Physician's Manual

VNS Therapy® Programming System

For Healthcare Professionals

May 2017

CE 0344

Note: This manual contains information on the use of the VNS Therapy programming software programming system. Physicians should refer to the VNS Therapy Pulse Generator physician's manuals for additional important prescribing and safety information.

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1. DESCRIPTION AND USE

1.1. General Description

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

- Model 102 Pulse
- Model 102R Pulse Duo
- Model 103 Demipulse
- Model 104 Demipulse Duo
- Model 105 ApsireHC
- Model 106 AspireSR
- Model 1000 SenTiva

Note: For a list of symbols and terms used with the LivaNova VNS Therapy Programming System, go to www.VNSTherapy.com/???.

1.1.1. Intended Use

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

1.2. System Communication

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

The system allows you to:

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

1.2.1. Programmer Communications

The programmer will indicate communication in the following ways:

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

1.2.2. Wand Communications

The wand indicator lights will illuminate when the:

- wand is powered on (two green lights below power button)
- wand is connected to the programmer (four green lights around the power button)
- wand is communicating with the generator (white flashing generator icon)
- wand battery is low (orange battery indicator)

1.2.3. Communication Distance

1.2.3.1. Wand and Programmer

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

1.2.3.2. Wand and Generator

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

2. PRECAUTIONS

For optimal performance and safety, review the following:

- Do not load other software onto the programmer. Doing so may interfere with the efficiency and function of the pre-installed VNS Therapy Software.
- The programmer is tested to the same level as typical consumer electronic devices. However, the equipment is not rated for use in the patient environment (as defined by IEC 60601-1). Do not simultaneously touch the patient and programmer while programming. Additionally, do not plug the programmer into AC power while it is being used in a patient environment.

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

Warning: Do not modify the system unless directed to by LivaNova.

Warning: 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.

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

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

Warning: MR Unsafe devices include the programming wand, computer, and patient magnet. Theses devices must not be brought into the MR scanner room.

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

3. GET STARTED

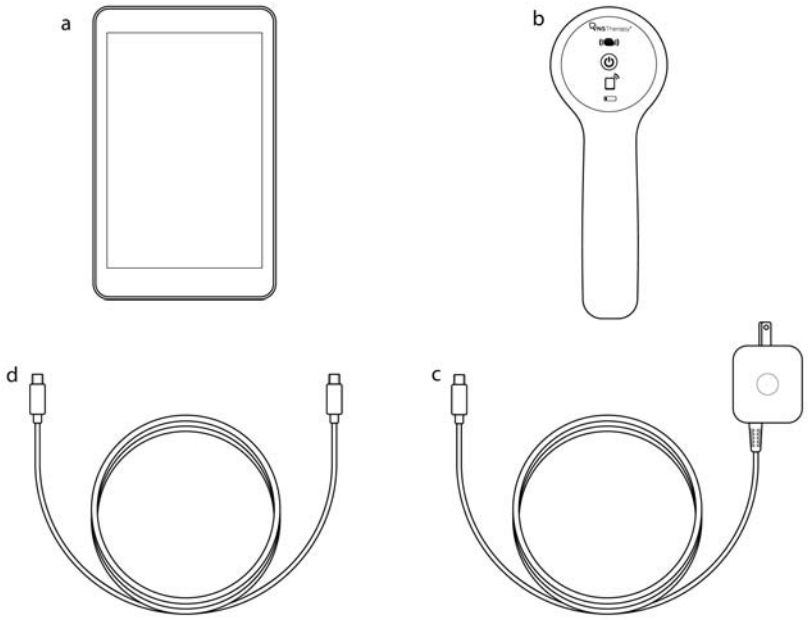
3.1. Parts Included

The system includes the following items (Figure 1):

- Touch-screen Programmer preloaded with the VNS Therapy Software
- A/C power adapter
- Wand model 2000 with two AA batteries
- Backup wand USB cable

