Boston Scientific

OPERATOR'S MANUAL

Pacing System Analyzer (PSA)

Application for use with the LATITUDE™ Programming System

REF 3922 Pacing System Analyzer (PSA)

REF 3300 LATITUDE™ Programming System

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INFORMATION FOR USE

Trademark Statement

The following are trademarks of Boston Scientific or its affiliates: LATITUDE, and Quick Start.

DisplayPort is a trademark of the Video Electronics Standards Association (VESA).

All other trademarks are the property of their respective owners.

Description and Use

The Pacing System Analyzer (PSA) is an application of the LATITUDE Programming System, Model 3300, which is a portable cardiac rhythm management system designed to be used with compatible Boston Scientific systems, i.e., implantable pulse generators (PGs) and leads.

The PSA application provides the ability to:

- Assess electrical performance and placement of cardiac lead systems during implant of cardiac rhythm management devices and provide other diagnostic information.

Note: *The screen images used in this manual are representative and may not exactly match your screens.*

Intended Use

The LATITUDE Programming System, Model 3300 is intended for use in hospital and clinical environments to communicate with Boston Scientific implantable systems. The PSA application is intended to be used during the implantation of pacemakers and defibrillators (including Cardiac Resynchronization Therapy or CRT devices) to evaluate the placement of pacing and defibrillation leads.

Intended Audience

This literature is intended for use by health care professionals trained or experienced in device implant and/or follow-up procedures.

Clinical Benefits of the Device

The Model 3300 LATITUDE programmer contains an integrated Pacing System Analyzer (PSA), and the Model 3922 PSA software support application, which eliminates the need for a stand-alone PSA device. The benefit of using the PSA as an integrated function of the programmer includes being able to measure and record device parameters required during device implantation, and to verify lead system status at device changeout, including lead impedance, pacing threshold, and sensing threshold. The PSA has the added clinical benefit to be used for temporary pacing from an external source during device implantation, while the patient is being continuously monitored by medical personnel. The PSA is contraindicated as an external pacemaker.

Required Expertise and Knowledge

Users must be thoroughly familiar with electrotherapy of the heart. Only qualified medical specialists having the special knowledge required for the proper use of the device are permitted to use it.

Physician Supervision

The LATITUDE Programming System may only be operated under the constant supervision of a physician. During a procedure, the patient must be continuously monitored by medical personnel with the aid of a surface ECG monitor.

Medical Product Operator's Ordinance

National regulations may require that the user, manufacturer or manufacturer representative perform and document safety checks of the device during installation. They may also require that the manufacturer or its representative provide training to users on the proper use of the device and its accessories.

If you do not know the national regulations in your country, please contact your local Boston Scientific representative.

Essential Performance

In order for the LATITUDE Programming System to meet its intended use, it must communicate with Boston Scientific implantable pulse generators. Therefore those functions that pertain to communications with the implanted pulse generators using telemetry wands are considered essential performance.

LATITUDE Programming System performance determined to be essential by Boston Scientific for electromagnetic compatibility (EMC) testing, as per IEC 60601-1-2, is the ability to:

- Initiate a PG STAT PACE, PSA STAT PACE, STAT SHOCK, or DIVERT THERAPY command to a PG where supported
- Display real-time intracardiac electrograms
- Supports touchscreen tap and button press interactions
- Deliver pacing and perform impedance lead measurements with the Pacing System Analyzer (PSA) function

Note: *No recurring calibration of the LATITUDE Programming System or its applications is required or needed.*

Contraindications

The LATITUDE Programming System is contraindicated for use with any pulse generator other than a Boston Scientific pulse generator. For contraindications for use related to the pulse generator, refer to the associated product literature for the pulse generator 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[1]

WARNINGS

Refer to the *LATITUDE Programming System Operator's Manual*, Model 3300 for additional 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.

- **Radio Frequency (RF) communications equipment.** Keep all RF communications equipment (including peripherals such as antennas, wands, and cables) at least 30 cm (12 inches) 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 to a grounded/earthed power source.

- **Electrostatic charges.** The PSA lead system is in electrical contact with the patients' heart and blood.
  - Do not touch the metal clips on the PSA 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 PSA cable or the device.

- **Electrical currents.** Unused PSA cable connections 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.
  - Whenever possible disconnect the PSA cables from the pacing leads when performing an electrocautery procedure.

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

- If the Programmer is connected to the patient during an electrocautery procedure, check its operation afterwards.
- If there is an electrical overload, the Programmer will reset and reboot. During the reset and reboot, which takes about one minute, there will be no pacing support. 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 Model 3300 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.

- **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.[2] 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 after defibrillation.

- **Loss of Power.** Operating the Programmer with a depleted internal battery or no battery can suspend Programmer function if AC power is temporarily interrupted.

2. Kanal E, Barkovich AJ, Bell C, et al. ACR guidance document on MR safe practices: 2013. J. Magn. Reson. Imaging 2013;37:501-530.

- 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.
- An attention message displays on the Programmer screen when the battery reaches 25% depletion. When the battery reaches 10% depletion or less, an additional warning displays. At 5%, there is a warning dialog followed by a 60 second automatic shutdown.

- **Loss of pacing support.** Always have external cardiac pacing equipment in an operational status available for emergency situations.
  - 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.
- **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 pacing to intrinsic action.
- **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 clips 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.

- **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.

PRECAUTIONS

Refer to the LATITUDE Programming System Operator's Manual, Model 3300 for additional Precautions.

- **Functional impairment due to external damage.** Mechanical impact, for example dropping the Model 3300 Programmer unpackaged can permanently impair the function of the system. Do not use the device if there is apparent damage. If damage has occurred, contact Boston Scientific using the information on the back cover of this manual to return the unit.

- **LATITUDE Programming System.** Use only the current software to perform PSA functions.

- **Stylus use.** Ensure that any stylus used is a projected capacitance stylus. The use of any other object could damage the touchscreen.

- **Electrocautery cables.** Keep all electrocautery cables at least 30 cm (12 in.) away from the LATITUDE Programming System to avoid false signals due to electrocautery energy.

- **Leakage current.** Although optional external equipment connected to the Model 3300 Programmer must meet the applicable leakage-current requirements for commercial products, it may not meet the more stringent leakage requirements for medical products. Consequently, all external equipment must be kept outside the patient environment.

  - Never touch the electrical contacts on the side panels of the Model 3300 Programmer and the patient, the telemetry wand, or any cable at the same time.

- **PSA connections.** Ensure leads are connected appropriately for desired use; incorrect setup can result in pacing/sensing events, which display under a different chamber on the screen. The PSA application user interface associates specific lead connections with the RA, RV and LV chambers on screen to support testing all three chambers with minimal change of physical connections. Saved PSA measurements are also labeled automatically based upon the chamber in use on the screen. These labels can later be adjusted by the user if the decision is made to use one physical connection to test other chambers (for example, using only the RV connection to test RA, RV and LV leads).

- **PSA connector clips.** Do not clip any PSA connector directly to the skin, pocket, or other tissue of the patient.

- **Ventricular Pacing and Sensing.** During a PSA session, ventricular sensing behavior is driven by the most recently selected ventricular pacing configuration: RV-only, LV-only, or BiV.

- At system startup, the PSA mode is set to ODO (non-pacing) and the effective ventricular pacing configuration is BiV.
- When a non-pacing mode (ODO or OVO) is selected from the Mode panel, sensing is set to BiV to ensure sensing is enabled on both leads regardless of any prior configuration.

- **Cross-chamber over-sensing.** A unipolar configuration may lead to cross-chamber artifact over-sensing that affects pacing behavior.
  - In a unipolar configuration, it is common to see cross-chamber artifacts on electrograms (EGMs). If you move the A+ connector clip back to the atrial lead anode while the Can electrode button and "Use the A+ connection" button are still selected, the PSA remains programmed to a unipolar configuration. In this case, you may see pronounced cross-chamber artifacts on the EGMs which may lead to over-sensing that affects pacing behavior.

- **System Power up.** Boston Scientific recommends attaching all necessary cables and devices before turning on the Model 3300 Programmer.

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

Any serious incident that occurs in relation to this device should be reported to Boston Scientific and the relevant local regulatory authority.

PSA FEATURES

The Pacing System Analyzer application determines in-situ lead characteristics of impedance, capture threshold, P/R Wave Amplitude, and slew rate. It supports three chambers (RA, RV, and LV) and provides the following features and functions:

- Real-time surface ECG
- Real-time intrinsic E-grams (EGM)
- Real-time Brady event markers
- Brady settings (programmable modes are ODO, OAO, OVO, AOO, VOO, DOO, AAI, VVI, VDI, DDI, VDD, and DDD)
- Real-time heart rate display
- Intrinsic amplitude(s)

- Intrinsic P/R Interval
- Slew rate
- Pace impedances
- Pace threshold tests (amplitude and pulse width)
- PSA STAT pacing operation
- Conduction testing (Antegrade and Retrograde)
- Burst pacing
- High output pacing (10 V @ 2 ms) for evaluating Phrenic Nerve Stimulation (PNS)
- RV-LV interval
- Detailed EGM viewing for Current of Injury diagnostics
- LV quadripolar testing support
- Noise filter for 50 Hz and 60 Hz frequencies
- Real-time Log storage and viewing
- Test results screen
- Preferred Settings

The Pacing System Analyzer application performs the following functions:

- Display real-time lead signals for testing RA, RV and LV Leads (including quadripolar leads) that are appropriately connected to the Programmer via PSA cables
- Display real-time signals for surface ECG and telemetered PG EGM signals (if in session with implanted device)
- Capture, annotate and review Real-time Log recordings of lead signal traces and markers
- Provide PSA configuration parameters for pacing and sensing, including burst pacing therapy
- Provide ability to perform and (as applicable) record lead evaluation results: intrinsic amplitude, slew rate, impedance, threshold and timing
- Provide ability to review recorded results, and save (to a USB pen drive or the Programmer hard drive) or print the PSA results

The Programming System supports PSA operation by:

- Displaying the PSA user interface on an external display during implant
- Exporting saved patient data from the Programmer hard drive to a removable USB pen drive
- Providing the option to encrypt patient data prior to exporting to a USB pen drive
- Transferring final measured data to the implanted PG (if in session with the implanted device)

Refer to the *LATITUDE Programming System Operator's Manual, Model 3300* for details on the operation of other features.

