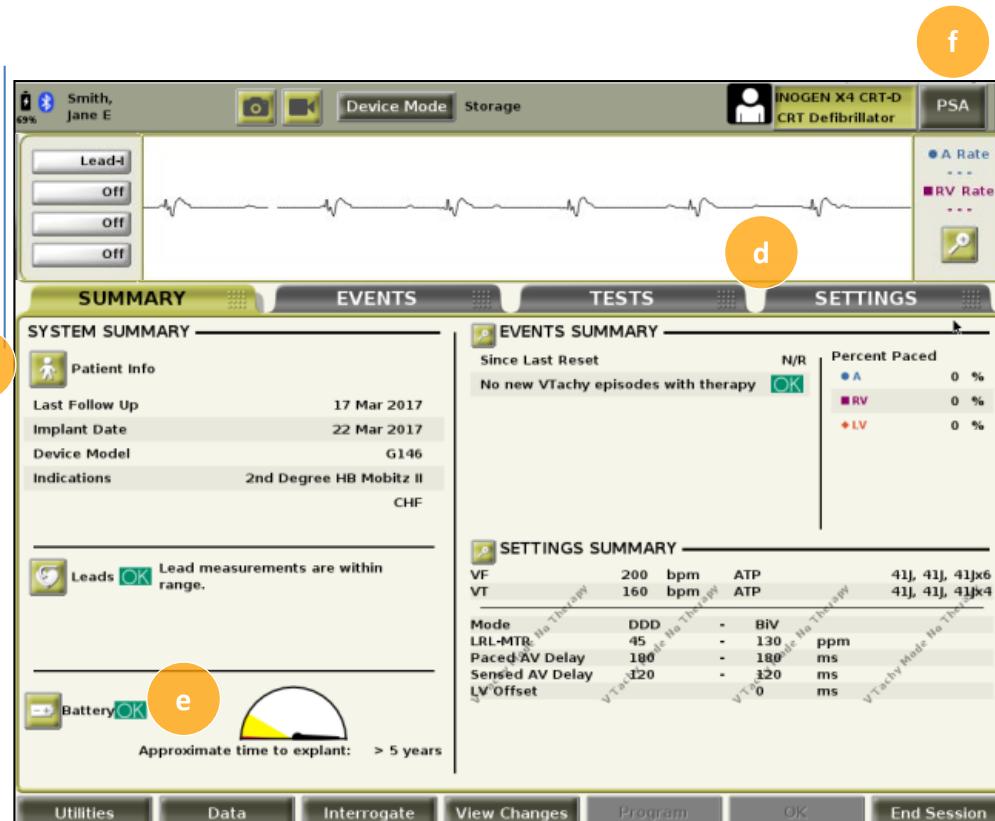
- Select **(b) Data tab**
- Select method to **Save**, either **(c) Hard Drive** or **USB Drive**

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Startup Work Flow



- Enter and Program **(d) Patient Information** and any preferred device settings
- Check device **(e) Battery** and reform capacitor if a high-voltage device
- Select **(f) PSA application**

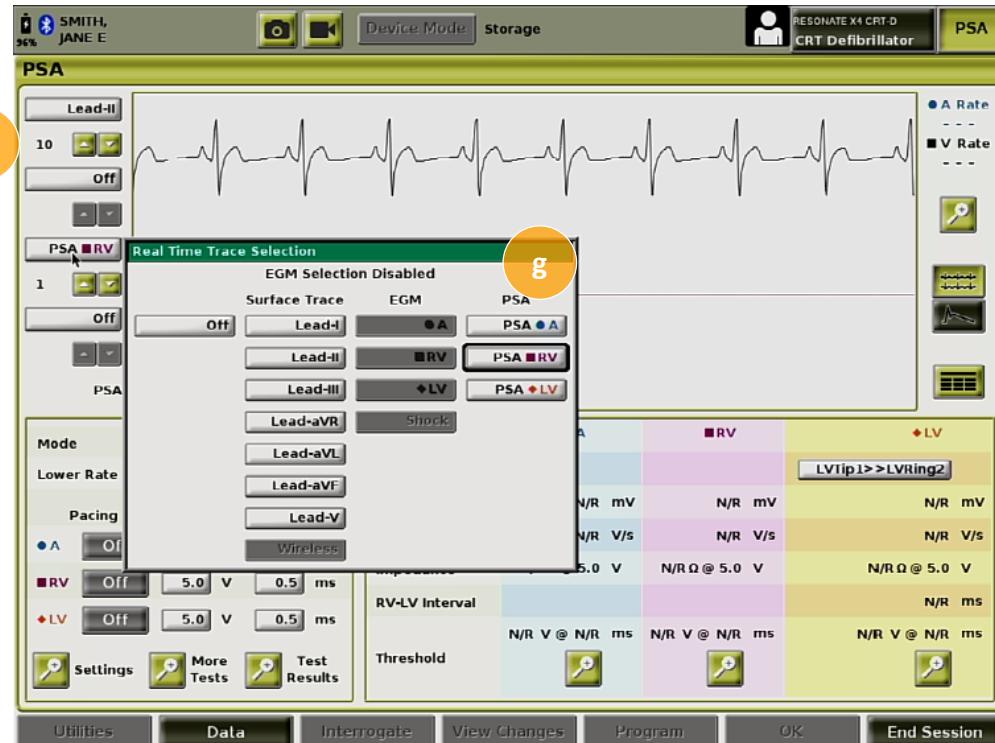
PSA application remains active until Programmer is powered OFF

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Select PSA Setting and Lead Traces



- Select (g) PSA traces
- Choose (h) Gain settings using the Up or Down arrows

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PSA Main Screen Layouts

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(a) Lead Traces panel

- 3-chamber pacing and sensing
- Displays real-time EGMs and markers

(b) Magnify and Additional Settings

- Gain, surface filter, markers, pacing spikes

(c) Lead Trace button

(d) Current of Injury

(e) PSA Real-time Log

(f) PSA Pacing and Amplitude panel

- Enables / disables pacing
- Mode adjusts accordingly

(g) PSA Settings button

(h) More Tests button

(i) Test Results button

(j) PSA Test Chamber Measurements panel





Lead Trace Panel

ECG / EGM Full Screen Display

(a) Gain

- Select the appropriate value to adjust the surface gain of the traces that are captured on printouts; range: AUTO, 0.5, 1, 2, 5, 10, 20 mm/mV



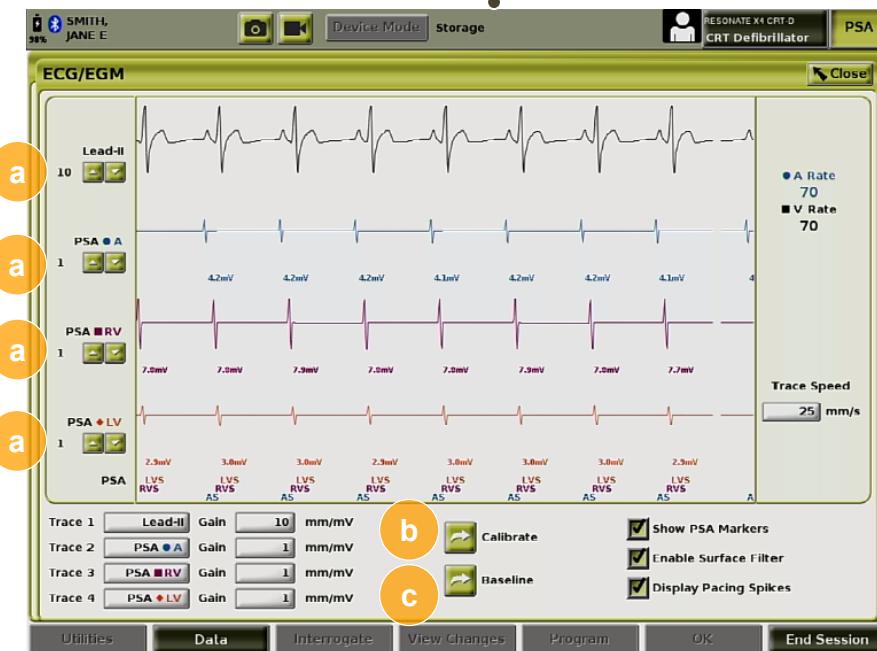
From the PSA Main Screen
the **Magnify button**
enlarges the lead trace area

(b) Calibrate button

- Transmits a 1 mV calibration pulse to the ECG display to establish a reference point to evaluate amplitudes

