



Physician's Manual

VNS Therapy® Programming Software

Model 250 Version 11.0

Programming Computer

For Healthcare Professionals

June 2019

US Version

RxOnly

Note: This manual contains information on the use of the LivaNova® VNS Therapy Programming Software, Model 250 Version 11.0. Physicians should refer to the VNS Therapy Pulse Generator physician's manuals for additional important prescribing and safety information.

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1 BRIEF DEVICE DESCRIPTION

1.1 General Description

The LivaNova® VNS Therapy® Programming Software, Model 250 Version 11.0, enables you to interrogate and program LivaNova pulse generators 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 programming computer.
- Use of screen displays that provide prompts and messages to aid in interrogating and programming.



Note: For a list of symbols and glossary terms used with the VNS Therapy System, go to www.livanova.com.

1.2 Intended Use

The Model 250 Version 11.0 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: Only the programming computer provided by LivaNova should be used with the Model 250 v11.0 Programming Software to program the LivaNova' pulse generators.



Note: For additional specifications regarding the Motion tablet and power adapter, see the Motion Safety and Regulatory Compliance manual located online at www.livanova.com.

1.3 System Configuration

The programming computer provided by LivaNova is the Motion CL 900/910 (Model FWS-001), Windows Embedded Standard 7, tablet computer with power adapter model SADP-65NB or power adapter model ADP-65WH BB. The Model 250 v11.0 Programming Software is pre-installed on the computer. A SD card (4GB) is also provided with the programming computer.

1.4 Conventions Used

The following conventions are used throughout this manual:

- Screen titles appear in all capital letters.
- The names of selectable buttons, fields, and drop-down menus appear in bold typeface. Each of these buttons or fields represents an operation, parameter, or parameter value.
- The words ON and OFF appear in all capital letters only when they refer to VNS stimulation or Tachycardia Detection.
- References to model 102 include both models 102 and 102R.
- SD card is synonymous with FlashCard.
- USB to Serial Adapter is synonymous with programming computer cable.

1.5 Communication Signals

i **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.

i **Note:** See the physician's manual for the programming wand for a description of the programming wand.

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

Rapid, *descending* musical tones and a screen message in the programming software signal a warning or a failed operation.

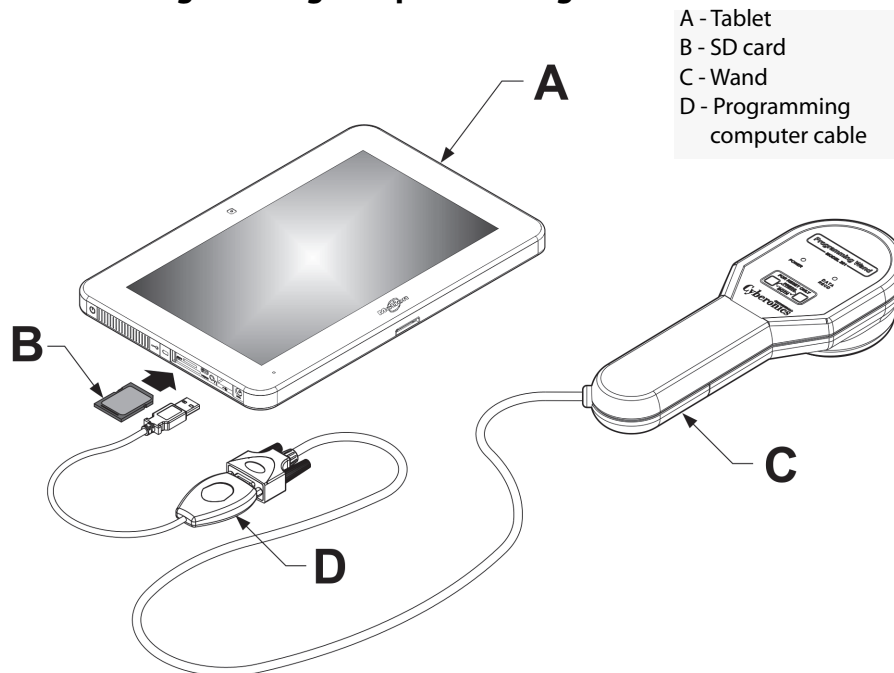
The DATA/RCVD indicator on the programming wand lights up when the wand is in communication with the pulse generator and data is being exchanged between the two devices. Additionally, it may light up or flicker in the presence of electromagnetic interference (EMI) or noise. For more information on the DATA/RCVD indicator, please refer to the physician's manual for the programming wand.

2 HOW TO GET STARTED

2.1 Programming Computer Configuration

The programming computer is a tablet-style computer with a touch-screen interface. See Figure 1 below for the programming computer configuration. For more details, see the *Programming Computer Connection Instructions* manual.

Figure 1. Programming Computer Configuration*



*Graphic does not include port covers on the left side of the programming computer.
 Note: Some of the programming computers may have volume buttons on the top side of the computer. They are non-functional and should not be used.

When in use, LivaNova recommends the programming computer to be operated on battery power only (unplugged from AC power). Having the programming computer plugged into AC power during use may contribute to communication difficulties and interfere with the Verify Heartbeat Detection feature for the model 106 generator. When not in use, the programming computer should be powered off and plugged into AC power to maintain charge.

2.2 Using the On-screen Keyboard

The VNS Therapy Programming Software Model 250 Version 11.0 operates in a Windows environment with drop-down menus and selectable buttons and fields. You can select buttons or fields by tapping the screen with your finger. Some information may be entered into the software via the on-screen keyboard.

To use the on-screen keyboard, you must first tap the field where data is to be entered, and then tap the keyboard icon. You can type letters or numbers by tapping them with your finger. To exit the on-screen keyboard, tap the "x" on the top right corner of the keyboard or any area outside of the keyboard.

2.3 Programming Computer Startup

After properly connecting all components of the programming system as detailed in Section 2.1, the VNS Programming Computer may be turned on by pressing the power button located on the left side of the computer (Figure 2)..

Do the following to power on from standby mode:

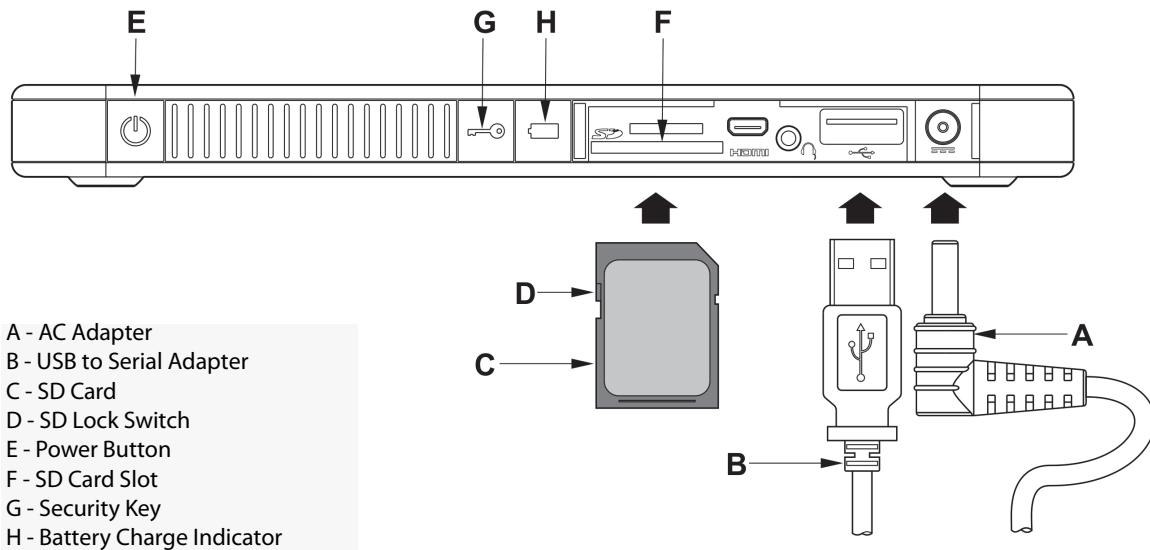
If the programming computer was not shut down during prior use, the computer may be in standby mode. If the computer is in standby mode, the power button will flash green. If powering on the computer from standby mode, the computer will display the same screen it was displaying prior to it entering standby mode. If the computer doesn't display the MAIN Menu (see Figure 3), select **Exit** or **Menu** until the MAIN Menu is displayed. You can select **User Preferences** to check the date and time.

Note: For information on the programming computer setup, see the *Programming Computer Connection Instructions* manual.

Caution: Do not press the security key button located on the left side of the programming computer (see item G in Figure 2) during power on or operation of the programming software. Doing so may interrupt the software.

If the programming computer was shut down during prior use, the computer will proceed through the startup process. Allow time for the programming computer to power on.

Figure 2. Side Panel of Programming Computer



After the programming computer has powered on, the v11.0 Programming Software will automatically load. The first screen which will be displayed is the MAIN Menu (see Figure 3). Once at the MAIN Menu, select **User Preferences** and verify the date and time displayed in the middle of the screen. If this is not correct, select **Set Time** and follow the prompts to reset the date and time. If this is correct, tap **Exit** to return to the MAIN Menu.

Figure 3. MAIN Menu



3 HOW TO USE THE SOFTWARE

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

There are four options available once you access the MAIN Menu. A brief overview of each option is provided below. Additional details for each software feature are provided in the remaining sections of this physician's manual.

1. **Interrogate Device:** This option is used to establish communication with the implantable device (pulse generator). Interrogation is the first step in interacting with a pulse generator with the programming system. Once an interrogation is performed, you may perform other tasks with the pulse generator such as program new parameters or perform Diagnostics testing.
1. **View Database:** This option is used to view all information from previously recorded interrogation, programming, and diagnostic events performed by your programming computer and the programming software. This option does not require real-time interaction with a pulse generator.
1. **View Last Parameters:** This option is used to view the most recent parameters selected for a specific patient or pulse generator. This option does not require real-time interaction with a pulse generator.
1. **User Preferences:** This options allows you to select values for the following user settings:
 - The number of minutes that the computer may be idle before a new interrogation becomes necessary
 - The current date and time
 - The maximum number of records viewable at a time
 - Language selection when available
 - Computer screen brightness
 - Computer screen calibration

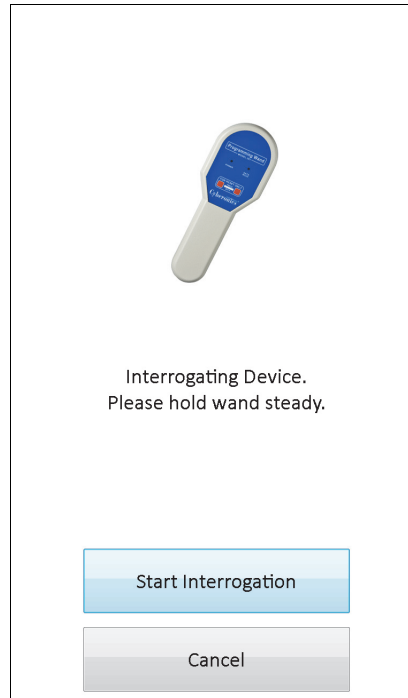
4 INTERROGATE DEVICE

4.1 How to Interrogate a Generator

i Note: If the programming computer cable has just been inserted into the programming computer or the programming computer has just been powered on, wait 15 seconds and then select **Start Interrogation**.

In order to interact with the pulse generator, you must first interrogate it by selecting the **Interrogate Device** button from the MAIN Menu. The START INTERROGATION Screen will be displayed (see Figure 4).

Figure 4. 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 unless an error condition (e.g., Generator End of Service, High Lead Impedance, etc.) is detected with the pulse generator. If an error condition is detected with the pulse generator, the associated warning message is displayed first and must be acknowledged before proceeding to the PARAMETER screen.

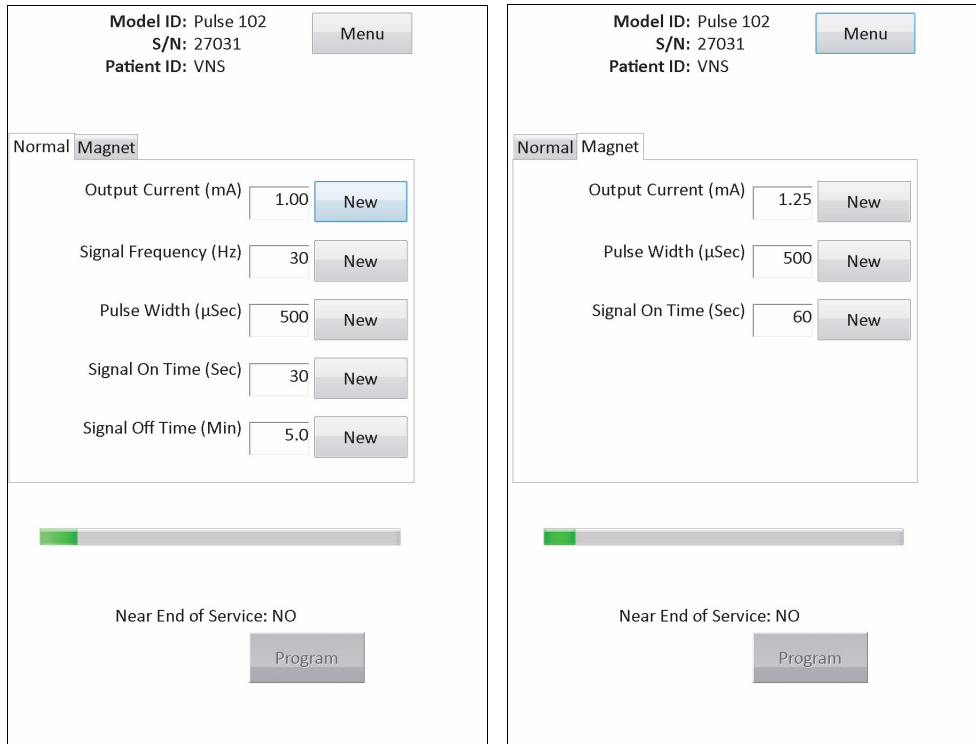
i Note: For additional information regarding potential error conditions with the pulse generator, see Section 5.3 and Section 6.8.

The PARAMETER screen displays the operating parameters of the pulse generator with their current settings in two or more tabs. In addition, the PARAMETER screen also displays information specific to the pulse generator interrogated such as its model and serial number, the generator battery status, and patient information. You may view information presented on each tab by tapping on the individual tab name. See Figure 5 below for examples of the PARAMETER screen across different models of pulse generators.

For the model 101 and 102(R) 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 you will need to reinterrogate the generator before programming. The inactivity timeout period can be adjusted on the USER PREFERENCES Screen described in section 13.1.

Figure 5. PARAMETER Screens For Pulse Generators

Model(s) 101,102(R)



↑ Inactivity Timeout Indicator (Progress Bar)

↑ Inactivity Timeout Indicator (Progress Bar)

Model(s) 103, 104, 105

Model ID: Demipulse
103
S/N: 4745
Patient ID: vns
Firmware Build No.: 6.5.24.14

Menu

Normal Magnet

Output Current (mA) 1.00 New

Signal Frequency (Hz) 30 New

Pulse Width (µSec) 500 New

Signal On Time (Sec) 30 New

Signal Off Time (Min) 5.0 New

Program

Model ID: Demipulse
103
S/N: 4745
Patient ID: vns
Firmware Build No.: 6.5.24.14

Menu

Normal Magnet


Output Current (mA) 1.25 New

Pulse Width (µSec) 500 New

Signal On Time (Sec) 60 New

Program

Model 106


Model ID: AspireSR 106
S/N: 20433
Patient ID: VNS
Firmware Build No.: 10.10.26.12


Output Current (mA)

Signal Frequency (Hz)

Pulse Width (µSec)

Signal On Time (Sec)


Signal Off Time (Min)


Model ID: AspireSR 106
S/N: 20433
Patient ID: VNS
Firmware Build No.: 10.10.26.12

Output Current (mA)

Pulse Width (µSec)


Signal On Time (Sec)


Model ID: AspireSR 106
S/N: 20433
Patient ID: VNS
Firmware Build No.: 10.10.26.12


Output Current (mA)


Pulse Width (µSec)

Signal On Time (Sec)


Model ID: AspireSR 106
S/N: 20433
Patient ID: VNS
Firmware Build No.: 10.10.26.12

Tachycardia Detection


 Heartbeat Detection (sensitivity)


 Threshold for AutoStim (heart rate change)(%)

4.2 Generator-Specific Information on the PARAMETER Screen

Some information presented on the PARAMETER screen is specific to the model of the pulse generator interrogated. They include:

4.2.1 Pulse Generator Identification / Patient Information

At the top of the PARAMETER screen, the pulse generator Model number, serial number, firmware version number (if available) and Patient ID (if available) are displayed.

4.2.2 Pulse Generator Battery Status

For model 101 and 102(R) pulse generators, the programming software has one battery status indicator, Near End of Service (Near EOS). For model 103-106 pulse generators, the programming software has three indicators, Intensified Follow-up, Indicator (IFI), Near End of Service (N EOS), and End of Service (EOS).

On the PARAMETER screen, the Near EOS status for model 101 and 102(R) pulse generators is displayed on the lower portion of the screen (see Figure 5). For model 103-106 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 5). 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 enters states of IFI = Yes, N EOS = Yes or EOS = Yes, an additional indicator is displayed at the bottom of the PARAMETER screen (see Figure 6).

⚠ Caution: The IFI, N EOS, and EOS battery status indicators for M103 – M106 generators are displayed according to the generator battery voltage level. Due to small variations in voltage measurement, you may see alternating battery status indicators if the voltage level is near the threshold for the various battery status indicator flags. This is expected behavior and will self-resolve over time as the battery voltage settles past the threshold value.










Figure 6. PARAMETER Screen with ACTIVE BATTERY STATUS INDICATOR




Models 103, 104, 105, 106

In addition to the battery status indicators displayed on the PARAMETER screen, warning messages are also displayed upon successful interrogation or Diagnostics testing should the pulse generator battery reach Near EOS for models 101 and 102(R) and IFI, N EOS, or EOS for models 103-106. 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 |
|-------------------------|--|---|--|
| 101/102(R) | 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. |
| 101/102(R) | 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 to perform a System Diagnostics test to verify battery status and to replace the pulse generator as soon as possible. |
| 103/104/105/106 | >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. |
| 103/104/105/106 | >50% to 75% |  | |
| 103/104/105/106 | >25% to 50% |  | |
| 103/104 | >18% to 25% |  | |
| 105/106 | >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. |
| 105/106 | >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. |
| 105/106 | >0% to 5% |  | |

| Pulse Generator Model # | Estimated % Battery Power Remaining | Battery Icon Displayed | Pulse Generator Battery Status / Recommendations |
|-------------------------|-------------------------------------|---|--|
| 103/104/105/106 | 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. |

4.2.3 AutoStim and Tachycardia Detection (Model 106 only)

For the model 106 generator, parameters relating to the AutoStim feature are displayed on the PARAMETER screen under the **AutoStim** and **Tachycardia Detection** tabs. Additional details regarding these parameters and how to configure the AutoStim feature are described in Section 5.2.

