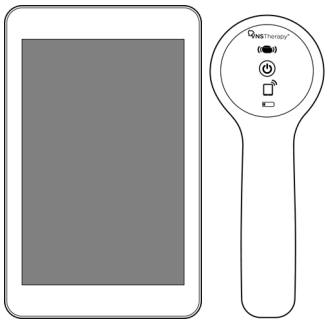
VNS Therapy™

PHYSICIAN'S MANUAL

VNS Therapy™ Programming System



Model 3000 Version 1.0 / 1.5 / 1.6

Model 2000

September 2022

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CHAPTER 1

Description and Use

NOTE: For a list of symbols and glossary terms used with the VNS Therapy system, see www.livanova.com.

This topic includes the following concepts:

1.1. What's New

The latest release of the LivaNova® VNS Therapy™ programming system consists of the following:

- VNS Therapy Programmer, Model 3000 version 1.6
- Programming Wand, Model 2000 version 1.1

If you have a Wand with firmware below v 1.1, it must be updated to v 1.1 firmware for use with the Model 3000 v 1.6 Programmer (see "Programmer Model 3000 and Wand Model 2000 Compatibility " on page 12). Wand firmware update files are included on the Model 3000 v 1.6 Programmer. A Wand USB Cable (See "Brief Description" on the next page) is needed to complete the Wand firmware update to v 1.1.

NOTE: Refer to "Check Wand Firmware (Model 3000 v1.6 only)" on page 26 for instructions on how to check the Wand firmware version.

The latest update includes the following:

Update	
Additional ability to interrogate and program the Model 8103 Symmetry™ Generator and Model 1000-D SenTiva Duo™ Generators (where available).	
Issues Resolved	
Software issues observed in previous versions of the Model 3000 Software and corrected in Model 3000 v 1.6.	Wand connection to the Programmer was unnecessarily prolonged after it was identified to be incompatible with Programmer over Bluetooth®.
	Incorrect information was populated in "Last Performed on" field of Session Reports in certain situations.
	User can receive a false high impedance warning messages on a Model 3000 v 1.5 Programmer when performing system diagnostics on Model 102/ Model 102R devices with output current > 0 mA.

Behavior Differences	
Model 3000 v 1.6 software behavior differences compared to previous software versions.	When a generator is disabled, software shows “Device Disabled” and original settings instead of 0 mA 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. Brief Description

The VNS Therapy programming system provided by LivaNova includes a programming computer with Model 3000 version 1.0 / 1.5 / 1.6 software, and a Model 2000 programming wand ("Wand").

The system allows you to perform the following:

- Interrogate and adjust therapy parameters for the generator
- Assess generator and lead function
- View device histories
- Export session reports

1.3. Compatibility

The programming system allows you to interrogate and program the following compatible VNS Therapy generators:

Table 1. Compatible Generator Models

Single Receptacle	Dual-Receptical
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)	

The table below provides a description of compatibility between Programmer and Wand versions.

Table 2. Programmer Model 3000 and Wand Model 2000 Compatibility

	Model 2000 v1.0.3	Model 2000 v1.0.4	Model 2000 v1.1.1
Model 3000 v1.0.2	Yes	No	No
Model 3000 v1.5.2	Yes	Yes	No
Model 3000 v1.6+	No	No	Yes

1.4. Intended Use

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

1.5. System Communication

The Wand and the Programmer connect wirelessly.

1.5.1. Programmer Communications

The Programmer will indicate communication in the following ways:

- Audible tones for a successful interrogation, diagnostics, or applied changes
- Screen messages for successful, failed, or suggested operation

1.5.2. Wand Communications

The Wand indicator lights will illuminate when the Wand is in the following situations:

- Powered on (two green lights below power button)
- Connected to the Programmer (four green lights around the power button)
- Communicates with the generator (white flashing generator icon)
- Battery is low (orange battery indicator)
- Wand (1.1+) is updating (green lights rotate around the power button)

1.5.3. Communication Distance

Table 3. Communication Distance

System	Communication Distance
Wand and Programmer	The wireless connection operates 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.
Wand and Generator	1 inch or less

CHAPTER 2

Warnings and Precautions

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

This topic includes the following concepts:

2.1. ⚠ Warnings

Follow these warnings for optimal performance and safety.

Unapproved Equipment

Do not connect unapproved equipment. This can damage the system and/or cause injury.

Do Not Modify

Do not modify the system unless directed by LivaNova.

Use of Unauthorized Accessories

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.

Proximity to Other Equipment

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 ensure normal operation.

Proximity to Portable RF Communications Equipment

Portable RF communications equipment (e.g., antenna cables, external antennas) should not be used within 30 cm (12 inches) of any part of the Wand or cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Safeguard Against Theft and Unauthorized Connections

Safeguard the programming system against theft. Theft could lead to malicious activities against the system. Use the system in a controlled area to prevent unauthorized connections.

Anomalous Behavior

Anomalous behavior may occur (e.g., a nearby Wand erroneously connects to a Programmer). If this happens, see "Troubleshooting" on page 93.

MR Unsafe Devices

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

Battery – Risk of Fire

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.

2.2. Precautions ⚠

Follow these precautions for optimal performance and safety.

Do Not Load Other Software

Do not load other software onto the Programmer. This may interfere with the efficiency and function of the pre-installed software.

Use in Patient Environment

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 when it is used in a patient environment.

CHAPTER 3

Get Started

This topic includes the following concepts:

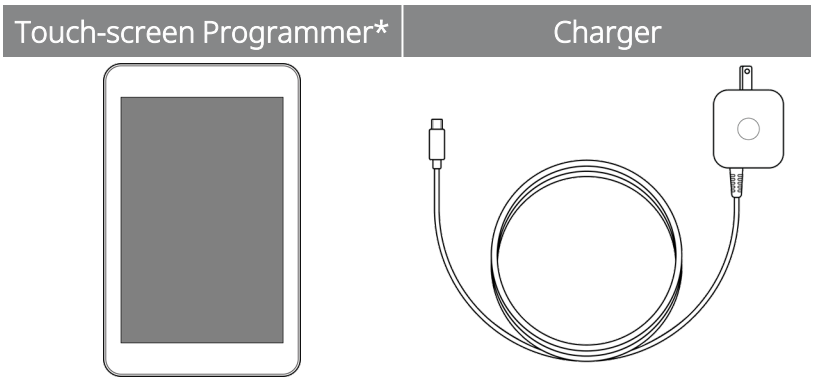
3.1. Programming System Parts

The programming system includes a computer, pre-installed with VNS Therapy programming software ("Programmer"), and a programming wand ("Wand").

NOTE: If parts of the system are missing, contact "Technical Support" on page 120.

3.1.1. Parts Included

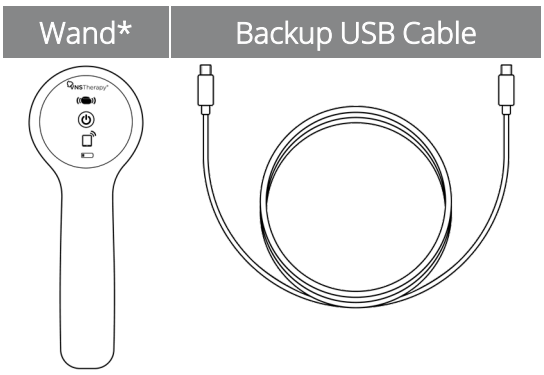
Figure 1. Programmer Parts Included



*With preloaded VNS Therapy Software

NOTE: The Model 201 is not depicted (see the Model 201 Wand Physician's Manual for details).

Figure 2. Wand Parts Included



*2 AA batteries included

3.1.2. Parts Not Included

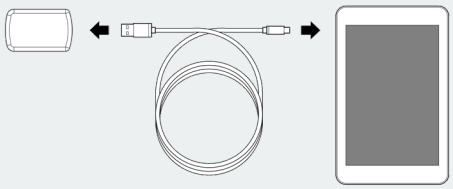
Sterile covers are not included with the system. If the programming system is used in a sterile field, follow aseptic practices. Each part of the programming system is designed to fit inside commonly available sterile covers (e.g. laser / camera arm drapes). It is recommended to use one sterile cover for each part of the programming system.

3.2. Prepare System for Use

Before you use the programming system in a patient session, make sure the Programmer and Wand are fully charged and ready to use. Verify that the date and time on the Programmer are correct.

3.3. Basic Operation

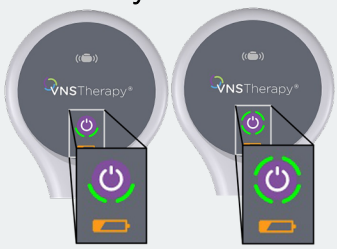
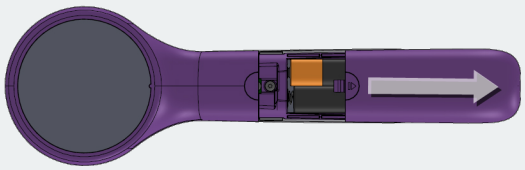
3.3.1. Programmer

Charge the Programmer 	To charge the Programmer, connect it to the charger (on the left) and plug it into an outlet. Charge the Programmer when not in use to ensure sufficient battery power is available for the next patient session. View the battery status icon, located at the top right of the screen, after the Programmer has been powered on.
Turn Programmer ON/OFF 	Turn the Programmer ON — Press and hold the power button for 3 seconds and then release. A few seconds after the power button is released, an on-screen logo displays, followed by automatic start-up of the software. Turn the Programmer OFF — 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 again until the Programmer has completely shut down. Wait for 30 seconds after a shutdown to restart the Programmer.

Turn the Programmer Screen ON/OFF	The screen automatically turns off after 10 minutes of inactivity. You can also quickly press and release the power button to turn the screen on or off. Use this method when you want to preserve battery, but not shut down the Programmer.
Check Programmer Battery	After software start-up is complete, view the Programmer battery status indicator at the top right corner of any screen. For more information, see "How to Use the Software" on page 37.
Set the Programmer Time and Date	Accurate patient and device history stored in the Programmer depends on correct time and date settings. **Access the change date and time screen:** Tap Settings on the bottom navigation bar → Programmer settings →Date and Time. **Change the Time and Date:** Tap the current time and scroll up or down to adjust it. Tap the left or right arrow to adjust the calendar month and year and then tap the desired date. When finished tap **Save Changes**. NOTE: The Programmer does not automatically adjust for Daylight Saving Time or a change in location. Adjust the time and date manually as needed.
Programming System Update	LivaNova will provide programming system updates as needed. NOTE: The Programmer is not connected to the internet and does not search for updates.

3.3.2. Wand

Power On Wand 	Press and release the power button to turn the Wand on. NOTE: Once powered on, the Wand will automatically power down (standby) after 2 minutes of inactivity to conserve battery.
OK Battery Indicator 	If the battery is OK, green lights illuminate.

Low Battery Indicator 	If the battery is low, the low battery indicator illuminates.
No Battery Power Indicator – No Communication 	If only the orange battery icon illuminates, communication will not be possible until you replace the batteries.
Wand Battery Replacement 	If the battery is low, replace the batteries. Remove the cover located on the back of the Wand.

3.4. Connect Wand and Programmer

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

Figure 3. Wand Connected to Programmer

3.4.1. Wireless Wand Connection Options

3.4.1.1. Preferred Wireless Wand

Set up a preferred Wand connection that is always used with the same Programmer. This setup is recommended for a Wand and Programmer that are always used together. It provides a quicker connection, since the Programmer will automatically look for preferred Wand.

NOTE: To setup a preferred Wand, see "Setup Preferred Wireless Wand" on page 25.

NOTE: For details on how to interrogate with a preferred Wand, see "Interrogate (Preferred Wand)" on page 34.

3.4.1.2. No Preferred Wand

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

NOTE: For details on how to interrogate without a preferred Wand, see "Interrogate (No Preferred Wand)" on page 31.

3.4.2. Wired Wand Connection

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.

NOTE: For details on how to interrogate with a wired Wand, see "Interrogate (Wired Wand)" on page 36.

CHAPTER 4

Programmer and Wand Settings

Access Programmer and Wand settings 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. See "Guided Programming" on page 54.

To access programmer settings, tap **Settings** on the navigation bar at the bottom of the Main screen. From the next menu, tap Programmer settings, Wand settings, or Guided Mode options.

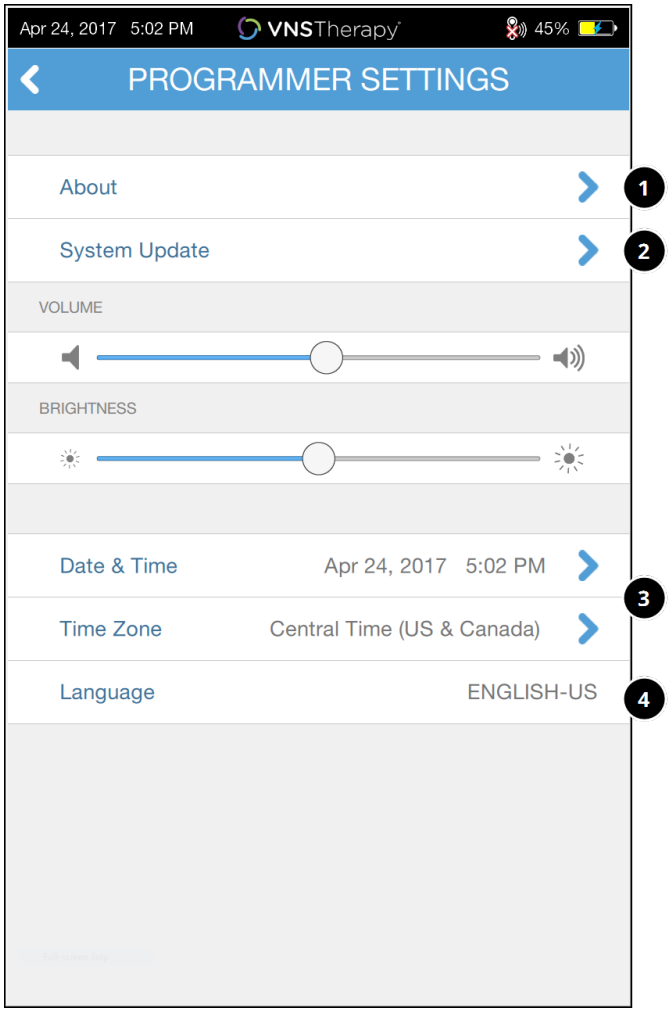
This topic includes the following concepts:

4.1. Programmer Settings

4.1.1. View or modify Programmer Settings

Programmer settings are accessed from the navigation bar while out-of-session.

Figure 4. Programmer Settings Screen



1 Provides details about Programmer serial number, software version, and preferred Wand firmware version.

2 View information on software updates.

3 Access Programmer date, time, and time zone.

4 Change the display language settings.

4.1.2. Programmer Updates

LivaNova provides programming system updates as needed. The Programmer is not connected to the internet and does not search for updates.

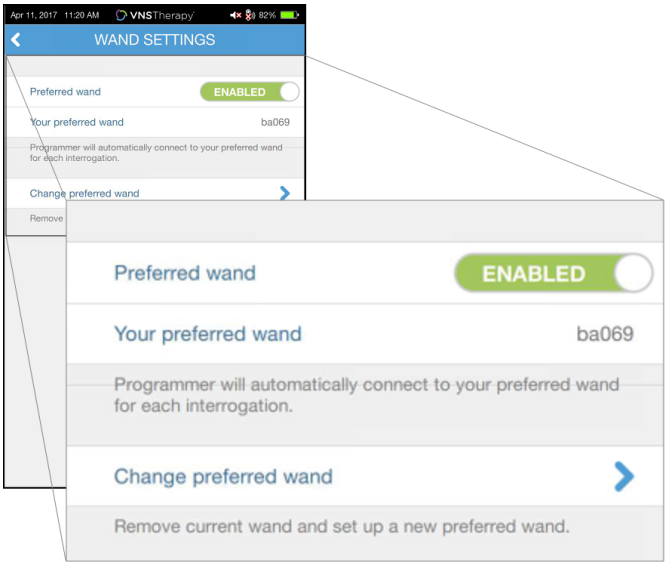
4.2. Wand Settings

4.2.1. Setup Preferred Wireless Wand

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

1. Power on the Programmer.
2. Tap **Settings** from the bottom navigation bar.
3. Power on the Wand.
4. Tap the Wand Settings menu option
5. Toggle the preferred Wand setting from **Disabled** to **Enabled** to automatically connect to this particular Wand during each interrogation.
6. Tap the desired Wand serial number. Once connected, the software will show this serial number as your preferred Wand and provide an option to change that selection.

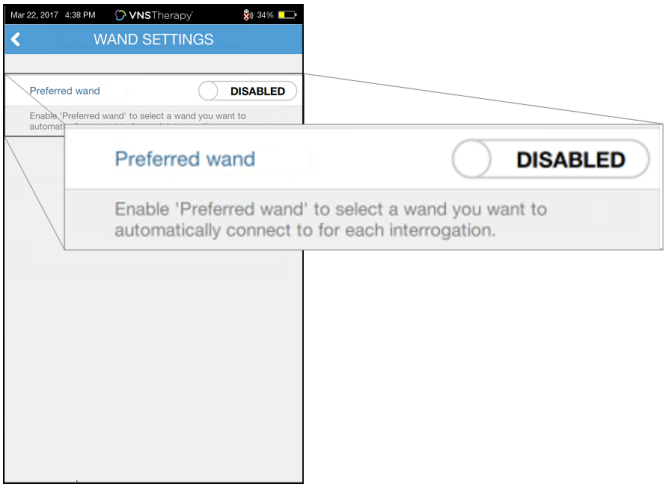
Figure 5. Enable Preferred Wand Settings



4.2.2. Disable Preferred Wireless Wand

To return to manual Wand selection, toggle the setting to **Disabled**.

Figure 6. Disable Preferred Wand



4.2.3. Check Wand Firmware (Model 3000 v1.6 only)

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

4.2.4. Wand Updates

LivaNova provides programming system updates as needed.

Wand update files are available on Programmers with v1.6 Software. Follow on screen instructions to update. Wand USB Cable (Figure 1) is needed to complete the Wand firmware update.

If you need assistance with the Wand update, contact "Technical Support" on page 120.

4.3. Guided Mode Settings

The **Therapy Protocols** selection is used to set up custom protocols. Instructions are provided in "Custom Therapy Protocols" on page 56.

Model 1000 Model 1000-D	Retains and starts in the last mode programmed.

Model 106 Model 105 Model 104 Model 103 Model 8103 Model 102 Model 102R	The **Start in Guided Mode** option allows you to automatically start in Guided Mode when Normal Mode output is less than 1.75 mA.

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" on page 62 for more details.

