Physician's Manual

VNS Therapy® Programming System

For Healthcare Professionals

April 2021

Rx Only

$C\epsilon$ **0344**

The year of authorization to affix the CE mark:
Model 2000 - 2017
Model 3000 - 2018

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1. DESCRIPTION AND USE

1.1. What's New

The latest release of the LivaNova® VNS Therapy® Programming System consists of VNS Therapy Programmer, Model 3000 version 1.6, and Programming Wand, Model 2000 version 1.1 ("Wand").

If you have a Wand with firmware below v1.1 (Table 1), it must be updated to v1.1 firmware for use with the Model 3000 v1.6 Programmer. Wand firmware update files are included on the Model 3000 v1.6 Programmer. A Wand USB Cable (Figure 1) is needed to complete the Wand firmware update to v1.1.

> ⓘ **Note**: Refer to "Check Wand Firmware (Model 3000 v1.6 only)" for instructions on how to check the Wand firmware version.

Update includes:

- Additional ability to interrogate and program the Model 8103 Symmetry and Model 1000-D SenTiva DUO Generators (where available).

- The following software issues were observed in previous versions of the Model 3000 software and have been corrected in Model 3000 V1.6

    - Wand connection to the Programmer was unnecessarily prolonged after it was identified to be incompatible with Programmer over *Bluetooth®*

    - User can receive a false high impedance warning messages on a Model 3000 v1.5 Programmer when performing system diagnostics on M102/M102R devices with output current >0mA

    - Incorrect information was populated in "Last Performed on" field of Session Reports in certain situations.

- Model 3000 v1.6 software behavior differences compared to previous software versions

    - When a generator is disabled, software shows "Device Disabled" and original settings instead of 0mA for output current. The original settings are listed for information purposes; the generator does not provide therapy at those settings when disabled.

    - When a generator is disabled, it can only be re-enabled by programming the generator. Previously, re-enabling could be achieved by running Diagnostics or by programming the generator.

    - Therapy state information is included in Session Reports

1.2. General Description

The LivaNova VNS Therapy Programmer, Model 3000 version 1.0/1.6, and Programming Wand Model 2000 ("Wand"), allow you to interrogate and program the following VNS Therapy generators:

- Model 102 Pulse
- Model 102R Pulse Duo
- Model 103 Demipulse
- Model 104 Demipulse Duo
- Model 105 AspireHC
- Model 106 AspireSR
- Model 1000 SenTiva
- Model 1000-D SenTiva DUO (Model 3000 v1.6/Model 2000 v1.1 only)
- Model 8103 Symmetry (Model 3000 v1.6/Model 2000 v1.1 only)

Table 1 provides a description of compatibility between Programmer and Wand versions.

Table 1.   Programmer/Wand Compatibility

	Model 2000 v1.0.3	Model 2000 v1.0.4	Model 2000 v1.1.1
Model 3000 v1.0.2	✓		
Model 3000 v1.5.2	✓	✓	
Model 3000 v1.6+			✓

(i) **Note**: For a list of symbols and terms used with the LivaNova VNS Therapy Programming System, go to www.LivaNova.com.

1.2.1.   Intended Use

The VNS Therapy Programming System is intended for use only with VNS Therapy generators in a professional healthcare facility environment, and is subject to the same indications for use.

1.3.   System Communication

The VNS Therapy Programming System includes a computer pre-installed with VNS Therapy programming software and a programming Wand. The Wand and the Programmer connect wirelessly.

The system allows you to:

- interrogate and adjust therapy parameters for the generator
- assess generator and lead function
- view device histories
- export session reports

1.3.1.   Programmer Communications

The Programmer will indicate communication in the following ways:

- Musical notes for a successful interrogation, diagnostics, or applied changes
- Screen messages for successful, failed, or suggested operation

1.3.2.   Wand Communications

The Wand indicator lights will illuminate when the:

- Wand is powered on (two green lights below power button)
- Wand is connected to the Programmer (four green lights around the power button)
- Wand is communicating with the generator (white flashing generator icon)
- Wand battery is low (orange battery indicator)
- Wand (v1.1+) is updating (green lights rotate around power button)

1.3.3.   Communication Distance

1.3.3.1.   Wand and Programmer

The wireless connection between the Programmer and Wand will operate up to 3 meters (approximately 10 feet) under most conditions. If communication is unstable, use the supplied USB cable to connect the Wand and the Programmer instead.

1.3.3.2.   Wand and Generator

The communication distance between the Wand and the generator should not be more than 1 inch.

2. WARNINGS AND PRECAUTIONS

Follow the described warnings and precautions in this section for optimal performance and safety.

2.1. Warnings

■ Do not connect unapproved equipment. Doing so can damage the system and/or cause injury.

■ Do not modify the system unless directed by LivaNova.

■ Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

■ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

■ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Wand, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

■ MR Unsafe devices are the programming Wand, computer, and patient magnet. These devices are projectile hazards and must not be brought into the MR scanner room.

■ Safeguard the VNS Therapy Programming System against theft. Theft could lead to malicious activities against the System.

■ Use system in a controlled area to prevent unauthorized connections to the system.

■ Anomalous behavior may occur, such as a nearby Wand erroneously connecting to a Programmer. If this occurs, see Figure 45 for instructions on how to reset the Wand and Programmer pairing.

2.2. Precautions

■ Do not load other software onto the Programmer. Doing so may interfere with the efficiency and function of the pre-installed VNS Therapy Software.

■ The Programmer is tested to the same level as typical consumer electronic devices. However, the equipment is not rated for use in the patient environment (as defined by IEC 60601-1). Do not simultaneously touch the patient and Programmer while programming. Additionally, do not plug the Programmer into AC power while it is being used in a patient environment.

3. GET STARTED

3.1. Parts Included

The system includes the following items (Figure 1):

- Touch-screen Programmer preloaded with the VNS Therapy Software
- Programmer Charger
- Wand with two AA batteries
- Backup Wand USB cable

Figure 1. System Parts

a. Programmer
b. Wand
c. Programmer Charger
d. Wand USB Cable
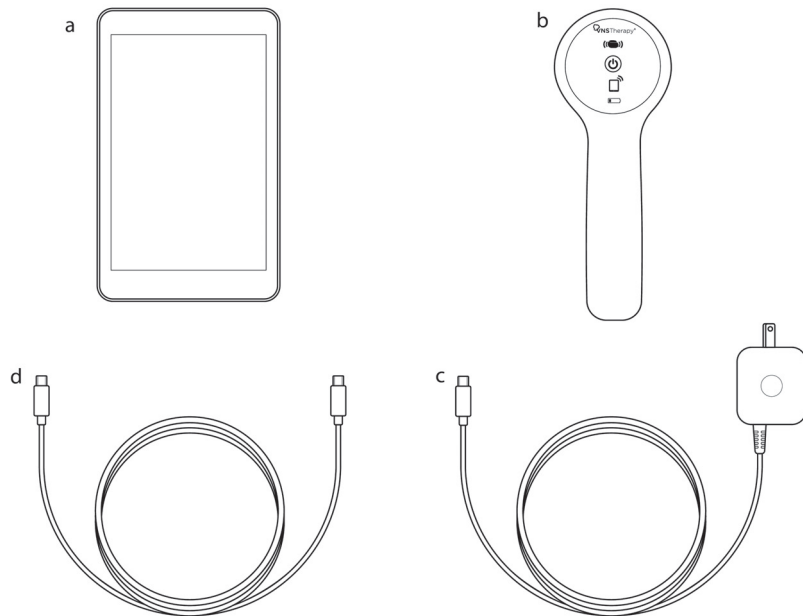
If preparing for use in a sterile field, follow aseptic practices. Each part of the Programming System is designed to fit inside commonly available sterile covers (e.g. laser/camera arm drapes). LivaNova recommends using one sterile cover for each Programming System part.

If any parts of the system are missing, contact LivaNova.

3.2. Prepare System for Use

Before using the Programming System in a patient session, make sure the Programmer and Wand are fully charged and ready to use. Verify the date and time on the Programmer are correct.

3.3.   Basic Operation

3.3.1.   Charge the Programmer

To charge the Programmer, connect the charger and plug into an outlet (see Figure 2). Charge the Programmer when not in use so that there is enough battery power when using during a patient session.

Figure 2.   Connect the Charger
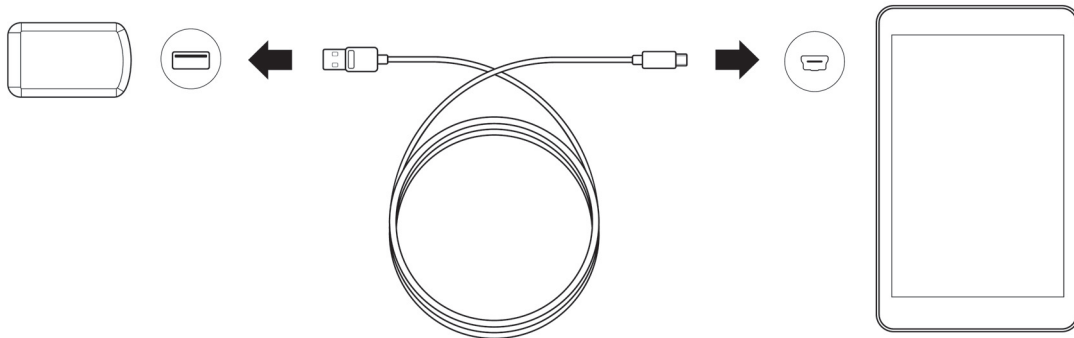
3.3.2.   Turn Programmer ON/OFF

To turn on the Programmer, press and hold the power button for 3 seconds and then release (Figure 3). A few seconds after releasing the power button, you will see an on-screen logo, followed by automatic startup of the VNS software.

Figure 3.   Power On Programmer
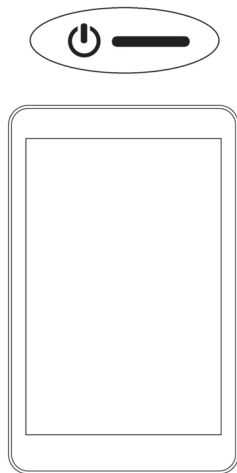
To turn off the Programmer, press and hold the power button for 3 seconds and then release. Follow on-screen instructions to shut down the Programmer.

> **ⓘ** **Note**: The power button may not respond if the Programmer is still shutting down. Wait for 30 seconds after a shut down to restart the Programmer.

3.3.3.　　Turn the Programmer Screen ON/OFF

Once the Programmer is turned on, the screen will automatically turn off after 10 minutes of inactivity. You can also turn the screen on or off by quickly pressing and releasing the power button. Use this method when you want to preserve battery, but not shut down the Programmer.

3.3.4.　　Check Programmer Battery

After VNS software startup is complete, the Programmer battery status can be checked at any time by viewing the indicator at the top right corner of any software screen. For more information, refer to "How to Use the Software".

3.3.5.　　Set the Programmer Date and Time

Accurate patient and device history stored in the Programmer depends on correct time and date settings. To adjust the date and time, select **Settings** from the bottom navigation bar, then Programmer settings, and Date & Time. You can adjust the time by tapping the current display and scrolling up or down. To change the date, use the left or right arrow to adjust the calendar, and then tap the desired date. When finished, choose Save Changes. See Figure 4.

Figure 4.　　Adjust Programmer Time and Date
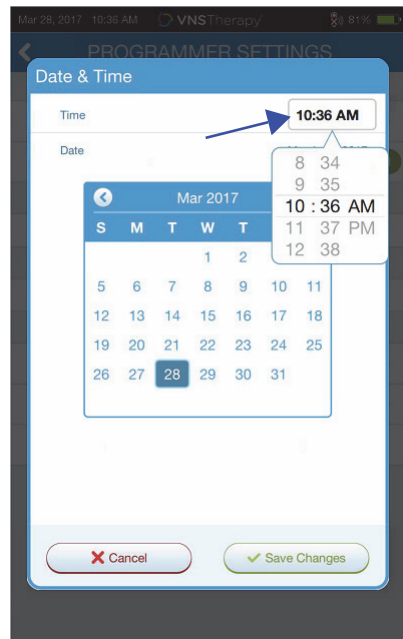
Select time to adjust time
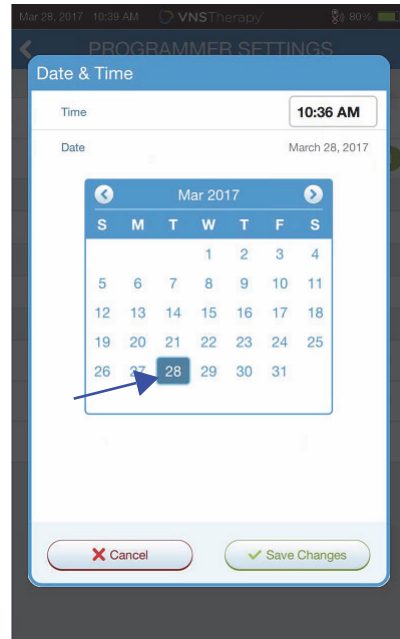
Select day on calendar to adjust date

> ⓘ **Note**: The Programmer does not automatically adjust for Daylight Saving Time or a change in location. Adjust the time and date manually as needed.

3.3.6. Turn on Wand/Check Wand Battery

Turn on the Wand by pressing and releasing the power button (Figure 5). If the battery is OK, green lights will illuminate (Figure 6). If the battery is low, the low battery indicator will illuminate (Figure 7). If the battery is low, replace the batteries by removing the cover located on the back of the Wand (Figure 9). If only the orange battery icon illuminates, communication will not be possible until you replace the batteries (Figure 8).

Figure 5.   Power On Wand

Figure 6.   OK Battery Indicator

Figure 7.   Low Battery Indicator

Figure 8. **No Battery Power Indicator - No Communication**

Figure 9. **Wand Battery Replacement**

Push and slide to open battery compartment

Bottom of Wand
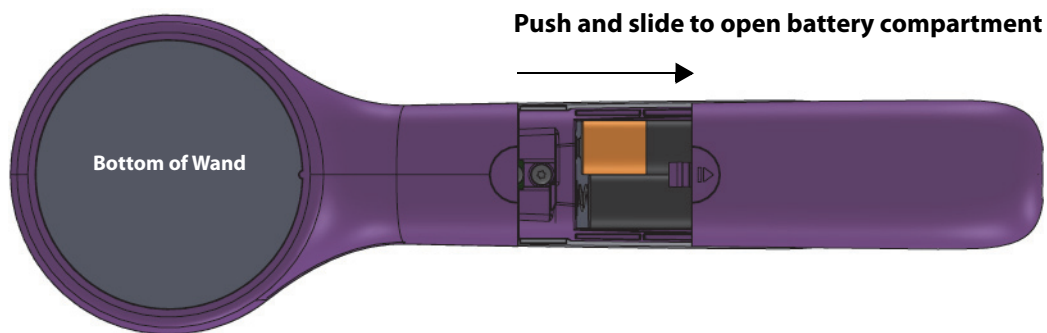
> (i) **Note**: Once powered on, the Wand will automatically power down (standby) after 2 minutes of inactivity to conserve battery.

3.4. Connect Wand/Programmer

The system allows you to connect the Wand to the Programmer wirelessly or with backup USB cable.

3.4.1. Wireless Wand Options

To connect wirelessly, you have two options:

■ Set up a preferred Wand connection that is always used with that Programmer. This setup is recommended for wands and programmers that are always used together. It provides a quicker connection when interrogating the patient's generator, since the Programmer will automatically look for the preferred Wand.

■ Choose a Wand as part of interrogating the patient's generator. This method is recommended if you have several interchangeable programming systems in your area. When interrogating a patient's generator, the Programmer will search for all available wands in range.

3.4.2.   Preferred Wireless Wand Setup

To set up a preferred wireless connection between the Wand and the Programmer, do the following:

1. Power on the Programmer
2. Select **Settings** from the bottom navigation bar
3. Power on the Wand
4. Select the Wand Settings menu option, and enable the Preferred Wand selection (while the Wand is powered on)
5. Select the desired Wand serial number. Once connected, the software will show this serial number as your preferred Wand.
6. Use the back button (upper left) to return to the Main screen

3.4.3.   Wired Wand Setup

Included with the system is a USB cable that connects the Wand to the Programmer. Use this as a back up method when a wireless connection is not available. Once connected, the software will identify the specific Wand connected via the cable. After interrogate is selected, the four green indicators will light up once the Wand begins communicating with the generator.

4.   INTERROGATING THE GENERATOR

4.1.   Interrogate (No Preferred Wand)

You must interrogate the generator before performing other functions, such as applying new parameters or performing Diagnostics tests.

To begin, power on the Programmer. Upon startup, the Main screen will display (Figure 10).

Figure 10.   Main Screen

Uncheck box for rapid interrogation (Model 1000/1000-D only)

Rapid Interrogation is a quick interrogation available for all generator models that only downloads the current programmed settings and generator information. **Advanced Interrogation** is an interrogation available for Model 1000/1000-D that downloads events and trend data for the previous 180 days, in addition to rapid interrogation information.

In order to obtain additional events and trends data for Model 1000/1000-D, the **Advanced Interrogation** box must be selected. Due to the additional data being downloaded an "Advanced Interrogation" can take more time than a "Rapid Interrogation".

> **Note**: To initiate a "Rapid Interrogation" for Model 1000/1000-D the **Advanced Interrogation** box must be unselected. For Model 102-106 and Model 8103 generators, "Rapid Interrogation will be performed regardless of whether the **Advanced Interrogation** box is selected.

> **Note:** A System Diagnostics is performed for Model 1000/1000-D during the initial interrogation, regardless of the type of interrogation (Advanced or Rapid). The results are displayed on the Summary Screen and logged as part of Diagnostics history. To perform a diagnostic test for a Model 1000/1000-D after the initial interrogation you can manually perform a System Diagnostic test while in session.

> **Note:** A System Diagnostics is NOT performed for Model 102-106 and Model 8103 generators during the initial interrogation. To perform a diagnostic test for Model 102-106 and Model 8103 generators after the initial interrogation you can manually perform a System Diagnostic test while in session.

Next, turn on the Wand by pressing and releasing the power button. Two green lights will illuminate indicating the Wand is ready to connect. While the green Wand lights are illuminated (Figure 6), select **Interrogate** on the Programmer screen. The Programmer will search for available wands. See Figure 11.

Figure 11.   Wand Search Screen
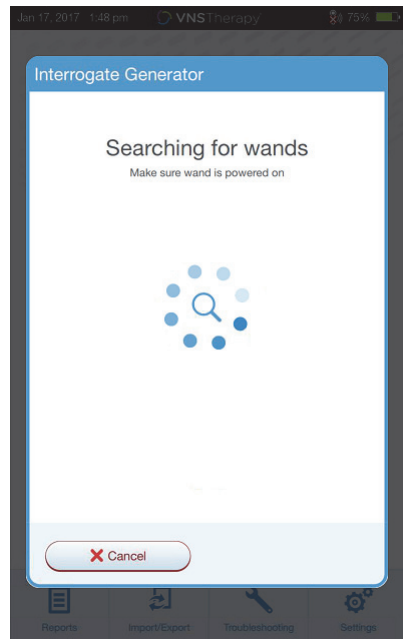
The Programmer will show all powered-on wands in range. Select the Wand you intend to use (Figure 12), using the Wand serial number (SN). The Wand SN is located on the back of the Wand.

