

Physician's Manual

**VNS Therapy[®]
Programming Software**

**Model 250 Version 8.0
Handheld Computer**

For Healthcare Professionals

June 2017

Worldwide Version

Caution: U.S. federal law restricts this device to sale by or on the order of a physician.

CE 0344
2011

Note: This manual contains information on the use of the LivaNova[®] VNS Therapy Programming Software, Model 250 Version 8.0. Physicians should refer to the VNS Therapy Pulse Generator physician's manuals for additional important prescribing and safety information. A copy of this VNS Therapy manual is posted at www.livanova.com.

26-0007-6100/3

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1. BRIEF DEVICE DESCRIPTION ---

1.1. General Description









The LivaNova[®] VNS Therapy[®] Programming Software, Model 250 Version 8.0, enables you to interrogate and program LivaNova's Pulse Generator using the Programming Wand.

Software capabilities include:

- Use of the software *with the Programming Wand* to interrogate and program a Pulse Generator's parameters and assess Pulse Generator function.
- Use of the software *without the Programming Wand* to display the operating histories of all the Pulse Generators interrogated with your handheld computer.
- Use of screen displays that provide prompts and messages to aid in interrogating and programming.

1.2. Symbols

Symbols and definitions used for the VNS Therapy System include the following:

	Notice for reader to pay special attention to details that follow
	Serial Number
	Storage
	Batch Code
	Date of Manufacture
	Information
	Sidebar Note (cross-references and other useful information)
	MRI Unsafe

1.3. Intended Use

The Model 250 VNS Therapy Programming Software is intended for use only with the LivaNova Pulse Generators and Programming Wand and is subject to the same indications for use.



Caution: LivaNova recommends that the software be loaded on a dedicated computer used only to program the Pulse Generator.

1.4. System Requirements

The computer must have the following minimum specifications:

- Microsoft® Pocket-PC (2002, 2003 Operating System) or Windows Mobile (2003 2nd Edition)
- At least 16 MB of memory
- Compact FlashCard
- Serial communication capability



Note: See “List of Approved Computers” on page 89 for a list of computers that have been qualified for use with the VNS Therapy Programming Software Model 250 Version 8.0.

The communication system of the VNS Therapy Programming Software Model 250 Version 8.0 is designed to minimize the possibility of misprogramming or “phantom” programming. Phantom programming is the inadvertent programming via environmental sources of electromagnetic interference.

For Models 100, 101, and 102 Pulse Generators, each parameter is programmed and verified individually during a programming event. For the Models 103, 104, and 105 Pulse Generators the parameters are programmed and verified as a group during a programming event.



Note: See the physician's manual for the VNS Therapy Pulse Generators for a complete description of the Pulse Generator, its indications for use, and its operation.

1.5. Conventions Used in this Manual

The following conventions are used throughout this manual:

- The VNS Therapy Programming Software Model 250 Version 8.0 operates in a Windows environment with drop-down menus. You will use a stylus to navigate through a Windows environment on the handheld computer. The stylus resembles a small pen and is kept with handheld computer.
- Screen titles appear in all capital letters. The names of selectable buttons (or fields) and drop-down menus appear in bold typeface. Each of these buttons or fields represents an operation, parameter, or parameter value.
- To select a button or field, tap it with the stylus.
- Some information can be entered with a “soft” or “on-screen” keyboard (an example of the soft keyboard is shown at the bottom of Figure 27 on page 44). To maximize (enable) or minimize (disable) the soft keyboard, tap the keyboard icon at the lower right-hand corner of



Note: See the physician's manual for the Programming Wand for a description of the Programming Wand.

the screen. You can type letters or numbers by tapping them with the stylus.

- When a selection requires communication with the Pulse Generator, a message will appear prompting you to hold the Programming Wand over the Pulse Generator.
- When a button is selected, a border will appear around the button (as on the **Interrogate Device** button in Figure 1 on page 12).
- To return to a previous screen, tap **Menu** or **Exit**.
- A list of symbols is found in the front of this manual.
- A glossary is found in the back of this manual.
- The words ON and OFF appear in all capital letters only when they refer to VNS stimulation.
- References to Model 102 include both Models 102 and 102R.
- For more information, see “Troubleshooting ” on page 61.

1.6. Communication Signals

Four rapid, *ascending* musical tones and a screen message signal the successful completion of an interrogation or programming operation.

Four rapid, *descending* musical tones and a screen message signal a warning or a failed operation.

The DATA/RCVD indicator on the Programming Wand lights up during a successful programming operation or interrogation.



Caution: If the Procedure Failed message appears on the screen, check both the connection between the handheld computer and the Programming Wand and the positioning of the Programming Wand in relation to the Pulse Generator (see the physician's manual for the Programming Wand). If you continue to have communication problems, change the battery in the Programming Wand.



Caution: The DATA/RCVD indicator on the Programming Wand may also light up or flicker in the presence of electromagnetic interference (EMI) or noise. Information on how to detect EMI is provided in the physician's manual for the Programming Wand, sections entitled Understanding the Indicator Lights and Troubleshooting. If the presence of EMI or noise is suspected, you must verify that the programming or interrogation occurred successfully by reviewing the PARAMETER Screen shown in Figure 3 on page 15.

2. HOW TO GET STARTED

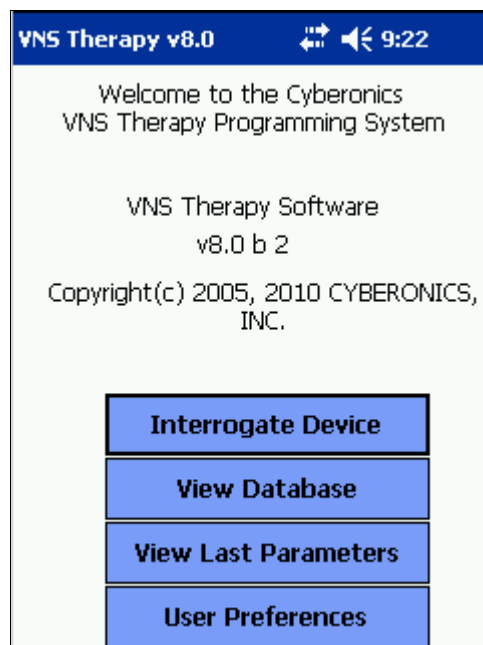
The VNS Therapy Programming Software Model 250 Version 8.0 has been pre-installed on the handheld computer. Before proceeding to the next section, be sure you have arrived at the MAIN Menu as shown in Figure 1. If for any reason the software must be reinstalled, directions for doing so are provided in the *Troubleshooting* section of this manual.

1. Turn on the handheld computer by pressing the on-off button. The handheld computer will display the same screen it was displaying when it was last turned off (unless it was reset since the last use).
2. If the computer doesn't display the MAIN Menu, select **Exit** or **Menu** until the MAIN Menu is displayed.
3. If you haven't been able to access the MAIN Menu after following Steps 1 and 2 above, see "Precautions" on page 59 and "Troubleshooting" on page 61 before proceeding.



Caution: When in use, LivaNova recommends the handheld computer to be operated on battery power only (unplugged from AC power). Having the handheld computer plugged into AC power during use may contribute to communication difficulties. When not in use, the handheld computer should be plugged into AC power to maintain charge.

Figure 1. MAIN Menu



3. HOW TO USE THE SOFTWARE ---


It is LivaNova's intent to make the software as intuitive and "user friendly" as possible. Messages and prompts will guide you through this software.

There are four menus in this software. The first is the MAIN Menu.

3.1. MAIN Menu


The following sections provide an overview of each of the MAIN Menu's four primary functions, as shown in Figure 1.

3.1.1. *Interrogate Device overview*

 **Note:** See "Interrogate Device" on page 14 for more information.


The first option, Interrogate Device, is used to establish communication with the implantable device (Pulse Generator). The other three options work with data stored on the handheld computer itself and require no link to the device via the Programming Wand.

3.1.2. *View Database overview*

 **Note:** See "View Database" on page 47 for more information.


View Database is used to view information from all Pulse Generator interrogations and programming events performed by your handheld computer and the Programming Software.

3.1.3. *View Last Parameters overview*

 **Note:** See "View Last Parameters" on page 53 for more information.

View Last Parameters is used to view the most recent parameters selected for a specific patient or Pulse Generator.

3.1.4. *User Preferences overview*

 **Note:** See "User Preferences Screen" on page 54 for more information.

User Preferences allows you to select values for five user settings:

- The number of minutes that the computer may be idle before a new interrogation becomes necessary (applicable for Models 100C, 101, and 102 only).
- The maximum number of records viewable at a time
- The size of type font for the diagnostics screens
- The current time and date
- Language selection, when available

4. INTERROGATE DEVICE

To retrieve information from the Pulse Generator or to program the Pulse Generator, you must first select the **Interrogate Device** button from the MAIN Menu. The START INTERROGATION Screen will be displayed (see Figure 2).

Figure 2. START INTERROGATION Screen



To interrogate the Pulse Generator, place the Programming Wand over the Pulse Generator and tap **Start Interrogation**. Tap **Cancel** to return to the previous screen.

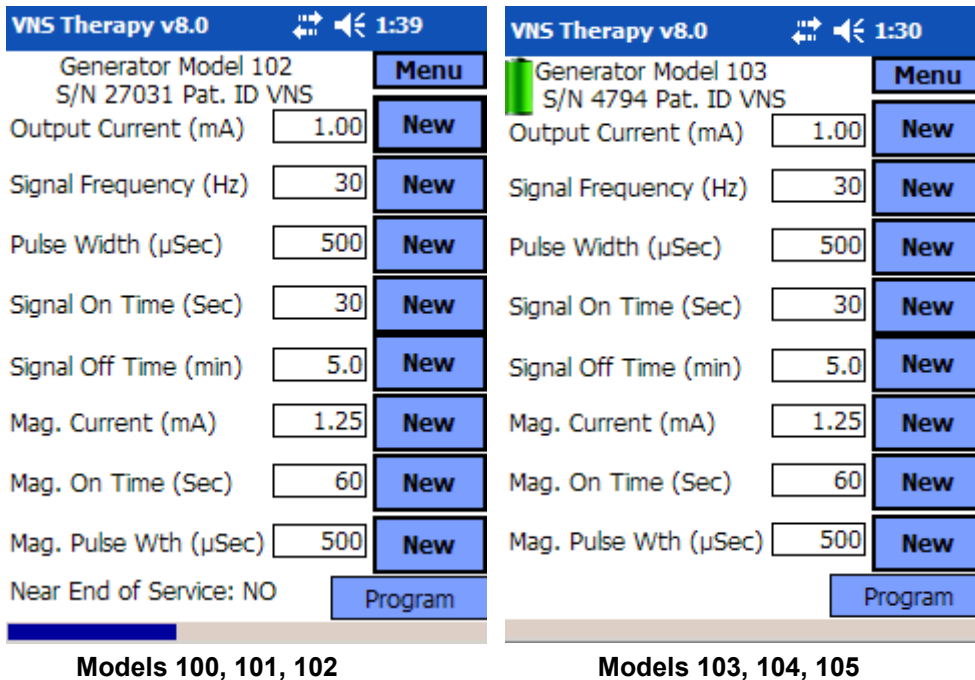
Upon completion of a successful interrogation, the Programming Software automatically displays the PARAMETER screen (see Figure 3 on page 15) unless an error condition (i.e., Generator End of Service or High Lead Impedance) is detected with the Pulse Generator. If an error condition is detected with the Pulse Generator, the associated warning message is displayed and must be acknowledged by the user before proceeding to the PARAMETER screen. The PARAMETER screen displays the operating parameters of the Pulse Generator with their current settings.

There is one line for each of the eight parameters. Each line contains three types of information:

1. The name of the parameter and the units used to express its values
2. The present setting for that particular parameter (***** is shown for any unknown or out of range parameter values)

- The **New** button, when tapped, displays the range of possible settings for that parameter

Figure 3. PARAMETER Screen

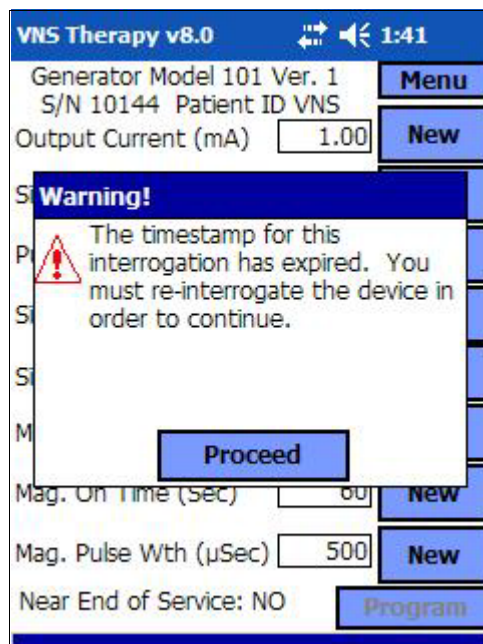


↑ Inactivity Timeout Indicator (Progress Bar)

Note: The inactivity timeout function is not used in Models 103, 104, and 105.

For the Models 100, 101, 102 Pulse Generators, the progress bar across the bottom of the screen is an “inactivity timeout” indicator. When the bar reaches the right margin, the most recent interrogation will have expired and the warning shown in Figure 4 on page 16 will be displayed. Also, it will be necessary to reinterrogate the Pulse Generator before programming. The inactivity timeout period can be adjusted on the USER PREFERENCES Screen as described in Section 7 on page 51.

Figure 4. TIMEOUT WARNING Screen



Note: For more information on the timeout function, see “User Preferences Screen ” on page 54.

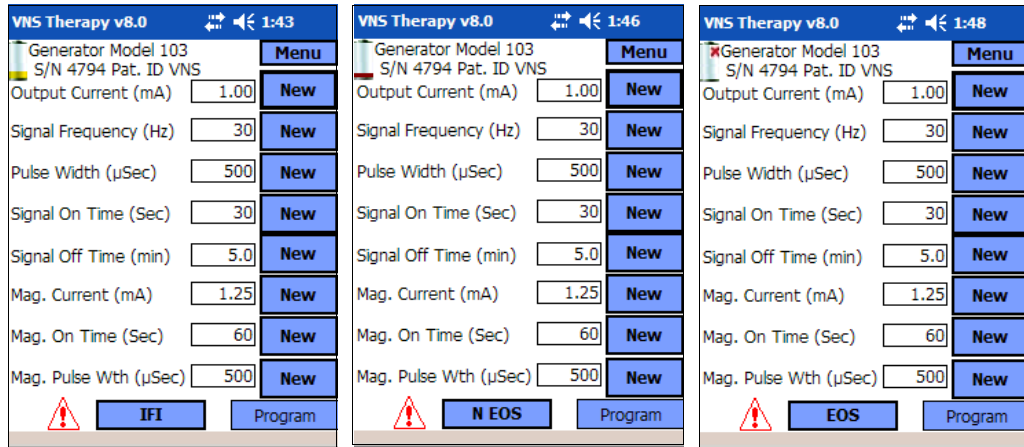
Note that the timeout bar has advanced to the right margin.

In addition to the eight programmable parameters, the PARAMETER screen will also indicate battery status for the Pulse Generator. The Programming Software has one battery status indicator, Near End of Service (Near EOS), for Models 100, 101, and 102 Pulse Generators. The Programming Software has three indicators, Intensified Follow-up Indicator (IFI), Near End of Service (N EOS), and End of Service (EOS), for Models 103, 104, and 105 Pulse Generators. On the PARAMETER screen, the Near EOS status for Models 100, 101, and 102 Pulse Generators is displayed on the lower portion of the screen (see Figure 3 on page 15). For Model 103, 104, and 105 Pulse Generators, the remaining generator battery power is indicated by the battery icon located in the top left portion of the PARAMETER screen (see Figure 3 on page 15). The battery icon is shaded and colored to indicate various levels of remaining generator battery power. As the battery level decreases and the Pulse Generator enter states of IFI = Yes, N EOS = Yes or EOS = Yes, an additional indicator is displayed at the bottom of the PARAMETER screen (see Figure 5 on page 17).



Caution: LivaNova recommends that you reinterrogate the Pulse Generator after each programming event to verify that the programming occurred as planned.

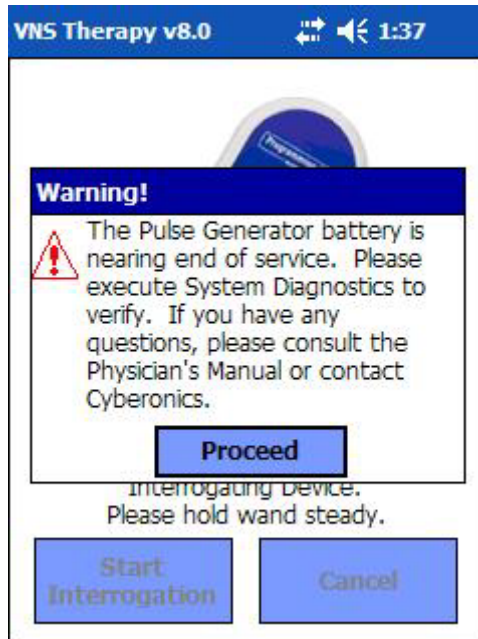
Figure 5. PARAMETER Screen with ACTIVE BATTERY STATUS INDICATOR



Models 103, 104, 105

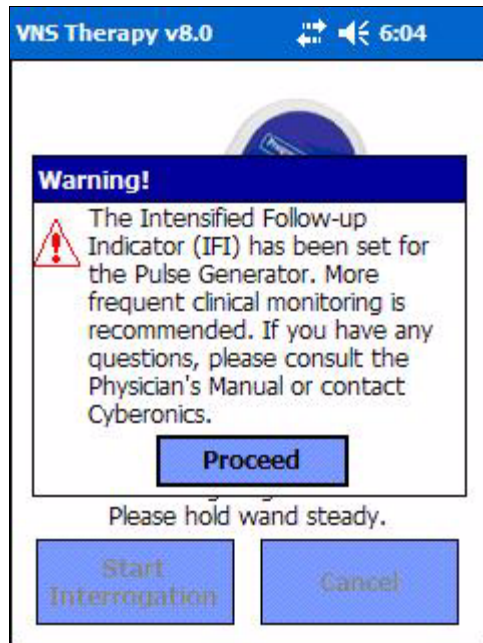
Upon completion of an interrogation or Diagnostics testing, the Programming Software will display the associated warning message should the Pulse Generator battery reach Near EOS for Models 100, 101, and 102 (see Figure 6 on page 17) and IFI, N EOS, or EOS for Models 103, 104, and 105 (see Figure 7, Figure 8, and Figure 9 on pages 17 and 18).