(c) Baseline button

- Forces the trace back to the baseline



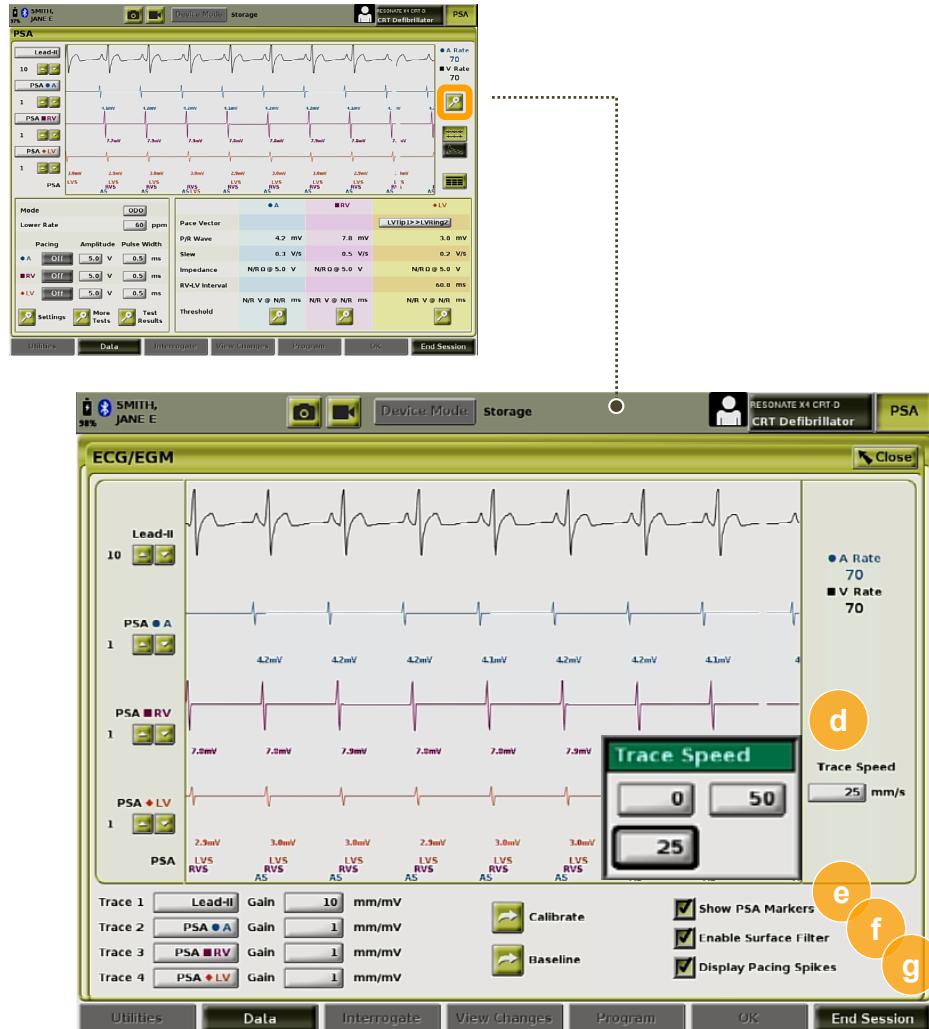
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Lead Trace Panel

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ECG / EGM Full Screen Display

(d) Trace Speed

- Select the desired speed on the ECG display: 0 (stop), 25, or 50 mm/s

(e) PSA Markers

- When in a PSA application session, select the check box to enable the PSA markers

(f) Surface Filters

- Select the check box to minimize noise on the surface ECG

(g) Pacing Spikes

- Select the check box to show detected pacing spikes, annotated by a marker on the top waveform

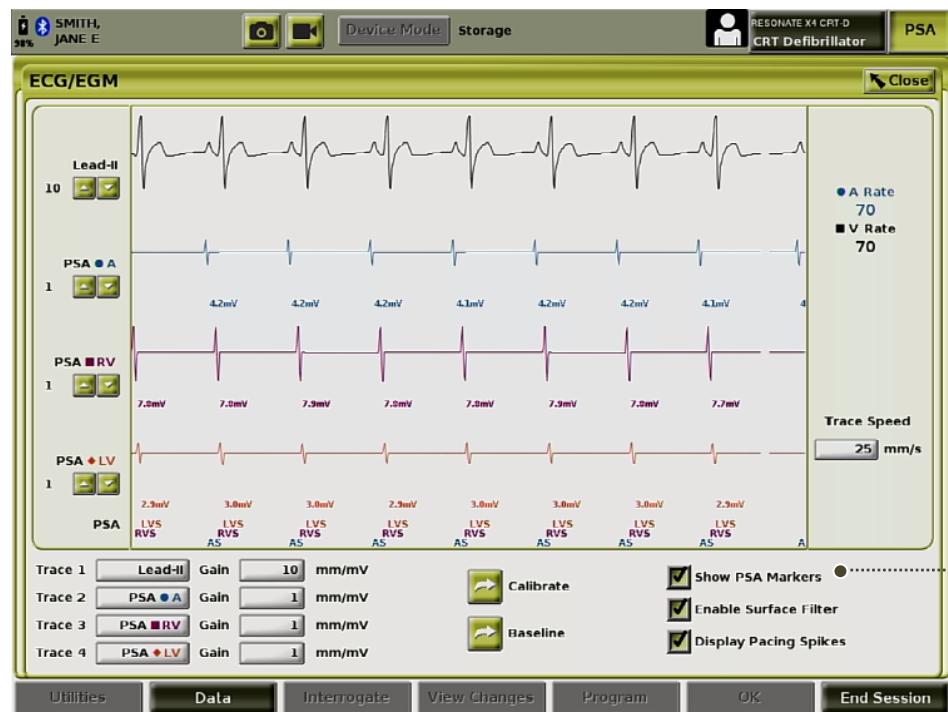
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Lead Trace Panel

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PSA Markers

Parameter	Measurement
AS	Atrial Sense after refractory
(AS)	Atrial Sense during refractory
AP	Atrial Pace
RVS	Right Ventricular Sense after refractory
RVP	Right Ventricular Pace
LVS	Left Ventricular Sense after refractory
LVP	Left Ventricular Pace

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Dual Chamber Devices, PSA Cable Connections

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Dual Chamber
Pacemaker

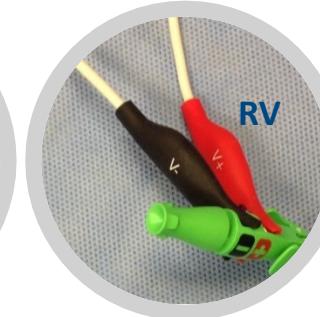
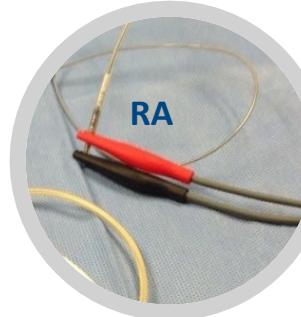


Model 6763
PSA Cables



Dual Chamber
DF4 ICD

Model 7001EZ-4
Connector Tool

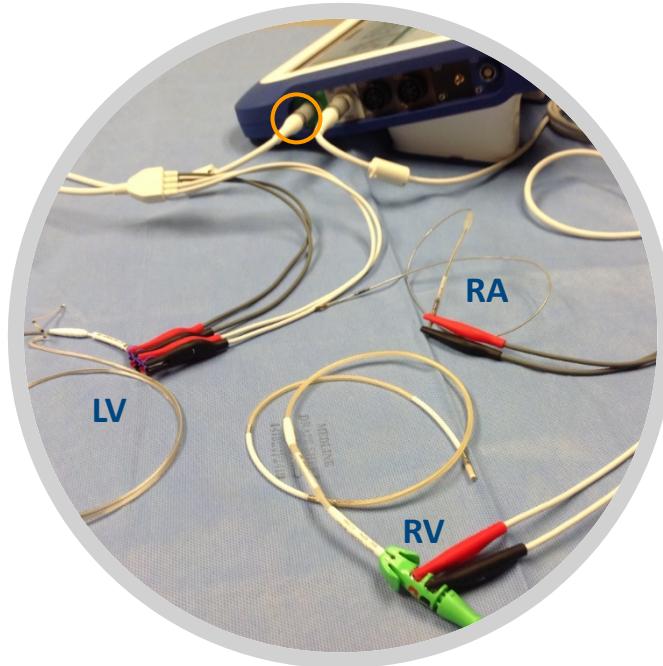




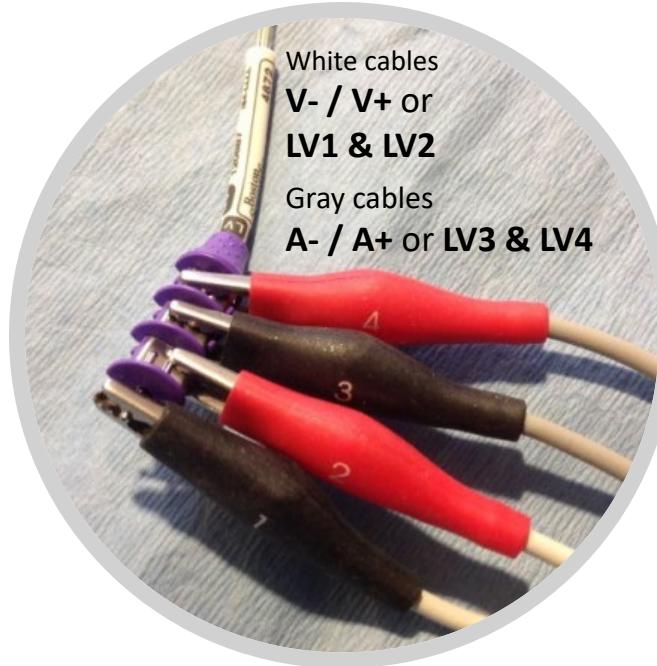
BiV Quadripolar PSA Cable Connections

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BiV Quadripolar
CRT-D



Model 4625
Quadripolar Connector Tool



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BiV Quadripolar PSA Cable Connections

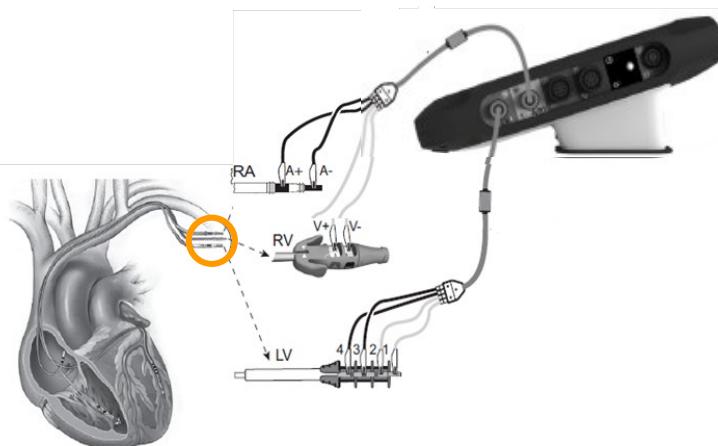
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LV Pace/Sense Vector