Figure 12.   Wand (SN) Selection Screen
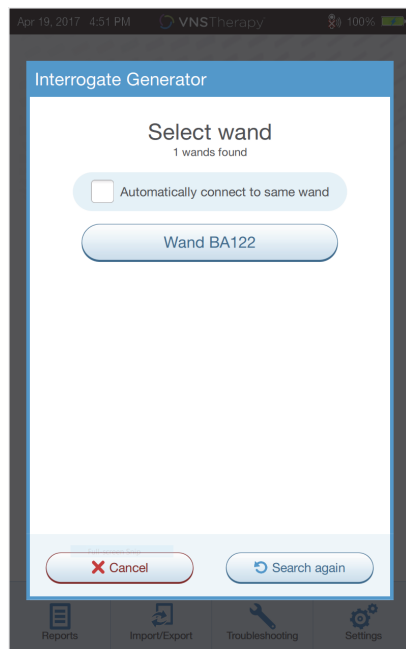
SN location on back of Wand

> **Note**: To use a specific Wand in subsequent sessions, check the **Automatically connect to the same Wand** box on the screen before choosing a Wand.

Once the Wand has connected, the software will indicate a successful connection and four green lights will illuminate around the Wand power button (Figure 13).

Figure 13.   Successful Wand Connection
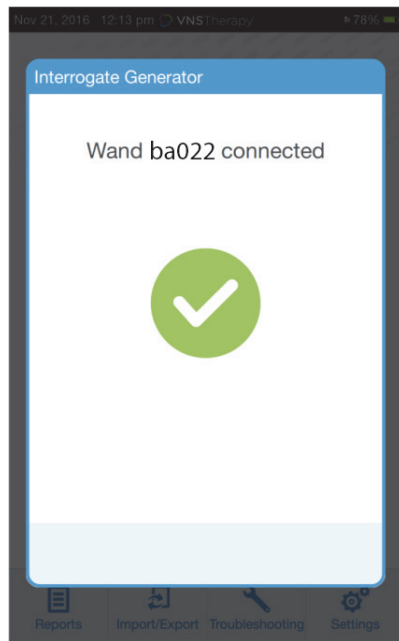
Successful Wand connection lights illuminated

Place the Wand over the generator as shown on the software screen (Figure 14). Once the Wand recognizes the generator, the interrogation will complete and the software will display the summary screen. For more details refer to "Summary Screen".

Figure 14.   Interrogate Generator Screen
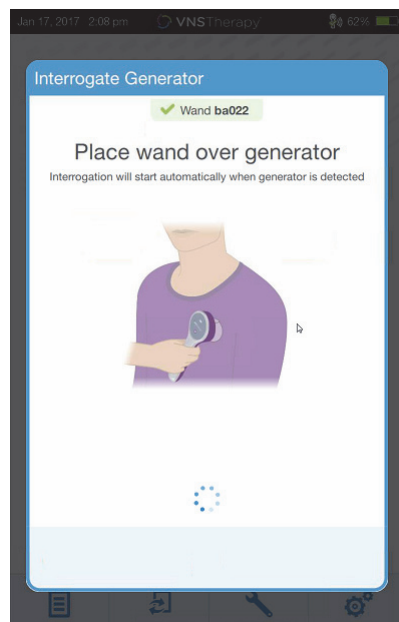
Generator icon will flash during interrogation

4.2. Interrogate (With Preferred Wand)

If you have set up a preferred Wand, the Programmer will automatically connect to that Wand when you press Interrogate.

The Main screen will display to the preferred Wand information. See Figure 15. Make sure Wand is powered on before selecting interrogate. After the Programmer and Wand are connected, place the Wand over the generator to complete the interrogation.

Figure 15.   Main Screen - Preferred Wand

Uncheck box for rapid interrogation (Model 1000/1000-D only)
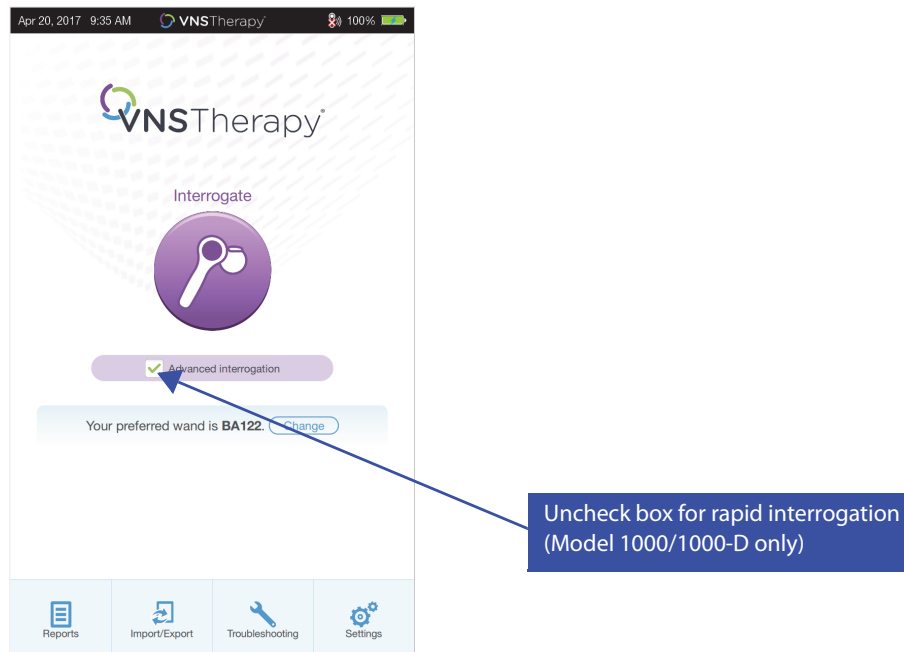
4.3. Interrogate (Change Preferred Wand)

If you have set up a preferred Wand, but want to connect to a different Wand, perform the following steps:

1. Power on the new Wand

2. Select **Change** on the Main screen.

The Programmer will search for all wands that are powered on and in range. Select the intended Wand serial number from the list. When you connect to the new Wand, it will become the new preferred Wand and the Programmer will automatically connect to it in future sessions. Place the Wand over the generator to complete the interrogation.

(i) **Note**: To clear the preferred Wand and connect manually, select **Settings** from the Main screen. Within the Wand Settings, set the Preferred Wand status to Disabled. Select the back button on the upper left of the screen to return to the Main screen. Next time you interrogate, manually connect to a Wand following the steps in "Interrogate (No Preferred Wand)".

5. HOW TO USE THE SOFTWARE

Messages and prompts will guide you through the software.

> (i) **Note**: If a software update is needed see "Programming System Updates" for more details.

5.1. Summary Screen

After a successful interrogation, the Summary screen (Figure 16) will display. From this screen, you can perform the following functions:

- View generator ID information, including model number and serial number
- View and edit patient data, such as patient ID and implant date
- View last known diagnostics data, such as lead impedance and battery status
- Change settings to generator parameters, such as Normal, Magnet, AutoStim, or Detection settings
- Perform diagnostics
- View events and trends such as magnet activations and daily average AutoStims
- Access device history, including parameter settings associated with prior office visits
- Interrogate the generator again to verify parameters or refresh data
- End programming session
- Access other software options

> (i) **Note**: The information displayed is specific to the generator model. Not all parameters, features or modes will be applicable for all generator models.

Figure 16.   Summary Screen Example
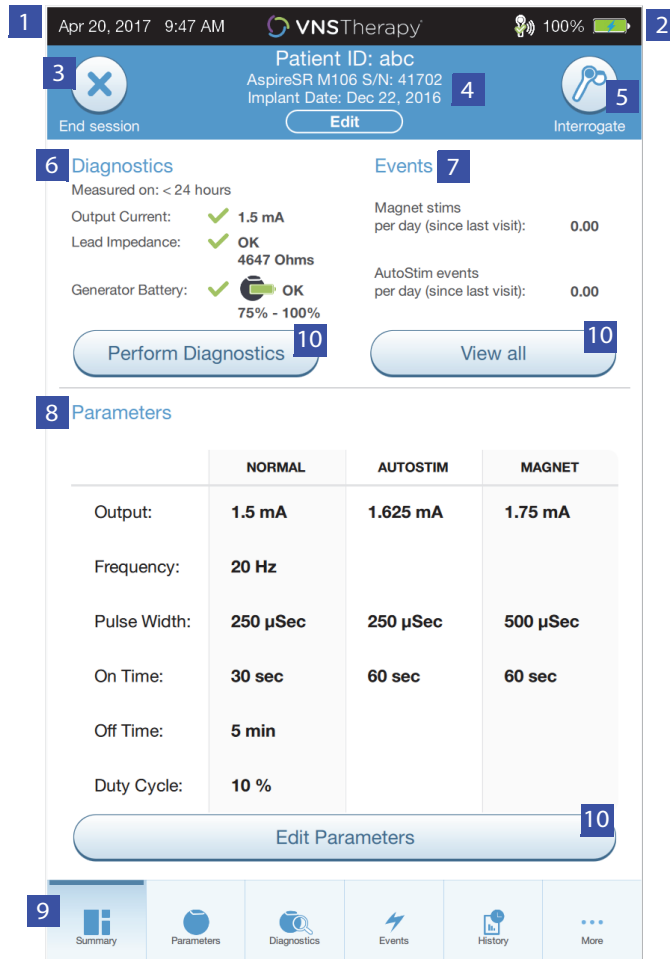
1	Current Programmer date and time
2	Wand connection and Programmer battery status
3	Ends current session
4	Generator and patient information
5	Interrogate generator again
6	Last known diagnostics measurements
7	View stimulation events
8	Current parameters
9	Navigation bar to additional software features
10	Shortcut buttons

5.2.   Quick Access Bar

From any software screen, tap the VNS Therapy logo on the title bar (black bar at the top of the screen) to access Programmer settings and system information (Figure 17). This drop-down bar shows the following:

- Programmer date and time (edit out-of-session only)
- Wand connection status
- Programmer battery level
- Sliders to adjust system volume and display brightness
- Programming software version
- Wand software version and generator firmware, when in-session (i.e. connected)

Figure 17. Quick Access Bar
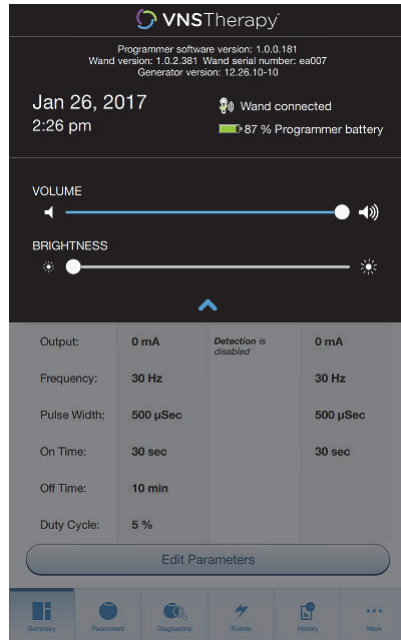
6. PROGRAM THE GENERATOR

To program any information into the patient's generator, you must interrogate the generator. Disregard error or "not available" messages when not connected to a lead, except low battery indicator.

6.1. Edit Patient Data

For each patient's generator, enter the following information:

- Patient ID: three alpha-numeric characters (maximum)
- Implant date: the date the generator was implanted

After successful interrogation, the Patient ID, implant date, generator model, and serial number display at the top of the Summary screen.

To enter or edit this information, do the following:

1. Interrogate the patient's generator
2. Review the generator information displayed at the top of the screen
3. Select **Edit** and enter the desired information (Figure 18)
4. Apply Changes and Confirm to program the information into the generator

Figure 18.   Edit Patient ID Screen
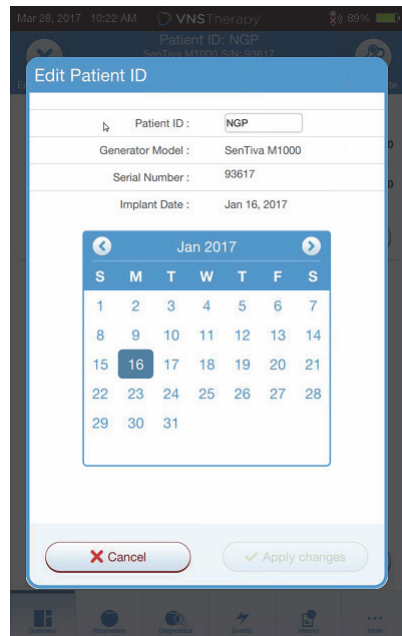
6.2. How to Adjust Parameter Settings

After interrogation, the summary screen will display. To change generator settings from this screen, select **Edit Parameters** or select **Parameters** on the navigation bar at the bottom.

From the Parameters screen (Figure 19), you can change stimulation or detection parameters, depending on the model of generator. Refer to the generator technical manual for a full list of programmable parameters available for each generator.

ⓘ **Note**: For Model 8103, only Normal Mode stimulation parameters are available.

ⓘ **Note**: For Models 102-105, only Normal Mode and Magnet stimulation parameters are available.

ⓘ **Note**: For Models 106 and 1000/1000-d, AutoStim and Detection parameters are also available in addition to Normal and Magnet Mode.

Detection parameters will display on a separate tab. Review all tabs when adjusting parameters.

Figure 19.   Parameter Screen - Stimulation/Detection Tabs

Models 106 and 1000/1000-D
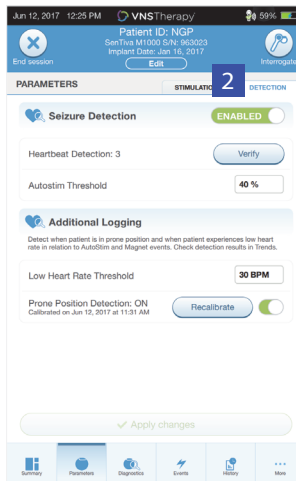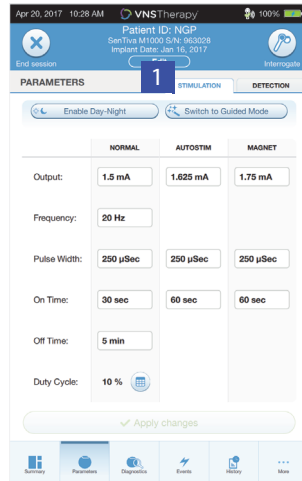
1 | Stimulation Tab

2 | Detection Tab
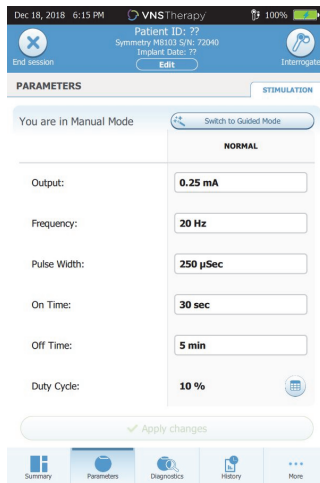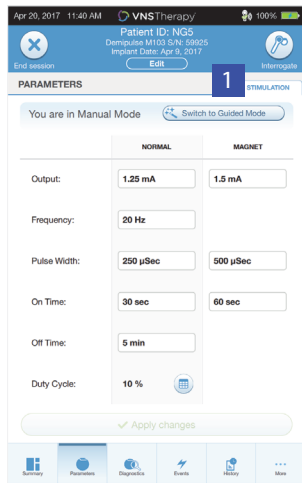
Models 102-105   **Model 8103**

To change a parameter setting, first select the **Stimulation** or Detection tab on the Parameter screen, and then follow these steps:

1. Tap the Value for the parameter you want to change. A pop-up menu displays the range of possible values. If there are values greater than or less than those shown on the screen, you can view them by scrolling up or down.

2. Select the new target value for the parameter. For Output Current, if the target value selected is greater than 0.25 mA compared to the currently programmed value in the generator, an Output Caution will appear (Figure 20).

    ⓘ   **Note**: LivaNova recommends that during the initial parameter adjustments after implant, the output current be set to 0 mA and then slowly increased by 0.25 mA increments until the patient feels the stimulation at a comfortable level. Patients who are receiving replacement generators may also be started at 0 mA Output Current, followed by incremental increases of 0.25 mA to allow for re-accommodation to the therapy.

Figure 20.   Output Caution Screen
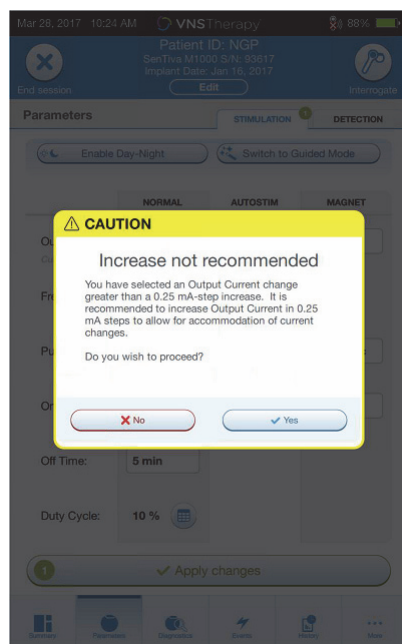
3. New parameter selections that have not been programmed to the generator are in green. Programmed, unchanged, settings are in black.

4. Select **Apply changes** at the bottom of the Parameter screen, to proceed to the Confirmation screen (Figure 21).

5. Confirm the updated parameter setting(s) are correct. If correct, place the Wand over the generator and select **Confirm** to program the new settings to the generator. If incorrect, select **Cancel** to return to the Parameter screen to make further adjustments.

6. Upon successful update to parameters, you will be notified with an on-screen message showing the newly programmed parameter settings.

Figure 21.   Confirmation Screen Example
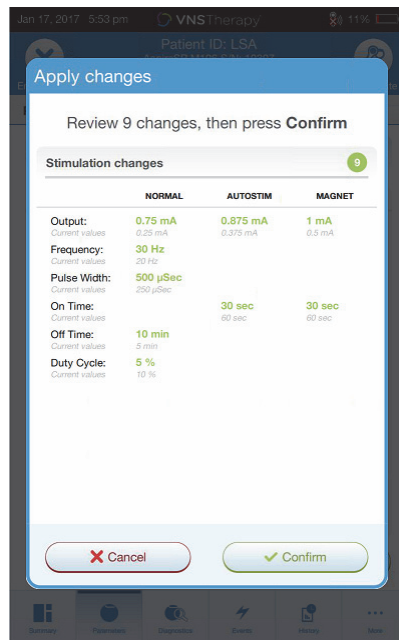
> ⓘ **Note**: The information displayed is specific to the generator model. Not all parameters, features or modes will be applicable for all generator models.