CHAPTER 5

Interrogate the Generator

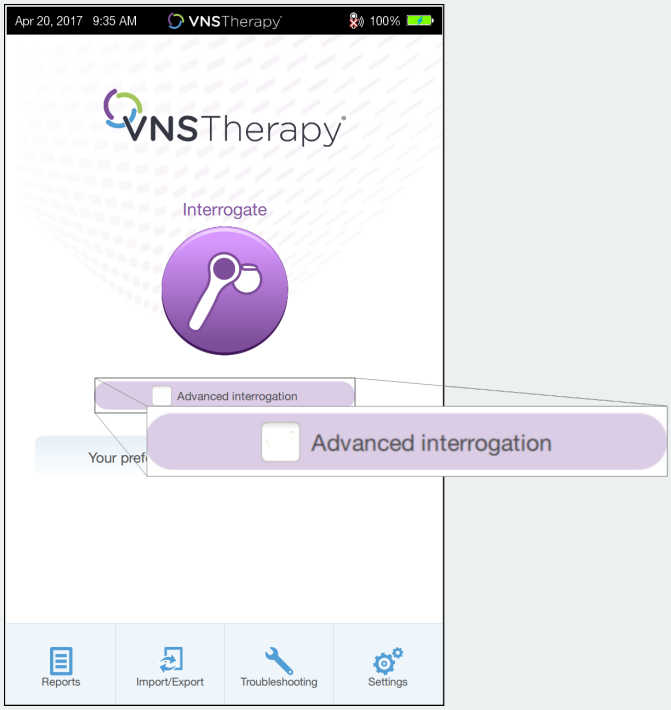
You must interrogate the generator before you can perform other functions (e.g., apply new parameters, perform diagnostic tests).

This topic includes the following concepts:

5.1. Interrogation Types

5.1.1. Rapid Interrogation

Rapid Interrogation is a quick interrogation available for all generator models that only downloads the current programmed settings and generator information.

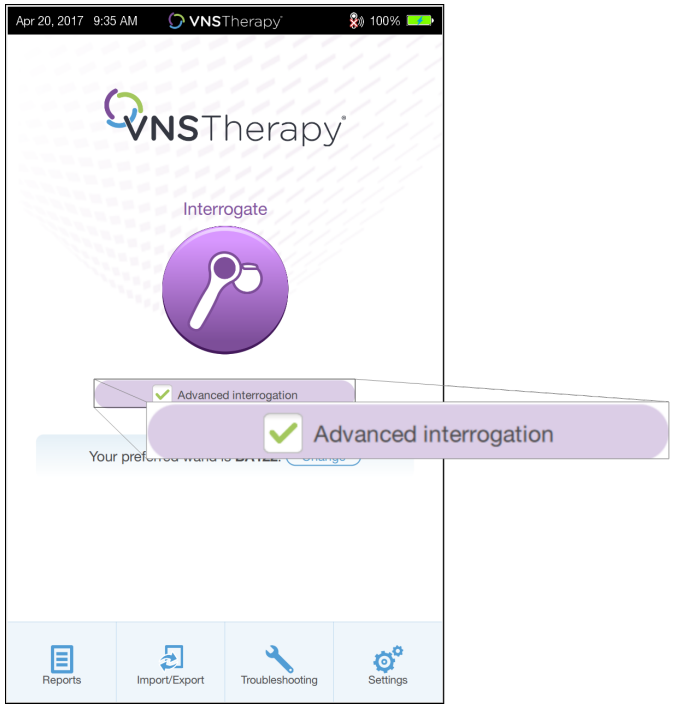
Model 1000 Model 1000-D	The Advanced Interrogation box *must be unchecked* (as shown below) in order to initiate a rapid interrogation. **Figure 7. Uncheck Advanced Interrogation** 
Model 106 Model 105 Model 104 Model 103 Model 8103 Model 102 Model 102R	A rapid interrogation is performed regardless of whether the Advanced Interrogation box is selected.

5.1.2. Advanced Interrogation

Applicable Models: Model 1000 Model 1000-D

Advanced Interrogation is an interrogation that downloads events and trend data for the previous 180 days, in addition to current programmed settings and generator information. This box *must be selected* (as shown below) in order to obtain additional events and trends. Because of the additional data, an advanced interrogation can take more time than a rapid interrogation.

Figure 8. Advanced Interrogation Check Box



5.2. Diagnostics Performed as Part of Initial Interrogation

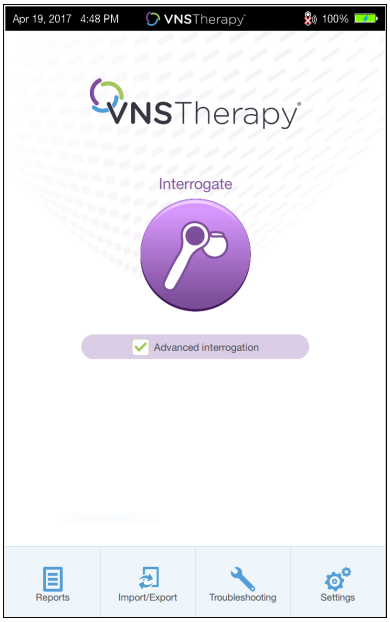
Model 1000 Model 1000-D	A System Diagnostics is performed the initial interrogation, regardless of the type of interrogation (Advanced or Rapid). The results are displayed on the Summary Screen and logged as part of Diagnostics history. To perform a diagnostic test after the initial interrogation you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

Model 106 Model 105 Model 104 Model 103 Model 8103 Model 102 Model 102R	A System Diagnostics is NOT performed during the initial interrogation. To perform a diagnostic test for these generators after the initial interrogation you can manually perform a System Diagnostics test while in session.

5.3. Interrogate (No Preferred Wand)

1. Power on the Programmer. Upon startup, the **Main Screen** displays.

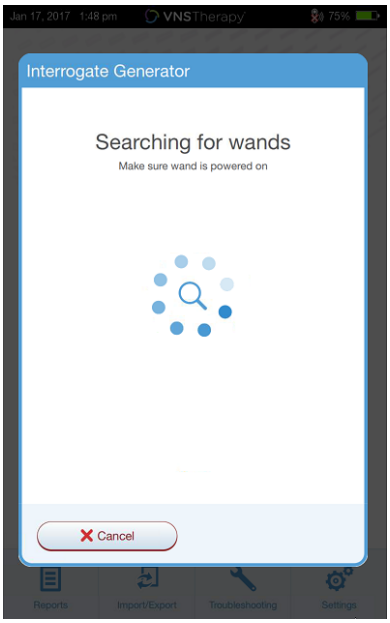
   Figure 9. Main Screen (No Preferred Wand)



2. Check or uncheck the Advanced Interrogation box. See "Interrogation Types " on page 29 for details.
3. Turn on the Wand (press and release the power button). Two green lights illuminate when the Wand is ready to connect.

4. Tap **Interrogate** on the Programmer screen. The Programmer searches for Wands that are powered on and in range.

Figure 10. Wand Search Screen



5. (Optional) If you wish to use a specific Wand in subsequent sessions, check the **Automatically connect to the same Wand** box.

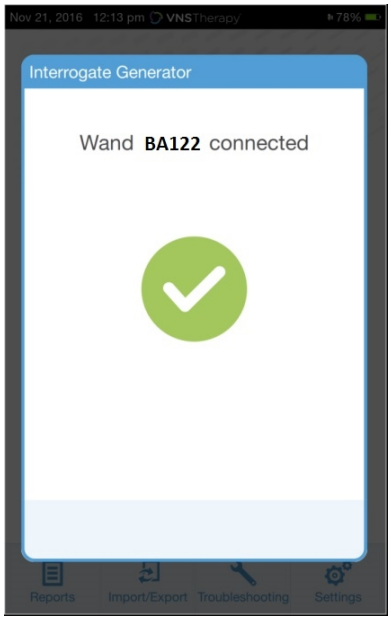
6. Tap the serial number (SN) of the Wand you intend to use. The SN of the Wand is located on the back of the Wand.

Figure 11. Wand Selection Screen Example

List of Wands on Programmer Screen	SN on Back of Wand

7. Once the Wand is connected, the software indicates a successful connection and four green lights illuminate around the Wand power button.

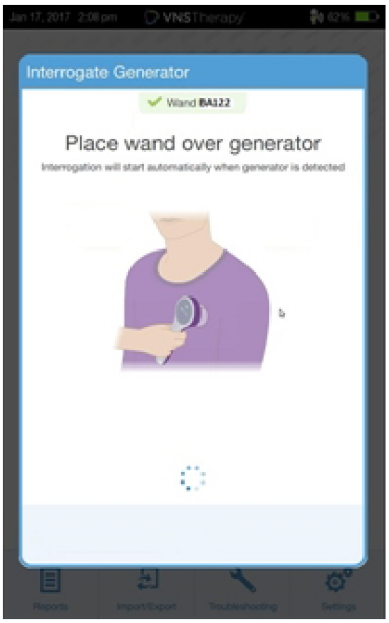
Figure 12. Successful Wand Connection Screen



Four green lights illuminate on the Wand.

8. Place the Wand over the generator as shown on the software screen. When the Wand recognizes the generator, the interrogation begins. Upon completion of the interrogation, the software displays the "Summary Screen" on page 38.

Figure 13. Interrogate Generator Screen



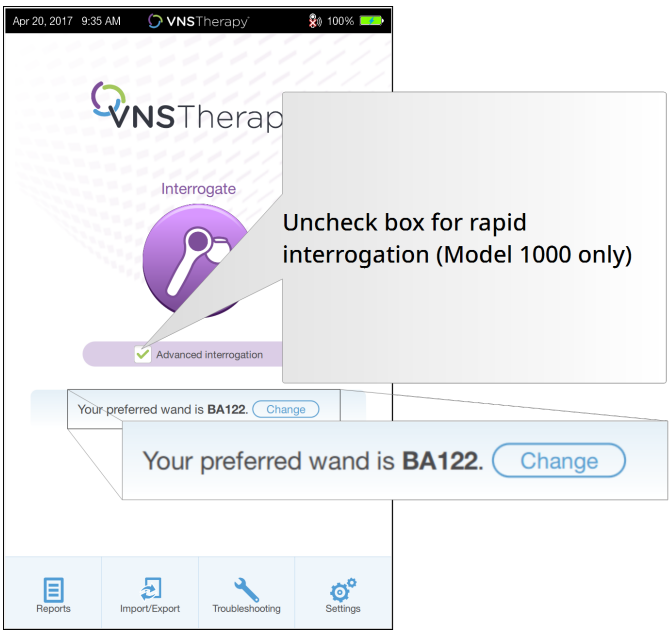
The generator icon on the Wand flashes during interrogation.

5.4. Interrogate (Preferred Wand)

If you have set up a preferred Wand, the Programmer automatically connects to that Wand when you tap **Interrogate**. To set up a preferred Wand, see "Setup Preferred Wireless Wand" on page 25.

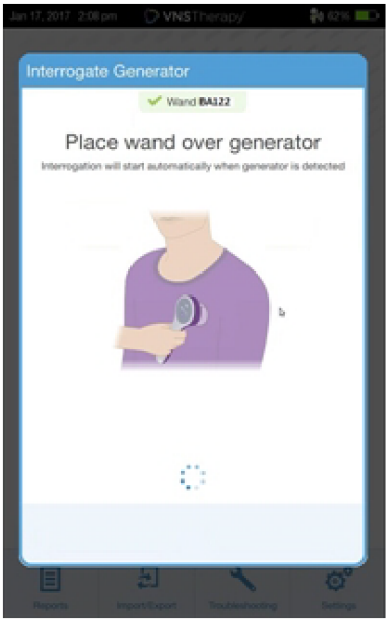
The Main Screen on the Programmer displays the serial number of the preferred Wand. Make sure the Wand is powered on before you select **Interrogate**. Check or uncheck the Advanced Interrogation box. For Model 1000 and Model 1000-D you must uncheck the box for rapid interrogation. See "Interrogation Types " on page 29 for details.

Figure 14. Main Screen (Preferred Wand) Example



After the Programmer and Wand are connected, place the Wand over the generator to complete the interrogation. Upon completion of the interrogation, the software displays the "Summary Screen" on page 38.

Figure 15. Interrogate Generator Screen



The generator icon on the Wand flashes during interrogation.

5.5. 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. Tap **Change** on the Main Screen.
3. The Programmer searches for 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 becomes the new preferred Wand and the Programmer automatically connects to it in future sessions.
4. Place the Wand over the generator to complete the interrogation.

To disable the preferred Wand and connect manually, see "Disable Preferred Wireless Wand" on page 25

5.6. Interrogate (Wired Wand)

To interrogate with a wired Wand perform the following steps:

1. Use the supplied USB cable to connect the Wand to the Programmer.
2. The software will identify the Wand connected via the cable.
3. Tap **Interrogate**. The four green indicators light up once the Wand begins to communicate with the generator.
4. Place the Wand over the generator to complete the interrogation.

CHAPTER 6

How to Use the Software

Messages and prompts will guide you through the software.

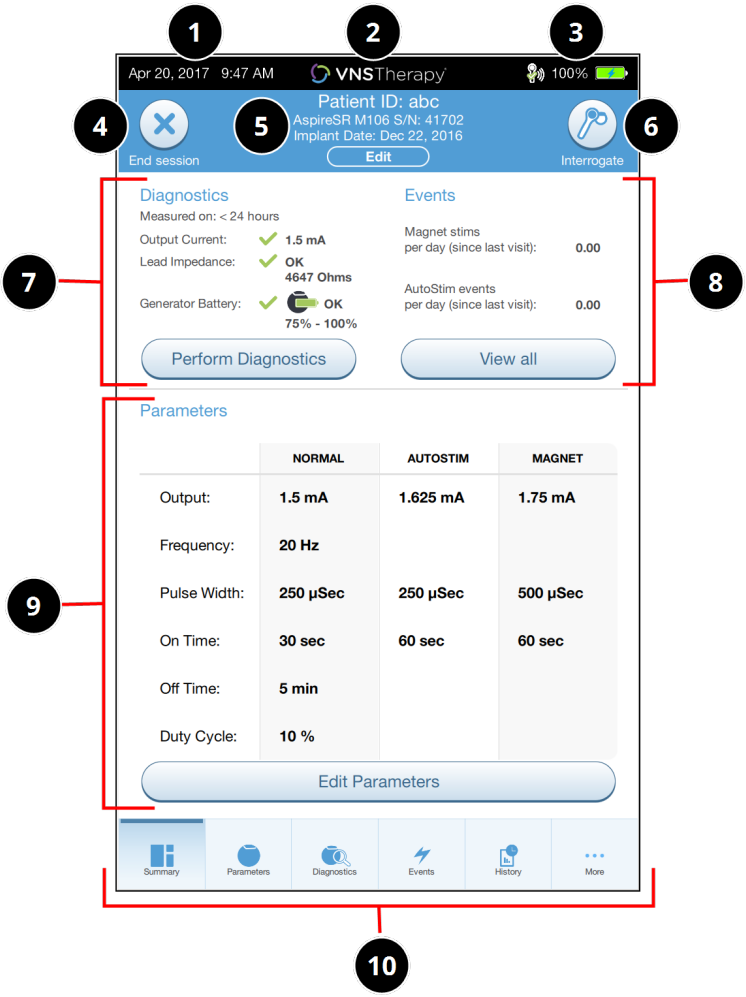
NOTE: If a software update is needed, see "Programmer Settings" on page 24.

This topic includes the following concepts:

6.1. Summary Screen

After a successful interrogation, the **Summary screen** displays. From this screen, you can perform or view the following:

Figure 16. Summary Screen Example



1 View current Programmer date and time.

2 Quick Access Bar (For details, see "Quick Access Bar" on the next page).

3 View Wand connection and Programmer battery status.

4 End current session.

5 View and edit patient data (e.g., Patient ID, implant date) and view generator information (e.g., model and serial numbers).

6 Interrogate button again (to verify parameters or refresh data).

7 View last known diagnostic data and shortcut button to **Perform Diagnostics**.

8 View events and trends (e.g., magnet activations, daily average AutoStims) and shortcut button to **View all** events and trends.

9 View current parameters. and shortcut button to **Edit Parameters** (to access or change Normal, Magnet, AutoStim, or Detection settings).

10 Navigation bar (access to additional software features) (e.g., Access device history such as parameter settings associated with prior office visits).

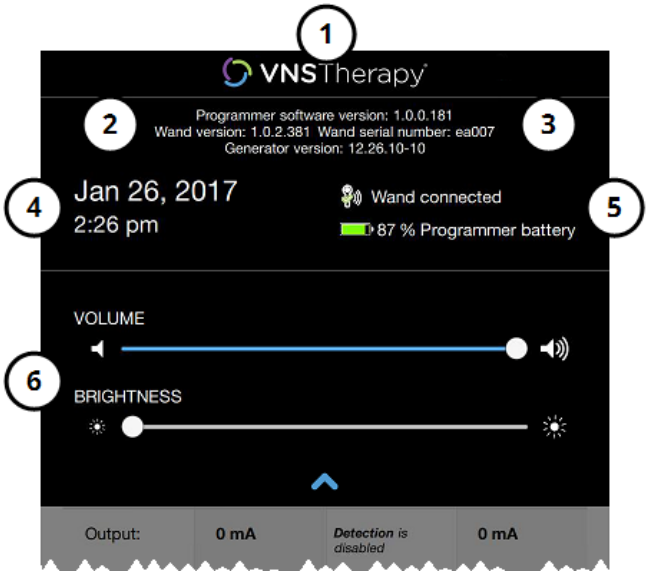
NOTE: The information displayed is generator model specific. Not all parameters, features, or modes are applicable for all generator models.

NOTE: For Model 3000 version 1.5, if a Model 1000 / Model 1000-D generator output current is set to 0 mA, then the lead impedance is expected to be displayed as "Not Available."

6.2. Quick Access Bar

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

Figure 17. Quick Access Bar Example



1 Title Bar logo.

2 Programming software version.

3 When in-session (connected): Wand version and serial number, and generator version.

4 Programmer date and time (Edit out-of-session only).

5 Wand connection and Programmer battery level.

6 Sliders to adjust system volume and display brightness.

CHAPTER 7

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.

This topic includes the following concepts:

7.1. How to Edit Patient Data

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

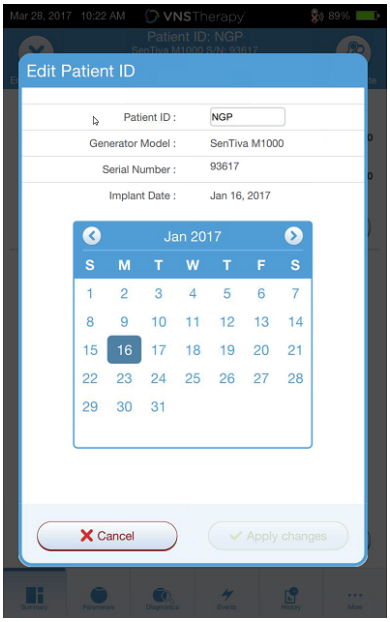
- Patient ID: three alpha-numeric characters (maximum)
- Implant date: the date the generator was implanted

After successful interrogation, the Patient ID, implant date, generator model, and serial number display at the top of the Summary Screen. See "Summary Screen" on page 38.