Figure 6. BATTERY STATUS INDICATOR - NEAR EOS WARNING Screen



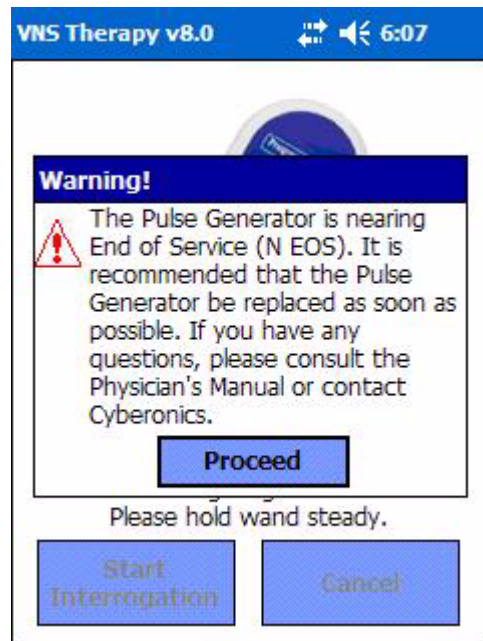
Models 100, 101, 102

Figure 7. BATTERY STATUS INDICATOR - IFI WARNING Screen



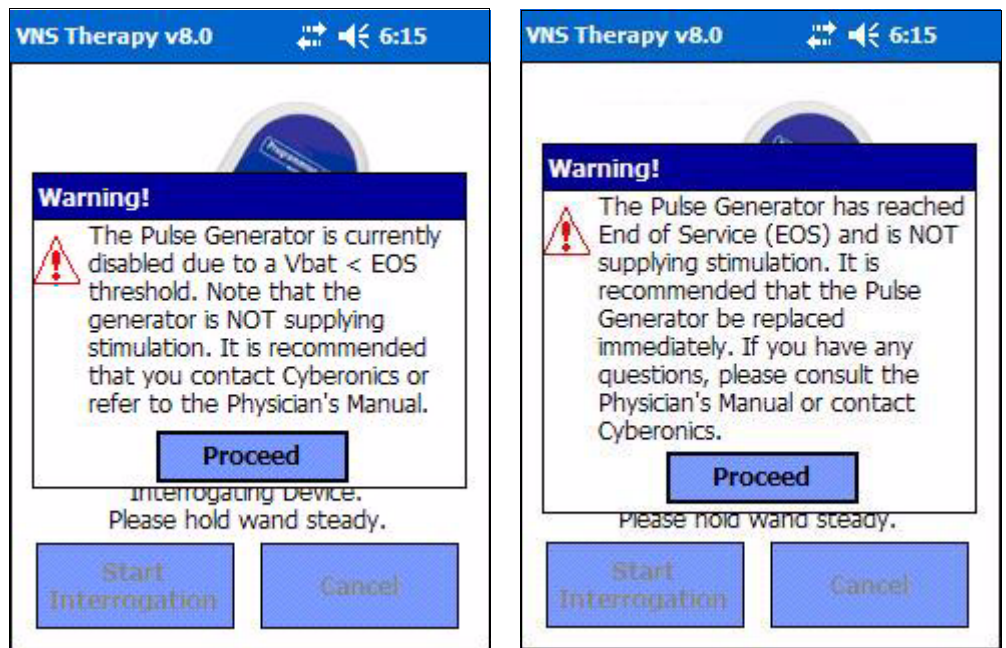
Models 103, 104, 105

Figure 8. BATTERY STATUS INDICATOR - N EOS WARNING Screen



Models 103, 104, 105

Figure 9. PULSE DISABLED and BATTERY STATUS INDICATOR - EOS WARNING Screen










Models 103, 104, 105

Table 1 shows the various indications of Pulse Generator battery level and the associated recommendations.

Table 1. Pulse Generator Battery Level Indications and Recommendations

Pulse Generator Model #	Estimated % Battery Power Remaining	Battery Icon Displayed	Pulse Generator Battery Status / Recommendations
100/101/102	Battery measurement not supported by Generator	None displayed	Near EOS = No The Pulse Generator battery level is good. No warning message is displayed from the Programming Software and no special attention is required.
100/101/102	Battery measurement not supported by Generator	None displayed	Near EOS = Yes The Pulse Generator is nearing End of Service (EOS). The Programming Software will display a warning message indicating this status upon completion of interrogation or Diagnostics testing. It is recommended that the Pulse Generator be replaced as soon as possible.

Pulse Generator Model #	Estimated % Battery Power Remaining	Battery Icon Displayed	Pulse Generator Battery Status / Recommendations
103/104/105	>75% to 100%		IFI = No The Intensified Follow-up Indicator (IFI) has not been set. The Pulse Generator battery level is good. No warning message is displayed from the Programming Software and no special attention is required.
103/104/105	>50% to 75%		
103/104/105	>25% to 50%		
103/104 105	>18% to 25% >11% to 25%		
103/104	>8% to 18%		IFI = Yes The Intensified Follow-up Indicator (IFI) has been set for the Pulse Generator and a warning message will be displayed by the Programming Software to indicate this status upon completion of interrogation or Diagnostics testing. The Pulse Generator battery has depleted to a level where more frequent clinical monitoring is recommended.
105	>5% to 11%		
103/104	>0% to 8%		N EOS = Yes The Pulse Generator is near End of Service (N EOS). The Programming Software will display a warning message indicating this status upon completion of interrogation or Diagnostics testing. It is recommended that the Pulse Generator be replaced as soon as possible.
105	>0% to 5%		
103/104/105	0%		EOS = Yes The Pulse Generator has reached End of Service (EOS) and is NOT supplying stimulation. The Programming Software will display a warning message indicating this status upon completion of interrogation or Diagnostics testing. Immediate replacement of the Pulse Generator is recommended. If the Pulse Generator is not replaced, it will eventually lose the ability to communicate with the Programming Software.

4.1. How to Program New Parameter Settings

The PARAMETER Screen shown in Figure 3 on page 15 is used to change the Pulse Generator's parameter settings. Table 2 shows the range of possible settings for all parameters.

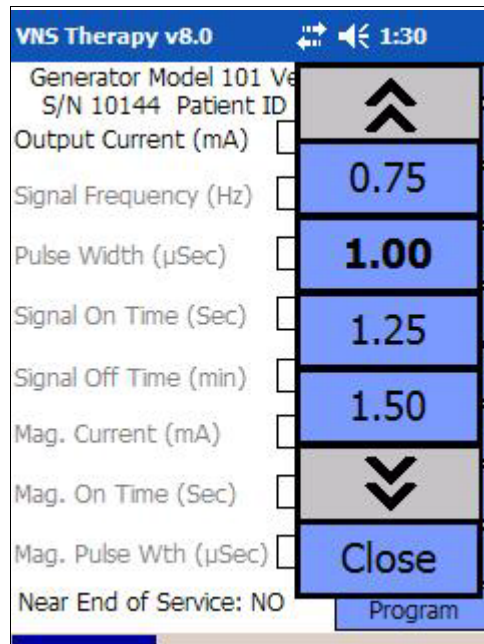
Table 2. Programmable Parameters for the Pulse Generator

Programmable Parameters	Settings
Output Current	0.0-3.5 milliamperes (in 0.25-mA steps)
Frequency	1, 2, 5, 10, 15, 20, 25, 30 Hz
Pulse Width	130, 250, 500, 750, 1,000 μ sec
Signal ON Time	7, 14, 21, 30, 60 sec
Signal OFF Time	0.2, 0.3, 0.5, 0.8, 1.1, 1.8, and 3 min; 5 to 60 in 5-min steps; 60 to 180 in 30-min steps

To change a parameter setting, follow these steps from the PARAMETER Screen (Figure 3 on page 15):

1. Tap the **New** button for the parameter you want to change. A pop-up menu displays the range of possible values, with the current value setting appearing in boldface type (see Figure 10). If there are values greater than or less than those shown on the screen you can view them by tapping the appropriate set of the double arrows. Look at the left half of the screen and note that the parameter for which the value is being changed is enabled (clearly visible) and the other parameters are disabled ("grayed-out"). In the example in Figure 10, **Output Current** is enabled and the other parameters are disabled. The value of 1.00 mA has been selected for the **Output Current** parameter.

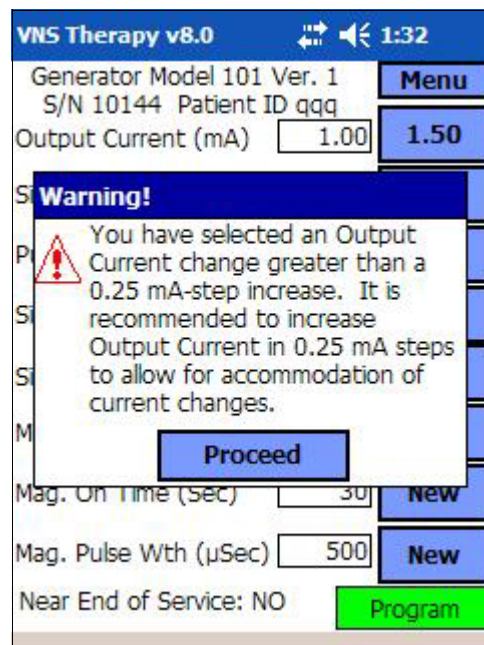
Figure 10. PARAMETER SETTINGS POP-UP Menu



Note: LivaNova recommends that during the initial programming, the output current be programmed at 0 mA and then slowly increased by 0.25 mA increments until the patient feels the stimulation at a comfortable level. Even patients who are receiving replacement generators should be started at 0 mA Output Current, followed by incremental increases of 0.25 mA to allow for reaccommodation to the therapy.

2. Select the new target value for the Output Current by tapping the desired value on the screen. If the target value selected is greater than 0.25 mA above the currently programmed value setting in the Pulse Generator, an Output Warning will appear (see Figure 11 on page 22).

Figure 11. OUTPUT WARNING



3. Tap the **Program** button, which turns green when a new parameter value is selected, at the bottom of the PARAMETER Screen to access the START PROGRAMMING Screen (see Figure 12).

Figure 12. START PROGRAMMING Screen



4. Place the Programming Wand over the Pulse Generator.
5. From the “Start Programming” screen, tap **Start Programming** to program the new value or **Cancel** to return to the PARAMETER screen menu.



Caution: For the Models 100, 101, and 102 Pulse Generators, do not use frequencies of 5 Hz or less for long-term stimulation. These frequencies always generate an electromagnetic trigger signal which results in excessive battery depletion of the implanted Pulse Generator; therefore, use these low frequencies for short periods of time only.



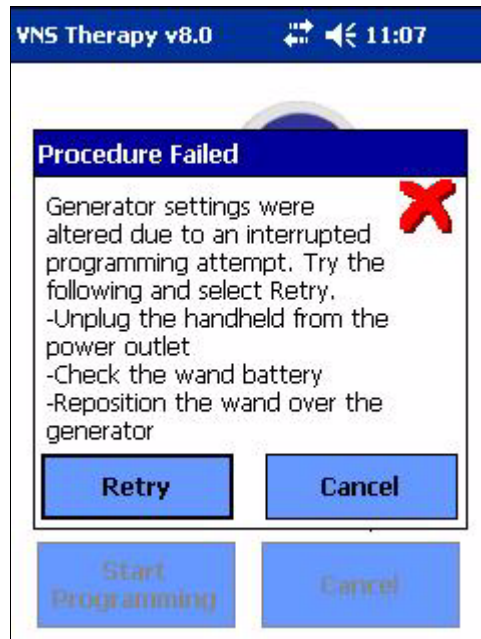
Caution: Stimulation at a combination of high frequency (≥ 50 Hz) and ON time \geq OFF time has resulted in degenerative nerve damage in laboratory animals. ON time \geq OFF time can be simulated by very frequent magnet activation. LivaNova recommends that stimulation at these combinations of ranges be avoided.

4.1.1. Partial Programming Due to Interrupted Programming Operation

For Models 100, 101, and 102 Generators, each parameter is programmed and verified individually during a programming event. Therefore, these Pulse Generators can be partially programmed to unintended settings if the communication between the Wand and the Pulse Generator is interrupted during programming. If this occurs, the Programming Software displays a

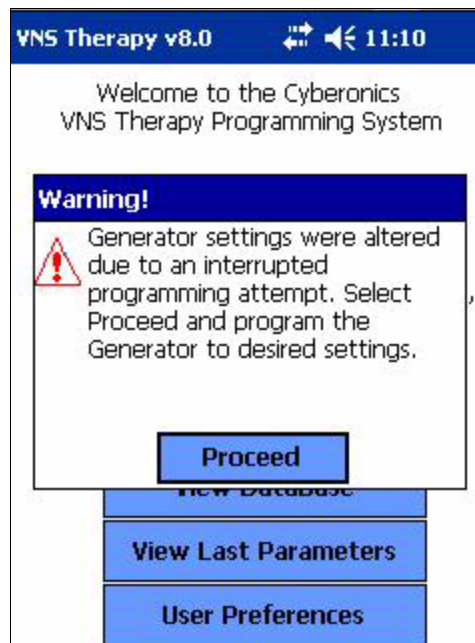
warning message indicating that the procedure failed and device settings were altered due to the interrupted programming attempt (see Figure 13 on page 24). The warning message also indicates some troubleshooting options and allows the user to retry or cancel the programming operation. If the user selects **Retry**, the Programming Software will re-program the Pulse Generator. If the user selects **Cancel**, the Programming Software will default back to the START INTERROGATION screen (see Figure 2). It is recommended that the Pulse Generator be interrogated immediately, as this will verify the currently programmed settings. After completion of the interrogation, the Programming Software displays a warning message stating that device settings were altered due to the interruption (see Figure 14) and allows the user to re-program the Pulse Generator to desired settings upon selecting **Proceed**.

Figure 13. PROGRAMMING FAILED WARNING Screen



Models 100, 101, 102

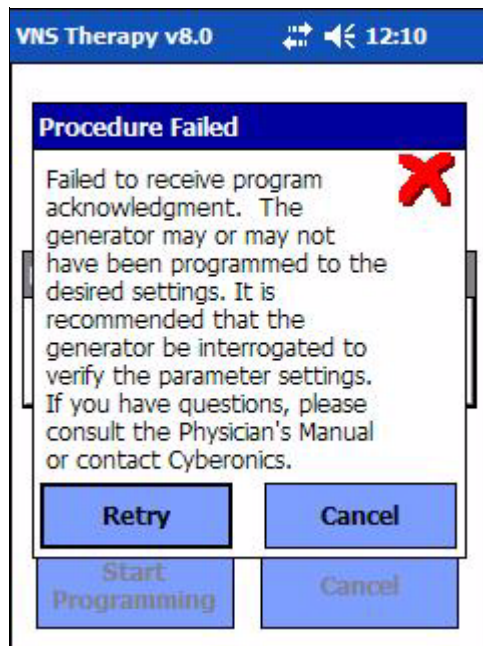
Figure 14. CHANGED SETTINGS PROGRAMMING WARNING Screen



Models 100, 101, 102

For Models 103, 104, and 105 Generators, the device parameters are programmed and verified as a group during a programming event; therefore, these Pulse Generators are not susceptible to partial programming. If an interruption occurs during a programming step for these Pulse Generators, the Programming Software displays a warning message indicating that the procedure failed and allows the user to retry or cancel the programming operation (see Figure 15 on page 26). If the user selects **Retry**, the Programming Software will re-program the Pulse Generator. If the user selects **Cancel**, the Programming Software will return to the PARAMETER screen where the user can re-program the Pulse Generator to desired settings (see Figure 3 on page 15).

Figure 15. PROGRAMMING FAILED WARNING Screen



Models 103, 104, 105

4.1.2. ***Cross-programming (applicable to Model 100, 101, and 102 Pulse Generators ONLY)***

Models 100, 101, and 102 Pulse Generators are susceptible to an event known as cross-programming, where parameter settings from one patient's Pulse Generator are inadvertently programmed to another patient's Pulse Generator. Cross-programming occurs when all the following conditions are met:

1. Patient A is implanted with the same model Pulse Generator as Patient B
2. Patient A's Pulse Generator was interrogated/programmed with the Programming Software and the Programming Software is left on the PARAMETER screen
3. Inactivity timeout has not expired, or is disabled
4. Patient B's Pulse Generator is programmed at the PARAMETER screen in step 2 without first performing an interrogation

The result of the above scenario is that Patient B's output current and magnet output current settings are programmed to Patient A's output current and magnet output current settings, unless those parameters values were changed as part of step 4. In addition, the Programming Software database will incorrectly indicate Patient A to be programmed to setting changes made in step 4. Table 3 gives an example of cross-programming

and its effect on device parameters. The parameters marked with asterisks indicate unintentionally altered or incorrectly displayed values.

Table 3. Cross-programming Example

Parameter	After Step 2		At Step 4	After Step 4	
	Patient A Final Settings	Patient B Initial Settings	Patient B Intended Final Settings	Patient B Actual Final Settings	Patient A Final Settings in Database
Output Current (mA)	0.25	0.75	No Change	0.25*	0.25
Frequency (Hz)	30	20	15	15	15*
Pulse Width (µs)	250	500	No Change	500	250
On Time (s)	30	7	No change	7	30
Off Time (min)	5	1.8	3	3	3*
Mag. Output Current (mA)	0.5	1.00	No Change	0.5*	0.5
Mag. On Time (s)	30	30	60	60	60*
Mag. Pulse Width (µs)	500	500	250	250	250*

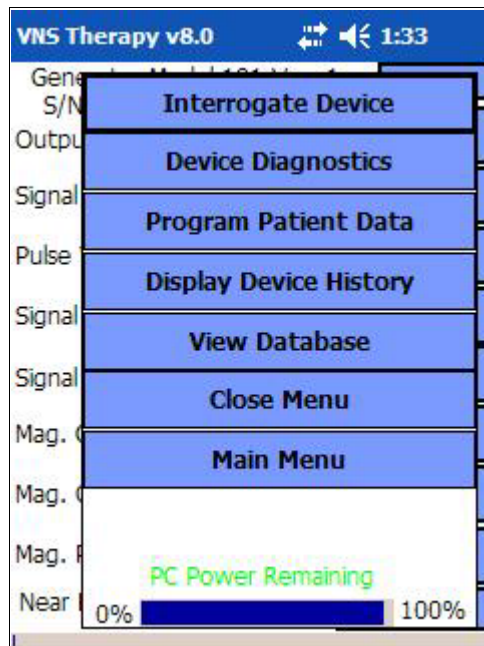
*Unintentionally altered or incorrectly displayed values.

Due to the susceptibility of Model 100, 101, and 102 Pulse Generators to cross-programming, LivaNova recommends that an initial and a final interrogation be performed at each office visit for all VNS patients in order to verify parameter settings.

4.2. PARAMETER Screen Menu

Tapping the **Menu** button at the right top of the PARAMETER Screen causes the PARAMETER Screen Menu to be displayed, as shown in Figure 16 on page 28.

Figure 16. PARAMETER Screen Menu



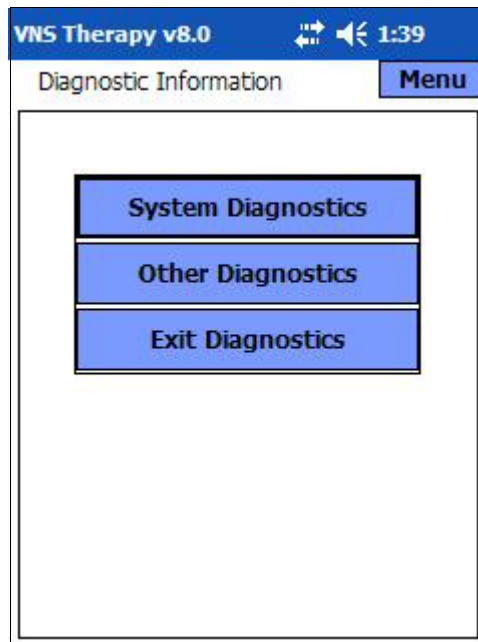
The functions available via this menu are explained in the following paragraphs.

4.2.1. *Interrogate Device*

Interrogation of the Pulse Generator is required to reach the menu shown in Figure 16. An **Interrogate Device** button is available here so you can interrogate the device after each programming event. A post-programming interrogation should be performed to ensure that the Pulse Generator was programmed as desired.

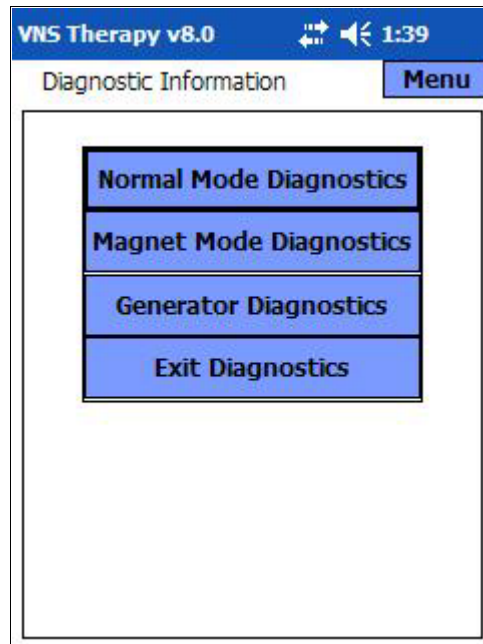
4.2.2. *Device Diagnostics*

Tap the **Device Diagnostics** button on the PARAMETER Screen Menu to display the DEVICE DIAGNOSTICS Menu (see Figure 17 on page 29).