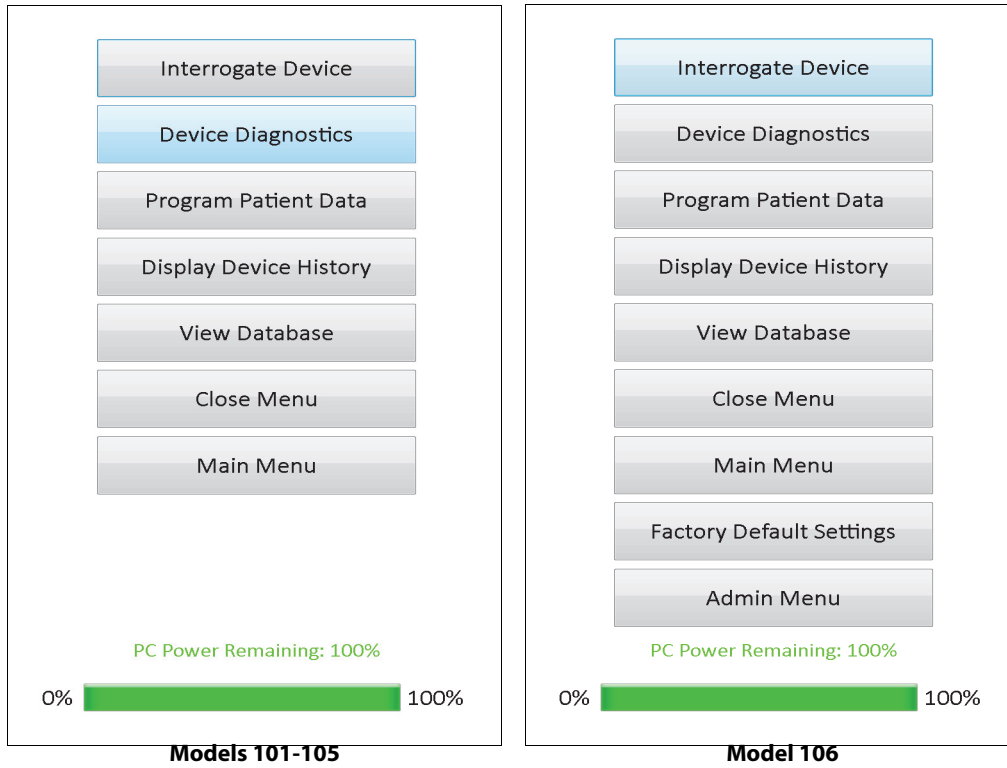
4.3 PARAMETER Screen Menu

Once an interrogation has been completed with a pulse generator, tapping the **Menu** button at the top right of the PARAMETER Screen causes the PARAMETER Screen Menu to be displayed, as shown in Figure 7.



Note: The functions available via this menu are explained in detail in Section 6 – Section 11.

Figure 7. PARAMETER Screen Menu



5 PROGRAM DEVICE

5.1 How to Program New Parameter Settings

After an interrogation is completed, you may change the pulse generator's settings at the PARAMETER screen (see Figure 5). The programmable parameters are split by stimulation mode and are presented on separate tabs. Depending on the model of pulse generator, you may be able to program Normal and Magnet Mode parameters (models 101-105), or Normal, Magnet, AutoStim Mode and Tachycardia Detection parameters (model 106).

On each tab, there is one line for each programmable parameter of the pulse generator. Each line contains three types of information:

- The name of the parameter and the units used to express its values
- The present setting for that particular parameter
- The **New** button, when tapped, displays the range of possible settings for that parameter


 **Note:** ***** is displayed for out of range parameter values. If this is observed at the PARAMETER Screen, please contact Technical Support for assistance.

Table 2 shows the range of programmable settings for all pulse generators supported by the Model 250 v11.0 Programming Software.

Table 2. Programmable Parameters for the Pulse Generator

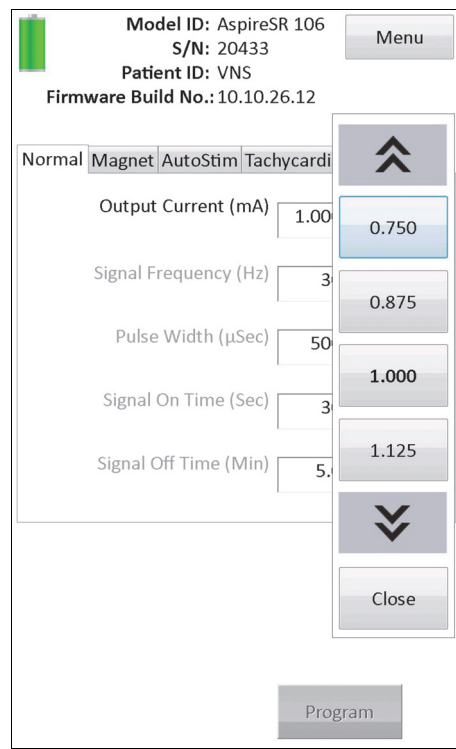
| Tab | Parameter Name | Generator Model(s) | Programmable Values |
|-----------------------|--|---------------------------------|---|
| Normal | Output Current (mA) | 101, 102(R), 103, 104, 105 | 0.00-3.50 mA, in 0.25 mA increments |
| | | 106 | 0.000-2.000 mA, in 0.125 mA increments; 2.000-3.500 mA, in 0.250 mA increments |
| | Signal Frequency (Hz) | 101, 102(R), 103, 104, 105, 106 | 1, 2, 5, 10, 15, 20, 25, 30 Hz |
| | Pulse Width (µSec) | | 130, 250, 500, 750, 1000 µSec |
| | Signal ON Time (Sec) | | 7, 14, 21, 30, 60 Sec |
| Signal OFF Time (Min) | 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 | | |
| Magnet | Output Current (mA) | 101, 102(R), 103, 104, 105 | 0.00-3.50 mA, in 0.25 mA increments |
| | | 106 | 0.000-2.000 mA, in 0.125 mA increments; 2.000-3.500 mA, in 0.250 mA increments |
| | Pulse Width (µSec) | 101, 102(R), 103, 104, 105, 106 | 130, 250, 500, 750, 1000 µSec |
| | Signal ON Time (Sec) | | 7, 14, 21, 30, 60 Sec |

| Tab | Parameter Name | Generator Model(s) | Programmable Values |
|-----------------------|--|--------------------|--|
| AutoStim | Output Current (mA) | 106 | 0.000-2.000 mA, in 0.125 mA increments; 2.000-3.500 mA, in 0.250 mA increments |
| | Pulse Width (µSec) | | 130, 250, 500, 750, 1000 µSec |
| | Signal ON Time (Sec) | | 30, 60 Sec |
| Tachycardia Detection | Tachycardia Detection | 106 | ON, OFF |
| | Heartbeat Detection (sensitivity) | | 1, 2, 3, 4, 5 |
| | Threshold for AutoStim (heart rate change) (%) | | 20, 30, 40, 50, 60, 70 % |

In order to change a parameter setting, first select the tab of interest on the PARAMETER screen, and then follow these steps:

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 8). 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 8, Output Current is enabled and the other parameters are disabled. The value of 1.00 mA has been selected for the Output Current parameter.

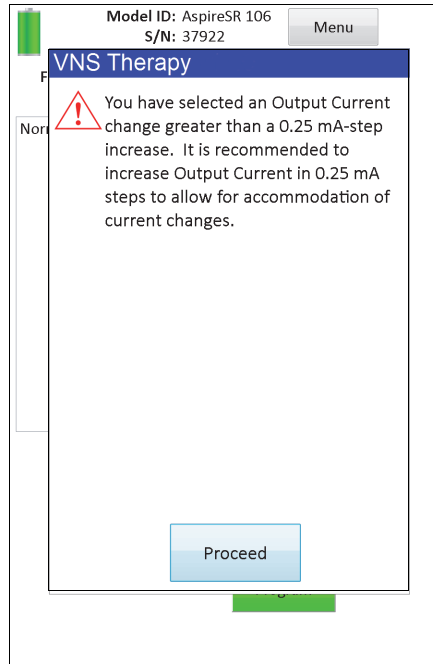
Figure 8. PARAMETERS SETTINGS POP-UP Menu



2. Select the new target value for the parameter by tapping the desired value on the screen. For Output Current, 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 9).

i **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 re-accommodation to the therapy.

Figure 9. OUTPUT WARNING Screen



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 PARAMETERS CONFIRMATION Screen (see Figure 10).

Figure 10. PARAMETERS CONFIRMATION Screen

The screenshot shows a confirmation screen with two buttons at the top: 'Modify' (grey) and 'Confirm' (blue). Below the buttons are five tables of parameters, each with a header row and three columns: 'Parameter', 'Current Value', and 'Updated Value'. Updated values are shown in blue and bold.

| Patient Parameters | | |
|--------------------|---------------|---------------|
| Parameter | Current Value | Updated Value |
| Patient ID | VNS | VNS |
| Implant Date | 2013-10-01 | 2013-10-01 |

| Normal Parameters | | |
|-------------------|---------------|----------------|
| Parameter | Current Value | Updated Value |
| Output Current | 1.000mA | 0.750mA |
| Signal Frequency | 30Hz | 30Hz |
| Pulse Width | 500µs | 500µs |
| Signal On Time | 30sec | 30sec |
| Signal Off Time | 5.0min | 5.0min |

| Magnet Parameters | | |
|-------------------|---------------|---------------|
| Parameter | Current Value | Updated Value |
| Output Current | 1.250mA | 1.250mA |
| Pulse Width | 500µs | 500µs |
| Signal On Time | 60sec | 60sec |

| AutoStim Parameters | | |
|---------------------|---------------|---------------|
| Parameter | Current Value | Updated Value |
| Output Current | 1.000mA | 1.000mA |
| Pulse Width | 500µs | 500µs |
| Signal On Time | 60sec | 60sec |

| Tachycardia Detection and Configuration Parameters | | |
|--|---------------|---------------|
| Parameter | Current Value | Updated Value |
| Tachycardia Detection | ON | ON |
| Heartbeat Sensitivity | 1 | 1 |
| Threshold for AutoStim | 70% | 70% |

4. Review the updated parameter setting(s), indicated in blue and bold typeface, to confirm that the values are correct. If correct, select **Confirm**. If incorrect, select **Modify** to go back to the PARAMETER Screen. After **Confirm** has been selected, the START PROGRAMMING screen is displayed (see Figure 11).


Figure 11. START PROGRAMMING Screen


The screenshot shows a handheld programming device at the top. Below it, the text reads: 'Programming Device. Please hold wand steady.' At the bottom, there are two buttons: 'Start Programming' (blue) and 'Cancel' (grey).

- From the START PROGRAMMING screen, place the programming wand over the pulse generator and tap **Start Programming** to program the new value or **Cancel** to return to the PARAMETER screen menu. After programming is complete, you will be notified with an on-screen message and the resulting PARAMETER screen will show the newly programmed parameter settings.

If any programming changes were made during a particular patient visit, it is recommended to perform a final interrogation prior to the end of the patient visit in order to confirm the pulse generator was programmed as desired. An **Interrogate Device** button is available in the PARAMETER Screen Menu for you to interrogate the device after any programming event.


Interrogate Device may also be accessed at the MAIN Menu.

 **Caution:** For the models 101 and 102(R) 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 > OFF time has resulted in degenerative nerve damage in laboratory animals. ON time > OFF time can be simulated by very frequent magnet activation. LivaNova recommends that stimulation at these combinations of ranges be avoided.


5.2 How to Configure AutoStim and Tachycardia Detection Settings (M106 only)

AutoStim is an optional feature that can be used in conjunction with Normal Mode stimulation. The feature allows physicians to enable AutoStim to be delivered in response to detection of rapid, relative heart rate rises (Tachycardia) that may be associated with seizures. The parameters under the **AutoStim** and **Tachycardia Detection** tabs work together to allow adjustment of settings related to the AutoStim feature and the resultant AutoStim therapy.

 **Note:** Limitations Associated with the AutoStim Mode - The LivaNova VNS Therapy System has been demonstrated to reduce seizure frequency in patients with partial onset seizures. A subset of these patients have tachycardia associated with their seizures. The effect of AutoStim Mode on reducing seizure frequency has not been evaluated above what has been established for VNS Therapy. Please refer to the "Receiver Operating Characteristic (ROC) Curve for Tachycardia Detection Associated with Seizures" in the Technical Information chapter of the physician's manual for additional data (i.e., sensitivity and false positive rates).

5.2.1 Turning the Tachycardia Detection feature ON/OFF

Under the **Tachycardia Detection** tab, you may program the Tachycardia Detection ON or OFF. If Tachycardia Detection is programmed OFF, then the model 106 generator performs with only Normal Mode and Magnet Mode therapies as programmed. If Tachycardia Detection is programmed ON, then all three modes work together and parameters under both the **AutoStim** and **Tachycardia Detection** tabs become applicable.

 **Note:** If Tachycardia Detection is OFF, the remaining parameters on the **Tachycardia Detection** tab are not visible and AutoStim is not activated.

5.2.2 Configuring the Heartbeat Detection Setting

The Heartbeat Detection (sensitivity) setting is a configurable threshold for declaring heart beats. This sensitivity value must be adjusted to tune the sensing components of the model 106 generator so it only declares heart beats based on the R-wave of the ECG morphology. The most sensitive setting is 5 while the least sensitive setting is 1.

5.2.2.1 Using the Verify Heartbeat Detection feature

The **Verify Heartbeat Detection** feature allows you to check that the appropriate Heartbeat Detection setting was selected. In order to use this feature, you must hold the programming wand over the model 106 generator during the entire calibration process. You can either manually activate this feature by pressing the **Verify Heartbeat Detection** button on the **Tachycardia Detection** tab (see Figure 5) and then select **Start** on the resultant VERIFY HEARTBEAT DETECTION screen (see Figure 12), or program a new Heartbeat Detection value which will automatically start this calibration process.


Figure 12. VERIFY HEARTBEAT DETECTION Screen





Caution: Manual activation of the Verify Heartbeat Detection feature will check the heartbeat detection performance of the model 106 at the *currently* programmed Heartbeat Detection setting. Therefore selecting a new Heartbeat Detection setting, and then manually activating the Verify Heartbeat Detection process will not evaluate performance at the new setting. You must first *program* the new Heartbeat Detection value, which will activate the Verify Heartbeat Detection process automatically.

Once the **Verify Heartbeat Detection** process is initiated, the model 106 will transmit a signal for two minutes to the programming wand while it is held over the generator. This signal communicates the perceived heart rate of the patient to the programming software and is displayed in beats per minute (BPM) on the VERIFY HEARTBEAT DETECTION screen. You should compare the BPM value reported by the programming software against an independently measured BPM (such as from another ECG monitor or a manual pulse count) in order to verify proper heartbeat detection. If the perceived heart rate reported by the programming software is too high, then the Heartbeat Detection setting should be adjusted downward. If the perceived heart rate reported by the programming software is too low, then the Heartbeat Detection setting should be adjusted upward. This process should be repeated until the model 106 generator detects heart beats accurately. The time remaining of the model 106 transmitting the signal is displayed at the bottom of the screen. If heartbeat detection is verified before two minutes fully elapse, you can stop the process by selecting **Stop**.

When you're done with the Verify Heartbeat Detection feature, select **Exit** to return back to the PARAMETER screen.


 **Note:** In addition to numerical values, three other visual indicators may be displayed in the BPM window: ????? indicates lost/no communication, ***** indicates that the detected BPM is out of range. Finally, ----- is displayed in the BPM window when the Verify Heartbeat Detection feature is OFF.

 **Caution:** If AutoStim or Magnet Mode stimulation is programmed on, there may be a chance for the Verify Heartbeat Detection feature to be interrupted if AutoStim or Magnet Mode stimulation is activated while the Verify Heartbeat Detection Timer is counting down. In this case, the model 106 generator will not be able to report detected heartbeats as it is stimulating (????? will be displayed).

 **Caution:** Since the Model 106 generator cannot simultaneously sense heartbeats and stimulate at the same time, it is highly recommended that all output currents be temporarily disabled (i.e. programmed to 0mA) prior to using the Verify Heartbeat Sensitivity feature. After the calibration process is completed, the output currents can be programmed back on as appropriate.


5.2.3 Configuring the Threshold for AutoStim Setting


The Threshold for AutoStim (heart rate change) is an algorithm setting on the **Tachycardia Detection** tab that is available in value from 20% to 70% (in 10% increments). The setting allows you to determine the detection sensitivity according to changes in heart rate. For the most sensitive detection, choose 20%, for the least, choose 70%.

 **Note:** Additional guidance for how to program this patient-specific setting can be found in the physician's manual for the Model 106 generator.

5.2.4 Stimulation Settings on the AutoStim Tab

The parameter settings on the **AutoStim** tab determine the stimulation output which will be delivered when Threshold for AutoStim is reached.

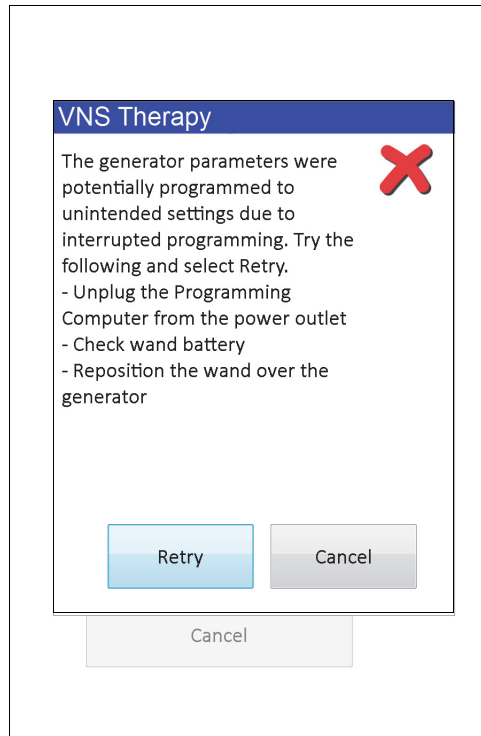
 **Note:** In order to allow enough detection time between scheduled stimulation periods, the programming software will not allow you to program certain combinations of Normal Mode and Autostimulation values. You will be prompted to change the values should you try to program a Normal Mode Off Time of 0.8 minutes or less while AutoStim/Tachycardia Detection is enabled. Otherwise, Tachycardia Detection will be turned OFF at the next programming attempt.

 **Caution:** Care should be taken when programming stimulation parameters so that they are comfortable for the patient. LivaNova recommends that the patient be monitored briefly after dosing to ensure that the level of stimulation is tolerable. In particular, it is recommended that the output current for the AutoStim Mode not exceed the output current for the Normal Mode or the Magnet Mode, especially for patients who experience discomfort or adverse stimulation effects (e.g. during sleep).