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. Tap **Edit** and enter the desired information.

Figure 18. Edit Patient ID Screen Example



4. Tap **Apply changes** and **Confirm** to program the information into the generator.

7.2. How to Adjust Parameter Settings

After interrogation, the "Summary Screen" on page 38 displays. To change generator settings from this screen, tap **Edit Parameters** or **Parameters** on the navigation bar at the bottom.

From the Parameters Screen, you can change stimulation or detection parameters, which are generator model specific.

NOTE: For a full list of programmable parameters available for each generator, see "Stimulation Parameters" in the indication specific physician's manual. Review all tabs when you adjust parameters.

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

Table 4. Parameter Screen - Stimulation and Detection Tabs

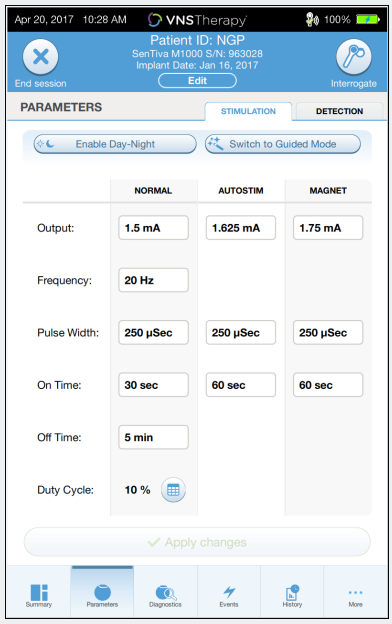
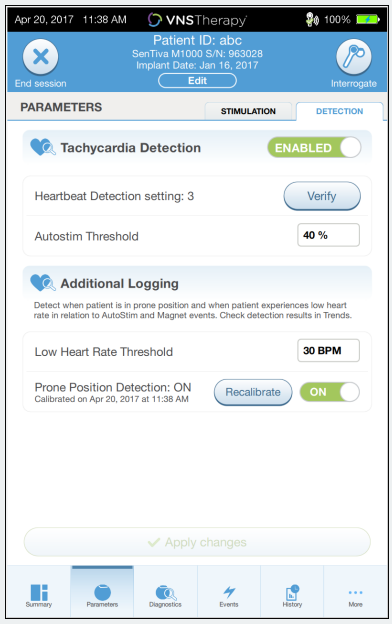
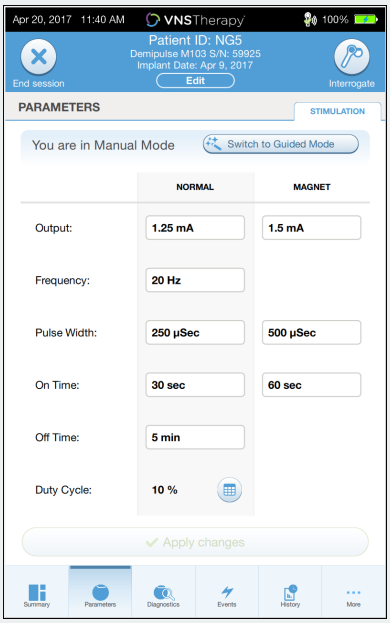
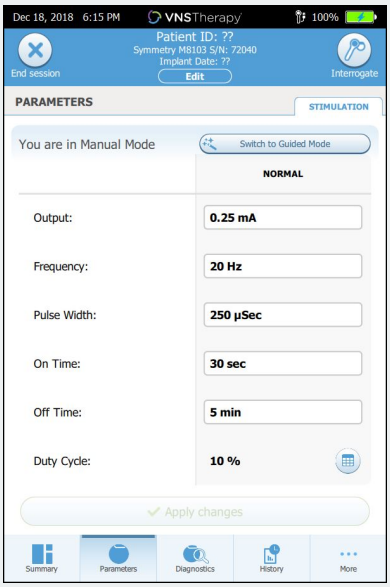
Model	Tab	Parameter Screen	Available Parameters
Model 1000 Model 1000-D Model 106	Stimulation		Normal Mode Magnet Mode AutoStim Mode
Model 1000 Model 1000-D Model 106	Detection		Detection parameters Additional logging options (Model 1000 / Model 1000-D only)

Table 4. Parameter Screen - Stimulation and Detection Tabs (continued)

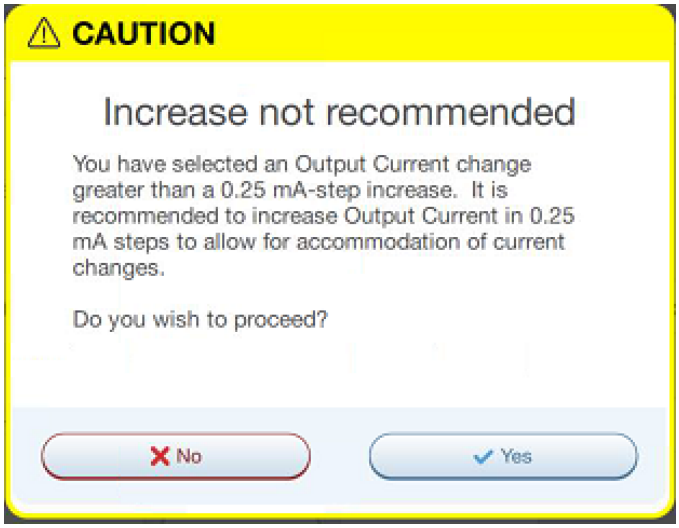
Model	Tab	Parameter Screen	Available Parameters
Model 105 Model 104 Model 103 Model 102 Model 102R	Stimulation		Normal Mode Magnet Mode
Model 8103	Stimulation		Normal Mode

To change a parameter setting, perform the following steps:

1. Tap the **Stimulation** or **Detection** tab on the Parameter Screen.
2. 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, scroll up or down to view them.
3. Tap 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.

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.

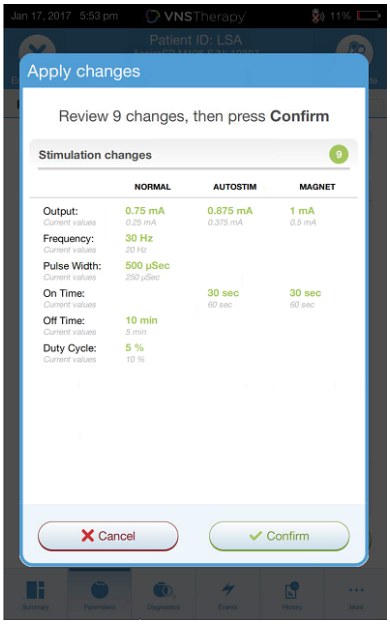
Figure 19. Parameter Settings Output Caution



4. Tap Apply changes at the bottom of the Parameter screen to proceed to the Confirmation screen.

NOTE: New parameter selections that have not been programmed to the generator are in green. Programmed, unchanged, settings are in black.

Figure 20. Parameter Confirmation Screen Example



NOTE: Not all parameters, features, or modes are applicable for all generator models.

5. If updated parameter settings are correct, place the Wand over the generator and tap **Confirm** to program the new settings to the generator. If incorrect, tap **Cancel** to return to the Parameter Screen to make further adjustments.
6. Upon successful update to parameters, an on-screen message appears that shows the newly programmed parameter settings.
7. If any parameter changes are made during a patient visit, LivaNova recommends a final interrogation be performed 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, navigate to the Parameter Screen and tap **Interrogate** at the top right portion of the screen.

CAUTION: For Model 102 and Model 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 warn epilepsy patients with Magnet Mode activated about continuous or frequent magnet use as this could lead to early battery depletion.

7.3. How to Configure Detection Settings

Applicable Models:	Model 1000	Model 1000-D	Model 106

Adjust Detection settings on the Parameter screen under the **Detection** tab.

NOTE: Detection Settings are only intended for use in epilepsy patients.

7.3.1. Enable or Disable Detection

You may enable or disable Detection. If Detection is **Disabled**, then the generators use only Normal Mode and Magnet Mode stimulation. If Detection is **Enabled**, then parameters for AutoStim Mode will become available, in addition to Normal Mode and Magnet Mode parameters.

NOTE: If Detection is disabled, the parameters on the Detection tab are not visible and AutoStim Mode 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 accurately detects the patient's heartbeats, and sets the criterion for AutoStim Mode delivery based on changes in heart rate, respectively. Once Detection is **Enabled**, you can adjust the settings from the Detection tab as needed.

7.3.2. Set Heartbeat Detection

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 to 5):

- 1 (least sensitive; for use with largest amplitude ECG signals)
- 5 (most sensitive; for use with smallest amplitude ECG signals)

The setting will not change unless manually programmed to a different value.

7.3.3. Verify Heartbeat Detection

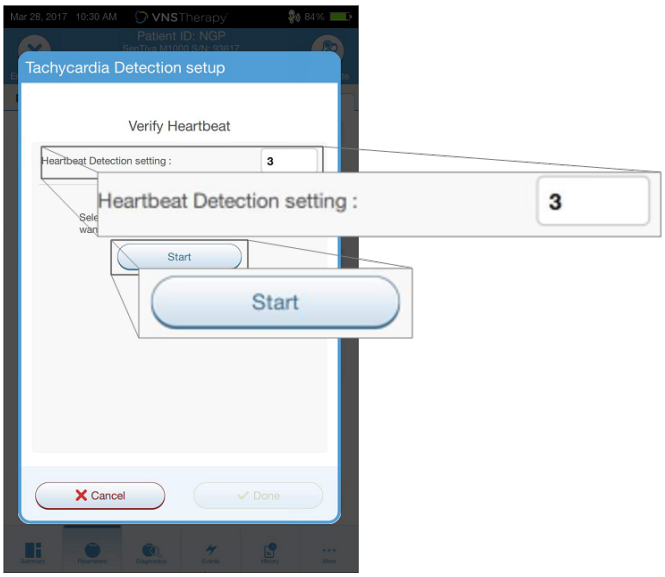
When Detection is enabled, the software walks you through Heartbeat Detection setting verification and AutoStim Threshold selection.

To confirm the accuracy of the heart rate detected by the generator or to change the Heartbeat Detection setting, complete the following steps:

1. Tap **Verify** on the Detection tab to advance to the Verify Heartbeat Detection Screen. If Detection has been enabled, the Verify Heartbeat Detection Screen displays automatically.

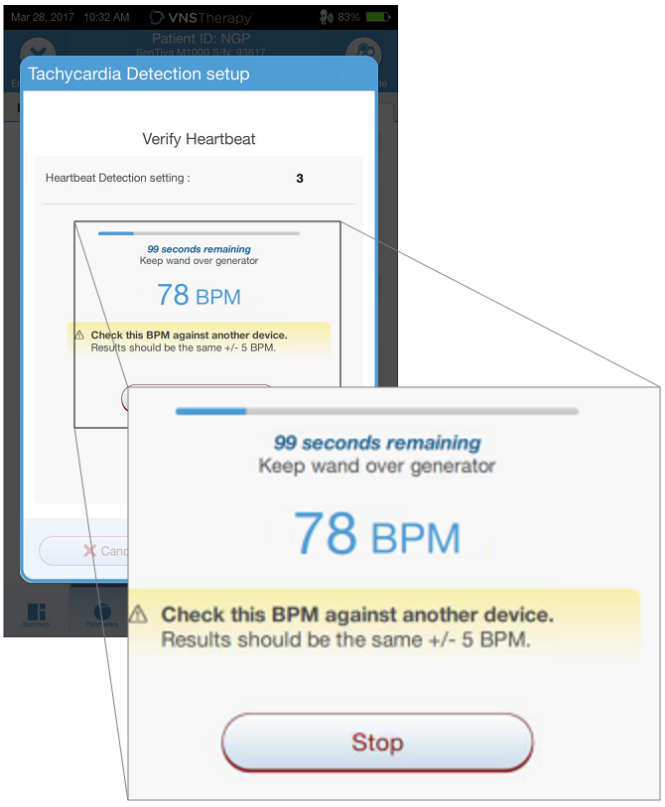
2. On the Verify Heartbeat Detection screen, tap in the **Heartbeat Detection setting** field to change the value (if desired). Place the Wand over the generator and tap **Start** to begin the test.

Figure 21. Start Verify Heartbeat Detection Screen Example



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

Figure 22. Verify Heartbeat Detection Screen –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 (i.e., bpm from another ECG monitor or a manual pulse count). Accurate detection should be within ± 5 bpm or 10%.
5. If the heart rate reported by the Programmer is too high or low, follow these recommendations:
    - Heart rate too high — Adjust the Heartbeat Detection setting downward (toward setting 1).
    - Heart rate too low or displays "?? BPM" — Adjust the Heartbeat Detection setting upward (toward setting 5).

    NOTE: See "Heartbeat Detection Inaccurate (Over / Under) in the OR or at Follow-Up (Generators Capable of AutoStim)" on page 110 for more information.

6. If the Heartbeat Detection is verified before the two-minute test completes, keep the Wand over the generator and tap **Stop** on the screen.
7. Once you observe accurate heartbeat detection, you have completed the verification process. If you want to enable Detection, tap **Next** to set the AutoStim Threshold. Otherwise, tap **Done** to return to the Parameter screen.

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

Table 5. Visual Indicators During Verify Heartbeat Detection

Visual Indicator	Indications
?? BPM	Lost or no communication, or no heart beats detected by the system
<40 BPM	The system detects a heart rate below this lower limit
>230 BPM (Model 3000 v1.0)	The system detects a heart rate above this upper limit
>180 BPM (Model 3000 v1.5+)	The system detects a heart rate above this upper limit
40 – 230 BPM (Model 3000 v1.0)	The actual system-calculated heart rate displays
40 – 180 BPM ((Model 3000 v1.5+)	The actual system-calculated heart rate displays

CAUTION: For generators capable of heartbeat detection, if AutoStim or Magnet Mode stimulation is programmed on, the Verify Heartbeat Detection feature may be interrupted if AutoStim Mode or Magnet Mode 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.

7.3.4. 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%.

NOTE: For Additional guidance for how to program this patient-specific setting, see the indication specific physician's manual.

7.3.5. AutoStim Settings on the Stimulation Tab

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

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 Mode 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: It is recommended that 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.

7.3.6. Low Heart Rate / Prone Detection Introduction

Applicable Models: Model 1000 Model 1000-D

NOTE: For a compatibility table for generator models, modes, and features, see "System Compatibility" in the indication specific physician's manual.

CAUTION: Low heart rate and prone position events are for informational purposes only. Detected events are not to be used for alarms or medical diagnosis.

Clinical data suggest that events of cardiac arrest and/or respiratory arrest, possibly aggravated by the prone position, are precursors to instances of Sudden Unexplained Death in Epilepsy (SUDEP)[1] . The generator can detect and log low heart rate and prone position events if they are of interest to the physician. These events

[1]Ryvlin, Philippe et al. Incidence and mechanisms of cardiorespiratory arrests in epilepsy monitoring units (MORTEMUS): a retrospective study. The Lancet Neurology, Volume 12 , Issue 10 , 966 - 977

are detected after AutoStim Mode or Magnet Mode stimulation, and Tachycardia Detection must be enabled in order to log low heart rate and prone position events.

Detection for low heart rate and prone position events are independently configurable. For use of Low Heart Rate Detection, the physician must define a detection threshold, specific for the patient, from 30 to 60 bpm in 10 bpm increments. For Prone Position Detection, a calibration with the patient in supine and upright positions is required prior to the feature activation. Detected events are stored within the generator's memory and viewable during patient follow-up visits through the Programmer.

NOTE: For details on how to use this feature, see "How to Setup Low Heart Rate Threshold and Prone Position Detection" below .

7.3.7. How to Setup Low Heart Rate Threshold and Prone Position Detection

Applicable Models: Model 1000 Model 1000-D

To receive extra patient-specific information, configure the 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 Mode or Magnet Mode activation. Tachycardia Detection must be enabled to log low heart rate or prone position.

7.3.7.1. Choose the Low Heart Rate Threshold

From the Parameters screen, with the Detection tab active, tap the **Low Heart Rate Threshold** field. A pop up menu displays a range of 30 to 60 bpm. Once you have selected a threshold, tap **Apply changes** and **Confirm** to program the generator.

NOTE: The generator stores up to 20 low heart rate event timestamps for display within **Event and Trends**. See "Events and Trends Data" on page 87").

NOTE: Low heart rate events are only logged if the heart rate falls below the programmed threshold within 7.5 minutes after an AutoStim Mode or Magnet Mode activation. These stimulations trigger the monitoring period, since they may be associated with seizure activity.

NOTE: If the programming system communicates with the generator during the monitoring period for low heart rate events, it may cause an unexpected low heart rate event to be logged.

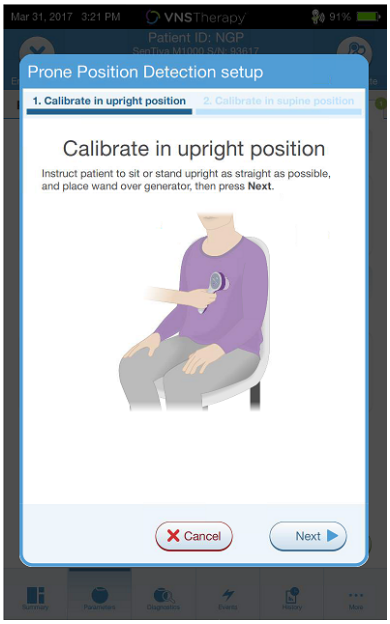
7.3.7.2. Enable Prone Position Detection

Enable Prone Position Detection from the Parameters screen, with the Detection tab active. When you enable this feature, the software prompts you to calibrate the generator to account for generator orientation within the body.

Follow the steps below to setup Prone Position Detection.

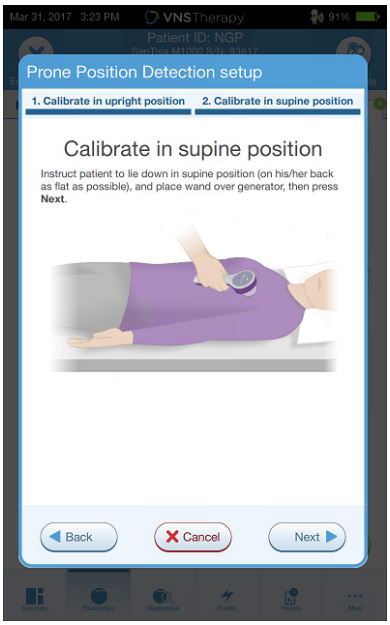
1. Instruct the patient to sit or stand upright as straight as possible and place the Wand over the generator, then tap **Next**.