If any parameter changes were made during a patient visit, it is recommended to perform a final interrogation prior to the end of the patient visit in order to confirm the generator is set to the desired values. To perform the final interrogation, first navigate to the Parameter screen and press the **Interrogate** button at the top right portion of the screen.

> ⚠ **Caution**: For Models 102/102R generators, do not use frequencies of 5 Hz or less for long-term stimulation. These frequencies always generate an electromagnetic trigger signal that results in excessive battery depletion of the implanted generator; therefore, use these low frequencies for short periods of time only.

> ⚠ **Warning**: Excessive stimulation is the combination of an excess duty cycle (i.e. one that occurs when ON time is greater than OFF time) and high frequency stimulation (i.e. stimulation at 50 Hz). Excessive stimulation has resulted in degenerative nerve damage in laboratory animals. Furthermore, excess duty cycle can be produced by continuous or frequent magnet activation (> 8 hours) in patients with magnet mode activated (epilepsy only). While LivaNova limits the maximum programmable frequency to 30 Hz, it is recommended that you do not stimulate with excess duty cycle. Physicians should also warn epilepsy patients with magnet mode activated about continuous or frequent magnet use as this could lead to early battery depletion.

6.3.   How to Configure Detection Settings

You can adjust detection settings under the Detection tab on the Parameter screen for Models 106 and 1000/1000-D generators.

> ⓘ **Note**: Detection Settings are only intended for use in epilepsy patients.

6.3.1. Turning the Detection Feature ON/OFF

You may enable or disable Detection. If Detection is Disabled, then the Model 106 and 1000/1000-D generators use only Normal and Magnet stimulation. If Detection is Enabled, then parameters for AutoStim will become available, in addition to Normal and Magnet parameters.

> (i) **Note**: If Detection is disabled, the parameters on the Detection tab are not visible and AutoStim is not activated.

When you enable Detection for the first time, the software will prompt you to set the Heartbeat Detection setting and AutoStim Threshold. These settings work together to ensure the generator is accurately detecting the patient's heartbeats, and set the criterion for AutoStim delivery based on changes in heart rate, respectively. Once Detection is enabled, you can adjust the settings from the Detection tab as needed.

6.3.2. Set Heartbeat Detection

In order for the generator to accurately detect heartbeats, the heartbeat detection must be set for the individual patient. Manually select from a range of heartbeat detection sensitivity values: 1 (least sensitive; for use with largest amplitude ECG signals) to 5 (most sensitive; for use with smallest amplitude ECG signals). The setting will not change unless manually programmed to a different value.

6.3.3. Use Verify Heartbeat Detection

When Detection is enabled, the software will walk you through heartbeat detection setting verification and AutoStim threshold selection. Afterwards, select **Verify** on the Detection tab to confirm the accuracy of the heart rate detected by the generator or to change the heartbeat detection setting. To do so, complete the following steps:

1. Press **Verify** to advance to the Verify Heartbeat Detection screen (Figure 22). If Detection has been Enabled, the Verify Heartbeat Detection screen will automatically display.

Figure 22. Verify Heartbeat Detection Screen
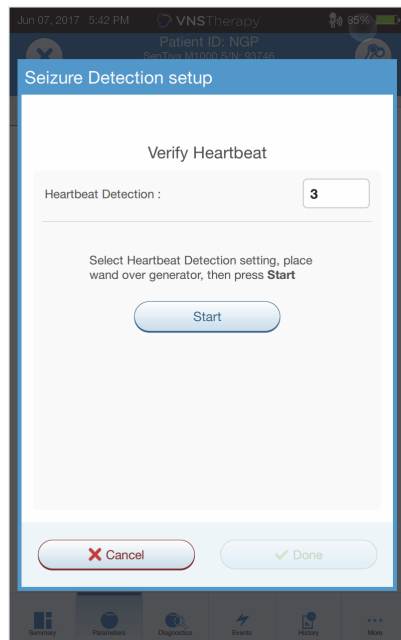
2. On the Verify Heartbeat Detection screen, tap the Heartbeat Detection setting field to change the value (if desired). Place the Wand over the generator and press **Start** to begin the test.

3. Keep the Wand over the generator during the entire Verify Heartbeat Detection process. The generator will transmit a signal and the Programmer will display the detected heart rate in beats per minute (BPM) for up to two minutes (Figure 23).

Figure 23.   Verify Heartbeat Detection - Test in Progress
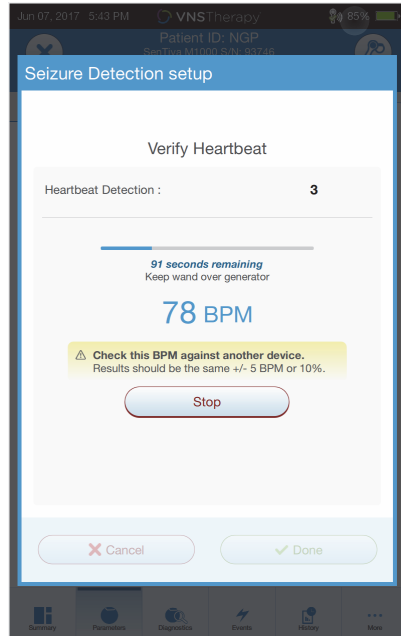
4. Wait for the heart rate display to stabilize (at least 10 seconds) and compare the generator-detected heart rate displayed on the Programmer with an independent source (such as BPM from another ECG monitor or a manual pulse count). Accurate detection should be within ±5 BPM or 10%. If the heart rate reported by the Programmer is too high, then the Heartbeat Detection setting should be adjusted downward (toward setting 1). If the heart rate reported by the Programmer is too low or displays "?? BPM", then the Heartbeat Detection setting should be adjusted upward (toward setting 5). Refer to "Troubleshooting" for more information.

5. If the heartbeat detection is verified before the two minute test completes, keep the Wand over the generator and select **Stop** on the screen.

Once you observe accurate heartbeat detection, you have completed the verification process. If you are enabling Detection, select **Next** to set the AutoStim Threshold. Otherwise, select **Done** to return back to the Parameter screen.

6.3.3.1.   Visual Indicators During Verify Heartbeat Detection

During heartbeat verification, the following visual indicators will display in the BPM window:

- "?? BPM" indicates lost/no communication, or no heart beats detected by the generator
- "<40 BPM" will display if the system detects a heart rate below this lower limit
- ">230 BPM" (Model 3000 v1.0) or ">180 BPM" (Model 3000 v1.6+) will display if the system detects a heart rate above this upper limit
- Between the ranges described above, the actual system-calculated heart rate will display

⚠ **Caution**: For generators capable of heartbeat detection, if AutoStim or Magnet stimulation is programmed on, the Verify Heartbeat Detection feature may be interrupted if AutoStim or Magnet stimulation is activated during the Verify Heartbeat Detection Process. In this case, "?? BPM" will display on the screen. If "?? BPM" displays, LivaNova recommends you temporarily disable all output currents for generators capable of heartbeat detection (i.e. program to 0 mA) and retry the heartbeat verification. After the calibration process is completed, you may reprogram the output currents as appropriate.

6.3.4. Set the AutoStim Threshold

The AutoStim Threshold is a setting on the Detection tab that can be set from 20% to 70% (in 10% increments). This setting allows you to determine minimum heart rate change required for AutoStim, and should be tailored to the individual patient. For the most sensitive detection and the smallest heart rate change for stimulation, choose 20%. For the least sensitive detection and thus the largest heart rate change for stimulation, choose 70%.

> **(i) Note**: Additional guidance for how to program this patient-specific setting can be found in the VNS Therapy System Physician's Manual.

6.3.5. Stimulation Settings on the AutoStim Tab

The AutoStim parameter settings determine the stimulation output delivered when AutoStim Threshold is reached. Alter these settings from the stimulation tab on the Parameter screen.

6.3.5.1. Detection and Time Restraints

In order to allow enough detection time between Normal Mode stimulation periods, the programming software will not allow you to program certain combinations of Normal Mode and AutoStim values. If you program a Normal Mode Off Time of less than 1.1 minutes while AutoStim/ Detection is enabled, you will be prompted to change the values. Otherwise, detection will be turned OFF at the next programming attempt.

> **⚠ Caution:** LivaNova also recommends the output current for the AutoStim Mode does not exceed the output current for the Normal Mode or the Magnet Mode, especially for patients who experience discomfort. You may monitor the patient briefly after parameter changes made in office to ensure stimulation is tolerable.

6.3.6. Low Heart Rate and Prone Position Detection (Model 1000/1000-D)

To receive extra patient-specific information, you can configure the Model 1000/1000-D generator to log low heart rate episodes and/or the occurrence of prone position, when these events occur within 7.5 minutes of an AutoStim or Magnet Mode activation. Seizure detection must be enabled to use low heart rate or prone position logging.

6.3.6.1. Choose the Low Heart Rate Threshold (Model 1000/1000-D)

From the Parameters screen, with the Detection tab active, tap the Low Heart Rate Threshold field. A pop up menu will display a range of 30 to 60 BPM. Once you have selected a threshold, apply changes and confirm the selection to program the generator.

> **(i) Note**: The generator will store up to 20 low heart rate event timestamps for display within Event and Trends. See "Events and Trends").

> **(i) Note**: Low heart rate events are only logged if the heart rate falls below the programmed threshold within 7.5 minutes following an AutoStim or Magnet mode activation. These stimulations trigger the monitoring period, since they may be associated with seizure activity.

> **(i) Note**: If the programming system communicates with the generator during the monitoring period for low heart rate events, if may cause an unexpected low heart rate event to be logged.

6.3.6.2. Turn On Prone Position Detection (Model 1000/1000-D)

From the Parameters screen, with the Detection tab active, you can turn on Prone Position Detection. When you enable this feature, the software will prompt you to calibrate the generator to account for generator orientation within the body (Figure 24). To set up detection, do the following:

1. Instruct the patient to sit or stand upright as straight as possible
2. Place the Wand over the generator and press **Next** on the software screen

3. Instruct the patient to lie down in the supine position (lying flat on back)
4. Place the Wand over the generator and press **Next** on the software screen

Figure 24.   Two-Step Prone Detection Setup
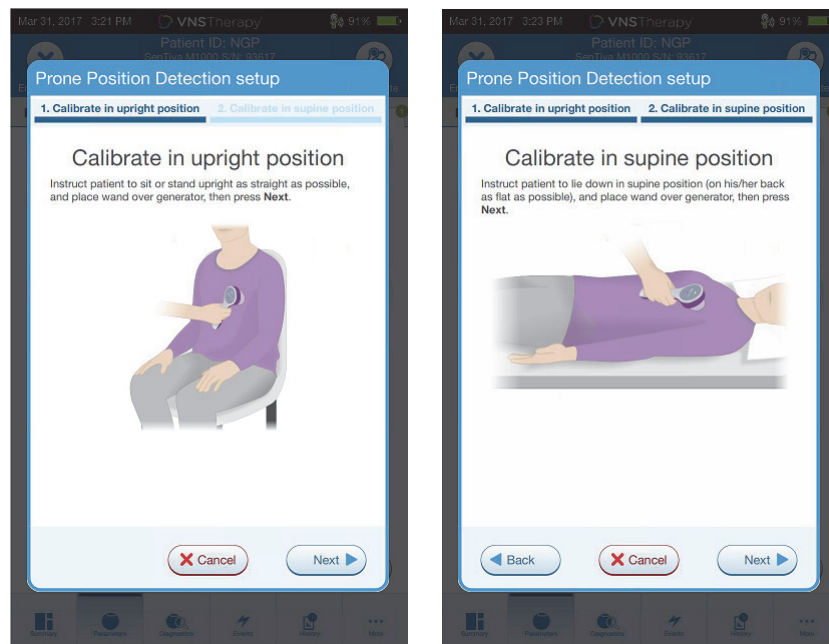
6.4.   Potential Error Conditions Related to Programming

6.4.1.   Partial Programming (Model 102/102R)

Each parameter is programmed and verified individually during a programming event for model 102/102R generators. If the communication is interrupted during programming, generators can be set to unintended settings. The software will display a warning message indicating that the programming failed and device settings were altered or potentially altered due to the interrupted programming attempt. If this occurs, you should interrogate the generator immediately to verify current programmed settings. If necessary, reprogram to desired settings.

6.4.2.   Partial Programming (Model 1000/1000-D)

In the Model 1000/1000-D generator, all modes (Normal, AutoStim, Magnet) are programmed as a set. If programming is interrupted, it is possible not all of the modes were updated leaving one or more modes with an outdated set of parameters. A warning message will display on the Programmer indicating altered or potentially altered device settings due to the interruption. If this occurs, interrogate the generator immediately to verify current programmed settings. If necessary, reprogram to desired settings.

(i) **Note**: AutoStim and Magnet Modes are only intended for epilepsy patients.

6.4.3.   Partial Programming Interruption (Models 103-106 and 8103)

For Models 103-106 and 8103 generators, the device parameters are programmed and verified as a group during a programming event, which is not susceptible to partial programming. If an interruption occurs during programming, the software displays a warning message indicating that the procedure failed and allows the user to retry or cancel the programming operation (Figure 25). If you decide to cancel, interrogate the generator to verify settings before reattempting the programming operation.

Figure 25.   Programming Failed Warning Screen
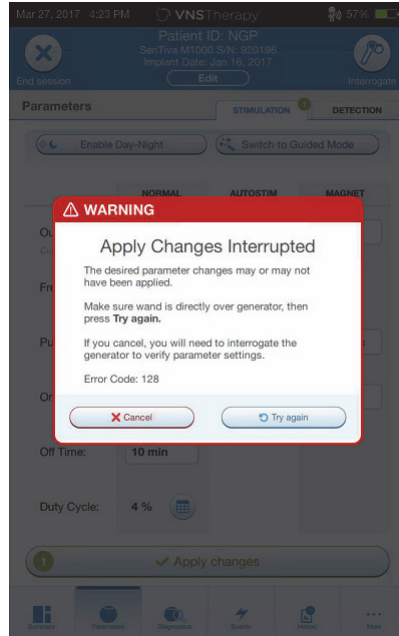
6.4.4.   Cross-programming (Model 102)

Model 102/102R generators are susceptible to an event known as cross-programming. This occurs when parameter settings from a patient's generator are inadvertently programmed to another patient's generator. This can happen if you don't interrogate the generator between patients visits and both patients have the Model 102 or 102R generator. Always perform an initial and final interrogation to verify parameter settings at each office visit for all patients.

7. GUIDED PROGRAMMING

For ease of programming, use the Guided Programming feature to adjust therapy parameters during a follow-up office visit. This feature simplifies programming, by allowing you to increase or decrease parameters with a single button.

For all generators, Guided Mode can be used to adjust parameters according to a Standard Therapy Protocol. See "The Standard Protocol" below. For the Model 1000/1000-D generators, you can create a customized therapy protocol. See "Custom Therapy Protocols (Model 1000/1000-D)" for instructions on how to set up custom therapy protocol before a patient office visit.

ⓘ **Note**: Guided Programming is not recommended for depression patients implanted with generator models lower than Model 1000/1000-D. If Guided Programming is used for a depression patient implanted with a Model 1000/1000-D Generator, a Custom Protocol should be entered and selected where both the Magnet Mode and AutoStim Mode outputs are both 0.0 mA for each desired step.

7.1. The Standard Protocol

ⓘ **Note**: If programmer software has not been updated to v1.6 or higher, contact Technical Support for an update.

The Standard protocol increases output current to 1.75 mA in 7 protocol steps. Each step increases output current by 0.25 mA. See Table 2 for more details. Multiple steps may be applied per office visit if desired. All other parameters (e.g. frequency, pulse width, on and off times) remain constant as shown in Table 3.

Since efficacy may reached prior to step 7, consider evaluating efficacy at each step. To program values that differ from the Standard Protocol, exit Guided Programming and adjust the parameters manually.

ⓘ **Note**: AutoStim and Magnet Modes are only intended for use in epilepsy patients.

ⓘ **Note**: For Model 8103 the Standard Protocol programs Magnet output to 0mA for all steps.

Table 2.   Standard Therapy Protocol Steps

	Normal	AutoStim	Magnet
Step 1	0.250 mA	0.375 mA	0.500 mA
Step 2	0.500 mA	0.625 mA	0.750 mA
Step 3	0.750 mA	0.875 mA	1.000 mA
Step 4	1.000 mA	1.125 mA	1.250 mA
Step 5	1.250 mA	1.375 mA	1.500 mA
Step 6	1.500 mA	1.625 mA	1.750 mA
Step 7	1.750 mA	1.875 mA	2.000 mA

Table 3.   Standard Therapy Protocol Persistent (Constant) Parameter Settings

	Normal	**AutoStim**	**Magnet**
Frequency	20 Hz	20 Hz	20 Hz
Pulse Width	250 μsec	250 μsec	500 μsec
On Time	30 sec	60 sec	60 sec
Off Time	5 min	N/A	N/A
Duty Cycle	10%	N/A	N/A

7.2.   Custom Therapy Protocols (Model 1000/1000-D)

Custom protocols can be created from the Main screen (see Figure 10) prior to interrogation. This option allows you to define the output current for each step and mode (e.g. Normal, Magnet, and AutoStim), and select different persistent parameter settings (versus Table 2). Persistent parameter settings are applied to each step of the custom protocol.

Note: Output current for any mode may not be increased by more than 0.25mA from the previous protocol step

To create a custom protocol do the following:

1. Select **Settings** from the navigation bar of the Main screen
2. Select **Guided Mode Options**
3. Select T**herapy Protocols**
4. Choose **Create protocol**
5. Select **Start from scratch** or **Standard Protocol**
6. Add or delete steps (maximum of 7) and set the output currents for each therapy mode (Figure 26, left panel)
7. Choose the custom persistent parameters that will be used in all protocol steps (Figure 26, right panel)
8. Follow on-screen prompts to name and save the custom protocol, then navigate back to the Main screen using the back arrow.

Figure 26.   Create Protocol Steps
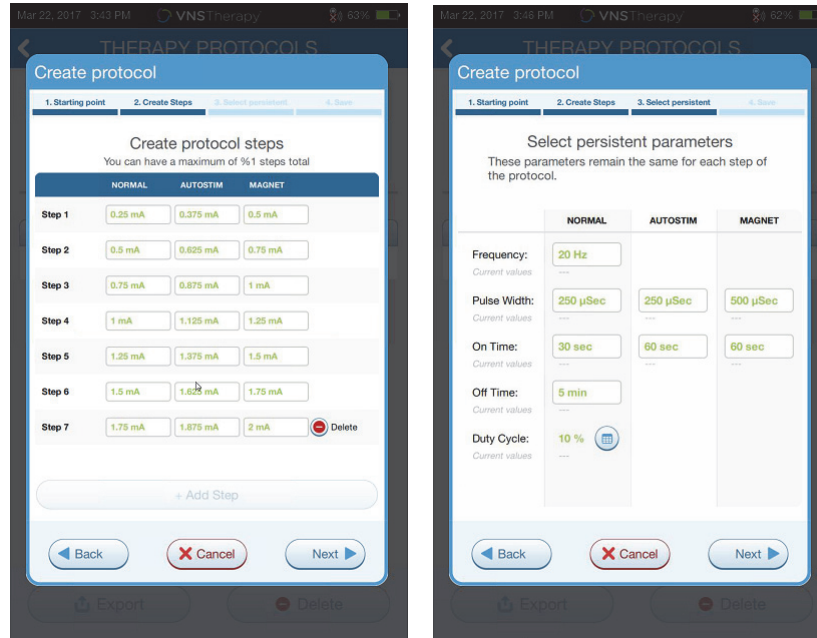
Additional options can be performed from the Therapy Protocols screen. See Figure 27 for more details. These options allow you to import or export protocols to move them between Programmer tablets, delete unneeded protocols, and review protocols details.