Figure 1. System Parts

a. Programmer
b. AC Power Adapter
c. Wand
d. Wand USB Cable



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

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

3.2. Prepare System for Use

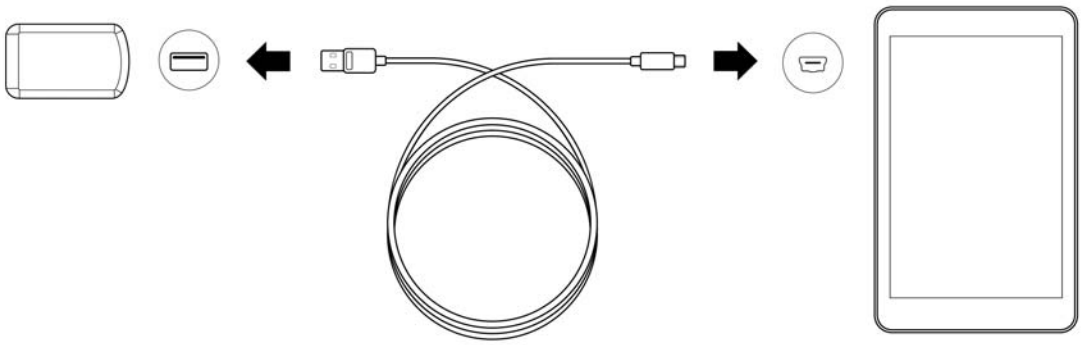
Before using the programming system in a patient session, make sure the programmer and wand are fully charged and ready to use. Verify the date and time on the programmer are correct.

3.3. Basic Operation

3.3.1. Charge the Programmer

To charge the programmer, connect the AC adapter and plug into an outlet (see figure below). Charge the programmer when not in use so that there is enough battery power when using during a patient session.

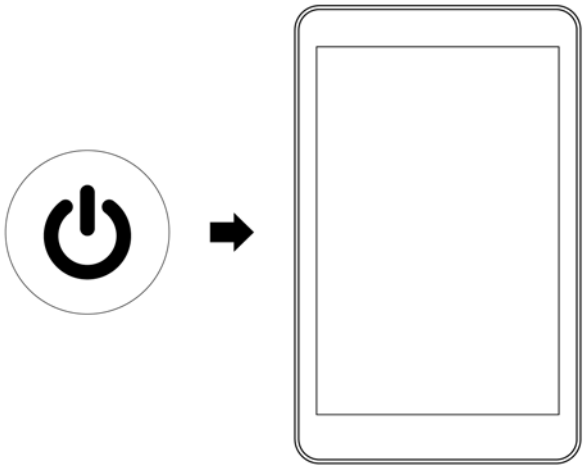
Figure 2. Connect the Charger



3.3.2. Turn Programmer ON/OFF

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

Figure 3. Power On Programmer



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

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

3.3.3. Turn the Programmer Screen ON/OFF

Once the programmer is turned on, the screen will automatically turn off after 5 minutes of inactivity. You can also turn the screen on or off by quickly pressing and releasing the power button. Use this method when you want to preserve battery, but not shut down the programmer.

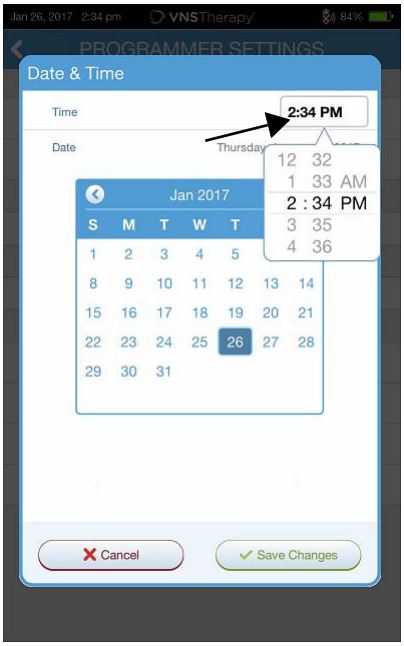
3.3.4. Check Programmer Battery

After VNS software startup is complete, the programmer battery status can be checked at any time by viewing the indicator at the top right corner of any software screen. For more information, refer to "How to Use the Software" on page 19.

3.3.5. Set the Programmer Date and Time

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

Figure 4. Adjust Programmer Time and Date



Select time to adjust time

Select day on calendar to adjust date

Note: The programmer does not automatically adjust for Daylight Saving Time or changes in time zone. Adjust the time and date manually as needed.