   Figure 23. Prone Position Calibration in Upright Position

2. Instruct the patient to lie down in the supine position (lying flat on back) and place the Wand over the generator, then tap **Next**.

Figure 24. Prone Position Calibration in Supine Position

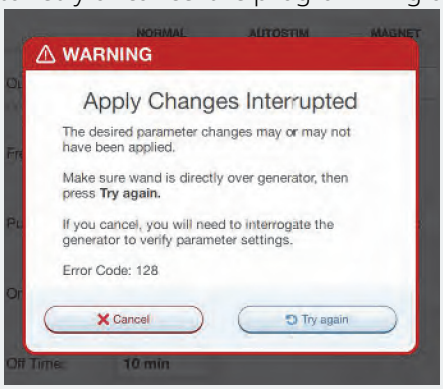


7.4. Potential Error Conditions Related to Programming

Table 6. Potential Error Conditions Related to Programming

Model	Error	Description
Model 1000 Model 1000-D	Partial Programming	Normal Mode, AutoStim Mode, and Magnet Mode are programmed as a set. If programming is interrupted, it is possible not all of the modes were updated, which can leave one or more modes with an outdated set of parameters. The software displays a warning message that indicates 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.

Table 6. Potential Error Conditions Related to Programming (continued)

Model	Error	Description
Model 106 Model 105 Model 104 Model 103 Model 8103	Programming Interruption	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 that indicates the procedure failed and allows the user to retry or cancel the programming operation.  If you decide to cancel, interrogate the generator to verify settings before you reattempt the programming operation.
Model 102 Model 102R	Partial Programming	Each parameter is programmed and verified individually during a programming event. If the communication is interrupted during programming, generators can be set to unintended settings. The software displays a warning message, which indicates 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.
Model 102 Model 102R	Cross-Programming	These 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 this generator. Always perform an initial and final interrogation to verify parameter settings at each office visit for all patients with this generator.

CHAPTER 8

Guided Programming

This topic includes the following concepts:

8.1. Guided Programming Introduction

NOTE: For a compatibility table for generator models, modes, and features, see "System Compatibility" in the indication specific physician's manual.

For ease of programming, use the Guided Programming feature to adjust therapy parameters during a follow-up visit. This feature simplifies programming because it allows 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.

NOTE: See "Standard Therapy Protocol Steps " on the next page

For the Model 1000 or Model 1000-D generator, you can create a Custom Therapy Protocol before an office visit.

NOTE: See "Custom Therapy Protocols" on the next page.

NOTE: For details on how to use the Guided Programming feature, see "How to Use Guided Mode" on page 59.

NOTE: Guided Programming is not recommended for depression patients implanted with generator models lower than Model 1000. If Guided Programming is used for a depression patient implanted with a Model 1000 or Model 1000-D generator, a Custom Therapy Protocol should be entered and selected where both the Magnet Mode and AutoStim Mode outputs are 0 mA for each desired step.

8.2. Therapy Protocols

8.2.1. Standard Therapy Protocol

NOTE: If programmer software has not been updated to v 1.6 or higher, contact "Technical Support" on page 120 for an update.

The Standard Therapy Protocol increases output current to 1.75 mA in 7 protocol steps. Each step increases output current by 0.25 mA as shown below.

Table 7. Standard Therapy Protocol Steps

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

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 below.

Table 8. 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

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

NOTE: AutoStim Mode and Magnet Mode are only intended for use in epilepsy patients.

NOTE: For Model 8103 the Standard Therapy Protocol programs Magnet Mode output to 0 mA for all steps.

8.2.2. Custom Therapy Protocols

Applicable Models: Model 1000 Model 1000-D

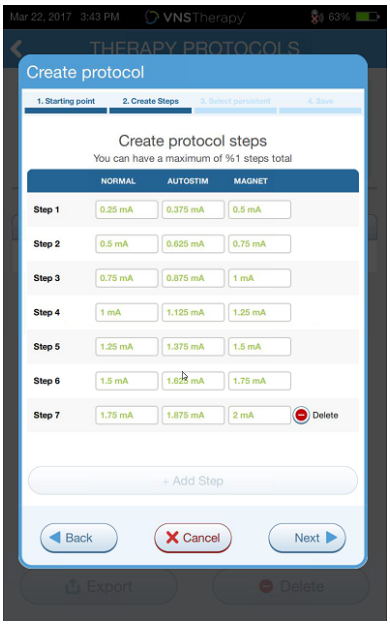
A Custom Therapy Protocol allows you to define the output current for each step and mode (e.g. Normal Mode, AutoStim Mode, and Magnet Mode), and select different persistent parameter settings than shown in "Standard Therapy Protocol Steps " above. Persistent parameter settings are applied to each step of the Custom Therapy Protocol.

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

To create a custom protocol do the following:

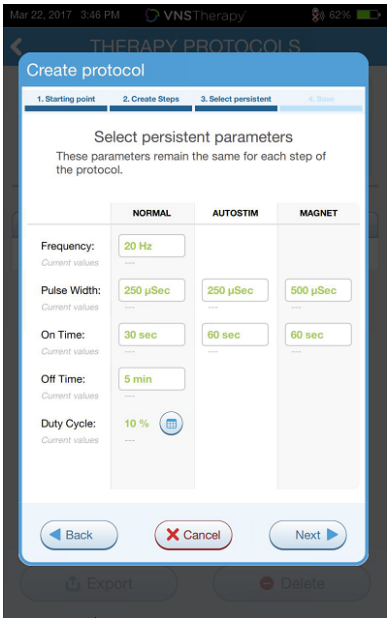
1. Tap **Settings** from the navigation bar of the Main screen
2. Tap **Guided Mode Options**.
3. Tap **Therapy Protocols**.
4. Tap **Create protocol**.
5. Tap **Start from Scratch** or choose an existing protocol as a base template.
6. Add or delete steps (maximum of 7) and set the output currents for each therapy mode.

Figure 25. Create Protocol Steps Screen Example



7. Choose the custom persistent parameters that will be used in all protocol steps.

Figure 26. Select Persistent Parameters Screen Example

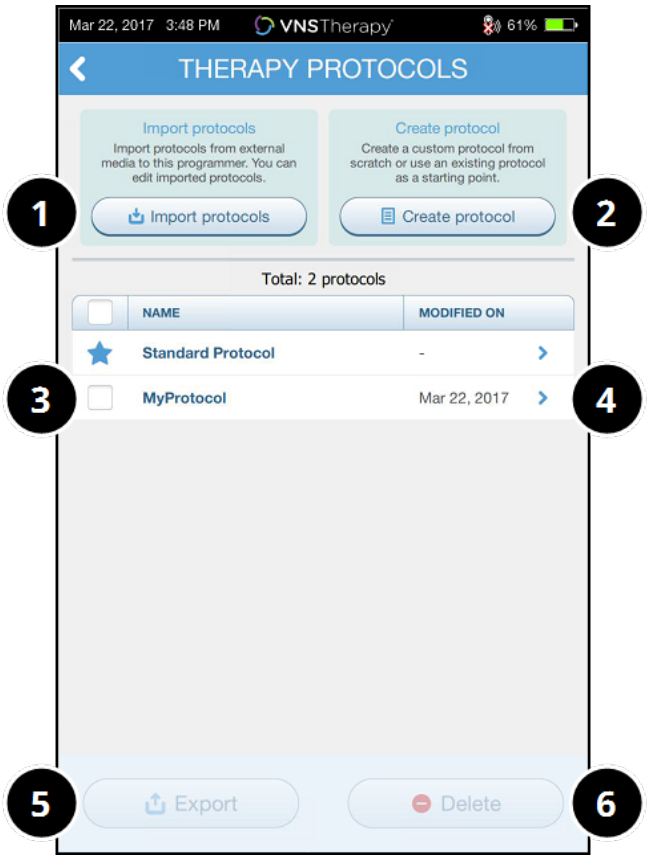


8. Follow on-screen prompts to name and save the custom protocol, then use the back arrow to navigate back to the Main screen.

8.2.3. Additional Guided Programming Options

Additional options can be performed from the Therapy Protocols screen. 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 Options



1 Import one or more protocols from external media.

2 Create a new protocol.

3 Select protocols to delete or export.

4 Review protocol steps.

5 Export selected protocols to external media.

6 Delete selected protocols.

8.3. How to Use Guided Mode

8.3.1. Start Guided Mode

1. Interrogate the generator.
2. Tap **Parameters** to go to the Parameters screen.

3. Tap **Switch to Guided Mode**.

Figure 28. Enable Guided Mode

4. For the Model 1000 / Model 1000-D generator, the software prompts you to select a **Standard Protocol** or a **Custom Protocol**. Guided Mode determines the closest match between the current generator parameters and the selected protocol. Proposed setting changes are shown in green on the confirmation screen.
5. Tap **Apply changes** to program the guided protocol.

Figure 29. Review and Apply Parameter Settings

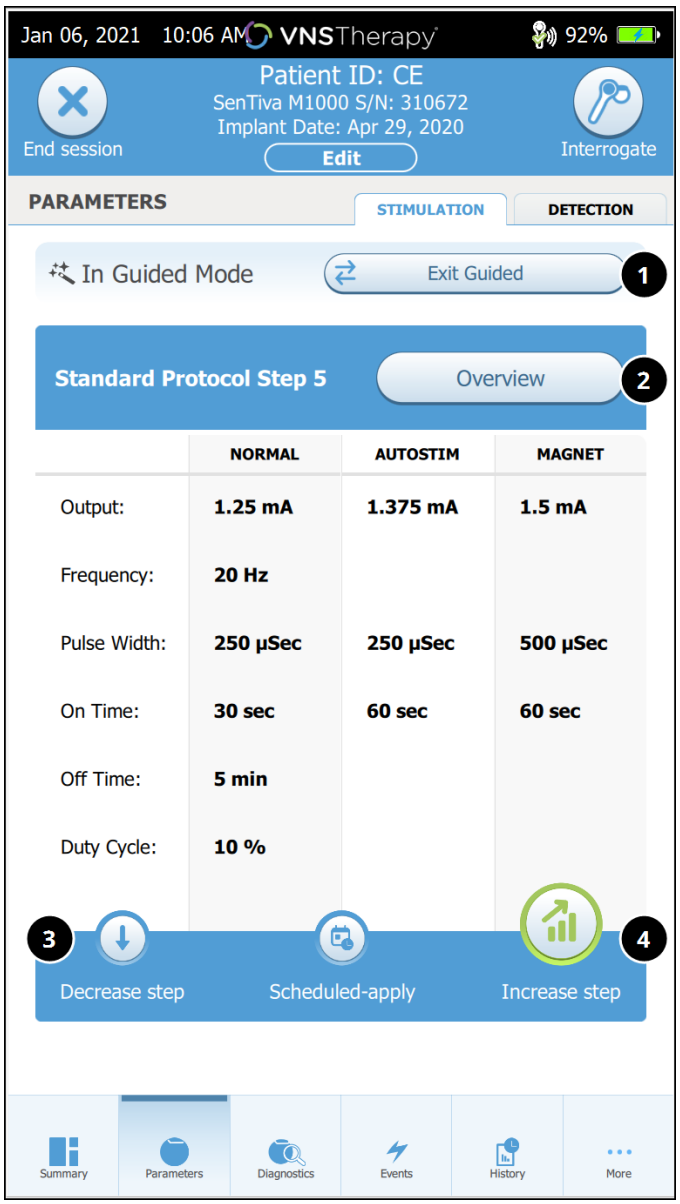
NOTE: If you do not agree with the proposed Guided Mode steps, or you reach the last step in a therapy protocol and wish to make further changes, exit Guided Mode and adjust the parameters manually.

NOTE: For the Model 1000 / Model 1000-D generator, Guided Mode is unavailable if Day-Night Programming is enabled.

NOTE: Not all parameters, features, or modes are applicable for all generator models.

8.3.2. Guided Mode Options

Figure 30. Guided Mode Options



1 **Exit Guided Mode**
Tap **Exit Guided** to exit Guided Mode and manually adjust parameters. Follow and confirm prompts to exit.

NOTE: You can switch back to Guided Mode at any time.

2 **Review Therapy Protocol Steps**
Tap **Overview** to view all the protocol steps and see which steps have been applied.

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.

3 **Change Parameters—Decrease Stimulation**
If the patient cannot tolerate the increased settings, tap **Decrease step** to decrease the parameters to the previous protocol step. Tap **Apply changes** to program the generator.

4 **Change Parameters—Increase Stimulation**
Tap **Increase step** to increase stimulation intensity to the next protocol step. Tap **Apply changes** to accept changes and program the proposed settings.

CHAPTER 9

Scheduled Programming

This topic includes the following concepts:

9.1. Scheduled Programming Introduction

Applicable Models: Model 1000 Model 1000-D

NOTE: If Scheduled Programming is used for a depression patient, a Custom Therapy Protocol should be entered and selected where both the Magnet Mode and AutoStim Mode outputs are both 0 mA for each desired step.

NOTE: For a compatibility table for generator models, modes, and features, see "System Compatibility" in the indication specific physician's manual.

CAUTION: This feature may not be appropriate for use in patients who are nonverbal or are unable to use the patient magnet to stop undesired stimulation. Similarly, exercise caution for use of this feature in patients with a history of obstructive sleep apnea, shortness of breath, coughing, swallowing difficulties, or aspiration.

Scheduled Programming is an optional feature that allows you to program the generator so that it automatically increases stimulation therapy parameters while the patient is in the comfort of his or her home. This feature is intended to be used during the titration phase and could potentially lessen the number of office visits the patient will need to travel to and from the clinic for programming increases. Physicians have the option to create a custom programming schedule, or to select and confirm the use of a standard schedule. The programming schedule is limited to a maximum of 7 steps and the physician specifies the parameter settings for each step as well as the time between steps. Once programmed into the generator, the generator will deliver the stimulation increases for each step at the times and dates set by the physician.

If this feature is used, it is highly recommended that physicians communicate the dates and times of the programming schedule to the patient and/or caregiver so the patient is aware of upcoming parameter increases. If a patient is unable to tolerate a scheduled therapy increase, instruct the patient to disable stimulation with the magnet (i.e. place magnet over the generator) and follow-up with the physician for programming adjustment.

NOTE: For details on how to use the Scheduled Programming feature, see "How to Use Scheduled Programming" below.

9.2. How to Use Scheduled Programming

9.2.1. Set Number of Scheduled Steps

The Programmer settings determine how many automatic (scheduled) parameter increases are allowed. The maximum number of scheduled steps is set from the Main screen prior to interrogation.

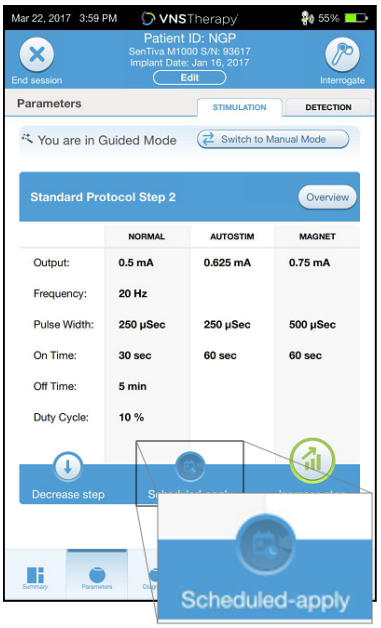
Tap **Settings** and then **Guided Mode Options**. The default value is 2 scheduled programming steps and may be increased up to 6.

9.2.2. Enable Scheduled Programming

To schedule programming changes, perform the following steps:

1. Enable Guided Mode and select a therapy protocol. See "Guided Programming" on page 54.
2. On the Stimulation tab, tap **Scheduled-apply**.

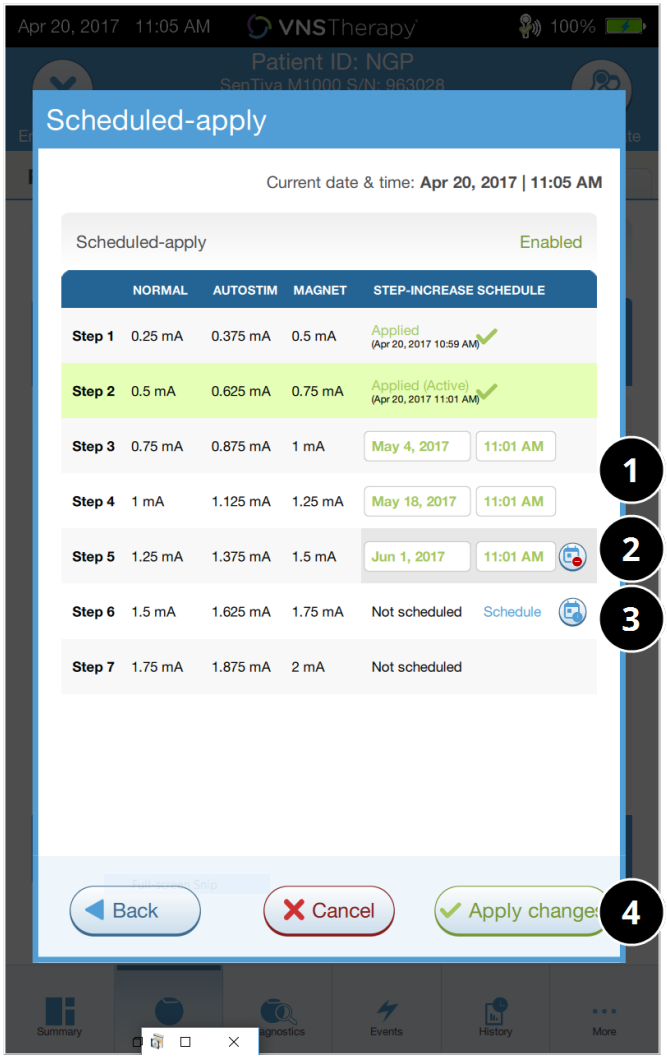
Figure 31. Enable Scheduled Programming



3. Choose the time interval between programming parameter changes.
4. Tap **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)
5. Edit the dates and times for scheduled programming changes.

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.

Figure 32. Edit the schedule screen (example)



1 Adjust the date and time.

2 Remove from the schedule.

3 Add to the schedule.

4 Program schedule into the generator.

6. Tap **Apply changes** to program the schedule into the generator.

9.2.3. Disable Scheduled Programming

The patient must be in the office to turn off Scheduled Programming.

To disable Scheduled Programming perform the following steps:

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

CHAPTER 10

Day-Night Programming

This topic includes the following concepts:

10.1. Day-Night Programming Introduction

Applicable Models: Model 1000 Model 1000-D

⚠ CAUTION: Time-based features do not automatically adjust for Day Light Savings or time zone changes. Tell the patient to follow-up with the physician for reprogramming if needed.

ⓘ NOTE: For a compatibility table for generator models, modes, and features, see "System Compatibility" in the indication specific physician's manual.