Figure 27.   Therapy Protocol Screen Options
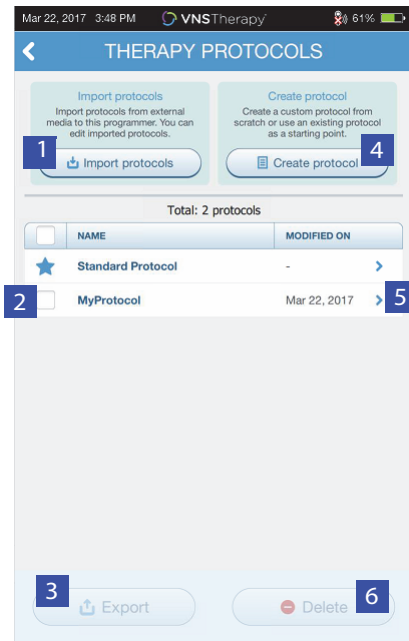
1	Import one or more protocols from external media
2	Select protocols to delete or export
3	Export selected protocols to external media
4	Create new protocol
5	Review protocol steps
6	Delete selected protocol

7.3.   Start Guided Mode

To enable Guided Programming, interrogate the generator and then go to the Parameters screen. On the Stimulation tab, select the **Switch to Guided Mode** button at the top of the screen to enable this feature (Figure 28). For Model 1000/1000-D generators, the software will prompt you to select either Standard Protocol or Custom Protocol. Guided Mode will then determine the closest match between the current generator parameters and the selected protocol. Proposed setting changes are shown in green on the confirmation screen. Select **Apply changes** to program the guided protocol (Figure 29).

> (i) **Note**: If you do not agree with the proposed Guided Mode steps, or you reach the last step in a therapy protocol and wish to make further changes, exit Guided Mode and adjust the parameters manually.

> (i) **Note**: For Model 1000/1000-D generators, Guided Mode is unavailable if Day/Night programming is enabled.

> (i) **Note**: The information displayed is specific to the generator model. Not all parameters, features or modes will be applicable for all generator models.

Figure 28.   Switch to Guided Mode
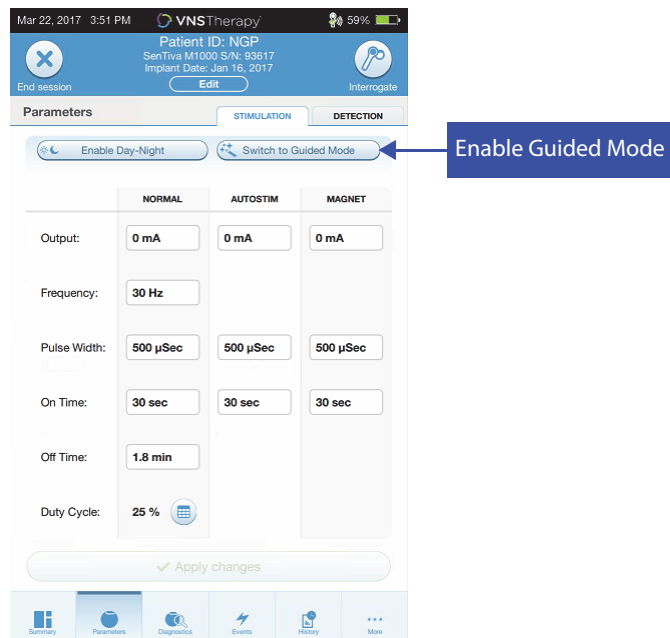
Figure 29.   Review Guided Programming Parameter Settings
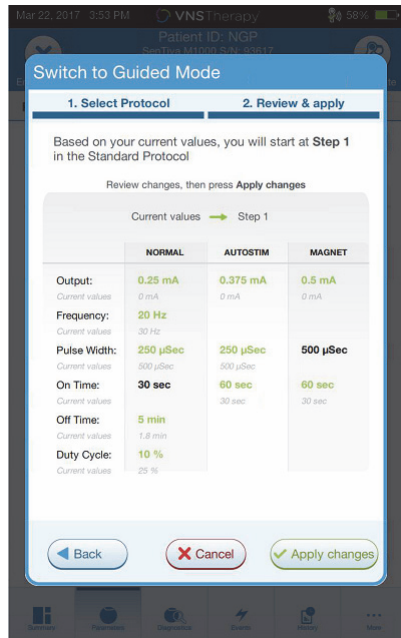
7.4.   Change Parameters in Guided Mode

See Figure 30 for available options once you are in Guided Mode.

Figure 30.   Guided Mode at a Glance
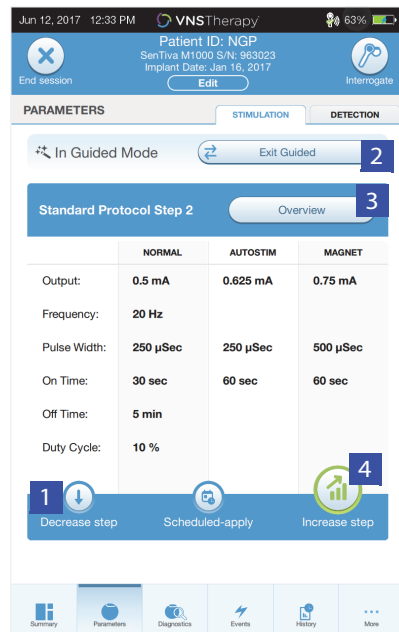
1	Decrease Parameter Step
2	Exit Guided
3	Review Therapy Protocol Steps
4	Increase Parameter Step

7.4.1.   Increase Stimulation

Select **Increase step** to increase stimulation intensity to the next protocol step. To accept changes, and program the proposed settings, select **Apply changes**.

7.4.2. Decrease Stimulation

If the patient cannot tolerate the increased settings, decrease the parameters by selecting Decrease step. Decreasing a step changes the parameters to the previous protocol step. Select **Apply changes** to program the generator.

7.5. Review Protocol

Press **Overview** to view all the protocol steps and see which step(s) have been applied.

> **(i)** **Note**: AutoStim settings on the overview screen always reflect the values from the Guided Mode protocol. Refer to the parameters or summary screen to view current generator AutoStim settings

7.6. Exit Guided Mode

Select **Switch to Manual mode** at the top of the Parameters screen to exit Guided Mode and manually adjust parameters (Figure 31). Follow and confirm prompts to exit. Note, you can switch back to Guided Mode at any time.

Figure 31.   Exit Guided Mode
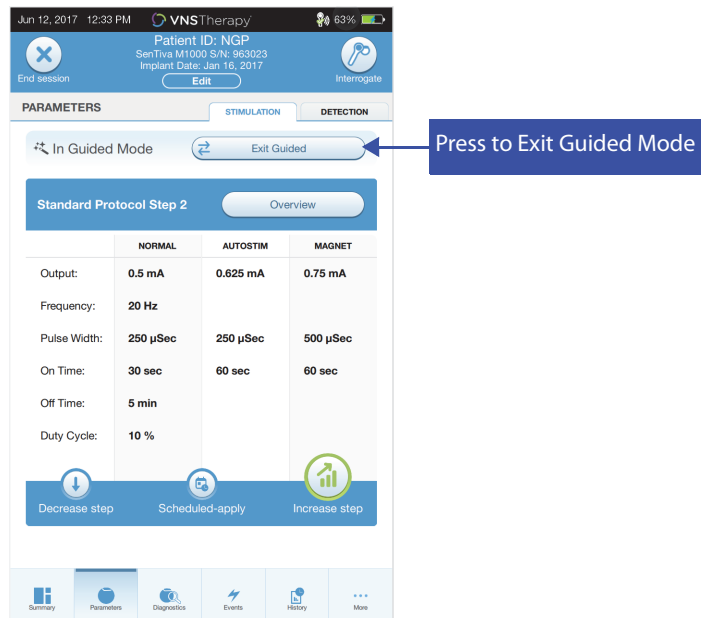
8. SCHEDULED PROGRAMMING

This feature allows you to schedule a series of automatic generator stimulation parameter changes. Scheduled programming may be useful to patients who live far from their healthcare provider. Before using this feature, you must first enable Guided Mode and select a therapy protocol. Refer to "Start Guided Mode".

> **(i)** **Note**: Available for Model 1000/1000-D generators only. If Scheduled Programming is used for a depression patient implanted with a Model 1000/1000-D Generator, a Custom Protocol should be entered and selected where both the Magnet Mode and AutoStim Mode outputs are both 0.0 mA for each desired step

8.1. Set Number of Scheduled Steps

The Programmer settings determine how many automatic (scheduled) parameter increases are allowed. The maximum number of scheduled steps can be set from the Main screen (Figure 10) prior to interrogation, by accessing Settings and then Guided Mode Options. The default value is 2 scheduled programming steps and may be increased up to 6.

8.2. Turn On Scheduled Programming

To schedule programming changes:

1. Enable Guided Mode and select a therapy protocol. See "Start Guided Mode".

2. Select the **Scheduled-apply** button at the bottom of the Parameters screen (stimulation tab active). See Figure 32.

3. Choose the time interval between programming parameter changes and then press **Generate Schedule**. The interval can be 7 days (for protocols with 0.125 mA increases per step), or range from 14 to 28 days (for protocols with 0.25 mA increases per step)

4. Edit the date(s) and time(s) for scheduled programming changes (Figure 33).

5. Select **Apply changes** to program the schedule into the generator (Figure 33).

Figure 32. Enable Scheduled Programming

Figure 33.   Editing the Schedule
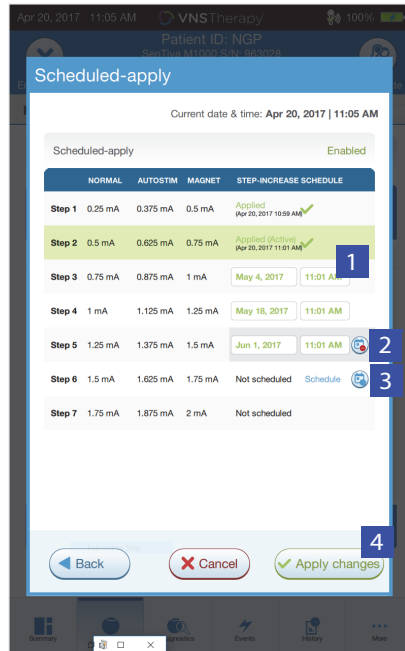
1	Adjust date and/or time
2	Remove from schedule
3	Add to schedule
4	Program schedule into generator

ⓘ **Note**: If the patient resides in a different time zone or plans to travel, program the schedule based on the patient's local time zone to ensure therapy changes occur at the intended times.

8.3.   Turn Off Scheduled Programming

The patient must be in the office to turn off Scheduled Programming. To turn off Scheduled Programming do the following:

1. Interrogate the generator
2. Select **Switch to Manual Mode** from the Parameters screen (Stimulation tab active).
3. Follow on-screen prompts to apply this change.

9. DAY/NIGHT PROGRAMMING

Day/Night Programming is an optional feature that allows the generator to deliver two independent sets of therapy parameters at different times during a 24-hour period. This feature allows you to do the following:

- Choose unique daytime and nighttime settings
- Define the time each parameter set is active

> **(i)** **Note**: Available for Model 1000/1000-D generators only.

> **(i)** **Note**: Day/Night Programming is not available in Guided Mode.

9.1. Using the Feature

Perform the following steps to enable the day/night programming:

1. Select **Enable Day-Night Program** (Figure 34) on the Parameters screen (Stimulation tab active). Daytime and nighttime tabs will then replace the stimulation tab.

2. On the Nighttime tab, select the active time period for nighttime settings and customize applicable mode parameters (Figure 35).

3. On the Daytime tab, the remaining hours from the 24-hour cycle are automatically shown as the daytime active period. Customize stimulation parameters as desired.

4. On the detection tab, unique AutoStim Thresholds (epilepsy only) can be selected for the Daytime and Nighttime periods (if Seizure Detection is enabled) (Figure 36).

5. A green icon indicates the number of pending changes within each tab. Selections that have not yet been programmed to the generator are shown as green text (Figure 35).

6. To program selections from the Daytime, Nighttime, and Detection tabs to the generator press **Apply changes** and confirm new selections.

Figure 34. Enable Day/Night Programming
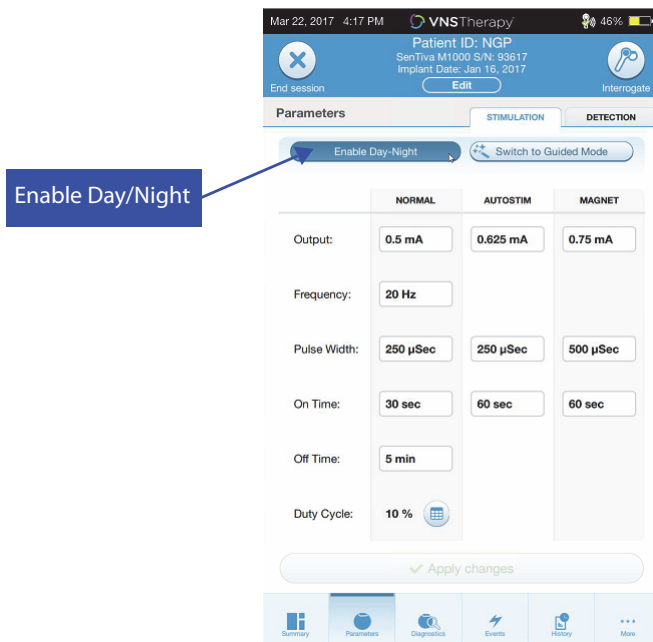
Figure 35.   Nighttime Settings

1	Set active period for nighttime
2	Apply changes from all tabs
3	Number of pending changes in each tab (green circles)
4	Mode Parameters

Figure 36.   Customize Day/Night AutoStim Thresholds
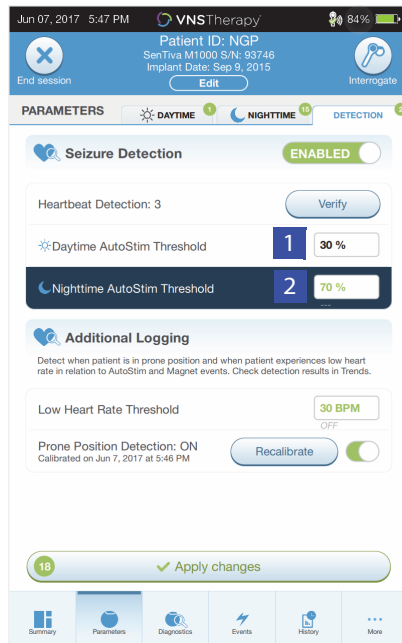
1	Day AutoStim Threshold
2	Night AutoStim Threshold

Note: If the patient resides in a different time zone or plans to travel, choose the day/night intervals based on the patient's local time zone to ensure therapy changes occur at the intended times.

9.2.   Test the Day/Night Programming Feature

When you adjust day/night settings, ensure the patient can tolerate both sets of parameters. When you first enable the feature, the generator will stimulate using the alternate period parameters for 15 minutes, and then revert to the current period settings. For example, if you enable the day/night feature during the day period, the generator will stimulate using night parameters for 15 minutes before reverting to daytime settings. Similar testing will occur anytime you adjust a setting(s) outside the current period (e.g. if you modify the night setting during the daytime period).

> **(i)** **Note**: If you perform additional programming during the 15-minute trial period, the alternate period test will end.

> **(i)** **Note**: You do not need to keep the Wand over the generator during the 15-minute trial period or afterward. The generator controls the alternate period testing and transitioning back to the current period.

9.3.   Turning Off Day/Night Programming

To turn off Day/Night Programming, and use the daytime parameters for the full 24-hour period:

1. Navigate to the Nighttime tab on the Parameters screen
2. Select the **Enabled** switch to toggle to Disabled
3. Press **Apply changes** to review and confirm changes

10. DEVICE DIAGNOSTICS

Several Diagnostics tests are available in the programming software to assess functionality of the implanted system. You may access them after a completed interrogation by selecting **Diagnostics, or Perform Diagnostics on the Summary screen** (see Figure 37).

Figure 37.   Accessing Diagnostics
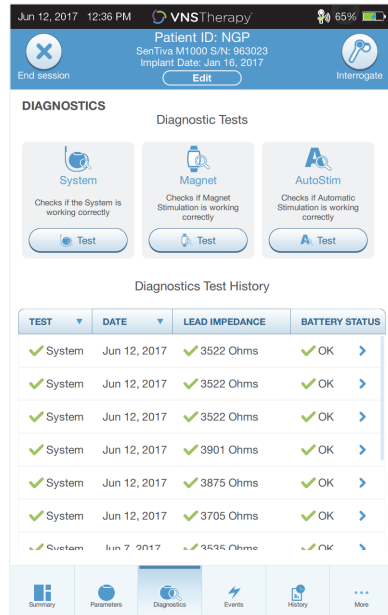
Note: The information displayed is specific to the generator model. Not all parameters, features or modes will be applicable for all generator models.

Depending on the model of generator interrogated, you may have access to different types of tests. Typical tests include System Diagnostics, Normal Mode Diagnostics, Magnet Diagnostics, and AutoStim Diagnostics. Make sure to follow all the instructions on the Programmer screen, as they vary for each selection.

It's important to note that the tests described in this section are designed for assessing system functionality using the implanted components. Another test, Generator Diagnostics, is designed specifically for use with a test resistor and should only be accessed for troubleshooting scenarios during implantation surgery. Please see "Troubleshooting" for more details on accessing Generator Diagnostics.

10.1.   Reading Test Results

Figure 38 shows a typical results screen after completion of a diagnostics test.