PSA APPLICATION OVERVIEW

The Pacing System Analyzer application is used to assess electrical performance and placement of cardiac lead systems during implant of cardiac rhythm management devices.

The following will help integrate the data, organize the behavior, and provide optimal flexibility to switch between the PSA and the PG application during implant. When these steps are used, all saved data is organized together and associated with the PG Model/Serial being implanted.

1. Identify the PG to be implanted and start a session/interrogate using the Quick Start button.
2. Access the PSA application from within the PG application once the PG session has started.
3. Switch back and forth between PSA and PG applications as desired during the procedure.

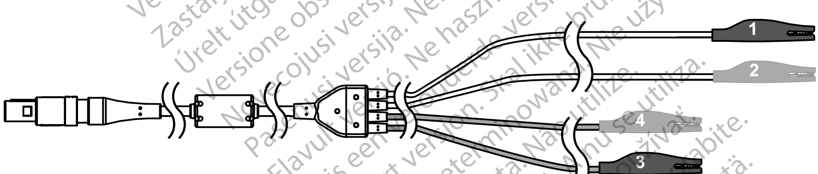
Note: *Even if the PSA application is switched to a PG session, PSA operation (pacing and sensing) continues until the Programmer is turned off.*

Note: *Boston Scientific recommends using PSA within the PG session because the data can be easily transferred to the pulse generator.*

SYSTEM ACCESSORIES

The Pacing System Analyzer application of the Programming System supports use of the following accessories:

- Model 6763 PSA Cable, re-sterilizable and re-usable; the cable clip protective covers contain Elastosil R 401, (silicone rubber)
- Model 6697 (Remington Model S-101-97) PSA Disposable Cable, single use only and requires a Model 6133 Safety Adapter
- Model 6133 (Remington Model ADAP-2R) Safety Adapter



[1] reverse side of black clip is marked V- [2] reverse side of red clip is marked V+ [3] reverse side of black clip is marked A- [4] reverse side of red clip is marked A+

Figure 1. Model 6763 PSA cable, clip markings

To order accessories, contact Boston Scientific using the information on the back cover of this manual.

WARNING: 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.

Optional External Equipment

For information about optional external equipment, refer to the *LATITUDE Programming System Operator's Manual, Model 3300*.

PSA SETUP AND CONNECTION

Before starting a PSA session, the LATITUDE Programming System must be started and the PG should be interrogated.

1. Ensure that the PSA cable(s) are sterile.

   The Model 6763 PSA cable is shipped non-sterile. If this cable is being used in a sterile procedure, then follow the sterilization procedures in the Instructions For Use (IFU) for this cable.

2. Select the PSA button to turn on the PSA function (Figure 2 on page 10).

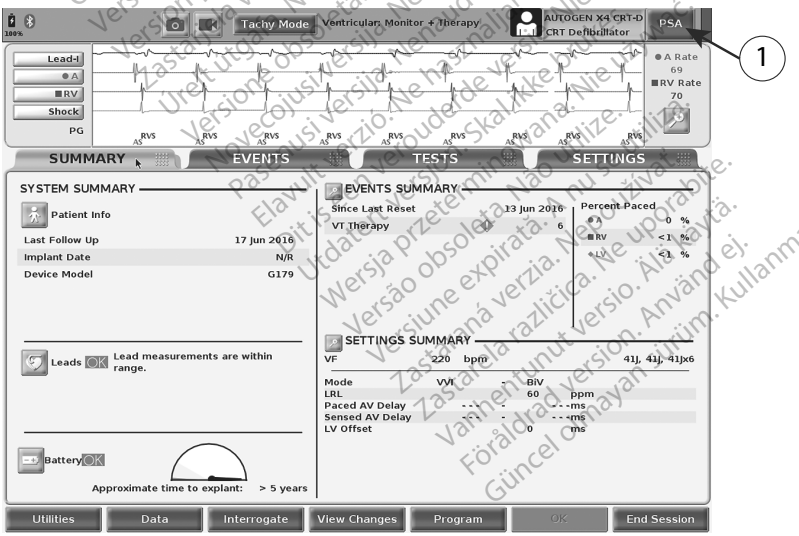
   Note: *Once the PSA application starts it continues to operate until the Programmer is turned off and restarted.*

3. Continue with "Connect the PSA cable to the Programmer and Leads" on page 11.

   Note: *Manually powering Off the Programmer and powering it back On resets all PSA parameters to the nominal values and discontinues any pacing output.*

CAUTION: If you want to use a stylus, ensure that it is a projected capacitance stylus. The use of any other object could damage the touchscreen.

Note: *The screen images in this manual are representative and may not exactly match the screens displayed.*



[1] PSA application button

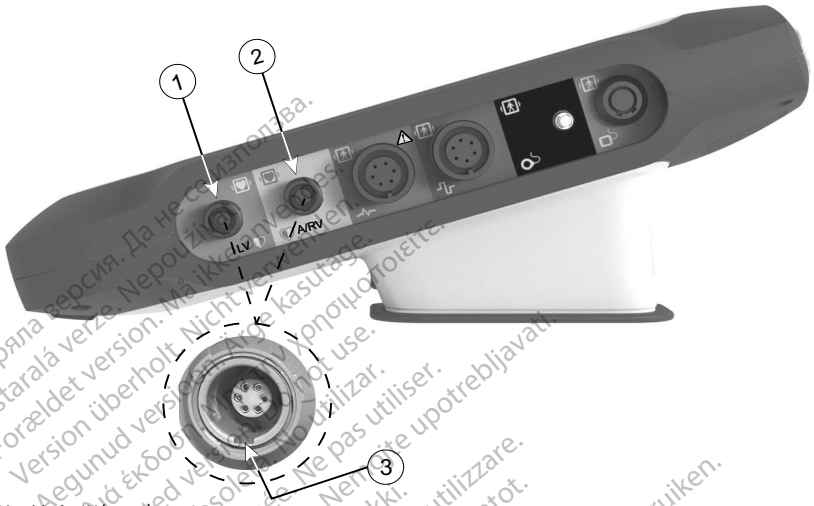
Figure 2. Main PG screen after Quick Start

Connect the PSA cable to the Programmer and Leads

For the PSA cable connection, refer to the illustration of the Programming System right side (Figure 3 on page 11).

For an example of a dual lead PSA connection, refer to Figure 4 on page 12.

For an example of a quadripolar PSA connection, refer to Figure 5 on page 14.



[1] PSA cable for LV (green)
[2] PSA cable for A/RV (light gray)
[3] PSA port keyway at bottom of connector

Figure 3. Right side panel of the Programming System

1. Connect the PSA cable to the appropriate connector (LV or A/RV) on the right side panel of the Programming System.

   Note: *Orient the PSA cable so that its key aligns with the connector keyway.*

2. For cables with protective sleeves (e.g. Model 6763 PSA cable), position the protective sleeves so that they cover the cable clips.

   Note: *The Model 6763 PSA cable protective sleeves must cover the clips when in use.*

3. Connect the PSA cable clips to the lead(s) and consider the following:

   a. Clips of cable and leads.

      - Do not allow yourself or others to touch the metal clips on the PSA cable or the pacing lead. The device is in electrical contact with the patient's heart and blood via the implanted leads.
      - Touching the metal clips on the PSA cable or the pacing lead may expose the patient's heart to dangerous electrical currents.

   b. Connecting PSA cable to leads.

- Verify that the PSA cable clips are attached to the correct lead(s).
- Connecting the PSA cable clips to the wrong lead may result in ineffective sensing and pacing behavior and loss of pacing support.

Note: *Refer to Figure 1 on page 9 for PSA cable connector identification.*

Note: *Refer to Figure 12 on page 19 for a lead connection example.*

c. Keep PSA cable dry.

- Do not use wet cables.

d. Unused PSA cable connections.

- Attach unused cable connections to surgical draping near the patient.

CAUTION: Ensure the left side of the unit is accessible at all times so that the power cord can be connected or disconnected.

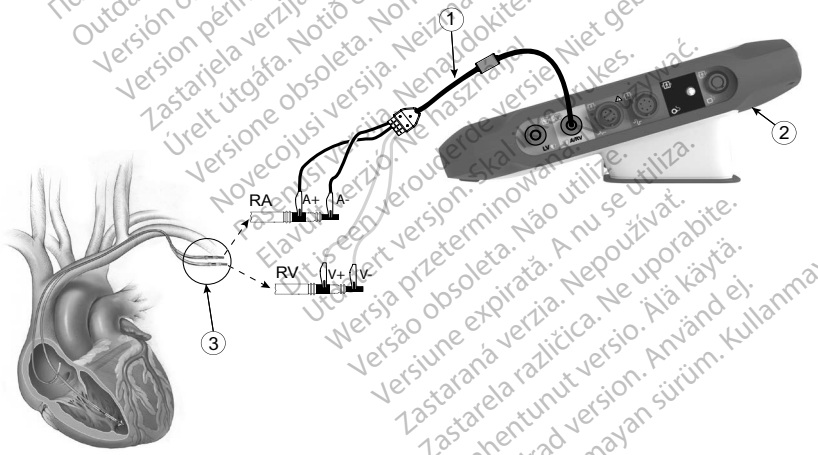
WARNING: The PSA cable must be disconnected from the lead(s) before using external defibrillation.

WARNING: Do not use the Programming System adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, check the Programming System for normal operation in that configuration.

This completes the PSA setup section. Continue with "Navigating the PSA Settings" on page 14.

PSA Dual Chamber Brady Leads Hookup, example

Figure 4 on page 12 illustrates the proper PSA cable hookup for dual chamber Brady leads.



[1] PSA cable (Model 6763) for A/RV [2] Model 3300 Programmer [3] RA and RV leads expanded to show PSA connections to lead terminal pins

Figure 4. PSA Dual Chamber Lead hookup, example using Model 6763 PSA cable

Note: *See Model 6697/S-101-97 IFU for cable connection information.*

PSA Quadripolar Lead Hookup, example

When using a quadripolar lead, Figure 5 on page 14 illustrates the proper PSA cable hookup for a unipolar configuration.