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

The physician specifies what parameters will change, and a time period during the 24-hours when the alternate parameter set should be active. After the Day-Night program has been defined, the generator will alternate between the 2 independent parameter sets on a daily basis. This feature provides the physician the ability to further customize the delivery of VNS Therapy to accommodate to each individual patient's needs after a target level has been established for the patient.

As with any therapy setting change, the risk and benefits of altering a patient's known efficacious settings should be considered when adjustments are made. Inform your patients about when to expect a setting change (i.e. when Daytime settings transition into Nighttime settings). In addition, patient tolerability of the alternate parameter set should be assessed prior to the patient leaving the office visit.

ⓘ NOTE: Day-Night Programming is not available in Guided Mode.

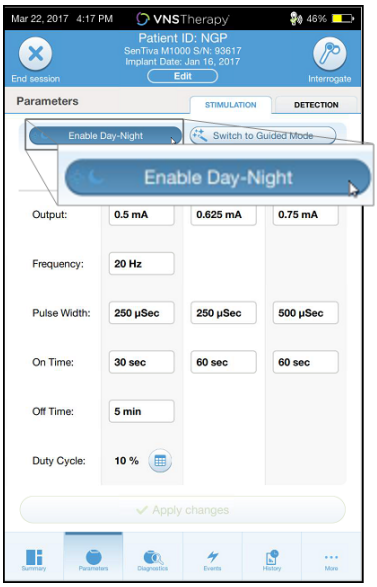
ⓘ NOTE: For details on how to use Day-Night Programming, see "How to Use Day-Night Programming" below.

10.2. How to Use Day-Night Programming

10.2.1. Enable Day-Night Programming

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

Figure 33. Enable Day-Night Program



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

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.

Figure 34. Nighttime Tab Example

1 Set the active period for nighttime.

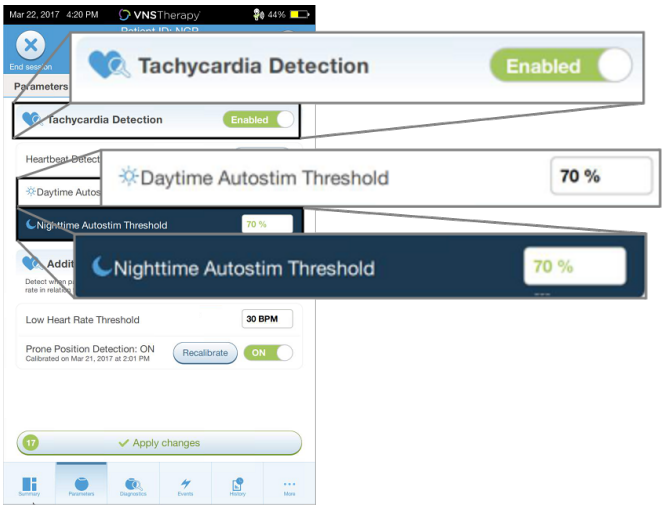
2 Number of pending changes tallied for each tab.

3 Set mode parameters.

4 Apply changes from all tabs.

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 Tachycardia Detection is enabled).

Figure 35. Custom Day-Night AutoStim Thresholds Screen Example



5. To program selections from the Daytime, Nighttime, and Detection tabs to the generator tap **Apply changes**, then review and **Confirm** new selections.

10.2.2. Test the Day-Night Program

When you adjust day-night settings, ensure the patient can tolerate both sets of parameters. When you first enable the feature, the generator stimulates using the alternate period parameters for 15 minutes, and then reverts to the current period settings.

For example, if the Day-Night Programming feature is enabled during the day period, the generator uses nighttime stimulation parameters for 15 minutes before it reverts back to daytime settings. Similar tests occur anytime you adjust settings outside the current period (e.g. modify nighttime settings during the daytime period).

NOTE: If you perform additional programming during the 15-minute trial period, the alternate period test will end.

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.

10.2.3. Disable Day-Night Programming

To disable Day-Night Programming, and use the daytime parameters for the full 24-hour period, follow these steps:

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

CHAPTER 11

Device Diagnostics

This topic includes the following concepts:

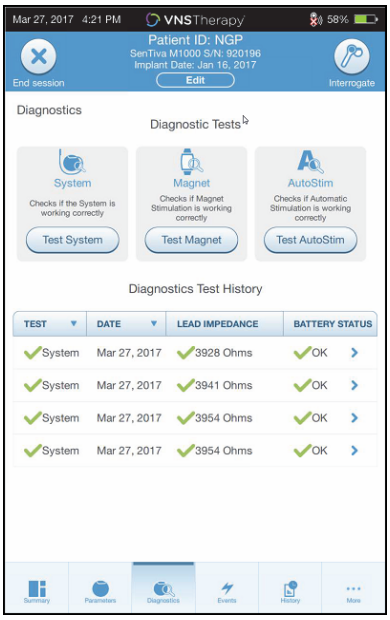
11.1. Access Device Diagnostics

Several Diagnostics tests are available in the programming software to assess functionality of the implanted system.

Access to the different diagnostic tests is generator model specific. Not all parameters, features, or modes are applicable for all generator models. Make sure to follow all the instructions on the Programmer screen, as they vary for each selection.

To access the Diagnostics Tests screen after a completed interrogation, select **Diagnostics** or **Perform Diagnostics** on the "Summary Screen" on page 38.

Figure 36. Diagnostics Screen Example



11.2. Diagnostic Tests

Typical diagnostic tests include the following:

- "System Diagnostics" on the next page
- "Normal Mode Diagnostics" on page 73
- "Magnet Mode Diagnostics" on page 73
- "AutoStim Mode Diagnostics" on page 74
- "Generator Diagnostics" on page 74

System, Normal Mode, Magnet Mode, and AutoStim Mode tests are designed to assess system functionality of the implanted components. Generator Diagnostics is designed for troubleshooting during implantation surgery.

NOTE: If a diagnostics test 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.

11.2.1. 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. This test may be performed 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.

Model 1000 Model 1000-D	A System Diagnostics is performed 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 after the initial interrogation you can manually perform a System Diagnostics test while in session.
Model 106 Model 105 Model 104 Model 103 Model 8103 Model 102 Model 102R	A System Diagnostics is NOT performed during the initial interrogation. To perform a diagnostic test, after the initial interrogation, you can manually perform a System Diagnostics test while in session.

11.2.2. Normal Mode Diagnostics

Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	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.
Model 102 Model 102R	The Normal Mode Diagnostics test lets 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.

11.2.3. Magnet Mode Diagnostics

NOTE: Magnet Mode is only intended for use in epilepsy patients.

The Magnet Mode Diagnostics test determines if the generator is able to deliver the programmed magnet output current.

To perform this test, do the following:

1. Tap **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.
4. If the test does not successfully activate magnet stimulation, a message that indicates the magnet presence was not detected, displays on the Programmer screen. Pass the magnet over the generator again and restart the test.

Model Numbers	Model Specific Notes
Model 8103	Magnet Mode is not available.
Model 106	Do not leave the magnet over the generator for longer than 3 seconds during the Magnet Mode Diagnostics test. Otherwise, stimulation will stop and you will receive a message that indicates the magnet presence was not detected. Repeat the Magnet Mode Diagnostics test.

Model Numbers	Model Specific Notes
Model 102	Magnet Mode Diagnostics cannot run if output current is < 0.75 mA, or the frequency < 15 Hz, or ON time less than 30 seconds (similar to Normal Mode Diagnostics).

11.2.4. AutoStim Mode Diagnostics

NOTE: AutoStim Mode is only intended for use in epilepsy patients.

The AutoStim Mode 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.

11.2.5. Generator Diagnostics

The Generator Diagnostics test is used with a test resistor and should only be accessed for troubleshooting scenarios during implantation surgery.

See "Troubleshooting" for steps that include Generator Diagnostics:

- "High Lead Impedance in the OR" on page 99
- "Low Lead Impedance in the OR" on page 101
- "Low Battery or End of Service Indications in the OR" on page 107

11.3. Diagnostic Test Summary

Some diagnostic tests are generator model specific. The tests are described in the table below.

Table 9. Diagnostic Test Summary

Diagnostic Tests	Model 1000 Model 1000-D	Model 106 Model 105 Model 104 Model 103 Model 8103	Model 102 Model 102R
System Diagnostics	Delivery of programmed output for approximately 4 seconds, followed by one brief pulse at 0.25 mA for less than 130 µsec.*	**Normal Mode Output Current = 0 mA**: Assesses impedance at 0.25 mA and stimulates at 1.0 mA, 500 µsec, and 20 Hz for approximately 14 seconds. ⚠ CAUTION: Patients with lower parameter settings may feel discomfort during this test. **Normal Mode Output Current > 0 mA**: Assesses impedance at 0.25 mA and stimulates at the programmed Normal Mode parameters for approximately 14 seconds.	Stimulates at 1.0 mA, 500 µsec, and 20 Hz for approximately 14 seconds ⚠ CAUTION: Patients with lower parameter settings may feel discomfort during this test.
Normal Mode Diagnostics	Test not available, use System Diagnostics	Test not available, use System Diagnostics	Requires Normal Mode settings of 0.75 mA, 15 Hz, and 30 sec (or greater). Stimulates at Normal Mode settings for approximately 14 seconds.

Table 9. Diagnostic Test Summary (continued)

Diagnostic Tests	Model 1000 Model 1000-D	Model 106 Model 105 Model 104 Model 103 Model 8103	Model 102 Model 102R
Generator Diagnostics	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 0 mA, then only the impedance measurement is collected.	Assesses impedance at 0.25 mA and stimulates at programmed Normal Mode parameters for approximately 4 seconds. If output is 0 mA, then only the impedance measurement is collected.	Stimulates at 1.0 mA, 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.
Lead Impedance	The actual lead impedance measurement is reported. ⓘ NOTE: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours	The actual lead impedance measurement is reported. ⓘ NOTE: Once programmed ON, lead impedance measurement readings are automatically performed once every 24 hours	The estimated lead impedance range at 1 mA and 500 µsec is reported.

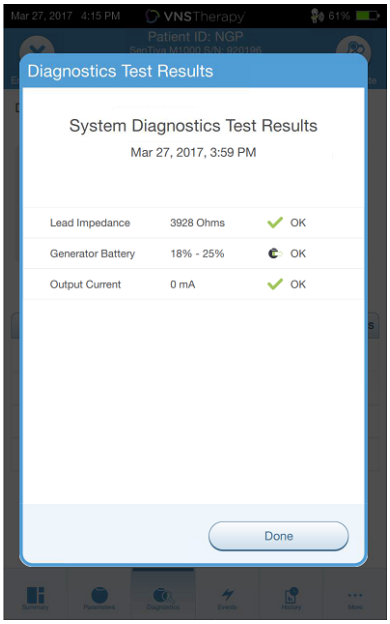
*Minor differences in the system diagnostics test exist for Model 1000 with serial numbers < 100,000. For more information, see Model 1000 (Serial Numbers < 1000,000 Only) in the indication specific physician's manual.

11.4. 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 / Model 102R 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.

11.5. Read Diagnostic Test Results

Figure 37. Diagnostics Test Results Screen Example



11.5.1. Diagnostic / Parameter Result Summary

The various test parameters and their values / meanings across the different diagnostics tests are summarized in the tables below.

NOTE: For abnormal results, refer to "Troubleshooting" on page 93 for additional instructions.

Table 10. Diagnostic / Parameter Result Summary — Lead Impedance

Parameter Name	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 is within normal range.	Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103 Measured lead impedance value (Ω) and overall status of **OK**, **LOW**, or **HIGH**	**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 93 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 93 for additional instructions.
Lead Impedance	Indicates measured or estimated impedance when delivering the output current during testing and whether it is within normal range.	Model 102 Model 102R Estimated lead impedance range (Ω) and overall status of **OK** or **HIGH**. See Skin/Formats/CrossReferencePrintFormat ("" on page 1). NOTE: If you use software v1.0 or 1.5, update to v1.6.	**OK**: Impedance is within acceptable operating range. No special attention is required. **HIGH**: Impedance is higher than expected and the generator may not be able to deliver the programmed therapy. See "Troubleshooting" on page 93 for additional instructions.

Table 11. Diagnostic / Parameter Result Summary — Generator Battery

Parameter Name	Parameter Description	Parameter Values / Results	What Does the Value or Result Mean?
Generator Battery	Indicates battery status of the generator using one of the following: 1. OK 2. Intensified follow-up indicator (IFI) 3. Near end of service (NEOS) 4. End of service (EOS)	Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103 OK IFI NEOS 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. NEOS: The 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.
Generator Battery	Indicates battery status of the generator using one of the following: 1. OK 2. Intensified follow-up indicator (IFI) 3. Near end of service (NEOS) 4. End of service (EOS)	Model 102 Model 102R OK NEOS	OK: Battery level is within normal operating range and no special attention is required. NEOS: A System Diagnostics test is recommended to verify the NEOS status. If confirmed, the generator should be replaced as soon as possible.

Table 12. Diagnostic / Parameter Result Summary — Output Current / Current Delivered

Parameter Name	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	Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103 Output current value (mA) and overall status of **OK** or **LOW**	Value indicates the stimulation output delivered during the diagnostic test. **OK**: Current is being delivered at the programmed level. **LOW**: Programmed current is possibly not being delivered at the specified level.
Output Current / Current Delivered	Indicates the stimulation output current delivered during the Diagnostics test, and the test status based on the programmed settings	Model 102 Model 102R 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. **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 diagnostic tests.

11.5.2. DC DC Code and Lead Impedance

Applicable Models: Model 102 Model 102R

For these models the lead impedance values are estimated based on DC DC code (displayed in previous versions of VNS Therapy software). The conversion between DC DC code and estimated impedance range are listed in the table below.

Table 13. DC DC Code Conversion and Estimated Impedance Range Lead Impedance

DC DC Code	Estimated Impedance Range (Lead Impedance Value at 1 mA, 500 µsec)
0	≤ 1700 Ω
1	1800–2800 Ω
2	2900–4000 Ω
3	4100–5200 Ω
4	5300–6500 Ω
5	6600–7700 Ω
6	7800–8900 Ω
7	≥ 9000 Ω

11.6. Review Diagnostic 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.

CHAPTER 12

History

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

This topic includes the following concepts:

12.1. Parameter Settings History

On the Parameter History screen, you can view a history of settings.

Table 14. Parameter Settings History

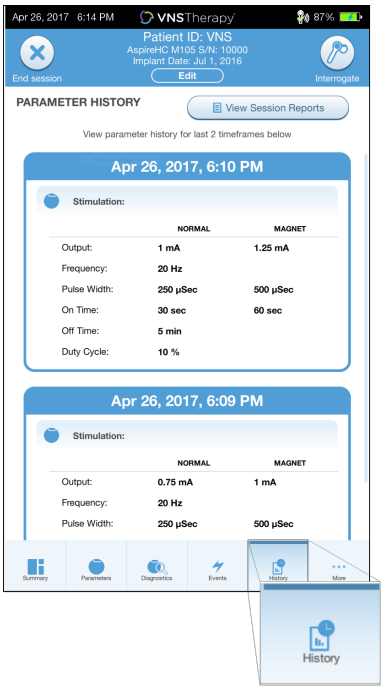
Parameter History	Model 1000 Model 1000-D	Model 106	Model 105	Model 103 Model 104	Model 8103	Model 102 Model 102R
Programming Type						
Manual	Yes	Yes	Yes	Yes	Yes	Yes
Guided	Yes*	Yes	Yes	Yes	Yes	Yes
Scheduled	Yes*	No	No	No	No	No
Day / Night	Yes	No	No	No	No	No
Stimulation Parameters for:						
Normal Mode	Yes	Yes	Yes	Yes	Yes	Yes
AutoStim Mode	Yes	Yes	No	No	No	No
Magnet Mode	Yes	Yes	Yes	Yes	No	Yes
Active Time Periods and Parameter Settings						
Day / Night	Yes	No	No	No	No	No
AutoStim Thresholds						
	Yes	Yes	No	No	No	No
Low Heart Rate / Prone Detection						
	Yes	No	No	No	No	No

*History displays the timestamps for the two most recent guided or scheduled programming steps.

To view Parameter History, complete the following steps:

1. Interrogate the generator.
2. Select **History** on the navigation bar.

Figure 38. Parameter History Screen Example



12.2. 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 programming protocols, including history of steps

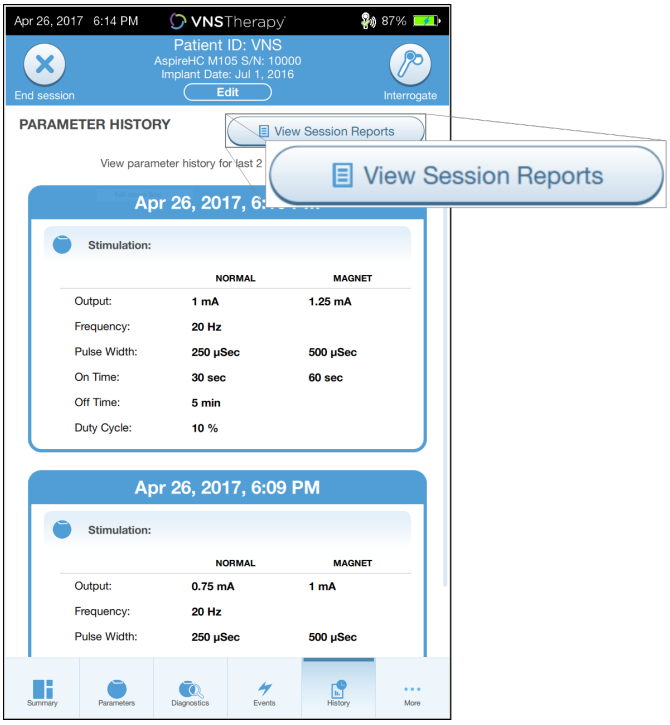
Session reports are generated when **End session** is selected. To view the most recent session report, select **Reports** on the navigation bar while out-of-session. See "Import and Export" on page 92 for details.

NOTE: The information displayed is generator model specific.Not all parameters, features, or modes are applicable for all generator models.

To view a session report, complete the following steps:

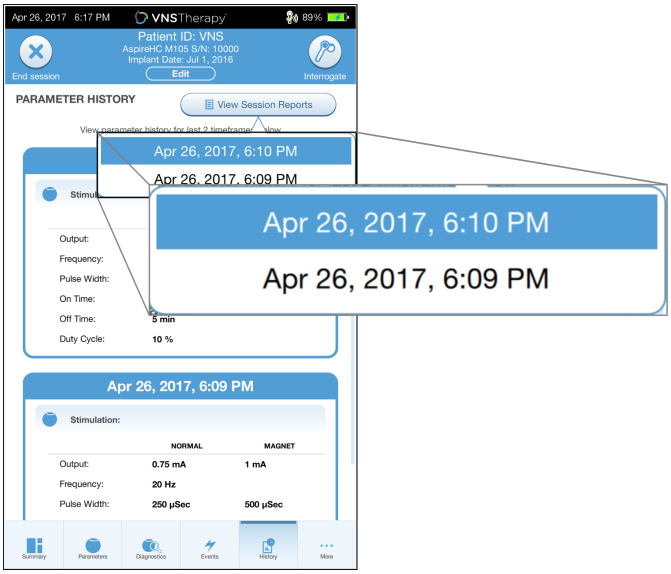
1. Select **View Session Report.**

Figure 39. View Session Reports Screen Example



2. Select the time and date of the desired report. Use the touch screen to scroll or enlarge and reduce the session report display.