3.3.6. Turn on Wand/Check Wand Battery

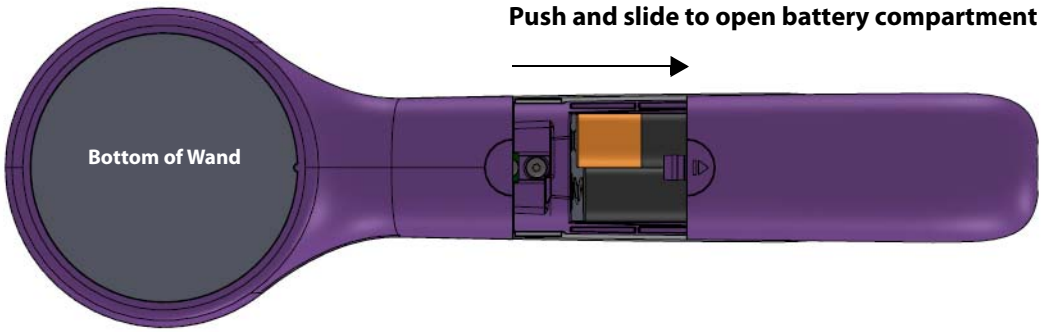
Turn the wand on by pressing and releasing the power button (Figure 5). If the battery is OK, green lights will illuminate (Figure 6). If the battery is low, the low battery indicator will illuminate (Figure 7). If the battery is low, replace the batteries by removing the cover located on the back of the wand (Figure 8).

Figure 5. Power On Wand

Figure 6. Power Indicator (Battery OK)

Figure 7. Low Battery Indicator

Figure 8. Wand Battery Replacement



Note: Once powered on, the wand will automatically power down (standby) after 60 seconds of inactivity to conserve battery.

3.4. Connect Wand/Programmer

The system allows you to connect the wand to the programmer wirelessly or with backup USB cable.

To connect wirelessly, you have two options:

- Set up a preferred wand connection that is always used with that programmer. This setup is recommended for wands and programmers that are always used together. It provides a quicker connection when interrogating the patient's generator, since the programmer will automatically look for the preferred wand.
- Choose a wand as part of interrogating the patient's generator. This method is recommended if you have several interchangeable programming systems in your area. When interrogating a patient's generator, the programmer will search for all available wands in range.

3.4.1. Preferred Wireless Wand Setup

To set up a preferred wireless connection between the wand and the programmer, do the following:

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

3.4.2. Wired Wand Setup

Included with the system is a USB cable that connects the wand to the programmer. Use this as a back up method when a wireless connection is not available. Once connected, the software will identify the specific wand connected via the cable. After interrogate is selected, the four green indicators will light up once the wand begins communicating with the generator. The green indicator lights will turn off after 60 seconds of inactivity.

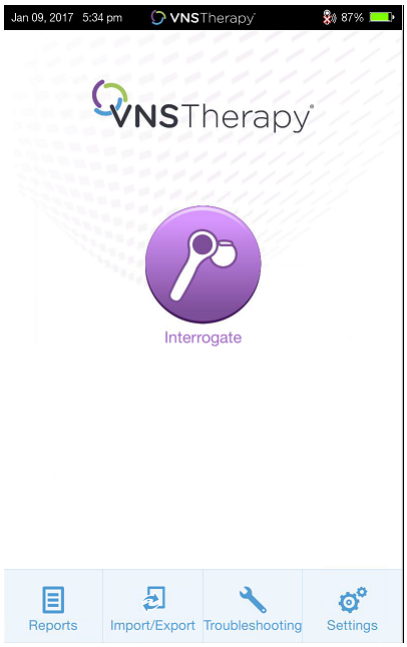
4. INTERROGATING THE GENERATOR

4.1. Interrogate (No Preferred Wand)

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

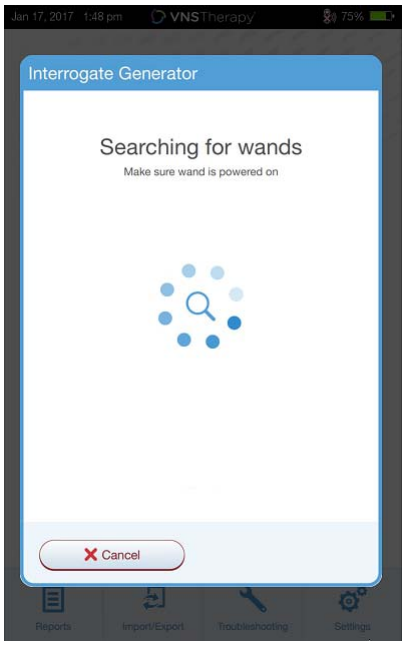
To begin, power on the programmer. Upon startup, the Main screen will display (Figure 9).