If you want a unipolar configuration using the Can as a vector, use any LV lead electrode as a cathode, move the A+ connector clip from the atrial lead to a temporary, indifferent electrode (e.g. hemostat, pocket spreader) placed at the patient's implant site to serve as the anode. Select both the "Use the A+ connection..." button and the desired Can button (see Figure 13 on page 20), then select the Accept button.

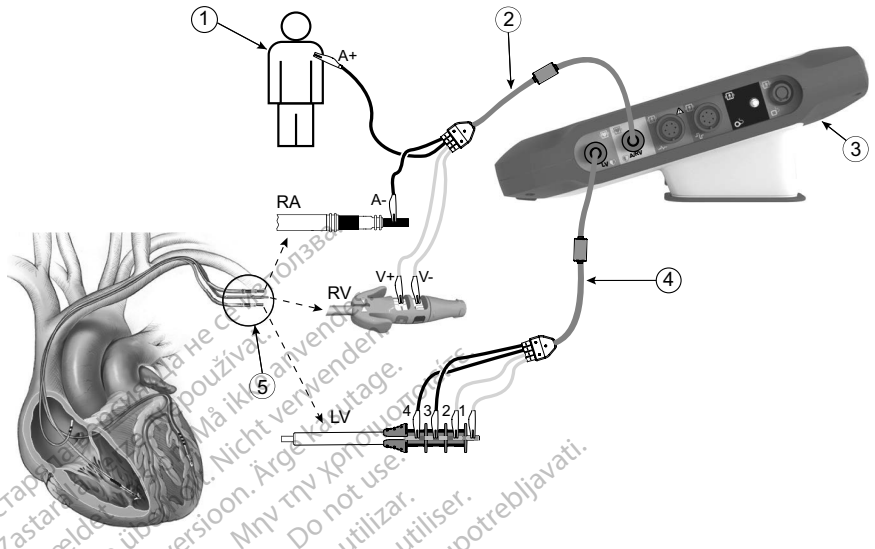
CAUTION: A unipolar configuration may lead to cross-chamber artifact over-sensing that affects pacing behavior.

- In a unipolar configuration, it is common to see cross-chamber artifacts on electrograms (EGMs). If you move the A+ connector clip back to the atrial lead anode while the Can electrode button and "Use the A+ connection" button are still selected, the PSA remains programmed to a unipolar configuration. In this case, you may see pronounced cross-chamber artifacts on the EGMs which may lead to over-sensing that affects pacing behavior.

To end a unipolar configuration, you must deselect the Can electrode button and deselect the "Use the A+ connection..." button. Press the Accept button to return to a bipolar configuration of the atrial lead.

CAUTION: Do not clip any PSA connector directly to the skin, pocket, or other tissue of the patient.

Note: *For unipolar configurations, attach the A+ connector on the PSA cable to a temporary, indifferent electrode (e.g. hemostat, pocket spreader) placed at the patient's implant site to simulate the PG device connection.*



[1] A+ connector to a temporary indifferent electrode placed at the patient's implant site [2] PSA Cable on RA/RV leads using Model 7001 connector tool for RV [3] Model 3300 Programmer [4] PSA Cable on LV connector using Model 4625 connector tool [5] RA, RV, and LV leads expanded to show PSA connections to lead terminal pins

Figure 5. PSA Quad Lead Hookup using Model 6763 PSA cable

Note: *See Model 6697/S-101-97 IFU for cable connection information.*

NAVIGATING THE PSA SETTINGS

When the PSA application is started, a check of the battery level is performed. The user is warned that PSA support may be terminated if the programmer's optional internal battery is at a low level (or missing) in the event that AC power is lost.

Note: *The PSA performs a self-test prior to each use. If the self-test fails, the PSA considers this a non-recoverable fault. The PSA monitors for non-recoverable faults while active and indicates to the user when it has experienced one.*

Note: *If the PSA is programmed in a Brady Pacing mode when a non-recoverable fault occurs, PSA falls back to the nominal set of pacing parameters in DOO pacing mode with the LV vector maintained as previously programmed.*

Note: *Once the PSA application starts it continues to operate until the Programmer is turned off.*

Ventricular Pacing and Sensing

CAUTION: During a PSA session, ventricular sensing behavior is driven by the most recently selected ventricular pacing configuration: RV-only, LV-only, or BiV.

At system startup, the PSA mode is always set to ODO BiV, which is the default setting. Sensing chamber options include:

- BiV enabled: sensing (and pacing if in a pacing mode) in both the RV and LV
- RV-only enabled: sensing (and pacing if in a pacing mode) in the RV but not LV
- LV-only enabled: sensing (and pacing if in a pacing mode) in the LV but not RV

LV Quadripolar Support[3]

CRT can improve survival and symptoms in patients with heart failure and LBBB. However, lead location, phrenic nerve stimulation, timing between RV and LV, and high capture thresholds can impact benefit. Quadripolar LV leads, compared to bipolar leads, may be associated with improved survival and decreased risk of replacement and deactivation. Ongoing follow-up and vector configuration of the quadripolar lead may be essential to sustain its potential benefits.

The LV Quadripolar feature supports the implant assessment of left-ventricle leads. It allows additional vectors to be used when evaluating and configuring the location for lead operation.

The LV Quadripolar feature provides organized control of the LV pacing/sensing vectors, thus avoiding manual repositioning of the pacing cable clips by the user for each vector test. It provides measurement of the time between the RV and LV signals and displays that measurement to the user as a surrogate replacement measure for a QLV interval measurement.

The role the PSA plays in LV Quadripolar support is to:

- Provide an electrical/mechanical interface that does not require manual repositioning of the PSA cable clips to test each vector
- Support programmatic control of the LV pacing/sensing vector

This feature is designed to allow evaluation convenience and operational efficiency for the user.

Note: *PSA uses the same sensing vector as the pacing vector for LV leads.*

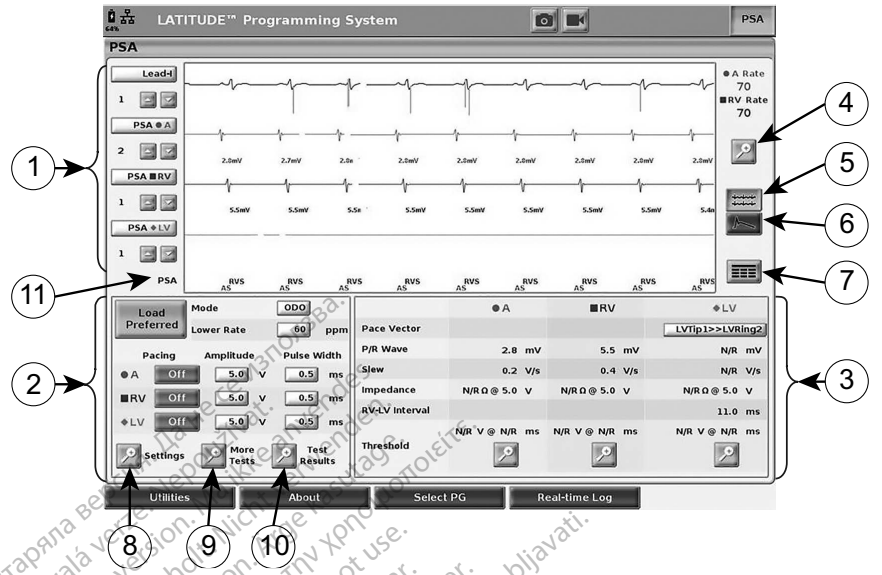
Screen Layout and Options

PSA Main Screen panels

This section provides details on each of the three PSA main screen panels:

1. Lead Traces (page 16)
2. PSA Pacing and Output (page 17)
3. PSA Measurements (page 18)

3. Reference: Mintu PT, et al. Reduced Mortality Associated With Quadripolar Compared to Bipolar Left Ventricular Leads in Cardiac Resynchronization Therapy. JACC: Clinical Electrophysiology 2016;2:426-433.



[1] Lead Traces panel (Lead-I, A, RV, and PSA LV) [2] PSA Pacing and Output panel (A, RV, LV) [3] PSA Measurements panel [4] Magnify Traces button [5] Trace button [6] Current of Injury button [7] Real-time Logs button [8] PSA Settings button [9] More Tests button [10] PSA Test Results button [11] Identifier that indicates which markers (PG or PSA) are being displayed

Figure 6. PSA Main Screen layout

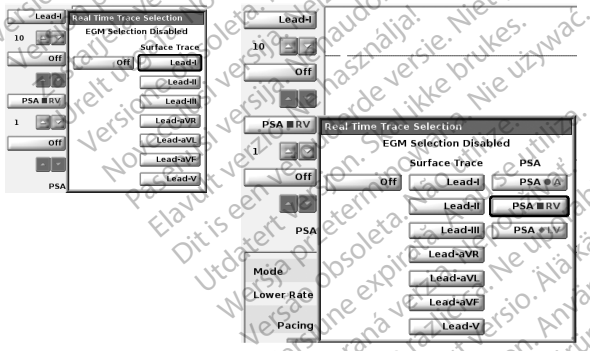


Figure 7. PSA Lead Trace selection examples, low voltage PG (Lead-I and PSA RV)

Lead Traces panel

The PSA displays real-time surface ECG, EGM traces, and event markers for each enabled channel (lead) including a heart rate indicator.

Note: *Before evaluating the lead(s), confirm that the PSA EGMs are selected using the Lead trace selections (Figure 7 on page 16).*

Note: *PSA Test Results and Real-time Logs should be saved before powering off the Programmer in order to avoid losing the PSA data.*

Event markers generated by the PSA may overlap on the Real-time EGM display based upon the selected display speed and event intervals. If overlap occurs, the most recent marker information will be visible as the top layer. To reduce/remove overlap, the Real-time display speed can be adjusted. Also, a Snapshot or Real-time Log can be captured for review at an appropriate display speed.