		Anode (+)				Cathode (-)
Vectors	LVRing2	LVRing3	LVRing4	Coil	Can	
LVTip1	✓					
LVRing2		✓				
LVRing3			✓			
LVRing4				✓		

Use the A+ connection, from the A/RV cable, as the can electrode

Accept Cancel



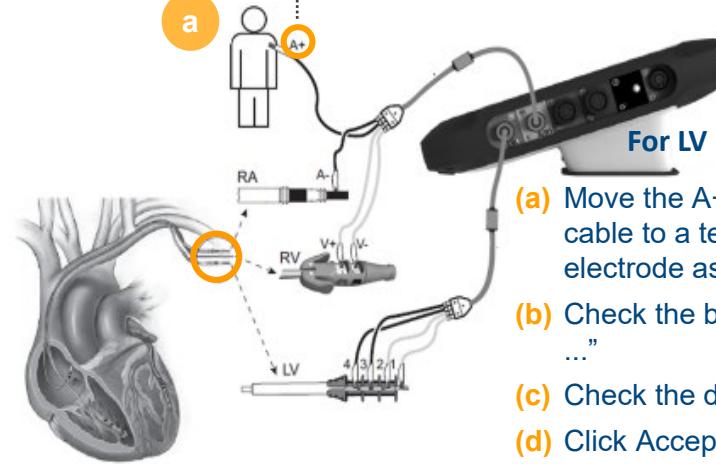
**13 Bipolar
LV Lead Vectors**

LV Pace/Sense Vector

		Anode (+)				Cathode (-)
Vectors	LVRing2	LVRing3	LVRing4	Coil	Can	
LVTip1	✓					
LVRing2		✓				
LVRing3			✓			
LVRing4				✓		

Use the A+ connection, from the A/RV cable, as the can electrode

Accept Cancel



**4 Unipolar
LV Lead Vectors**

- For LV Unipolar Connection:**
- Move the A+ (red) clip of the A / RV cable to a temporary indifferent electrode as the can
 - Check the box “Use the A+ connection ...”
 - Check the desired Can electrode
 - Click Accept
- To end a unipolar configuration, select the desired bipolar LV configuration and deselect the “Use the A+ connection ...” box; this results in normal operation of the atrial lead anode



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LV Impedance Parameter Ranges

*The specified tolerance does not apply to LV lead impedance measurements using the LV PSA cable in combination with either the RV or RA cables. Clinical decisions using LV lead impedance values should be based on measurements using the LV PSA cable only.

Impedance	Voltage	Pulse Width	Tolerance
100 - 3000 Ω	0.5 - 7.5 volts	0.4 to 2.0 ms	$\pm 25\%^*$

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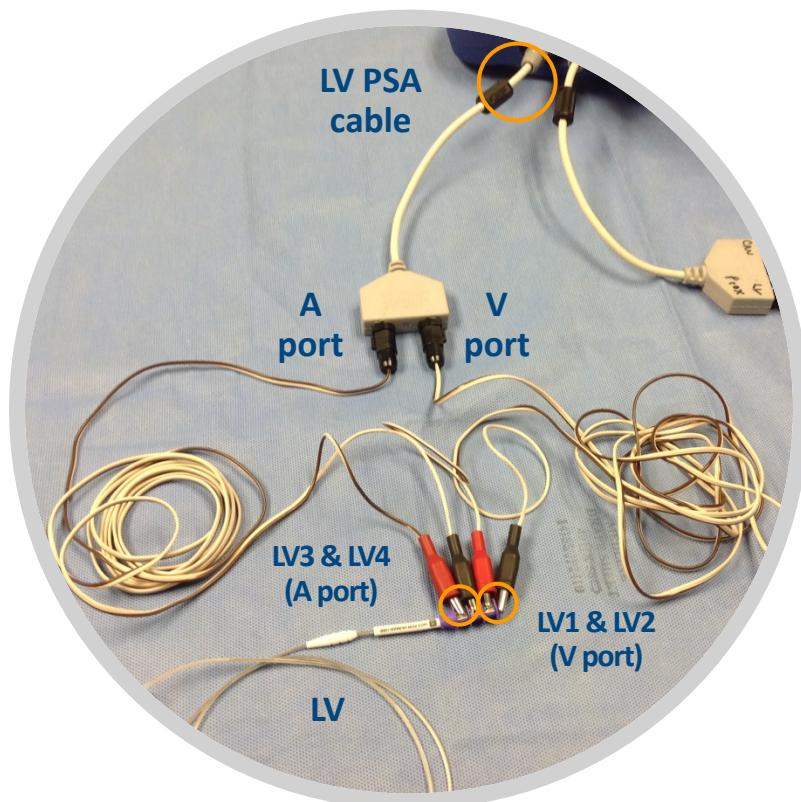
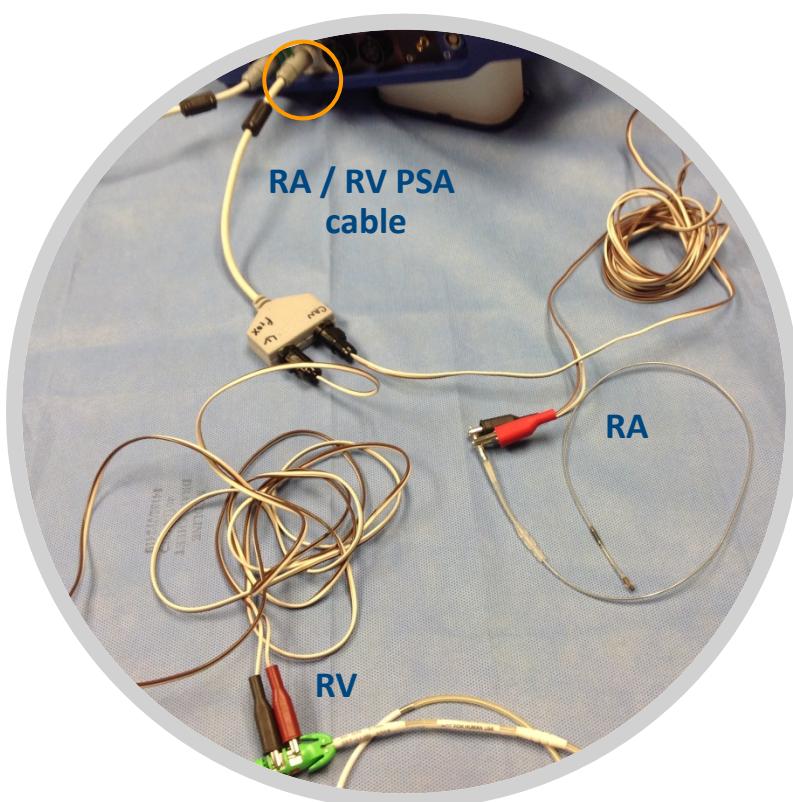




PSA Cable Connections (Model 6697)

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Optional Remington Cables (Disposable)



LV PSA
cable

A
port

V
port

LV3 & LV4
(A port)

LV1 & LV2
(V port)

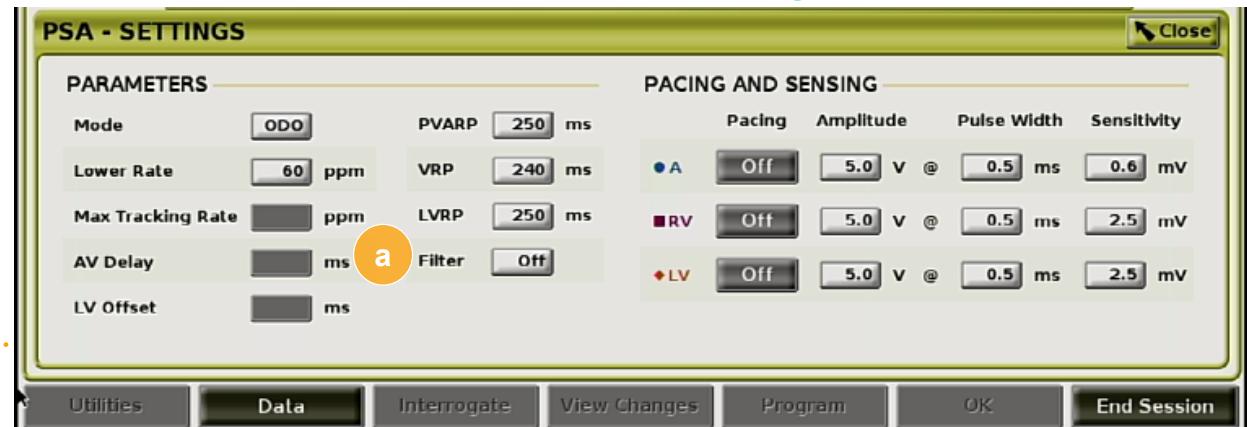
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PSA Settings

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NOTE: Verify PSA Settings prior to beginning lead testing, making modifications as necessary



Noise Filter

If noise is evident on electrogram trace, turn ON **(a)** **Filter** for **(b)** 50Hz or 60Hz frequencies

This feature is nominally OFF.