Figure 17. DEVICE DIAGNOSTICS Menu

Use this screen to select function assessments to be performed on the Pulse Generator. The System Diagnostics, as well as the DC-DC Converter Code, can be used at patient follow-up visits to assess lead impedance status for Models 100, 101, and 102. An actual impedance measurement is reported for Models 103, 104, and 105. The System Diagnostics is also used during implantation and routine follow-up visits to assess nerve-electrode impedance. The Normal Mode Diagnostics, Magnet Mode, and Generator Diagnostics can be accessed by tapping **Other Diagnostics** (see Figure 18 on page 30).

Figure 18. DEVICE DIAGNOSTICS Sub-menu



In the event that the System Diagnostics fails, the Generator Diagnostics (Pulse Generator Test), which uses the resistor assembly connected at implantation, verifies proper Pulse Generator operation.

When you select any of the four diagnostics tests from the DEVICE DIAGNOSTICS Menu, additional instructions will be provided on the handheld screen. These instructions vary for each selection. Follow them carefully.

Because delivery of an output stimulation is required for diagnostic data collection, the Programming Software will automatically program the output current at the initiation of a Generator or System diagnostic tests. The automatic programming is not performed for the Magnet or Normal Mode diagnostics.



Caution: For the System Diagnostics on Models 100, 101, and 102 Pulse Generators, the Programming Software automatically programs the Pulse Generator to 1.0 mA, 500 μ sec, and 20 Hz. Patients whose Pulse Generator output current, pulse width, and frequency are normally set below these values may experience increased sensation, coughing, a flushed face, or other effects. See the physician's manual for the VNS Therapy Pulse Generators for a complete list of possible adverse events.



Caution: During a System Diagnostic for Model 103, 104, and 105 Pulse Generators, a test pulse of 0.25mA is first used to assess the Lead impedance. After the Impedance assessment, the behavior of the diagnostic test is dependent upon the value of the output current programmed in the Pulse Generator. If the output current is set to 0.0 mA, the diagnostic test is run with an output current of 1.0 mA, a pulse width of 500 µsec, and a frequency of 20 Hz. If the output current is programmed greater than 0.0 mA, the diagnostic test is run at the programmed settings.



Caution: LivaNova recommends interrogating the Pulse Generator after any diagnostics in order to verify parameter settings.



Caution: If an error message occurs and the Communication parameter reads “FAULT”, return to the MAIN Menu and select **Interrogate Device** to verify that the Pulse Generator is programmed to the correct parameters. The “FAULT” message also means the diagnostic test was not completed and may need to be performed again.

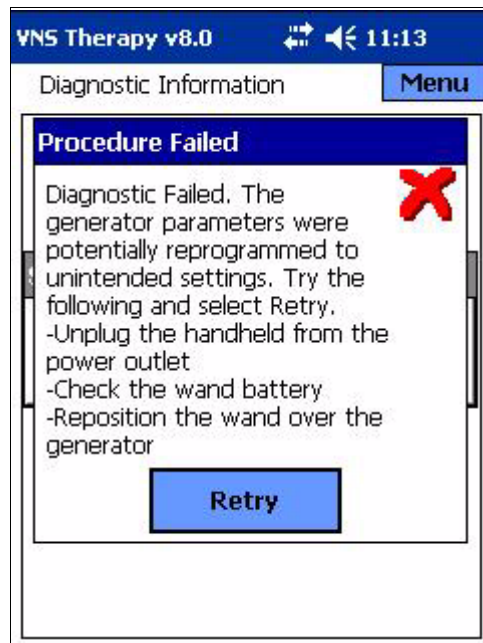


Caution: A device status of STANDBY indicates that the Pulse Generator was not stimulating and that the diagnostic test must be repeated.

4.2.2.1. Interrupted System and Generator Diagnostics

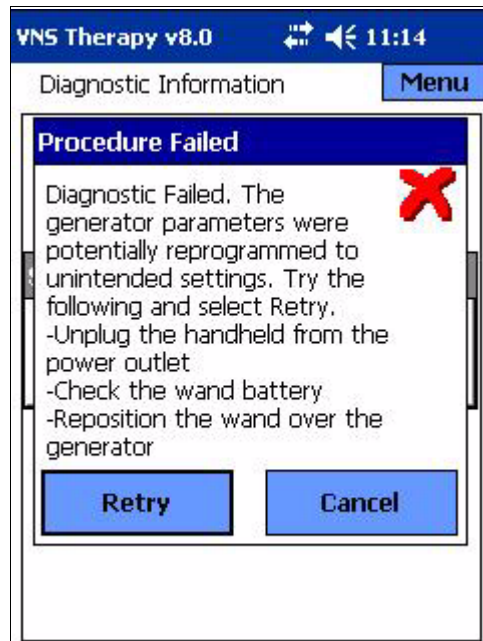
For Models 100, 101, and 102 Generators, device parameters may be programmed to unintended settings if the communication between the Programming Wand and the Pulse Generator is interrupted during System or Generator Diagnostics. When the Diagnostics test is first interrupted, the Programming Software displays a warning message indicating that the procedure failed and device settings were potentially altered (see Figure 19 on page 32). The warning message also indicates some troubleshooting options and allows the user to retry the testing. If the testing fails for the second time due to an interruption in communication, the user will have the option to retry again, or to cancel the operation (see Figure 20 on page 32). If the user chooses to cancel the operation, a warning message is displayed indicating that device parameters were potentially reprogrammed and an interrogation is recommended (see Figure 21 on page 33). Upon selecting **Proceed**, the Programming Software displays the PARAMETER screen where parameter values are shown as [*****] to indicate that exact values are unknown due to the interruption in communication (see Figure 22 on page 33). The user may then perform an interrogation or program the Pulse Generator back to desired settings.

Figure 19. DIAGNOSTIC - SINGLE FAILURE WARNING Screen



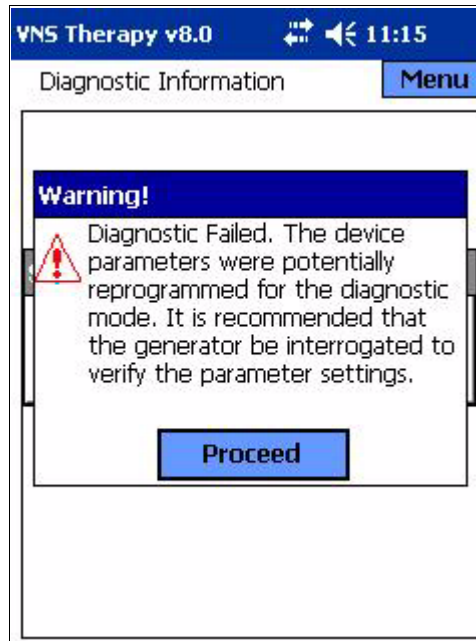
Models 100, 101, 102

Figure 20. DIAGNOSTIC - MULTIPLE FAILURE WARNING Screen



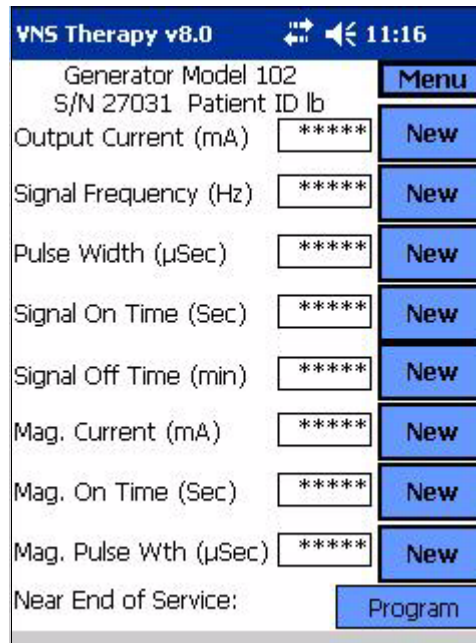
Models 100, 101, 102

Figure 21. CHANGED SETTINGS - INTERRUPTED DIAGNOSTIC WARNING Screen



Models 100, 101, 102

Figure 22. PARAMETER Screen with UNKNOWN SETTINGS



Models 100, 101, 102

For Models 103, 104, and 105 Generators, if an interruption occurs during a System or Generator Diagnostics test, the Programming Software displays an error message indicating that the procedure failed and then proceeds to display the test result (Fault). An interrogation is recommended after a failed System or Generator Diagnostics to verify device settings.

4.2.2.2. Diagnostic test parameters

There are 14 test parameters for the diagnostics tests:

1. **Patient ID:** This parameter is a three-character alphanumeric code selected by the physician and programmed into the Pulse Generator.
2. **Model ID:** Model designator of the Pulse Generator being interrogated.
3. **Serial Number:** This parameter is a numeric code assigned to the Pulse Generator and programmed into the Pulse Generator by LivaNova.
4. **Implanted:** This parameter represents the implant date as programmed by the physician.
5. **Communication:** This parameter is an indicator of the communication status during diagnostics. Table 4 shows the possible values and interpretation for the communication parameter. If the communication indicator shows the “FAULT” message, an error has occurred during a communication. The error may be the result of improper positioning of the Programming Wand over the Pulse Generator, of EMI or noise being sensed by the System, or of a depleted battery in the Programming Wand or Pulse Generator. Information on overcoming EMI, repositioning the Programming Wand, and resolving wand battery problems can be found in the physician’s manual for the Programming Wand. An explanation for detecting when a Pulse Generator has reached end of service is found in the physician’s manual for the VNS Therapy Pulse Generators.

Table 4. Device Diagnostic Screen Status Readings for Communication

Communication Status Reading	Significance Communication
OK	Programming operation performed successfully.
FAULT	Error occurred during communication due to improper Programming Wand positioning, electromagnetic interference, or depleted Pulse Generator or Programming Wand batteries.

6. **Output Status:** For the Models 100, 101, and 102 Pulse Generators, this parameter indicates whether the program current is being delivered at the specified value. Table 5 shows the possible values and interpretation for this parameter. This parameter is not displayed for the Models 103, 104, and 105 Pulse Generators.

Table 5. Device Diagnostic Screen Status Readings for Output Status

Output Status Status Reading	Significance
*****	1. MAGNET MODE diagnostics found Pulse Generator in STANDBY MODE. Use the magnet to reactivate stimulation. Retry diagnostics. 2. NORMAL MODE diagnostics found Pulse Generator in STANDBY MODE. Retry diagnostics.
OK	Current is being output at the programmed value.
LIMIT	Programmed current is possibly not being delivered at the specified level (possibly limited by battery voltage, lead impedance, or other reason). Reprogram the Pulse Generator to a lower output current and a wider pulse width.

7. **Output Current:** For the Models 100, 101, and 102, this parameter indicates the stimulation output current applied during the diagnostic test. Table 6 shows the possible values and interpretation for this parameter. For the Models 103, 104, and 105 this parameter indicates whether the programmed current is being delivered during the diagnostic tests.
8. **Current Delivered:** On the Models 103, 104, and 105 Pulse Generators, this parameter indicates the output current delivered during the execution of the diagnostic test. This parameter is not displayed for Models 100, 101, 102 Pulse Generators.

Table 6. Device Diagnostic Screen Status Readings for Output Current for Models 100, 101, and 102

Output Current Status Reading	Significance
OUTPUT CURRENT Setting	Shows the current at which the diagnostic test was run. For System Diagnostics and Generator Diagnostics (Pulse Generator Test), the software automatically programs the Pulse Generator to 1.0 mA. After the System diagnostics, the Pulse Generator will be reprogrammed to the pretest output current setting. After the Generator Diagnostics (Pulse Generator Test), the Pulse Generator will be programmed to standard settings (0mA/30Hz/500µs/30s/5min/0mA/60s/500µs).
*****	The Pulse Generator is in STANDBY MODE and is not delivering stimulation.

9. **Lead Impedance:** On the Models 100, 101, and 102 Pulse Generators, this parameter is used in conjunction with the DC-to-DC Converter to assess how hard the device has to work to deliver a selected output current, or how much the flow of current is impeded. For the Models 103, 104, and 105 Pulse Generators this parameter is used to assess whether the impedance is within acceptable range. Table 7 shows the possible values and interpretation for this parameter.

Table 7. Device Diagnostic Screen Status Readings for Lead Impedance

Lead Impedance Status Reading	Significance
OK	Impedance is within acceptable operating range.
HIGH	Impedance is higher than expected. Indicates a possible discontinuity of the Lead, or fibrosis between the nerve and Lead.
UNKNOWN	Impedance cannot be assessed. Reprogram the Pulse Generator for parameters in the ranges noted in Table 10.
LOW	Impedance is lower than expected. Indicates a possible circuit condition with the lead or a defective Pulse Generator

10. **DC-to-DC Converter:** On the Models 100, 101, and 102 Pulse Generators, this parameter is used in conjunction with Lead

Impedance to assess how hard the device has to work to deliver a selected output current, or how much the flow of current is impeded (see Table 8, and Table 9). This parameter is not displayed for Models 103, 104, and 105.

Table 8. DC-DC Converter Codes and Lead Impedance (Model 100, SN ≥10,000)

DC-DC Converter Code	Estimated Lead Impedance (1mA, 500 μsec)
0	< 0.8 kOhms
1	0.8–2 kOhms
2	2–4 kOhms
3	4–6.5 kOhms
4	6.5–10 kOhms
5	10–16 kOhms
6	16–20 kOhms
7	> 20 kOhms

Table 9. DC-DC Converter Codes and Lead Impedance (Model 101)

DC-DC Converter Code*	Estimated Lead Impedance (1mA, 500 μsec)
0	≤1.7 kOhms
1	1.8-2.8 kOhms
2	2.9-4.0 kOhms
3	4.1-5.2 kOhms
4	5.3-6.5 kOhms
5	6.6-7.7 kOhms
6	7.8-8.9 kOhms
7	≥ 9 kOhms

* See the physician's manual for the Pulse Generator for details.

Table 10. DC-DC Converter Codes and Lead Impedance (Model 102)

DC-DC Converter Code*	Estimated Lead Impedance (1mA, 500 μsec)
0	≤1.7 kOhms
1	1.8-2.8 kOhms
2	2.9-4.0 kOhms
3	4.1-5.2 kOhms
4	5.3-6.5 kOhms
5	6.6-7.7 kOhms
6	7.8-8.9 kOhms
7	≥ 9 kOhms

11. **Impedance Value:** On the Models 103, 104, and 105 Pulse Generators, this parameter indicates the actual lead impedance value measured during the execution of the diagnostic test. This parameter is not displayed for the Models 100, 101, and 102.
12. **Intensified Follow-up Indicator (IFI):** This indicator is only applicable for Models 103, 104 and 105 Pulse Generators. When the IFI is No, the battery level is good and no special attention is required. When the IFI is Yes, the battery has depleted to a level where more frequent clinical monitoring is recommended. The Programming Software also displays a warning message when the IFI is set to "Yes" to notify the user (see Figure 7 on page 18).
13. **Near End of Service (Near EOS/N EOS):** This indicator applies to all models Pulse Generators. The Programming Software displays a warning message if it detects a near End of Service indicator of "Yes" (see Figure 6 on page 17). When this message is displayed, LivaNova recommends performing a System Diagnostics Test to verify the Near EOS status for the Models 100, 101, 102 Pulse Generators. If Near EOS is confirmed, it is recommended that the Pulse Generator be replaced as soon as possible. Similarly, for the Model 103, 104, and 105 Pulse Generators, the Programming Software will also display a warning message for near End of Service (N EOS) (see Figure 8 on page 18). For these models, no additional testing is necessary to confirm the N EOS status and LivaNova recommends that the Pulse Generator be replaced as soon as possible.



Caution: Battery depletion may occur between visits and may not be detected by the various battery indicators. Therefore, LivaNova recommends daily magnet activation by the patient as the primary test for battery depletion for patients with magnet activation enabled.

14. **End of Service (EOS):** This indicator is only applicable for Models 103, 104 and 105 Pulse Generators. When the Pulse Generator has reached EOS, it is no longer supplying stimulation and immediate replacement is recommended. The Programming Software will display a warning message to the user indicating EOS status (see Figure 9 on page 19). If the Pulse Generator is not replaced, it will eventually lose the ability to communicate with the Programming Software.

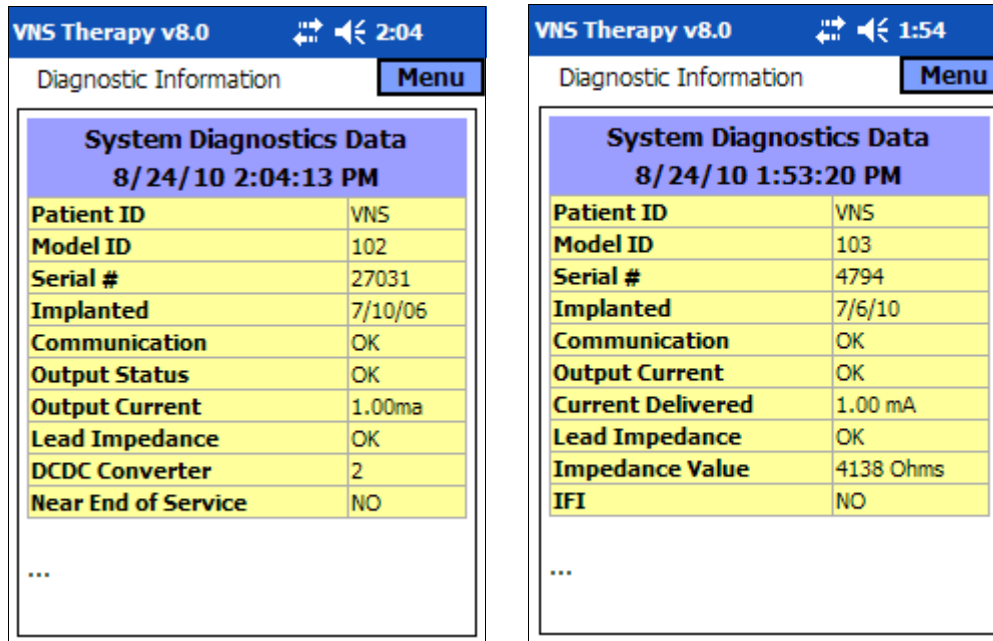
4.2.2.3. System Diagnostics

The System Diagnostics (as shown in Figure 23 on page 40), which LivaNova recommends you perform before other tests, is performed with the Bipolar Lead and the Pulse Generator connected. A successful System Diagnostics during surgery shows that both components are working properly. Test failure may be due to defects of either of the components or a faulty electrical connection between the Pulse Generator and the Bipolar Lead connector pins. If a defective component is suspected, disconnect the Bipolar Lead and perform the Generator Diagnostics (Pulse Generator Test) using the resistor assembly supplied with the Pulse Generator (see Figure 26 on page 43).

A successful Generator Diagnostics (Pulse Generator Test) confirms that the Pulse Generator is functioning properly, independent of the Bipolar Lead. For a failed Generator Diagnostics, see “Troubleshooting ” on page 61.

If either component is defective or damaged, contact LivaNova and return the item (following the disinfection procedure described in the physician's manual for the VNS Therapy Pulse Generators) with a completed Returned Product Form.

Figure 23. SYSTEM DIAGNOSTICS Screen



Models 100, 101, 102

Models 103, 104, 105



Caution: For Models 100, 101, and 102 Pulse Generators, avoid performing the System Diagnostics on Pulse Generators for which the output current is normally less than 1 mA because the patient may experience increased sensation, coughing, a flushed face, or other adverse effects. See the physician's manual for the VNS Therapy Pulse Generators for a complete list of possible adverse events.



