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Boston Scientific

Labeling Update

This update provides information about the PaceSafe™ LVAT feature and LV VectorGuide™ for AUTOGEN™ X4, DYNAGEN™ X4, INOGEN™ X4, and ORIGEN™ X4 devices.

PaceSafe Left Ventricular Automatic Threshold (LVAT):

PaceSafe LVAT is now available in AUTOGEN X4 devices. It is designed to dynamically adjust the left ventricular pacing output to ensure capture of the left ventricle using a programmable Safety Margin. LVAT can be programmed on by selecting Auto from the Left Ventricular Amplitude parameter option. The fundamental behavior of LVAT in Quadripolar devices is the same as in non-Quadripolar devices.

NOTE: *If Wireless ECG is enabled for a Quadripolar device, the ECG will temporarily be set to Lead II during commanded LVAT testing.*

LV VectorGuide:

LV VectorGuide streamlines the testing required to determine the optimal LV Pacing Lead Configuration for each individual patient. The clinician can quickly evaluate multiple Quadripolar LV pacing vectors and then program the desired configuration.

The following tests are available within the LV VectorGuide screen (Figure 1) which is accessed from the Tests tab:

- RVS-LVS Delay: The LV electrode with the site of latest activation can be determined by performing the RVS-LVS test, which measures the time between an RV sensed and an LV sensed event. LV events are sensed between the selected LV electrode (cathode) and Can.
- LV Lead Impedance: LV lead impedance testing uses the same testing methods and results as impedance tests run via the Lead Tests tab.
- Phrenic Nerve Stimulation (PNS): Diaphragmatic stimulation from the LV lead can be tested using temporary parameters on the Phrenic Nerve Stimulation test.
- LV Pace Threshold: LV Pace Threshold testing accessed from the LV VectorGuide uses the same testing methods and results as threshold tests run via the Lead Tests tab.
- In addition to the manual and commanded threshold tests, the Quick Capture™ feature is available as a Test Type when LV Threshold Testing is accessed from the LV VectorGuide screen. This feature allows the clinician to quickly evaluate capture in multiple vectors at a fixed pacing output. Manual or Commanded threshold testing can then be performed in the pacing vectors which have a capture threshold below the output used for Quick Capture. This reduces the number of vectors which undergo regular threshold testing and tests can begin at a lower starting amplitude.

  NOTE: *Commanded Automatic Left Ventricular Pace Threshold testing is available in devices with the LVAT feature.*

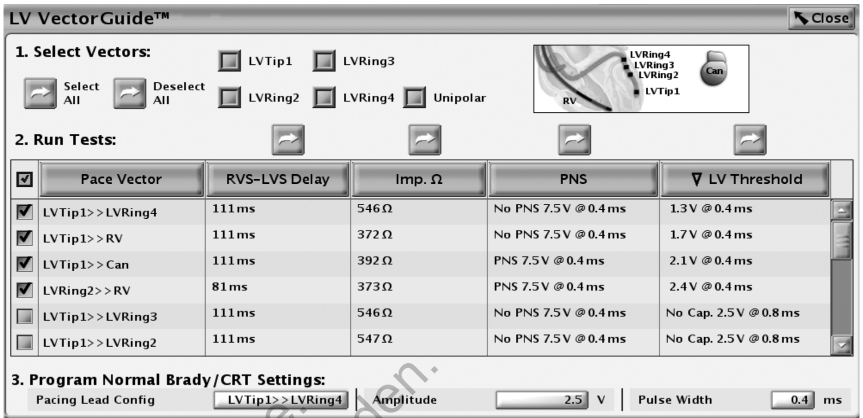

Figure 1. LV VectorGuide Screen

Use the following steps to perform LV VectorGuide testing:

1. Select vectors to be tested.

   The scroll bar can be used to view all available vectors. Multiple methods are available to control which vectors will be tested:

   - Use the Select All button in the Select Vectors area to test all available vectors. The checkboxes next to all available vectors will automatically populate in the Run Tests area.

   - Select one or more of the cathodes or Unipolar vectors listed in the Select Vectors area. The checkboxes next to those corresponding vectors will automatically populate in the Run Tests area.

   - Individually select the checkbox next to desired vectors in the Run Tests area.

   - Use the Deselect All button or deselect individual checkboxes to exclude vectors from testing.

2. Run Test(s).

   Select the Run button above the column of the desired test. Where applicable, adjust the temporary parameters on the testing screen based on individual patient characteristics. A notification will be provided if a particular test cannot be attempted.

   Tests will run sequentially in each of the selected vectors. Select the Cancel button or follow the on-screen instructions to stop testing and return to the LV VectorGuide screen. Alternatively, pressing the STAT PACE, STAT SHOCK, or DIVERT THERAPY key on the PRM will cancel any testing in progress.

   Once testing is complete in all selected vectors, results will be displayed in the corresponding test's column (Figure 1). If the same test is performed multiple times in a particular vector, only the most recent result will be displayed. LV VectorGuide results can be printed via the Reports tab.

   Testing details are described below:

   - RVS-LVS Delay:

     CAUTION: Ensure the patient is clinically capable of tolerating low rate RV backup pacing and lack of LV pacing during an RVS-LVS Delay test.

     - The patient must have RV and LV sensed beats in order for testing to be successful.

- When testing is complete for a particular cathode, the result will be displayed for all vectors which use that same cathode.
- If testing is unsuccessful for a particular vector, one of the following failure codes will be displayed in the RVS-LVS Delay column:
  - “N/R” : Displayed if too many paced beats, PVC’s or noise beats occurred during testing. This will also be displayed if the RV sensed rate is either < 40 min $^{-1}$ or >110 min $^{-1}$.
  - “N/R: Unstable RV-LV”
  - “N/R: Unstable RV-RV”

- LV Lead Impedance:
  - Impedance results from LV VectorGuide will not overwrite existing results on the Lead Tests screen.
- Phrenic Nerve Stimulation:
  - Select either "Yes PNS" or "No PNS" as appropriate to stop the current test and proceed to the next pacing vector. Perform additional testing at different outputs, as necessary. PNS results will display as "PNS" or "No PNS" at the tested pacing output.
- LV Pace Threshold:

  CAUTION: During manual LV Threshold and Quick Capture tests, RV Backup Pacing is unavailable.

  - For Quick Capture testing, pacing output will remain constant and not step-down as with other threshold test selections. Select either "Capture" or "No Capture" as appropriate to stop the current test and proceed to the next pacing vector. Results will be displayed as "Cap." or "No Cap." at the tested pacing output.
  - Manual or Commanded LV Threshold test results from LV VectorGuide will overwrite the existing result on the Lead Tests screen. But an automatic Snapshot will not occur for LV Threshold tests accessed from the LV VectorGuide screen.

Reduce the number of vectors to be tested and perform additional tests as necessary.

Testing results will be displayed in the appropriate column. Select a column header button to sort the data by that column's values. Vectors with a populated checkbox will be sorted at the top of the list.

Deselect the checkbox for any vectors that will be excluded from consideration and require no further evaluation. Perform additional tests on the remaining vectors as described above.

3. Program the device.

Once the evaluation is complete, use the LV VectorGuide results to select the desired Pacing Lead Configuration, Amplitude, and Pulse Width at the bottom of the screen and select Program.

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