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Sensing

Typical Method for P/R Wave Amplitude Measurements

- Select desired **(a) Surface ECG / PSA Lead Traces** based on lead connected
- If testing **(b) LV Lead**, ensure Pace / Sense configuration is set from the PSA Test Chamber Measurements panel
- Go to the **(c) PSA Settings and Output (PW and amplitude) panel** and turn OFF pacing to all channels where no leads are connected
- Disable **(c) Pacing** and enable sensing in the channel you want to measure (alternatively, decrease **(d) pacing rate** below the intrinsic rate of patient)
- Sense measurement values are now displayed on the **(e) EGM** with each corresponding sensed beat
- Repeat procedure for other channels



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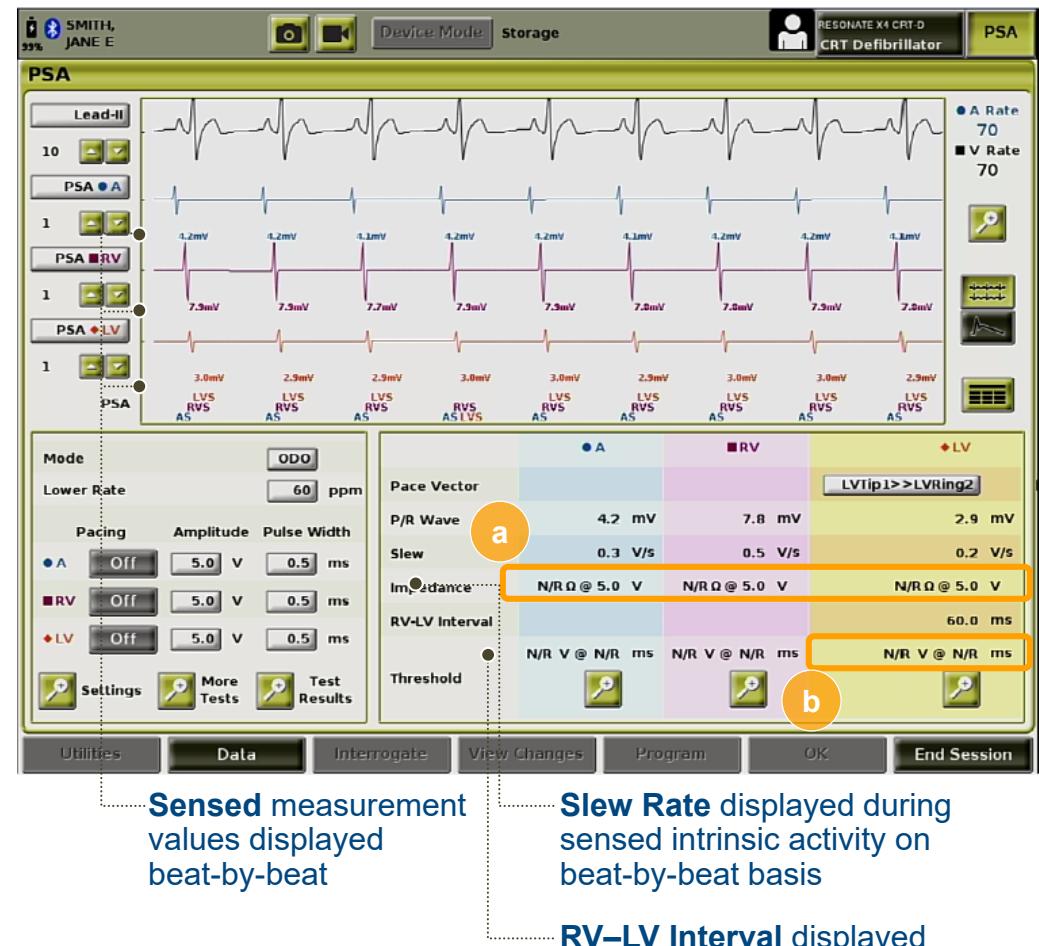




Sensing

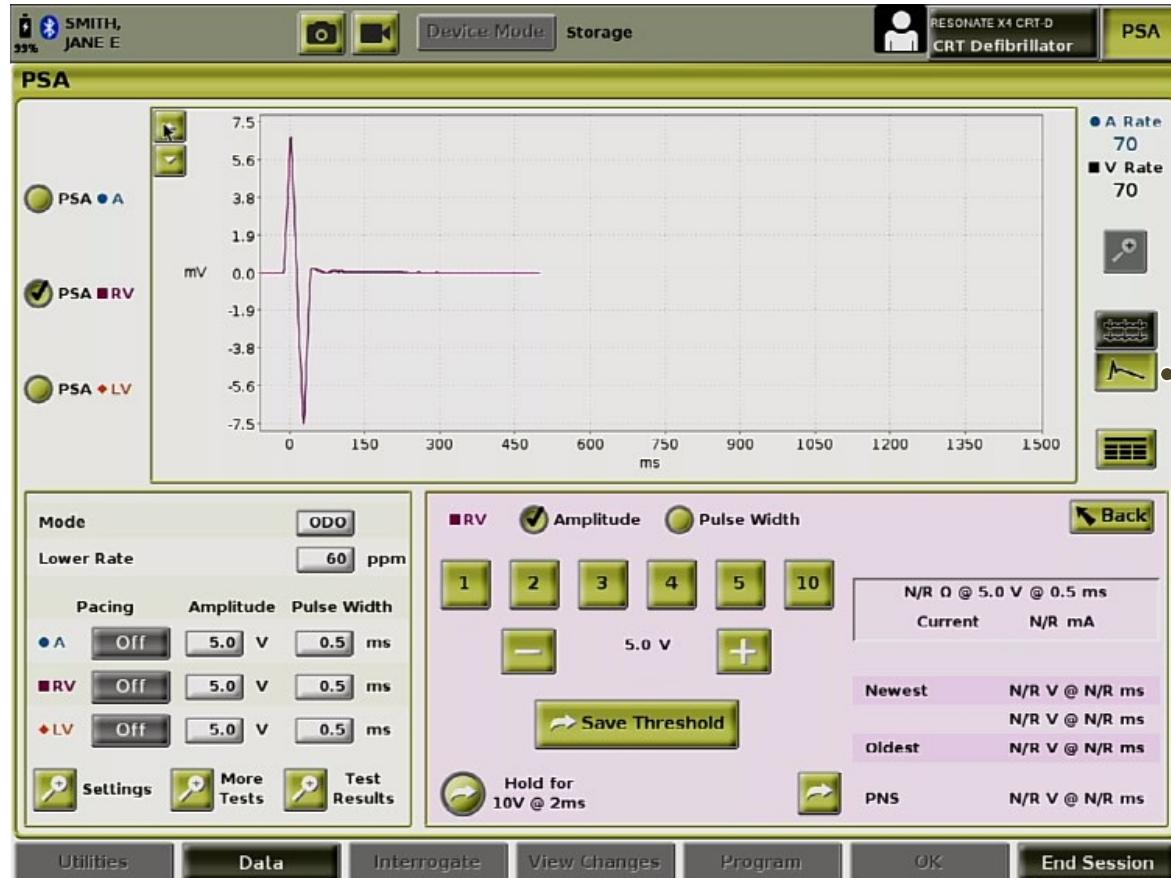
Slew Rate and RV-LV Timing

- (a) **Slew** displayed with each sensed intrinsic activity
- (b) **RV–LV interval** displayed when RV and LV cables are connected; a negative value will be displayed if LV is sensed before RV



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Current of Injury

Provides information that can be used in addition to measured information (i.e., pacing threshold, impedance, sensing) and may help indicate that lead repositioning is required

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Current of Injury Background

- **Displays** the injury to the myocardium at the site of anchoring the lead
- **Manifests** as an increase in the duration of the intracardiac electrogram and elevation of the ST-segment compared to the baseline—and then recovers
- Studies have suggested “adequate values of COI measured” in order to **predict good midterm performance** of the lead
- The **waveform display is updated** each time a pace or sense event is detected by the PSA in the selected chamber
- **No storage** of COI available

Current of Injury is readily visualized when present without the need for specific measurements. Boston Scientific does not make recommendations of ST-segment elevation measurements that are representative of an adequate Current of Injury.

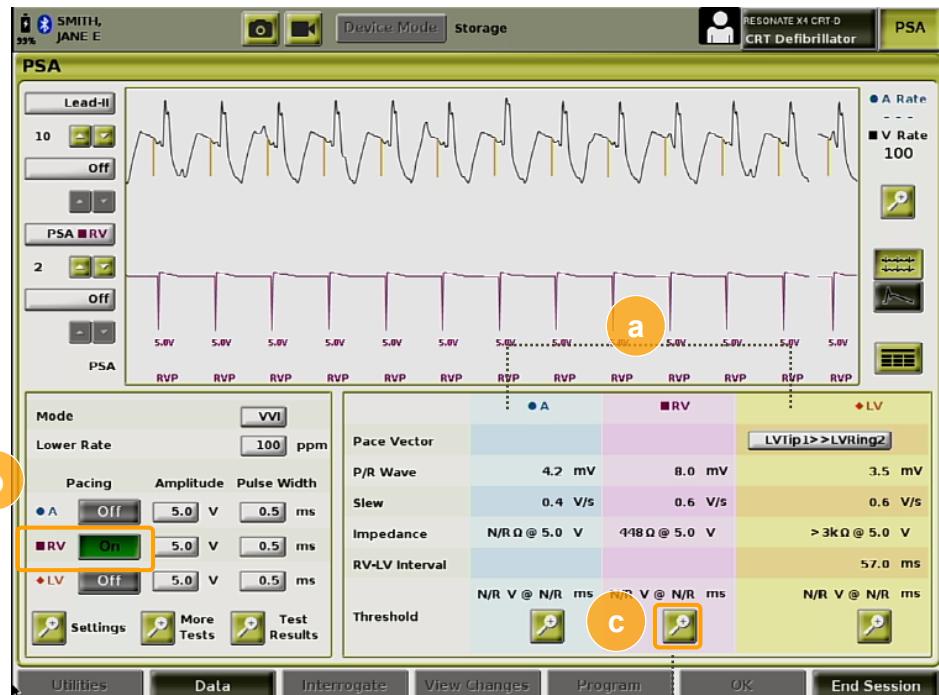
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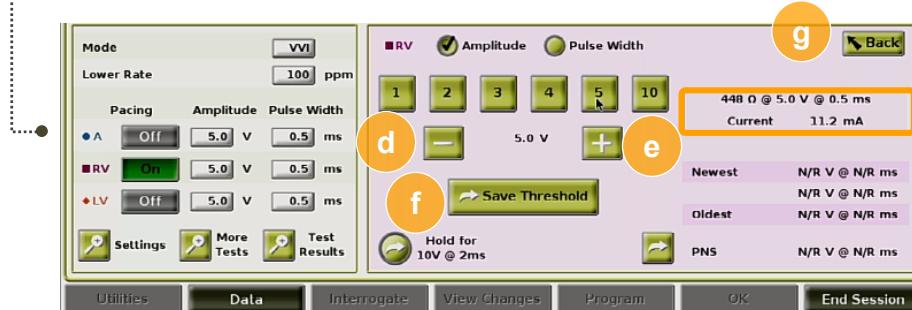
Capture Threshold Testing