Caution: During a System Diagnostic for Model 103, 104, and 105 Pulse Generators, a test pulse of 0.25 mA is first used to assess the Lead impedance. After the Impedance assessment, the behavior of the diagnostic test is dependent upon the value of the output current programmed in the Pulse Generator. If the output current is set to 0.0 mA, the diagnostic test is run with an output current of 1.0 mA, a pulse width of 500 μ sec, and a frequency of 20 Hz. If the output current is programmed greater than 0.0 mA, the diagnostic test is run at the programmed settings.

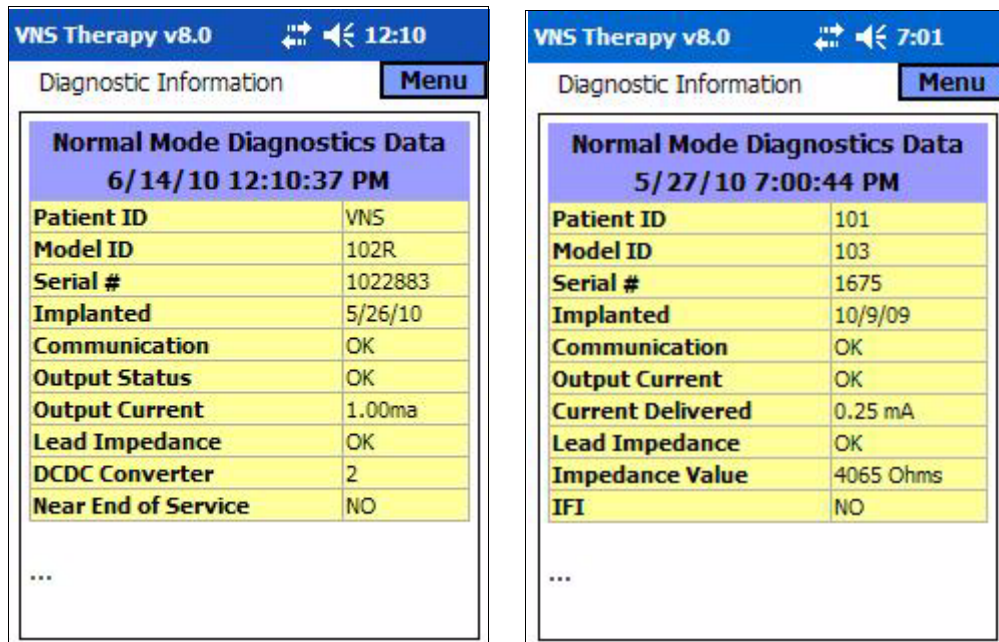
4.2.2.4. Normal Mode Diagnostics

The Normal Mode Diagnostics test indicates whether or not the device (Models 100, 101, and 102) is able to deliver the programmed output current (see Figure 24). The test should be performed routinely at follow-up visits if the patient can tolerate an output current of at least 0.75 mA. Results for this test are generally not reliable if the output current is programmed to less than 0.75 mA, frequency to less than 15 Hz, or ON time to less than 30 sec.

If Normal Mode test results indicate high lead impedance, a System Diagnostics can aid in diagnosing the cause. An output status reading of "LIMIT" for the Normal Mode Diagnostics indicates that the programmed output current is not being delivered. Possible reasons for failure to deliver the programmed output current include high lead impedance and low battery voltage.

For Models 103, 104, and 105 Pulse Generators, performing a Normal Mode Diagnostics is the same as performing System Diagnostics. All parameters are acceptable. If the output current is programmed to 0.0 mA, the generator will only produce one pulse of 0.25 mA in order to assess the lead impedance.

Figure 24. NORMAL MODE DIAGNOSTICS Screen



Models 100, 101, 102

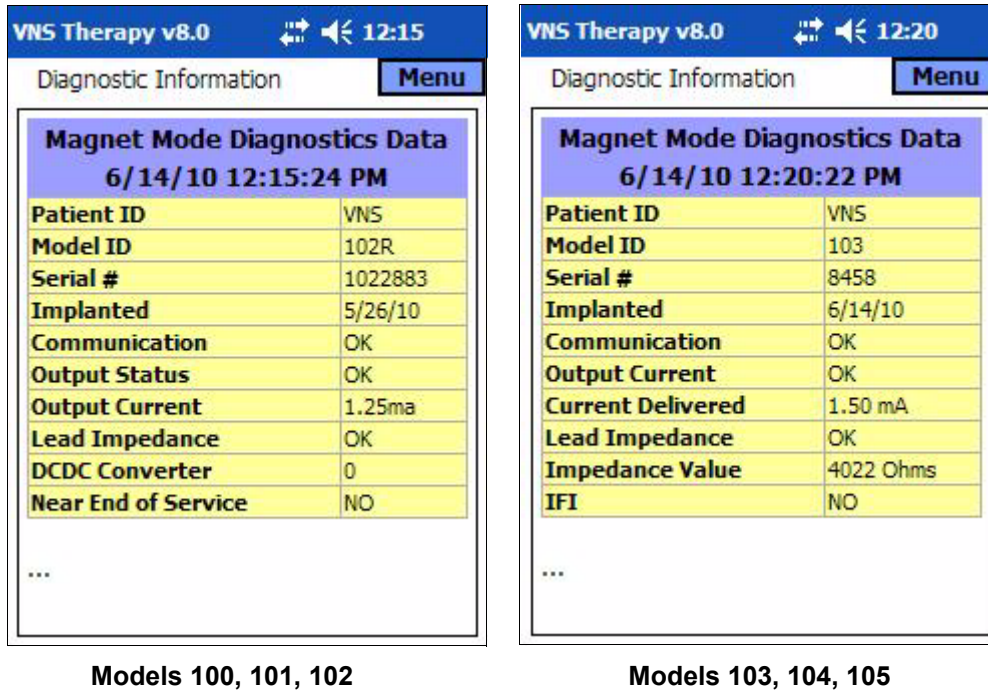
Models 103, 104, 105

4.2.2.5. Magnet Mode Diagnostics

The Magnet Mode Diagnostics test is similar to the Normal Mode test (see Figure 25 on page 42). This test determines whether the device is delivering the programmed magnet output current. While performing the Magnet Mode Diagnostics test, hold the magnet over the Pulse Generator for at least one second, immediately remove it from the area, and quickly place the Programming Wand over the Pulse Generator. This action, described in greater detail in the section entitled "Initiating Stimulation with a Magnet" of the physician's manual for the VNS Therapy Pulse Generators, enables output current stimulation. If this action is not performed correctly the Magnet Mode Diagnostics test will be invalid and

a message stating that the magnet swipe was not detected will be displayed for all Model Pulse Generators. In addition, the message "Magnet Mode Standby" will be displayed at the top of the screen for the Models 100, 101, and 102 Pulse Generators.

Figure 25. MAGNET MODE DIAGNOSTICS Screen



To obtain accurate information on Models 100, 101, and 102 Pulse Generators from the device diagnostics, program the Pulse Generator to values shown in Table 11 for both normal and magnet modes.

Table 11. Minimum Normal Mode and Magnet Mode Diagnostic Settings (Models 100, 101, and 102)

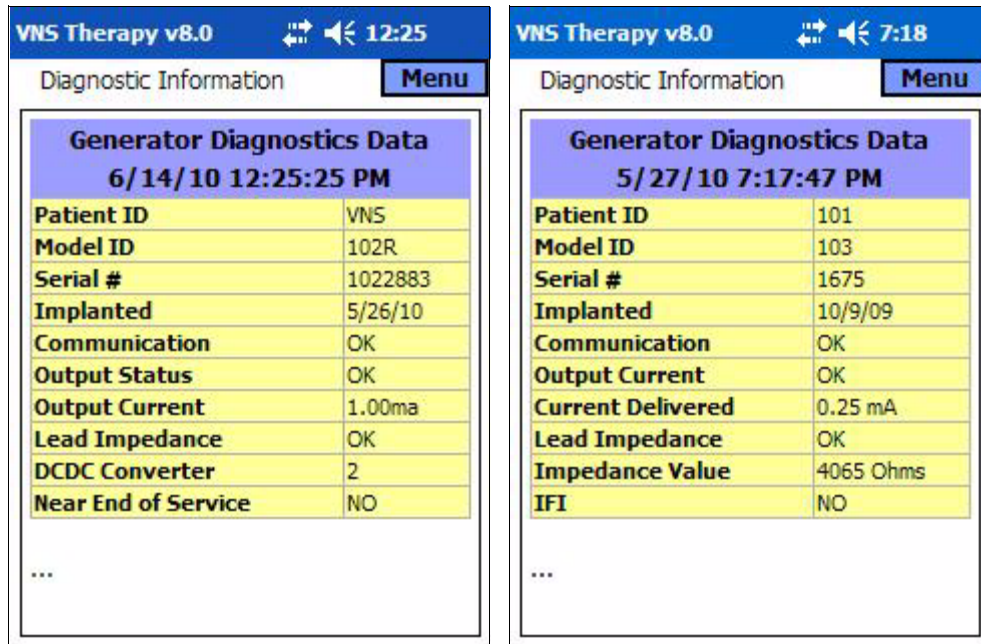
Output Current / Magnet Current	0.75 mA
Frequency	15 Hz
Signal / Magnet ON Time	30 sec

4.2.2.6. Generator Diagnostics

The optional Generator Diagnostics (Pulse Generator Test), as shown in Figure 26 on page 43, is performed when the System Diagnostics fails during the surgical implant procedure.

Note: See “System Diagnostics” on page 39.

Figure 26. GENERATOR DIAGNOSTICS Screen



Models 100, 101, 102

Models 103, 104, 105

For the Models 100, 101, 102 Pulse Generators, if the Generator Diagnostics (Pulse Generator Test) is successfully completed, the output current will automatically be programmed to 0 mA.

For the Models 103, 104, and 105 Pulse Generators, if the Generator Diagnostics (Pulse Generator Test) is successfully completed, the output current will remain as programmed. If the Pulse Generator is programmed to 0.0 mA, the Generator Diagnostics will report the 0.25 mA pulse used to access the impedance, but the programmed current will remain at 0.0 mA.



Caution: For the Models 100, 101, and 102 Pulse Generators, during both the **System Diagnostics** and the **Generator Diagnostics** (Pulse Generator Test), the Programming Software automatically programs the output current to 1.0 mA, the pulse width to 500 µsec, and the frequency to 20 Hz.



Caution: During a System Diagnostic for Model 103, 104, and 105 Pulse Generators, a test pulse of 0.25 mA is first used to assess the Lead impedance. After the Impedance assessment, the behavior of the diagnostic test is dependent upon the value of the output current programmed in the Pulse Generator. If the output current is set to 0.0 mA, the diagnostic test is run with an output current of 1.0 mA, a pulse width of 500 µsec, and a frequency of 20 Hz. If the output current is programmed greater than 0.0 mA, the diagnostic test is run at the programmed settings.



Caution: For Models 103, 104, and 105 Pulse Generators, during the **Generator Diagnostics** on a device with the output current set to 0.0 mA the Programming Software will deliver only a 0.25 mA pulse to assess the impedance value. If the device output is programmed greater than 0.0 mA, the Pulse Generator will deliver a 0.25 mA pulse followed by stimulation at programmed settings.



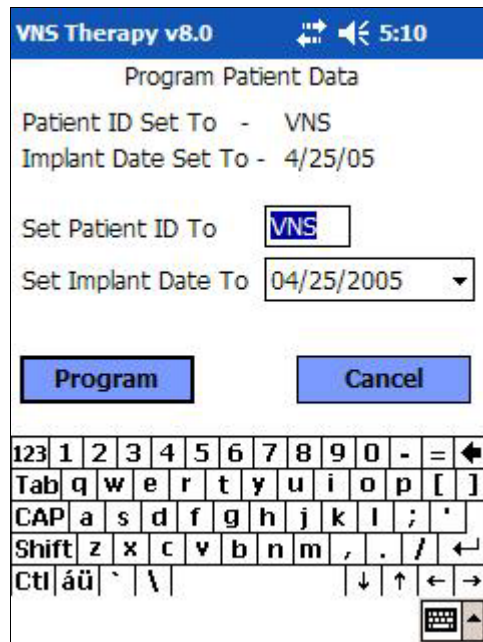
Caution: For Models 100, 101, and 102 Pulse Generators, if either the System Diagnostics or the Generator Diagnostics is interrupted, the output current may be left at 0 mA or 1 mA. See “Interrupted System and Generator Diagnostics” on page 31.

4.2.3. Program Patient Data screen

A three-character patient identification code (to be selected by the physician) and the implant date become a permanent part of the Device History when they are programmed into the Pulse Generator.

To enter the Patient ID and implant date, first select the Program Patient Data button on the PARAMETER Screen Menu. The PROGRAM PATIENT DATA Screen will appear, as shown in Figure 27 on page 44. Enter the Patient ID by tapping the Set Patient ID To field and then typing the ID on the soft keyboard at the bottom of the screen.

Figure 27. PROGRAM PATIENT DATA Screen



The implant date can be entered by tapping the downward-pointing arrow in the Set Implant Date To button and then tapping the right- or left-pointing arrows to scroll to the appropriate month and year. As you tap the

correct day for that month and year, the calendar closes and the selected month/day/year is entered into the button.

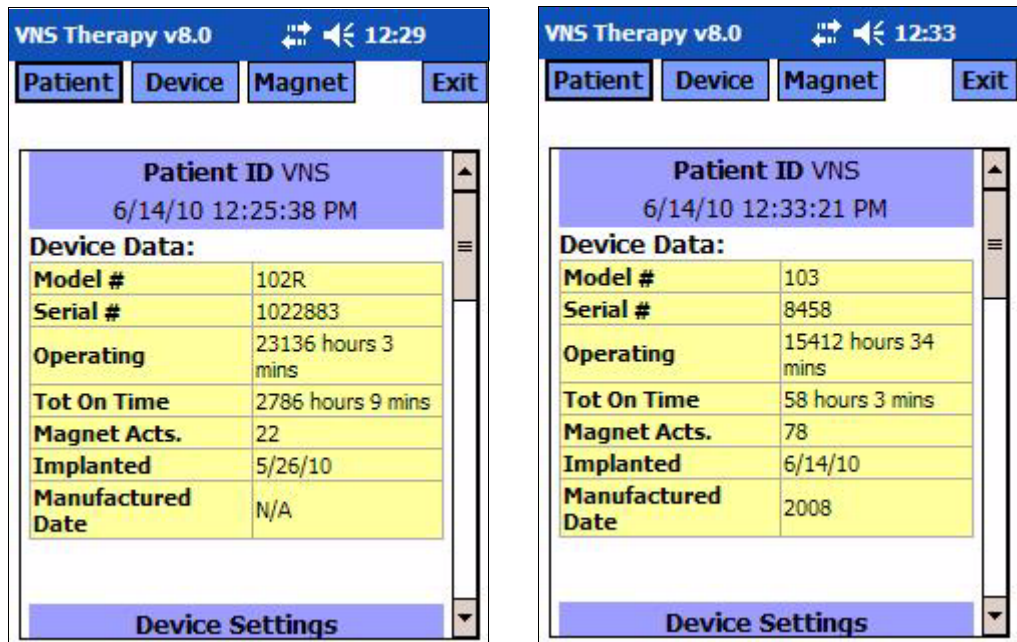
You can also enter the date by tapping on the digits representing the month/day/year and entering the new values on the soft keyboard.

After entering the data, tap the Program button, then tap the Start Programming button. Tapping the Cancel button will return you to the PARAMETER Screen.

4.2.4. Display Device History screen

When you tap the Display Device History button, the DEVICE HISTORY Screen will be displayed, as shown in Figure 28 on page 45. Via this screen you can access Patient data, Device data, and the 15 most recent Magnet activations. For Models 100, 101, and 102 Pulse Generators the Manufactured Date parameter is shown as N/A.

Figure 28. DEVICE HISTORY Screen



Models 100, 101, 102

Models 103, 104, 105

To see all the information contained on this screen, use the scroll bar on the right edge of the screen. Tapping the Patient, Device, or Magnet buttons also causes the respective patient, device, or magnet data to be displayed.

4.2.5. View Database screen

You can view the database by tapping View Database from either the MAIN Menu or the PARAMETER Screen Menu. For more information regarding the VIEW DATABASE function, see “View Database” on page 47.

4.2.6. Close Menu

Tapping **Close Menu** closes the PARAMETER Screen Menu and returns you to the PARAMETER Screen.

4.2.7. Main Menu

Tapping **Main Menu** closes the PARAMETER Screen and returns you to the MAIN Menu.

4.2.8. Handheld computer battery status

The bars at the bottom of the PARAMETER Screen menu and the USER PREFERENCES screen indicate the battery status on the handheld computer. When the handheld computer is operating on battery power this power bar status should be checked regularly so as to prevent a loss of power.



Caution: When in use, LivaNova recommends the handheld computer be operated on battery power only (unplugged from AC power). Having the handheld computer plugged into AC power during use may contribute to communication difficulties. When not in use, the handheld computer should be plugged into AC power to maintain charge.

5. VIEW DATABASE ---

Each successful interrogation and programming event is recorded in the database of the handheld computer.

Likewise, every time a magnet is successfully used to initiate activation of a Pulse Generator, the event is recorded in the database of the Pulse Generator. During an interrogation, the total number of magnet events (as well as the date and approximate time of the last 15 magnet events) will be copied from the Pulse Generator to the database of the handheld computer.

Historical programming events (including the latest) can be viewed using either of two methods:

1. Tap the **View Database** button on the PARAMETER Screen Menu
2. Tap the **View Database** button on the MAIN Menu

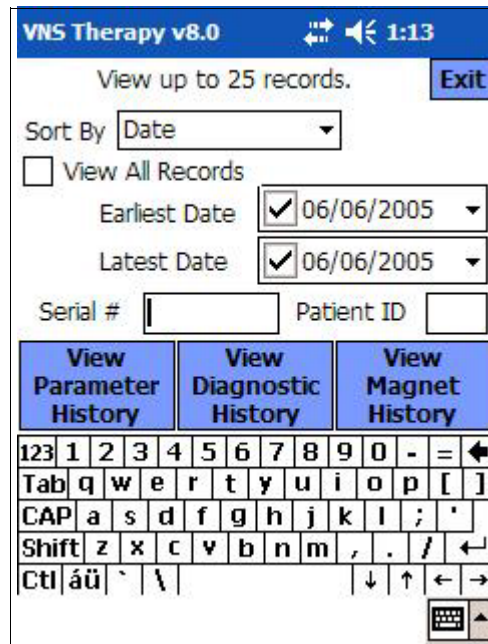
The VIEW DATABASE Screen will be displayed, as shown in Figure 29 on page 48.

5.1. Specify Search Limits

Before you actually view patient information records in the database, determine whether you want to:

1. Sort the retrieved records by **Date**, **Patient ID**, or the **Serial Number** of the Pulse Generator
2. **View All Records** in the database or limit your search to a particular **Patient ID**, Pulse Generator **Serial Number**, and/or time period (using the **Earliest Date** and **Latest Date** buttons)
3. View a Parameter History, Diagnostic History, or Magnet History

Figure 29. VIEW DATABASE Screen



The message at the top of the screen indicates that only 25 records can be retrieved at a time. (That value can be changed to 50, 75, or 100 by selecting the **User Preferences** button from the MAIN Menu.)

5.1.1. Sort by Date, Patient ID, or Serial Number

To indicate whether you want to sort by Date, Patient ID, or the Serial Number of the Pulse Generator, tap the Sort By field. A drop-down menu lets you indicate your choice.

Tapping Date arranges chronologically the records you retrieve. Tapping Patient ID arranges records by ascending Patient ID codes. Tapping Serial Number arranges the records by ascending Pulse Generator serial numbers.