- Up to four real-time traces can be displayed (see callout [1] in Figure 6 on page 16). Selecting a lead trace button displays the Real-time Trace Selection panel. Figure 6 lists two of the lead trace names (Lead-I and PSA A) for a low voltage PG. Other selections display when high voltage PGs are interrogated.
- For each displayed trace, Gain buttons  provide the ability to increase or decrease the gain for each trace. The amount of gain displays to the left of the Gain buttons. See Figure 8 on page 17 and see callout [1] in Figure 6 on page 16.
- The Magnify Traces button  enlarges the lead trace area to fill the display window and provides additional information at the bottom of the traces display. See Figure 8.
    - The Calibrate button transmits a 1 mV calibration pulse so the user has a reference point to evaluate amplitudes.
    - The Baseline button forces the trace back to the baseline, and is normally used after a defibrillation shock.

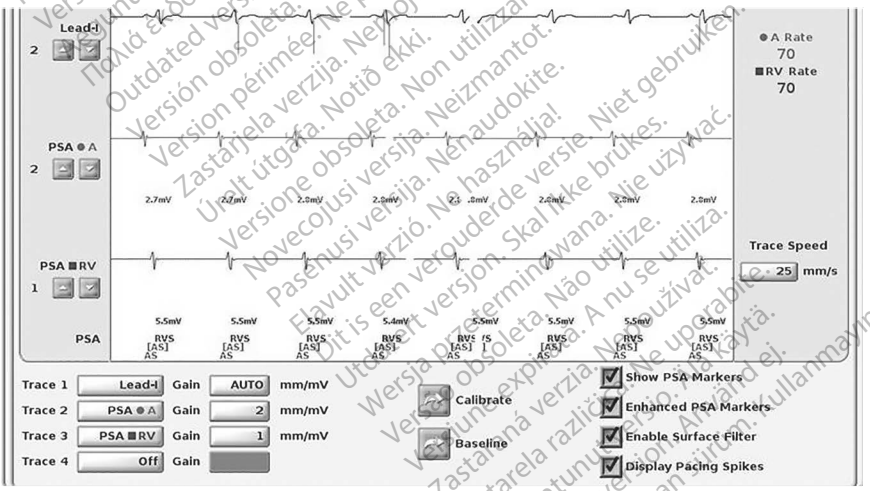


Figure 8. Lead Traces panel example (lower portion, magnified)

Pacing and Output panel

In preparing for PSA tests, verify the settings on the PSA Pacing and Output panel (Pacing, Amplitude, and Pulse Width) and the PSA Settings panel.

From the PSA Pacing and Output panel, verify the Mode, Lower Rate, Pacing chamber, and Amplitude. Make modifications as necessary.

The Settings magnify button provides for additional PSA settings (see "PSA Settings panel" on page 18).

The More Tests magnify button provides for More Tests (see "PSA - More Tests" on page 24).

The Test Results magnify button provides for Test Results (see "PSA - Test Results" on page 27).

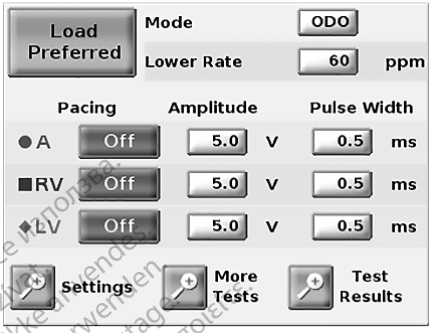


Figure 9. PSA Pacing and Output panel

PSA Settings panel

From the PSA Pacing and Output panel, click on the Settings button to display the PSA Settings panel. Verify the Parameters and Pacing and Sensing settings prior to beginning a lead testing session. Make modifications as necessary.

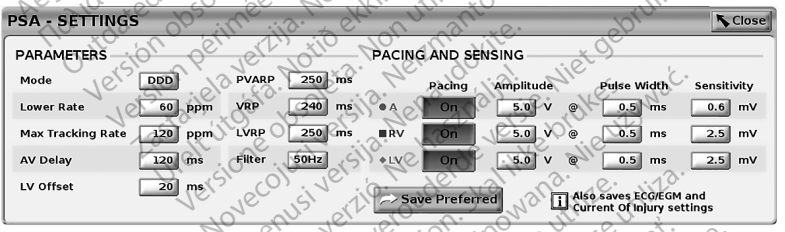


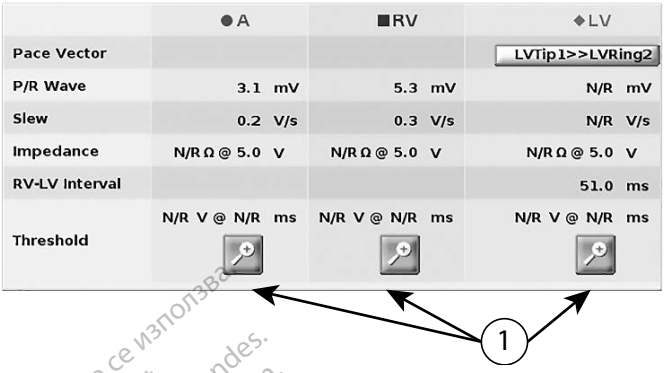
Figure 10. PSA Settings panel

PSA Measurements panel

The information for each lead (P/R Wave Amplitude, Slew, Impedance, and RV-LV Interval) updates on a beat by beat basis when the PSA clips are attached to the corresponding lead.

The tolerance for lead impedance measurements is as indicated in "Lead Impedance Parameter Ranges" on page 37.

From the PSA Measurements panel (Figure 11), use the magnify buttons (A, RV, and LV) to select the chamber to test.

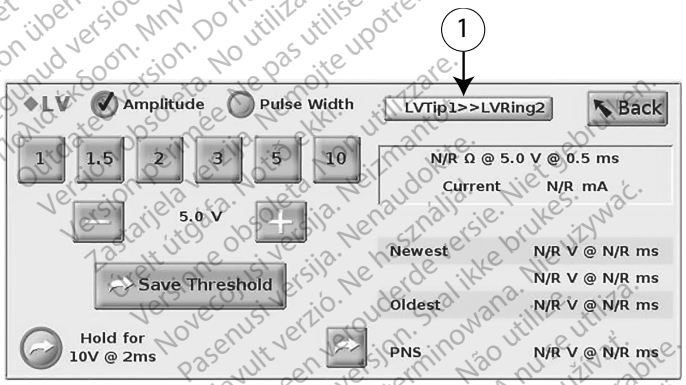


[1] Magnify buttons for A, RV, and LV lead Thresholds

Figure 11. PSA Measurements panel

Use the Magnify button to display the Threshold panel (Figure 12).

Once threshold is determined, click the Save Threshold button to store the result in Test Results.



[1] LV Pace/Sense Vector selection button

Figure 12. PSA Threshold panels (A, RV, and LV lead)

On the PSA LV Threshold panel, select the LV Pace/Sense Vector button to configure the desired cathode/anode pacing and sensing configuration (Figure 13 on page 20).

Be sure to select the "Use the A+ connection ..." button when a configuration including the Can vector is desired, and ensure that the A+ PSA clip uses an indifferent electrode to make electrical contact with the patient in the sterile field.

CAUTION: Do not clip any PSA connector directly to the skin, pocket, or other tissue of the patient.

Preferred Settings

The Preferred Settings feature allows the user to save frequently used PSA operational parameters in addition to Real-time and Current of Injury settings.

To save settings, press the Save Preferred button from the PSA Settings panel (Figure 10 on page 18).

To load saved settings with one click, press the Load Preferred button in the PSA Pacing and Output panel ("Figure 9. PSA Pacing and Output panel" on page 18).

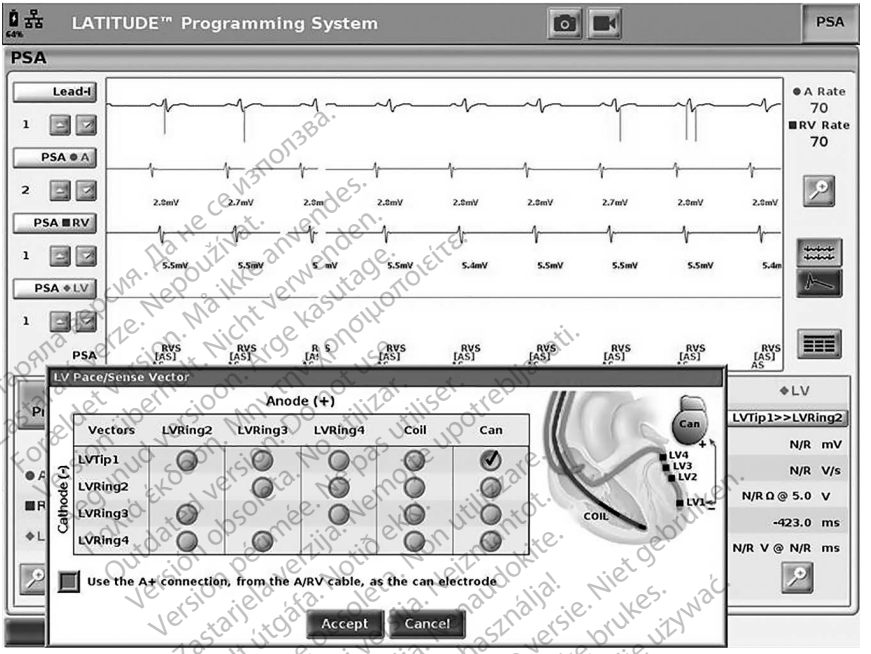


Figure 13. PSA LV Pace/Sense Vector panel with the Can vector selected

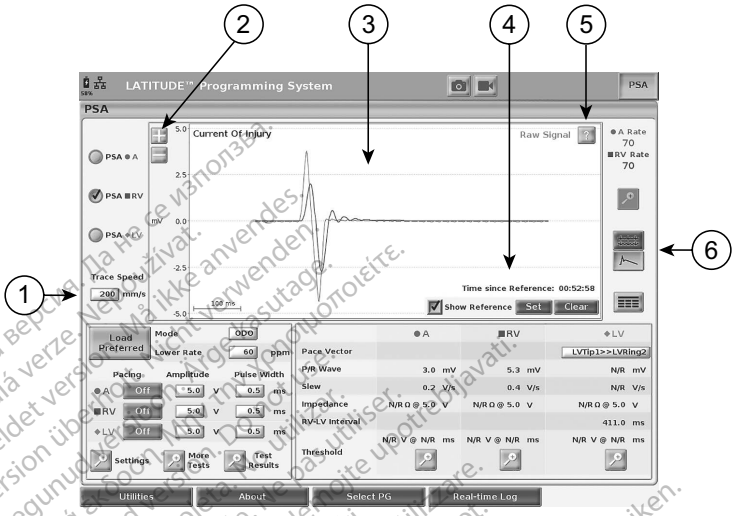
Current of Injury Support[4]

The Current of Injury feature displays the injury to the myocardium at the site of anchoring the lead. The Current of Injury manifests itself as an increase in the duration of the intracardiac electrogram and elevation of the ST-segment compared to the baseline.