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RV Lead Testing

- (a) **Channels** are color coded: ● A Blue, ■ RV Pink, ◆ LV Yellow
- (b) **Enable pacing** by changing from Off to On in a selected chamber or by (c)
- (c) **Enable pacing** by selecting the **magnifying button** in the chamber to be tested which will then display the Threshold panel
- (d) **Decrement or increment** pacing Amplitude or Pulse Width
- (e) **Impedance** value displayed beat-to-beat
- (f) **Save Threshold** to save data for P/R Wave, Slew, Impedance, and Threshold
- (g) Press **Back** to return



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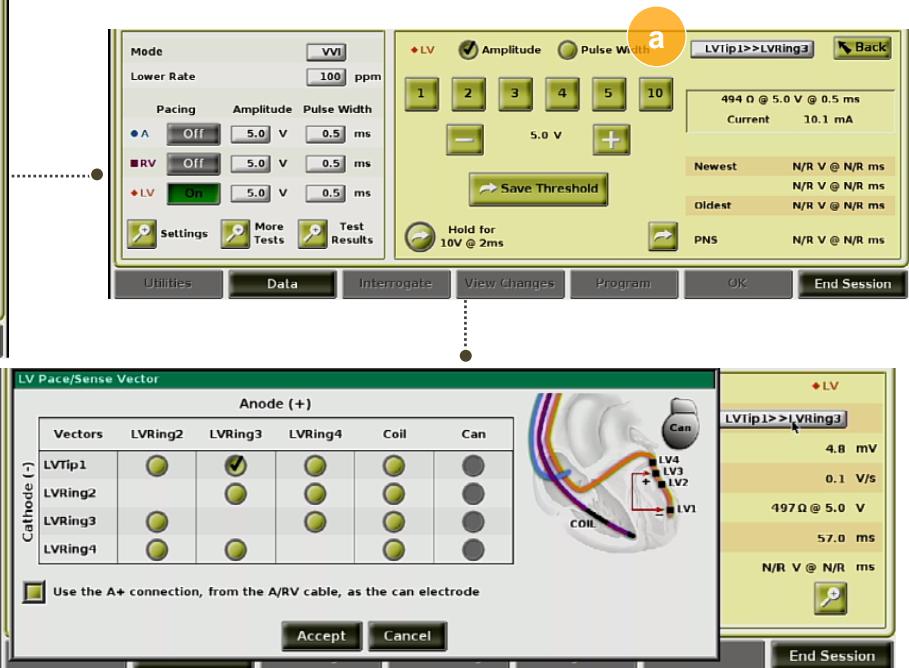
Capture Threshold Testing

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LV Lead Testing

Same process as with RV Lead testing with addition of (a) LV Pace / Sense Vector button



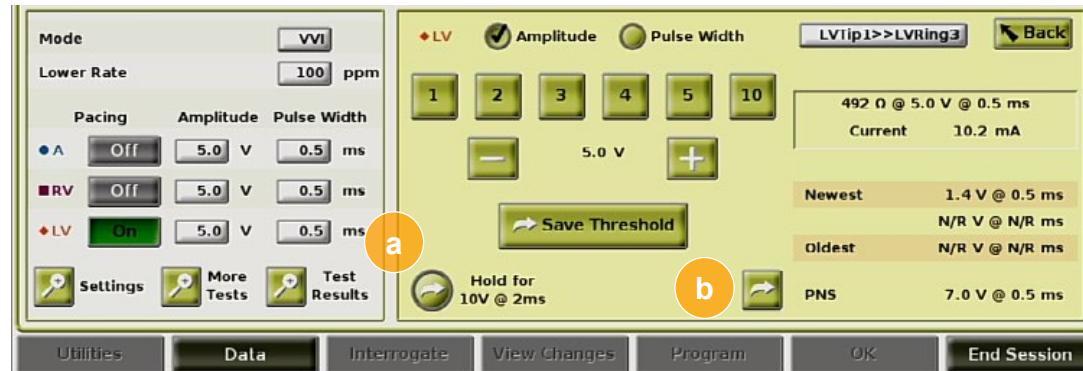
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Testing for Phrenic Nerve Stimulation

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Check for Phrenic Nerve Stimulation at max output

Press (a) Hold for 10V @ 2ms to check for extracardiac stimulation at maximum output; this button will not document results of the test.

- If desired for future reference, document the current voltage / PW of the Phrenic Nerve Stimulation (PNS) threshold using the (b) **PNS button**
- **The PNS button does not perform a PNS test** (simply stores the pacing values at the time the button is pressed, i.e., in this example, 7.0V @ 0.5ms)

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PSA Pacing and Amplitude Panel

PSA Test Results

- Select the **Test Results** button
- Check the **(a)** box to select desired results to **(b)** Save and/or Print to **PSA Report** (see next slide)

NOTE: If PSA Test Results are not **(c)** saved, there will be no data on the PSA Report

- You may edit text in **(d) Notes column** and edit the **Lead (a)** of a result in any of the three chambers
- Additionally, most recent selected results saved for each chamber automatically transfer to the Programmer Implant Data - Patient Information Summary screen



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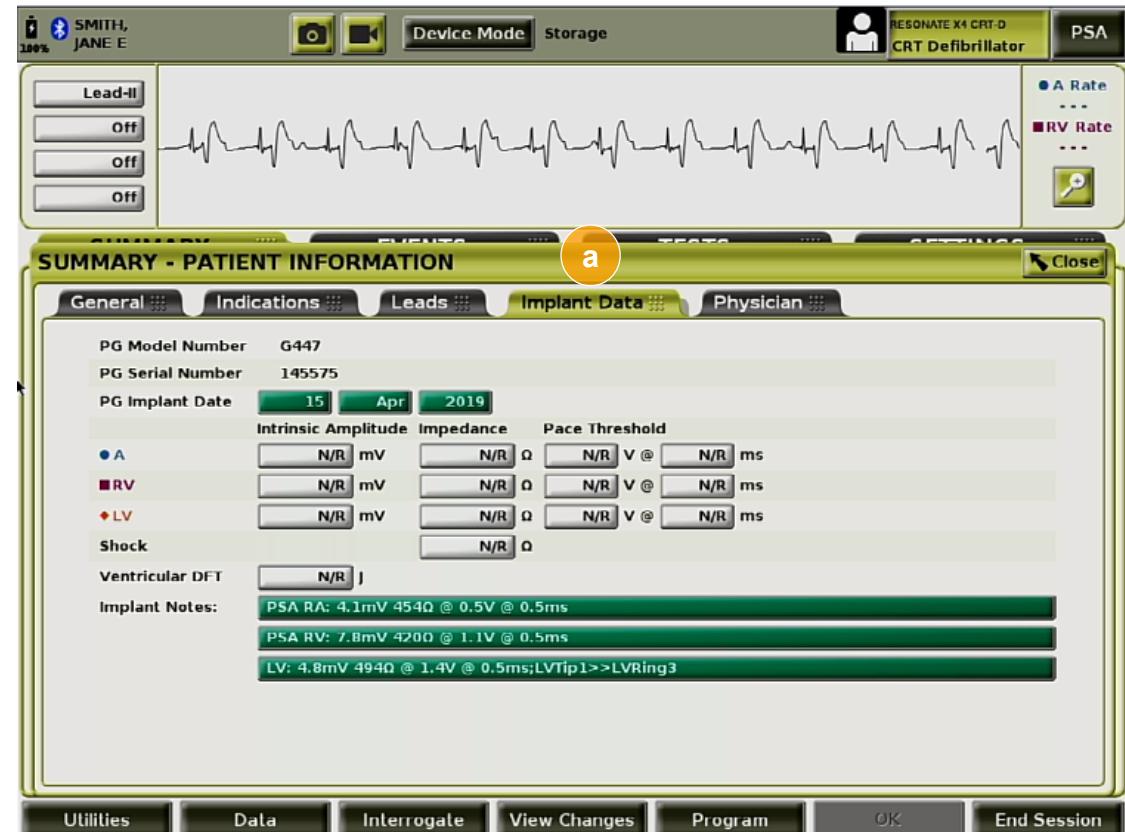




AutoSaving PSA Data in the Programmer

PSA Implant Data

- Saved PSA data will be seen in the **(a) Implant Data window** of the PG application
- This provides a set of data from the implant PSA session to the implanted device for future reference
- It is recommended this data be captured in the PG
- This functionality provides an automated replacement for a previously manual entry



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PSA Report

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PSA Test Results

The following information can be saved to a **PSA Report** for each lead

- (a) Date / Time Stamp
- (b) Intrinsic Amplitude
- (c) Slew Rate
- (d) Lead Impedance
- (e) Pace Threshold Amplitude and Pace Threshold PW
- (f) Notes
- (g) RV-LV Interval
- (h) LV Pacing Vector
- (i) PNS (Phrenic Nerve Stimulation) Documentation