Figure 40. Select Time and Date Screen Example



CHAPTER 13

Events and Trends

This topic includes the following concepts:

13.1. Events and Trends Data

Table 15. Events and Trends Data by Model

Data	Model 1000 Model 1000-D	Model 106	Model 105	Model 103 Model 104	Model 8103	Model 102 Model 102R
Event Data						
Summary data from up to 3 recent office visits (defined by 2 interrogations that are at least 12 hours apart)						
Pie-chart [stimulation distribution percentage contributions (Normal Mode, AutoStim Mode, and Magnet Mode) to the overall therapy]	Yes	Yes	No	No	No	No
Average Number of Stimulations per Day for Normal Mode, AutoStim Mode, and Magnet Mode	Yes	Yes	No	No	No	No
Magnet Mode Activation Counts and Timestamps	Yes (up to 50 stored)	Yes (up to 15 stored)	Yes (up to 15 stored)	Yes (up to 15 stored)	No	Yes (up to 15 stored)
Inhibited Stimulation* Counts and Timestamps	Yes (up to 10 stored)	No	No	No	No	No
Trend Data - Daily and Hourly Histograms						
Tachycardia Detection (Without stimulation)	Yes	Yes	No	No	No	No
AutoStim Mode Stimulations	Yes	Yes	No	No	No	No
AutoStim Mode Recent Timestamps	Yes (up to 350 stored)	Yes (up to 4096 stored)	No	No	No	No
Magnet Mode Stimulations	Yes	Yes	No	No	No	No
Prone Position Detection	Yes	No	No	No	No	No
Low Heart Rate Detection	Yes	No	No	No	No	No

* Prevented Normal and AutoStim stimulation

13.2. How to View Event Data

To view event data, complete the following steps:

1. Interrogate the generator. For Model 1000 / Model 1000-D, you must select the **advanced interrogation** option.
2. Tap **Events** on the navigation bar. The display is generator model specific. See "Events and Trends Data" on the previous page.
3. To navigate between office visits, use the left and right arrows.
4. To view recent magnet events, tap **View last [...] timestamps**.

Figure 41. Events and Trends Screen Example

13.3. How to View Trend Data

Applicable Models:	Model 1000	Model 1000-D	Model 106

To view a histogram of trend data, tap **Events** on the navigation bar and then tap the **Trends tab**. You can change the histogram to show day-by-day or hour-by-hour format. The display is generator model specific. See "Events and Trends Data" on the previous page.

13.3.1. Daily View

1. Tap **Event per day** to show one month of detection data in day-by-day format .
2. Tap the time-frame and event types that you want to display.

3. Tap the bar on the histogram to view additional data for a particular day (i.e., Event counts, Parameter thresholds, and Event timestamps). Timestamp information requires an additional interrogation. For details, see "Timestamp Download" on the next page.

Figure 42. Trends - Daily View Screen Example

1 Select to change month.

2 Check event types to include on graph.

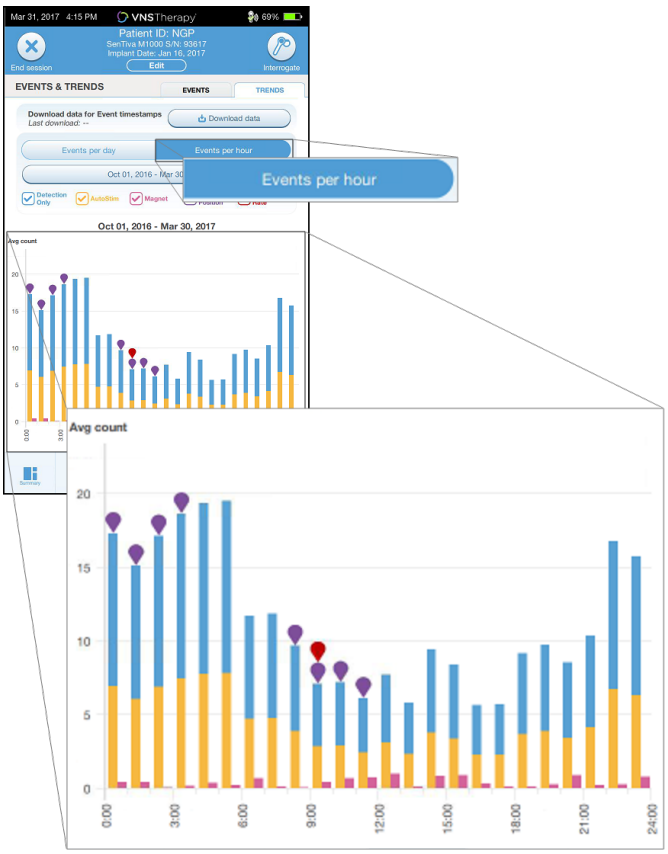
3 Tap on a bar to show more details. Additional data includes:

- Event counts
- Parameter thresholds
- Event timestamps

13.3.2. Hourly View

1. Tap **Events per hour** to show detection data in hour-by-hour format.
2. Tap the time frame (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 43. Trends - Hourly View Screen Example



13.3.2.1. Timestamp Download

To download timestamp information for Daily View, place the Wand over the generator, and tap **Download data**. For Model 1000 / Model 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 and Export" on page 92.

CHAPTER 14

Manage Programmer Information

While out-of-session (prior to generator interrogation), 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

This topic includes the following concepts:

14.1. View and Export Session Reports

To view all session reports saved on the Programmer, tap **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" on page 84.

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. Tap **Export**, and follow on-screen instructions.

14.2. Import and Export

To transfer data between programmers, tap **Import/Export** on the navigation bar from the Main screen. 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. Tap **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. Tap **Import data**.
3. Choose the database copy that will be merged with the existing Programmer database.

14.3. Out-of-Session Troubleshooting Menu

If you have eliminated possible environmental hazards, and completed all possible troubleshooting steps, a generator reset may be necessary. Contact "Technical Support" on page 120 for assistance with a generator reset.

CHAPTER 15

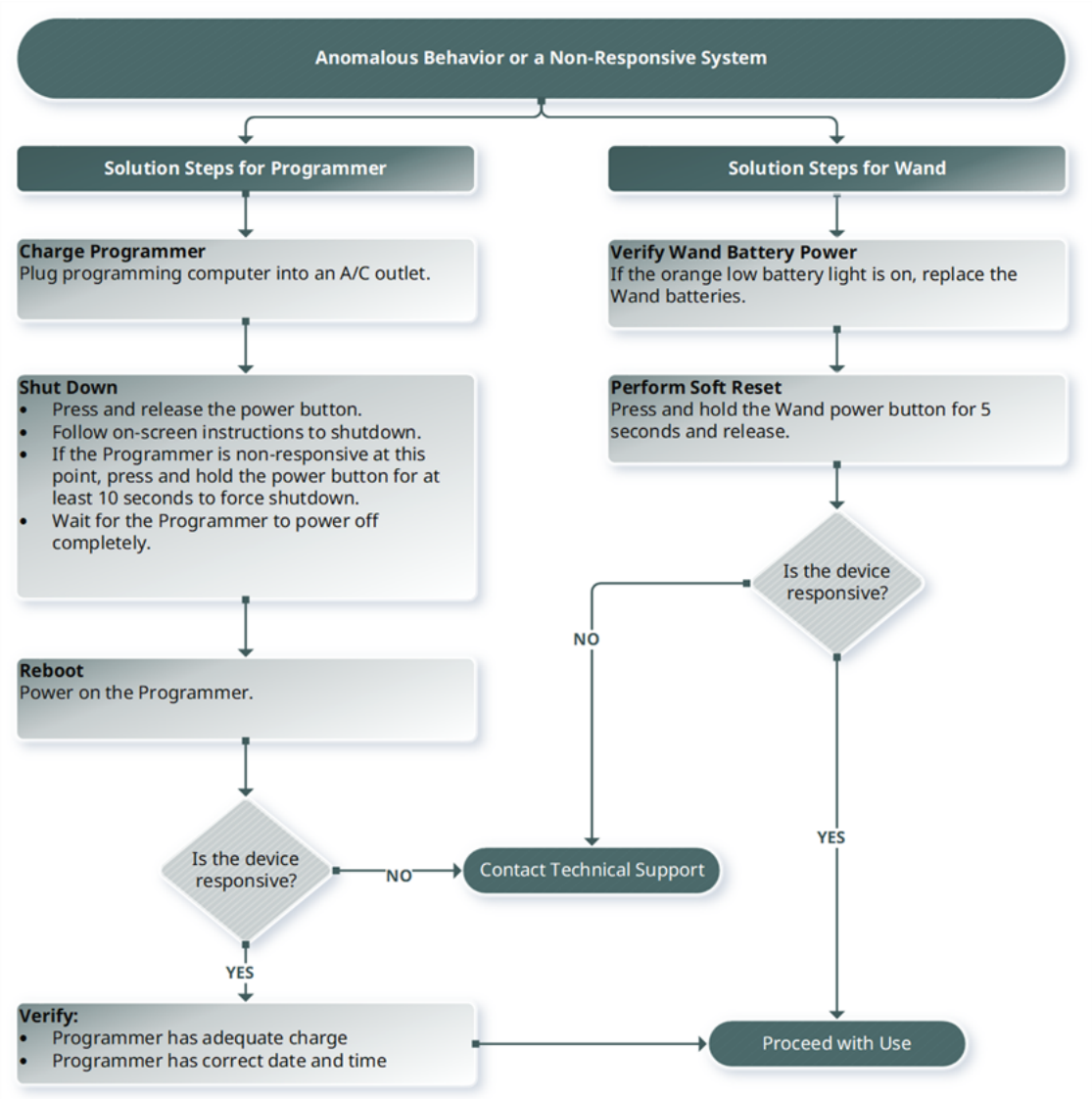
Troubleshooting

For other programming system issues not included in this section, contact "Technical Support" on page 120.

This topic includes the following concepts:

15.1. Anomalous Behavior or Non-Responsive System

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



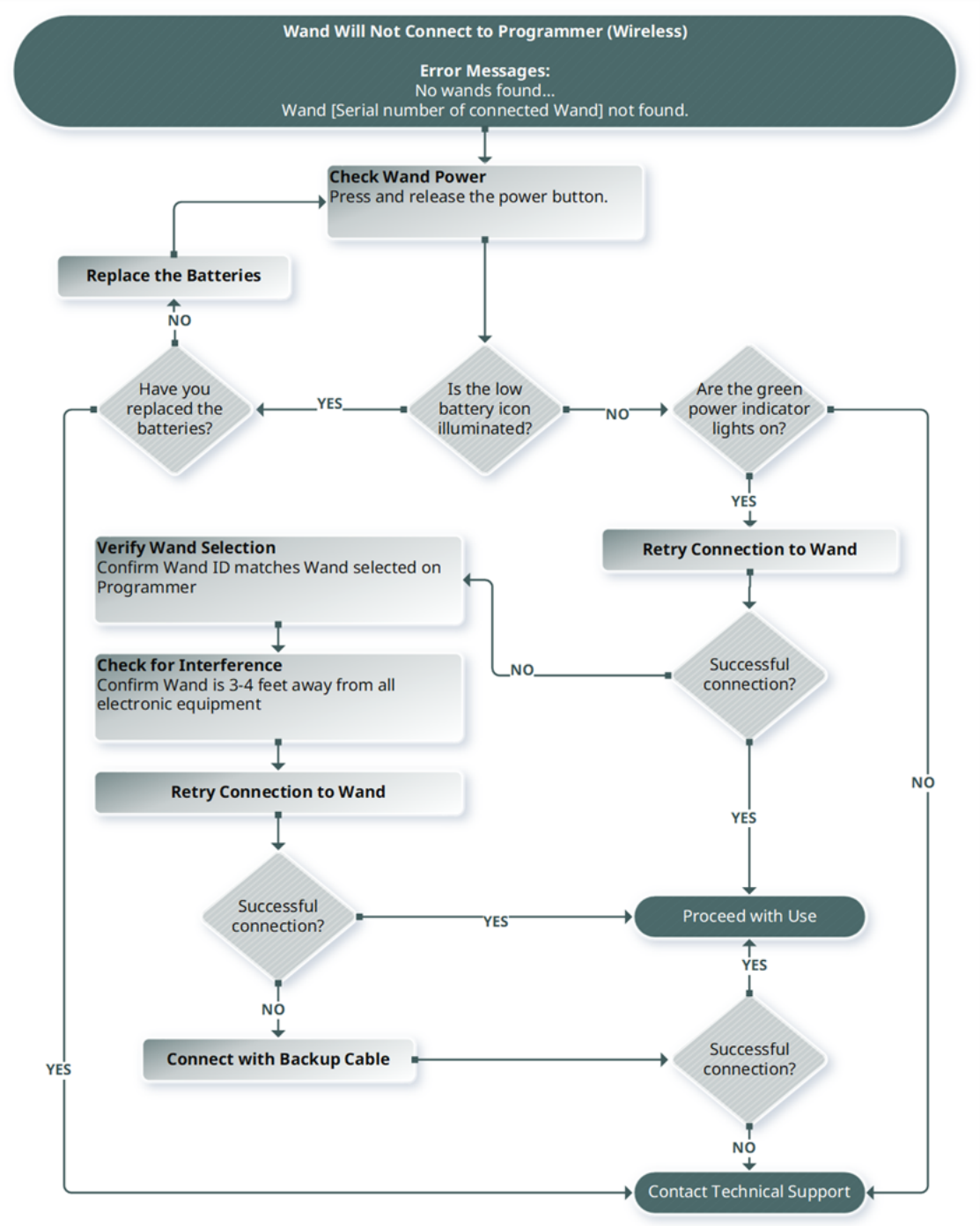
15.2. Communication Issues

15.2.1. Wand Will Not Connect to Programmer (Wireless)

15.2.1.1. Possible Causes

- Wand not powered on
- Depleted Wand batteries
- Electromagnetic interference (EMI) (e.g., OR lights)
- Defective Wand
- Defective Programmer

15.2.1.2. Solution Steps

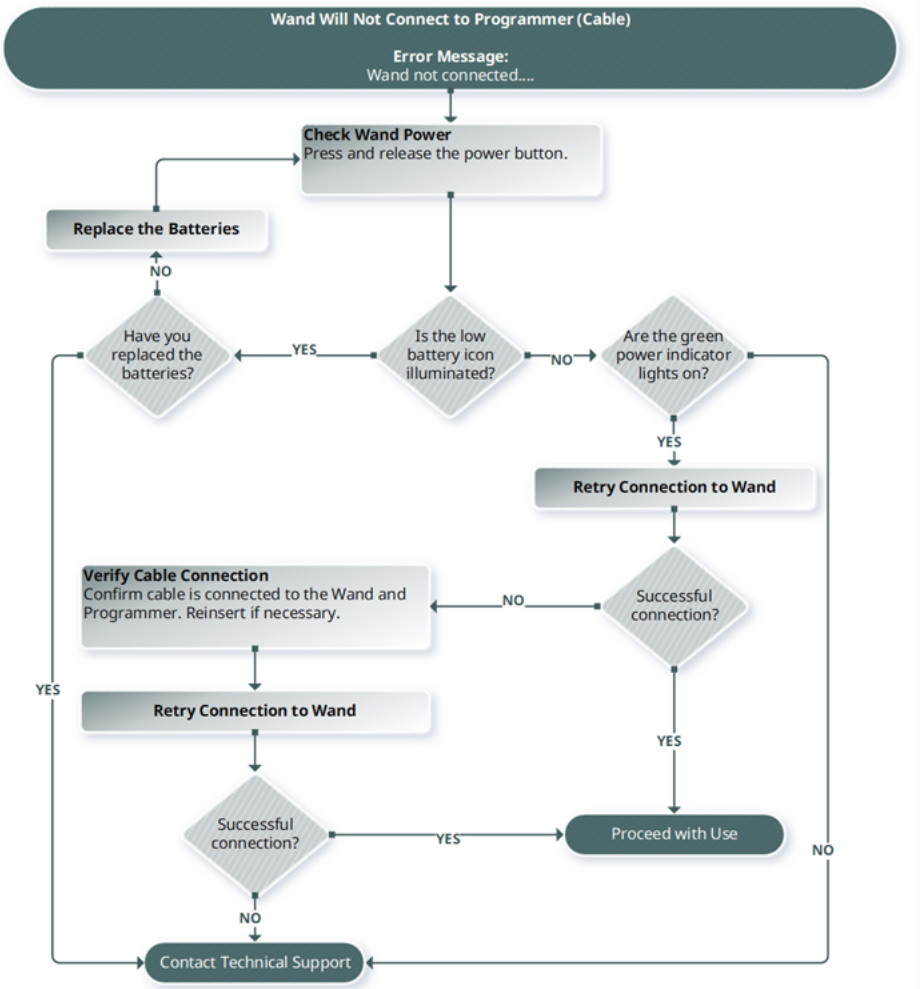


15.2.2. Wand Will Not Connect to Programmer (Cable)

15.2.2.1. Possible Causes

- Wand not powered on
- Improper cable connection between Wand and Programmer
- Depleted Wand batteries
- Improper USB port recognition of the Programmer cable
- Defective Wand
- Defective Programmer