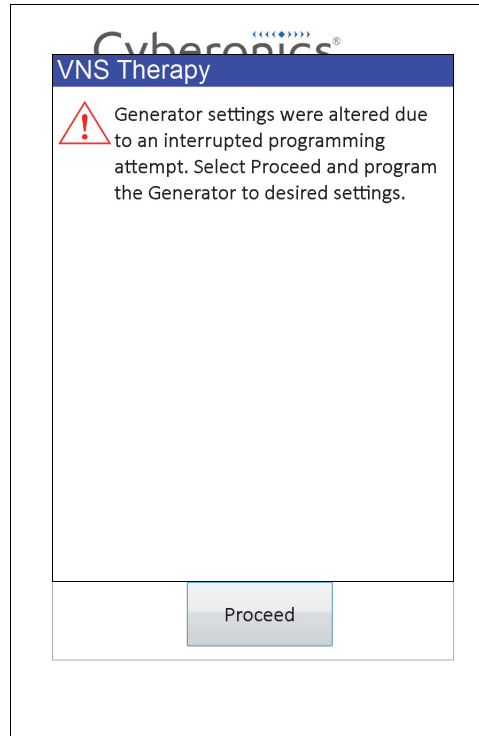
5.3 Potential Error Conditions Related to Programming

5.3.1 Partial Programming Due to Interrupted Programming Operation

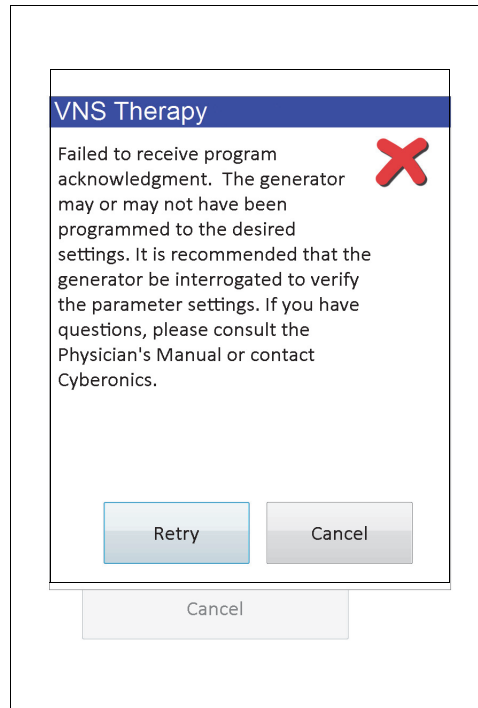
For models 101 and 102(R) generators, each parameter is programmed and verified individually during a programming event. Therefore, these pulse generators can be partially programmed to unintended settings if the communication between the wand and the pulse generator is interrupted during programming. 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).

Figure 13. PROGRAMMING FAILED WARNING (M101-102) Screen

This 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 4). 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 14. CHANGED SETTINGS PROGRAMMING WARNING SCREEN

For models 103, 104, 105 and 106 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). If the user selects **Retry**, the programming software will reprogram the pulse generator. If the user selects **Cancel**, the programming software will return to the START INTERROGATION screen (see Figure 4) so the pulse generator can be re-interrogated and then programmed to desired settings.

Figure 15. PROGRAMMING FAILED WARNING (M103-106) Screen**5.3.2****Cross-programming (applicable to Model 101 and 102 Pulse Generators ONLY)**

Models 101 and 102(R) 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
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* |

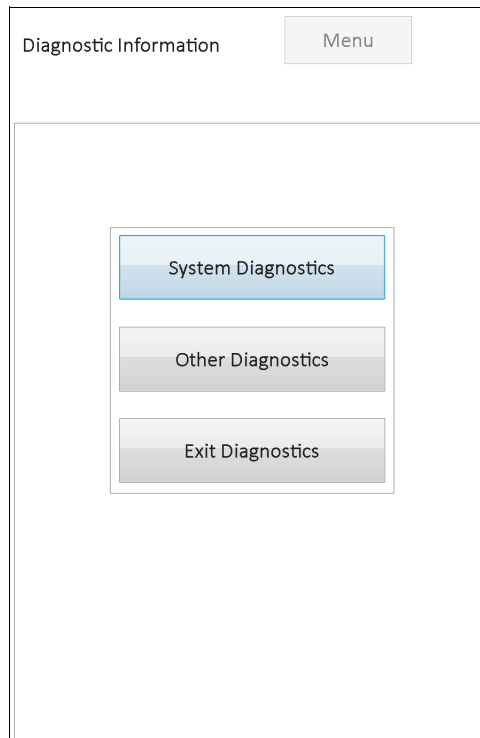
*Unintentionally altered or incorrectly displayed values

Due to the susceptibility of models 101 and 102(R) 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.

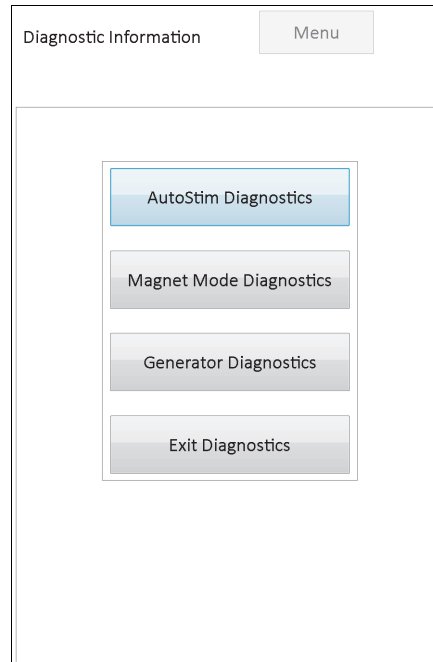
6 DEVICE DIAGNOSTICS

Several Diagnostics tests are available in the programming software to assess the pulse generator functionality. You may access the DEVICE DIAGNOSTICS Menu after a completed interrogation by selecting **Menu** and then **Device Diagnostics** (see Figure 16).

Figure 16. DEVICE DIAGNOSTICS Menu



Depending on the model of the pulse generator interrogated, different Diagnostics tests are available. **System Diagnostics** is available directly under the DEVICE DIAGNOSTICS Menu and additional tests such as Normal Mode Diagnostics, Magnet Mode Diagnostics, Generator Diagnostics, and AutoStim Diagnostics (some of these are generator-model dependent) are available when you tap **Other Diagnostics** (see Figure 17).

Figure 17. DEVICE DIAGNOSTICS Sub-Menu


When you select any of the diagnostics tests from the DEVICE DIAGNOSTICS Sub-menu, additional instructions will be provided on the programming computer screen. These instructions vary for each selection. Follow them carefully.

6.1 Diagnostic Test Parameters

Table 4 summarizes test parameters and their values/meanings across the different Diagnostics tests. Additional details regarding specific Diagnostics tests are further detailed in the remaining sections of this physician's manual.

Table 4. Diagnostic/Parameter Result Summary

| Parameter Name(s) | Parameter Description | Parameter Values/ Results | What Does the Value or Result Mean? |
|----------------------|--|----------------------------|--|
| Patient ID | A three-character alphanumeric code selected by the physician and programmed into the pulse generator. | Patient/Generator specific | Patient / Generator identification information. |
| Model ID | Model designator of the pulse generator being interrogated. | | |
| Serial Number | A numeric code assigned to the pulse generator and programmed into the pulse generator by LivaNova. | | |
| Implant Date | Implant date as programmed by the physician. | | |
| Communication Status | An indicator of the communication status during Diagnostics. | OK | Test completed successfully. |
| | | FAULT | Test was interrupted due to communication error, and should be repeated. |

| Parameter Name(s) | Parameter Description | Parameter Values/ Results | What Does the Value or Result Mean? |
|--|--|---|--|
| Output Status (M101/102) Output Current Status (M103/104/105/106) | Whether the programmed current is being delivered at the specified value. | ***** | Unknown / Unable to assess as the Generator is in STANDBY Mode. Pulse Generator was not stimulating and the Diagnostic test should be repeated. |
| | | OK | Current is being delivered at the programmed level. |
| | | LIMIT (M101/102) LOW (M103-M106) | Programmed current is possibly not being delivered at the specified level. |
| Output Current (M102/102) | Indicates the stimulation output current applied/delivered during the diagnostic test. | Generator-specific and test-specific | Indicates the stimulation output current applied/delivered during the diagnostic test. |
| Current Delivered (M103/104/105/106) | Indicates the stimulation output current applied/delivered during the diagnostic test. | Generator-specific and test-specific | Stimulation output current applied/delivered during the diagnostic test.  Caution: If the EOS indicator = Yes, the diagnostic results may show that current was delivered. However, stimulation is NOT being delivered if EOS = Yes. If EOS = Yes, see Table 1. |
| Lead Impedance | Indicates how much the current flow is impeded when delivering the output current during testing and whether it's within normal range. | OK | Impedance is within acceptable operating range. |
| | | HIGH | Impedance is higher than expected. |
| | | UNKNOWN | Impedance could not be assessed. |
| | | LOW | Impedance is lower than expected. |
| DC-DC Converter Code (M101/102) | Indicates how much the current flow is impeded when delivering the output current during testing. | 0 | $\leq 1.7 \text{ k}\Omega^*$ |
| | | 1 | 1.8-2.8 $\text{k}\Omega^*$ |
| | | 2 | 2.9-4.0 $\text{k}\Omega^*$ |
| | | 3 | 4.1-5.2 $\text{k}\Omega^*$ |
| | | 4 | 5.3-6.5 $\text{k}\Omega^*$ |
| | | 5 | 6.6-7.7 $\text{k}\Omega^*$ |
| | | 6 | 7.8-8.9 $\text{k}\Omega^*$ |
| | | 7 | $\geq 9.0 \text{ k}\Omega^*$ |
| Impedance Value (M103/104/105/106) | Indicates lead impedance value measured during execution of the diagnostics test. | Generator-specific | Indicates lead impedance value measured during execution of the diagnostics test. |

| Parameter Name(s) | Parameter Description | Parameter Values/ Results | What Does the Value or Result Mean? |
|---|---------------------------------|---------------------------|--|
| Intensified Follow-up Indicator (IFI) (M103/104/105/106) | Intensified Follow-up Indicator | No | The battery level is good and no special attention is required. |
| | | Yes | The battery has depleted to a level where more frequent clinical monitoring is recommended. |
| Near End of Service (Near EOS or N EOS) | Near End of Service Indicator | No (M101/102) | The battery level is good and no special attention is required. |
| | | Yes | M101/102 - A System Diagnostics Test is recommended to verify the Near EOS status. If confirmed, the pulse generator should be replaced as soon as possible. M103/104/105/106 - The generator should be replaced as soon as possible. |
| End of Service (EOS) (M103/104/105/106) | End of Service Indicator | Yes | The pulse generator is no longer supplying stimulation and immediate replacement is recommended. If the pulse generator is not replaced, it will eventually lose the ability to communicate with the programming software. |

*Correspondence to estimated lead impedance value at 1 mA, 500 μ s

6.2 System Diagnostics

The System Diagnostics test assesses the electrical continuity between the pulse generator and the bipolar lead; therefore, these two components must be connected prior to running this test. The test measures the ability of the pulse generator to deliver programmed Output Current as well as lead impedance status. This test is available to perform for all pulse generator models supported by the programming software, and may be performed during implantation and patient follow-up visits. It is recommended that you perform this test before other Diagnostic tests.

A successful System Diagnostics during surgery or post-implant shows that both the pulse generator and lead are working properly. Abnormal test results may be due to defects of either of the implanted components or a faulty electrical connection between the pulse generator and the bipolar lead connector pins. If a defective component is suspected during implant, disconnect the bipolar lead and perform the Generator Diagnostics test using the resistor assembly supplied with the pulse generator (see Section 6.3 for more details). If abnormal test results are received post-implant, surgical intervention may be needed to troubleshoot/resolve the issue (see Sections 16.4.2 and 16.4.3 for more details).

Note: If either the pulse generator or the bipolar lead is found to be defective or damaged in surgery, 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.


6.3 Generator Diagnostics

The Generator Diagnostics test should only be run in the operating room environment in case the System Diagnostics test yields abnormal results during the surgical implant procedure. This test must be run with the pulse generator connected to the LivaNova-supplied test resistor assembly. A successful Generator Diagnostics confirms that the pulse generator is functioning properly, independent of the bipolar lead. An abnormal Generator Diagnostics indicates that the pulse generator may not be functioning correctly, and should not be used for implantation.

For models 101 and 102(R) generators, the Generator Diagnostics test programs the device to 0 mA/30 Hz/500 μ sec/30 sec/5 min/0 mA/60 sec/500 μ s after completion of the test.


6.4 Normal Mode Diagnostics (applicable to M101/M102 only)

The Normal Mode Diagnostics test indicates whether or not the device is able to deliver the programmed output current. 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 Normal Mode output current is programmed to less than 0.75 mA, frequency to less than 15 Hz, or ON time to less than 30 sec. Therefore please verify that the patient's settings meet these minimum requirements prior to running the diagnostic.

 **Note:** For models 103/104/105/106 generators, performing the System Diagnostics serves the same function as Normal Mode Diagnostics since the test is run at the programmed device settings.

6.5 Magnet Mode Diagnostics

The Magnet Mode Diagnostics test determines whether the device is delivering the programmed magnet output current. Just prior to starting the Magnet Mode Diagnostics test, you must pass 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 is described in greater detail in the physician's manual for the pulse generator. Performing this action enables Magnet Mode output current stimulation. If this action is not performed correctly prior to the start of the test, the Magnet Mode Diagnostics test will be invalid and a message stating that the magnet swipe was not detected will be displayed. If this occurs, you will need to repeat passing of the magnet over the pulse generator and then restarting the test.

 **Caution:** For the Model 106 generator, you must remove the magnet presence from the generator in less than 3 seconds after you perform the magnet swipe. Otherwise stimulation will be inhibited (instead of activated) and the Magnet Mode Diagnostics results will not be valid.

Similar to Normal Diagnostics, results for this test are generally not reliable if the Magnet Mode output current is programmed to less than 0.75 mA, Normal Mode frequency to less than 15 Hz, or Magnet Mode ON time to less than 30sec. Therefore, please verify that the patient's settings meet these minimum requirements prior to running the diagnostic.



6.6 AutoStim Diagnostics (applicable to M106 only)

The AutoStim Diagnostics test determines whether the device is delivering the programmed AutoStim output current. The desired AutoStim current should be programmed into the pulse generator before execution of this diagnostic. The result will indicate whether the programmed AutoStim current is being delivered given the lead impedance that is present.

6.7 Diagnostic Test Differences Between Models of Generators

Some Diagnostic tests operate differently between models of pulse generators. These differences are outlined below in Table 5.

Table 5. Diagnostic Test Differences Between Models of Generators

| Items of Interest | Models 101 and 102(R) | Models 103, 104, 105, and 106 |
|---|---|--|
| Parameter Settings During System Diagnostics | <p>The programming software automatically programs the pulse generator to 1.0 mA, 500 μS, and 20 Hz during the System Diagnostics test and programs the pulse generator to its previous settings after completion of the diagnostic.</p> <p> Caution: 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.</p> | <p>Normal Mode Output Current is programmed to 0 mA: A test pulse of 0.25 mA is used to assess lead impedance and the diagnostic is run at output current of 1.0 mA, a pulse width of 500 μs, and a frequency of 20 Hz.</p> <p>Normal Mode Output Current is programmed to > 0mA: A test pulse of 0.25 mA is used to assess lead impedance and the diagnostic is run at the programmed settings.</p> |
| Parameter Settings During Generator Diagnostics | <p>The programming software automatically programs the pulse generator to 1.0 mA, 500 μS, and 20 Hz during the Generator Diagnostics test and programs the pulse generator Output Current to 0mA after the test.</p> <p> Caution: The Generator Diagnostics test should only be run in the operating room setting with the LivaNova-supplied test resistor assembly. If the Generator Diagnostics test is run on a model 101/102 pulse generator in the post-operative setting, the Output Current will be programmed to 0 mA after the test, effectively turning off VNS Therapy.</p> | <p>Normal Mode Output Current is programmed to 0mA: A test pulse of 0.25 mA is used to assess lead impedance/current delivered.</p> <p>Normal Mode Output Current if programmed to > 0mA: A test pulse of 0.25 mA is used to assess lead impedance, followed by stimulation at programmed settings.</p> |
| Lead Impedance | <p>These models of pulse generator are not capable of directly measuring the lead impedance. Instead, a DC-DC Converter Code is reported which is indicative of the estimated lead impedance at 1 mA and 500 μs.</p> <p>During normal operations, lead Impedance should = OK.</p> | <p>The actual lead impedance measurement (a numeric number) is reported.</p> <p>The normal range for lead impedance (Lead Impedance = OK) is 600 - 5300 Ω.</p> |
| Generator Battery Status | <p>The programming software displays one of the following indicators:</p> <p>N EOS = No N EOS = Yes</p> | <p>The programming software displays one of the following indicators:</p> <p>IFI = No IFI = Yes N EOS = Yes EOS = Yes</p> |

6.8 Potential Error Conditions Observed in Diagnostics

⚠ 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.

If the Diagnostic test was able to successfully complete, the programming software will display a screen with the results. If indicators on the results screen show OK and are in black font, there are no issues with the pulse generator and lead. If unexpected / abnormal values are detected during Diagnostics testing, the affected text on the results screen will be highlighted in bold and red font, and warning messages are typically displayed prior to the display of the results screen. Figures 18-22 illustrates examples of normal results for each Diagnostic Mode.