Current of Injury may be present during placement of passive leads and active fixation leads. The passive leads may cause focally injured cell membranes consequent to the trauma of electrode pressure against the endocardium. With active-fixation leads, the ST-segment elevation is expected to be even more pronounced. It has been shown that the magnitude of ST-segment elevation can predict adequate performance in the acute phase during implant of active-fixation leads. Studies have suggested 'adequate values of Current of Injury measured' in order to predict good midterm performance of the lead. Boston Scientific does not make recommendations of ST segment elevation measurements that are representative of an adequate Current of Injury.

4. References:
Haghjoo, M et al. Prediction of Midterm Performance of Active-Fixation Leads Using Current of Injury. Pace 2014; 37: 231-236.
Saxonhouse SJ, Conti JB, Curtis AB. Current of Injury Predicts Adequate active lead fixation in permanent pacemaker / defibrillation leads. J Am Coll Cardiol 2005; 45:412-417.

The role the PSA plays in Current of Injury is to minimize filtering of displayed EGM signals in order to preserve signal morphology, and to isolate the most recent EGM cycle to promote visual detection and measurement of changes in morphology. This feature is an enhancement (for user convenience) that allows the user to zoom into a single real-time waveform for the chamber selected. The waveform display is updated each time a pace or sense event is detected by the PSA in the selected chamber. The view allows a high resolution view of each waveform in order to allow observable changes to the intrinsic waveform in real-time.



[1] Trace Speed [2] Vertical scale [3] Current of Injury trace [4] Reference Signal [5] Raw Signal [6] Current of Injury button

Figure 14. Current of Injury panel

On the Current of Injury screen, a trace speed selector (callout [1] in "Figure 14. Current of Injury panel" on page 21) is used to change the width of the signal. A pair of buttons (callout [2] in "Figure 14. Current of Injury panel" on page 21) change the vertical scale of the Current of Injury signal (from 1 to 40 mV).

The Reference Signal (callout [4] in Figure 14 on page 21) on the Current Of Injury screen is designed to allow the user to freeze a Reference Signal to allow visual comparison of the signal morphology. The Reference Signal can be cleared (Clear) and reset (Set) with a new Reference Signal as needed. This allows the physician to assess the Current of Injury changes as the tissue matures during the implant. The time since last reset is displayed. This assessment may provide additional information about the performance of the lead.

The Raw Signal button (callout [5] in "Figure 14. Current of Injury panel" on page 21) on the Current of Injury screen informs the user that the displayed EGM is used to evaluate Current of Injury ("Figure 15. Raw Signal dialog" on page 22). The raw intracardiac signal is displayed in a peak-to-peak format with enhanced morphology and should not be used to determine the P/R Wave Amplitude.

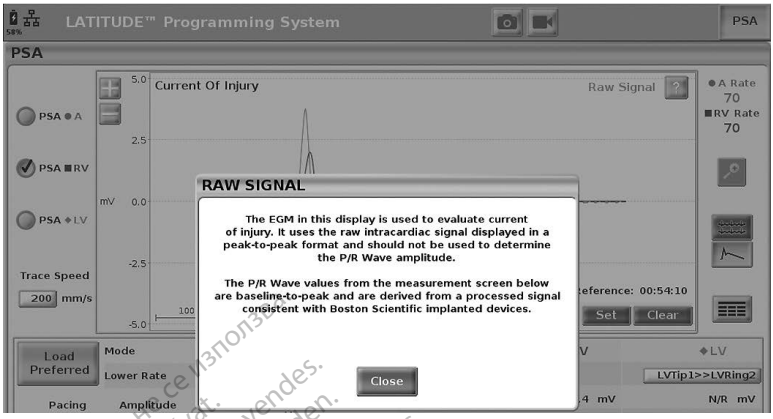


Figure 15. Raw Signal dialog

The measured event in the PSA Measurements panel should be used for diagnostic decisions. The measured value is designed to more closely match Boston Scientific pulse generators. Current of Injury visual representation could be larger or smaller than Measured Value.

Selecting the Current of Injury button (callout [6] in Figure 14 on page 21) provides information that can be used in addition to the measured pacing information (i.e. pacing threshold, sensing) and may assist in determining adequate lead position.

LEAD IMPLANT EVALUATION STEPS

1. Preparation

1. Interrogate the PG.
2. Select the PSA button in the upper right of the screen.
3. Change the Real-time lead trace selection(s) to view the PSA lead trace(s). Refer to callout [1] in Figure 6 on page 16 and the PSA Lead Trace selections in Figure 7 on page 16.
4. Use the PSA Settings button (callout [8] in Figure 6 on page 16) to open the PSA Settings panel (Figure 10 on page 18).Then, select/confirm the desired parameters for the PSA settings. Select the Close button to close the panel and continue the session.
5. If desired, press the Load Preferred button to load previously saved preferred settings, without having to change parameters individually.

2. Measure P/R Wave Amplitude and Current of Injury

1. Use the PSA Measurements panel (Figure 11 on page 19) to assess the P Wave, R Wave, and Slew rate, for the attached lead(s). The RV (paced or sensed) and LV (sensed) interval may also be assessed.

   Note: *If the signal is noisy, first try to remove the source of interference. If noise is still evident on*

your electrogram trace, consider turning on the filter for 50/60 Hz to reduce the noise on the electrogram.

2. To assess Current of Injury morphology select the Current of Injury button  (callout [6] in Figure 6 on page 16).

3. Complete a Pacing Threshold Test

For the following steps, refer to:

- PSA Pacing and Output panel (Figure 9 on page 18)
- PSA Threshold panels (Figure 12 on page 19)
- PSA Measurements panel (Figure 11 on page 19).

1. Adjust the Lower Rate to overdrive the intrinsic rate and outputs (e.g., 10 bpm above intrinsic rate) from the PSA Pacing and Output panel. Press the Settings button and verify the sensitivity.
2. Turn on Pacing for the lead to be threshold tested (A, RV, or LV) from the PSA Pacing and Output panel. This will automatically adjust the mode setting to the appropriate value (AAI, VVI, or DDD) and display the PSA Threshold panel based on the lead(s) selected. If desired, the mode can be manually changed.
3. Check the impedance from the PSA Threshold panel.

   Note: *Impedance also displays in the current calculation box (Figure 12 on page 19).*
4. Determine the Pacing Threshold by decrementing Amplitude or Pulse Width.

   Note: *Allow 1-2 intervals for the decremented output to occur and before requesting another decrement.*
5. Press the Save Threshold button to save the data for P/R Wave Amplitude, Slew, Impedance, and Threshold.

   - The most recent sensed settings are retained and, upon press of the "Save Threshold" button, are saved with the pace threshold results. So for a given lead placement, the lead's sensing values are checked first, then pacing characteristics are checked. The settings, although not from the same instant in time are from the same lead placement location. Therefore checking sensing, then relocating or moving the lead and proceeding immediately to pacing tests would result in an inconsistent measurement.
   - When the "Save Threshold" button is pressed, the pacing amplitude for the chamber under test automatically changes to 5.0 volts, but the pulse width is unchanged. This change is also made when pressing the "Back" button with unsaved changes entered on the PSA threshold panel.
   - This data will be saved in the PSA Test Results, and PSA report (which is accessed by pressing the Data button at the bottom of the screen to display the Data Management panel) during the active session.

     Note: *A Real-time Log event is captured automatically (each time the Save Threshold button is pressed), which can be reviewed later, saved, or printed as a PDF while in the current session.*
6. Check for extracardiac stimulation by pressing and holding the "Hold for 10V @ 2ms" button from the

PSA Threshold panel (see Figure 12 on page 19).

a. If there is no stimulation, continue with the next step.

b. If there is stimulation, adjust the amplitude and/or pulse width and check again for extracardiac stimulation. Press the PNS button to store the amplitude and pulse width where the Phrenic Nerve Stimulation (PNS) occurred.

Note: *The PNS button simply stores the most recent amplitude and pulse width in Test Results at the time the button is pressed. It does not perform a PNS test.*

4. Store and Save Lead Evaluation Data

PSA results are stored in Test Results (Figure 6 on page 16) and in the PSA report. Press the Data button at the bottom of the screen (see Figure 6 on page 16) to display the Data Management panel.

1. Review the Real-time Logs. Save and/or print as desired (see Figure 25 on page 30).
2. Review the PSA Test Results. Save and/or print as desired (see Figure 21 on page 27).

Note: *PSA test results and Real-time Logs should be saved or printed before exiting the PG session or powering off the Programmer in order to avoid losing the PSA data. Any unsaved recorded thresholds/results, snapshots or Real-time Logs will be lost upon any transition into or out of a PG session.*

Note: *PSA functional state (pacing/sensing configuration) is retained when transitioning into a PG session if the PSA was used prior to interrogating a device. This allows the PSA function to continue providing pacing support while transitioning between applications. When the PSA application is active, pressing the PSA button or powering off the Programmer (manually, or loss of power) ends the PSA function.*

Note: *If PSA is not used within a PG session, the user must manually re-enter the PSA data to the PG during the PG session.*

Note: *If during implant testing, the physician changes to another PG, the PSA data must be manually entered to the new PG.*

PSA - MORE TESTS

The More Tests button (see Figure 6 on page 16) is available as clinically needed. More Tests include antegrade and retrograde conduction tests and Burst Pacing as illustrated in Figure 16 on page 25.