Boston Scientific		LATITUDE™ Programming System					Report Created 15 Apr 2019				
PSA Report		SMITH, JANE E									
Date of Birth		N/R N/R N/R					Last Office Interrogation				
Device		RESONATE X4 CRT-D G447/ 145575					15 Apr 2019	Implant Date			
Atrial Saved Results a Date/Time 15 Apr 2019 14:43		b P-Wave	4.1mV	c Slew	0.4V/s	d Impedance	454 Ω	e Threshold	0.5V@0.5ms	f Notes	
Right Ventricle Saved Results b Date/Time 15 Apr 2019 14:39		b R-Wave	7.8mV	c Slew	0.6V/s	d Impedance	420 Ω	e Threshold	1.1V@0.5ms	f Notes	
Left Ventricle Saved Results c Date/Time 15 Apr 2019 14:55 i PNS 7.0V@0.5ms		b R-Wave	3.8mV	c Slew	0.3V/s	d Impedance	487 Ω	e Threshold	3.9V@0.5ms	g RV-LV	h Notes 65.0ms LVTip1>>LVRing3

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PSA Real-time Log

There are 3 types of Real-time Log Events

1. Snapshot

Pressing this button saves up to 10 seconds of real-time data prior to pressing and 2 seconds after

2. Real-time Recording

Pressing this button starts and stops a Real-time Log recording; minimum of 3 second segment, maximum of 3 minute segment, up to 100 segments per session

3. Triggered Captures

Initiated by an event without user action

Events can be saved to Programmer's hard drive or to USB drive, printed, transferred, and/or deleted

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Automatic Real-time Log Events

PG Events

Event Type	Trigger Event	Duration of Recording (seconds)
Presenting	Initial Interrogation Completed	12
Electrocautery Mode	Electrocautery Mode Entered	12
STAT PACE	STAT PACE Commanded	12
DIVERT THERAPY	Divert Therapy Commanded	12
PACE THRESHOLD TEST (AUTO, A, V, RV, LV, Ampl. and PW)	Threshold Test Ended	12
INTRINSIC AMPL TEST (A, RV, LV, and SSI)	Intrinsic Ampl Test Completed	12
TEMP BRADY	Temp Start Entered, Temp End Entered	Temp Start to Temp End
STAT SHOCK	STAT SHOCK Commanded	48
Commanded V ATP	ATP Commanded	12
Commanded V Shock	Shock Commanded	12
Fib Induction High	Fib Induction Commanded	24
Fib Induction Low	Fib Induction Commanded	24
Shock on T Command	Shock on T Commanded	43
Ventricular PES	PES Commanded	24
Atrial PES	PES Commanded	24
PG Ventricular Burst Pacing	PG Burst Completed	24
PG Atrial Burst Pacing	PG Burst Completed	24
PG Ventricular 50 Hz Burst Pacing	PG Burst Completed	24
PG Atrial 50 Hz Burst Pacing	PG Burst Completed	24
PG Fault	PG Fault Occurred	12

PSA Events

Event Type	Trigger Event	Duration of Recording (seconds)
PSA PACE THRESHOLD TEST (A, RV, and LV)	PSA Save Threshold button pressed	12
PSA BURST PACING	PSA Burst button released	24

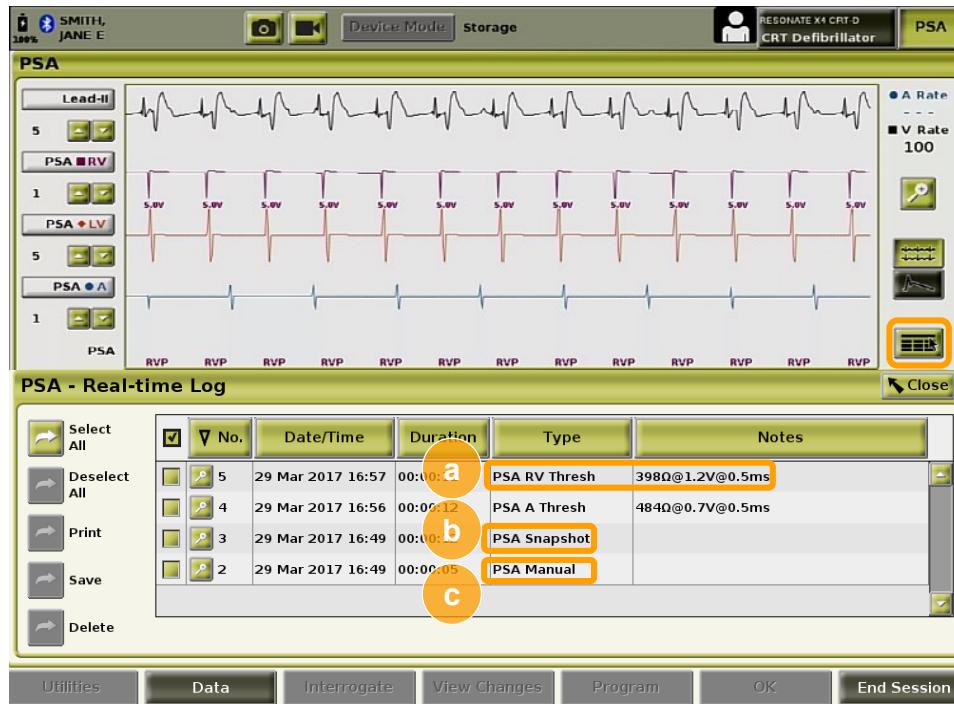
Note: Presenting event for a CRT-D device will show Surface lead and A, RV, and Shock EGMs, no LV EGM; if desired, select LV instead of Shock and press Snapshot

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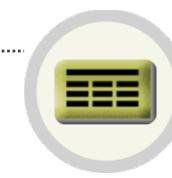


PSA Real-time Log



PSA Real-time Log

- Use Real-time Log button to view details
- Full markers on EGMs
- Notes area to add comments
- Real-time Log Events are not automatically saved when a session ends



- (a) PSA Threshold (stored when Save Threshold button pressed)
(b) PSA Snapshot
(c) PSA Real-time Recording

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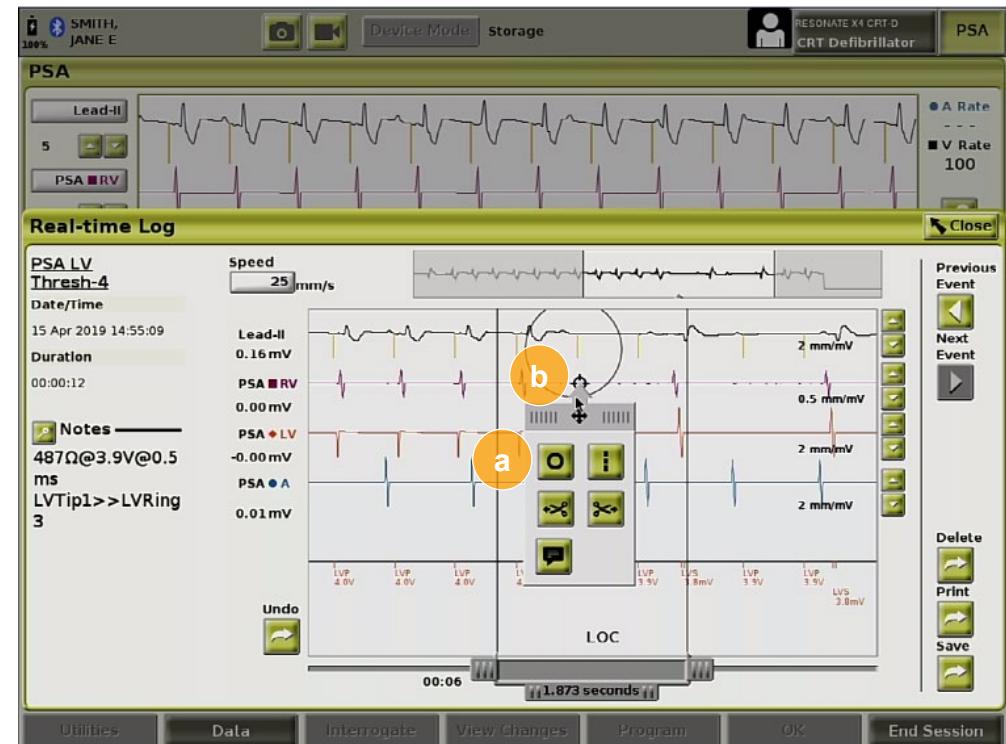




PSA Real-time Log

Caliper and Tool Pop-up

- The timeframe measured between the calipers is measured in seconds
 - A **caliper** can be repositioned by selecting it and then dragging it to expand or collapse the timeframe
- Customize an Event** by touching any part of the Real-time Log Event to display the **Tools pop-up**
- At the top center of the **(a) Tool pop-up** is an **(b) arrow** and a **target icon**
 - When a specific **tool is selected**, the tool action occurs at that **target point** on the screen



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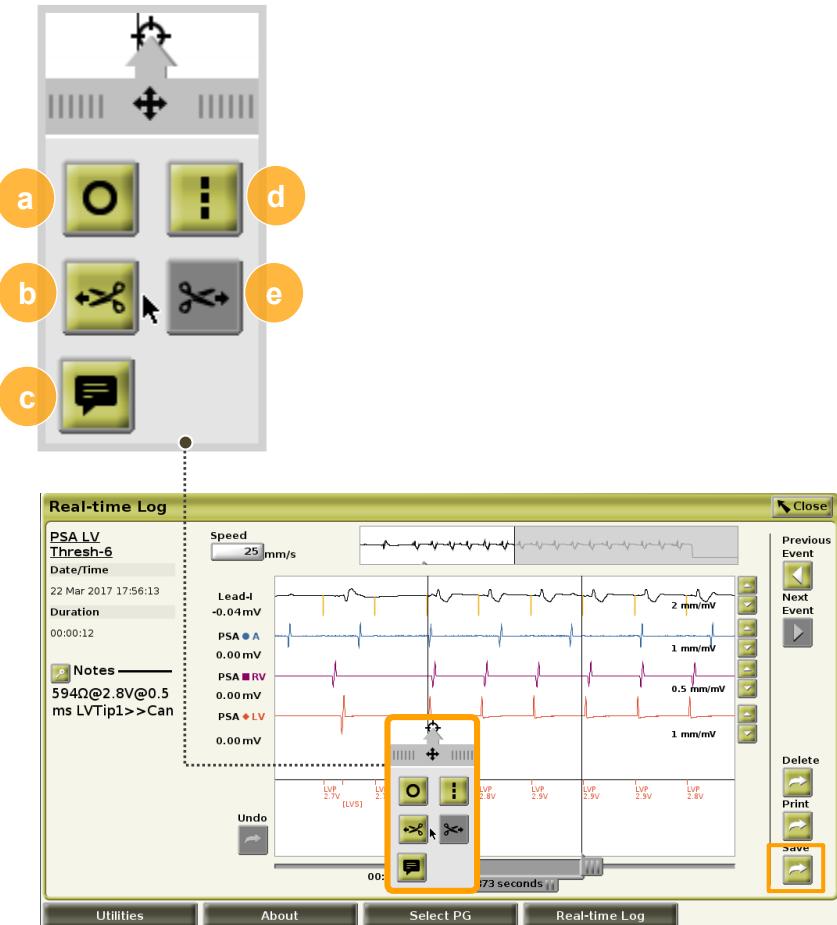