Figure 18. Normal System Diagnostics Results

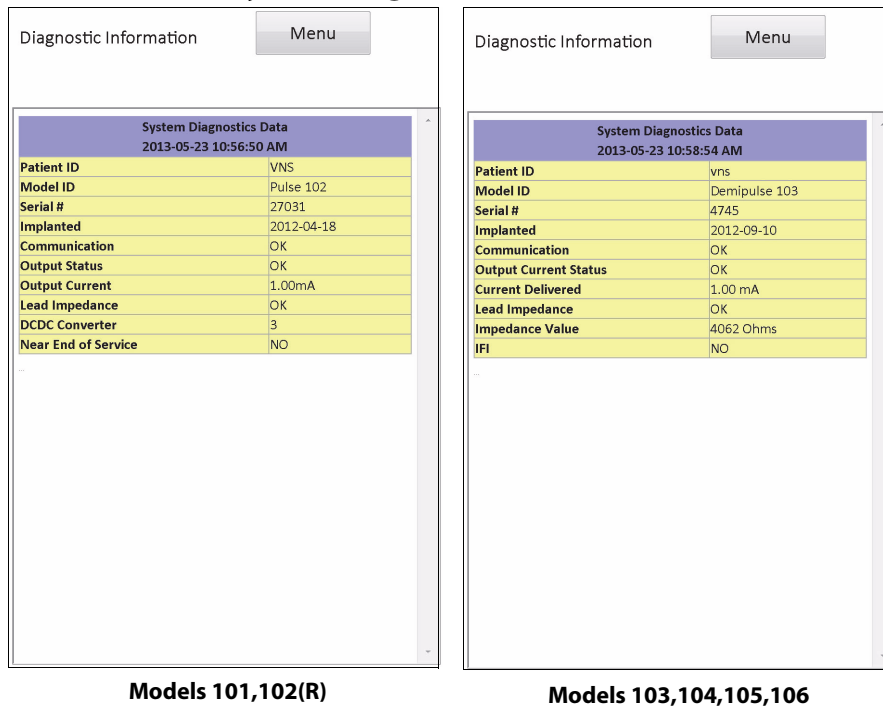


Figure 19. Normal Generator Diagnostics Results

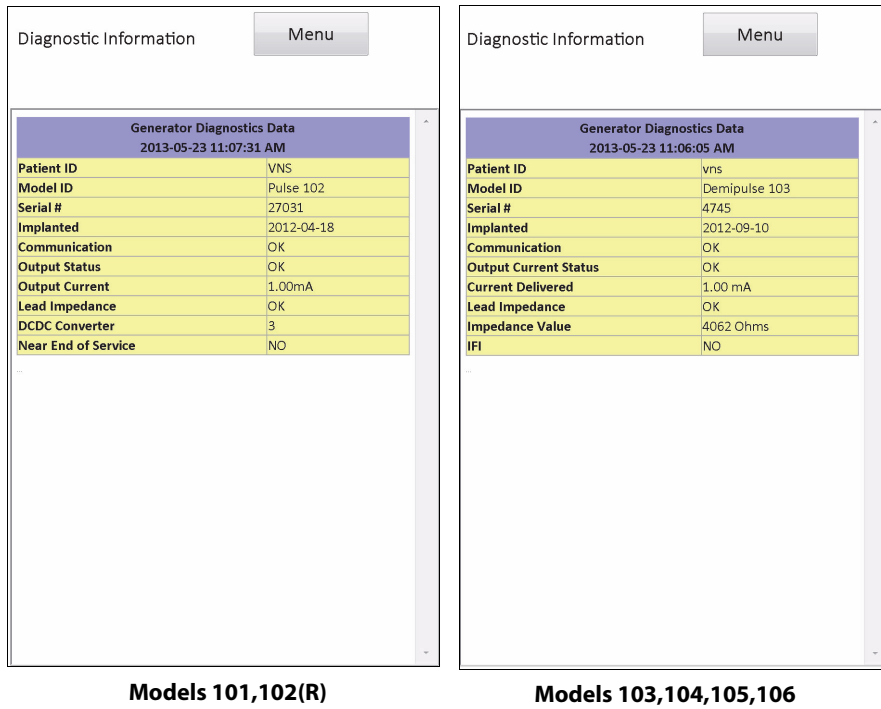


Figure 20. Normal Mode Diagnostics Result

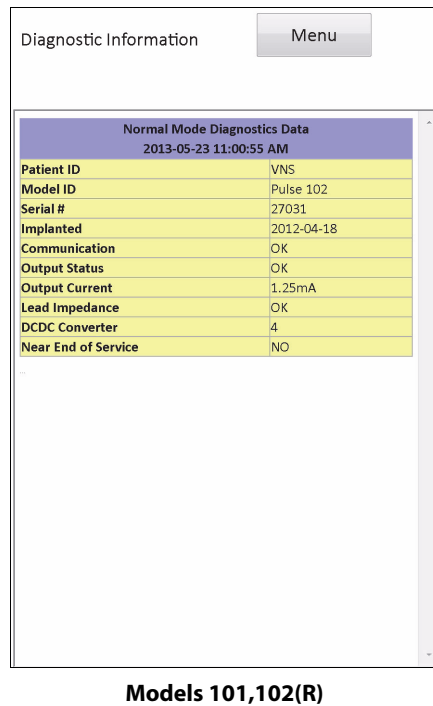


Figure 21. Normal Magnet Mode Diagnostics Result

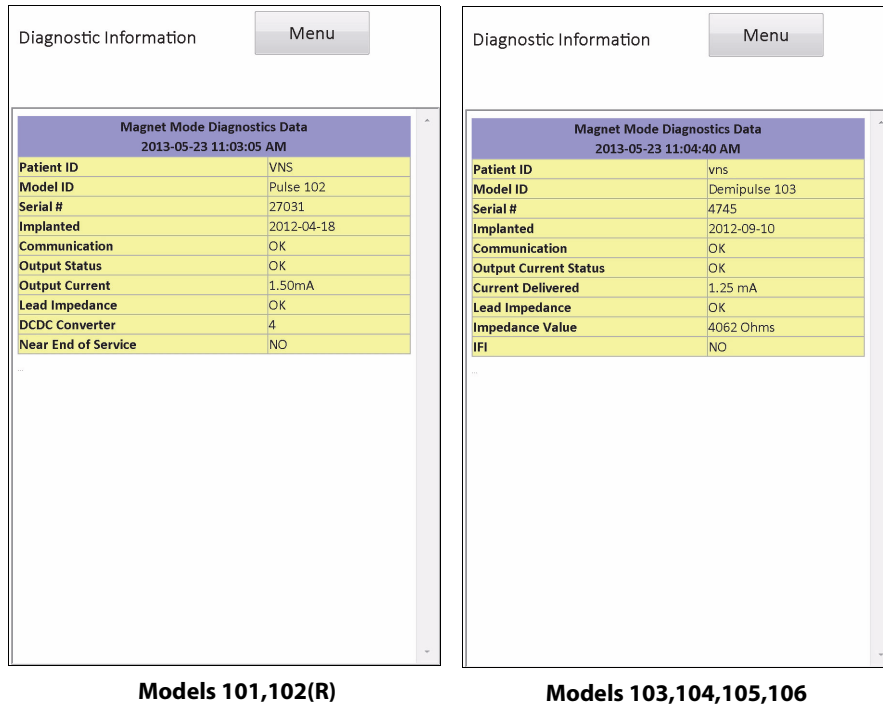
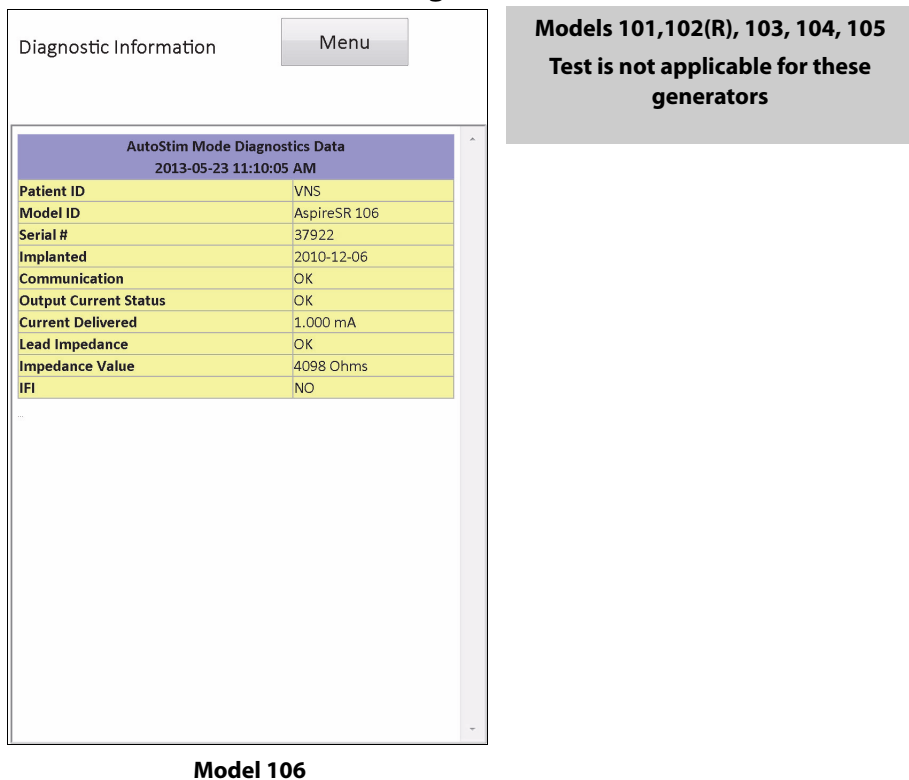


Figure 22. Normal AutoStim Diagnostics Result



There are three general categories of error conditions observed during Diagnostics testing:

1. Error conditions relating to improper test execution
2. Error conditions relating to interruptions during the execution of the test
3. Error conditions relating to abnormal/unexpected results received after test execution

6.8.1 Errors relating to improper test execution

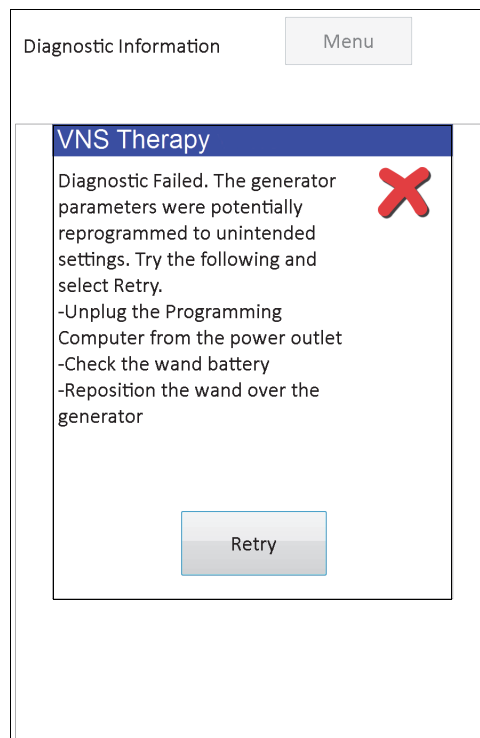
For models 101 and 102(R) generators, running the Normal Mode or Magnet Mode Diagnostics below the recommended parameter settings (output current < 0.75 mA, frequency < 15 Hz, or ON time < 30 sec) may result in "Unknown" Impedance. As test results are generally not reliable when the Diagnostic is run below the recommended settings, please ensure that the patient's parameters are set to the minimum recommended settings prior to execution of the test.

Prior to running Magnet Mode Diagnostics, you must first pass the magnet over the generator. If this action is not performed, you will not be able to see the test results and you must pass the magnet over the generator and then re-run the test.

6.8.2 Errors Relating to Diagnostics Interruptions

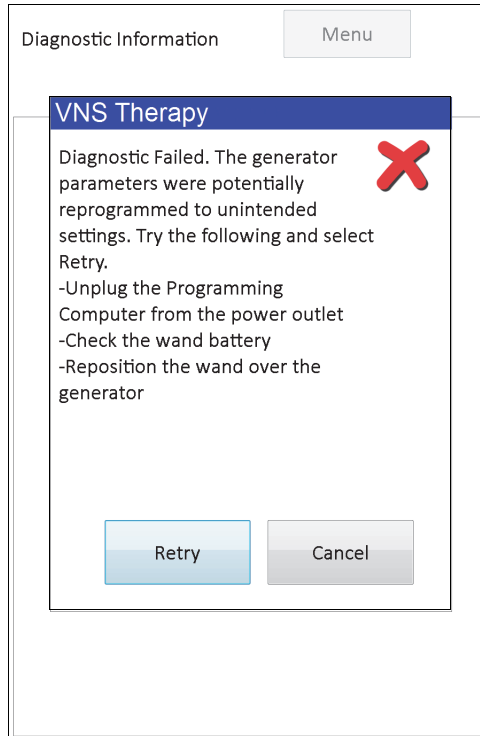
For models 101 and 102(R) generators, device parameters may be programmed to unintended settings if the communication between the programming wand and the pulse generator is interrupted during System or Generator Diagnostics. When the Diagnostics test is first interrupted, the programming software displays a warning message indicating that the procedure failed and device settings were potentially altered (see Figure 23).

Figure 23. DIAGNOSTIC - SINGLE FAILURE WARNING Screen



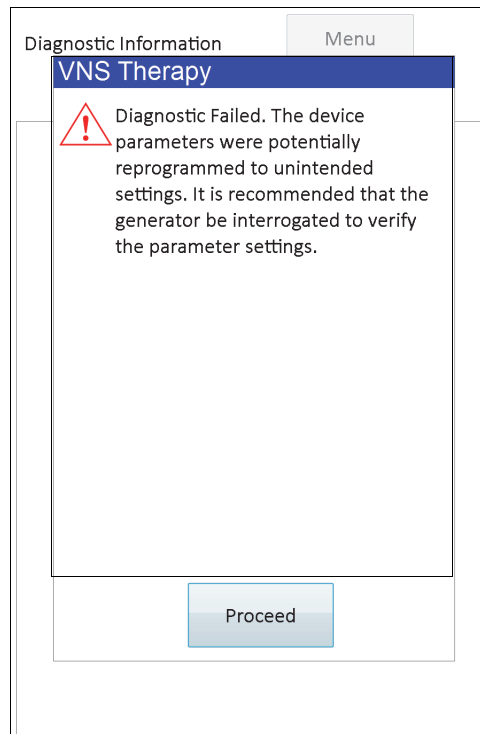
The warning message also indicates some troubleshooting options and allows you to retry the testing. If the testing fails for the second time due to an interruption in communication, you will have the option to retry again, or to cancel the operation (see Figure 24).

Figure 24. DIAGNOSTIC - MULTIPLE FAILURE WARNING Screen



If you choose to cancel the operation, a warning message is displayed indicating that device parameters were potentially reprogrammed and an interrogation is recommended (see Figure 25).

Figure 25. CHANGED SETTINGS WARNING (INTERRUPTED DIAGNOSTIC) Screen



Upon selecting **Proceed**, the programming software redirects you to perform the interrogation. After the interrogation, the programming software displays a warning message that the generator settings were altered due to the interruption in programming (see Figure 26). When you select **Proceed**, the PARAMETER screen is displayed with the previously interrogated values for the pulse generator pre-populated in the **New** column (see Figure 27). You may program the pulse generator back to desired settings at this time.

Figure 26. CHANGED SETTINGS WARNING (AFTER INTERROGATION) Screen

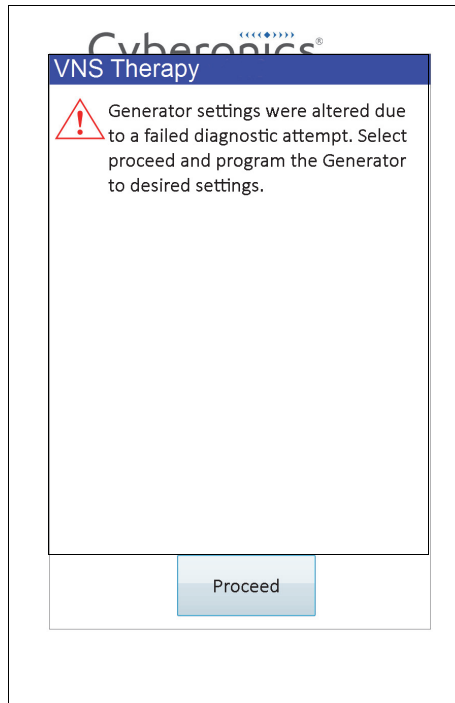
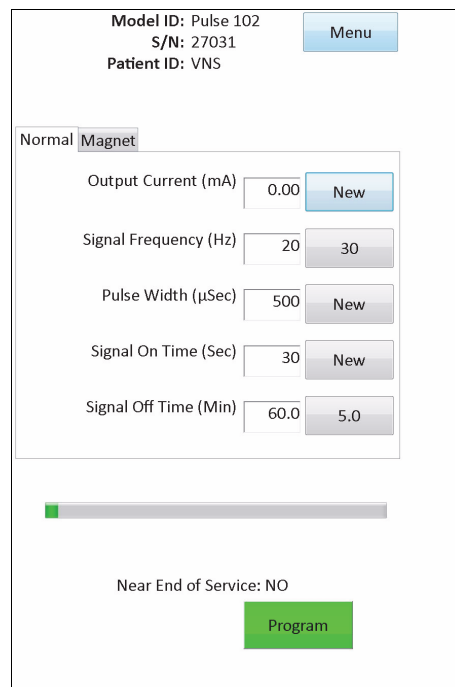


Figure 27. PARAMETER Screen with PRE-POPULATED VALUES



For models 103, 104, 105, and 106 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.

6.8.3 Errors Relating to Abnormal / Unexpected Results

The following error conditions occur when the Diagnostic is able to complete successfully (i.e. proper test conditions and no communication errors / interruptions) but the programming software detected abnormal or unexpected results.

6.8.3.1 Generator Battery Status Indicators


When the pulse generator reaches near EOS (M101/102) or IFI, N EOS, or EOS (M103-106), the associated indicator is displayed after diagnostics testing. Please follow the detailed recommendations outlined in Table 1 if you see one of these indicators after testing.

6.8.3.2 High or Low Lead Impedance

If the lead impedance is too high or too low, the pulse generator may not be able to deliver the programmed therapy. Follow the steps to resolve lead impedance errors in the OR in Figure 43, Figure 44, or Figure 45. Follow the steps to resolve high lead impedance at follow-up visits in Figure 48 or Figure 49.

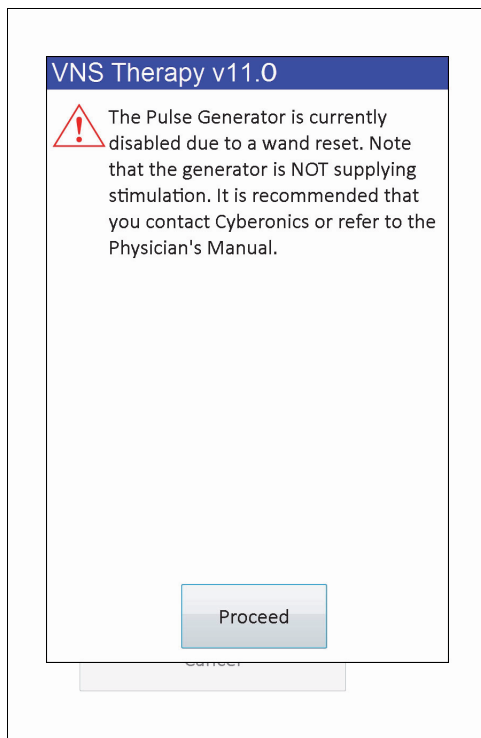
6.8.3.3 Output Status/Output Current Status LIMIT/LOW

Output Status/Output Current Status indicate whether the generator was able to deliver the programmed output during the diagnostic test. A LIMIT/LOW test result means that the generator was not able to deliver the output. Follow the steps in Figure 49.

 **Note:** Refer to the Indications, Warnings, and Precautions section of the Pulse Generator Physician's Manual for additional details relating continued stimulation in the presence of a lead fracture.

6.8.3.4 Pulse Disabled Warning (Model 103-106 Only)

In certain situations, the pulse generator automatically turns off all of its programmed output currents as a safety control. If this has occurred, the programming software will display a PULSE DISABLED warning message upon successful interrogation of the pulse generator (see Figure 28 for an example - note that the reason for Pulse Disable may vary).

Figure 28. PULSE DISABLED Warning

The Pulse Disabled status will be cleared once you perform a programming. Once you dismiss the warning message and arrive at the PARAMETER screen, previously programmed Output Current values are retained in the generator and are displayed in the **New** column. After you verify the values and complete the programming, you will no longer see the PULSE DISABLED warning message at the next interrogation.



Caution: With the exception of PULSE DISABLED warning messages associated with a generator hard reset (via wand) or normal/expected End of Service, you should report any PULSE DISABLED warning to LivaNova Technical Support as it may be indicative of a device malfunction.

7 PROGRAM PATIENT DATA

The PROGRAM PATIENT DATA Screen may be accessed through the PARAMETER Screen Menu after an interrogation (see Figure 29). This allows you to enter a three-character patient identification code and the implant date for the pulse generator, which will become a permanent part of the Device History when the information is programmed into the pulse generator.

Figure 29. PROGRAM PATIENT DATA Screen

The screenshot shows a screen titled "Program Patient Data". It contains the following information:

- Patient ID Set To - VNS
- Implant Date Set To - 2010-12-06
- Set Patient ID To -
- Set Implant Date To -

At the bottom of the screen, there are two buttons: a blue "Program" button and a grey "Cancel" button.