Conduction Test Support[5]

It has been demonstrated that 45% of patients who require dual chamber system implantation for any indication have retrograde conduction at some paced rate if paced from the ventricle. Even patients who have had AV block for many years may retain retrograde conduction.

The mean range of V-A conduction time is 110 - 450 ms. The existence of retrograde conduction via the natural pathway, and antegrade conduction via the implanted dual-chamber system provides a reentry circuit. Measurement of antegrade and retrograde conduction intervals allows evaluation of the state of AV and VA conduction as supporting evidence for device system implantation and to allow the setting of

5. Reference: Furman S, Hayes DL, Holmes Dr. - A Practice of Cardiac Pacing, 1989, p. 66-69.

the atrial refractory interval after the ventricular event to avoid retrograde conduction and the onset of the endless loop tachycardia.

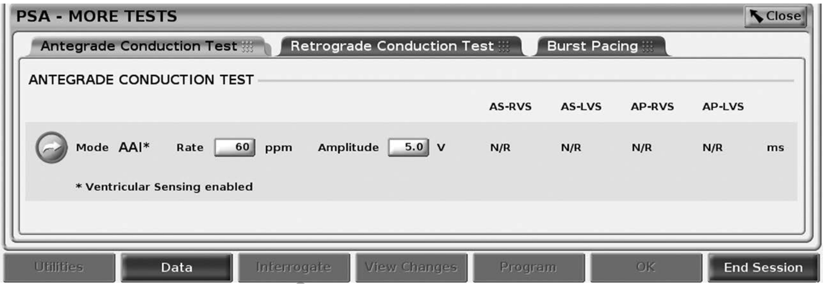


Figure 16. PSA More Tests (Antegrade and Retrograde Conduction and Burst Pacing)

When you push a conduction test button you see beat by beat conduction measurements for the selected test.

Note: *No automatic Real-time Logs are captured for Antegrade or Retrograde conduction tests. If desired, these tests must be manually recorded using a Snapshot or the Real-time recorder. Burst Pacing does automatically capture a Real-time Log of this event.*

Antegrade Conduction Test

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

Note: *If there is no conduction in A, ventricular sensing continues.*

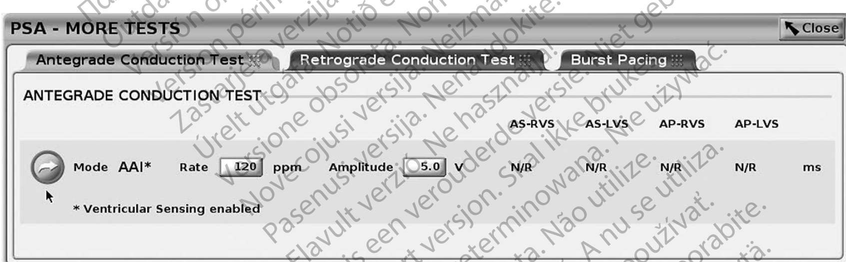


Figure 17. Antegrade conduction test

Retrograde Conduction Test

The Retrograde Conduction Test measurement uses the VDI Brady mode to measure the patient's V-A conduction times based on either a paced or sensed ventricular event.

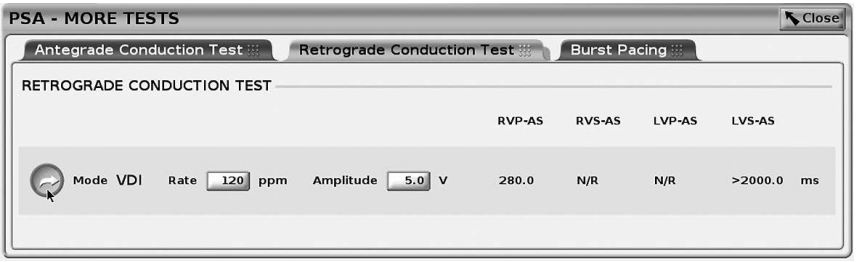


Figure 18. Retrograde conduction test

Burst Pacing

Burst Pacing is used to induce or terminate arrhythmias when delivered to the desired chamber. Only the selected chamber receives Burst Pacing.

Burst Pacing can be enabled for an A, RV, or LV lead as illustrated in Figure 19.

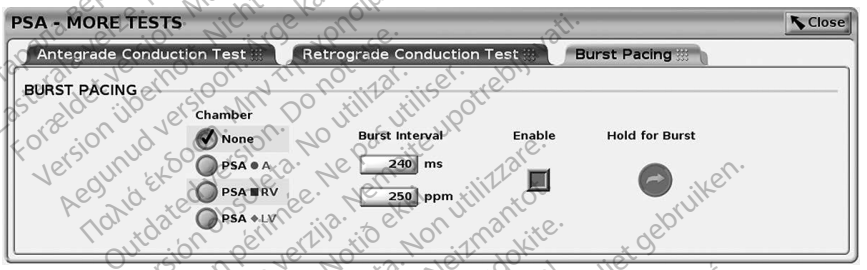


Figure 19. PSA Burst Pacing

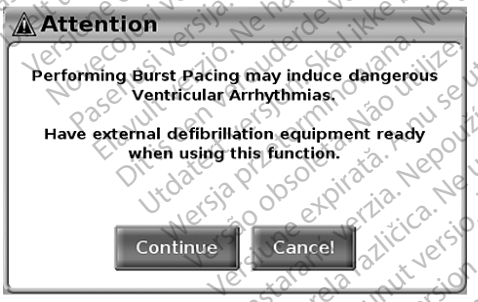


Figure 20. PSA Burst Pacing Warning message

WARNING: 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.

To deliver Burst Pacing, perform the following steps:

Note: *Before you begin Burst Pacing, ensure that pacing is active in the chamber where you will deliver the burst pacing.*

1. Select the chamber (A, RV, or LV).
2. Select a Pacing Interval.
3. Select the Enable box.
4. A warning displays indicating burst pacing will be activated (Figure 20 on page 26).
5. Press and hold the "Hold for Burst" button. (There is a timeout maximum at 45 seconds for A and 30 seconds for RV and LV.)
6. If PSA Pacing is on before the burst test, PSA Pacing will resume after Burst Pacing completes.
7. An automatic Real-time recording is triggered when Burst Pacing stops.

   Note: *Pacing resumes (as needed) at the PSA lower rate limit and Mode (if programmed on) when Burst Pacing ends.*

PSA - Test Results

This screen presents the list of test results from the current PSA application session, including the Threshold Test Panel lead/chamber (Right Atrium, Right Ventricle or Left Ventricle) where the result was documented, the time the result was captured, as well as the Amplitude and Pulse Width captured for the result. The Notes column can be edited. The LV results, by default, contain the LV Pace/Sense Vector configured at the time of the result.

The user can edit the Lead location of a result to any of the three chambers; this supports the use case where leads in multiple chambers were tested using a single physical connection/chamber on the Programmer and PSA Application.

Check-boxes allow the user to select any and all valid and desired set(s) of results to print or save to PDF. If the PSA used within a PG application session is Saved, the most recent selected results for each chamber[6] automatically transfer to the PG application[7] for storage in the PG upon a subsequent Program operation. 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 and this functionality provides an automated replacement for a previously manual entry.

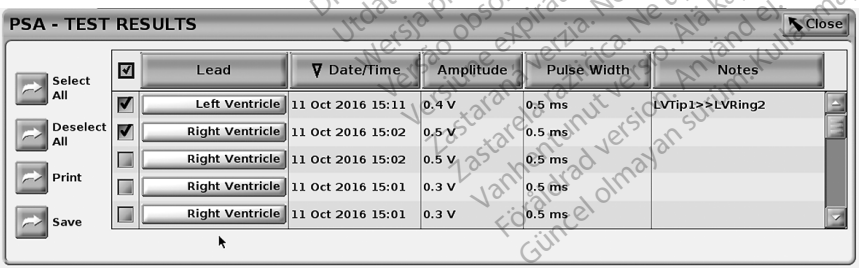


Figure 21. PSA - Test Results

6. Maximum of 3 chambers total, one for RA, RV and LV.
7. The transfer is into the Patient Implant Data.

STAT BUTTON

The red STAT button,  , is at the top right of the Model 3300 Programmer to provide a rescue shock or pacing. The STAT function is available in the same location at all times to initiate a PSA STAT PACE or deliver a rescue pace or shock. Pressing the STAT button with the PSA Application running displays the Emergency Function screen as shown in Figure 22 and Figure 23 on page 29 and Figure 24 on page 30. Check the pulse generator labeling for specific details of the STAT parameters.

Note: *Ensure there is effective connection between the PSA cable and the lead(s) before using the STAT button.*

1. Press the STAT button.

   The following conditions determine the actions available when the STAT button is pressed:

   - When the PG is in "Storage," "Off," or "Monitor Only" mode, a STAT SHOCK / PG STAT PACE is delivered. If the STAT SHOCK / PG STAT PACE is delivered in storage, the Tachy mode changes to "Off."
   - When in telemetry communication with a high voltage (ICD or CRT-D) PG, a pop-up displays allowing the user to initiate a PG STAT PACE, STAT SHOCK, or DIVERT THERAPY command. If a PSA session is in progress, a PSA STAT PACE option also displays as shown in Figure 22 on page 29.
   - When in telemetry communication with a low voltage PG, a pop-up displays allowing the user to initiate a PG STAT PACE or DIVERT THERAPY command. If a PSA session is in progress a PSA STAT PACE option also displays.
   - When not in communication with a PG, an Interrogate button displays with text prompting the user to perform Quick Start to attempt to identify the device (see Figure 24 on page 30). Once in a session with an implanted transvenous device, press the red STAT button again to display available options.

2. Select the desired action.

   After the STAT button is pressed, the following occurs when an action is clicked:

   - PSA STAT PACE – when a PSA session is active, it configures the PSA with STAT PACE settings and functionality.
   - PG STAT PACE – initiates PG pace functionality specific to the supported transvenous device (ICD, CRT-D, Pacemaker/CRT-P).