5.1.2. View All Records

Selecting View All Records allows you to view all the records in the database up to the limit set in the USER PREFERENCES Screen. The highest limit you can set is 100. If there are more than 100 records in the database, you must define the limits of your search using the Earliest Date and Latest Date buttons, the Serial Number button, and/or the Patient ID button.



Note: See “User Preferences Screen ” on page 54.

Note that selecting View All Records causes the buttons entitled Earliest Date and Latest Date, Patient ID and Serial Number to be disabled (or “grayed out”).

5.1.3. Earliest Date/Latest Date

Make sure the View All Records button is unchecked or you won't be able to use the date option. When you use the date option, the default for both the Earliest Date and Latest Date buttons is the current date. To see records from other dates, change the settings in these fields.

Tapping the drop-down arrow to the right of the Earliest Date (or Latest Date) displays a calendar of the current month. To scroll to earlier or later months, tap (or touch and hold) the small black arrows in the upper left- or right-hand corners. Tapping the day of the month representing the earliest (or latest) date closes the calendar and puts the dates you tapped into the Earliest Date and Latest Date buttons.

Dates can also be changed by tapping the month, day, or year values you want to change and then typing the new values on the soft keyboard at the bottom of the screen.

5.1.4. Patient ID

Make sure the View All Records button is unchecked or you won't be able to use the Patient ID option. To limit your search to a particular patient, tap the Patient ID button and enter the three-character patient ID code by typing it on the soft keyboard at the bottom of the screen. You should have previously defined the patient ID.

5.1.5. Serial Number

Make sure the View All Records button is unchecked or you won't be able to use this option. To limit your search to a particular Pulse Generator, tap the Serial Number button and then type the serial number of the Pulse Generator on the soft keyboard at the bottom of the screen.

5.2. View the Records

Now that you have specified limits for your record search, you can retrieve and view historical records stored in the handheld computer's database, as described in the following sections.

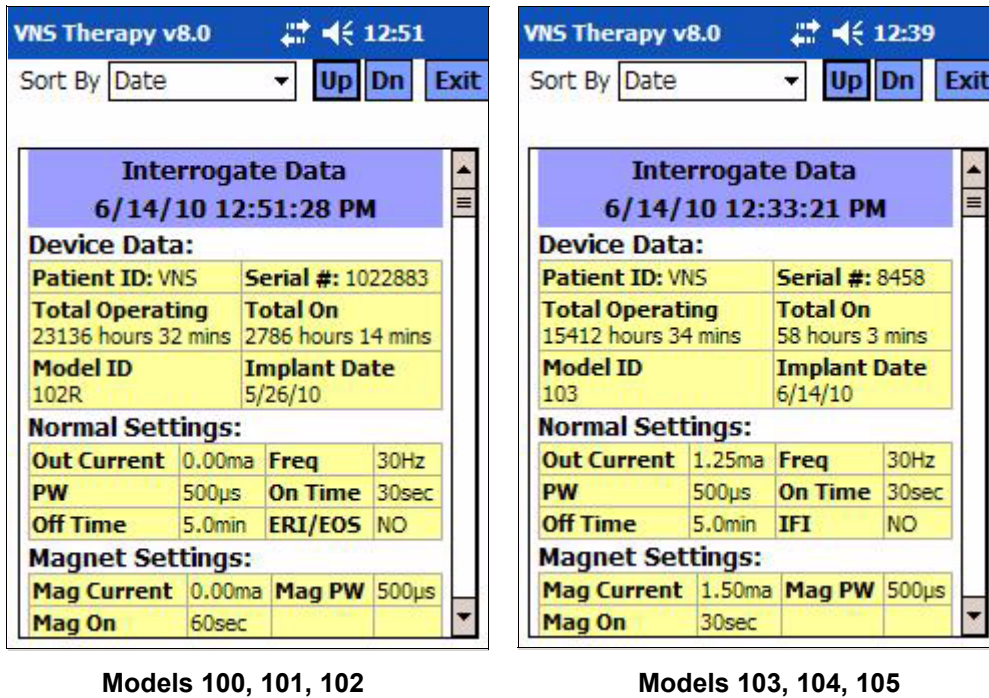
5.2.1. View Parameter History

Tap the View Parameter History button to access the VIEW PARAMETER HISTORY Screen (see Figure 30 on page 50).



Note: See “Program Patient Data screen” on page 44.

Figure 30. VIEW PARAMETER HISTORY Screen

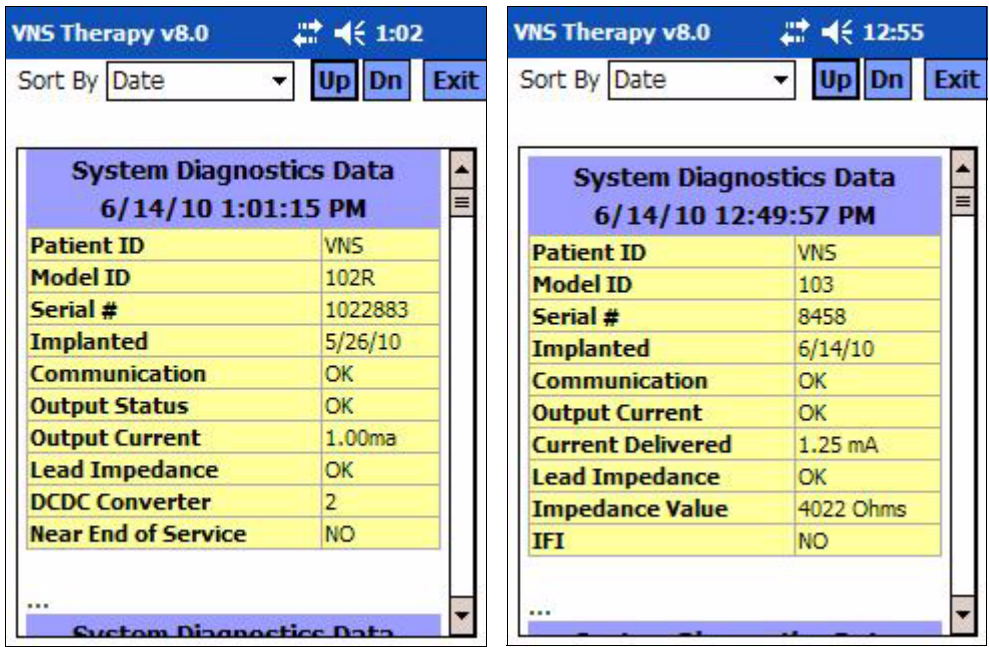


This screen is a scrollable screen that shows the parameter settings for each successful interrogation, programming event, and/or partial programming event. The scroll bar on the right allows you to view all the records you choose to access. The **Up** and **Dn** buttons at the top of the screen allow you to “page up” or “page down” from record to record. By indicating your preference from the drop-down menu at the top of the screen, you again have the choice to sort the records by Date, Patient ID, or Pulse Generator Serial Number.

5.2.2. View Diagnostic History

Tap the **View Diagnostic History** button to access the VIEW DIAGNOSTIC HISTORY Screen (see Figure 31 on page 51).

Figure 31. VIEW DIAGNOSTIC HISTORY Screen



Models 100, 101, 102

Models 103, 104, 105

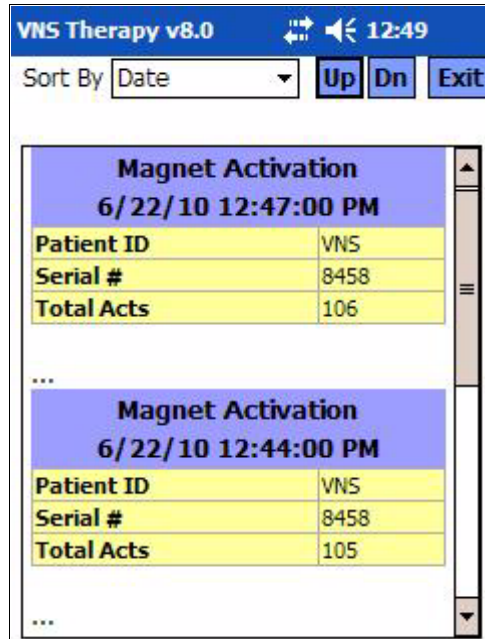
Note: The four diagnostic tests are Normal Mode, Magnet Mode, Generator Diagnostics (Pulse Generator Test), and System Diagnostics. These diagnostics are performed by selecting the **Device Diagnostics** button from the PARAMETER Screen Menu.

The VIEW DIAGNOSTIC HISTORY Screen is a scrollable screen that shows the Device Diagnostics that have been performed. By indicating your preference from the drop-down menu at the top of the screen, you can choose to sort the data according to Date, Patient ID, or Serial Number.

5.2.3. View Magnet History

Tap the **View Magnet History** button to access the VIEW MAGNET HISTORY Screen (see Figure 32).

Figure 32. VIEW MAGNET HISTORY Screen

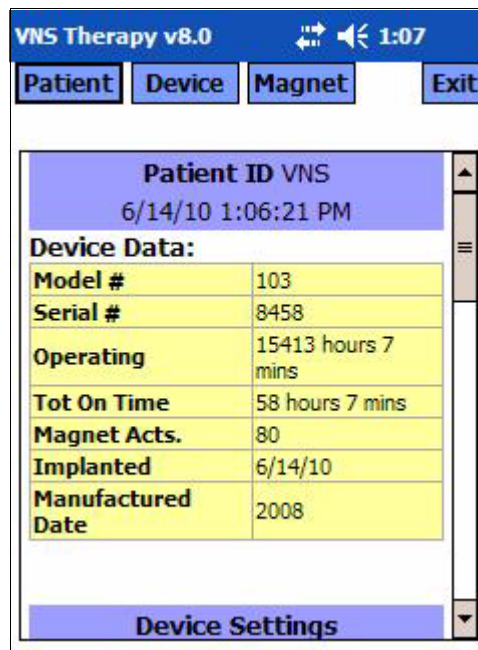


The VIEW MAGNET HISTORY Screen is a scrollable screen that shows a history of Magnet Activations of the Pulse Generator. You can sort these events by Date, Patient ID, or the Pulse Generator Serial Number by indicating your preference from the drop-down menu at the top of the screen.

6. VIEW LAST PARAMETERS

You can view the parameter settings from the most recent Pulse Generator interrogation via the VIEW LAST PARAMETERS Screen (see Figure 33 on page 53). This screen can be accessed from the MAIN MENU screen.

Figure 33. VIEW LAST PARAMETERS Screen



Tapping the Patient, Device, or Magnet buttons causes the respective patient, device, or magnet data to be displayed. Using the scroll bar on the right-hand side of the device can also access the data.



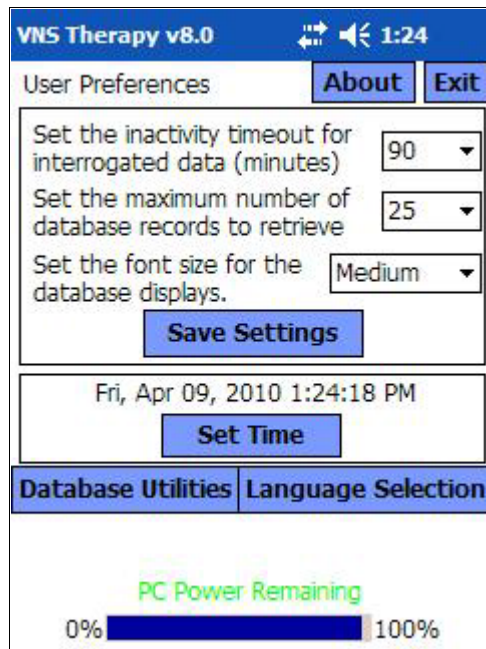
Caution: Magnet activation time-stamps and total activation counts may be duplicated for Model 105 Pulse Generator. See “Precautions ” on page 59 for more details.

For Model 105 Pulse Generator, using the cross pattern swiping technique for magnet activations may cause duplication in the magnet activation time-stamps and in the total magnet activation counts. Depending on Generator and Magnet orientation, one or two entries may be shown in the Magnet History data for each cross pattern swipe. This is an expected occurrence due to the Pulse Generator design and is not considered a device malfunction. For more information, see the Pulse Generator Physician's and Patient's manuals.

7. USER PREFERENCES SCREEN

Eight functions can be accessed from the USER PREFERENCES Screen (see Figure 34). This screen can be accessed via the MAIN MENU screen.

Figure 34. USER PREFERENCES Screen



7.1. Set Timeout

By tapping the drop-down menu to the right of *Set the activity timeout for interrogated data (minutes)*, the timeout function can be set for intervals from 1 minute to 90 minutes. Turning the timer to OFF is also available. If the handheld computer is idle for the amount of time indicated in the button, the Pulse Generator must be reinterrogated before performing any programming.

Tap **Save Settings** after making changes to this button.

This function serves as a safety device to help prevent the possibility of accidentally programming a patient's Pulse Generator to the settings from a previous database inquiry or programming event. This is only applicable to Model 100, 101, and 102 Pulse Generators.

Note: See “Cross-programming (applicable to Model 100, 101, and 102 Pulse Generators ONLY)” on page 26.

7.2. Set Maximum Number of Records to View

By tapping the drop-down menu to the right of *Set the maximum number of database records to retrieve*, the number of records available to view can be limited to 25, 50, 75, or 100.

Tap **Save Settings** after making changes to this button.

This function allows you to decide how many records are convenient to work with at one time.

7.3. Set the Font Size for Database Displays

By tapping on the drop-down menu to the right of *Set the font size for the database displays*, the type size of the various diagnostics screens can be set to Small, Medium, or Large. The type may be easier to view in a large size, but less information will be visible at a time; nevertheless, you'll still be able to scroll down to view all the information.

Tap **Save Settings** after making changes to this button.

7.4. Set Time and Date

Tap on the **Set Time** button to reset the date and time. Tapping the drop-down arrow to the right of the System Date displays a calendar of the current month. To scroll to earlier or later months, tap (or touch and hold) the small black arrows in the upper left- or right-hand corners. Tapping the day of the month for the current date closes the calendar and puts the date you tapped into the System Date button.

Setting the System Time is a slightly different process. Tap the digits representing hour, minute, or second to reset each of those values. Tapping the first two digits (the hour value) causes the hour setting to be highlighted. You can then tap (or touch and hold) the upward-pointing arrow to advance the hour setting. Tapping (or touching and holding) the downward-pointing arrow decreases the value. Repeat these steps for the minute and second values. Then select AM or PM.

When you are satisfied that the current date and current time are correctly represented on the screen, tap **Accept Changes** to set the date and time.

The accuracy of the displayed System Date and System Time determines the accuracy of the dates and time in the magnet history records.

7.5. Backup to FlashCard

Tap **Database Utilities** to access the FlashCard functions. The **Backup to FlashCard** function backs up the database in the handheld memory to the FlashCard. You may never need to use this function because a backup occurs every time a function is performed. You might use this function if your FlashCard is misplaced (or damaged) and a new one is installed.

7.6. Restore from FlashCard

This feature is not recommended by LivaNova in typical use conditions because database restoration occurs automatically. You could use this function to overwrite your existing database when transferring a database from another handheld computer to your handheld computer. However, if this is to be performed, the handheld computer from which the database is being transferred from **MUST** have the same underlying Operating System and the same version and build Programming Software as your handheld computer. Otherwise database corruptions (SQL errors) may occur.



Caution: The **Restore from FlashCard** function, also accessible from Database utilities, overwrites the database on the handheld computer with the database contained on the FlashCard. In other words, the original database will be erased.

7.7. Export Database to Text File

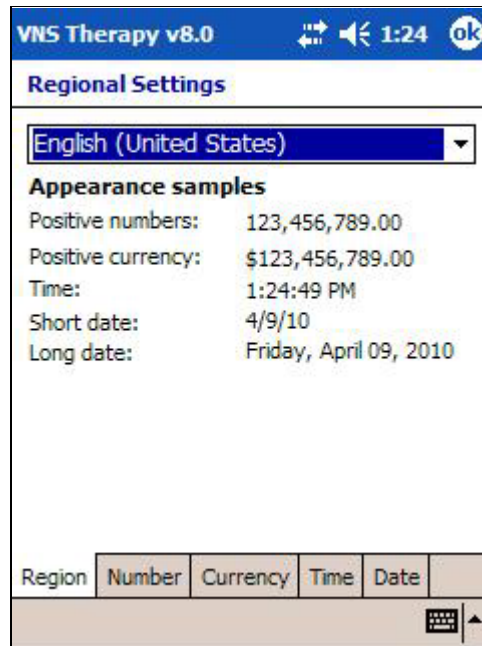
The user can use this function to export a Comma Separated Value (CSV) text file to the Flashcard. From the Database Utilities screen, tap the EXPORT DATABASE as TEXT button to export the data. Once data has been exported, view the CSV text file by removing the Flashcard and inserting it into a FlashCard reader. The feature saves the database information to three files:

- PIExport – contains all of the Interrogation and Programming events.
- DiagExport – contains all of the Diagnostics events.
- MagExport – contain all of the Magnet history data.

7.8. Language Selection

The **Language Selection** button on the USER PREFERENCES screen, when enabled, can be used to select the language preference for screen displays (see Figure 35 on page 57).

Figure 35. LANGUAGE SELECTION Screen



7.9. Handheld Computer Battery Status



Caution: When in use, LivaNova recommends the handheld computer be operated on battery power only (unplugged from AC power). Having the handheld computer plugged into AC power during use may contribute to communication difficulties. When not in use, the handheld computer should be plugged into AC power to maintain charge.

The bar at the bottom of the screen indicates the percentage of the battery charge still available on the handheld computer. When the handheld computer is operating on battery power the bar should be checked regularly to prevent a loss of power.

8. MAINTENANCE, HANDLING, AND STORAGE_

The FlashCard should be handled and stored in the standard manner for computer disks. Although no component of the VNS Therapy System will withstand rough handling or abuse, no unusual handling precautions are necessary.



Caution: The FlashCard should never be stored near a magnet and should always be left in the handheld computer.

9. PRECAUTIONS ---

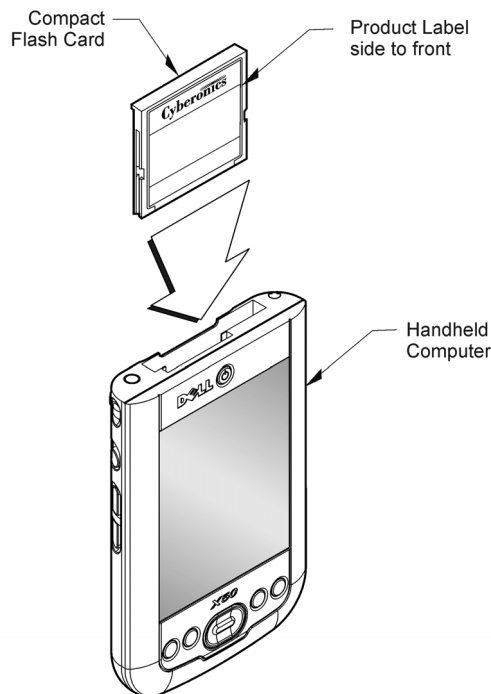
If problems occur with the Programming Software, review the information in this section:

- When in use, LivaNova recommends the handheld computer be operated on battery power only (unplugged from AC power). When not in use, the handheld computer should be plugged into AC power to maintain charge.
- LivaNova recommends that no other software be loaded onto the VNS Therapy System computer because it may interfere with proper functioning of the software already installed on the handheld computer.
- For Models 100, 101, and 102 Pulse Generators, if the **System Diagnostics** or **Generator Diagnostics** is interrupted, the output current may be left at 0 mA or 1 mA. See “Interrupted System and Generator Diagnostics” on page 31.
- The Pulse Generator stores a value representing the total number of magnet activations. It also stores the date and time of the previous 15 magnet activations (provided the date and time settings on the handheld are correct). Therefore, only the 15 most recent magnet activations will be stored in the database at each follow-up visit.
- Detecting EMI is possible only while the Programming Wand is turned on (indicated by the green “POWER” light). If the green light stops shining before the EMI source has been located, turn on the Programming Wand again. If EMI or other electrical noise is detected, the yellow DATA/RCVD light will come on and remain on as long as the Programming Wand is in the presence of an EMI signal. Programming in an area with EMI can be difficult or impossible, but problems can usually be resolved by repositioning the patient, the Programming Wand, or the EMI source.
- For Models 100, 101, and 102, in the **VIEW MAGNET HISTORY Screen**, only the hour of the magnet activation is shown. Although there are spaces for minutes and seconds, the software will not display those values.
- For Model 105 Pulse Generator, using the cross pattern swiping technique for magnet activations may cause duplication in the magnet activation time-stamps and in the total magnet activation counts. Depending on Generator and Magnet orientation, one or two entries may be shown in the Magnet History data for each cross-pattern swipe. This is an expected occurrence due to Pulse Generator design and is not considered a device malfunction. For more information, see the Pulse Generator Physician's and Patient's manuals.
- For Model Pulse Generators previously programmed to a treatment time per day of less than 24 hours (using earlier Versions of the Programming Software), attempts to interrogate the Pulse Generator

will bring up a warning screen. This warning screen provides instructions should communication with the Pulse Generator become impossible. It also serves as notification that the next time the Pulse Generator is programmed, treatment time per day will automatically be set to 24 hours per day.