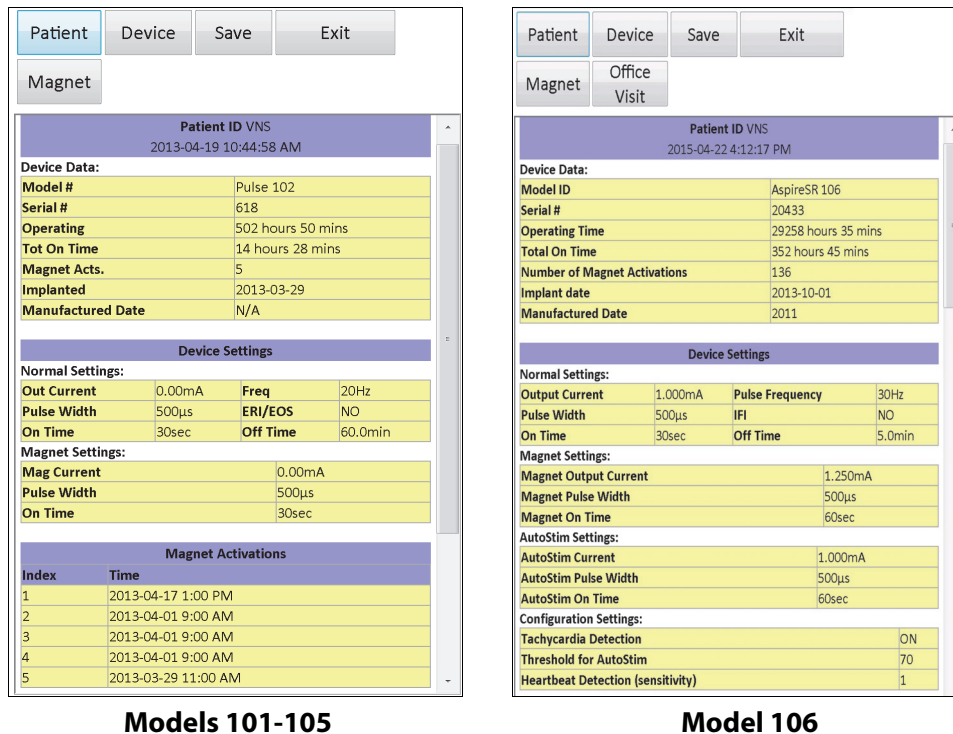
You can enter the Patient ID by tapping the **Set Patient ID To** field. When the on-screen keyboard icon appears, tap it to expand the keyboard and then type in the desired Patient ID. The implant date can be entered by tapping the downward-pointing arrow in the **Set Implant Date To** field and then 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 field.

After entering the data, tap **Program**, review the changes and tap **Confirm**, then the **Start Programming** button. Tapping the **Cancel** button will return you to the PARAMETER Screen Menu.

8 DISPLAY DEVICE HISTORY

When you tap the **Display Device History** button through the PARAMETER Screen Menu, the DEVICE HISTORY Screen will be displayed (see Figure 30).

Figure 30. DEVICE HISTORY Screen



Via this screen, you can access Patient data, Device data, the 15 most recent Magnet activations, and summary data from the last 3 office visits (Office Visit data - M106 only). You can also save this data to an SD Card, which can be transferred via a card reader and viewed on your desktop computer if desired, by selecting **Save**. The saved file is in "HTML" format and can be viewed in any Web browser application once transferred to a desktop computer.

Note: The Manufacture Date is shown as N/A for Models 101 and 102(R) generators.

Caution: An SD Card must be present in the programming computer before saving the device history data.

To see all the information contained on this screen, use the scroll bar on the right edge of the screen. Tapping the **Patient**, **Device**, **Magnet**, or **Office Visit** (M106 only) buttons also causes the respective patient, device, magnet, or office visit data to be displayed.

The office visit table displays summary data about the percentages of time each of the modes of operation (Normal Mode, Magnet Mode, or AutoStim Mode) have provided their individual treatments since the previous office visit. It also displays the number of days since the previous office visit, the average number of inhibited AutoStimulations per day, and parameter settings associated with the office visit. You may use this summary information in conjunction with the patient's clinical presentation in order to assess the model 106 tachycardia detection performance and/or adjustment of the Threshold for AutoStim setting.

Note: An "office visit" is defined by the programming software as an interrogation that has spanned for at least 12 hours since the last interrogation.

9 VIEW DATABASE

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

Historical programming events 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 (see Figure 31).

Figure 31. VIEW DATABASE Screen

The screenshot shows the 'VIEW DATABASE' screen with the following elements:

- Top left: 'View up to 25 records.'
- Top right: 'Exit' button.
- Sort By: 'Date' (dropdown menu).
- View All Records: checkbox.
- Earliest Date: 2013-04-18 (dropdown menu).
- Latest Date: 2013-04-18 (dropdown menu).
- Serial #: [Empty text input field]
- Patient ID: [Empty text input field]
- Model ID: 'All' (dropdown menu).
- View Parameter History: [Button]
- View Diagnostic History: [Button]
- View Magnet History: [Button]

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

The message at the top of the screen indicates how many records can be retrieved at a time.

9.1.1 Sort by Date, Patient ID, Serial Number or Model ID

To indicate whether you want to sort by Date, Patient ID, Serial Number, or the Model ID 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. Tapping **Model ID** arranges records by ascending model numbers.

9.1.2 View All Records

Selecting **View All Records** allows you to view all the records in the database (up to 100 records). 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** fields, the **Serial Number** field, the **Patient ID** field, and/or the **Model ID** field.



Note: Selecting **View All Records** causes the fields entitled **Earliest Date** and **Latest Date**, **Patient ID**, **Serial Number** and **Model ID** to be disabled (or "grayed out").

9.1.3 Earliest Date / Latest Date

Make sure the **View All Records** field 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** field 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 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** fields.

9.1.4 Serial Number

Make sure the **View All Records** field 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** field and then type the serial number of the pulse generator using the on-screen keyboard.

9.1.5 Patient ID

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

9.1.6 Model ID

Make sure the **View All Records** field is unchecked or you won't be able to use this option. To limit your search to a particular pulse generator model, tap the **Model ID** field and then select the model ID of the pulse generator from the drop down menu.

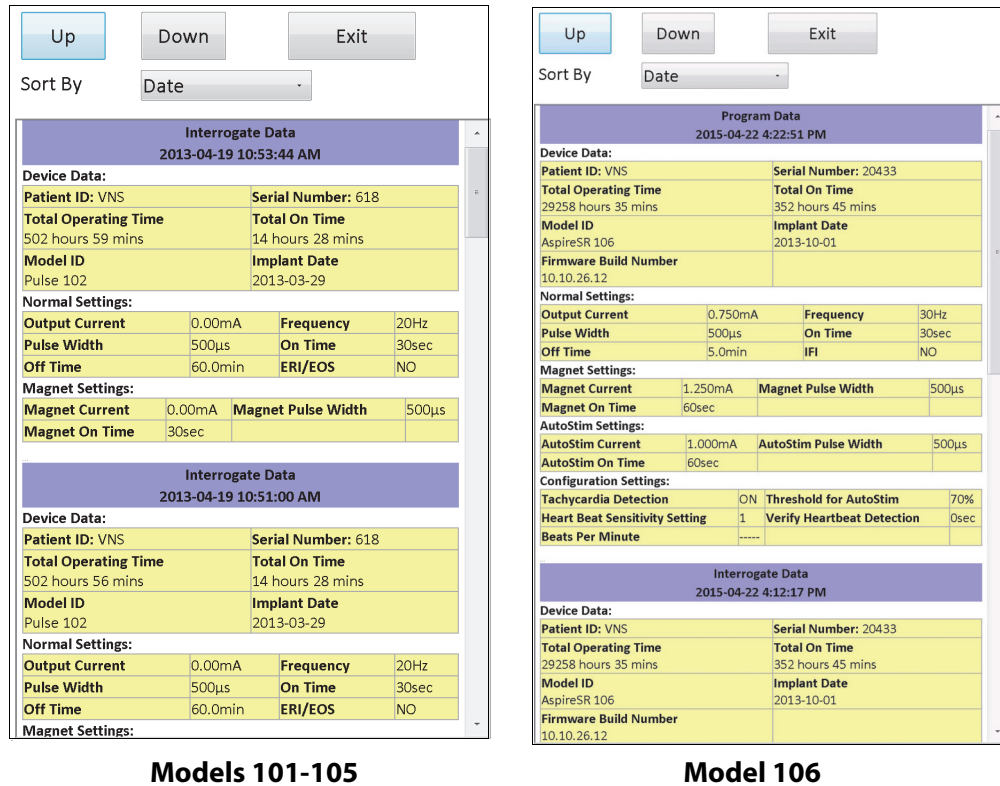
9.2 View the Records

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

9.2.1 View Parameter History

Tap the **View Parameter History** button to access the VIEW PARAMETER HISTORY screen (see Figure 32).

Figure 32. VIEW PARAMETER HISTORY Screen

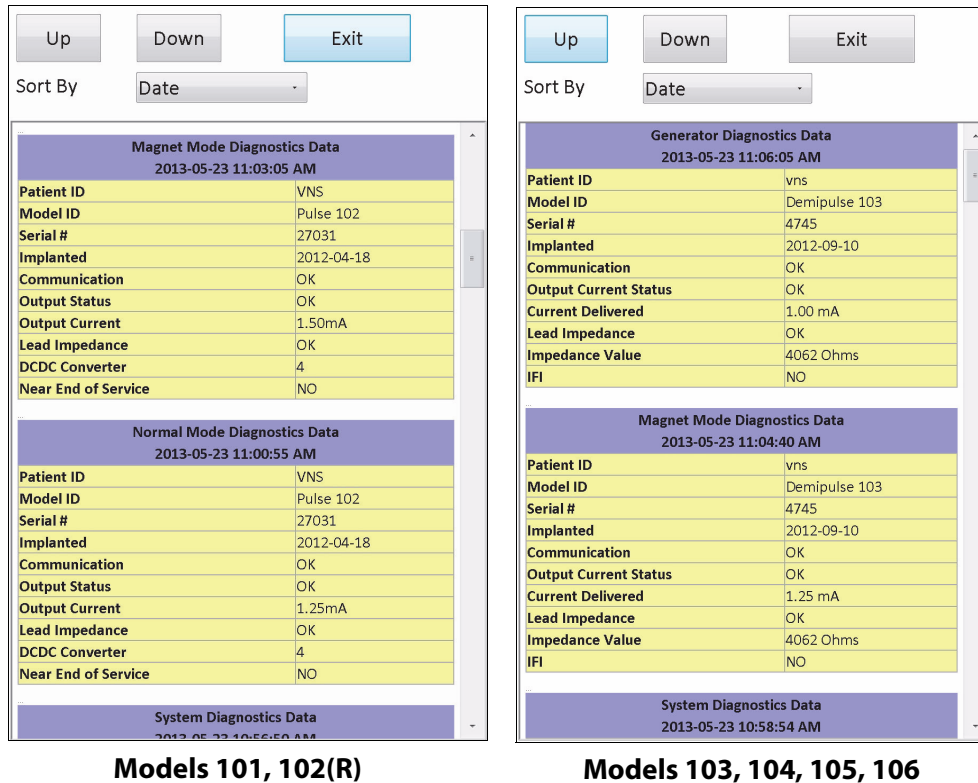


This screen is a scrollable screen that shows the parameter settings for each successful interrogation, programming event, and/or partial programming event. The scroll bar on the right allows you to view all the records you choose to access. The **Up** and **Down** buttons at the top of the screen allow 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, Pulse Generator Serial Number, or Model ID.

9.2.2 View Diagnostic History

Tap the **View Diagnostic History** button to access the VIEW DIAGNOSTIC HISTORY screen (see Figure 33).

Figure 33. VIEW DIAGNOSTIC HISTORY Screen



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, Serial Number, or Model ID.

Note: The five diagnostic tests are AutoStim (M106 only), Normal Mode (M101 and M102 only), Magnet Mode, Generator Diagnostics, and System Diagnostics.

9.2.3 View Magnet History

Tap the **View Magnet History** button to access the VIEW MAGNET HISTORY Screen (see Figure 34).

Figure 34. VIEW MAGNET HISTORY Screen

The screenshot shows the 'VIEW MAGNET HISTORY' screen. At the top, there are three buttons: 'Up' (highlighted in blue), 'Down', and 'Exit'. Below these is a 'Sort By' label and a drop-down menu currently set to 'Date'. The main content area displays a list of magnet activation events, each with a header row in purple and data rows in yellow. The events are as follows:

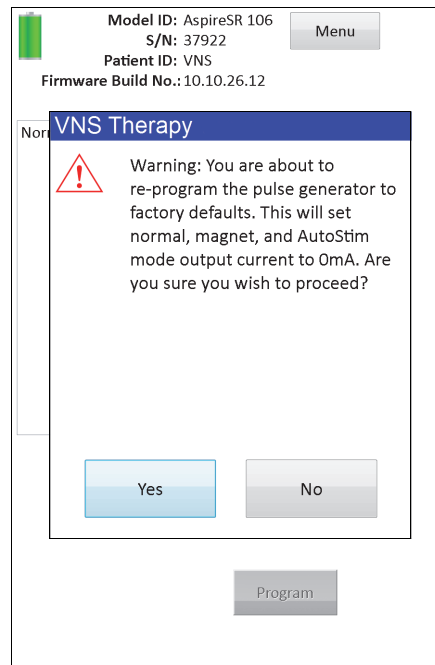
| Magnet Activation | |
|------------------------|---------------|
| 2013-04-17 1:00:00 PM | |
| Patient ID | VNS |
| Model ID | Pulse 102 |
| Serial Number | 618 |
| Total Activations | 5 |
| Magnet Activation | |
| 2013-04-01 10:59:00 AM | |
| Patient ID | vns |
| Model ID | Demipulse 103 |
| Serial Number | 4745 |
| Total Activations | 1079 |
| Magnet Activation | |
| 2013-04-01 10:59:00 AM | |
| Patient ID | vns |
| Model ID | Demipulse 103 |
| Serial Number | 4745 |
| Total Activations | 1079 |
| Magnet Activation | |
| 2013-04-01 9:00:00 AM | |
| Patient ID | VNS |
| Model ID | Pulse 102 |
| Serial Number | 618 |
| Total Activations | 5 |

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, the Pulse Generator Serial Number, or the Model ID by indicating your preference from the drop-down menu at the top of the screen.

10 FACTORY DEFAULT SETTINGS (M106 ONLY)

Factory Default Settings may be accessed through the PARAMETER Screen Menu after a completed interrogation on a model 106 generator. Tapping this button allows you to automatically select the factory settings with one-button push. A warning message appears first instructing you of the result of selecting these settings (see Figure 35).

Figure 35. FACTORY DEFAULT SETTINGS WARNING Screen



Once acknowledged, the parameters will be selected as shown in Figure 36. In particular, selecting Factory Default Settings prepares all of the output currents for programming to 0 mA and Tachycardia Detection to OFF.

Figure 36. FACTORY DEFAULT SETTINGS Screen

Model ID: AspireSR 106
 S/N: 20433
 Patient ID: VNS
 Firmware Build No.: 10.10.26.12

Menu

Normal Magnet AutoStim Tachycardia Detection

Output Current (mA) 1.000 0.000

Signal Frequency (Hz) 30 30

Pulse Width (µSec) 500 500

Signal On Time (Sec) 30 30

Signal Off Time (Min) 5.0 5.0

Program

Model ID: AspireSR 106
 S/N: 20433
 Patient ID: VNS
 Firmware Build No.: 10.10.26.12

Menu

Normal Magnet AutoStim Tachycardia Detection

Output Current (mA) 0.125 0.000

Pulse Width (µSec) 500 500

Signal On Time (Sec) 60 60

Program

Model ID: AspireSR 106
 S/N: 20433
 Patient ID: VNS
 Firmware Build No.: 10.10.26.12

Menu

Normal Magnet AutoStim Tachycardia Detection

Output Current (mA) 1.000 0.000

Pulse Width (µSec) 500 500

Signal On Time (Sec) 60 60

Program

Model ID: AspireSR 106
 S/N: 20433
 Patient ID: VNS
 Firmware Build No.: 10.10.26.12

Menu

Normal Magnet AutoStim Tachycardia Detection

Tachycardia Detection OFF OFF

Program

11 EXTENDED GENERATOR MEMORY DOWNLOAD (ADMIN MENU - M106 ONLY)

Extended Generator Memory Download is used to download certain data in the model 106 generator for troubleshooting purposes. You should only perform this download under the direction of LivaNova Clinical Technical Support.

If you were asked by LivaNova Clinical Technical Support to perform the Extended Generator Memory Download, you may access this function by tapping **Admin Menu** on the PARAMETER Screen Menu after a completed interrogation on a model 106 generator. You will see the EXTENDED GENERATOR MEMORY DOWNLOAD Screen (see Figure 37). LivaNova personnel will indicate to you how many records to interrogate/download and once you select the appropriate number of records, the amount of time required for the data download will be indicated on the screen. Similar to a normal interrogation, the wand must be held over the pulse generator during the Extended Generator Memory Download until completion. At the conclusion of the data download, a message is displayed indicating success (see Figure 38).

Figure 37. EXTENDED GENERATOR MEMORY DOWNLOAD Screen

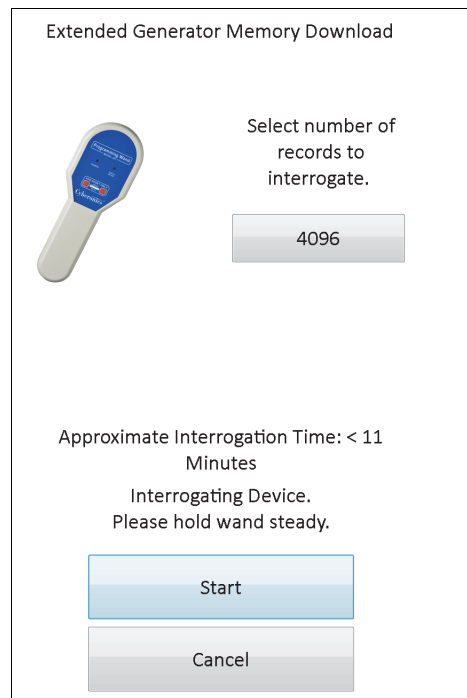


Figure 38. EXTENDED GENERATOR MEMORY DOWNLOAD SUCCESS Screen



Caution: An SD Card must be present in the programming computer in order to perform an Extended Generator Memory Download.



Caution: The Extended Generator Memory Download may take up to 20 minutes. Only perform procedure under the direction of Technical Support.

12 VIEW LAST PARAMETERS

You can view the parameter settings from the most recent pulse generator interrogation via the VIEW LAST PARAMETERS screen (see Figure 39). This screen can be accessed from the MAIN MENU screen.

Figure 39. VIEW LAST PARAMETERS Screen

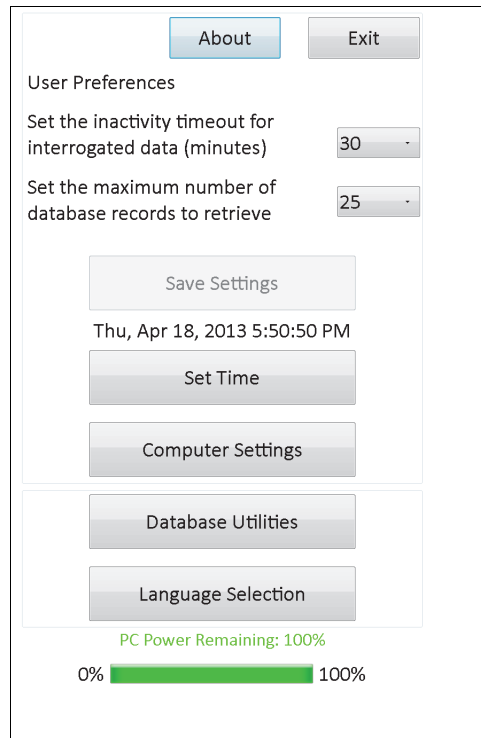
| | | | |
|---|---------------------|-----------------|--------|
| Patient | Device | Save | Exit |
| Magnet | Office Visit | | |
| Patient ID VNS 2015-04-22 4:12:17 PM | | | |
| Device Data: | | | |
| Model ID | AspireSR 106 | | |
| Serial # | 20433 | | |
| Operating Time | 29258 hours 35 mins | | |
| Total On Time | 352 hours 45 mins | | |
| Number of Magnet Activations | 136 | | |
| Implant date | 2013-10-01 | | |
| Manufactured Date | 2011 | | |
| Device Settings | | | |
| Normal Settings: | | | |
| Output Current | 1.000mA | Pulse Frequency | 30Hz |
| Pulse Width | 500µs | IFI | NO |
| On Time | 30sec | Off Time | 5.0min |
| Magnet Settings: | | | |
| Magnet Output Current | 1.250mA | | |
| Magnet Pulse Width | 500µs | | |
| Magnet On Time | 60sec | | |
| AutoStim Settings: | | | |
| AutoStim Current | 1.000mA | | |
| AutoStim Pulse Width | 500µs | | |
| AutoStim On Time | 60sec | | |
| Configuration Settings: | | | |
| Tachycardia Detection | ON | | |
| Threshold for AutoStim | 70 | | |
| Heartbeat Detection (sensitivity) | 1 | | |

The VIEW LAST PARAMETERS screen is organized and operated exactly like the DISPLAY DEVICE HISTORY screen (see Section 8). To see all the information contained on this screen, use the scroll bar on the right edge of the screen. Tapping the **Patient**, **Device**, **Magnet**, or **Office Visit** (M106 only) buttons also causes the respective patient, device, magnet, or office visit data to be displayed. You can also save the displayed data in HTML format to the SD card by tapping the **Save** button.