Figure 38.   Diagnostics Results Example
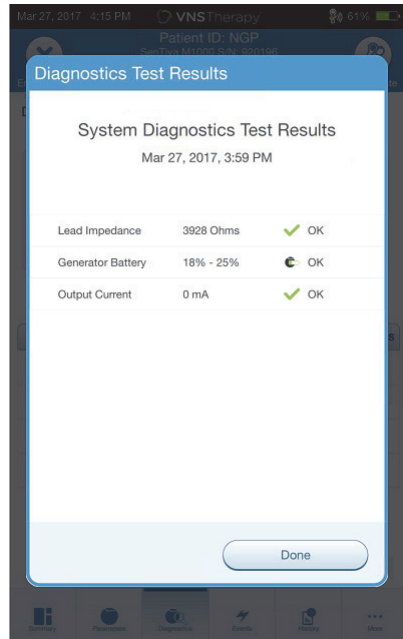
The various test parameters and their values/meanings across the different diagnostics tests are summarized in the Table 4. Additional details regarding specific Diagnostics tests are described in the remaining sections of this section. For Model 102 generators, the lead impedance values are estimated based on DC DC code (displayed in previous versions of VNS software). The conversion between DC DC code and estimated impedance range are listed in Table 5. For abnormal results, refer to "Troubleshooting", for additional instructions.

Table 4. Diagnostic/Parameter Result Summary

Parameter Name(s)	Parameter Description	Parameter Values/ Results	What Does the Value or Result Mean?
Lead Impedance	Indicates measured or estimated impedance when delivering the output current during testing and whether it's within normal range.	M103-106, 8103 and 1000/ 1000-D: Measured lead impedance value (ohms) and overall status of OK, LOW, or HIGH M102: Estimated lead impedance range (ohms) and overall status of OK or HIGH **Note: If using software version 1.0 or 1.5, update to version 1.6.**	**OK**: Impedance is within acceptable operating range. No special attention is required. **LOW**: Impedance is lower than expected and it may be indicative of a short circuit condition or a defective generator. See "Troubleshooting" on page 60 for additional instructions. **HIGH**: Impedance is higher than expected and the generator may not be able to deliver the programmed therapy. See "Troubleshooting" on page 60 for additional instructions.
Generator Battery	Indicates battery status of the generator using one of the following: ■ OK ■ Intensified Follow-up Indicator (IFI) ■ Near End of Service (N EOS) ■ End of Service (EOS)	M103 and subsequent models: OK IFI N EOS EOS M102: OK N EOS	**OK**: Battery level is within normal operating range and no special attention is required. **IFI**: The battery has depleted to a level where more frequent clinical monitoring is recommended. **N EOS**: ■ M103 and subsequent models: The Generator should be replaced as soon as possible. ■ M102: A System Diagnostics Test is recommended to verify the NEOS status. If confirmed, the pulse generator should be replaced as soon as possible. **EOS**: The generator is no longer supplying stimulation and immediate replacement is recommended. If the generator is not replaced, it will eventually lose the ability to communicate with the software.

Parameter Name(s)	Parameter Description	Parameter Values/ Results	What Does the Value or Result Mean?
Output Current / Current Delivered	Indicates the stimulation output current delivered during the Diagnostics test, and the test status based on the programmed settings	Parameter value M103 and subsequent models: Output current value (mA) and overall status of OK or LOW M102: Output current value (mA) and overall status of OK or LIMIT	Value indicates the stimulation output delivered during the diagnostic test. **OK**: Current is being delivered at the programmed level. M103-106, 8103 and 1000/1000-D: **LOW**: Programmed current is possibly not being delivered at the specified level. M102: **Limit**: Programmed current is possibly not being delivered at the specified level.

⚠ **Caution:** Battery depletion can occur between visits. Therefore, LivaNova recommends that epilepsy patients with magnet activation enabled should perform a daily magnet activation to check stimulation. If stimulation is not felt, instruct the patient to consult with the physician to perform diagnostics testing.

Table 5.   DC DC Code Conversion and Estimated Impedance Range

DC DC Code	Estimated Impedance Range (Ohm)*
0	<1700
1	1800-2800
2	2900-4000
3	4100-5200
4	5300-6500
5	6600-7700
6	7800-8900
7	>9000
*Lead impedance value at 1mA, 500µsec	

10.2.   Review Test History

All previously completed Diagnostics tests are listed in the history table on the Diagnostics screen. Use the drop down menus to filter the reports by type and/or date. In addition, select any test to view details.

10.3. System Diagnostics

The System Diagnostics test assesses the electrical continuity between the generator and the bipolar lead when connected. The test measures the generator's ability to deliver programmed output current and the lead impedance status. You can perform this test on all generators supported by the Programming System during implantation and patient follow-up visits. A successful System Diagnostics during surgery or post-implant shows that both the generator and lead are working properly. LivaNova recommends you perform a System Diagnostics test before other diagnostic tests.

> **(i)** **Note:** A System Diagnostics is performed for Model 1000/1000-D during the initial interrogation, regardless of the type of interrogation (Advanced or Rapid). The results are displayed on the Summary Screen and logged as part of Diagnostics history. To perform a diagnostic test for a Model 1000/1000-D after the initial interrogation you can manually perform a System Diagnostic test while in session.

> **(i)** **Note:** A System Diagnostics is NOT performed for Model 102-106 and Model 8103 generators during the initial interrogation. To perform a diagnostic test for Model 102-106 and Model 8103 generators after the initial interrogation you can manually perform a System Diagnostic test while in session.

10.4. Normal Mode Diagnostics (Model 102)

The Normal Mode Diagnostics test will let you know if the generator is able to deliver the programmed Normal Mode output current. Perform this test regularly at follow-up visits after the patient can tolerate at least 0.75 mA. The test can only run if the output current is at least 0.75 mA with a frequency ≥ 15 Hz and ON time ≥ 30 seconds.

> **(i)** **Note:** For Models 103-106, 8103 and 1000/1000-D generators, the System Diagnostics test serves the same function as Normal Mode Diagnostics since the test is run at the programmed output current, frequency, and pulse width. Results are not valid unless connected to a test resistor or lead.

10.5. Magnet Mode Diagnostics

> **(i)** **Note**: Magnet Mode is only intended for use in epilepsy patients.

The Magnet Mode Diagnostics test will let you know if the generator is able to deliver the programmed magnet output current. To perform this test do the following:

1. Select **Test Magnet**
2. Quickly pass the magnet over the generator (no more than 2 seconds)
3. Place the Wand over the generator and use the on-screen button to Start the test.

If you do not successfully activate magnet stimulation, a message will display on the screen indicating the magnet presence was not detected. Pass the magnet over the generator again and restart the test.

> **(i)** **Note:** Magnet Mode is not available for the Model 8103 generator.

> **(i)** **Note**: For the Model 106 generator, do not leave the magnet over the generator for longer than 3 seconds when performing Magnet Mode Diagnostics. Otherwise, stimulation will stop and you will receive a message indicating that the magnet presence was not detected. Repeat the Magnet Mode Diagnostics test.

> **(i)** **Note**: For the Model 102 generator, Magnet Mode Diagnostics cannot run if output current is less than 0.75 mA, or the frequency less than 15 Hz, or ON time less than 30 seconds (similar to Normal mode diagnostics).

10.6. AutoStim Diagnostics

ⓘ **Note**: AutoStim Mode is only intended for use in epilepsy patients.

The AutoStim Diagnostics test determines if the generator is able to deliver the programmed AutoStim output current. The desired AutoStim output current should be programmed before you perform the diagnostic test.

10.7. Generator Diagnostics

The Generator Diagnostics test is designed specifically for use with a test resistor and should only be accessed for troubleshooting scenarios during implantation surgery. Go to "Troubleshooting" for more details on using Generator Diagnostics.

10.8. Diagnostic Test Differences Between Models of Generators

Some Diagnostic tests operate differently depending on which model generator is used. These differences are outlined below in Table 6.

Table 6.   Diagnostic Test Differences Between Models of Generators

Items of Interest	Model 102/102R	Models 103-106 & 8103	Model 1000/1000-D
System Diagnostics	Stimulates at 1.0mA, 500µs, and 20 Hz for approximately 14 seconds ⚠ **Caution**: Patients with lower parameter settings may feel discomfort during this test.	**Normal Mode Output Current = 0mA**: Assesses impedance at 0.25 mA and stimulates at 1.0mA, 500µs, and 20Hz for approximately 14 seconds ⚠ **Caution**: Patients with lower parameter settings may feel discomfort during this test. **Normal Mode Output Current > 0mA**: Assesses impedance at 0.25 mA and stimulates at the programmed Normal Mode parameters for approximately 14 seconds	Delivery of programmed output for approximately 4 seconds, followed by one brief pulse at 0.25 mA for less than 130 µsec.*
Normal Diagnostics	Requires normal mode settings of 0.75mA, 15Hz, and 30sec (or greater). Stimulates at normal mode settings for approximately 14 seconds.	Test not available, use System Diagnostics	Test not available, use System Diagnostics

Items of Interest	Model 102/102R	Models 103-106 & 8103	Model 1000/1000-D
Generator Diagnostics	Stimulates at 1.0mA, 500 μsec, and 20 Hz. ⚠ **Caution**: The Generator Diagnostics test should only be run in the operating room setting with the test resistor. ⚠ **Caution**: The Model 102 generator will be set to 0 mA after the test.	Assesses impedance at 0.25mA and stimulates at programmed Normal Mode parameters for approximately 4 seconds. If output is 0mA, then only the impedance measurement is collected.	Delivery of programmed output for approximately 4 seconds, followed by one brief pulse at 0.25 mA for less than 130 μsec.* If output is 0mA, then only the impedance measurement is collected.
Lead Impedance	The estimated lead impedance range at 1mA and 500μsec is reported.	The actual lead impedance measurement is reported.	The actual lead impedance measurement is reported.

*Minor differences in the system diagnostics test exist for M1000 with serial numbers <100,000. Refer to the *Introduction to the VNS Therapy System* chapter for more information.

ⓘ **Note**: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours for Model 103 and higher generators.

10.9.   Potential Error Conditions Observed in Diagnostics

If diagnostics testing is interrupted, follow on-screen instructions to repeat the test and verify the patient's parameters. The Model 102 parameters are susceptible to unintended changes during a diagnostic test that is interrupted due to the break in communication. Always re-interrogate to verify settings after an interrupted diagnostics test.

11. HISTORY

The History feature allows you to view a patient's parameter settings from recent office visits. In addition, you can view session reports.

11.1. Parameter Settings History

On the Parameter History screen, you can view the following:

- Type of stimulation program (Manual program, Guided or Scheduled, Day/Night)
- Stimulation parameters for Normal mode (all models) and Magnet mode ((not available for Model 8103), and AutoStim mode (Models 106 and 1000/1000-D)
- Current and previously applied protocol steps (Guided and Scheduled modes, if applicable)
- Active time periods and parameter settings for Day/Night mode (Model 1000/1000-D only)
- AutoStim Thresholds (Models 106 and 1000/1000-D), and low heart rate and prone position detection (Model 1000/1000-D)

11.2. Session Reports

Session reports are automatically stored by the Programmer each time the user ends a session. Reports can be exported and printed, and added to patient medical records. Session reports show the following:

- Most recent diagnostic results
- Average number of stimulations per day (per mode), and distribution among modes
- Parameters at initial interrogation and final programming
- Details for guided or scheduled programming protocols, including history of applied steps and scheduled steps (if applicable)

11.3. How to View Parameter History and Session Reports

Before you view parameter history, you must interrogate the generator. However, you can view session reports in or out of session.

11.3.1. View Parameter History

To view parameter history, select **History** on the navigation bar (Figure 39).

11.3.2. View Session Reports

To create a session report, do the following:

1. Select **View Session Report** (Figure 39, left panel)
2. Select the time and date of the desired report (Figure 39, right panel). Use the touch screen to scroll (touch and drag) or enlarge/reduce (moving index finger and thumb apart or together) the session report display.

   (i) **Note**: To enlarge or reduce the displayed session report, move your index finger and thumb apart or together.

Session reports are generated when End session is selected. To view the most recent session report, select **Reports** on the navigation bar while out of session. See "Managing Programmer Information" for more details.

Figure 39.   View Generator History Example
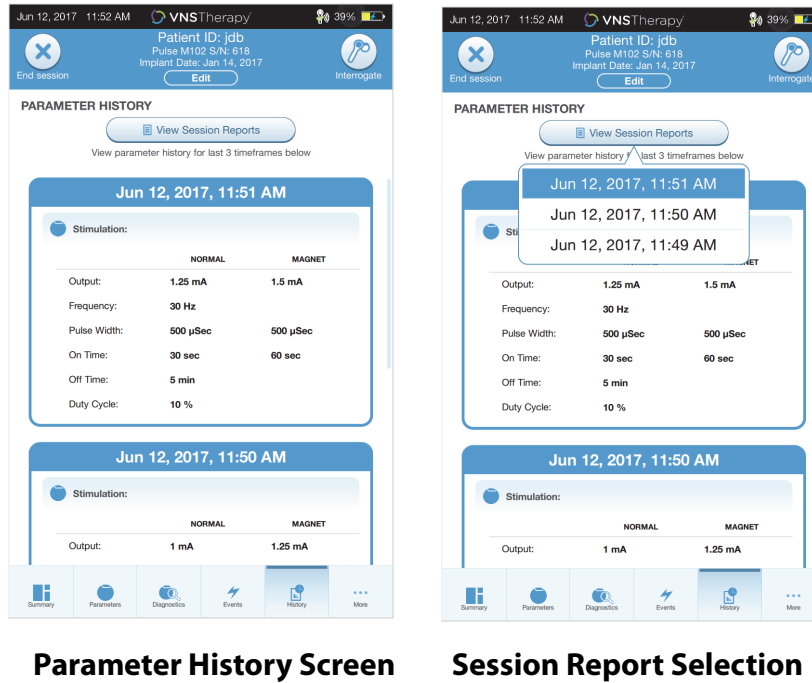
Parameter History Screen   Session Report Selection

ⓘ **Note**: The information displayed is specific to the generator model. Not all parameters, features or modes will be applicable for all generator models.

12. EVENTS AND TRENDS

Use the Events and Trends feature to view the following:

- Summary data from recent office visits (up to 3): including a pie chart showing the stimulation distribution among modes, and a summary of the average number of stimulations per day for each mode (Models 106 and 1000/1000-D only).

- Magnet activation counts and timestamps (not available for Model 8103)

- Inhibited stimulation timestamps (prevented normal and AutoStim stimulations) (Model 1000/1000-D only).

- Daily and Hourly histograms showing: seizure detections, AutoStims, Magnet stimulations (Models 106 and 1000/1000-D); and prone position or low heart rate detections (Model 1000/1000-D only)

Before you can view Event or Trend data, you must interrogate the generator. For Model 1000/1000-D, you must select the advanced interrogation option.

12.1.   View Event Data

To view Event data, select **Events** on the navigation bar. The display will depend on the patient's model generator.

12.1.1.   Limited Event Data (Model 102-105 Generators)

For the Models 102-105, the Events section lists the date and time of the 15 most recent magnet activations. No additional event data is available for these models.

12.1.2.   Model 106 and 1000/1000-D Event Data

The Model 106 and 1000/1000-D generators provide a summary of recent office visits (up to 3),defined by two interrogations that are at least 12 hours apart. Each summary:

- Provides a pie chart showing the percentage contributions of Normal, AutoStim, and Magnet Mode to the overall therapy, and

- Lists the average number of stimulations per day for Normal, AutoStim, and Magnet Mode.

To navigate between office visits use the left and right arrows. To view recent magnet activations, select the view timestamps button. See Figure 40 for an example Events screen.

> **(i)** **Note**: Model 106 (and earlier) stores the most recent 15 magnet activation timestamps for review. Model 1000/1000-D stores up to 50 recent magnet activation timestamps.

Figure 40.   Events Screen Example
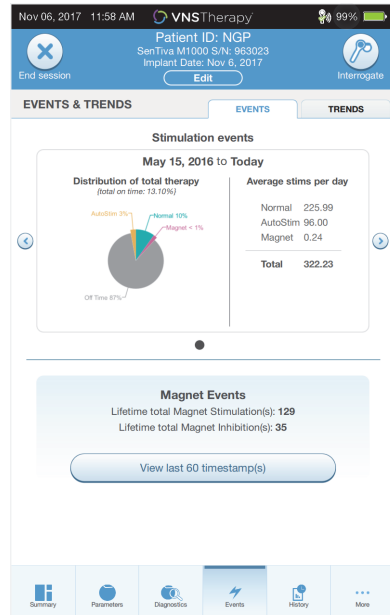
12.2.   View Trend Data (Models 106 and 1000/1000-D)

To view a histogram of trend data, select **Events** on the navigation bar and then select the Trends tab. You can change the histogram to show day-by-day or hour-by-hour format.

The histogram may include the following:

- Seizure detections (without stimulation)
- AutoStim Stimulations
- Magnet Mode Stimulations
- Prone position (Model 1000/1000-D only)
- Low heart rate (Model 1000/1000-D only)

12.2.1.   Daily View

Select **Events per day** to show one month of detection data in day-by-day format (Figure 41). Select the timeframe and event types that you want to display. To view more details for a particular day tap that bar on the histogram.

Additional data includes:

- Event counts
- Parameter thresholds
- Event timestamps

Timestamp information requires an additional interrogation. Refer to "Timestamp Download" for details.

Figure 41.   Trends - Daily View Example

Select to change month

Check event types to include on graph

Select a bar to show more details.
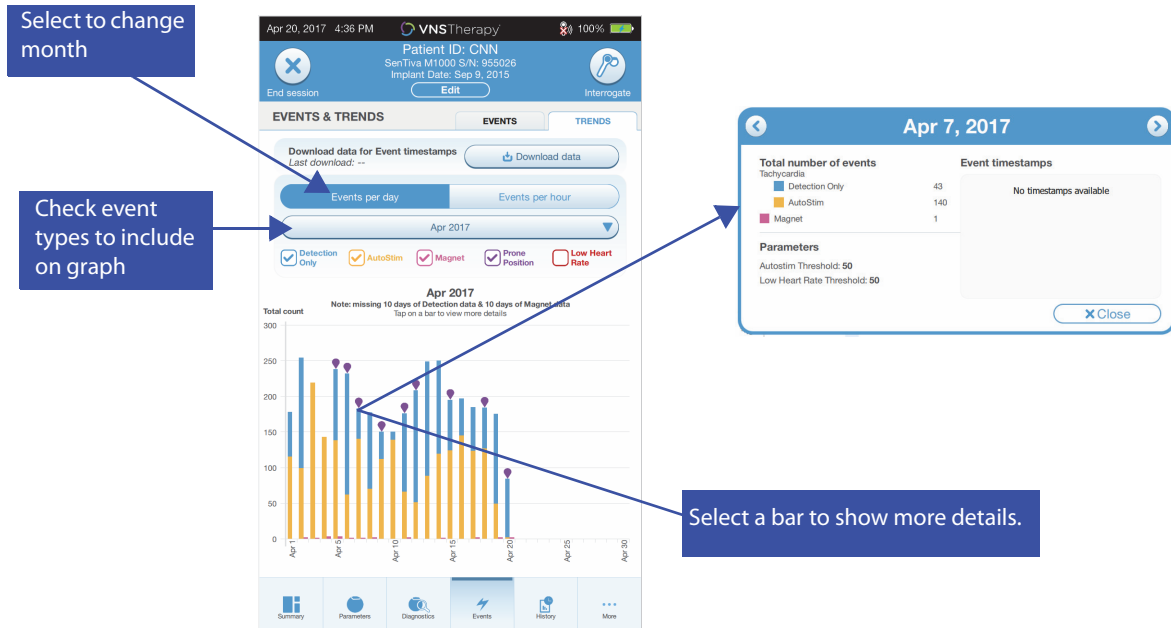
12.2.2.   Hourly View

Select **Events per hour** to show detection data in hour-by-hour format (Figure 42). Choose the timeframe (period between office visits) and event types that you want to display. Hourly view shows the average number of counts for each hour in a 24-hour period. The average is taken over the selected office visit period.