15.2.2.2. Solution Steps

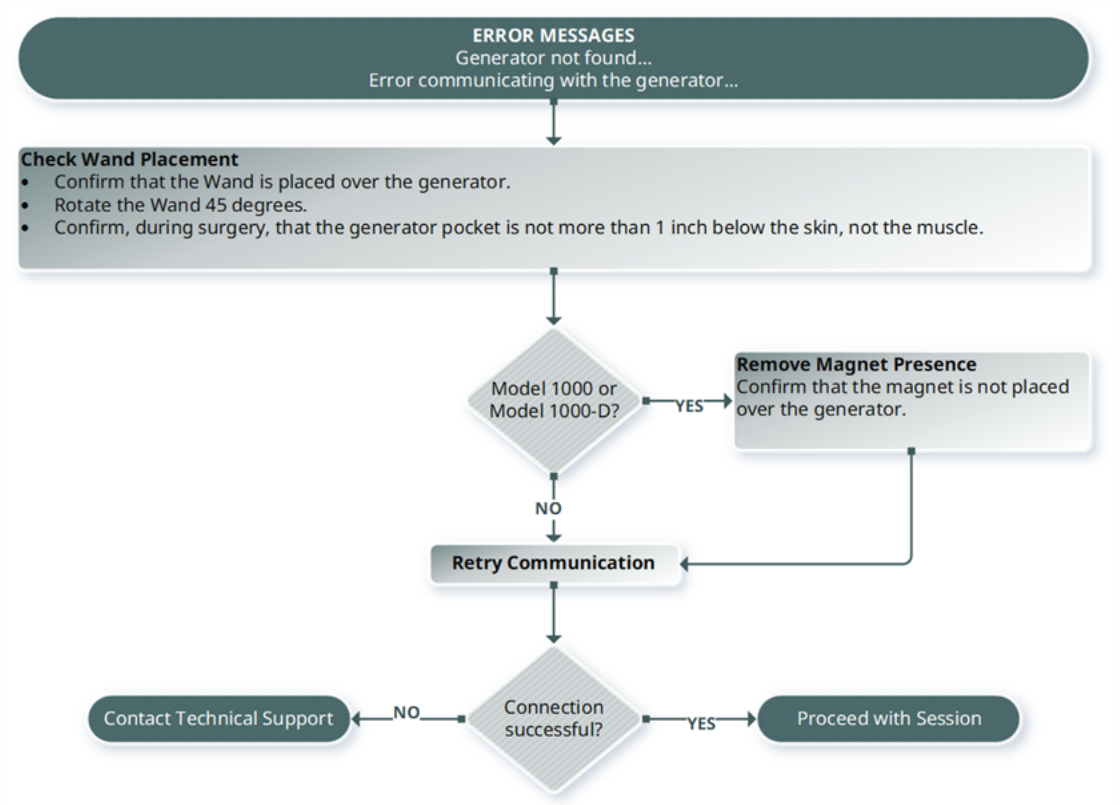


15.2.3. Wand Will Not Communicate with Generator

15.2.3.1. Possible Causes

- Depleted Wand batteries
- Wand is moved away from generator during communication
- Electromagnetic interference (EMI) (e.g., OR lights)
- Generator battery at end of service (EOS)
- Magnet placed over the generator (Model 1000 / Model 1000-D)
- Defective Wand
- Defective Programmer
- Defective generator

15.2.3.2. Solution Steps



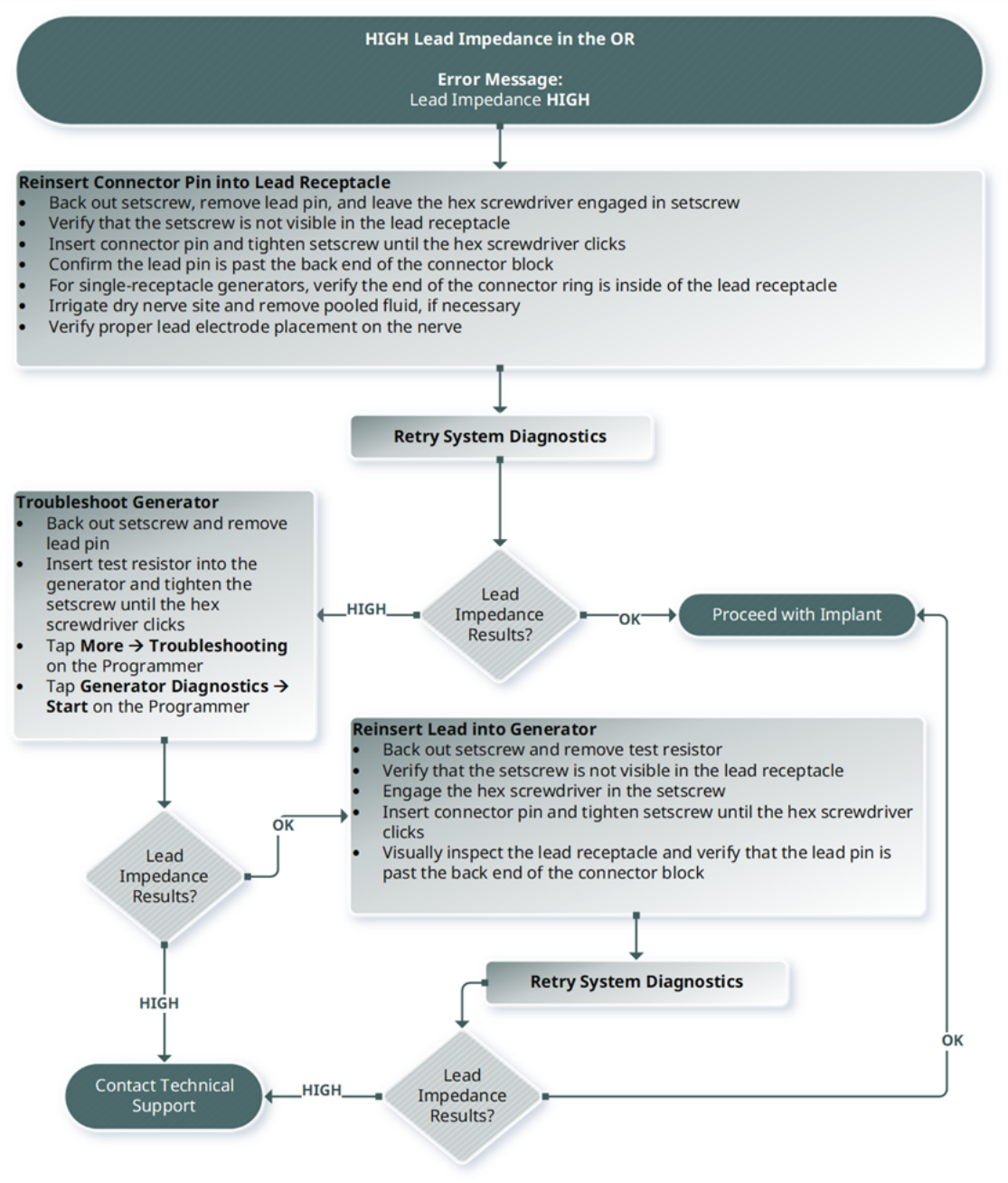
15.3. Lead Impedance Issues

15.3.1. High Lead Impedance in the OR

15.3.1.1. Possible Causes

- Improper connection between the lead and the generator
- Incorrect placement of lead on the nerve
- The nerve has become dry
- Defective generator
- Defective lead

15.3.1.2. Solution Steps

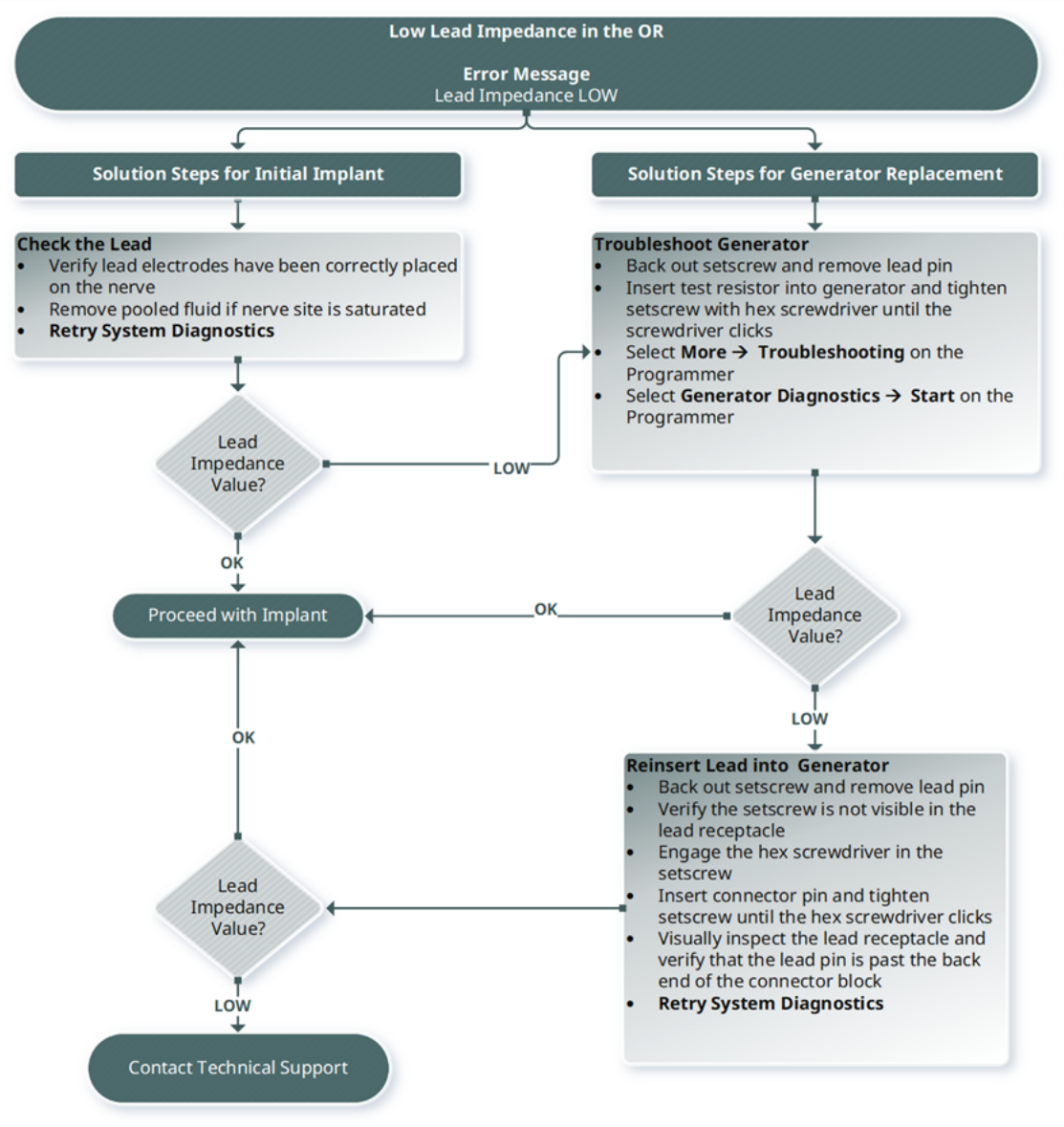


15.3.2. Low Lead Impedance in the OR

15.3.2.1. Possible Causes

- Incorrect placement of lead on the nerve
- Excessive irrigation of the nerve
- Defective generator
- Defective lead
- Short-circuit condition within the lead (during generator replacement surgery)

15.3.2.2. Solution Steps



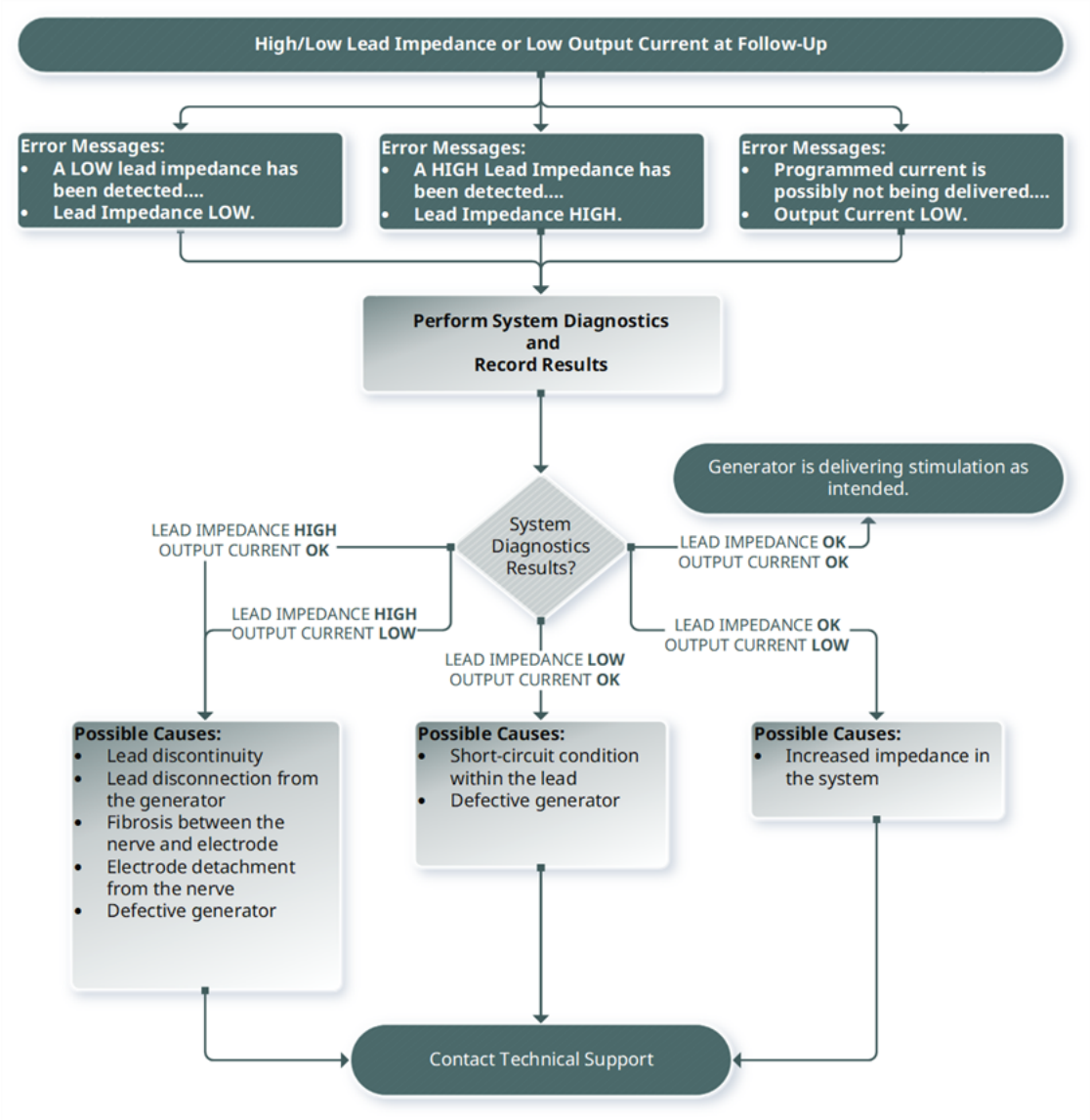
15.3.3. High / Low Lead Impedance or Low Output Current at Follow-Up

Applicable Models:	Model 1000	Model 1000-D	Model 106	Model 105	Model 104	Model 103	Model 8103

15.3.3.1. Possible Causes

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

15.3.3.2. Solution Steps



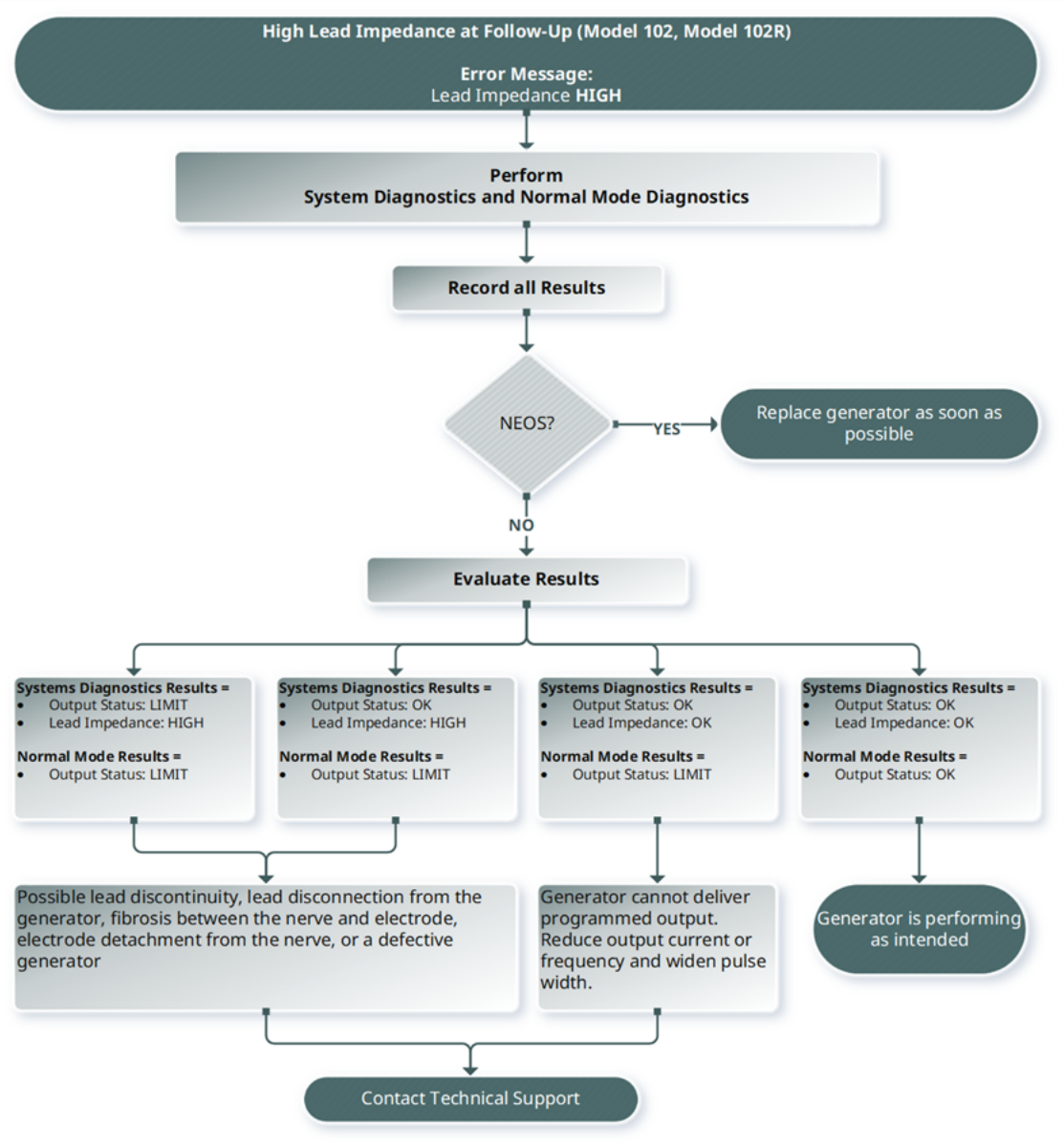
15.3.4. High Lead Impedance at Follow-Up

