Cyberonics[®]

Release Notes

VNS Programming Software Manual Model 250 Version 8.0

C E 0344

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What's New

1. Battery longevity estimation for the Model 103/104 Generators is no longer supported in Version 8.0 Programming Software. Instead, the remaining battery capacity is displayed using icons consistent with other portable electronic devices. New Generator battery status indicators for Model 103 and 104 Generators include: IFI (Intensified Follow-up Indicator), N EOS (Near End of Service), and EOS (End of Service).

For icons and recommended actions for the four different battery status indicators, see Table 1 below.

Table 1. Battery Status Indicators

IFI=No, which is indicated graphically by one of the four green battery status indicators:







The Pulse Generator battery has not depleted to a level where more frequent clinical monitoring is recommended. No special attention is required.

 $\textbf{IFI=Yes}, \ which \ is \ indicated \ graphically \ by \ the \ yellow \ battery \ status \ indicator:$



The Pulse Generator battery has depleted to a level where more frequent clinical monitoring is recommended.

N EOS=Yes, which is indicated by the red battery status indicator:



The Pulse Generator is Near End of Service and the Pulse Generator should be replaced as soon as possible.

Table 1. Battery Status Indicators

EOS=Yes, which is indicated by the empty battery status indicator:



The Pulse Generator has reached End of Service and is NOT supplying stimulation. Immediate replacement is recommended.

2. New workflow for interrupted System and Generator Diagnostic Testing for Models 100(C), 101, 102, and 102R Generators - This feature helps to reduce the instances of inadvertent programming of output current to 0mA which results in no stimulation.

If the System or Generator Diagnostic Test is interrupted due to communication problems, a warning message with troubleshooting information is displayed to help the user to restore communication and re-run the test. If the user wishes to exit from diagnostics without performing the test successfully, parameters are shown as "*****" to indicate that generator state is unknown due to the interrupted diagnostic testing. Performing an interrogation afterwards is highly recommended.

3. New workflow for partial programming for Models 100 (C), 101, 102, and 102R Generators - This feature helps to reduce the instances of inadvertent programming of output current to 0mA, which results in no stimulation.

If the programming event is interrupted due to communication problems, some parameters may be programmed to the Pulse Generator while others are not (depending on the timing of the interruption). This is called a partial programming event. If this occurs, a warning message with troubleshooting information is displayed to help the user to restore the communication and retry the programming attempt. If the user wishes to cancel the programming operation after a partial programming event, the user is taken to the interrogation screen so an interrogation can be performed to verify the current parameter settings in the generator.

4. Revised low impedance diagnostic threshold for Model 103/104.

The low impedance threshold has been increased from 200 Ω to 600 Ω to capture low impedance events more effectively.

5. Added Installation behavior.

The AutoInstall program installs the VNS Therapy Software from the flashcard when power is restored following battery depletion or when a hard reset is performed. In this version of the software, AutoInstall files reside only on the flashcard and hence the flashcard must be inserted at all times in order to install and execute the VNS Therapy Software successfully.

- 6. Added support for the Model 105 Pulse Generator (to be released at a future date).
- 7. Removed support for obsolete products:
 - Model 250 VNS Programming Software Version 8.0 is NOT compatible with 100(B) Pulse Generators and Model 200 Programming Wands.
 - Model 250 VNS Programming Software Version 8.0 is NOT able to run on HP Jornada handhelds.

Resolved Issues

- 1. Watchdog time-out issue in Model 103/104 Generators
- 2. False "Low output current" warnings eliminated
- 3. Minor inconsistent warning message issues
- 4. Minor user interface issues
- 5. Mis-spellings on a few software screens

Known Issues

The following known issues are displayed in order of occurrence and impact:

Table 2. Known Issues

Issue #	Issue Description	Solution
1.	Screen is frozen.	Wait for at least 1 minute for software to respond. If still frozen after waiting, perform a hard reset to re-install and launch the software.
2.	SQL database errors.	There is no workaround. Database is corrupted. Call Cyberonics Clinical Technical Services.
3.	Multiple magnet activation timestamps shown on a single line for a single magnet activation record.	This applies to models 100(C), 101, 102, 102-R generators only. This is only a temporary display issue and is resolved after 15 new magnet activations are performed.
4.	Magnet activation timestamp is not recorded within the first hour after generator reset.	This applies to models 100(C), 101, 102, 102-R generators only. The timestamps for magnet activations occurring after the first hour are displayed correctly.
5.	100B data from database not displayed correctly.	This version of the software does not support model 100B devices. For retrieving data for 100B devices, call Cyberonics Clinical Technical Services.
6.	Windows background is displayed instead of the VNS software.	Perform hard-reset and allow the software to re-install and launch.
7.	Daylight savings time update is performed in the incorrect month (follows pre-2007 transition dates).	Manually adjust the date and time with "Set Time" feature.

Table 2. **Known Issues**

Issue #	Issue Description	Solution
8.	Unable to input certain dates using on screen keyboard.	Use the drop down calendar to input the date.
9.	Handheld screen turns off prematurely.	Turn the handheld back ON and re- interrogate.
10.	Output current increase warning message is displayed earlier than expected.	Click "Proceed" to acknowledge the message.
11.	Screen displays one of the following error messages: "VNS 72", "VNS 80", "Hello World", or "Model ID mismatch".	Re-interrogate the generator from the Main Menu screen and repeat the last action.
12.	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.

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