     Note: *When selected, PG STAT PACE or PSA STAT PACE remain active until the Brady settings in the PG or PSA are changed.*

   - STAT SHOCK – initiates PG shock functionality specific to the high-voltage transvenous ICD and CRT-D pulse generators.

- DIVERT THERAPY – initiates PG divert therapy for any supported transvenous device (ICD, CRT-D, Pacemaker/CRT-P) and, while in a PG session, stops the pending therapy.

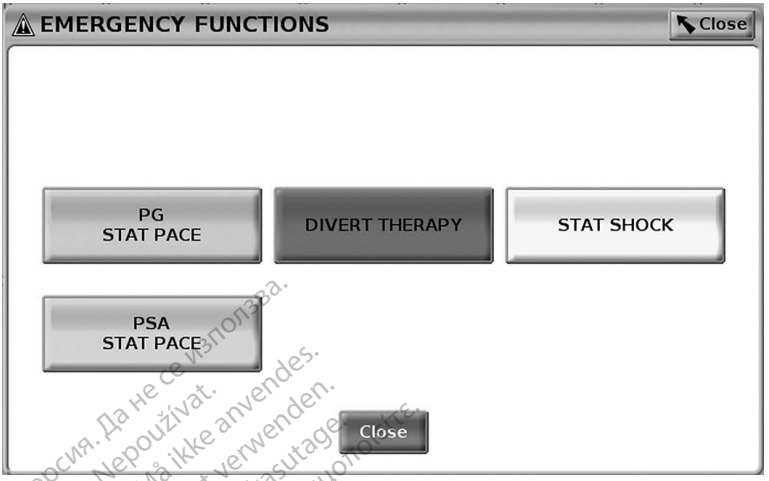


Figure 22. Red STAT button pop-up in a High Voltage transvenous PG session with the PSA application running

In Figure 22, the top row buttons (PG STAT PACE, DIVERT THERAPY, and STAT SHOCK) display only during a High Voltage transvenous PG session. PSA STAT PACE displays when the PSA feature is active.

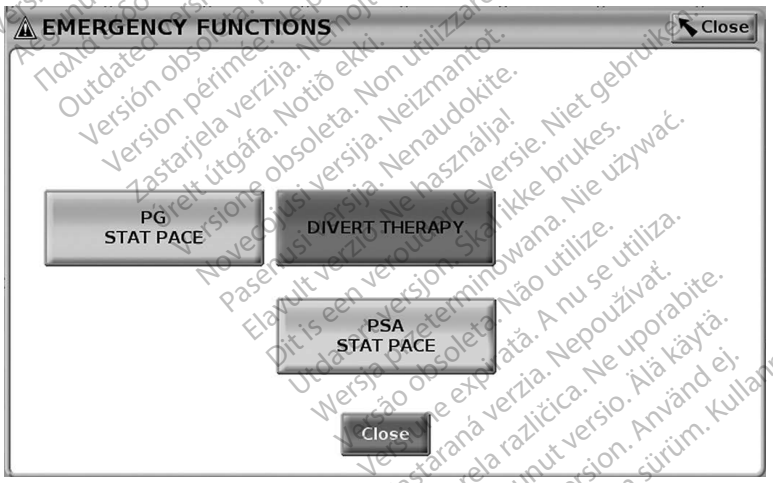


Figure 23. Red STAT button pop-up in a Low Voltage transvenous PG session with the PSA application running

In Figure 23, the top row button (PG STAT PACE) displays only during a Low Voltage transvenous PG session. PSA STAT PACE displays when the PSA feature is active.

If in a PSA session only (no PG interrogated), then the dialog in Figure 24 displays along with the PSA STAT PACE button.

If not in a transvenous PG session, pressing the STAT button displays the following dialog with no buttons - "There is no active device session. - Press interrogate to initiate the Quick Start function. - PSA Stat Pace is available below."

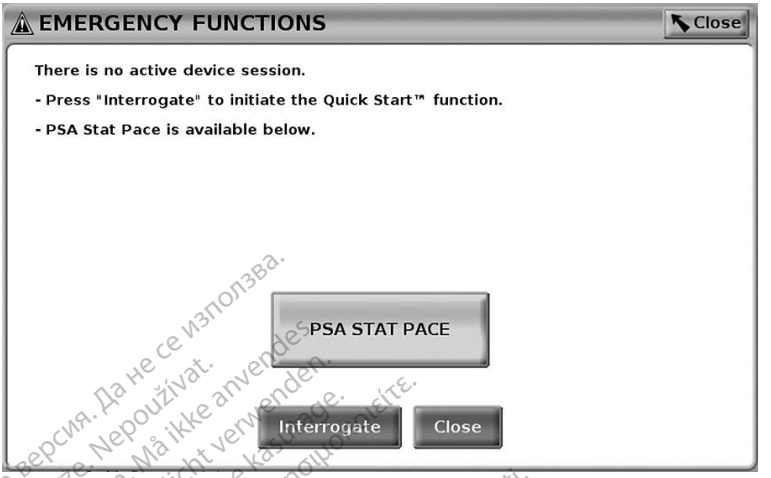


Figure 24. Red PSA STAT PACE button pop-up outside any PG session with the PSA application running

REAL-TIME LOGS

Use the two buttons, Snapshot and Real-time Recorder, to record real-time lead traces. Examples of recorded events and a sample snapshot are shown in the following two figures.

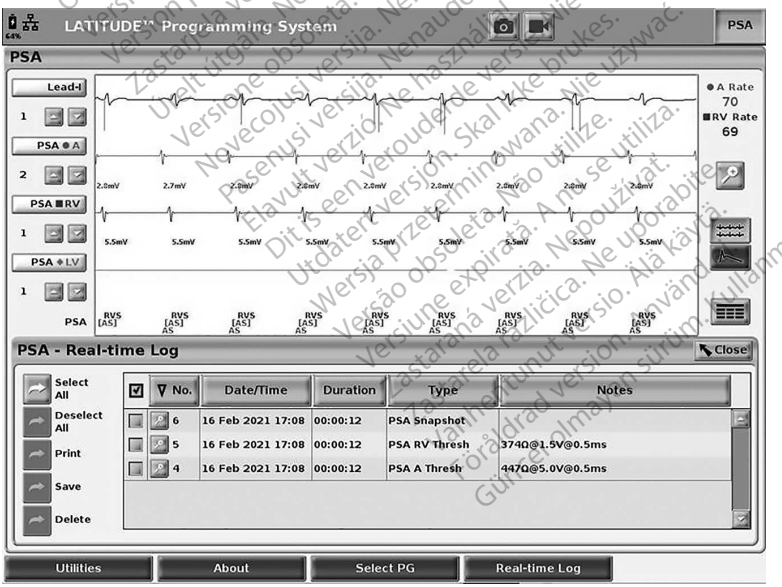
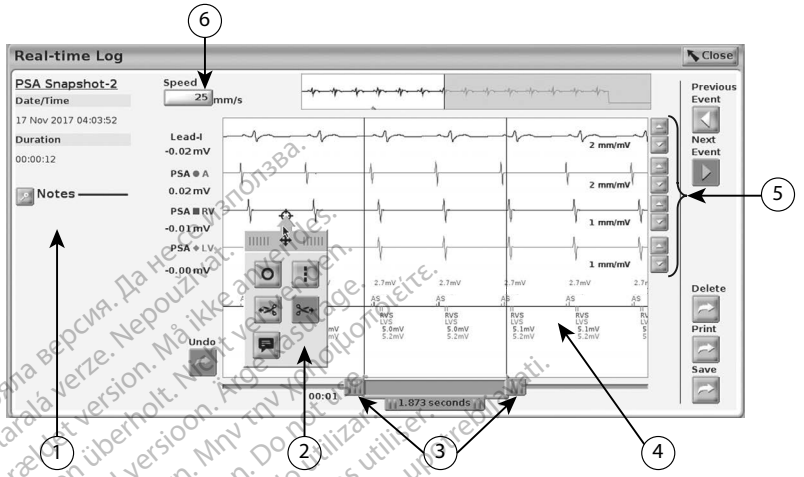


Figure 25. PSA Real-time Log Events example

Using the buttons on the left side of the screen, events can be selected/deselected and saved, printed or deleted. Events may be saved to the Programmer's hard drive or to a USB pen drive.

Note: *PSA events are not automatically saved when a PSA session ends. Use the Real-time Log to save, print, or delete these events before ending the PSA session.*

PSA Real-time Log



[1] Notes area [2] Snapshot tools [3] Electronic Calipers to adjust time span of event [4] Real-time Log event display [5] Gain increase/decrease buttons for each lead [6] Trace speed adjustment

Figure 26. PSA Real-time Log example

Electronic Calipers

Use the electronic calipers (slide bar) to measure the time span within the event. The time frame 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 time frame. For detailed instructions on using the electronic calipers, refer to the associated product literature for the pulse generator being interrogated.

Real-time Log Tools

Select any part of the Real-time Log event display and the tool pop-up displays as in Figure 26. At the top center of the pop-up is an arrow and a target icon. When a tool is selected, the tool action occurs at that target point on the screen. A new tool pop-up displays each time you select another part of the Real-time Log event display, so that you can use multiple tools anywhere on the display as shown in Figure 26 on page 31.

The five tools are:

- Circle tool - places a circle on the display at the target point.
- Line tool - places a dashed vertical line on the display at the target point.
- 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.
- 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.

- Note tool  - displays a keyboard to type in any Notes, which will then appear at the bottom of Real-time Log horizontally aligned with the target point.