Figure 9. Main Screen



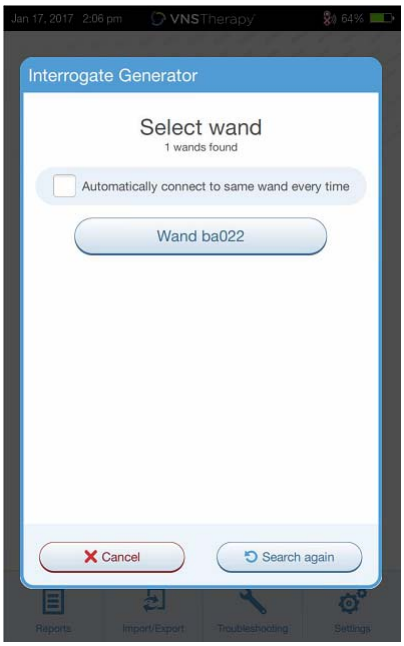
Next, turn on the wand by pressing and releasing the power button. Two green lights will illuminate indicating the wand is ready to connect. While the green wand lights are illuminated (Figure 6), select Interrogate on the programmer screen. The programmer will search for available wands. See Figure 10.

Figure 10. Wand Search Screen



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

Figure 11. Wand (SN) Selection Screen

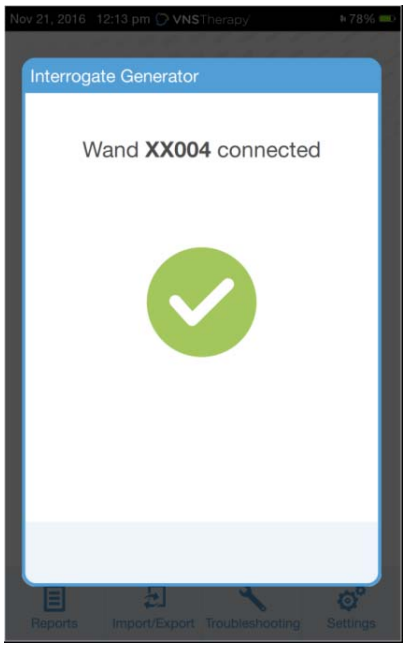


SN location on back of Wand

Note: To use a specific want in subsequent sessions, check the "Automatically connect to the same wand every time" box on the screen before choosing a wand.

Once the wand has connected, the software will indicate a successful connection and four green lights will illuminate around the wand power button (Figure 12).

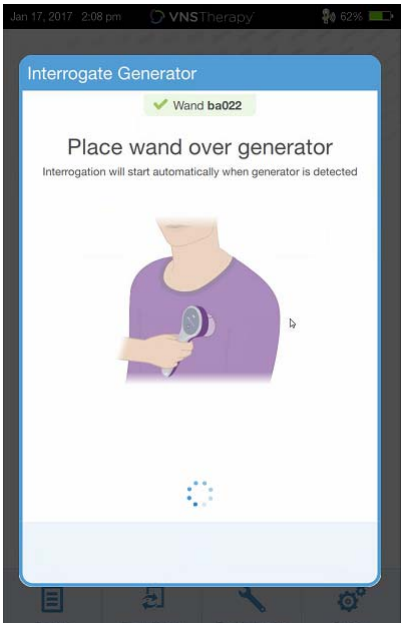
Figure 12. Successful Wand Connection



Successful wand connection lights illuminated

Place the wand over the generator as shown on the software (Figure 13). Once the wand recognizes the generator, the interrogation will complete and the software will display the summary screen. For more details refer to "How to Use the Software" on page 19.

Figure 13. Interrogate Generator Screen



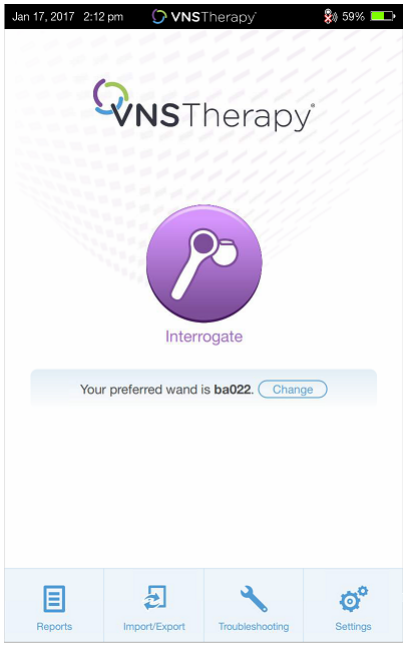
Generator icon will flash during interrogation

4.2. Interrogate (With Preferred Wand)

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

The main screen will display to the preferred wand information. See Figure 14. Make sure wand is powered on before selection interrogate. After the programmer and wand are connected, place the wand over the generator to complete the interrogation.