Figure 42.   Trends - Hourly View Example

12.2.3.   Timestamp Download

To download timestamp information for Daily View, place the Wand over the generator, and select **Download data**. For Model 1000/1000-D the maximum number of stored timestamps (350) will be downloaded. Model 106 can store up to 4096 records and you may select the desired download size (500, 1000, 2000, 3000, or all records). To retrieve an electronic copy of the detection timestamps, use the Import/Export feature while out-of-session. See "Import/Export".

13. MANAGING PROGRAMMER INFORMATION

While out of session (prior to interrogating a patient generator), you can do the following with the Programmer:

- View session reports
- Import/export data
- Perform advanced troubleshooting, if advised by Technical Support (Reset the generator)
- Edit Guided Programming options, including creation of custom therapy protocols
- Alter Programmer and Wand settings

13.1. View and Export Session Reports

To view all session reports saved on the Programmer, select **Reports** on the navigation bar from the Main screen. Use the search field and drop down menus to filter the reports by Date and Time, generator model, or Patient ID. Tap any session report to view. Contents of session reports are described in "Session Reports".

This feature also allows you to export individual session reports to a USB drive. To create an electronic copy (.pdf):

1. Insert external media into the Programmer USB drive (type C)
2. View the session report of interest
3. Press the **Export** button, and follow on-screen instructions

13.2. Import/Export

To transfer data between programmers, select **Import/Export** on the navigation bar from the Main screen (see Figure 10). This may be used to consolidate patient data between multiple computers, or to copy a custom therapy protocol from one Programmer to another.

To export a full Programmer copy do the following:

1. Insert external media into the Programmer USB drive (type C)
2. Select **Export data**, and follow on-screen instructions

To import data to a new Programmer do the following:

1. Insert the external media containing the copied data into the "new" Programmer USB drive
2. Select **Import data**
3. Choose the database copy that will be merged with the existing Programmer database

13.3. Out of Session Troubleshooting Menu

If you encounter any generator difficulties refer to "Troubleshooting". Technical Support will determine if a generator reset is appropriate. Contact Technical Support before using this feature.

14. PROGRAMMER SETTINGS

Programmer Settings can be accessed from the navigation bar while out of session. Use these options to do the following:

- Change Programmer settings such as volume, screen brightness, date, time, and language
- Choose Wand connection preferences (Model 3000 v1.0+) and check Wand firmware (Model 3000 v1.6 only)
- Select Guided Programming options, including setup of custom therapy protocols

14.1. How to Access Programmer Settings

To access the Settings feature, select **Settings** on the navigation bar at the bottom of the Main screen (Figure 10). From the next menu, you may select Programmer settings, Wand settings, or Guided Mode Options.

14.2. Programmer Settings

For a description of features you can adjust, see Figure 43. Details regarding Programmer and Wand software updates are described in "Programming System Updates".

Figure 43.   Programmer Settings Screen
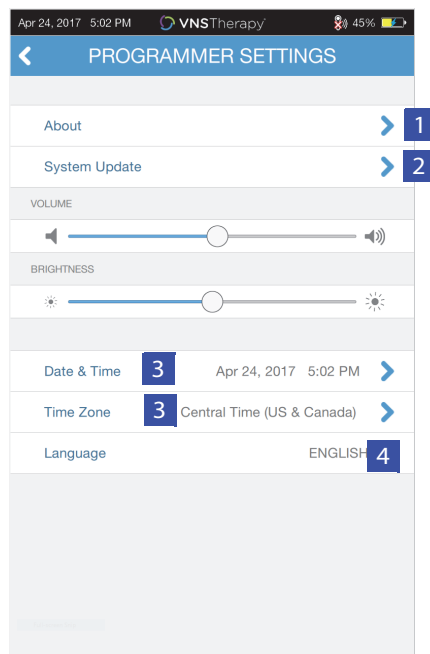
1   Provides details about Programmer serial number, software version, and Wand firmware version

2   Update to latest software

3   Access date and time

4   Select language

14.3. Wand Settings

14.3.1.   Setup Preferred Wand

Toggle the preferred Wand setting to Enabled to automatically connect to a particular Wand during each interrogation (Figure 44, left panel). After you set the preferred Wand, the screen will display the Wand serial number and provide an option to change that selection. To return to manual Wand selection, disable the preferred Wand option (interrogation without preferred Wand is described in "Interrogate (No Preferred Wand)").

Figure 44.   Preferred Wand Settings Screen
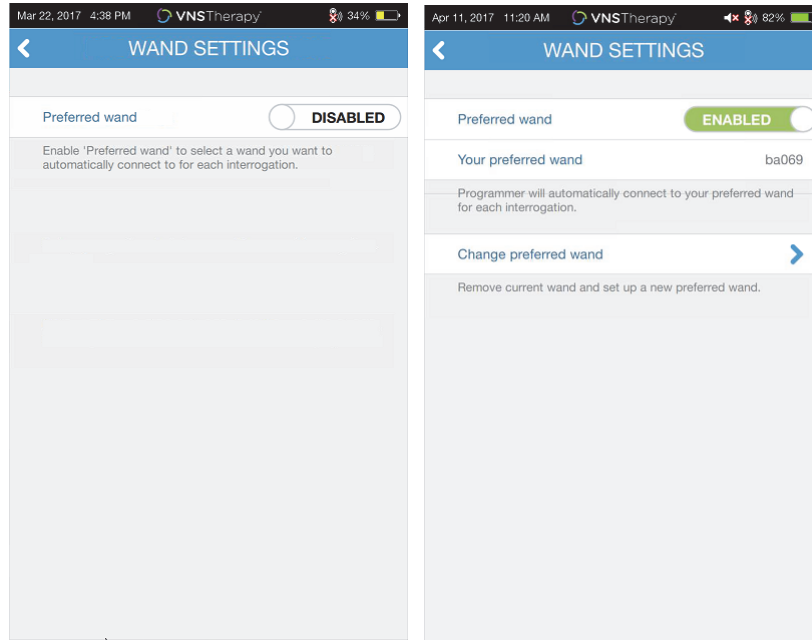
14.3.2.   Check Wand Firmware (Model 3000 v1.6 only)

Select this option to connect to a Wand and check its firmware version.

> **ⓘ** **Note**: If an update is needed see "Programming System Updates" for more details.

14.4.   Guided Programming Options

The Therapy Protocols selection is used to set up custom protocols. Instructions are provided in "Custom Therapy Protocols (Model 1000/1000-D)".

The Start in Guided Mode option allows you to automatically start in Guided Mode for all Models 102-106 and 8103generators when normal mode output is less than 1.75mA. The Model 1000/1000-D retains and starts in the last mode programmed.

Maximum number of scheduled steps is a setting that can be used to restrict the number of therapy protocol steps than can be automated using scheduled programming. See "Scheduled Programming" for more details.

14.5.   Programming System Updates

LivaNova will provide Programming System updates as needed.

> **ⓘ** **Note**: The Programmer is not connected to the internet and does not search for updates.

14.5.1.   Wand Updates

Wand update files are available on Programmers with v1.6 Software. Follow on screen instructions to complete the Wand update. A Wand USB Cable (Figure 1) is needed to complete the Wand firmware update. If you need assistance with the Wand update, contact Technical Support.

15. TROUBLESHOOTING

This section provides solution steps to resolve error conditions with the programming system components or with the implanted generator and lead. For other programming system issues not included in this section, contact Technical Support.

15.1. Anomalous Behavior or Non-responsive System

If your systems displays anomalous behavior or becomes non-responsive, follow the solution steps in Figure 45.

Figure 45.   Solution Steps for Anomalous Behavior or a Non-responsive System
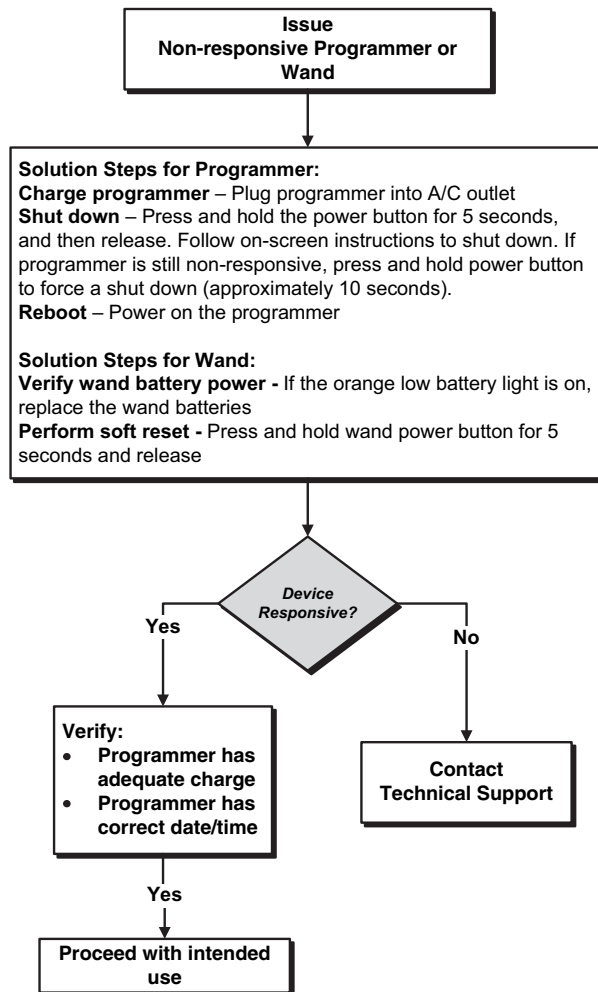
15.2. Communication Issues

15.2.1. Wand Not Connecting to Programmer (Wireless)

Potential reasons for no wireless connection between the Wand and the Programmer include the following:

- Wand not powered on
- Depleted Wand batteries
- Electromagnetic interference (EMI), such as OR lights
- Defective Wand or Programmer

See Figure 46 for solution steps to resolve problems between the Wand and Programmer via wireless connection.

**Figure 46.   Solution Steps For Wand Not Connecting to Programmer (Wireless)**
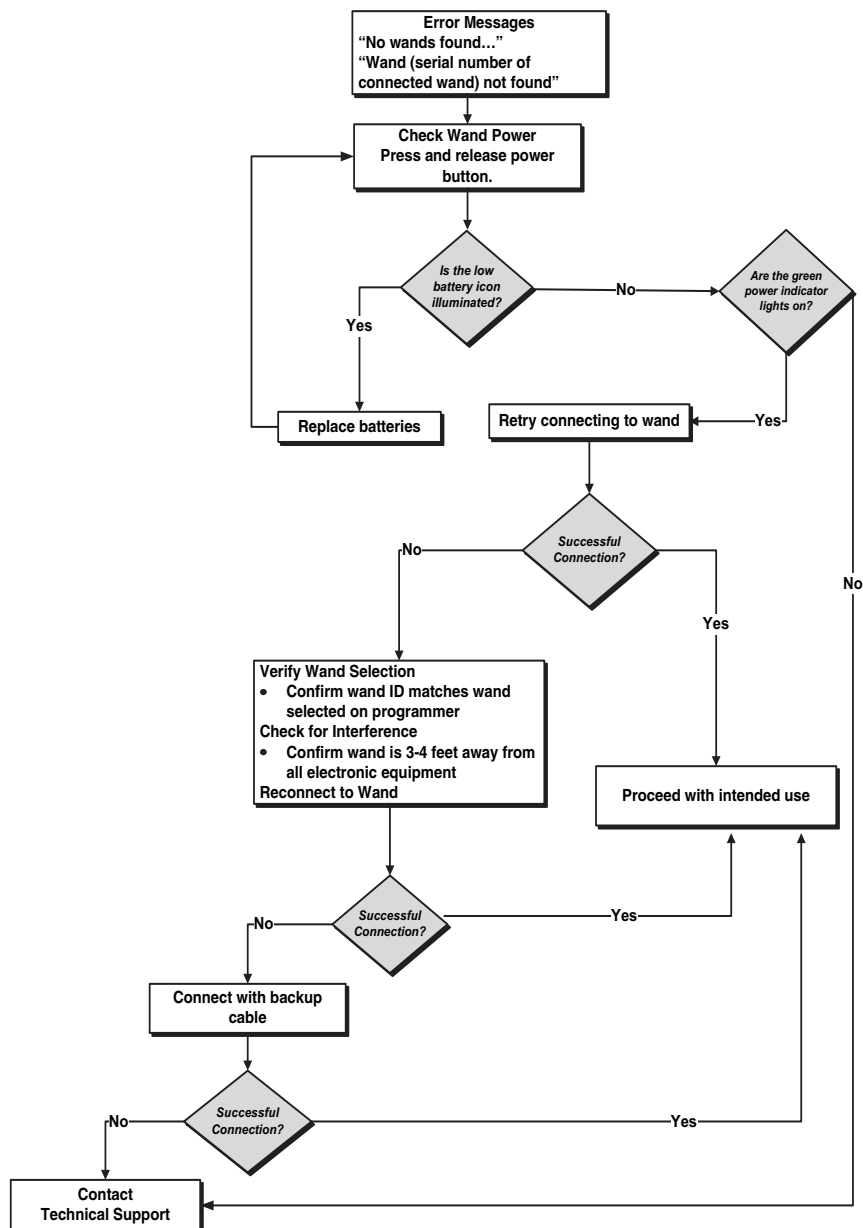
15.2.2.   Wand Not Connecting to Programmer (Backup Cable)

Potential reasons for no connection between the Wand and the Programmer via backup cable include the following:

- Improper cable connection between Wand and Programmer
- Depleted Wand batteries
- Improper USB port recognition of the Programmer cable
- Defective Wand or Programmer

See Figure 47 for solution steps to resolve problems between the Wand and Programmer via backup cable connection.

**Figure 47.   Solution Steps for Wand Not Connecting to Programmer (Backup Cable)**
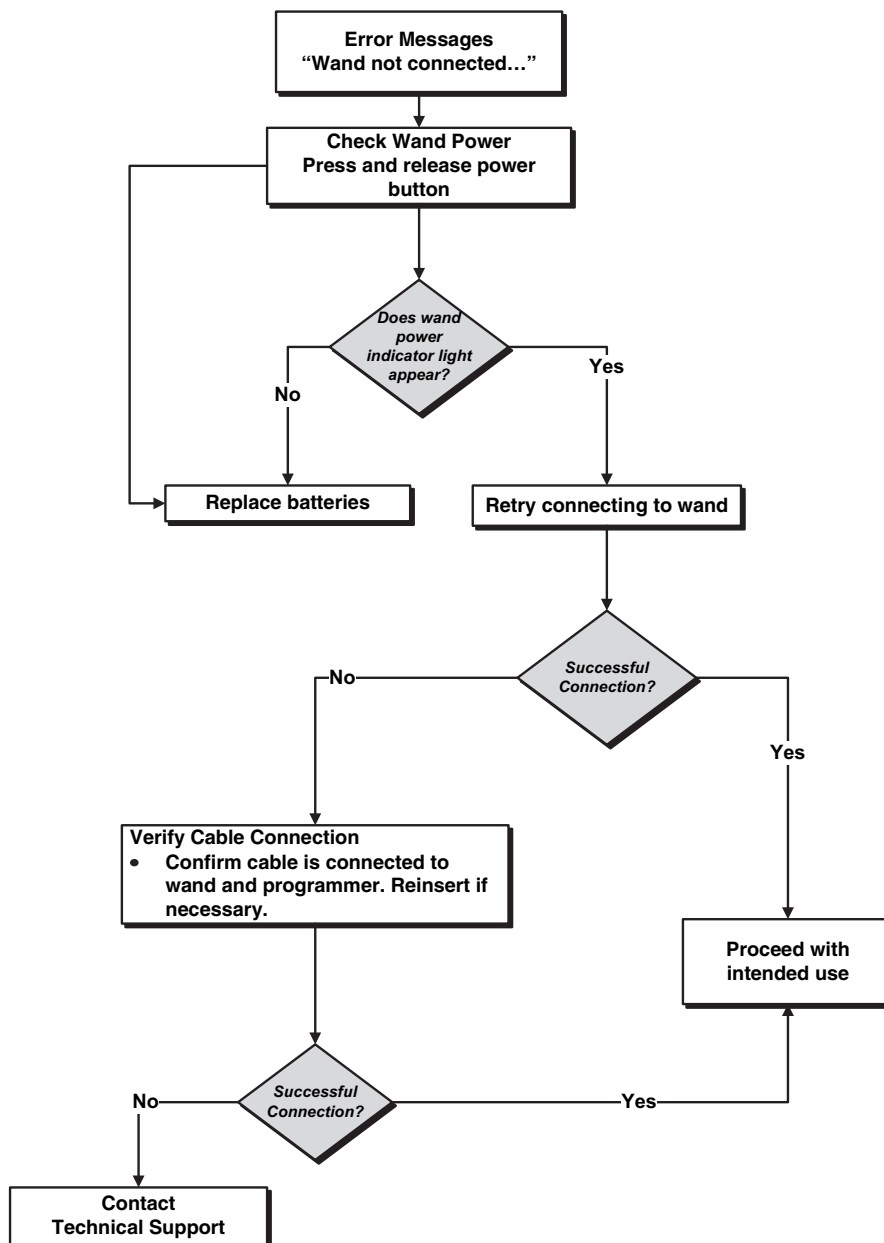
15.2.3. Wand Not Communicating with Generator

Potential causes for communication issues between the Wand and generator include the following:

- Depleted Wand batteries
- Moving Wand away from generator during communication
- Electromagnetic interference (EMI), such as OR lights
- Generator battery at End of Service (EOS)
- Magnet placed over generator (Model 1000/1000-D)
- Defective Wand, Programmer, or generator

See Figure 48 for solution steps to resolve communication problems between the Wand and generator.