13 USER PREFERENCES

You can access the USER PREFERENCES Screen (see Figure 40) via the MAIN Menu by tapping the **User Preferences** button. Functions that may be accessed through this screen are detailed below.

Figure 40. USER PREFERENCES Screen



13.1 Set Inactivity 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. If the programming computer is idle for the amount of time indicated in the button, the pulse generator must be re-interrogated before performing any programming. Tap **Save Settings** after making changes to this button.



Caution: You must tap **Save Settings** after making changes to this button or the changes will not take effect.

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 101 and 102 pulse generators.



Note: See Section 5.3.2, "Cross-programming (applicable to Model 101 and 102 pulse generators ONLY)" for more information.

13.2 Maximum Number of Records to View

By tapping on the drop-down menu to the right of **Set the maximum number of database records to retrieve**, you can view up to 100 records at a time in the Database screens. The minimum number of records to view is 25 and you may change the number of records in increments of 25. Tap **Save Settings** after making changes to this button.



Caution: You must tap **Save Settings** after making changes to this button or the changes will not take effect.

13.3 Set Time and Date

The system time and date for the programming computer is displayed in the middle of the screen. If this is not correct, tap on the **Set Time** button to reset the date and time. Tapping the dropdown arrow to the right of the **System Date** displays a calendar of the current month. To scroll to earlier or later months, tap 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** field.

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 the upward-pointing arrow to advance the hour setting. Tapping 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. It's important to keep the correct System Date and Time as its accuracy determines the accuracy of the dates and time in the patient history records (including Magnet activation timestamps).

13.4 Computer Settings

After tapping on **Computer Settings**, you will be able to adjust screen brightness or perform a screen calibration.

13.4.1 Adjust Screen Brightness

Adjust Screen Brightness allows you to adjust the screen illumination level under various operating conditions. In order to adjust screen brightness, tap on the + and - buttons until the desired screen brightness is achieved.

13.4.2 Screen Calibration



Note: The instructions for Screen Calibration are in available in English only.

If the programming computer touchscreen doesn't respond as expected or if it responds to unintentional input, you can recalibrate the display. Tap the **Screen Calibration** button, follow the on-screen instructions, and a calibration program will begin. Do not touch the display during the calibration process. A message will display indicating the calibration program has completed.

13.5 Database Utilities

Tap **Database Utilities** to access the SD card functions. You may back up the database to flashcard, restore a database from flashcard, or export database as text.

13.5.1 Backup to Flashcard

The Backup to FlashCard function backs up the database in the programming computer memory to the SD card. 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 SD card is misplaced (or damaged) and a new one is installed.



Caution: If a new SD card is inserted and is not being recognized by the programming computer (i.e. Database Utilities button is grayed out), remove and reinsert the SD card into the programming computer. If issues persist, you may reboot the programming computer by turning it off and then on.

13.5.2 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 programming computer to your programming computer. However, if this is to be performed, the programming 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 programming computer. Otherwise database corruptions may occur. Additionally, if attempting to transfer a database from another programming computer, make sure your programming computer is powered on before inserting the new SD card.



Caution: The Restore from FlashCard function, accessible from Database Utilities, overwrites the database on the programming computer with the database contained on the SD card. In other words, the original database will be erased.

13.5.3 Export Database as Text

You can use this function to export a Comma Separated Value (CSV) text file to the SD card. 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 SD card and inserting it into a SD card reader. The feature saves the database information to the following files:


- PIExport - contains all of the Interrogation and Programming events.
- DiagExport - contains all of the Diagnostics events.
- MagExport - contains all of the Magnet history data.
- OVExport (model 106 Only) - contains all of the Office Visit data.

13.6 Language Selection

This version of VNS programming software is **ENGLISH ONLY**.

13.7 Programming Computer Battery Status

The bar near the bottom of the USER PREFERENCES screen indicates the percentage of the battery charge still available on the programming computer. When the programming computer is operating on battery power, this bar should be checked regularly to prevent a loss of power.

 **Note:** This programming computer battery status bar is also visible under the PARAMETER SCREEN Menu once an interrogation has been performed.

13.8 Programming Computer Information

Tapping the **About** button on the USER PREFERENCES screen provides you with information about the programming computer and software. The version and copyright information about the VNS Therapy Software, operating system information, and the programming computer serial number are all displayed this screen.

14 HARDWARE MAINTENANCE, HANDLING, AND STORAGE

Special precautions should be taken when handling or storing the programming computer and its components. See Section 14.1 for a list of cautions.

14.1 Programming Computer and Components Cautions



Caution: Do not put the programming computer on your lap or other parts of the body to avoid injury from heat.



Note: For additional product safety and compliance information about the programming computer, refer to the Motion Safety and Regulatory Compliance manual located online at www.livanova.com. LivaNova has performed additional compliance testing to qualify the programming computer for use in a medical environment.

- Excessive handling may damage the SD card.
- The SD card should never be stored near a magnet and should always be left in the programming computer.
- When using the power adapter, refrain from covering with objects and do not place near any part of the body to avoid injury from heat.
- Before storing the programming computer, power off after each use to avoid overheating.
- Debris can damage the programming computer touchscreen display. Frequently wipe with a soft cloth using window-type cleaning solution or water. Be sure to power off computer and disconnect AC adapter from electrical outlet before cleaning.
- The programming computer may be damaged if placed in direct sunlight or near equipment that generates heat.
- Do not operate the programming computer near water or other fluids. Also, do not submerge the programming computer in water or other fluids.
- If the programming computer battery pack leaks, avoid skin and eye contact. If battery pack fluid exposure occurs, rinse affected area with clean water and seek medical attention immediately. Return the damaged programming computer to LivaNova.
- When recharging the battery, to avoid risk of electric shock, the programming computer must only be connected to a supply mains with protective earth. Verify with an electrician if you are unsure that your building has proper protective earth connections.



Note: Refer to the Programming Wand manual, Product Specification section, for guidance and manufacturer's declarations associated with IEC 60601-1-2 Electromagnetic Compatibility compliance information.

14.2 Storage and Operating Conditions

See the programming wand manual for proper storage and operating conditions.

14.3 Disposal

Return all unused programming systems to LivaNova for examination and safe disposal.

15 PRECAUTIONS

If problems occur with the programming software, review the information in this section:

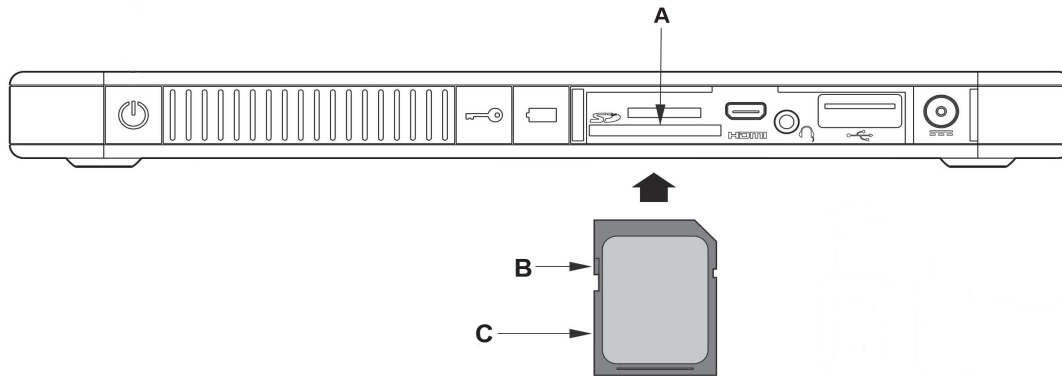
- The programming computer should not be plugged into AC power while being used in a patient environment. Having the programming computer plugged into AC power during use may contribute to communication difficulties and interfere with the Verify Heartbeat Detection feature (model 106 only). When not in use, the programming computer should be powered off and plugged into AC power to maintain charge. Always keep the charger in a convenient place for easy access.
- Upon startup, the programming computer may take 30 seconds or more for the VNS Therapy Programming Software to load. If the VNS Therapy Programming Software does not load, reset the programming computer by turning it off and back on.
- If the programming computer cable has just been inserted into the programming computer or the programming computer has just been powered on, wait 15 seconds before attempting to communicate with a pulse generator.
- 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 programming computer.
- Do not press the security key button located on the left side of the programming computer during power on or operation of the programming software. Doing so may interrupt the programming software.
- Do not tap on the VNS Therapy Software display screen during active interrogation, programming, and diagnostics testing sessions. Doing so may interrupt the programming software.
- The IFI, N EOS, and EOS battery status indicators for M103 - M106 generators are displayed according to the generator battery voltage level. Due to small variations in voltage measurement, you may see alternating battery status indicators if the voltage level is near the threshold for the various battery status indicator flags. This is expected behavior and will self-resolve over time as the battery voltage settles past the threshold value.
- For model 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 Section 6.8.2 for more details.
- 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 programming computer are correct). Therefore, only the 15 most recent magnet activations will be stored in the database at each follow-up visit.
- Magnet activation time-stamps and total activation counts may be duplicated when using the cross-pattern swiping-technique (model 103-106 generators). 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.

- For models 101 and 102 generators, 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 the model 106 generator, you must remove the magnet presence from the generator in less than 3 seconds after you perform the magnet swipe. Otherwise stimulation will be inhibited (instead of activated) and the Magnet Mode Diagnostics results will not be valid.
- 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 of 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.
- (Model 106 generator only) For model 106 generators previously programmed to a Blackout time of less than 30 seconds, a warning message will be displayed after interrogation to serve as notification that next time the pulse generator is programmed, blackout time will automatically be set to 30 seconds.
- Treatment time per day, treatment start delay time, and blackout time are nonprogrammable through the programming software user interface.
- Version 11.0 VNS Programming Software does not support model 100 pulse generators (B and C) or the model 200 programming wand.
- Only use the programming computer cable, power adapter, and SD card provided by LivaNova. Do not connect an unapproved device to any of the programming computer ports or insert an unapproved memory card into the SD card slot. Anyone connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with requirements for medical electrical systems.
- Do not modify any parts of the programming system unless directed to do so by LivaNova.
- If the touchscreen doesn't respond as expected or if it responds to unintentional input, you can recalibrate the display using the **Calibrate Display** function in the USER PREFERENCES Screen.

- Do not insert the SD card from one programming computer into any other programming computer, unless directed to do so by LivaNova Clinical Technical Support.
- Keep the switch located on the side of the SD card in the unlocked position. Moving this switch to the "Lock" position will prevent data backup and export to the SD card.
- SD cards should only be inserted in the programming computer with the label side up. Figure 41 shows the correct orientation for SD card insertion.

Figure 41. Correct SD Card Orientation



A - SD Card Slot
B - SD Card Lock Switch
C - SD Card

16 TROUBLESHOOTING

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

16.1 General Recommendations for Non-responsive Programming Computer

If the programming computer becomes non-responsive to user input, or if any other screen appears that is not part of the programming software, you may perform the following steps to reset the programming computer to resolve the problem:

1. Plug in the programming computer into the A/C outlet.
2. Press and release the power button to shut down the programming computer. If the programming computer is non-responsive at this point, press and hold the power button for at least 5 seconds and then release to shut down the programming computer.
3. Once the computer has powered off, turn it back on by pressing and releasing the power button quickly. Allow time for the programming computer to power on and go through the boot up sequence. The VNS Programming Software should load automatically and display the MAIN Menu.



Caution: If the programming computer is stuck in a boot up loop, turn off the computer, remove the SD card, and turn the computer back on. Once the programming software loads, reinsert the SD card.

4. Tap on **User Preferences** and verify that the programming computer has adequate charge and has the correct time/date. If so, unplug the programming computer from the A/C outlet prior to resuming use with the programming system. Otherwise, correct the time and date using the **Set Time** feature and/or let the programming computer charge completely prior to resuming use.
5. If you are still not able to restore the programming computer, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

16.2 Hardware Issues

For all hardware issues for the programming computer, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

16.3 Troubleshooting in the OR

16.3.1 Communication Problems in the OR

A communication problem can cause the following error messages:

- "There is an error establishing communication with the generator. Please try repositioning the programming wand." (message may be followed by error code)
- "Failed to retrieve diagnostic data."


- “Failed to receive program acknowledgment. The generator may or may not have been programmed to the desired settings. It is recommended that the generator be interrogated to verify the parameter settings. If you have questions, please consult the Physician's Manual or contact Cyberonics.”


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
- Improper USB port recognition of the programming computer cable
- Electromagnetic interference (EMI) e.g., 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. Performing these steps may restore communication (see Figure 42).

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.
 - c. While the VNS Programming Software is running, remove and reinsert the programming computer cable into the USB port. Wait 15 seconds.

 **Note:** If the error message indicates the port cannot be opened, it usually means the USB port is not recognizing the programming computer cable. Performing step 2c should resolve communication problems due to improper USB port recognition.
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.

 **Note:** For details, see the *Programming Wand* physician's manual.
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 electromagnetic interference (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.


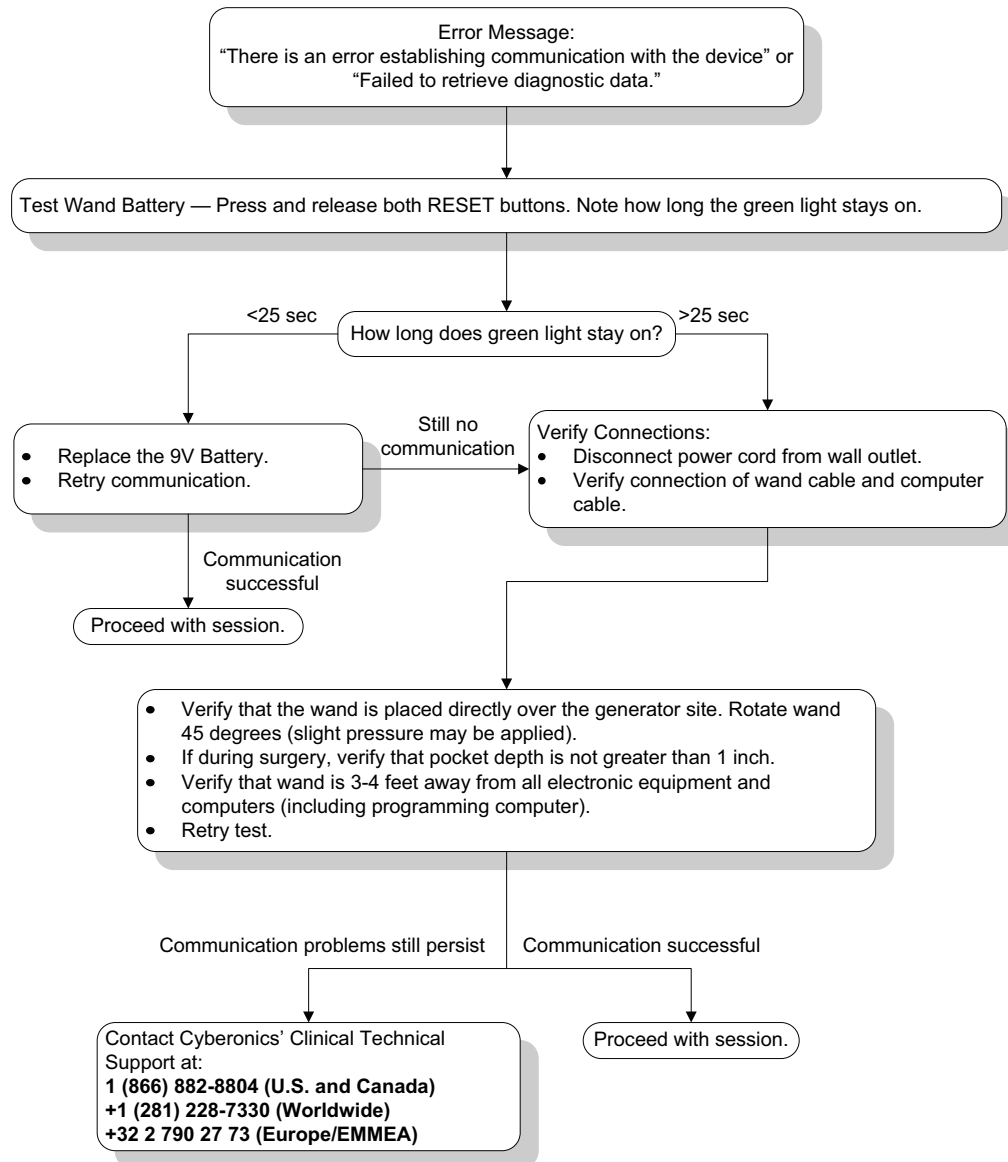
 **Note:** LivaNova recommends interrogating the pulse generator as the last step of any programming or diagnostic session to verify correct settings for each parameter.
8. If problems persist, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

Figure 42. Communication Problems in the OR and at Follow-up Visits

16.3.2 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 43):

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.



Note: See the physician's manual for the pulse generator.