Applicable Models: Model 102 Model 102R

15.3.4.1. Possible Causes

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

15.3.4.2. Solution Steps



15.4. Battery Issues

15.4.1. Low Battery or End of Service Indications in the OR

15.4.1.1. Possible Causes

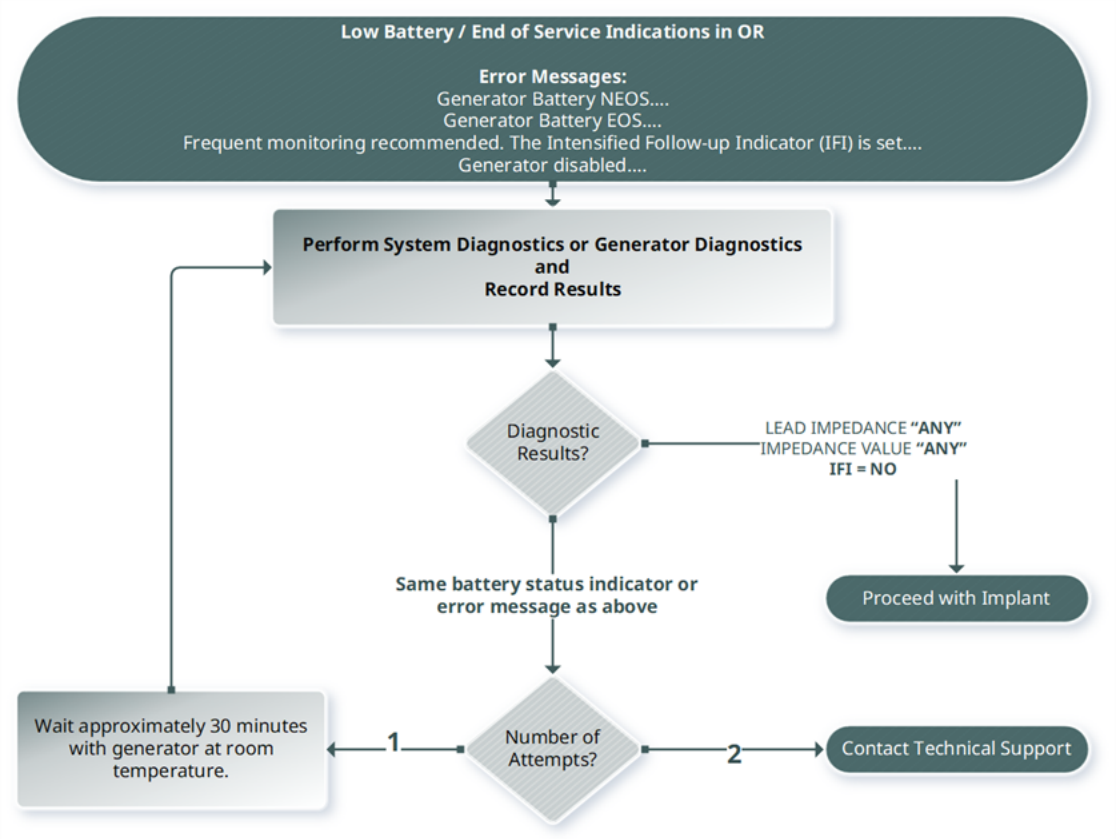
Prior to Surgery

- 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)

15.4.1.2. Solution Steps



15.4.2. New Generator Disabled Due to EOS at First Follow-Up

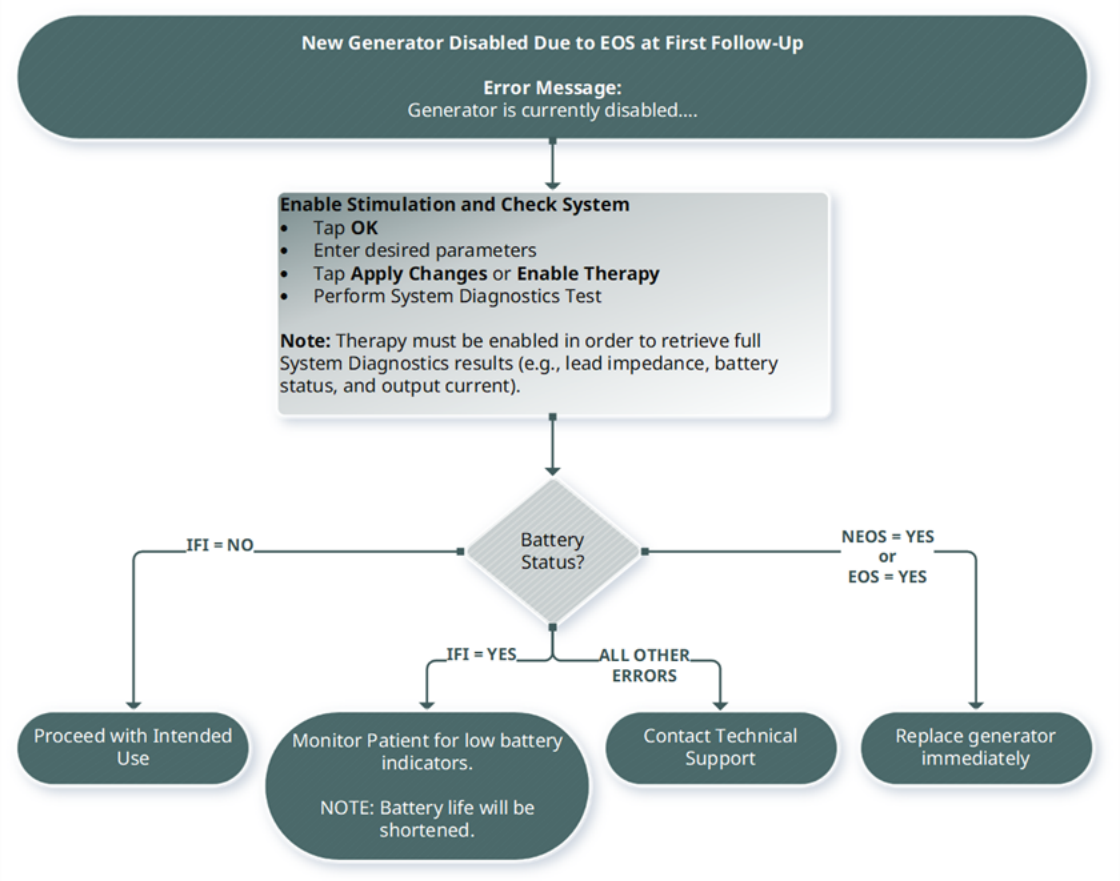
Applicable Models:	Model 1000	Model 1000-D	Model 106	Model 105	Model 104	Model 103	Model 8103

The batteries can temporarily drain and become disabled if exposed to certain conditions.

15.4.2.1. Possible Causes

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

15.4.2.2. Solution Steps



15.4.3. Sudden Decrease in Battery Power

If the generator battery power suddenly decreases, the following are possible causes:

- First visit after a surgery: The decrease may have been caused by exposure to certain conditions (e.g., electrocautery) during VNS or other surgery. If the condition occurred, but was not detected in the OR, it is possible you may detect the decrease at the follow-up visit. The device will still function normally, but will have decreased battery life. Monitor the patient closely for any low battery indicators.
- There has been a significant change in the lead impedance or an increase in programmed stimulation parameters. Evaluate battery power that remains between consecutive patient visits before stimulation parameters are adjusted. Review lead impedance for any significant changes.

If any device issue is suspected, contact "Technical Support" on page 120.

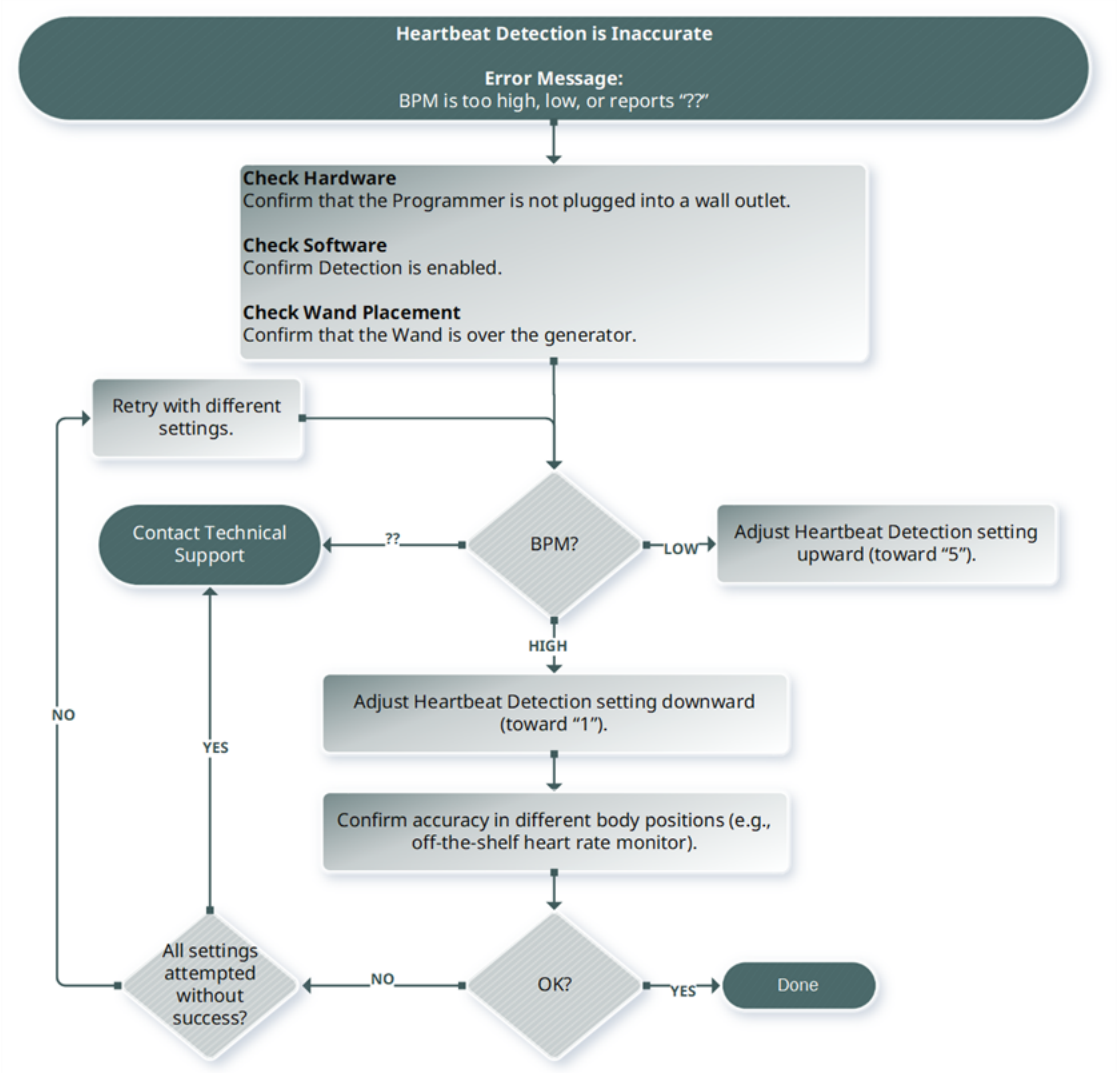
15.5. Detection Issues

Applicable Models: Model 1000 Model 1000-D Model 106

15.5.1. Heartbeat Detection Inaccurate (Over / Under) in the OR or at Follow-Up (Generators Capable of AutoStim)

The heartbeat detection setting may need to be adjusted to accurately detect heartbeats. The Wand must be held over the generator during the entire Verify Heartbeat Detection process.

15.5.1.1. Solution Steps



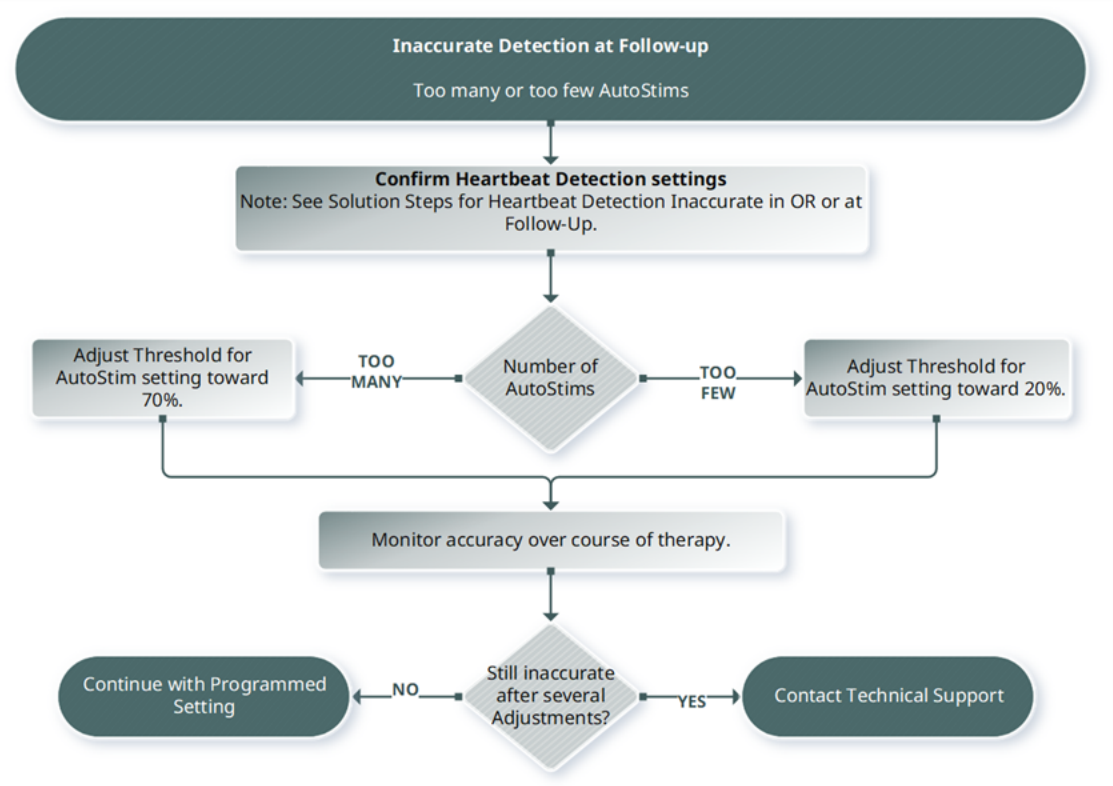
15.5.2. Issue - Inaccurate AutoStim at Follow-Up

Sometimes generator detection settings may miss detection of heart rate changes that may be associated with a seizure.

15.5.2.1. Possible 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.

15.5.2.2. Solution Steps



15.6. Generator Reset

The system allows the generator microprocessor to be reset in the event of a malfunction. A reset is necessary only in the rare case of microprocessor memory malfunction, which might be caused by conditions described in Contraindications, Warnings, and Precautions. A microprocessor reset may be appropriate when the generator and the programming system are unable to communicate.

NOTE: For suggestions in solving communication difficulties, see "Communication Issues" on page 95.

If you have eliminated possible environmental hazards, and completed all possible troubleshooting steps, a generator reset may be necessary. Contact "Technical Support" on page 120 for assistance with a generator reset.

Model 1000 Model 1000-D Model 106 Model 105 Model 104 Model 103 Model 8103	CAUTION: *Generator reset*: When the generator is reset, optional features (e.g., Day-Night Programming) and stimulation output are disabled (0 mA); however, all settings and device history are preserved. After a successful reset, the generator stimulation output may be re-enabled to resume operation at the previously programmed settings and optional features reactivated.
Model 102 Model 102R	CAUTION: *Generator reset*: When the generator is reset, all device history information is lost, and the reset parameters (0 mA, 10 Hz; 500 µsec; ON time, 30 sec; OFF time, 60 min) are internally programmed. A generator reset turns the device off (**output current** = 0 mA). After a successful reset, the generator stimulation output may be re-enabled to resume operation at the previously programmed settings and optional features reactivated.

CHAPTER 16

Maintenance, Handling, and Disposal

Follow the guidelines in this section for optimal performance and safety.

This topic includes the following concepts:

16.1. Maintenance, Handling and Disposal

Follow the guidelines below for proper maintenance, handling and disposal for the programming system.

16.1.1. System

Clean External Surfaces

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

Do not sterilize any parts of the system.

Inspect Parts

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

Liquids

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

16.1.2. Programmer

Touchscreen Display

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

Operating and Storage

For information on operating and storage conditions, see "Programming System Specifications and Guidance" on page 116.

16.1.3. Wand

Battery Status

Check the Wand battery periodically to verify battery status.

Battery Installation

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

Open Battery Compartment

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

Use and Storage

For information on use and storage conditions, see "Programming System Specifications and Guidance" on page 116.

16.1.4. Disposal

Battery Disposal

When you replace the Wand AA batteries, dispose the used batteries in accordance with all applicable federal, state, and local regulations.

Programming System Hardware Disposal

Return the programming system hardware to LivaNova for examination and safe disposal.

CHAPTER 17

Programming System Specifications and Guidance

This topic includes the following concepts:

17.1. Wand and Programmer Specifications

Table 16. Wand and Programmer Specifications

	Wand	Programmer
Storage Conditions		
Temperature	-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 (Wand to 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	N/A
Transmitter Operating Frequency	Inductive: 82 kHz; 89 kHz (102 only) *Bluetooth*® 2.1: 2402 - 2480 MHz	N/A
Receiver Bandwidth	Inductive: 12.5 to 135 kHz *Bluetooth*® 2.1: 2402 - 2480 MHz	N/A
Cables	USB Type C cable (2.87 m)	N/A
Applied Part	Entire device is Type BF	N/A

17.2. Wand Specifications

The Wand is intended to be used in the electromagnet conditions specified in the tables below.

Table 17. Wand Electromagnetic Emissions

EmissionsTest	Compliance Level
RF Emissions CISPR 11	Group 1, Class A

Table 17. Wand Electromagnetic Emissions (continued)

EmissionsTest	Compliance Level
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 18. Wand 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 19.

Wand 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
710 745 780	LTE Band 13, 17	9 V/m
810 870 930	GSM 800/900 TETRA 800 IDEN 820 CDMA 850 LTE Band 5	28 V/m
1720 1845 1970	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	28 V/m

Table 19. Wand Electromagnetic Immunity to Proximity Fields From RF Wireless Communications Equipment (continued)

Test Frequency	Service	Compliance Level
2450	*Bluetooth*® 2.1 WLAN 802.11 b/g/n RFID 2450 LTE Band 7	28 V/m
5240 5500 5785	WLAN 802.11 a/n	9 V/m

17.3. Wireless Security

Table 20. Programming System 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

Contacts and Resources

For information and support in use of the system or any of its accessories, contact LivaNova.

Contacts

	 LivaNova USA, Inc. 100 Cyberonics Blvd Houston, Texas 77058 USA
Tel:	+1 281 228 7200 (Worldwide)
Toll free:	+1 800 332 1375 (US/Canada)
Fax:	+1 281 218 9332
Website:	www.livanova.com

Technical Support

Available 24 hours per day	
Toll free:	+1 866 882 8804 (US/Canada)
Tel:	+1 281 228 7330 (Worldwide)

Regulatory Authority Websites

Report all adverse events related to the device to LivaNova and to your local regulatory authority.

US	https://www.fda.gov