Release Notes

**VNS Programming Software
Model 250
Version 8.1**

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

Consistent with this commitment, we are pleased to announce the release of the VNS Therapy® Programming Software, Model 250, Version 8.1. This software update is a continuation of our goal of providing a high quality and reliable programming experience. Version 8.1 addresses a variety of software features that are completely transparent to the user while enhancing the speed and reliability of the programming software.

See the Model 250, Version 8.1 Software Installation Instruction Guide for step-by-step instructions on how to upgrade your current VNS Software to version 8.1 and properly return your existing Version 8.0 LivaNova FlashCard. **The software upgrade should be performed before the next pre-operative work-up or the next VNS patient visit**. For more information regarding the upgrade process, please contact Clinical and Technical Support.

What's New

- Revised Model 103, 104, and 105 Generators high impedance threshold value from 7,000 Ohms to 5,300 Ohms
- New section in the M250 v8.1 Physician's manual detailing instructions for proper screen alignment for Dell handheld computers X5 and X50

Resolved Issues

- Corrected previously mistranslated foreign language screenshots in Danish, German and Italian

- Multiple Magnet activations per line for a single Magnet activation record [Model 100(C), 101, 102, and 102-R Generators only]

- User interface issues

- Inconsistent warning message issues

- Misspellings on a few software screens

Known Issues

The following known issues are displayed in order of occurrence and impact (See Table 1 below):

Table 1.   Known Issues

Issue #	Issue Description	Solution
1	Screen is Frozen.	Wait for at least 1 minute for the software to respond. If the screen is still frozen after waiting, perform a hard reset to re-install and launch the software.
2	SQL Database Errors.	Database is corrupted. Call LivaNova Clinical Technical Services.
3	Magnet activations are not recorded in the database for up to an hour after a Generator reset.	This only applies to Models 100(C), 101, 102, and 102R Generators. The timestamps for Magnet activations occurring after the first hour are displayed correctly.
4	Handheld computer battery status bar does not always increment when the device is charging, and the battery status bar indicates that the battery is fully charged when it may not be. When disconnected from the AC power, the correct battery power remaining will be shown.	Disconnect the handheld from the AC power and the correct battery power will be shown. When in use, LivaNova recommends the handheld computer to be operated on battery power only (unplugged from AC power).
5	Following an interrupted diagnostic test, extra warning messages appear with information regarding recommended settings.	Dismiss the messages, and re-interrogate the Generator to ensure proper device settings. Proceed with diagnostic testing as desired.
6	Generator Model 100B data from database is not displayed correctly.	This version of the software does not support Model 100B devices. For retrieving data for 100B devices, call LivaNova Clinical Technical Services.
7	Daylight savings time update is performed in incorrect month (follows pre-2007 transition dates).	Manually adjust the date and time in the 'User Preferences' menu with the 'Set Time' feature.
8	In the user preferences, language selection menu, when a language other than English is selected, and the user attempts to navigate to any other tab different than 'Region', the 'OK' button on the top right corner is disabled.	Perform hard reset and allow the software to re-install and launch. If a language other than English is desired, when in the user preferences/language selection menu, only select the desired language in the 'Region' tab, and confirm by selecting 'OK' on the top right corner.

Table 1. Known Issues

Issue #	Issue Description	Solution
9	In the View Database menu, if searching by Patient ID, the Patient ID box only shows the first two characters when entering capitalized letters, the last one is not displayed.	The text box is not large enough to display all the capital letters. Enter the Patient ID as programmed in the device, and the data will be displayed. There is no effect on the software performance.
10	Minor text truncations, typos or missing text in foreign languages; some of which are due to space limitations.	The user can infer the intended message from the display. There is no effect on software performance.
11	If the handheld goes into sleep mode for a long period of time (e.g. overnight) and is running on battery power, when the handheld power button is depressed, the Windows Start Menu Icon appears.	Perform hard reset and allow the software to re-install and launch.
12	An inappropriate "Low Output Current" message is displayed after a Magnet Mode diagnostics test, resulting from a scenario where the Magnet output current was increased prior to initiating the test and a Magnet swipe is not correctly performed or registered at the new setting.	Ensure that at least one successful Magnet Mode stimulation cycle is completed at the new setting prior to performing the Magnet Mode diagnostic test.
13	When viewing the last 15 magnet activations for Model 100, 101, 102, and 102R Generators in the 'View Last Parameters' menu, the activations may be out of sequential order if multiple magnet activations occurred within the same hour.	The data presented is correct; it is simply not sorted properly. The Magnet history data is sorted correctly in the database and this data can be exported to a Comma Separated Value (CSV) text file to the FlashCard, where the data can then be viewed on a personal computer by using a FlashCard reader.
14	Avoid moving any dialog boxes with the stylus. The screen can appear frozen if the user attempts to move a progress indicator box with the stylus, and subsequently covers a dialog box requiring some type of user response (i.e. selecting 'Retry' or 'Cancel' following an interrupted diagnostic test).	Move the progress indicator box off of the dialog box or perform a hard reset of the handheld to re-install and launch the software.