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.
 - ♦ 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) and +32 2 790 27 73 for LivaNova Europe.
 - ♦ 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 "HIGH" lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

16.3.3 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 43):

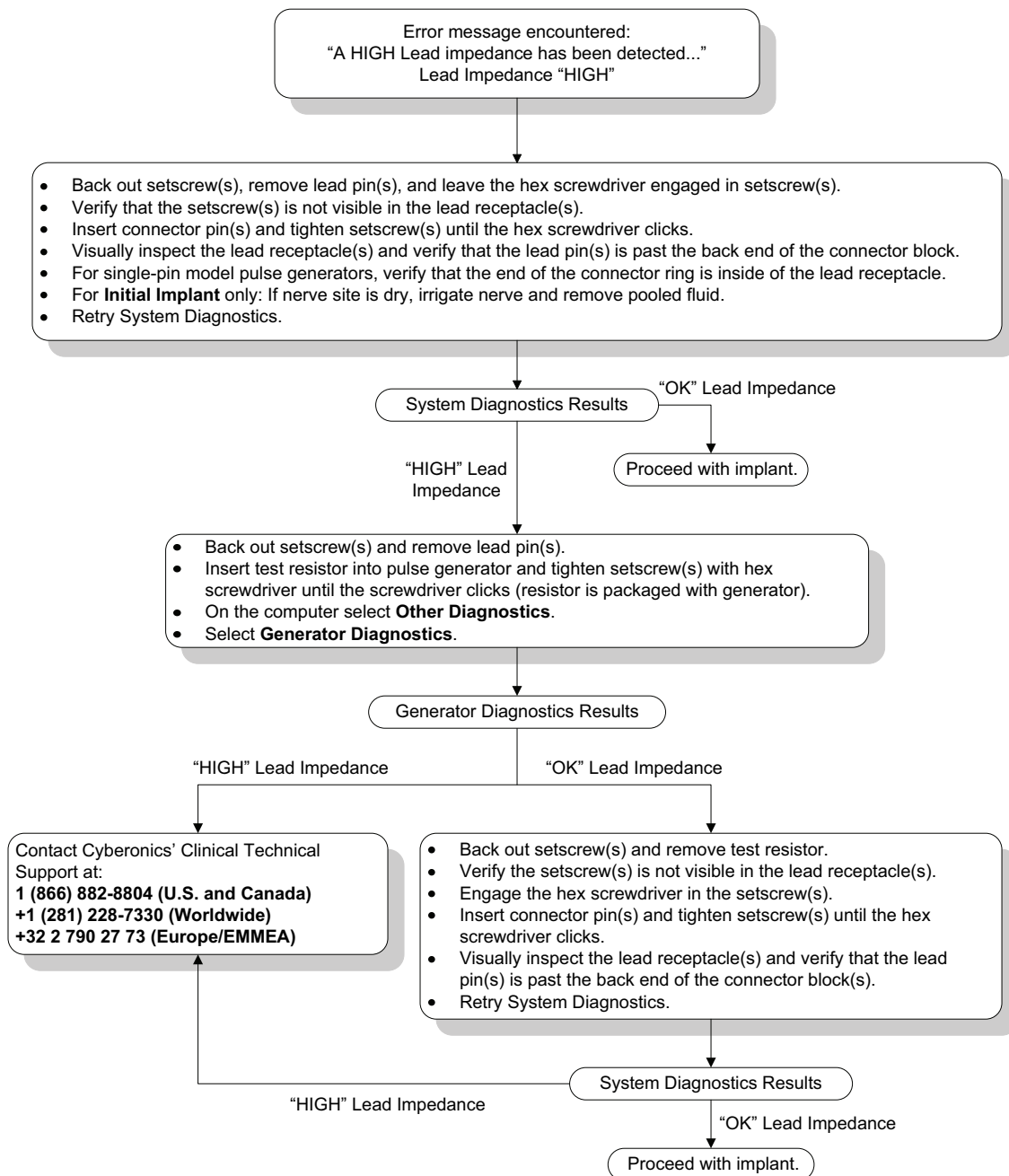
1. Reinsert the connector pin(s) into the lead receptacle(s).
 - a. Back out the setscrew(s), remove the lead pin(s), and leave the hex screwdriver engaged in the setscrew(s).
 - b. Verify that the setscrew(s) is not visible in the lead receptacle(s).
 - c. Insert the connector pin(s) and tighten the 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.



Note: See the physician's manual for the pulse generator.

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.
 - 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) and +32 2 790 27 73 for LivaNova Europe.
 - ◆ 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 "HIGH" lead impedance, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

Figure 43. High Lead Impedance on System Diagnostic Test in OR - Initial Implant or Generator Replacement



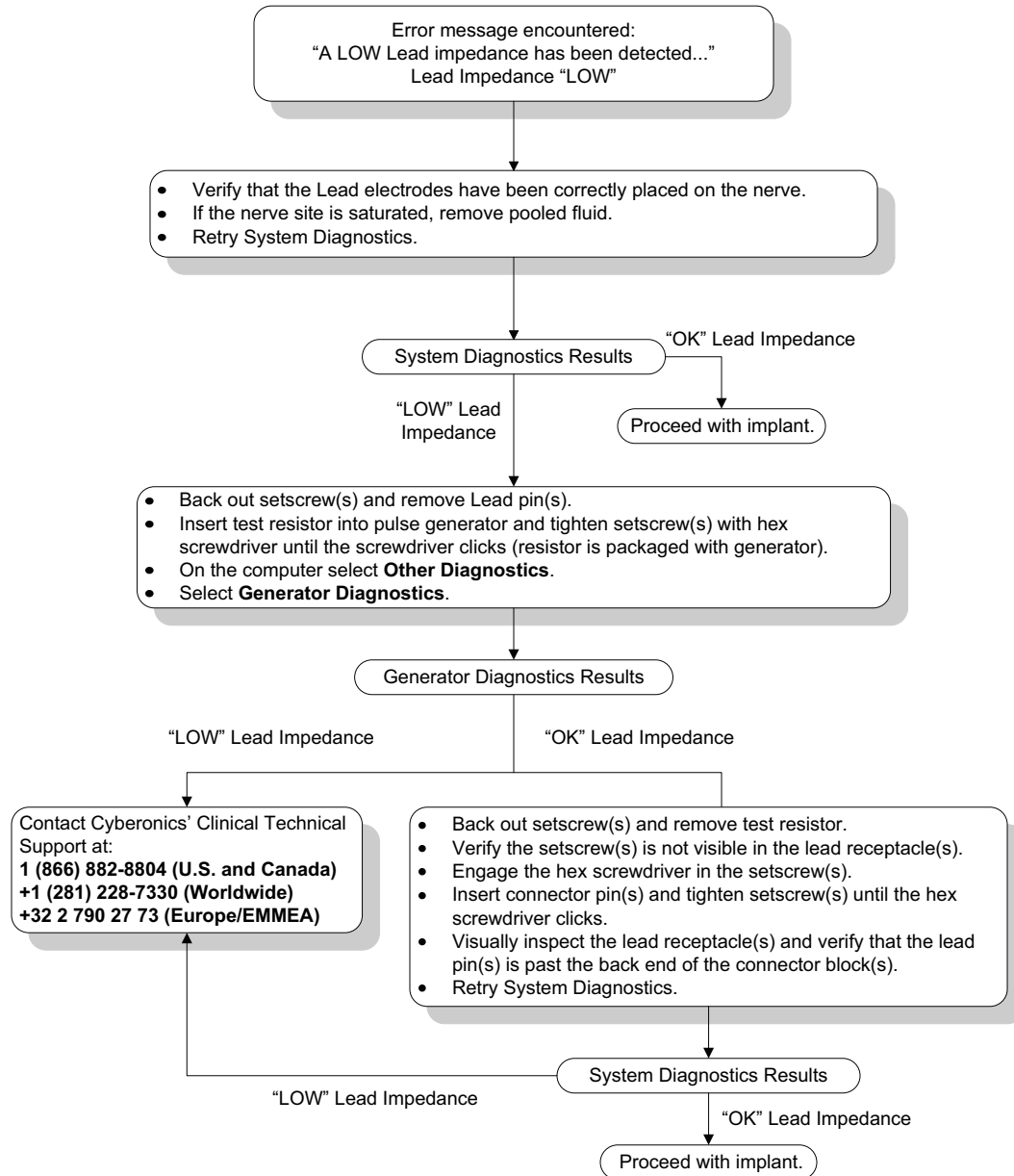
16.3.4 Low Lead impedance on System Diagnostics in OR - Initial Implant

Low lead impedance ($\leq 600 \Omega$) 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 44):

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) and +32 2 790 27 73 for LivaNova Europe.
 - ◆ 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) and +32 2 790 27 73 for LivaNova Europe.

Figure 44. Low Lead Impedance on System Diagnostics in OR - Initial Implant**16.3.5****Low Lead impedance on System Diagnostics in OR - Pulse Generator Replacement**

Low lead impedance ($\leq 600 \Omega$) in the OR can be attributed to:

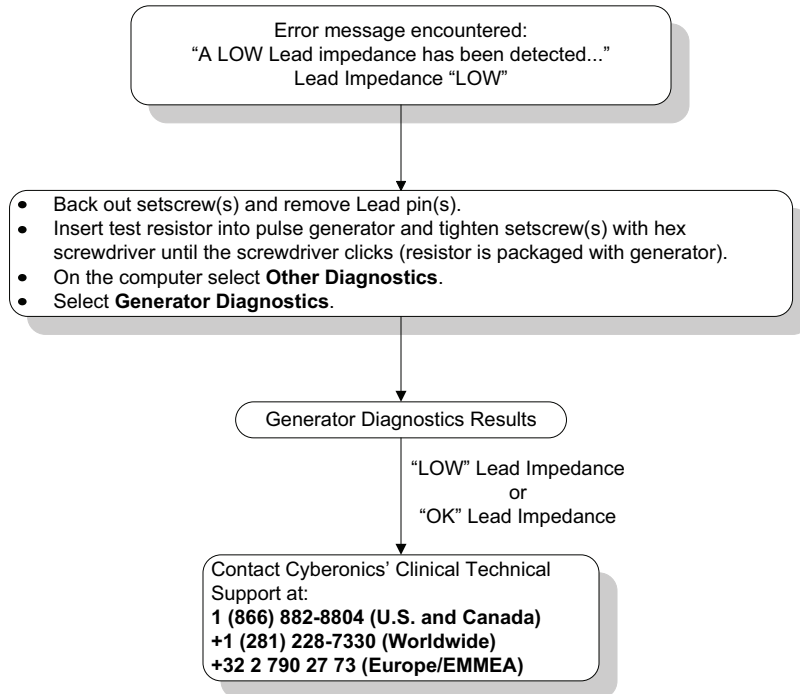
- Short-circuit condition within the lead
- Defective pulse generator

To alleviate the condition, perform these steps (see Figure 45):

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



16.3.6

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."
- 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."

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

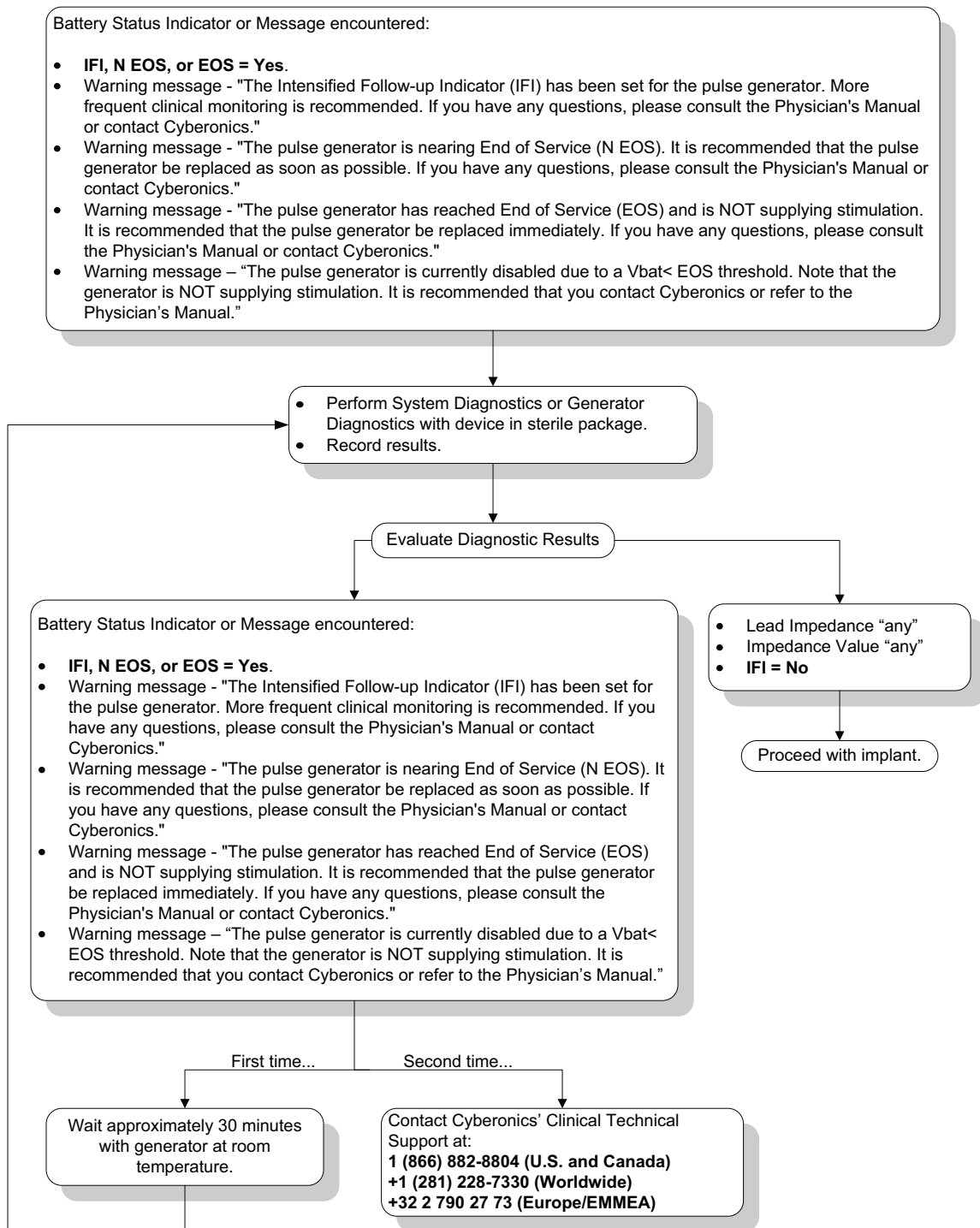
To update the battery status indicators perform the following steps with the device in the sterile package (Figure 46):

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) and +32 2 790 27 73 for LivaNova Europe.



Note: Ignore lead impedance status and impedance value.

Figure 46. Low Battery/End of Service Indications Prior to Surgery, Outside of the Sterile Field - Initial Implant or Pulse Generator Replacement



16.3.7 Low Battery/End of Service Indications During Surgery, Inside the Sterile Field - Initial Implant or Pulse Generator Replacement

Exposure of models 103, 104, 105, and 106 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) and +32 2 790 27 73 for LivaNova Europe.

16.3.8 Heartbeat Over/Under Detection (Model 106 Only)

Due to its configurability, the model 106 AutoStim Configuration may need to be adjusted to correctly detect heartbeats (see Figure 47).

1. Ensure the programming computer is unplugged from the AC adapter.
2. Interrogate the model 106 generator.
3. Select the **Tachycardia Detection** tab and ensure that Tachycardia Detection is ON.


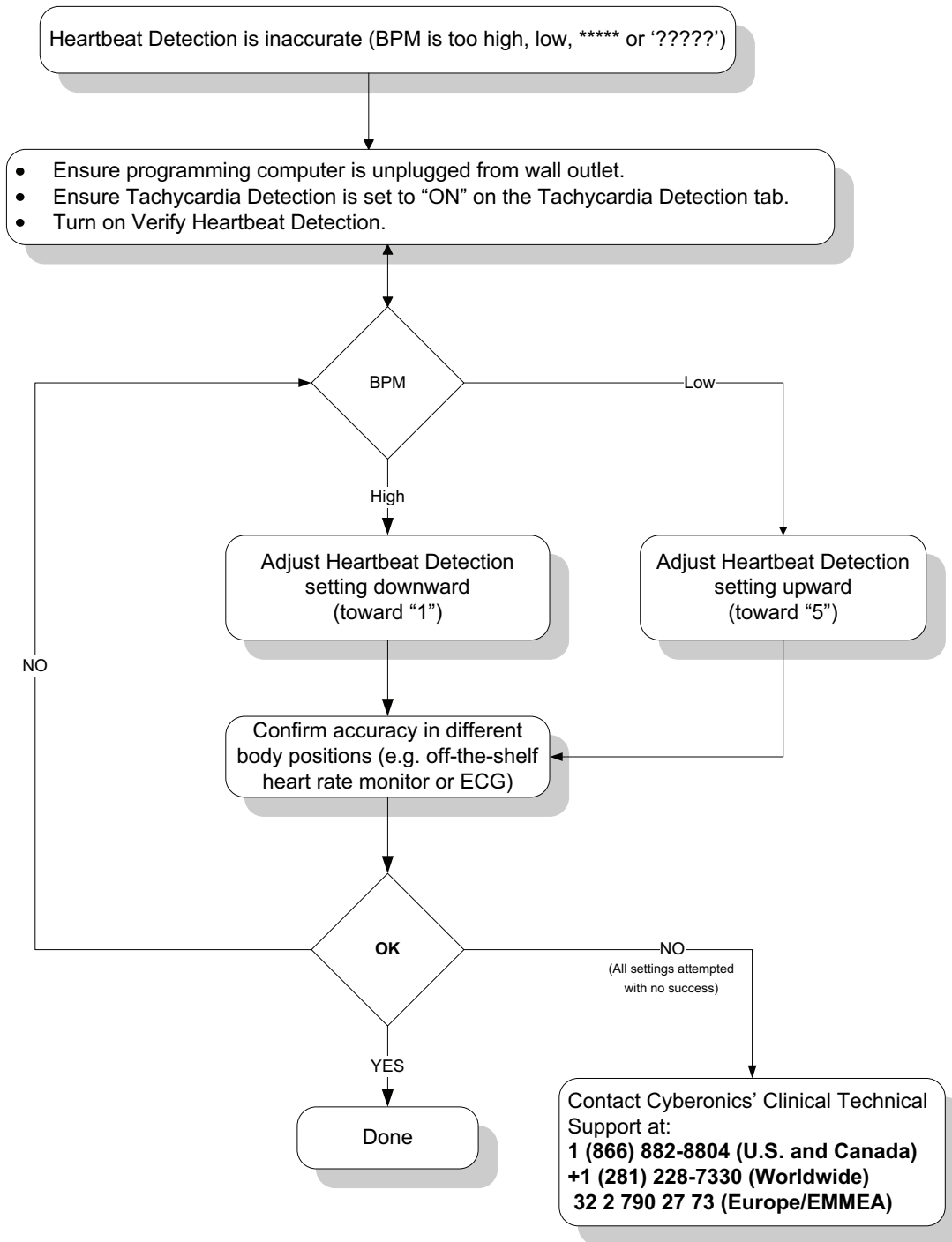
4. Assess heart beat detection at the currently programmed Heartbeat Detection setting using the Verify Heartbeat Detection feature:
 - If the reported heart rate (BPM) appears to be too high, or if ?????? or ***** is displayed, exit the VERIFY HEARTBEAT DETECTION screen by tapping on **Stop** and then **Exit**. Then reduce the Heartbeat Detection setting, program and reassess heartbeat detection performance.
 - If the reported heart rate (BPM) appears to be too low, or if ?????? or ***** is displayed, exit the VERIFY HEARTBEAT DETECTION screen by tapping on **Stop** and then **Exit**. Then increase the Heartbeat Detection setting, program and reassess heartbeat detection performance..
-  **Note:** The programming wand must be held over the generator during the entire Verify Heartbeat Detection process. For more information, refer to Section 5.2.2.1.
5. Repeat step 4 until heart rate is accurately detected at the programmed Heartbeat Detection setting. You should perform this assessment with the patient in several different body positions (e.g. sitting with arms at side, standing with arms at side, lying down on left side, etc.) to ensure that the model 106 generator is properly detecting heart beats.
6. If problems persist, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

Figure 47. Heartbeat Detection is Inaccurate (Over/Under Detection) in OR or at Follow-up Visit



16.4 Troubleshooting at follow-up visits

16.4.1 Communication Problems at Follow-up Visits

A communication problem can cause the following error messages:

- "There is an error establishing communication with the generator. Please try repositioning the programming wand." (message may be followed by error code)
- "Failed to retrieve diagnostic data."
- "Failed to receive program acknowledgment. The generator may or may not have been programmed to the desired settings. It is recommended that the generator be interrogated to verify the parameter settings. If you have questions, please consult the Physician's Manual or contact Cyberonics."

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
- Improper USB port recognition of the programming computer cable
- Electromagnetic interference (EMI) e.g., electronic equipment, 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. Performing these steps may restore communication (see Figure 42):

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.
 - c. While the VNS Programming Software is running, remove and reinsert the programming computer cable into the USB port. Wait 15 seconds.