Figure 48.   Solution Steps for Wand Not Communicating with Generator
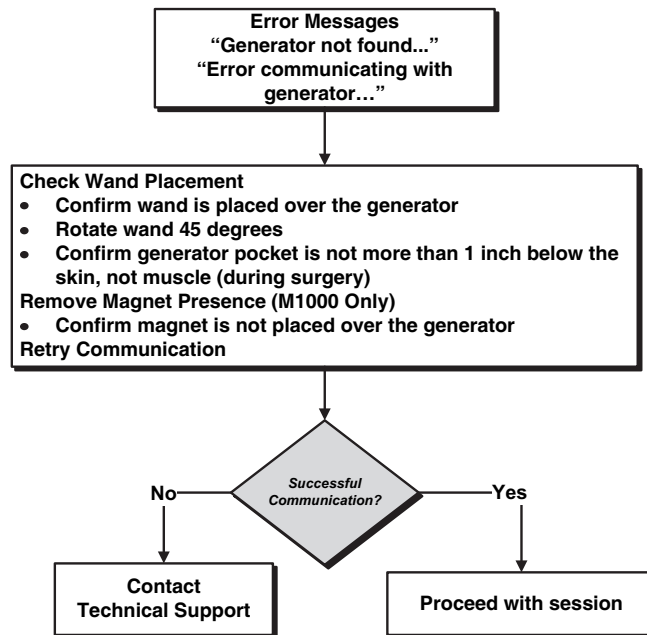
15.3. High/Low Lead Impedance and Low Output Current Issues

15.3.1. High Lead Impedance in the OR

If a system diagnostics test results in high lead impedance, the following are possible causes:

■ Improper connection between the lead and the generator

■ Incorrect placement of lead on the nerve (initial implant only)

■ Allowing nerve to become dry (initial implant only)

■ Defective lead or generator

See Figure 49 for solution steps.

Figure 49. Solution Steps for High Lead Impedance in OR
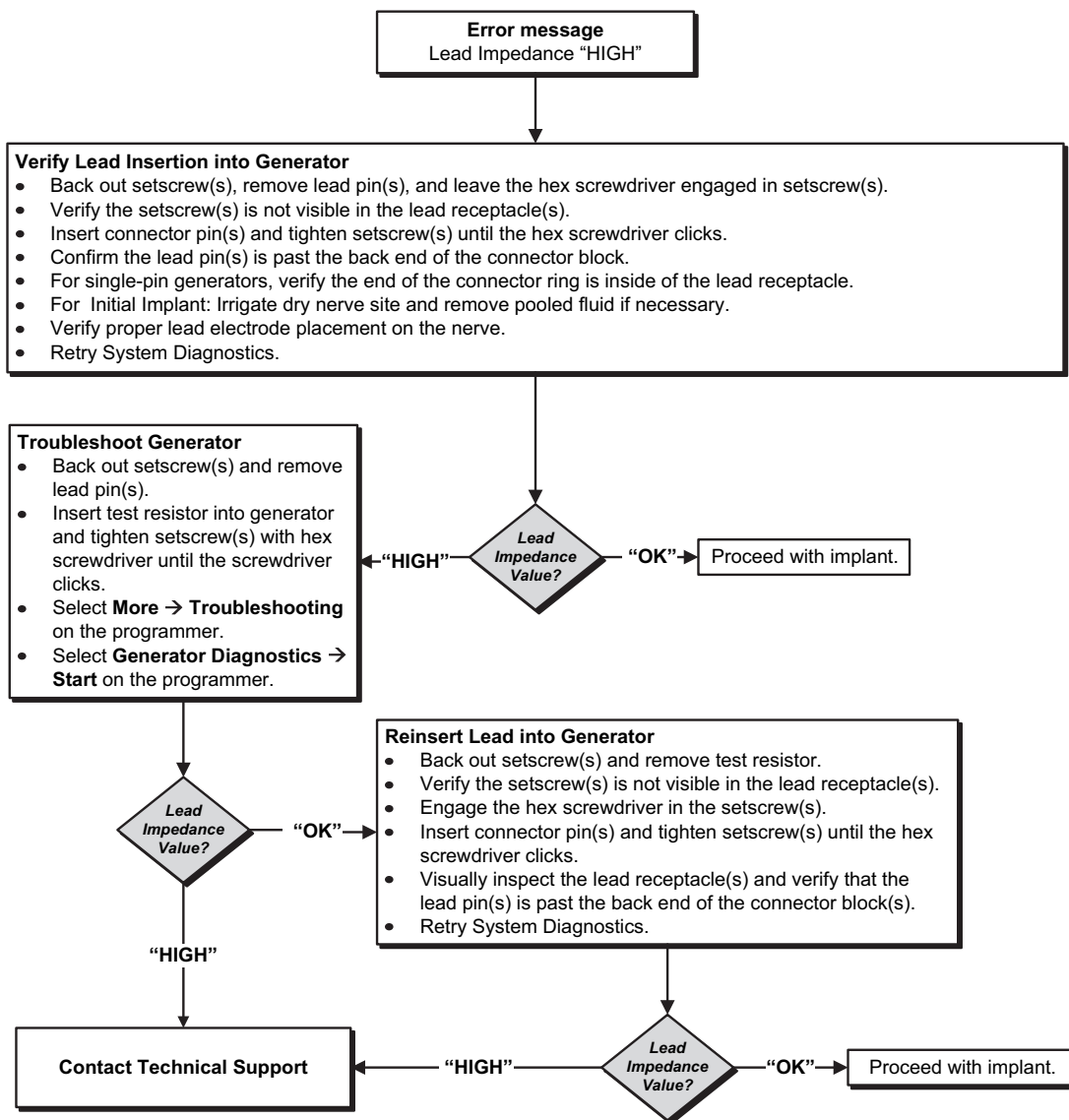
15.3.2.   Low Lead Impedance in OR

If a system diagnostics test results in low lead impedance, the following are possible causes:

■   Incorrect placement of the lead on the nerve

■   Excessive irrigation of the nerve

■   Defective generator or lead

■   Short-circuit condition within the lead (during generator replacement surgery)

See Figure 50 for solution steps.

Figure 50.   Solution Steps for Low Lead Impedance in OR
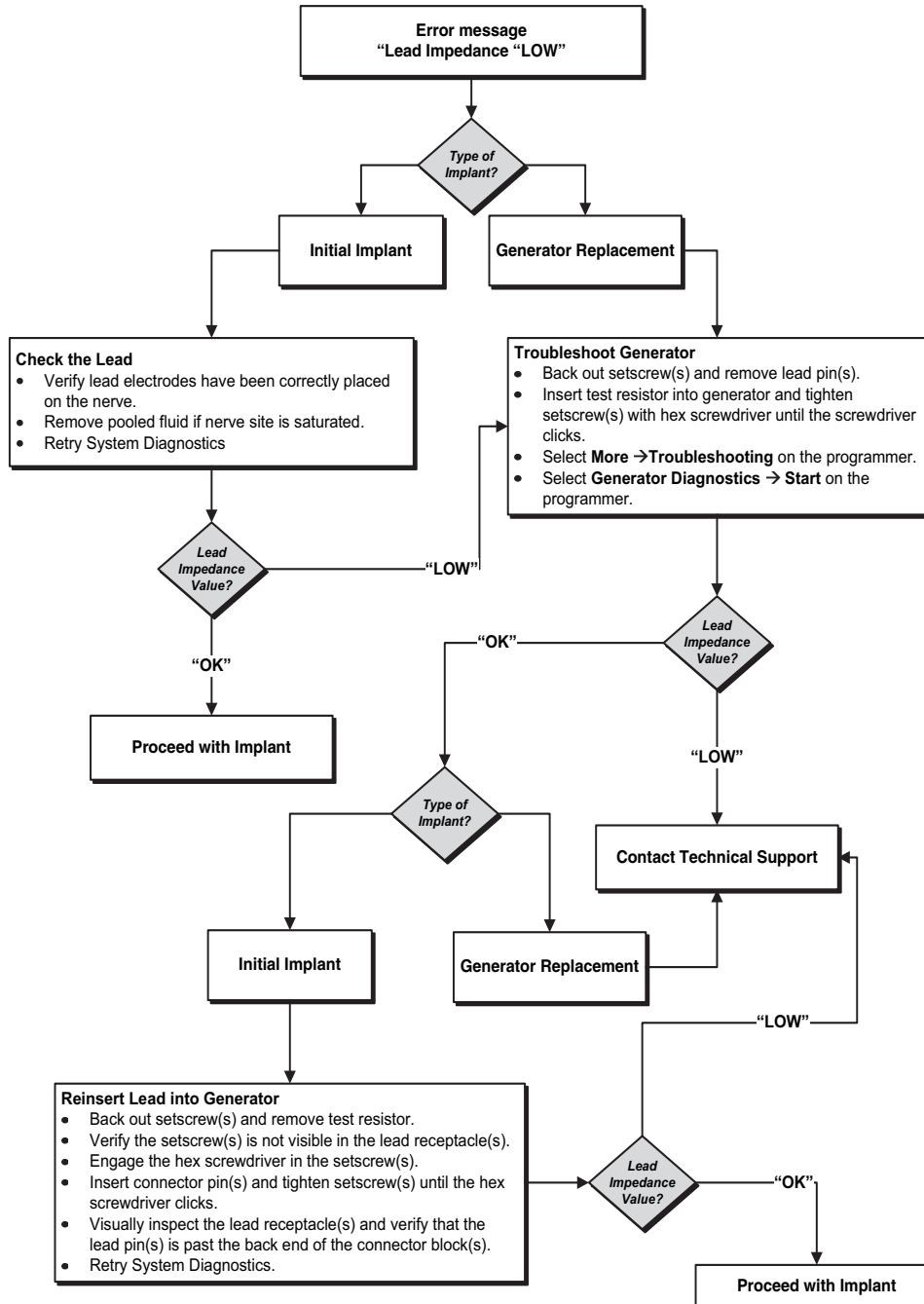
15.3.3.   High Lead Impedance at Follow-up Visits (Model 102)

Possible causes for high lead impedance at follow-up visits for the Model 102 generator include the following:

- Lead discontinuity
- Lead disconnected from generator
- Fibrosis between nerve and electrode
- Electrode detachment from nerve
- Defective generator
- High battery impedance, generator approaching EOS

See Figure 51 for solution steps.

Figure 51.   Solution Steps for High Lead Impedance at Follow-up Visits (Model 102)
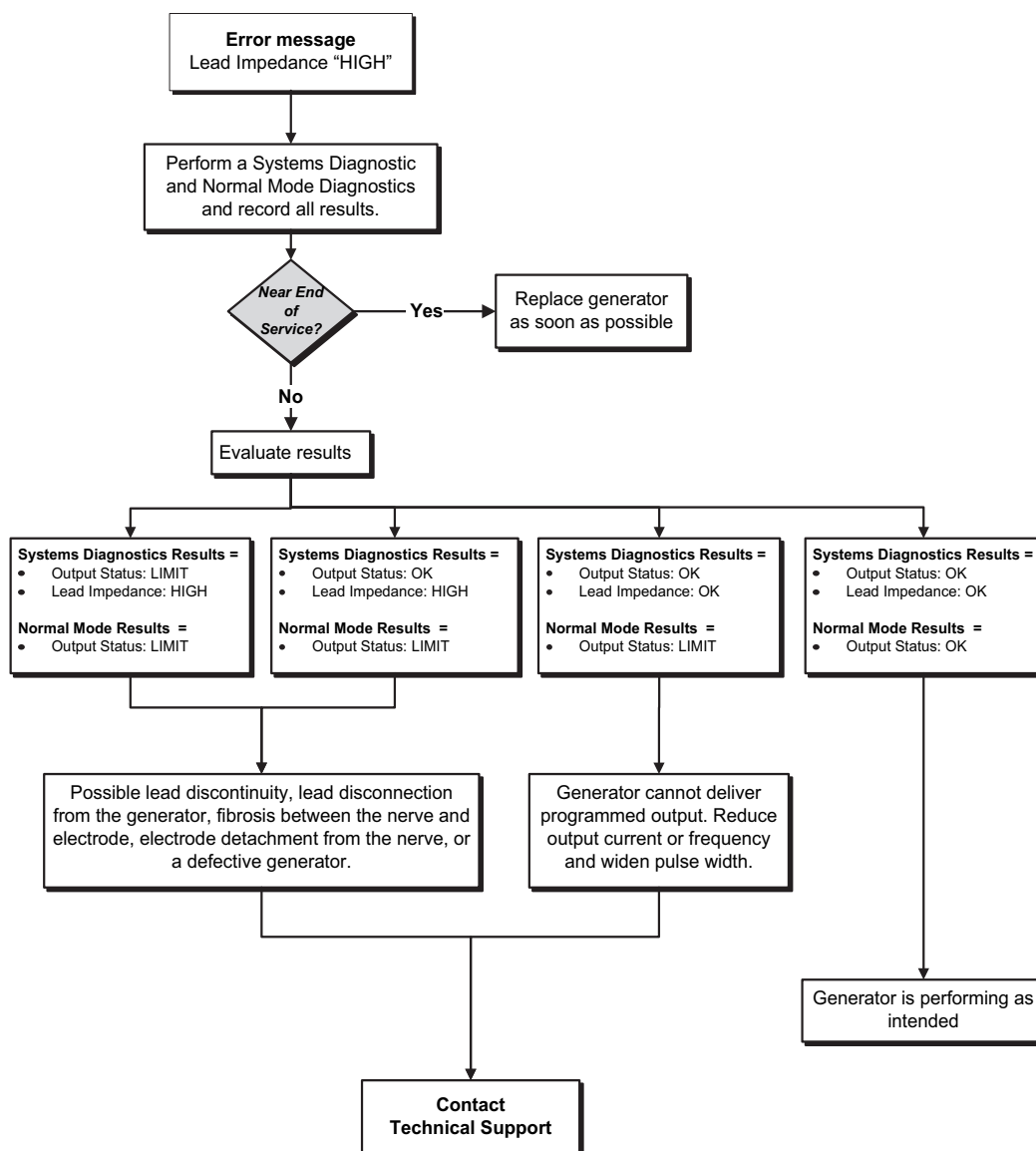
15.3.4. High/Low Lead Impedance or Low Output Current at Follow-up Visit (Models 103-106, 8103 and 1000/1000-D)

Possible causes for high or low lead impedance or low output current at follow-up visits for Models 103-106, 8103 and 1000/1000-D generators include the following:

- Lead discontinuity
- Lead disconnected from generator
- Fibrosis between nerve and electrode
- Electrode detachment from nerve
- Defective generator
- Short-circuit condition within the lead

See Figure 52 for solution steps.

Figure 52.   Solution Steps for High/Low Lead Impedance or Low Output Current at Follow-up Visit (Models 103-106, 8103 and 1000/1000-D)
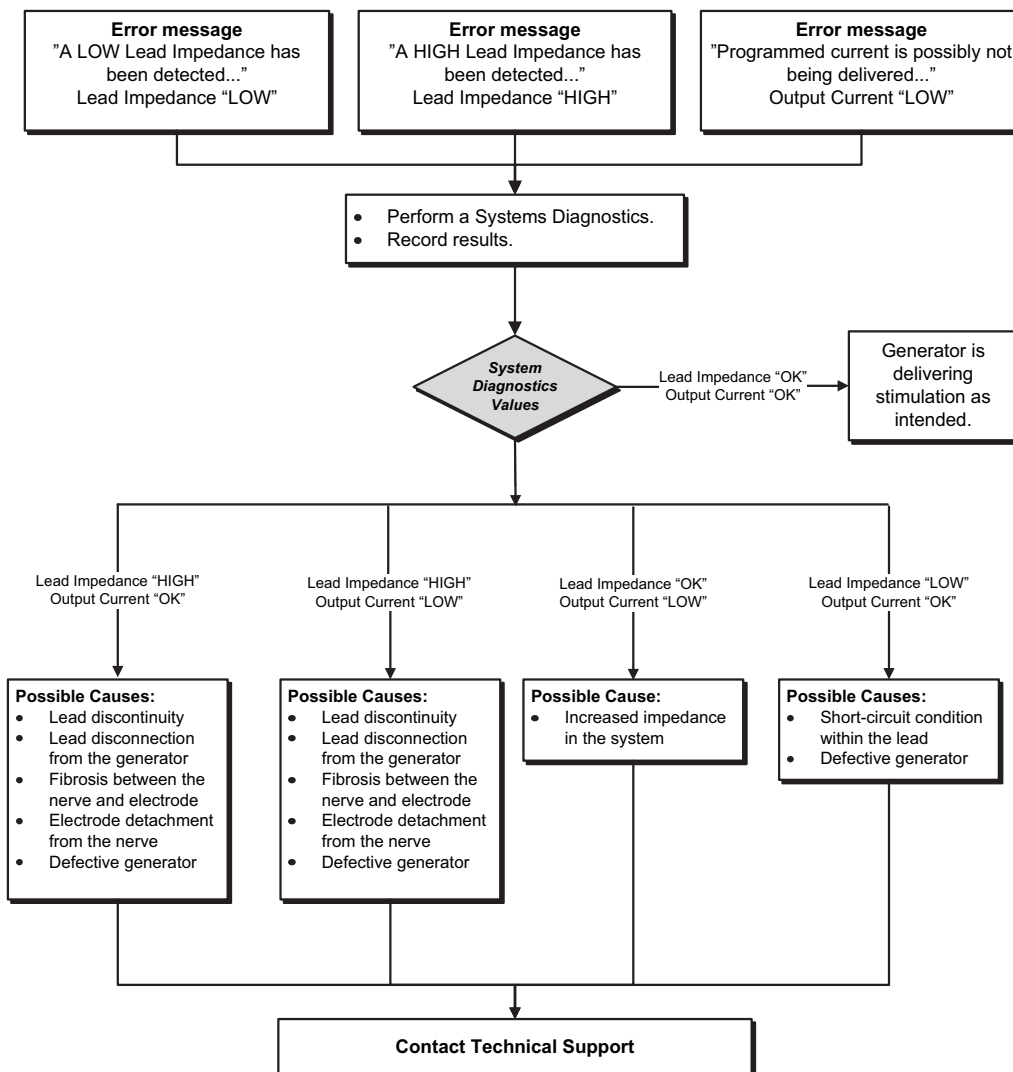
15.4.   Generator Battery Issues

15.4.1.   Low Battery/End of Service Indications in OR

If a generator displays a low battery or End of Service (EOS) indicator while implanting, the possible causes include the following:

Prior to Surgery:

- Generator has been recently exposed to low storage temperatures
- Defective generator

During Surgery:

- Electrosurgical equipment used near the generator
- Generator exposed to electrostatic discharge (ESD)

See Figure 53 for solution steps.