- Treatment time per day and treatment start delay time are *nonprogrammable*.
- Version 8.0 VNS Programming Software does not support the Model 100B Pulse Generator and the Model 200 Programming Wand. If a handheld computer is upgraded to Version 8.0 VNS Programming Software from a previous version of VNS Programming Software, previous records of Model 100B will not be completely transferred. The parameter setting information will be available, but the model number will be blank, the serial number will be shown as ****, and the End of Service status will be shown as "No" instead of "N/A".
- Only use a serial cable provided by LivaNova.
- FlashCards are generally not interchangeable! Do not insert the FlashCard from one handheld computer into any other handheld computer, unless directed to do so by LivaNova Clinical Technical Support.
- FlashCards should only be inserted in the handheld computer with the label side up. Figure 36 shows the correct orientation for FlashCard insertion.

Figure 36. Correct FlashCard Orientation



10. TROUBLESHOOTING ---


This section provides troubleshooting instructions in four parts: (1) general recommendations, (2) hardware issues, (3) problems in the Operating Room (OR) and (4) problems at patient follow-up visits.


10.1. General Recommendations

10.1.1. *Non-responsive Handheld Computer*

If the handheld computer becomes non-responsive to user input, you may perform the following steps to perform a hard reset of the handheld to resolve the problem.

1. Plug in the handheld computer into the A/C outlet.
2. Verify that the FlashCard is fully seated in the handheld computer. For Dell x50 handheld computers, verify also that the Screen Lock button on the side of the handheld is not set.
3. Press the **reset** and the **power** buttons simultaneously for at least 5 seconds.
4. When prompted, follow on-screen instructions to clear all data in the memory.

 **Note:** See the “Handheld Computer Connection Instructions” for the location of the reset button.

 **Note:** This operation only clears the data in the temporary memory of the handheld device and does NOT affect the VNS patient/programming data.

5. Follow the screen messages to tap cross-hair targets to realign the screen, tap the box labeled **Next**, and perform an exercise that shows you how to highlight, cut, and paste using the stylus. As these instructions are completed, the application software will reinstall and restore your transaction database.
6. As soon as the software and database are restored, a Cyberonics screen will appear. Check the time and date on the screen under "Cyberonics". If this is not correct, select **Set Time** and follow the prompts to reset the date and time. If this is correct, tap **Continue** to access the MAIN Menu.
7. Verify that the handheld has adequate charge and unplug the handheld computer from the A/C outlet prior to resuming use with the programming system.

If you are still not able to restore the database or reinstall the application software, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

10.2. Hardware Issues

10.2.1. *Restore and reinstall software*

The VNS Programming Software is contained on the FlashCard inside the handheld computer. When the battery in your handheld computer becomes depleted, the handheld computer will perform a hard reset once power is restored and the Programming Software will automatically be restored from the FlashCard. For this reason the Flashcard should always reside in the handheld. If a hard reset occurs while the Flashcard is not inserted into the handheld, the computer will display the default Windows Startup screen after the hard reset. If this occurs, simply reinsert the Flashcard to automatically re-install the VNS Therapy Programming Software.

In order to keep the handheld from performing hard resets, it is important to keep the handheld charged even when the handheld is not in use. A database of VNS Therapy transactions performed on your handheld computer is stored both in the memory resident on the handheld computer and the FlashCard.

10.2.2. *Other hardware issues*

For all other hardware issues for the handheld computer, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

10.3. Troubleshooting in the OR

10.3.1. *Communication problems in OR*

A communication problem can cause the following error messages:

- “There is an error establishing communication with the device”
- “Failed to retrieve diagnostic data”
- “Generator failed to respond to programming initialization”
- “Failure in programming data sequence”
- “Invalid data was received from generator”

Failure of the Pulse Generator and Programming Wand to clearly communicate with each other to interrogate, program, or run diagnostic tests can be attributed to several factors:

- Depleted Programming Wand battery

- Movement of the Programming Wand away from the Pulse Generator during communication
- Improper cable connection between Programming Wand and Programming Computer
- Electromagnetic interference (EMI) i.e., OR lights, Programming Computer
- Pulse Generator battery at end of service (EOS)
- Defective Programming Wand
- Defective Programming Computer
- Defective Pulse Generator

Communication problems are often intermittent and are rarely related to the Pulse Generator. The surrounding environment typically causes these problems.

A communication problem causes an error message such as “data transmission error between programmer and device” during interrogation, when programming of parameters or implant date/patient code, or when receiving “FAULT” results on a diagnostic test. Performing these steps may restore communication (see Figure 37 on page 65).

1. Test the Model 201 Programming Wand battery. Briefly press and release the two red RESET buttons simultaneously, and then verify that the green POWER light comes on and stays on for approximately 25 seconds after the buttons are released. If it does not, the battery should be replaced. The Programming Wand uses one standard 9-volt alkaline battery, which is located in the handle of the Wand.
2. Verify that the Programming Wand is properly connected to the Programming Computer (see Programming Wand physician's manual for details):
 - a. Disconnect power cord from wall outlet.
 - b. Verify connection of Programming Wand cable and Programming Computer cable.
3. Verify the proper positioning of the Programming Wand over the Pulse Generator. Reposition the Programming Wand by rotating the handle 45 degrees in either direction (see Programming Wand physician's manual for detail).
4. Extend the Programming Wand cable and ensure that the Wand is 3 to 4 feet away from the Programming Computer.
5. If communication was possible before the Pulse Generator was inserted into the chest pocket, but is not possible with the Pulse Generator inside the pocket, verify that the pocket is not deeper than 1 inch beneath the skin and is not below muscle.
6. Verify that the programming problem is not a result of EMI from nearby electrical or magnetic equipment. Examples of possible sources of EMI are computer displays, portable telephones,

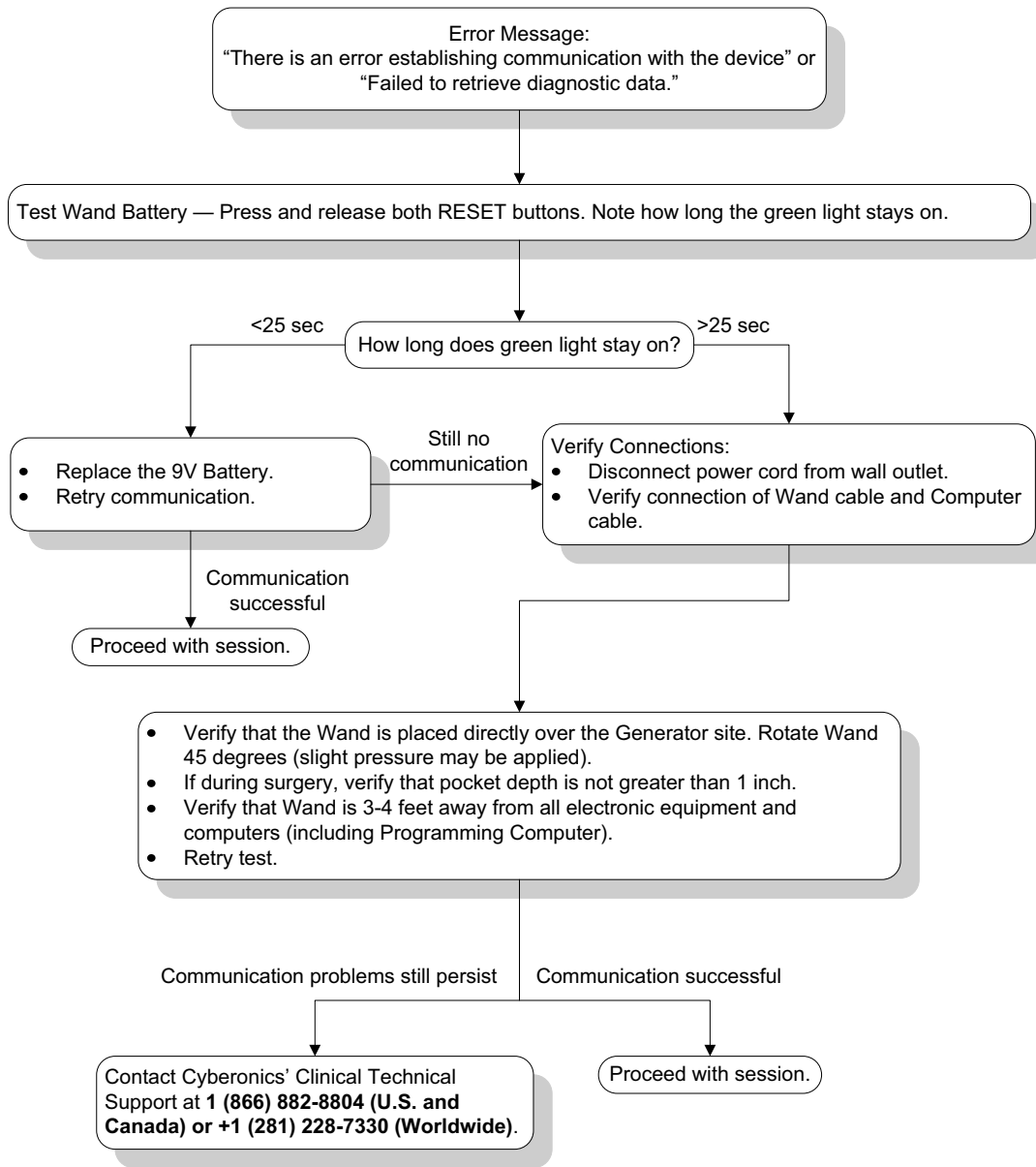
fluorescent lighting, OR lights, and magnetic pads for surgical instruments. To check for EMI, perform these steps.

- a. Press and release the red RESET button(s) on the Programming Wand. The green POWER light should stay on during EMI detection. When the green light turns off, press and release the RESET button(s) again.
 - b. Move the Programming Wand closer to the suspected equipment (Computer screen, OR lights, etc.).
 - ◆ If EMI is detected, the yellow DATA/RCVD light will come on and remain on while in the presence of EMI.
 - ◆ Programming, interrogating, or completing diagnostic tests in an area with EMI will be difficult or impossible. The problem can usually be resolved by repositioning the patient, the Programming Wand, or source of EMI.
7. Retry interrogation, diagnostic test, or programming.
 8. If problems persist, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).



Note: LivaNova recommends interrogating the Pulse Generator as the last step of any programming or diagnostic session to verify correct settings for each parameter.

Figure 37. Communication Problems in the OR and at Follow-up Visits



10.3.2. High Lead impedance on System Diagnostics in OR – initial implant

High Lead Impedance can cause the error message, “Impedance is higher than expected. Indicates a possible discontinuity of the lead, or fibrosis between the nerve and lead.” High Lead impedance in the OR can be attributed to several causes:

- Incorrect connection of the Pulse Generator and Lead
- Incorrect placement of the Lead on the nerve
- Allowing nerve to become dry
- Defective Lead
- Defective Pulse Generator

To alleviate the condition, perform these steps (see Figure 38 on page 69).

1. Reinsert the connector pin(s) into the Lead receptacle(s).
 - a. Back out the setscrew(s), remove the Lead pin(s), and leave the hex screwdriver engaged in the setscrew(s).
 - b. Verify that the setscrew(s) is not visible in the Lead receptacle(s).
 - c. Insert the connector pin(s) and tighten the setscrew(s) until the hex screwdriver clicks.
 - d. Visually inspect the Lead receptacle(s) and verify that the Lead pin(s) is past the back end of the connector block(s).
 - e. For the single-pin Model Pulse Generators, verify that the end of the Lead connector ring is inside the Lead receptacle.
 - f. Gently grasp and pull on the connector boot(s) to verify that the pin(s) is securely tightened.
2. Verify that the Lead electrode(s) has been correctly placed on the vagus nerve.
3. If nerve site is dry, irrigate nerve and remove pooled fluid.
4. Rerun the System Diagnostics.
5. If “HIGH” Lead impedance is still noted, perform these steps.
 - a. Remove the Lead connector pin(s) from the Lead receptacle(s).
 - b. Insert the connector pin(s) of the test resistor assembly into the Lead receptacle(s) in the Pulse Generator.
 - c. Tighten the setscrew(s) until the hex screwdriver clicks.
 - d. Perform the Generator Diagnostics.
6. If the Generator Diagnostics indicates “HIGH” Lead impedance, call LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).



Note: See the physician's manual for the Pulse Generator.

7. If the Generator Diagnostics indicates “OK” Lead impedance, perform these steps:
 - a. Back out the setscrew(s) and remove the test resistor.
 - b. Insert the Lead connector pin(s) into the Lead receptacle(s) in the Pulse Generator.
 - c. Tighten the setscrew(s) until the hex screwdriver clicks.
 - d. Perform the System Diagnostics.
8. If the System Diagnostics continues to indicate “HIGH” Lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

10.3.3. High Lead impedance on System Diagnostics in OR – Pulse Generator replacement

High Lead Impedance can cause the error message, “Impedance is higher than expected. Indicates a possible discontinuity of the lead, or fibrosis between the nerve and lead.” High Lead impedance in the OR during generator replacement can be attributed to several factors:

- Incorrect connection of the Pulse Generator and Lead
- Defective Lead
- Defective Pulse Generator

To alleviate the condition, perform these steps (see Figure 38 on page 69):

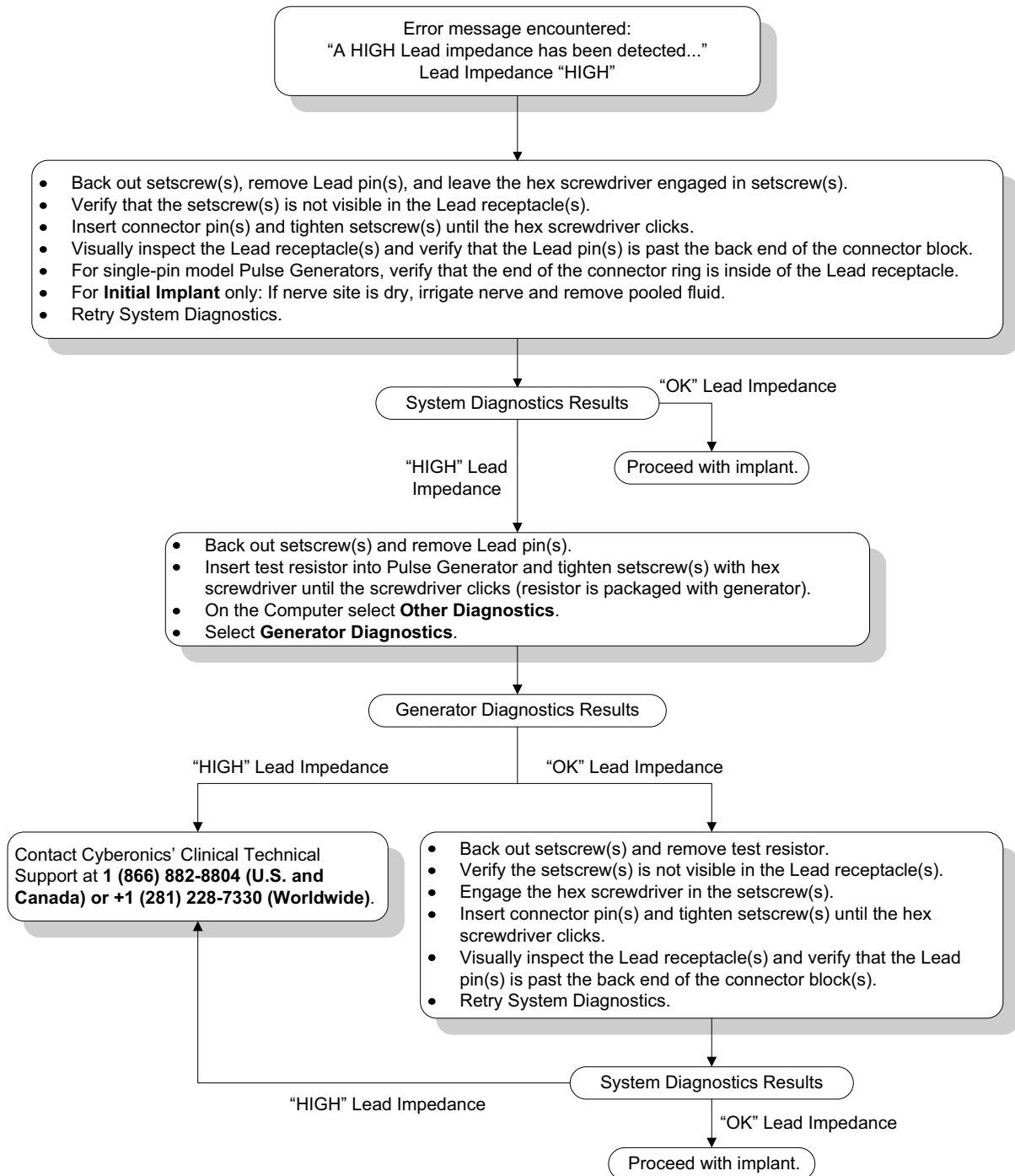
1. Reinsert the connector pin(s) into the Lead receptacle(s).
 - a. Back out the setscrew(s), remove the Lead pin(s), and leave the hex screwdriver engaged in the setscrew(s).
 - b. Verify that the setscrew(s) is not visible in the Lead receptacle(s).
 - c. Insert the connector pin(s) and tighten the setscrew(s) until the hex screwdriver clicks.
 - d. Visually inspect the Lead receptacle(s) and verify that the Lead pin(s) is past the back end of the connector block(s).
 - e. For the single-pin Model Pulse Generators, verify that the end of the Lead connector ring is inside the Lead receptacle.
 - f. Gently grasp and pull on the connector boot(s) to verify that the pin(s) is securely tightened.
2. Rerun the System Diagnostics.
3. If “HIGH” Lead impedance is still noted, perform these steps:
 - a. Remove the Lead connector pin(s) from the Lead receptacle(s).
 - b. Insert the connector pin(s) of the test resistor assembly into the Lead receptacle(s) in the Pulse Generator.



Note: See the physician's manual for the Pulse Generator.

