



# Release Notes

**VNS Programming Software  
Model 250  
Version 11.0**

**June 2017  
US Version**

As the leader in medical devices for epilepsy, LivaNova® is committed to providing our customers and their patients innovative, safe, and effective devices for the treatment of refractory epilepsy.

The upgraded LivaNova VNS Therapy® Software, Model 250 Version 11.0, enables the user to interact with LivaNova's pulse generators with a touchscreen tablet programming computer. A key feature with this version of the VNS Software is that it supports the Model 106 AspireSR® generator, which provides Automatic Stimulation for patients who have seizures that are accompanied by heart rate increases. The Model 250 Version 11.0 Software supports generator Models 101-106.

## What's New

### SOFTWARE

- Allows adjustment of Tachycardia Detection and Automatic Stimulation parameters of the AspireSR Generator (M106) to fit patients' needs, including:
  - ◆ Heartbeat Detection Sensitivity
  - ◆ Threshold for AutoStim
  - ◆ AutoStim Mode Therapy parameters
  - ◆ Ability to verify Heartbeat Detection on the M106
- Calculates and displays performance summary data and reports for the M106 for the last three office visits
- Shows a confirmation screen of the programming selection prior to sending changed parameters to the generator during the session
- Exports database reports to an .html file

### HARDWARE

- Touchscreen Motion Tablet programming computer with easier-to-read screens and buttons
- More reliable hard drive (solid state)
- Enhanced tablet battery longevity allows for more uses between charges

## UNIQUE DEVICE IDENTIFIER (UDI)

A UDI has been assigned for each released version of the 11.0 software. The specific UDIs are as follows:

- **Version 11.0.4** - (01)05425025750375(10)V1104
- **Version 11.0.5** - (01)05425025750368(10)V1105

## Troubleshooting

For Troubleshooting concerns, see Table 1 below:

**Table 1. Troubleshooting**

Description	Solution
Diagnostic results do not update when the magnet is held over the pulse generator (applicable to M103-M106 generators only)	Do not hold a magnet over the generator while attempting to perform a diagnostic test.
The Display Device History and View Last Parameters screens do not include all units for parameters displayed.	The units for parameters are displayed on the Parameter screen and described in the manuals.
If a warning message appears indicating the generator is disabled and not supplying stimulation, diagnostic test results may show that an output current was able to be delivered even though the output current was not actually delivered (applicable to M103-106 generators only).	If the generator is disabled, it is not supplying stimulation. Follow recommendations provided in the warning message.
Upon powering on the computer, the VNS software may not appear but instead shows a blank screen.	Tap the screen to see if the VNS software appears. If it does not appear, reboot the programming computer.
Upon powering on the computer, the VNS software may not appear but instead shows the custom OS shell.	Tap the screen to see if the VNS software appears. If it does not appear, reboot the programming computer.
Upon powering on the computer, the computer display may get stuck at the "Starting Windows" screen.	Power down and reboot the programming computer. If the problem persists, remove the SD card and then reboot the programming computer.
Some office visit data entries may be duplicated in the data export file (OVexport.csv) (only applicable to the Model 106 generator).	Duplications can be identified as they have the same date and timestamp.
Certain warning messages may not be displayed if the screen is touched during diagnostic testing.	Avoid touching the computer screen during interrogation, programming, and diagnostic tests.

**Table 1. Troubleshooting**

Description	Solution
Upon waking up the computer from hibernate mode, the VNS software may not appear but instead shows a blank screen.	Tap the screen and the VNS software should appear. If the software does not appear, reboot the programming computer.
Display anomalies when using the scroll bar on "View Parameter History" screen.	Use the software buttons to scroll up or down instead of the scroll bar.
Generator Diagnostic test results may show that the generator is capable of delivering output current even though lead impedance is high (applicable to M103-M106 generators only).	If generator diagnostic results show high lead impedance, stimulation will not be delivered at the programmed setting. Follow appropriate troubleshooting recommendations for high lead impedance results. A System Diagnostics test can be performed to verify the test results.
Moving the SD card switch to the "Lock" position may prevent data backup and export to the SD card.	Keep the switch located on the side of the SD card in the unlocked position.
The file name of the ".html" files saved to the SD card do not contain the generator model number.	The generator serial number and date and time of the export are included in the file name to help differentiate files. The generator model number can be seen in the actual file.
In the Display Device History screen, tapping on the "Office Visit" button displays the last Office Visit entry instead of the first entry.	Use the scroll bar to navigate to the desired Office Visit entry.
The first time that the Extended Generator Memory Download is attempted with an SD card inserted, an error message appears.	Select Retry on the error message.
In the magnet history data exports, the csv file will show an empty field for "Patient Date of Birth".	The patient date of birth is not populated in the generator and the field will be blank.
The Display Device History and View Last Parameters screens do not include all units for parameters displayed.	The units for parameters are displayed on the Parameter screen and described in the manuals.

**LivaNova USA, Inc.**  
100 Cyberonics Boulevard  
Houston, Texas 77058 USA

Telephone: +1 (281) 228-7200  
1 (800) 332-1375 (US and Canada)  
Fax: +1 (281) 218-9332

**LivaNova Belgium NV**  
Ikaroslaan 83  
1930 Zaventem BELGIUM

Telephone: +32 2 720 95 93  
Fax: +32 2 720 60 53

For 24-hour support, call:  
Telephone: 1 (866) 882-8804 (US and Canada)  
+1 (281) 228-7330 (Worldwide)

Internet: [www.livanova.com](http://www.livanova.com)