PSA Real-time Log

Editing Tools

- (a) **Places a circle** on the display at the target point
- (b) Left Scissor Tool **Creates a copy** of the Real-time Log and removes the entire portion of the recording to the **left of the target point** (the original recording is retained)
- (c) **Displays a keyboard** to type in any notes which then appear at the bottom of the Real-time Log
- (d) **Places a dashed vertical line** on the display at the target point
- (e) Right Scissor Tool **Creates a copy** of the Real-time Log and removes the entire portion of the recording to the **right of the target point** (the original recording is retained)



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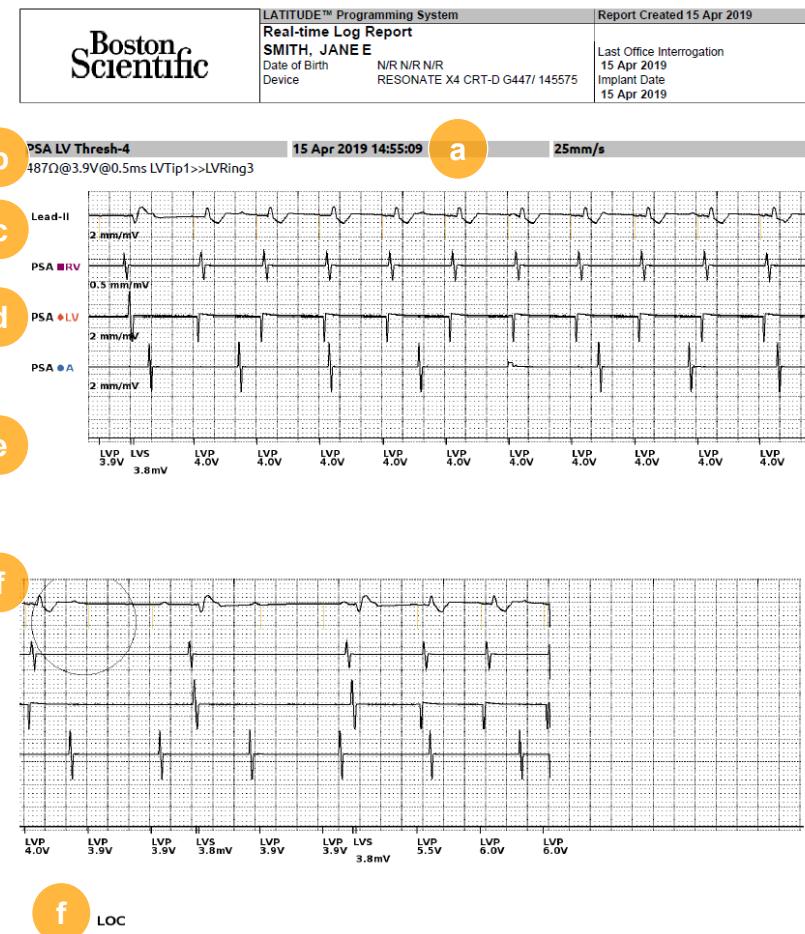
Real-time Log Report

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PSA Real-time Log Report

LV Threshold Example (12 seconds)

- (a) Date / Time stamp
- (b) Lead Impedance, Pace Threshold Amplitude, Pace Threshold PW, LV Pacing Vector
- (c) Surface Lead
- (d) Atrial, RV, LV EGMs
- (e) Markers / Voltage
- (f) Annotation





PSA Test Results & PSA Real-Time Log Comparison

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PSA Real-time Log

- Threshold measurements include Amplitude and PW
- **EGM**
- Notes section (keyboard will display)
- **Select and Save desired data to Print Event, Save to Hard Drive or USB, and/or transfer to LATITUDE Link™**

No.	Date/Time	Duration	Type	Notes
4	15 Apr 2019 14:55	00:00:12	PSA LV Thresh	487Ω@3.9V@0.5ms LVTip1>>LVRing3
3	15 Apr 2019 14:43	00:00:12	PSA A Thresh	454Ω@0.5V@0.5ms
2	15 Apr 2019 14:40	00:00:12	PSA LV Thresh	494Ω@1.4V@0.5ms LVTip1>>LVRing3
1	15 Apr 2019 14:39	00:00:12	PSA RV Thresh	420Ω@1.1V@0.5ms

Lead	Date/Time	Amplitude	Pulse Width	Notes
Atrial	15 Apr 2019 14:43	0.5 V	0.5 ms	
Right Ventricle	15 Apr 2019 14:39	1.1 V	0.5 ms	
Left Ventricle	15 Apr 2019 14:40	1.4 V	0.5 ms	LVTip1>>LVRing3
Left Ventricle	15 Apr 2019 14:55	3.9 V	0.5 ms	LVTip1>>LVRing3

PSA Test Results

- Threshold measurements include Amplitude and Pulse Width
- May edit lead selection
- Notes section (keyboard will display)
- Select and Save desired data for transfer to **PSA Report (PDF)** and to populate in **Implant Notes of Patient Information Screen**
- Save to hard drive or USB, and/or transfer to LATITUDE Link™

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PSA Pacing and Amplitude Panel

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More Tests

- (a) Antegrade Conduction Test
- (b) Retrograde Conduction Test
- (c) Burst Pacing



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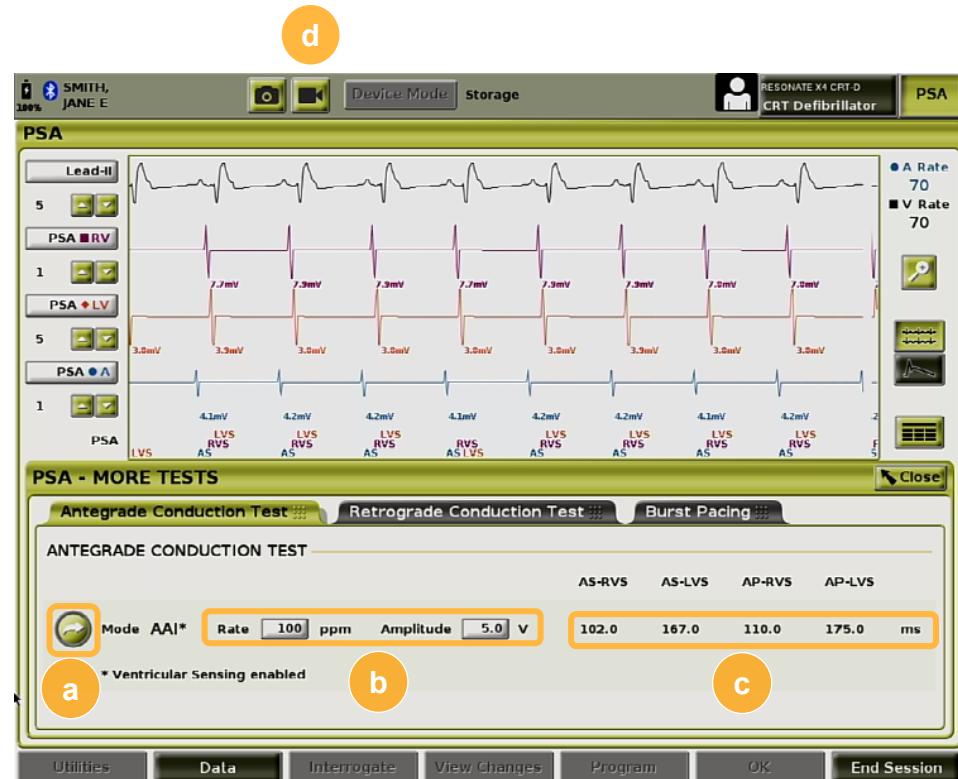


PSA More Tests

More Tests: Antegrade Conduction Test

Antegrade measurement uses AAI Brady mode with ventricular sensing enabled to measure patient's **A-V conduction times** based on either **paced or sensed atrial event**

- Press and hold **(a) arrow button** to activate test
- Select pacing **(b) Rate and Amplitude**
- **(c) Beat-to-beat conduction measurements displayed**
- No automatic Real-time Logs are captured for Antegrade or Retrograde conduction tests
- Select **(d) Real-time Recorder button** before beginning conduction test



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PSA More Tests

More Tests: Retrograde Conduction Test

Retrograde measurement uses VDI Brady mode to measure patient's **V-A conduction times** based on either **paced** or **sensed** ventricular events

- Press and hold **(a) arrow button** to activate test
- Select pacing **(b) Rate and Amplitude**
- **(c) Beat-to-beat conduction measurements displayed**
- No automatic Real-time Logs are captured for Antegrade or Retrograde conduction tests
- Select **(d) Real-time Recorder button** before beginning conduction test