- c. Tighten the setscrew(s) until the hex screwdriver clicks.
- d. Perform the Generator Diagnostics.
 - ♦ If the Generator Diagnostics indicates “HIGH” Lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).
 - ♦ If the Generator Diagnostics indicates “OK” Lead impedance, perform these steps:
 - 1) Back out the setscrew(s) and remove the test resistor.
 - 2) Insert the Lead connector pin(s) into the Lead receptacle(s) in the Pulse Generator.
 - 3) Tighten the setscrew(s) until the hex screwdriver clicks.
 - 4) If the System Diagnostics continues to indicate “HIGH” Lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

Figure 38. High Lead Impedance on System Diagnostic Test in OR - Initial Implant or Generator Replacement



10.3.4. Low Lead impedance on System Diagnostics in OR – initial implant

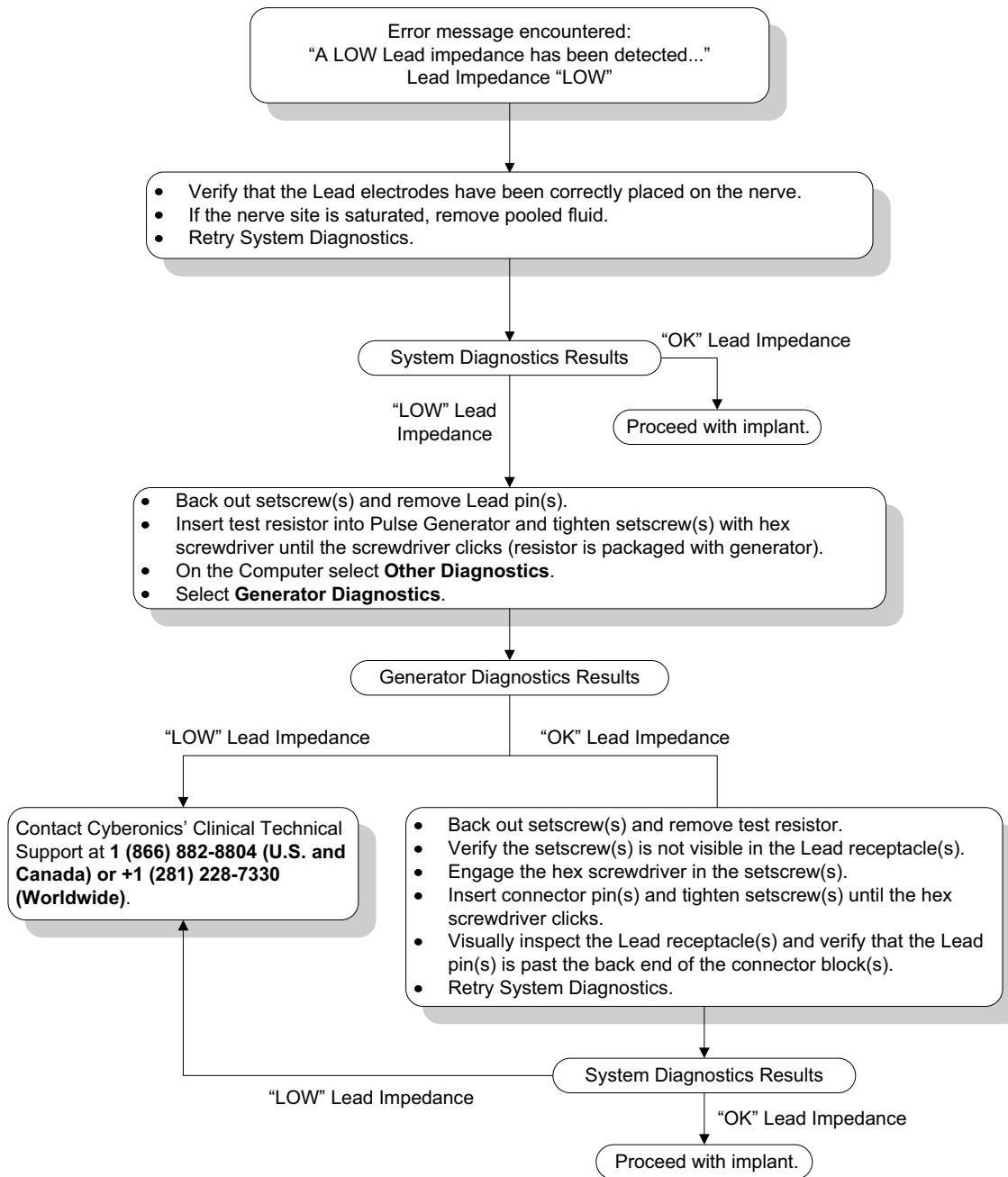
Low Lead impedance (≤ 600 Ohms) in the OR can be attributed to several causes:

- Incorrect placement of the Lead on the nerve
- Excessive irrigation of the nerve
- Defective Lead
- Defective Pulse Generator

To alleviate the condition, perform these steps (see Figure 39 on page 71):

1. Verify that the Lead electrode(s) has been correctly placed on the vagus nerve.
2. If the nerve site is heavily saturated, remove pooled fluid.
3. Rerun the System Diagnostics.
4. If “LOW” Lead impedance is still noted, perform these steps:
 - a. Remove the Lead connector pin(s) from the Lead receptacle(s).
 - b. Insert the connector pin(s) of the test resistor assembly into the Lead receptacle(s) in the Pulse Generator.
 - c. Tighten the setscrew(s) until the hex screwdriver clicks.
 - d. Perform the Generator Diagnostics.
 - ◆ If the Generator Diagnostics indicates “LOW” Lead impedance, call LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).
 - ◆ If the Generator Diagnostics indicates “OK” Lead impedance, perform these steps:
 - 1) Back out the setscrew(s) and remove the test resistor.
 - 2) Insert the Lead connector pin(s) into the Lead receptacle(s) in the Pulse Generator.
 - 3) Tighten the setscrew(s) until the hex screwdriver clicks.
 - 4) Perform the System Diagnostics.
 - ◆ If the System Diagnostics continues to indicate “LOW” Lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

Figure 39. Low Lead Impedance on System Diagnostics in OR - Initial Implant



10.3.5. **Low Lead impedance on System Diagnostics in OR – Pulse Generator replacement**

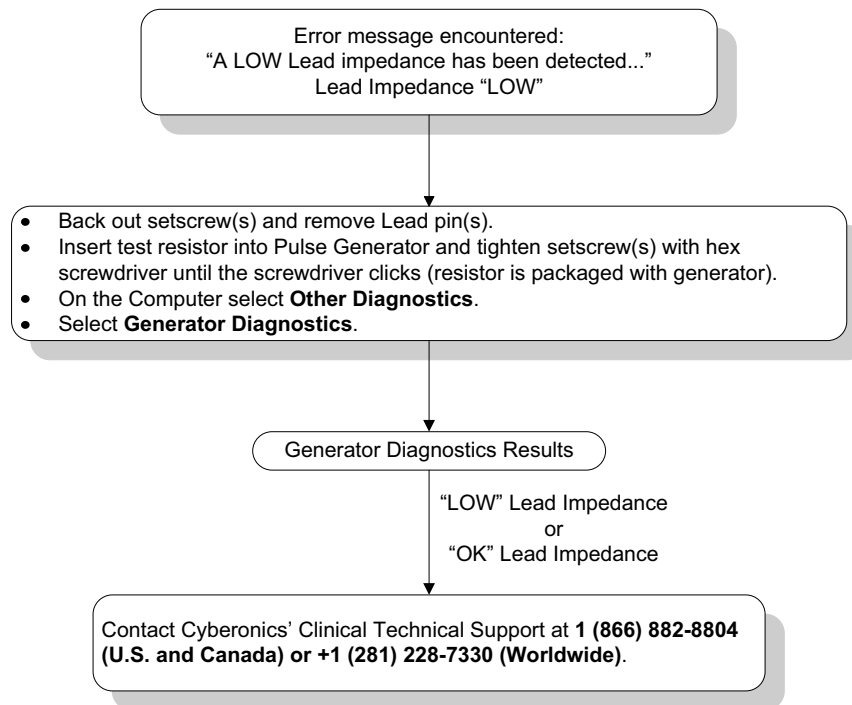
Low Lead impedance (≤ 600 Ohms) in the OR can be attributed to:

- Short-circuit condition within the Lead
- Defective Pulse Generator

To alleviate the condition, perform these steps (see Figure 40):

1. Remove the Lead connector pin(s) from the Lead receptacle(s).
2. Insert the connector pin(s) of the test resistor assembly into the Lead receptacle(s) in the Pulse Generator.
3. Tighten the setscrew(s) until the hex screwdriver clicks.
4. Perform the Generator Diagnostics.
 - If the Generator Diagnostics indicates “LOW” or “OK” Lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

Figure 40. Low Lead Impedance on System Diagnostics in OR - Pulse Generator Replacement




10.3.6. Low Battery/End of Service indications prior to surgery, outside of the sterile field – initial implant or Pulse Generator replacement

- Low storage temperatures may affect the battery status indicators. Battery indicators include any of the following:
- Intensified Follow-up Indicator (IFI) = Yes, Near End of Service (N EOS) = Yes, or End of Service (EOS) = Yes
- "Warning message - "The Intensified Follow-up Indicator (IFI) has been set for the Pulse Generator. More frequent clinical monitoring is recommended. If you have any questions, please consult the Physician's Manual or contact Cyberonics."
- "Warning message - "The Pulse Generator is nearing End of Service (N EOS). It is recommended that the Pulse Generator be replaced as soon as possible. If you have any questions, please consult the Physician's Manual or contact Cyberonics."
- "Warning message - "The Pulse Generator has reached End of Service (EOS) and is NOT supplying stimulation. It is recommended that the Pulse Generator be replaced immediately. If you have any questions, please consult the Physician's Manual or contact Cyberonics."

The potential causes for receiving any of these battery indications on a new device with output current set at "0 mA" are as follows:

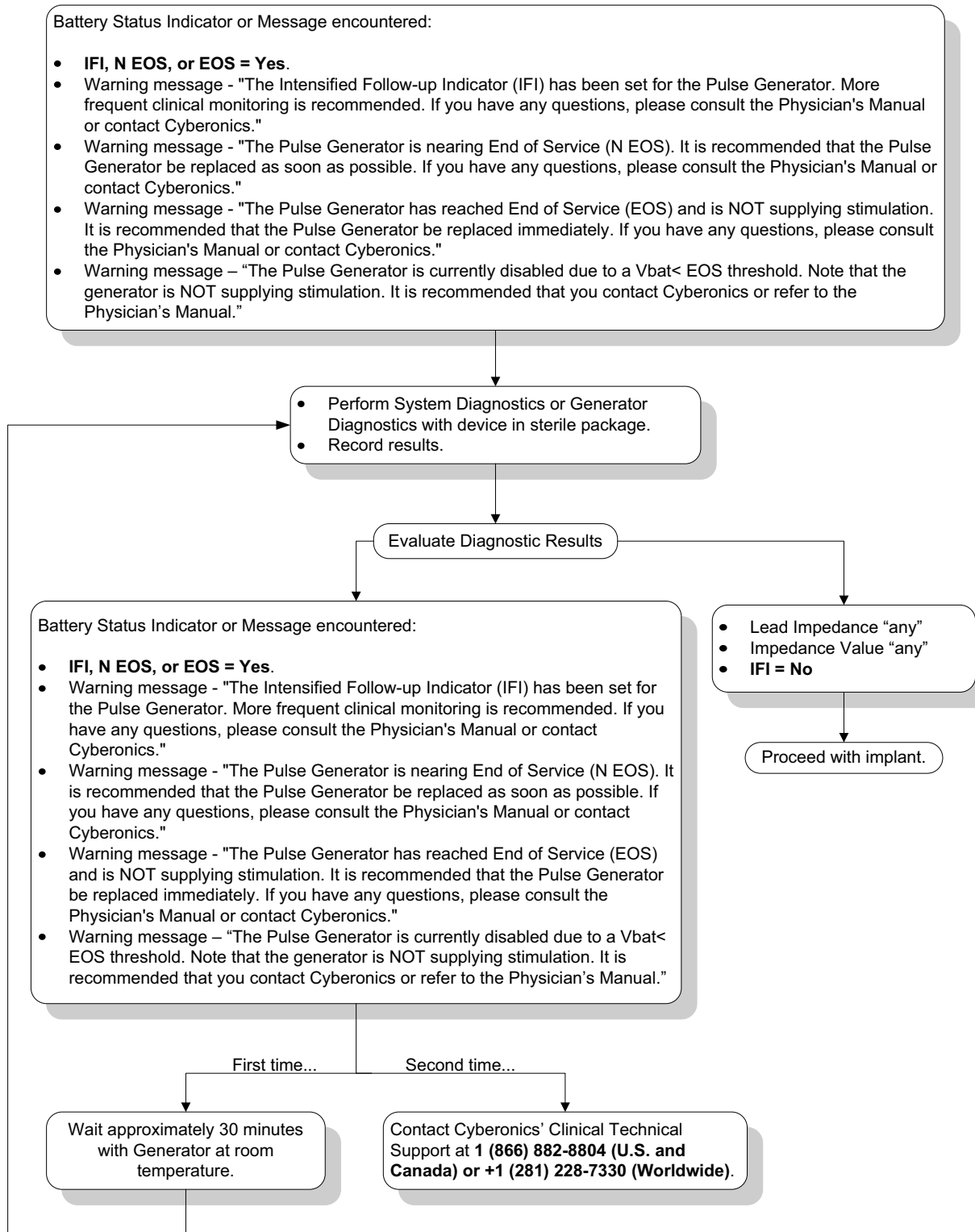
- Interrogated Pulse Generator has been exposed to low storage temperatures within the last 24 hours
- Defective Pulse Generator

To update the battery status indicators perform the following steps with the device in the sterile package (see Figure 41 on page 74):

 **Note: Ignore Lead Impedance status and Impedance Value.**

1. Place the Wand over the packaged Pulse Generator and perform a System Diagnostics or Generator Diagnostics.
2. Verify that the battery level indication from Diagnostic Information screen is IFI = No.
3. If any one of the battery level indicators (IFI, N EOS, EOS) is set to YES, or any other battery level warning message appears, wait 30 minutes and retry the diagnostic.
4. If the problem persists, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

Figure 41. Low Battery/End of Service Indications Prior to Surgery, Outside of the Sterile Field - Initial Implant or Pulse Generator Replacement



10.3.7. Low Battery/End of Service indications during surgery, inside the sterile field – initial implant or Pulse Generator replacement

Exposure of Models 103, 104, and 105 Generators to specific conditions can temporarily drain the Pulse Generator battery and shorten the battery life by approximately 50%. Possible conditions include:

- Electrosurgical equipment (e.g. electrocautery) used during implantation or other surgical procedure near the Pulse Generator
- Static electricity (i.e., electrostatic discharge or ESD) imparted to the device during a surgical procedure

A low battery/End of Service indicator during surgery may be an indication that the device has been damaged in this manner. Applicable indicators include any of the following (when the device is set to 0 mA):

- "Intensified Follow-up Indicator (IFI) = Yes, Near End of Service (N EOS) = Yes, or End of Service (EOS) = Yes
- "Warning message - "The Intensified Follow-up Indicator (IFI) has been set for the Pulse Generator. More frequent clinical monitoring is recommended. If you have any questions, please consult the Physician's Manual or contact Cyberonics."
- "Warning message - "The Pulse Generator is nearing End of Service (N EOS). It is recommended that the Pulse Generator be replaced as soon as possible. If you have any questions, please consult the Physician's Manual or contact Cyberonics."
- "Warning message - "The Pulse Generator has reached End of Service (EOS) and is NOT supplying stimulation. It is recommended that the Pulse Generator be replaced immediately. If you have any questions, please consult the Physician's Manual or contact Cyberonics."
- "Warning message - "The Pulse Generator is currently disabled due to a Vbat < EOS threshold. Note that the generator is NOT supplying stimulation. It is recommended that you contact Cyberonics or refer to the Physician's Manual."

If any of these indicators are observed during implant, perform a System Diagnostics to update the battery level indicator.

If the System Diagnostics test returns a battery level indicator other than IFI = No or any other battery level warning message appears when the device is programmed to "0 mA", contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

10.4. Troubleshooting at Follow-up Visits

10.4.1. *Communication problems at follow-up visits*

A communication problem can cause the following error messages:

- “There is an error establishing communication with the device”
- “Failed to retrieve diagnostic data”
- “Generator failed to respond to programming initialization”
- “Failure in programming data sequence”
- “Invalid data was received from generator”

Failure of the Pulse Generator and Programming Wand to clearly communicate with each other to interrogate, program, or run diagnostic tests can be attributed to several factors:

- Depleted Programming Wand battery
- Movement of the Programming Wand away from the Pulse Generator during communication
- Improper cable connection between Programming Wand and Programming Computer
- Electromagnetic interference (EMI) i.e., electronic equipment, Programming Computer
- Pulse Generator battery at EOS
- Defective Programming Wand
- Defective Programming Computer
- Defective Pulse Generator

Communication problems are often intermittent and are rarely related to the Pulse Generator. The surrounding environment typically causes these problems.

Performing these steps may restore communication (see Figure 37 on page 65):

1. Test the Model 201 Programming Wand battery. Briefly press and release the two red RESET buttons simultaneously, and then verify that the green POWER light comes on and stays on for approximately 25 seconds after the buttons are released. If it does not, the battery should be replaced. The Programming Wand uses one standard 9-volt alkaline battery, which is located in the handle of the Wand.
2. Verify that the Programming Wand is properly connected to the Programming Computer (see Programming Wand physician's manual for details).



Note: For details, see the Programming Wand physician's manual.

- a. Disconnect power cord from wall outlet.
- b. Verify connection of Programming Wand cable and Programming Computer cable.
3. Verify the proper positioning of the Programming Wand over the Pulse Generator. Reposition the Programming Wand by rotating the handle 45 degrees in either direction.
4. Extend the Programming Wand cable and ensure that the Wand is 3 to 4 feet away from the Programming Computer.
5. Verify that the programming problem is not a result of electromagnetic interference (EMI) from nearby electrical or magnetic equipment. Examples of possible sources of EMI are computer displays, portable telephones, fluorescent lighting. To check for EMI, perform these steps:
 - a. Press and release the red RESET button(s) on the Programming Wand. The green POWER light should stay on during EMI detection. When the green light turns off, press and release the RESET button(s) again.
 - b. Move the Programming Wand closer to the suspected equipment (Computer screen, office equipment, etc.).
 - ◆ If EMI is detected, the yellow DATA/RCVD light will come on and remain on while in the presence of EMI.
 - ◆ Programming, interrogating, or completing diagnostic tests in an area with EMI will be difficult or impossible. The problem can usually be resolved by repositioning the patient, the Programming Wand, or the source of EMI.
 - c. Retry interrogation, diagnostic testing, or programming.
 - d. If problems persist, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).



Note: LivaNova recommends interrogating the Pulse Generator as the last step of any programming session to verify correct settings for each parameter.