Figure 14. Main Screen - Preferred Wand



4.3. Interrogate (Change Preferred Wand)

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

1. Power on the new wand
2. Select the Change button on the Main Screen.

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

Note: To clear the preferred wand and connect manually, select Settings from the Main screen. Within the Wand Settings, set the Preferred Wand status to Disabled. Select the back button on the upper left of the screen to return to the Main screen. Next time you interrogate, manually connect to a wand following the steps in "Interrogate (No Preferred Wand)" on page 15.

5. How to Use the Software

The VNS Therapy Software displays messages and prompts to guide you through the software.

5.1. Summary Screen

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

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

Note: The information displayed is specific to the generator model. Not all parameters will be applicable for all generator models.

Note: An office visit is defined as any two interrogations separated by more than 12 hours.

Figure 15. Summary Screen

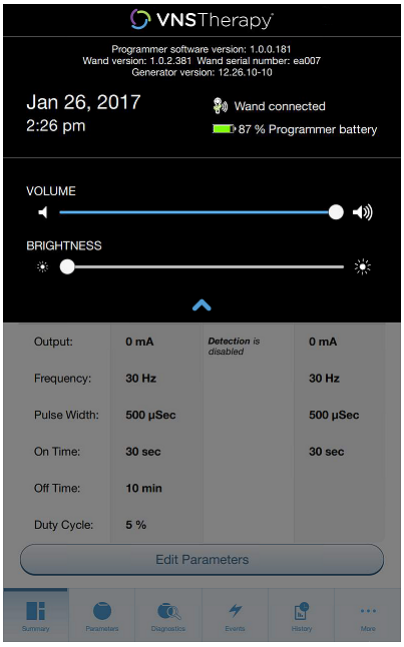
1. Current programmer date and time
2. Wand connection and programmer battery status
3. Ends current session
4. Generator and patient information
5. Interrogate generator again
6. Last known diagnostics measurements
7. View stimulation events
8. Current parameters
9. Navigation bar to additional software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

5.2. Quick Access Bar

From any software screen, tap the VNS Therapy logo on the title bar at the top of the screen to access programmer settings and system information (Figure 16). This drop-down bar shows the following:

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

Figure 16. Quick Access Bar



6. PROGRAM THE DEVICE

To program any information into the patient's generator, you must interrogate the generator.

6.1. Edit Patient Data

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

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

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

To enter or edit this information, do the following:

1. Interrogate the patient's generator
2. Review the generator information displayed at the top of the screen
3. Select "Edit" and enter the desired information (Figure 17)
4. Apply Changes and Confirm to program the information into the generator

Figure 17. Edit Patient ID Screen

6.2. How to Adjust Parameter Settings

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

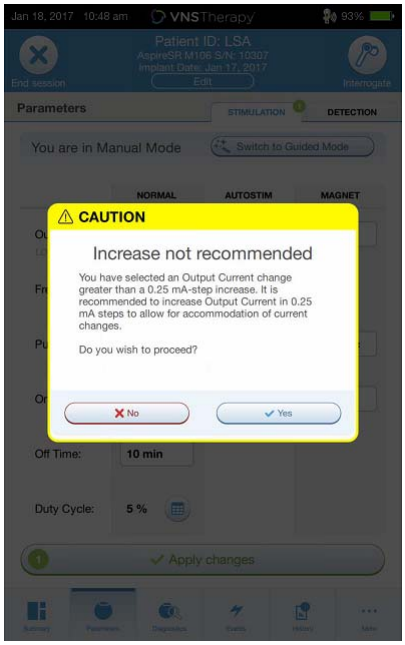
From the Parameters screen, you can change stimulation or detection parameters, depending on the model of generator. Refer to the Technical Manual for a full list of programmable parameters available for each generator. For models 102-105, only Normal Mode and Magnet stimulation parameters are available. For models 106 and 1000, AutoStim and Detection parameters are also available. Detection parameters will display on a separate tab. Review all tabs when adjusting parameters.