Note: If the error message indicates the port cannot be opened, it usually means the USB port is not recognizing the programming computer cable. Performing step 2c should resolve communication problems due to improper USB port recognition.

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.
 -  **Note:** For details, see the Programming Wand Physician's Manual.
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, and 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 source of EMI.
6. Retry interrogation, diagnostic test, or programming.
 -  **Note:** LivaNova recommends interrogating the pulse generator as the last step of any programming or diagnostic session to verify correct settings for each parameter.
7. If problems persist, contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe.

16.4.2 High Lead Impedance on a Diagnostic Test at Follow-up Visit for Models 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:

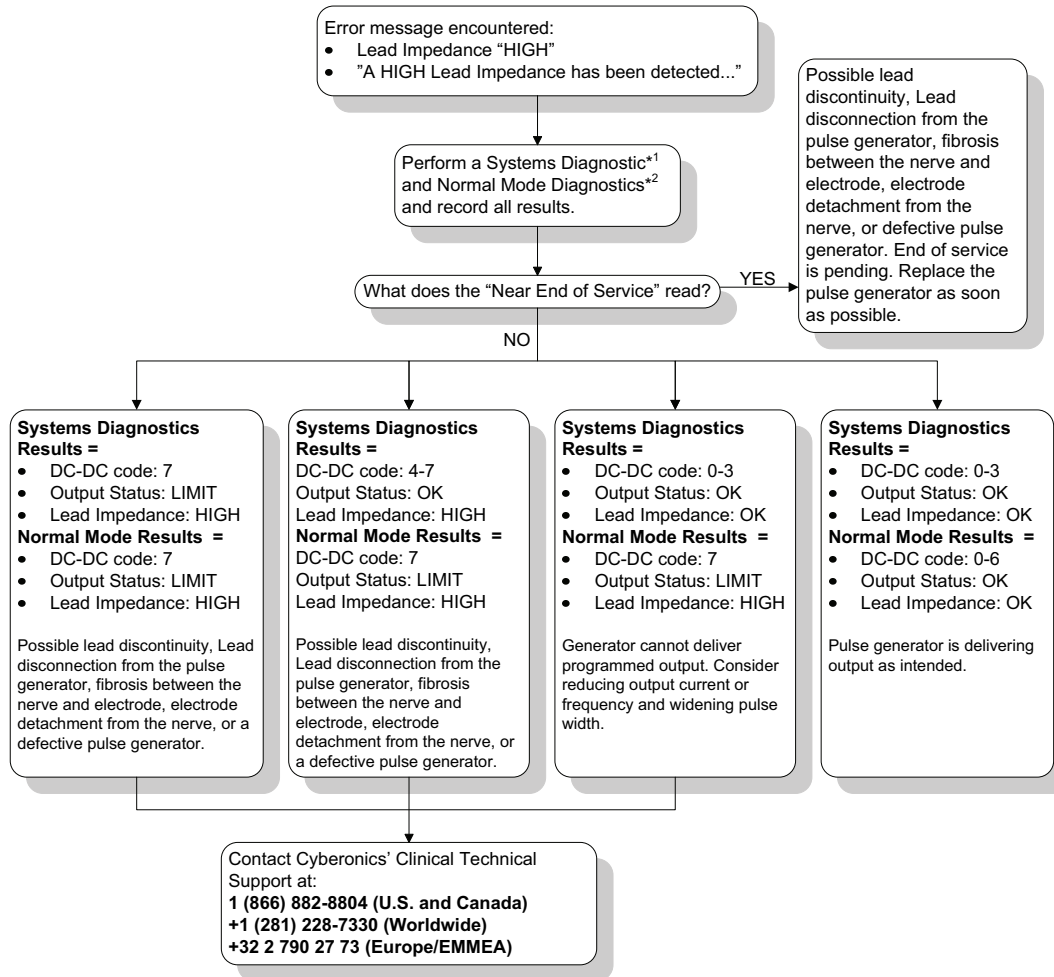
- Lead discontinuity
- Lead disconnection from the pulse generator
- Fibrosis between the nerve and the electrode
- Electrode detachment from the nerve
- Defective pulse generator
- High battery impedance, generator approaching End of Service (EOS)
- Defective pulse generator

To alleviate the condition, perform these steps (see Figure 48):

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 μ s, 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:
 - ◆ Lead discontinuity
 - ◆ Lead disconnection from the pulse generator
 - ◆ Fibrosis between the nerve and the electrode
 - ◆ Electrode detachment from the nerve
 - ◆ Defective pulse generator
 - Near End of Service reads "YES", then
 - ◆ Lead discontinuity
 - ◆ Lead disconnection from the pulse generator
 - ◆ Fibrosis between the nerve and the electrode
 - ◆ Electrode detachment from the nerve
 - ◆ Defective pulse generator
 - ◆ End of service is pending. Replace the pulse generator as soon as possible.
 - 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 the pulse generator cannot deliver programmed output and there is possible:
 - ◆ Lead discontinuity
 - ◆ Lead disconnection from the pulse generator
 - ◆ Fibrosis between the nerve and electrode
 - ◆ Electrode detachment from the nerve
 - ◆ Defective pulse generator

- Near End of Service reads "YES", then
 - ◆ Lead discontinuity
 - ◆ Lead disconnection from the pulse generator
 - ◆ Fibrosis between the nerve and the electrode
 - ◆ Electrode detachment from the nerve
 - ◆ Defective pulse generator
 - ◆ End of service is pending. Replace the pulse generator 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 "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
 - ◆ End of service is pending. Replace the pulse generator 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
 - ◆ End of service is pending. Replace the pulse generator as soon as possible.
4. Contact LivaNova at 1 (866) 882-8804 (U.S. and Canada) or +1 (281) 228-7330 (Worldwide) and +32 2 790 27 73 for LivaNova Europe to report any incidences of high lead impedance.

Figure 48. High Lead Impedance on a Diagnostic Test at Follow-up Visit for Models 101 and 102 Pulse Generators



*1 For the System Diagnostics, the Software automatically programs the pulse generator to 1.0 mA, 500 μ sec, 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.

16.4.3

High Lead Impedance, Low Lead Impedance, or Low Output Current on a Diagnostic Test at Follow-up Visit for Models 103-106 Pulse Generators

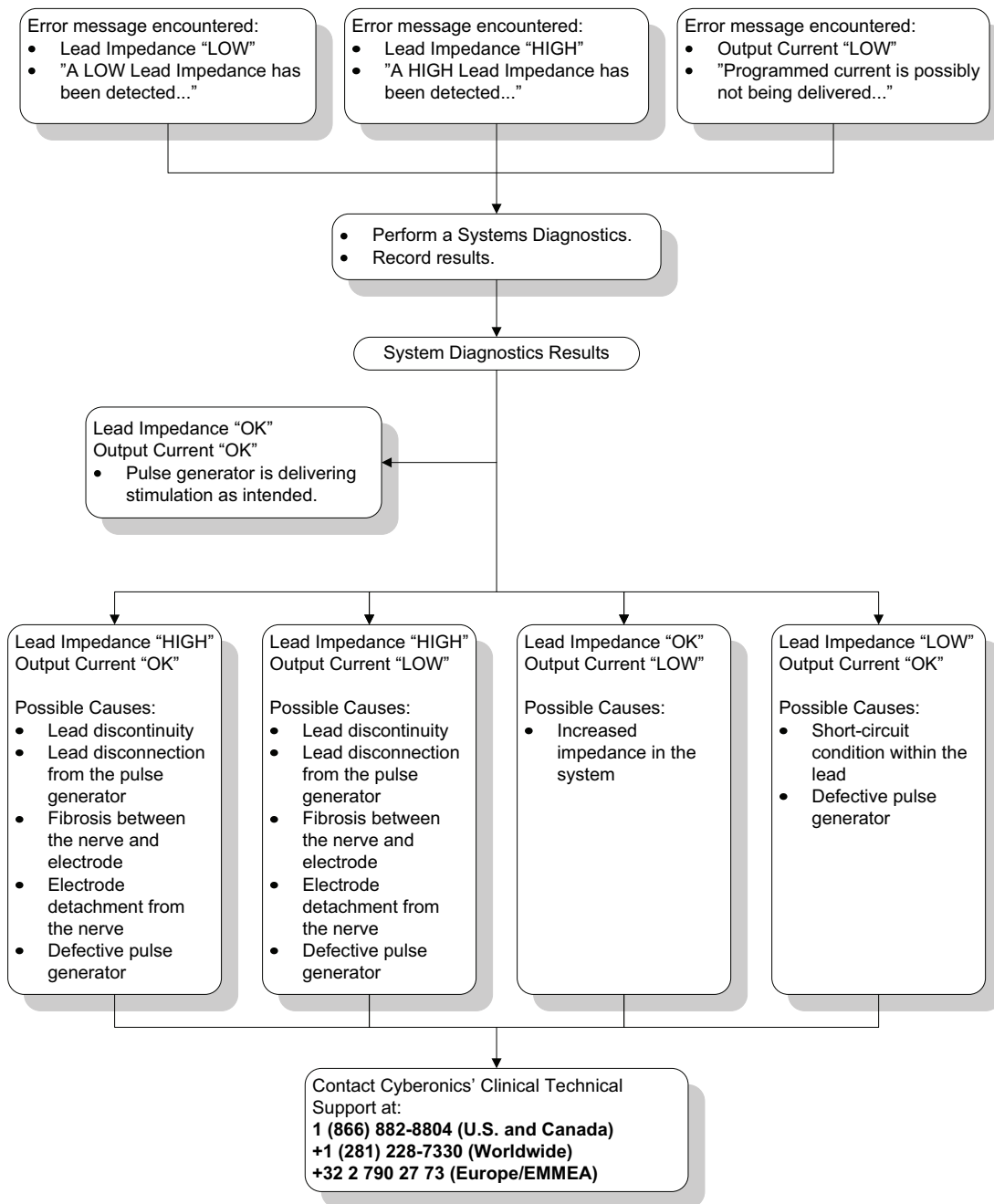
High lead impedance ($\geq 5300 \Omega$), low lead impedance ($\leq 600 \Omega$), or low output current at a follow-up visit can be attributed to any of these causes.

- Lead discontinuity
- Lead disconnection from the pulse generator
- Fibrosis between the nerve and the electrode
- Electrode detachment from the nerve
- 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 49):

1. Interrogate the device.
2. Perform a System Diagnostics and record the results.
 - If the output current reports "LOW" and lead impedance reports "HIGH" ($\geq 5300 \Omega$), then there is possible
 - ◆ Lead discontinuity
 - ◆ Lead disconnection from the pulse generator
 - ◆ Fibrosis between the nerve and the electrode
 - ◆ Electrode detachment from the nerve
 - ◆ Defective pulse generator
 - If the output current reports "OK" and lead impedance reports "LOW" ($\leq 600 \Omega$), 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" ($\geq 5300 \Omega$), then there is a possibility of a lead discontinuity, lead disconnection from the pulse generator, fibrosis between the nerve and the electrode, electrode detachment from the nerve, or defective pulse generator.
 - 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) and +32 2 790 27 73 for LivaNova Europe to report any incidents of high impedance, low impedance, or low output current.

Figure 49. High Lead Impedance, Low Lead Impedance, or Low Output Current on an Interrogation or Diagnostic Test at Follow-up Visit for Models 103-106 Generators



16.4.4 Pulse Generator Disabled due to Vbat < EOS Found at First Interrogation After Implantation or Other Surgical Procedure

Exposure of models 103, 104, 105, and 106 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 "Offbeat < 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) and +32 2 790 27 73 for LivaNova Europe.

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.

16.4.5 Sudden Decrease in Estimated Device Longevity (% Battery Power Remaining)

Exposure of model 103, 104, 105 and 106 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.

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

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) and +32 2 790 27 73 for LivaNova Europe.

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.

16.4.6 Too Many or Too Few AutoStims at Follow-up Visit (Model 106 only)

The model 106 AutoStim feature monitors and detects abrupt, relative heart rate increases ($\geq 20\%$) that may be associated with seizures. Following detection, on-demand stimulation is delivered. The threshold for tachycardia detection (Threshold for AutoStim) is designed to be configured on a patient-by-patient basis.

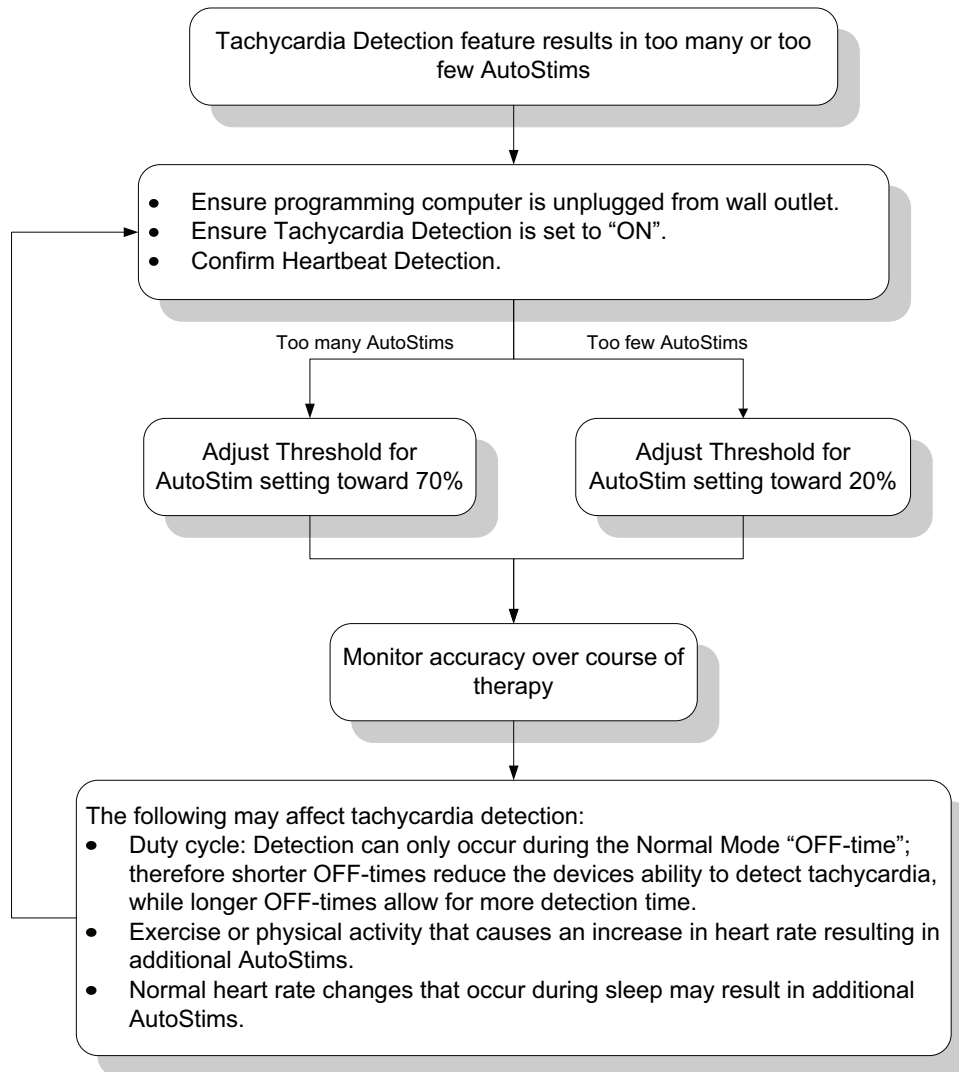
To configure the Threshold for AutoStim you should (see Figure 50):

1. Ensure the programming computer is unplugged from the AC adapter.
2. Interrogate the model 106 generator.
3. On the **Tachycardia Detection** tab, ensure Tachycardia Detection is "ON".
4. Confirm Heartbeat Detection setting is configured properly (see Section 16.3.8)
5. Assess Threshold for AutoStim setting.
6. Monitor the device's delivery of AutoStim carefully over the course of the therapy for future adjustments (see Office Visit data).

There are several conditions that may affect tachycardia detection:

1. Duty cycle: Since the device can only listen for heartbeats and detect tachycardia during the OFF-time, the shorter the OFF-time, the less likely the device can detect tachycardia. The longer the OFF-time, the more likely the device can detect tachycardia.
2. Exercise or other physical activity can increase the heart rate and contribute to additional detections.
3. Heart rate changes during normal sleep may result in additional detections.

Figure 50. Too Many or Too Few AutoStims at Follow-up Visit (Model 106 only)



16.5 Other Troubleshooting

For more troubleshooting concerns, see Table 6

Table 6. Other Troubleshooting

| Description | Solution |
|---|--|
| Diagnostic results do not update when the magnet is held over the pulse generator (applicable to M103-M106 generators only) | Do not hold a magnet over the generator while attempting to perform a diagnostic test. |
| The Display Device History and View Last Parameters screens do not include all units for parameters displayed. | The units for parameters are displayed on the Parameter screen and described in the manuals. |

| Description | Solution |
|---|---|
| If a warning message appears indicating the generator is disabled and not supplying stimulation, diagnostic test results may show that an output current was able to be delivered even though the output current was not actually delivered (applicable to M103-106 generators only). | If the generator is disabled, it is not supplying stimulation. Follow recommendations provided in the warning message. |
| Upon powering on the computer, the VNS software may not appear but instead shows a blank screen. | Tap the screen to see if the VNS software appears. If it does not appear, reboot the programming computer. |
| Upon powering on the computer, the VNS software may not appear but instead shows the custom OS shell. | Tap the screen to see if the VNS software appears. If it does not appear, reboot the programming computer. |
| Upon powering on the computer, the computer display may get stuck at the "Starting Windows" screen. | Power down and reboot the programming computer. If the problem persists, remove the SD card and then reboot the programming computer. |
| Some office visit data entries may be duplicated in the data export file (OVexport.csv) (only applicable to the Model 106 generator). | Duplications can be identified as they have the same date and timestamp. |
| Certain warning messages may not be displayed if the screen is touched during diagnostic testing. | Avoid touching the computer screen during interrogation, programming, and diagnostic tests. |
| Upon waking up the computer from hibernate mode, the VNS software may not appear but instead shows a blank screen. | Tap the screen and the VNS software should appear. If the software does not appear, reboot the programming computer. |
| Display anomalies when using the scroll bar on "View Parameter History" screen. | Use the software buttons to scroll up or down instead of the scroll bar. |
| Generator Diagnostic test results may show that the generator is capable of delivering output current even though lead impedance is high (applicable to M103-M106 generators only). | If generator diagnostic results show high lead impedance, stimulation will not be delivered at the programmed setting. Follow appropriate troubleshooting recommendations for high lead impedance results. A System Diagnostics test can be performed to verify the test results. |
| Moving the SD card switch to the "Lock" position may prevent data backup and export to the SD card. | Keep the switch located on the side of the SD card in the unlocked position. |
| The file name of the ".html" files saved to the SD card do not contain the generator model number. | The generator serial number and date and time of the export are included in the file name to help differentiate files. The generator model number can be seen in the actual file. |
| In the Display Device History screen, tapping on the "Office Visit" button displays the last Office Visit entry instead of the first entry. | Use the scroll bar to navigate to the desired Office Visit entry. |
| The first time that the Extended Generator Memory Download is attempted with an SD card inserted, an error message appears. | Select Retry on the error message. |
| In the magnet history data exports, the csv file will show an empty field for "Patient Date of Birth". | The patient date of birth is not populated in the generator and the field will be blank. |
| The Display Device History and View Last Parameters screens do not include all units for parameters displayed. | The units for parameters are displayed on the Parameter screen and described in the manuals. |

17 CONTACT INFORMATION AND SUPPORT

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



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