Figure 53.   Solution Steps for Low Battery/End of Service Indications in OR
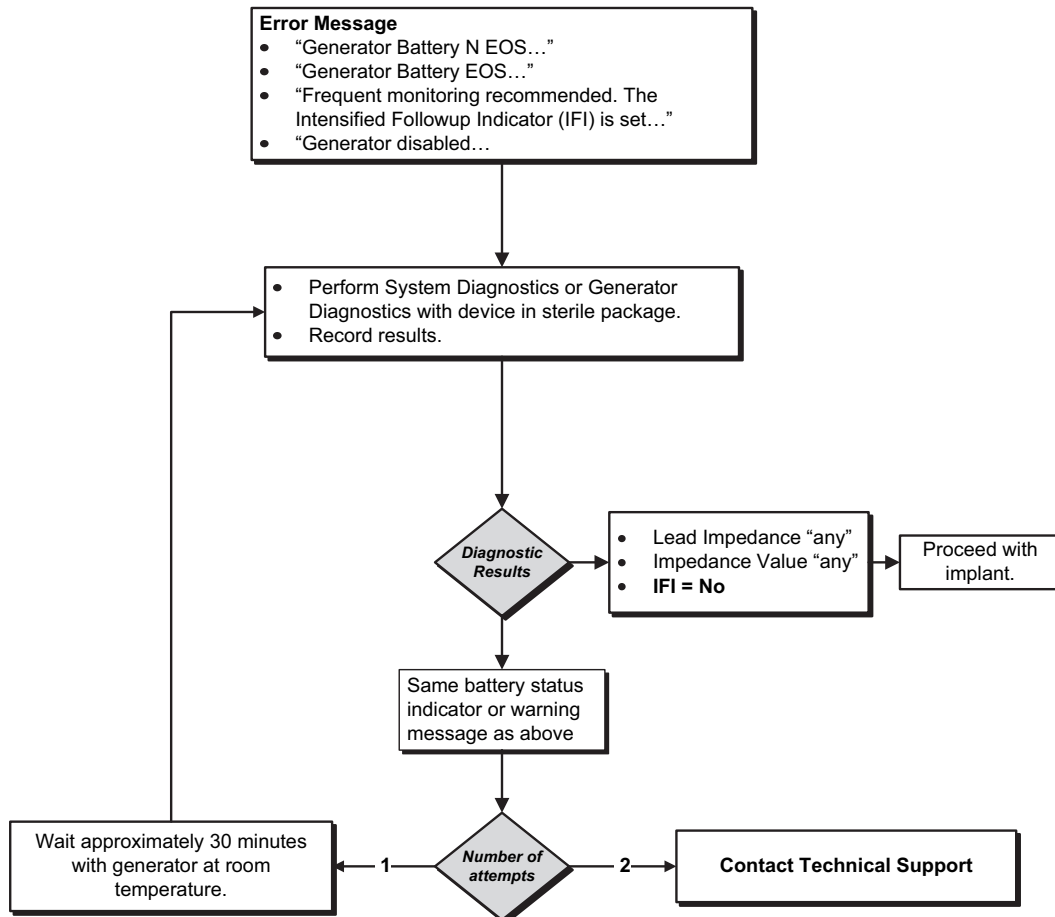
15.4.2. New Generator Disabled Due to EOS at First Office Visit

Generator Models 103-106, 8103 and 1000/1000-D batteries can temporarily drain and become disabled if exposed to certain conditions. These conditions include the following:

- Electrosurgical equipment used near the generator
- Generator exposed to electrostatic discharge (ESD)

See Figure 54 for solution steps.

Figure 54.   New Generator Disabled Due to EOS at First Office Visit
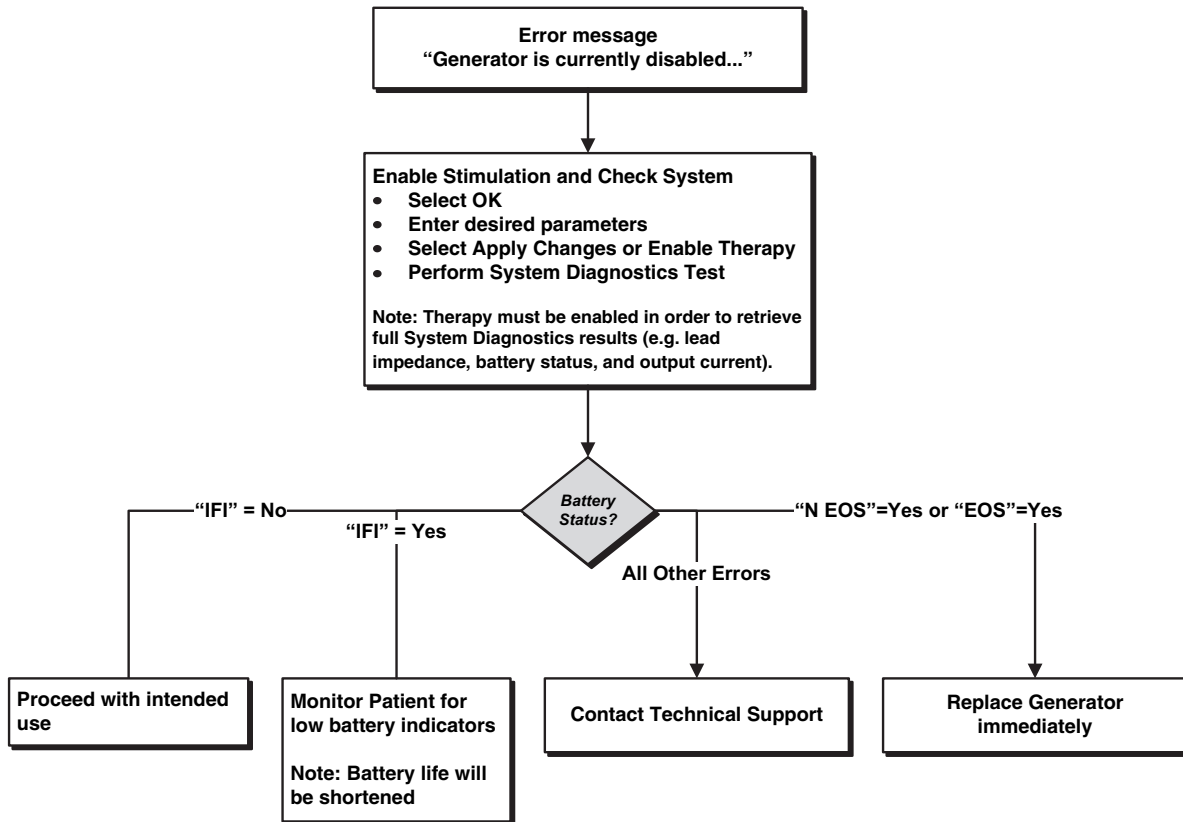
15.4.3. Sudden Decrease In Remaining Battery Power

If the remaining generator battery power suddenly decreases at an office visit, the following are possible causes:

- First visit after VNS or other surgery: exposure to specific conditions in the OR (see Low Battery/End of Service Indications in OR) during surgery. If this condition occurred and was not detected in the OR, it is possible you may detect this at the follow up visit. Device will still function normally, but will have decreased battery life. Monitor the patient closely for any low battery indicators.
- Significant change in the lead impedance or increase in programmed stimulation parameters can also result in a change in the estimated battery power remaining. Evaluate battery power remaining between consecutive patient visits before adjusting stimulation parameters. Review lead impedance for any significant changes.

If any device issue is suspected, contact Technical Support.

15.5.   Heartbeat Detection Issues (Models 106 and 1000/1000-D)

ⓘ **Note**: Heartbeat Detection is only intended for use in epilepsy patients.

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

The heartbeat detection setting may need to be adjusted to accurately detect heartbeats. See Figure 55 for solution steps to correct an over/under detection reading.

ⓘ **Note**: The Wand must be held over the generator during the entire Verify Heartbeat Detection process.

Figure 55.   Solution Steps for Heartbeat Detection Inaccurate in OR or at Follow-up Visit (Models 106 and 1000/1000-D)
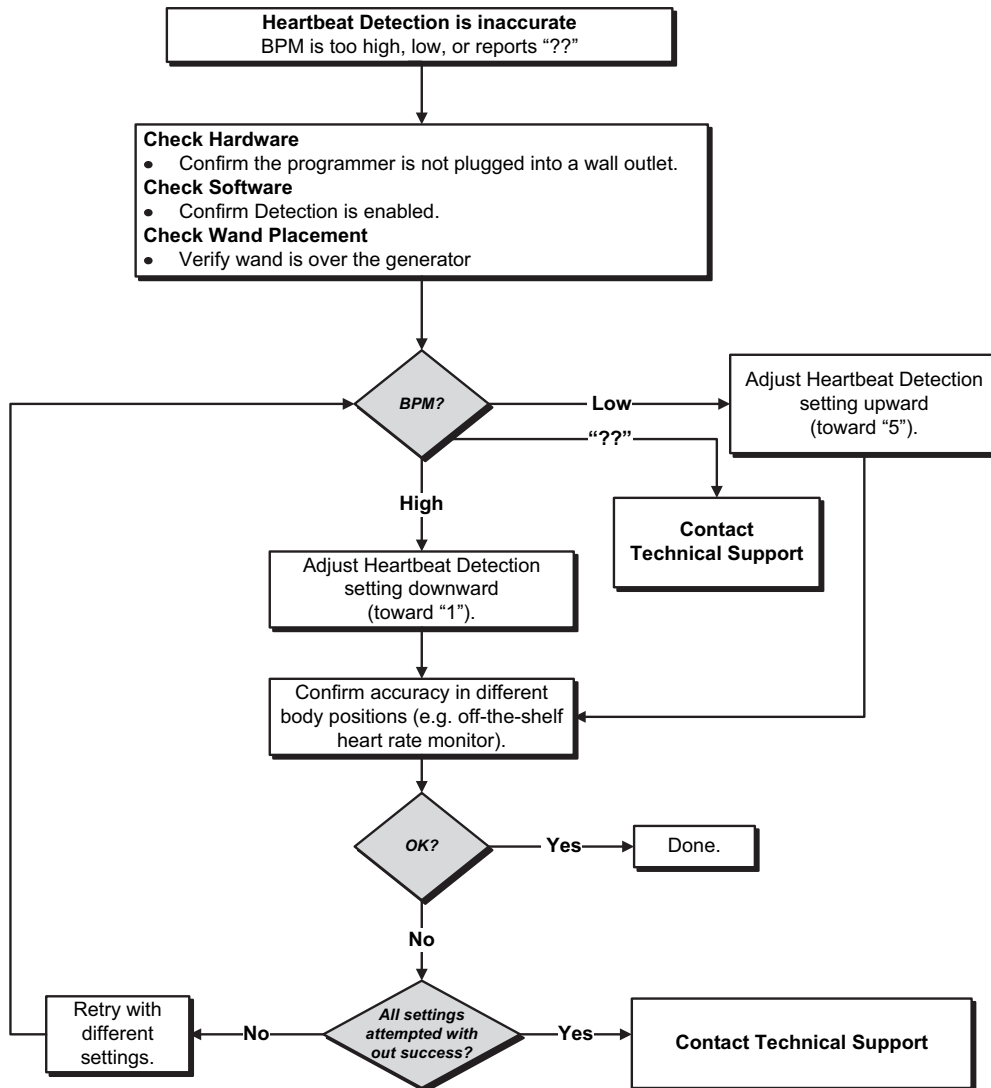
15.6.   Seizure Detection Issues (Models 106 and 1000/1000-D)

**ⓘ** **Note**: Seizure Detection is only intended for use in Epilepsy patients.

15.6.1.   Inaccurate AutoStims at Follow-up Visit for Generator Models 106 and 1000/1000-D

Sometimes generator detection settings may miss detecting heart rate changes that may be associated with a seizure. The following conditions may be potential causes:

- **Duty cycle** - Because the generator can only detect events during OFF time, the OFF time affects accuracy. Shorter OFF time means less chance for the generator to detect events. Longer OFF time, on the other hand, means more chance for the generator to detect events.

- **Heart rate changes** - Exercise, physical activity, and normal sleep can increase the heart rate and cause the generator to falsely declare an event.

See Figure 56 for solution steps.

Figure 56.   Solution Steps for Inaccurate Detection at Follow-up Visit (Models 106 and 1000/1000-D)
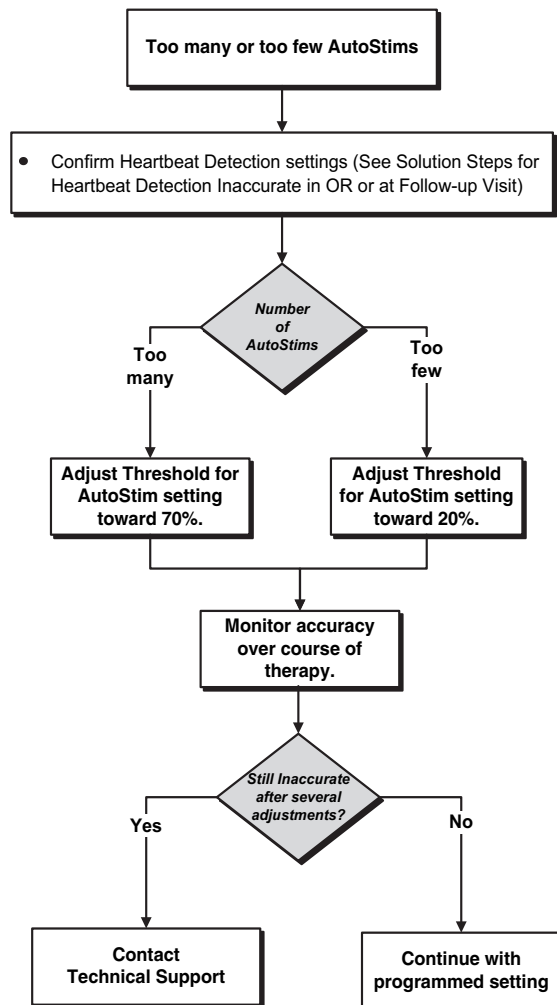
16. GENERATOR RESET

To reset the generator, you will need the programming system and a LivaNova Magnet. Contact Technical Support for assistance.

17. MAINTENANCE, HANDLING, AND DISPOSAL

Follow guidelines below for proper handling and storage for the programming system.

■   To clean external surfaces of the Programming System components, wipe with pre-moistened or damp cloth using one of the following cleaners: isopropyl alcohol (70-90%), ethanol, or CaviCide®.

■   Do not sterilize any parts of the system.

■   Regularly inspect the system parts for damage. Return any damaged parts to LivaNova.

■   Do not operate the system near water or other fluids. Do not immerse any components in liquids.

17.1.   The Programmer

■   Debris can damage the Programmer touchscreen display. Wipe with a soft cloth, using approved cleaners. Be sure to power off computer and disconnect AC adapter from electrical outlet before cleaning.

■   For information on operating and storage conditions, see Table 7.

17.2.   The Wand

■   Check the Wand battery periodically to verify battery status.

⚠️   **Warning**: Risk of Fire. Battery can explode or leak and cause injury if installed backwards, disassembled, charged, crushed, mixed with used or other battery types, or exposed to fire or high temperature. Dispose of used batteries promptly.

■   Remove (and install) the battery only when the Wand is not in contact with the patient and not connected to the Programmer

■   Never connect the Programming Wand to external equipment while the battery compartment is open.

■   For information on operating and storage conditions, see "Programming System Specifications and Guidance".

17.3.   Disposal

When replacing the Wand AA batteries, dispose the used batteries in accordance with all applicable federal, state, and local regulations. Return the programming system hardware to LivaNova for examination and safe disposal.

18. PROGRAMMING SYSTEM SPECIFICATIONS AND GUIDANCE

18.1. Wand and Programmer Specification

Table 7 provides a complete list of Wand and Programmer hardware specifications.

Table 7.   Programming System Specification

	Wand	**Programmer**
Storage Conditions		
Temperature	-20 °C to +55 °C	-20 °C to +55 °C
Relative Humidity	Up to 95%, including condensation	10% to 90%, non-condensing
Operation Conditions		
Temperature	+15 °C to +40 °C	+15 °C to +35 °C
Relative Humidity	15% to 93%, non-condensing	10% to 90%, non-condensing
Communication Distance between Wand and Programmer	From 0 to 3 Meters	
Power Source	Internally powered: 2 Alkaline AA Batteries (IEC LR6) or 2 Lithium AA Batteries (IEC FR6)	Operating: internally powered Recharge: Class II
Transmitter Power	Inductive: 1.5 dBm and -0.5 dBm *Bluetooth*® 2.1: 10.4 dBm	
Transmitter Operating Frequency	Inductive: 82 kHz 89 kHz (102 only) *Bluetooth*® 2.1:2402 - 2480 MHz	
Receiver Bandwidth	Inductive: 12.5 to 135 kHz *Bluetooth*® 2.1: 2402 - 2480 MHz	
Cables	USB Type C backup cable (2.87 m)	
Applied Part	Entire device is Type BF	N/A

18.2. Electromagnetic Emissions Guidance for Wand

The Wand is intended to be used in the electromagnetic conditions specified in tTable 8, Table 9 and Table 10.

Table 8.   Electromagnetic Emissions

Emissions Test	**Compliance Level**
RF Emissions CISPR 11	Group 1, Class A
Note: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	

Table 9.   Electromagnetic Immunity

Immunity Test	Compliance Level
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 8 kV contact discharge +/-15 kV air discharge
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 & 60 Hz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz
Conducted RF - SIP/SOP IEC 61000-4-6	3 V, 0.15 MHz - 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

Table 10.   Electromagnetic Immunity to Proximity Fields from RF Wireless Communications Equipment

Test Frequency	Service	Compliance Level
385	TETRA 400	27 V/m
450	GMRS 460, FRS 460	28 V/m
710	LTE Band 13, 17	9 V/m
745		
780		
810	GSM 800/900 TETRA 800, IDEN 820, CDMA 850, LTE Band 5	28 V/m
870		
930		
1720	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,4,25, UMTS	28 V/m
1845		
1970		
2450	*Bluetooth*® 2.1, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28 V/m
5240	WLAN 802.11 a/n	9 V/m
5500		
5785		

19. WIRELESS SECURITY

Table 11 provides wireless security information.

Table 11.   Wireless Security Information

Technology	Inductive Coil Telemetry	Radio Frequency
Quality of Service	Requires near field (within 1 inch) communication with the Programming Wand.	There is no degradation in wireless telemetry performance when the bit error rate is less than or equal to 0.1%. The distance between the Programmer and the Wand must be less than 10 feet.
Security	Coil communication requires close proximity and patient acceptance.	To pair the *Bluetooth®* Wand with the Programmer, the user must press the Wand power button and select the Wand identifier (printed on Wand) from the Programmer screen. After pairing, the Wand creates a unique session ID that is sent to the external device using application commands. The session will refresh with each new connection. The *Bluetooth®* security will authenticate and encrypt each session.
FCC Regulation	47 CFR 15.209	47 CFR Part 15.247

20. CONTACT INFORMATION AND SUPPORT

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

Manufacturer

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

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

EC REP Authorized Representative Europe

LivaNova Belgium NV
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1930 Zaventem Belgium
BELGIUM

Tel: +32 2 720 95 93
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Report all adverse events related to the device to LivaNova and to your local regulatory authority.

24-hour Clinical and Technical Support
Tel: +1 (866) 882-8804 (US and Canada)
          +1 (281) 228-7330 (Worldwide)
          +32 2 790 27 73 (Europe/EMMEA)

Internet
www.livanova.com

Australia - https://www.tga.gov.au/

Canada - https://www.canada.ca/en/health-canada.html

UK - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

EU - https://ec.europa.eu/growth/sectors/medical-devices/contacts_en