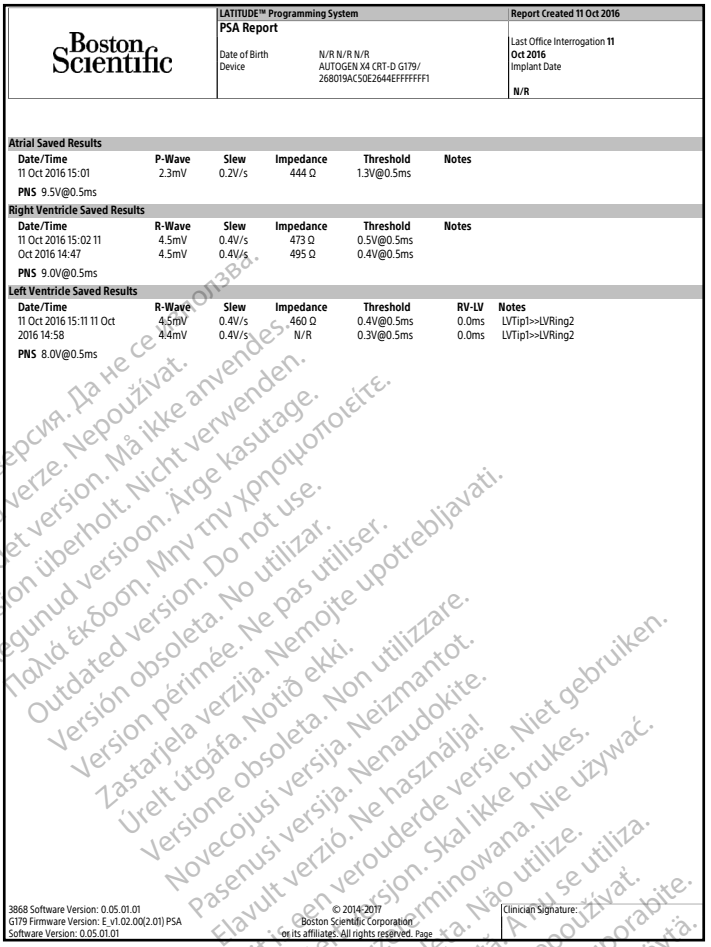
TEST REPORTS

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

- Date/Time Stamp
- Intrinsic Amplitude
- Lead Impedance
- Slew Rate
- Pace Threshold Amplitude
- Pace Threshold Pulse Width
- LV Vector (LV lead only)
- PNS (phrenic nerve stimulation)
- RV-LV Interval (LV lead only)
- Notes

PSA Reports

The following is an example of a PSA Report created in PDF format.



LATITUDE™ Programming System — Report Created 11 Oct 2016

Boston Scientific

PSA Report

Date of Birth: N/R N/R N/R
Device: AUTOGEN X4 CRT-D G179/ 268019AC50E2644EFFFFFFF1

Last Office Interrogation **11 Oct 2016**
Implant Date **N/R**

Atrial Saved Results

Date/Time	P-Wave	Slew	Impedance	Threshold	Notes
11 Oct 2016 15:01	2.3mV	0.2V/s	444 Ω	1.3V@0.5ms	

PNS 9.5V@0.5ms

Right Ventricle Saved Results

Date/Time	R-Wave	Slew	Impedance	Threshold	Notes
11 Oct 2016 15:02 11	4.5mV	0.4V/s	473 Ω	0.5V@0.5ms	
Oct 2016 14:47	4.5mV	0.4V/s	495 Ω	0.4V@0.5ms	

PNS 9.0V@0.5ms

Left Ventricle Saved Results

Date/Time	R-Wave	Slew	Impedance	Threshold	RV-LV	Notes
11 Oct 2016 15:11 11 Oct	4.5mV	0.4V/s	460 Ω	0.4V@0.5ms	0.0ms	LVTip1>>LVRing2
2016 14:58	4.4mV	0.4V/s	N/R	0.3V@0.5ms	0.0ms	LVTip1>>LVRing2

PNS 8.0V@0.5ms

3868 Software Version: 0.05.01.01
G179 Firmware Version: E_v1.02.00(2.01) PSA Software Version: 0.05.01.01

Clinician Signature:

Figure 27. PSA Report example

End Session

Note: *PSA test results and Real-time Logs should be saved before powering off the Programmer in order to avoid losing the PSA data.*

The only way to end a PSA session is to power off the Programmer. There is no Off button for the PSA application.

PSA EVENTS, NOISE DETECTION, PARAMETERS, AND SPECIFICATIONS

Table 1. PSA Events

Event Type	**Trigger** Event	**Duration** of Recording (seconds)
PSA Pace Threshold Test (A, RV, and LV)	PSA Save Threshold button press	12
PSA Burst Pacing	PSA Burst button release	24

Table 2. Burst Pacing Programmable Parameters

Parameter	**Programmable Values**	**Increment**	**Nominal**
Pacing Interval	100 - 750 ms	10 ms	240 ms
Chamber	A, RV, LV	n/a	n/a

Noise Detection

When noise is detected, the PSA switches to asynchronous pacing at the lower rate limit. The following table defines the PSA noise response:

Table 3. Noise Response

Brady Mode	**Noise** Response
AAI	AOO
VVI, VDI, VDD	VOO
DDI, DDD	DOO

Programmable Parameters

Note: *Manually powering Off the Programmer and powering it back On resets all PSA parameters to the nominal values.*

Table 4. Programmable Parameter Nominals

Parameter	**Nominal**
Brady Mode	ODO
Lower Rate Limit (LRL)	60 min^{-1}
Maximum Tracking Rate (MTR)	120 min^{-1}
Ventricular Sensing	Baseline to Peak
LV Offset	0 ms

Parameter	Nominal
AV Delay	120 ms
PVARP/ARP Interval	250 ms
VRP Interval	240 ms
LVRP Interval	250 ms
Atrial/RV/LV Pace Amplitude	5.0 V
Atrial/RV/LV Pulse Width	0.5 ms
Atrial Sensitivity	0.6 mV
RV Sensitivity	2.5 mV
LV Sensitivity	2.5 mV
LV Vector	(LV1)>>(LV2)
Noise Filter	OFF

Table 5. PSA STAT PACE Parameters

Parameter	Value
Brady Mode	VVI
Lower Rate Limit (LRL)	60 min^{-1}
Ventricular Pacing Chamber	BiV
LV Offset	0 ms
RV/LV Pace Amplitude	7.5 V
RV/LV pulse width	1.0 ms
RV/LV Sensitivity	2.5 mV
LV Vector	(LV1)>>(LV2)

Table 6. Parameter Ranges

Parameter	Range
PSA parameters	
Mode	OAO, AOO, AAI, DDI, OVO, VOO, VVI, VDD, ODO, DOO, VDI, DDD
Lower Rate Limit (LRL)	30 - 175 min^{-1} in increments of 5 min^{-1}
Maximum Tracking Rate (MTR)	50 - 175 min^{-1} in increments of 5 min^{-1}
AV Delay	30 - 300 ms in increments of 10 ms
LV Offset	± 100 ms in increments of 10 ms
PVARP/ARP Interval	150 - 500 ms in increments of 10 ms

Parameter	Range
Paced VRP interval	150 - 500 ms in increments of 10 ms
Paced LVRP interval	150 - 500 ms in increments of 10 ms
Filter values	Off, 50 Hz, 60Hz
Ventricular Pacing Chamber	BiV, RV, or LV
LV Pace /Sense vector	E1 to E2/E3/E4/Coil/Can E2 to E3/E4/Coil/Can E3 to E2/E4/Coil/Can E4 to E2/E3/Coil/Can
PSA EGM channel gain	0.5, 1.0, 2.0, 5.0, 10.0, and 20.0 mm/mV
Burst Pacing Interval	100 - 750 ms in increments of 10 ms 80 - 600 min^{-1} in various increments (maximum duration of 45 seconds for A and 30 seconds for RV and LV)
Atrial, LV, or RV pacing amplitude	0.1 - 5.0 V in increments of 0.1 V and between 5.0 - 10.0 V in increments of 0.5 V
Atrial, LV, or RV pulse width	0.1 - 2.0 ms in increments of 0.1 ms
Atrial, RV, or LV sensitivity [a]	0.2 - 1.0 mV in increments of 0.2 mV 1.0 - 8.0 mV in increments of 0.5 mV 8.0 - 10.0 mV in increments of 1.0 mV
Traces	Lead-I, Lead-II, Lead-III, Lead-aVR, Lead-aVL, Lead-aVF, Lead-V
Surface Gain	Auto, 0.5, 1, 2, 5, 10, 20 mm/mV
Trace Speed	0 (stop), 25, 50, 100, or 200 mm/s
Show PSA Markers	Off, On
Enhanced PSA Markers	Off, On
Enable Surface Filter	Off, On
Display Pacing Spikes	Off, On
P/R wave amplitude [b]	0.25 - 30 mV with an accuracy of ± 10% or ± 0.2 mV
P/R wave interval	0 - 500 ms
Conduction Rate	30 - 175 min^{-1} in increments of 5 min^{-1}
Conduction Amplitude	0.1 - 5.0 V in increments of 0.1 V and between 5.0 - 10.0 V in increments of 0.5 V
Slew Rate	0.5 - 4.0 V/s with an accuracy of ± 0.2 V/s or ± 20% whichever is greater

a. Sensitivity specifications are based on a CENELEC input signal.
b. Amplitude measurement specifications are based on a CENELEC input signal.

Table 7. Lead Impedance Parameter Ranges

Impedance	Voltage	Pulse Width	Tolerance
100 - 3000 Ω	0.5 - 7.5 volts [a]	0.4 to 2.0 ms [b]	± 25% [c]

a. 3300 PSA will not display an impedance using Pacing Voltages less than 0.5 V.
b. 3300 PSA will not display an impedance using a Pulse Width less than 0.4 ms.
c. 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.

Table 8. PSA Markers

Marker	Description
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

Table 9. PSA Enhanced Markers

Marker	Description
[AS]	Atrial Sense during noise window
AN	Atrial Noise
[RVS]	Right Ventricular Sense during noise window
RVN	Right Ventricular Noise
[LVS]	Left Ventricular Sense during noise window
LVN	Left Ventricular Noise
>2s	Large interval greater than 2 seconds

MAINTENANCE, TROUBLESHOOTING, SERVICE, AND STANDARDS

Refer to the *LATITUDE Programming System Operator's Manual, Model 3300* for maintenance, troubleshooting, handling (including symbols on devices and packaging), standards, and specifications information.

WARRANTY INFORMATION

For device warranty information visit: www.bostonscientific.com/warranty.

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