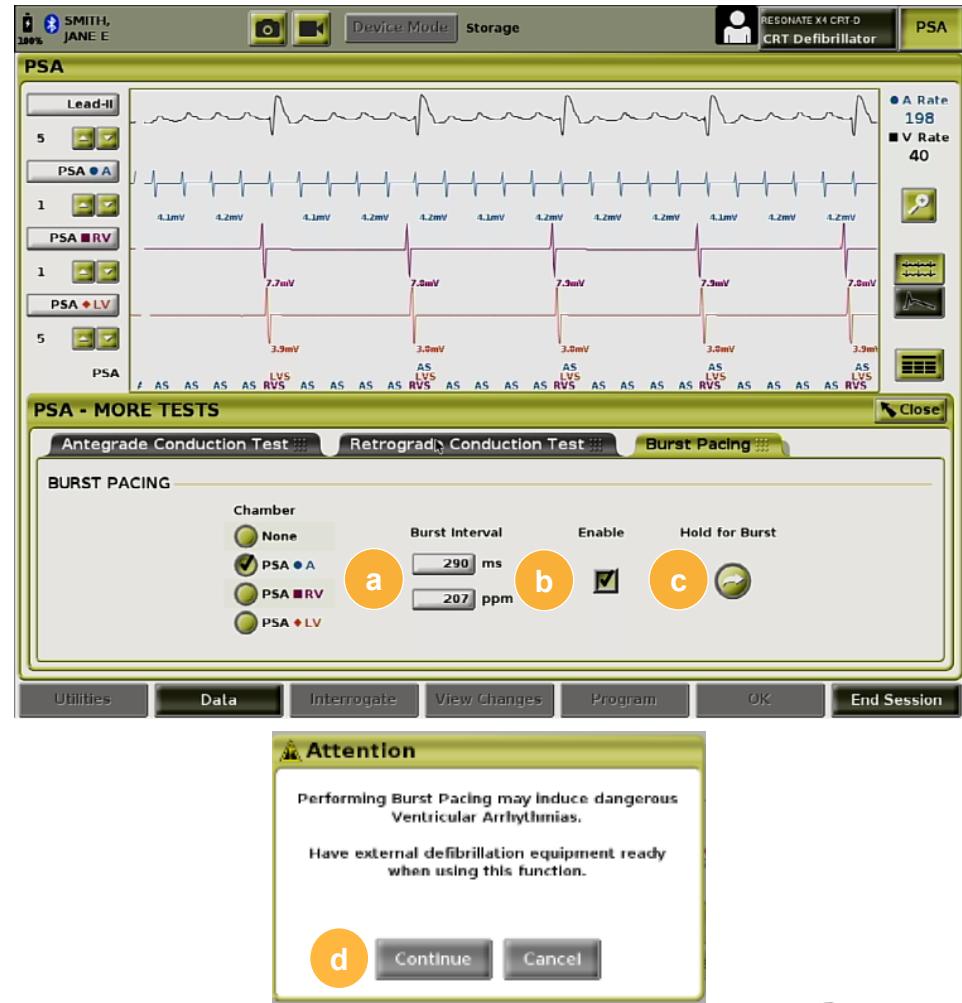


PSA More Tests

More Tests: Burst Pacing

Used to **induce** or **terminate arrhythmias** when delivered to desired chamber—only the selected chamber receives Burst Pacing

- Select **(a) desired chamber and pacing rate**
- Pacing Interval in ms and corresponding ppm
- Check **(b) Enable**
- **(c) Hold for Burst button**
 - Maximum Burst **45** seconds in atrium, **30** seconds in ventricle
 - Automatically creates PSA Burst Pacing Event **24** seconds in Real-time Log
- Select **(d) Continue** in Attention window



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Typical Implant Steps

- 1 **CONNECT** power cord, telemetry wand, ECG BNC slave cable, USB Printer cable if using, and cable to DisplayPort out if desired
- 2 **INSERT** pen drive into USB port if using to transfer data to LATITUDE™ Link or to save patient data
- 3 **POWER ON** Programmer
- 4 **ENSURE** Bluetooth® enabled for printing if desired
- 5 **CHECK** Internal battery status
- 6 **INTERROGATE** device to be implanted to allow toggling between PSA and Programmer applications
- 7 **SELECT** Data tab
- 8 **CHOOSE** method to save lead evaluation data (hard drive or USB drive)
- 9 **ENTER** patient data
- 10 **CHECK** device battery
- 11 **ADJUST** device settings if desired
- 12 **MANUAL RE-FORM** capacitor if high voltage device
- 13 **SELECT** PSA application
- 14 **GO TO** Settings and adjust parameters if desired for testing
- 15 **SELECT** PSA EGM traces

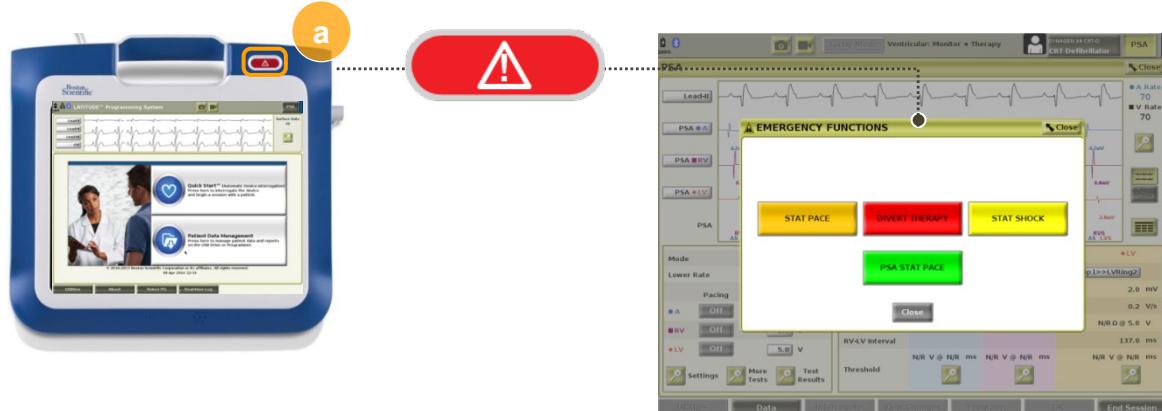


- 16 **HAND OFF** pacing cables to Scrub Technician
- 17 **OBTAIN** all PSA measurements for each lead: Sensing, Slew Rate, Current of Injury, Pacing Threshold, PNS
- 18 **PRESS** Save Threshold button for each chamber tested to save data for P/R Wave, Slew, Impedance, Threshold
- 19 **SELECT** PSA Test Results and Save data to generate a PSA Report and to automatically transfer implant measurements to Patient Information screen
- 20 **Go to** Real-time Log to review testing data
- 21 **SELECT** data to Save and /or Print. Real-time Log is available in both PSA and device applications
- 22 **SELECT** device application when PSA testing is completed
- 23 **CHANGE** PSA EGM traces to PG EGM traces
- 24 **PERFORM** device-based testing
- 25 **PERFORM** final device programming
- 26 **GO TO** Data Management Screen to save / print / store / transfer data
- 27 **REGISTER** device with Boston Scientific





Emergency Function Button



Real-time Log Event automatically stored when any of these functions are requested

After selecting the **(a) red STAT hard button**, press any of the onscreen buttons once to immediately initiate action

NOTE: No secondary confirmation screen

Function	What does it do?	Availability
STAT PACE	Programs immediate BiV pacing in CRT device, unipolar pacing in low-voltage device (pacemaker), bipolar pacing in ICD device VVI @ 60 PPM, 7.5V @ 1.0ms	Only available when in telemetry communication with high- or low-voltage transvenous device; reprogram pacing parameters in Settings to exit STAT PACE
PSA STAT PACE	Programs immediate BiV pacing VVI @ 60 PPM, 7.5V @ 1.0ms	Only available if PSA session is in progress; reprogram pacing parameters in Settings to exit PSA STAT PACE
DIVERT THERAPY	Stops pending therapy; pressing Cancel Telemetry will not divert therapy	Only available when in telemetry communication with high- or low-voltage transvenous device
STAT SHOCK	Shocks at maximum-output energy	Only available for high-voltage transvenous devices





Improving RF Performance

- Move Programmer closer to patient—ideally away from busy or crowded location in room
- Change Programmer orientation by rotating Programmer up to 45° clockwise or counter-clockwise
- Place Programmer into optional Model 6755 stand
- If there are any metal objects or electrical equipment (laptop, monitor, etc.) adjacent to Programmer, move them away from Programmer as much as possible
- If telemetry is still not consistent, connect Model 3203 S-ICD telemetry wand to its connector and place within two feet of implanted device, orienting the wand as necessary to improve RF telemetry; if in a sterile field, use Model 3203 sterile cover and place wand on top of patient's abdomen; the wand will act as an extra RF antenna
- Turn OFF RF; use inductive telemetry wand, Model 6395

Mitigating Noise

- Turn ON (a) 50Hz / 60Hz filter
- Use grounding USB adapter and cable to provide earth ground



<http://desco.descoindustries.com/DescoCatalog/Grounding-Hardware/Banana-PlugAdapters/09839/#.WM62hHzND8>



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Key Points when Operating the 3300 PSA

- ALWAYS press the ACCEPT button when changing LV Lead testing configurations for Pace/Sense vector when using the PSA
- When checking LV Lead impedance measurement with the PSA, use only LV lead electrodes
- To build a PSA Report, which will import data to the Patient Information screen, the user must press the ‘Save Threshold’ button while testing AND save the desired PSA Test Results
- When selecting the ‘Save Threshold’ button or selecting the ‘Back’ button when ending a pacing threshold test, the effective pacing voltage will revert to 5.0 volts, 0.5 ms pulse width

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LATITUDE™

PROGRAMMING SYSTEM
MODEL 3300



CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.