10.4.2. High Lead Impedance on a Diagnostic Test at follow-up visit for Models 100, 101, and 102 Pulse Generators

High Lead Impedance can cause the error message, “Impedance is higher than expected. Indicates a possible discontinuity of the lead, or fibrosis between the nerve and lead.” High Lead Impedance at a follow-up visit can be attributed to any of these causes:

- Fibrosis between the nerve and the electrode
- Lead discontinuity
- Lead disconnection from the Pulse Generator
- Generator at end of service (EOS)
- Defective Pulse Generator

To alleviate the condition, perform these steps (see Figure 42 on page 80):

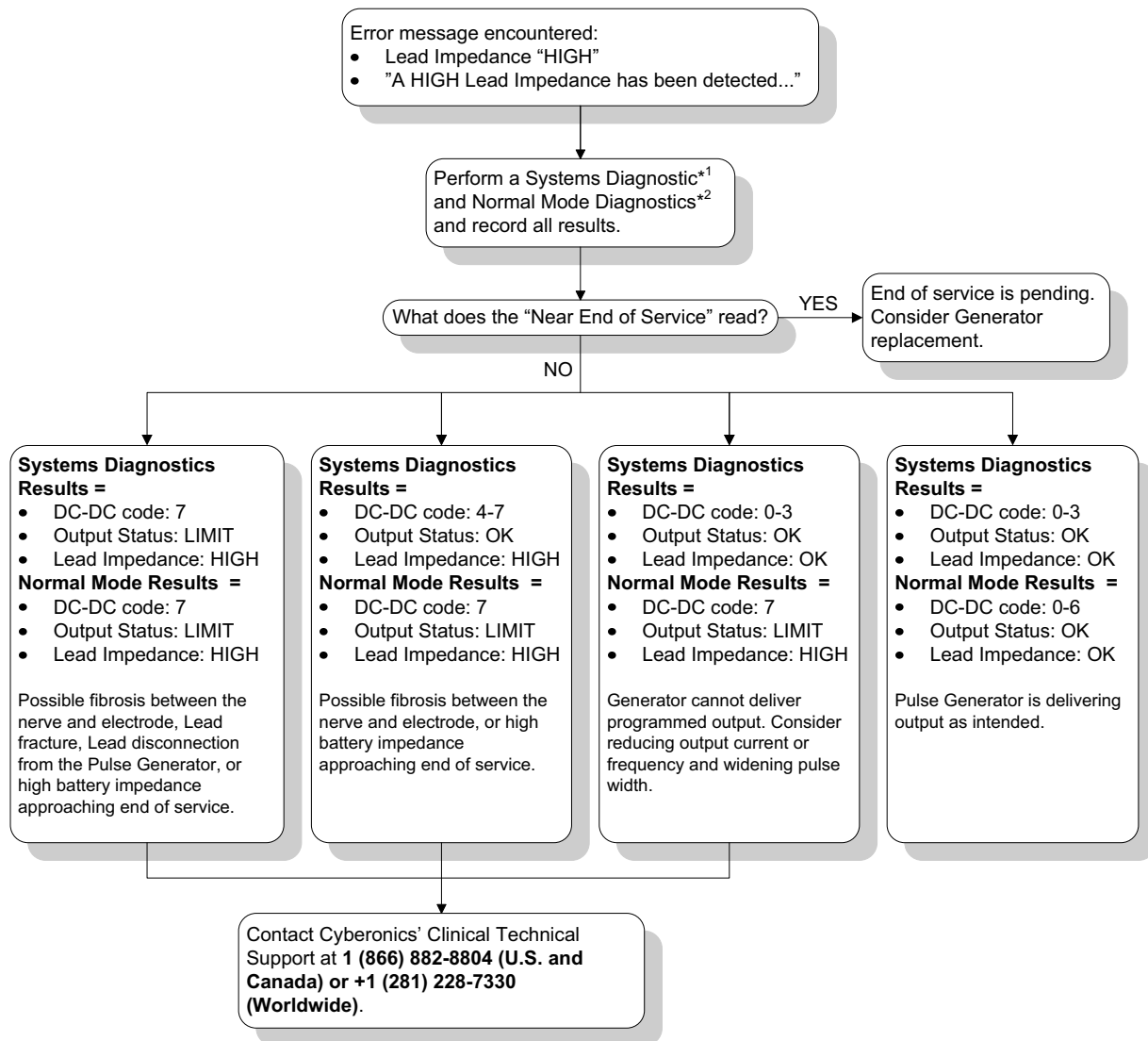
1. Interrogate the device.
2. Perform a System Diagnostics and record the results.
 - For the System Diagnostics, the Software automatically programs the Pulse Generator to 1.0 mA, 500 micro sec, and 20 Hz. Patients whose Pulse Generator output current is normally less than these values may experience increased sensation, coughing, a flushed face, or other effects. (See the physician's manual for the Pulse Generator, "Adverse Events" section.)
3. Perform a Normal Mode Diagnostics and record all the results.
 - If the System Diagnostics report Lead Impedance "HIGH", Output Status "LIMIT", DCDC Converter "7" and the Normal Mode Diagnostics reports Lead Impedance "HIGH", Output Status "LIMIT", DCDC Converter "7" while
 - ◆ Near End of Service reads "NO", then there is possible:
 - ◆Fibrosis between the nerve and electrode
 - ◆Lead discontinuity
 - ◆Lead disconnection from the Pulse Generator
 - ◆Generator at EOS
 - ◆ Near End of Service reads "YES", then
 - ◆Generator is nearing End of Service. Consider generator replacement.
 - If the System Diagnostics report Lead Impedance "HIGH", Output Status "OK", DCDC Converter "4-7" and the Normal Mode Diagnostics reports Lead Impedance "HIGH", Output Status "LIMIT", DCDC Converter "7" while
 - ◆ Near End of Service reads "NO", then there is possible:
 - ◆Fibrosis between the nerve and electrode
 - ◆High battery impedance approaching end of service.
 - ◆ Near End of Service reads "YES", then
 - ◆Generator is nearing End of Service. Consider generator replacement.
 - If the System Diagnostics report Lead Impedance "OK", Output Status "OK", DCDC Converter "0-3" and the Normal Mode Diagnostics reports Lead Impedance "HIGH", Output Status "LIMIT", DCDC Converter "7" while
 - ◆ Near End of Service reads "NO", then
 - ◆Generator cannot deliver programmed output. Consider lowering the output while increasing pulse width.
 - ◆ Near End of Service reads "YES", then



Note: To obtain accurate information from the device diagnostics, the Pulse Generator must be programmed to a **minimum** of .75 mA, 15 Hz, and **at least** 30 seconds ON time.

- ◆ Generator is nearing End of Service. It is recommended that the Pulse Generator be replaced as soon as possible.
- If the System Diagnostics report Lead Impedance “OK”, Output Status “OK”, DCDC Converter “0-3” and the Normal Mode Diagnostics reports Lead Impedance “OK”, Output Status “OK”, DCDC Converter “0-6” while
 - ◆ Near End of Service reads “NO”, then
 - ◆ Pulse Generator is delivering output as intended.
 - ◆ Near End of Service reads “YES”, then
 - ◆ Generator is nearing End of Service. Consider generator replacement.
- 4. Contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) to report any incidences of high Lead impedance.

Figure 42. High Lead Impedance on a Diagnostic Test at Follow-up Visit for Models 100, 101, and 102 Pulse Generators



*1 For the System Diagnostics, the Software automatically programs the Pulse Generator to 1.0 mA, 500 μsec, and 20 Hz. Patients whose Pulse Generator output current is less than these values may experience increased sensation, coughing, a flushed face, or other effects. See the physician's manual for the Pulse Generator, "Adverse Events" section, for a complete list of all possible adverse events.

*2 To obtain accurate information from the Normal Mode Diagnostics, the Pulse Generator must be programmed to a minimum of .75 mA, 15 Hz, and at least 30 seconds ON time.

10.4.3. High Lead Impedance, Low Lead Impedance, or Low Output Current on a Diagnostic Test at follow-up visit for Model 103, 104, and 105 Pulse Generators

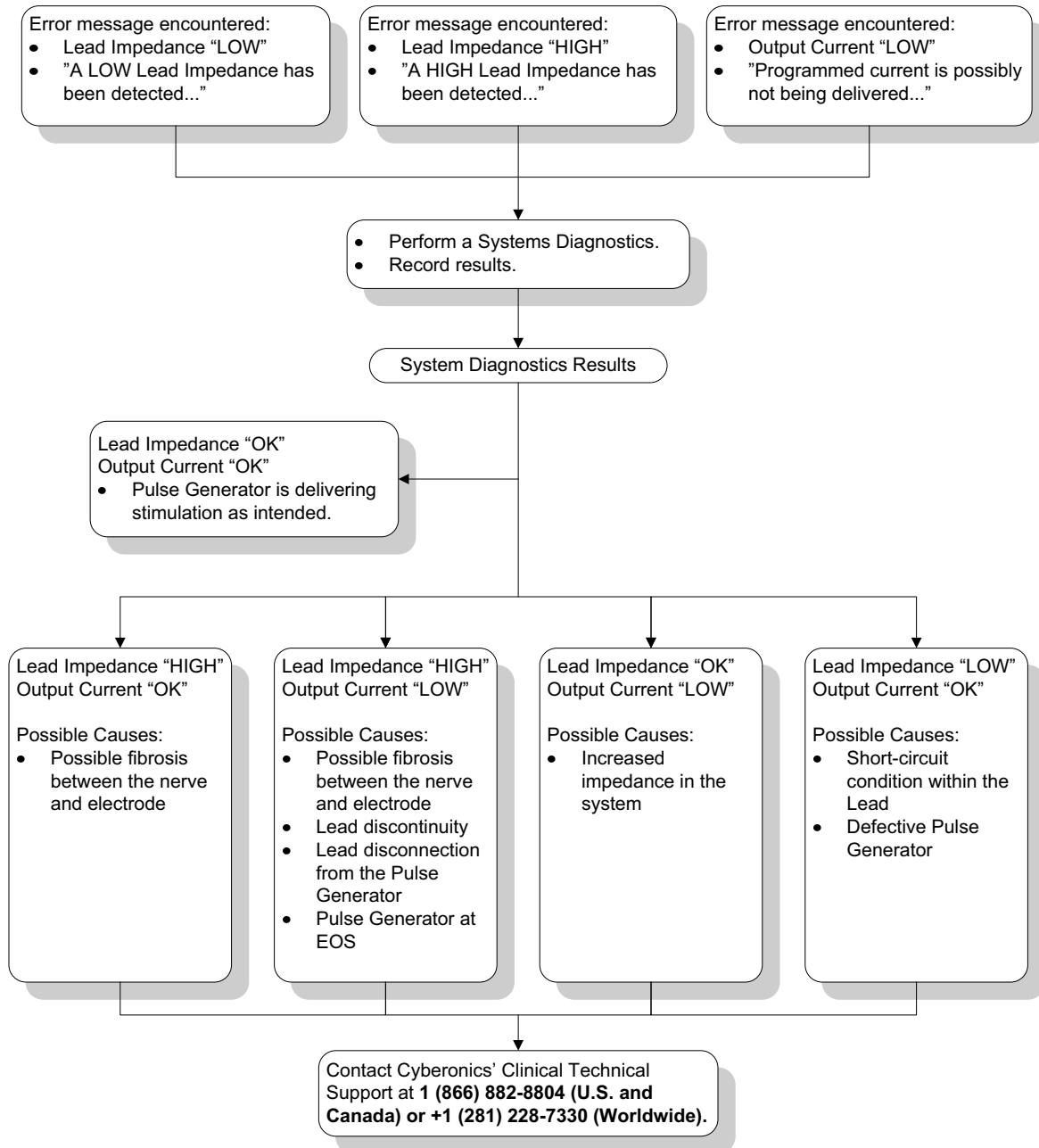
High Lead impedance (≥ 7000 Ohms), low Lead impedance (≤ 600 Ohms), or low output current at a follow-up visit can be attributed to any of these causes.

- Fibrosis between the nerve and the electrode
- Lead discontinuity
- Lead disconnection from the Pulse Generator
- Pulse Generator at end of service (EOS)
- Pulse Generator not able to deliver programmed stimulation
- Defective Pulse Generator
- Short-circuit condition within the Lead

To alleviate the condition, perform these steps (see Figure 43 on page 82):

1. Interrogate the device.
2. Perform a System Diagnostics and record the results.
 - If the output current reports “LOW” and Lead impedance reports “HIGH” (≥ 7000 Ohms), then there is possible
 - ◆ Fibrosis between the nerve and electrode
 - ◆ Lead discontinuity
 - ◆ Lead disconnection from the Pulse Generator
 - ◆ Pulse Generator at EOS
 - If the output current reports “OK” and Lead impedance reports “LOW” (≤ 600 Ohms), then there is a possibility of a short-circuit condition within the Lead or defective Pulse Generator.
 - If the output current reports “OK” and Lead impedance reports “HIGH” (≥ 7000 Ohms), then there is a possibility of fibrosis between the nerve and the electrode.
 - If the output current reports “LOW” and Lead impedance reports “OK”, then the Pulse Generator cannot deliver programmed output due to increased impedance. Consider lowering the output current while increasing pulse width.
3. Contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) to report any incidences of high impedance, low impedance, or low output current.

Figure 43. High Lead Impedance, Low Lead Impedance, or Low Output Current on an Interrogation or Diagnostic Test at Follow-up Visit for Models 103, 104, and 105 Pulse Generators



10.4.4. Pulse Generator disabled due to Vbat < EOS found at first interrogation after implantation or other surgical procedure

Exposure of Models 103, 104, and 105 Generators to specific conditions can temporarily drain the Pulse Generator battery and shorten the battery life by approximately 50%. Possible conditions include:

- Electrosurgical equipment (e.g. electrocautery) used during implantation or other surgical procedure near the Pulse Generator
- Static electricity (i.e., electrostatic discharge or ESD) imparted to the device during a surgical procedure

This occurrence is detectable during the implantation procedure by performing a System Diagnostics test after the device has been secured in the pocket as prescribed in the product labeling. However, if this condition occurred and was not detected, it is possible that the longevity of the implanted Pulse Generator could be degraded.

Display of the following message during the first interrogation following implantation may be an indication that the device was damaged during the surgery:

- “The Pulse Generator is currently disabled due to a Vbat < EOS threshold. Note that the generator is NOT supplying stimulation. It is recommended that you contact Cyberonics or refer to the Physician's Manual.”

If the device was damaged during the implantation, the device will still function normally but may have a decreased battery life. If the "Vbat < EOS" message is displayed during the first interrogation after implantation of the device or other surgical procedure, physicians should:

1. Select the **Proceed** button at the bottom of the error message. The Parameter screen appears.
2. Enter the desired device settings and select the **Program** button at the bottom of the screen.
3. Perform a System Diagnostics test. If the following acceptable results are obtained, the device is functioning normally, but the battery life will be shortened.
 - Output Current: OK
 - Lead Impedance: OK
 - IFI = No
4. If Near EOS (N EOS) or EOS = Yes, it is recommended that the Pulse Generator be replaced as soon as possible.
5. If any other error messages appear, see applicable Troubleshooting sections within this physician's manual for assistance or contact

LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

Patients should continue with regularly scheduled visits including System Diagnostic testing to ensure proper device functionality. Ensure that patients (epilepsy indication only) continue using their Magnets regularly to verify that stimulation is felt as described in the labeling. All patients should notify their physicians if stimulation feels different or not felt, so a System Diagnostics test may be performed. For some patients, stimulation may become less noticeable over time. A change in perception of stimulation, without clinical symptoms such as an increase in seizures/depressive symptoms or painful/erratic stimulation, may not indicate a true device issue. Performing a System Diagnostics test is the only valid way to ensure proper device function.

10.4.5. Sudden decrease in estimated device longevity (% battery power remaining)

Exposure of Demipulse Generators to specific conditions can temporarily drain the Pulse Generator battery and shorten the battery life by approximately 50%. Possible conditions include:

- Electrosurgical equipment (e.g. electrocautery) used during implantation or other surgical procedure near the Pulse Generator
- Static electricity (i.e., electrostatic discharge or ESD) imparted to the device during a surgical procedure

This occurrence is detectable during the implantation procedure by performing a System Diagnostics test after the device has been secured in the pocket as prescribed in the product labeling. However, if this condition occurred and was not detected, it is possible that the longevity of the implanted Pulse Generator could be degraded. A sudden and unexpected decrease in the % battery remaining is a possible indication that the battery life of the device has been reduced.

A significant change in the Lead impedance or increase in programmed stimulation parameters can also result in a change in the estimated % battery power remaining. Evaluation of the change in % battery power remaining between consecutive patient visits must be performed before any stimulation parameters are adjusted. The Lead impedance should be reviewed for a significant change if a sudden decrease in the estimated % battery power remaining is observed. For further assistance, call LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide).

If the device was damaged during the implantation, the device will still function normally but will have a decreased battery life. Monitor the patient closely for the Pulse Generator approaching IFI, N EOS, or EOS.



Note: For more information on battery longevity, see the *Technical Information* part of the device specific Physician's Manual.

11. GLOSSARY

Adverse Event (AE)

Any symptom, sign, illness, or experience that develops or worsens in severity and/or frequency during the course of the study (i.e., any changes from baseline)

AED

Antiepileptic drug(s)

duty cycle

Percentage of time during which stimulation occurs; stimulation time (programmed ON time plus two seconds of ramp-up time and two seconds of ramp-down time) divided by the sum of signal ON and OFF times

EMI

Electromagnetic interference

EOS

End of Service

excess duty cycle

Duty cycle for which the ON time is greater than the OFF time

generalized onset seizure (*epilepsy*)

Type of seizure that involves all parts of the brain and, usually, an alteration in consciousness

high Lead impedance

Resistance to the flow of output current produced by the Pulse Generator, caused by any of the following: possible fibrosis between the nerve and electrode, dry nerve (during surgery), Lead fracture, Lead disconnection from the Pulse Generator, or high battery impedance approaching end of service

IFI

Intensified Follow-up Indicator

LIMIT output current

Output current other than that which was programmed; not a sole indicator of a device malfunction

low Lead impedance

Lower than expected resistance to the flow of output current produced by the Pulse Generator potentially caused by a short-

circuit condition resulting from a break withing the Lead body connector boot

Magnet Mode activation

Brief magnet application and removal, which initiates a stimulation

microcoulomb

Product of current and time, or output current (in mA) multiplied by the pulse width (in msec)

NCP[®]

NeuroCybernetic Prosthesis

N EOS

Near End of Service

nominal parameters

Specific preset parameters available with the software; LivaNova suggests that the Pulse Generator be set to these parameters when patients are first stimulated



Note: See “How to Program New Parameter Settings” on page 21 for specific nominal settings.

output current

Amount of electrical current delivered in a single pulse of a stimulation, measured in mA

patient code

Any three-character value assigned by the treating physician; generally programmed at time of implantation; often patient's initials: first, middle, last

partial onset seizure

Type of seizure that begins focally with a specific sensory, motor, or psychic aberration that reflects the affected part of the cerebral hemisphere where the seizure originated

pulse width

Duration of a single pulse within a stimulation, measured in μsec

ramp-down

Gradual decrease over approximately two seconds in output current at the end of stimulation greater than 10 Hz in signal frequency

ramp-up

Gradual increase over approximately two seconds in output current at the beginning of stimulation greater than 10 Hz in signal frequency

refractory

Resistant to previous treatment alternatives defined by the treating physician; generally refers to the epilepsy of patients who have tried and failed two or more antiepileptic drugs



Note: See “How to Program New Parameter Settings” on page 21 for specific reset parameters.

reset parameters

Parameters to which the Pulse Generator internally programs when it is reset

SAE

Serious adverse event

signal frequency

Repetition rate of pulses in a stimulation; measured in number of pulses per second (Hz)

signal OFF time

Interval between stimulations when there is no stimulation; measured in minutes

signal ON time

Length of time the programmed output current is delivered (not including ramp-up and ramp-down times); measured in seconds

stimulation parameters

Programmed output current, signal frequency, pulse width, signal ON time, and signal OFF time

stimulation time

Therapeutic output of the VNS Therapy Pulse Generator; consists of the signal ON time, plus 2 seconds of ramp-up time and 2 seconds of ramp-down time

SUDEP

Sudden unexplained death in epilepsy

vagus nerve

Either of the pair of tenth cranial nerves arising from the medulla and supplying mainly the viscera, especially with autonomic sensory and motor fibers; in this document, *vagus nerve* always refers to the *left* vagus nerve

VNS

Vagus Nerve Stimulation

12. LIST OF APPROVED COMPUTERS _____

Computers that have been qualified for use with the Model 250 Version 8.0 Programming Software are listed below:

- Dell Axim X5 Pocket PC 2002 Handheld Computer
- Dell Axim X5 Pocket PC 2003 Handheld Computer
- Dell Axim X50 Windows Mobile 2003, 2nd Edition Handheld Computer

13. PRODUCT INFORMATION AND SUPPORT _____

If there are questions regarding use of the VNS Therapy System or any of its accessories, contact LivaNova:

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 Clinical and Technical support, call:

Telephone: 1 (866) 882-8804 (US and Canada)
+1 (281) 228-7330 (Worldwide)

Internet:

www.livanova.com