To change a parameter setting, first select the tab of interest on the Parameter screen, and then follow these steps:

1. Tap the Value for the parameter you want to change. A pop-up menu displays the range of possible values. If there are values greater than or less than those shown on the screen you can view them by scrolling up or down.
2. Select the new target value for the parameter. For Output Current, if the target value selected is greater than 0.25 mA compared to the currently programmed value in the generator, an Output Warning will appear (Figure 18).

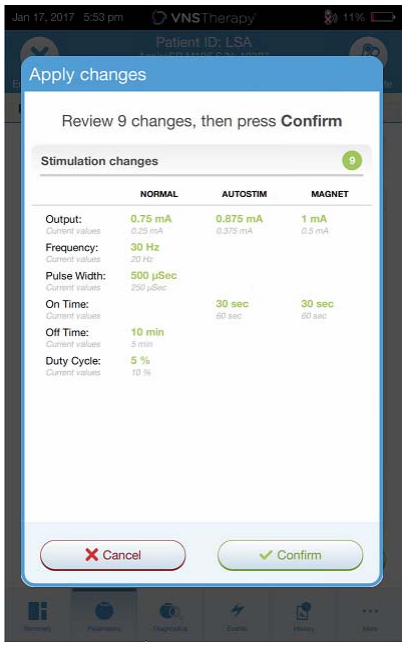
Note: LivaNova recommends that during the initial parameter adjustments after implant, the output current be set to 0 mA and then slowly increased by 0.25 mA increments until the patient feels the stimulation at a comfortable level. Patients who are receiving replacement generators may also be started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

Figure 18. Output Warning Screen



3. New parameter selections that have not been programmed to the generator are in green. Programmed, unchanged, settings are in black.
4. Select Apply Changes at the bottom of the Parameter screen, to proceed to the Confirmation screen (Figure 19).
5. Confirm the updated parameter setting(s) are correct. If correct, place the wand over the generator and select Confirm to program the new settings to the generator. If incorrect, select Cancel to return to the Parameter screen to make further adjustments.
6. Upon successful update to parameters, you will be notified with an on-screen message showing the newly programmed parameter settings.

Figure 19. Confirmation Screen



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

Caution: For models 102(R) 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.

Caution: 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). While LivaNova limits the maximum programmable frequency to 30 Hz, it is recommended that you do not stimulate with excess duty cycle. Physicians should also warn patients about continuous or frequent magnet use as this could lead to early battery depletion. [IS ALL THIS INFORMATION NECESSARY?]

6.3. How to Configure Seizure Detection Settings

You can adjust seizure detection settings under the Detection tab on the Parameter screen for models 106 and 1000 generators.

6.3.1. Turning the Detection Feature ON/OFF

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

Note: If Detection is disabled, the parameters on the Detection tab are not visible and AutoStim is not activated.

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

6.3.2. Set Heartbeat Detection

In order for the generator to accurately detect heartbeats, the heartbeat detection must be set for the individual patient.

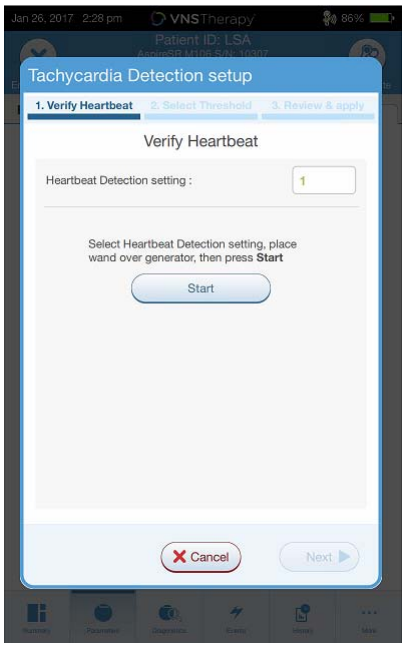
For model 106 and 1000 generators, you must manually select from a range of heartbeat detection sensitivity values: 1 (least sensitive; for use with largest amplitude ECG signals) to 5 (most sensitive; for use with smallest amplitude ECG signals). The setting will not change unless manually programmed to a different value.

6.3.3. Use Verify Heartbeat Detection

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

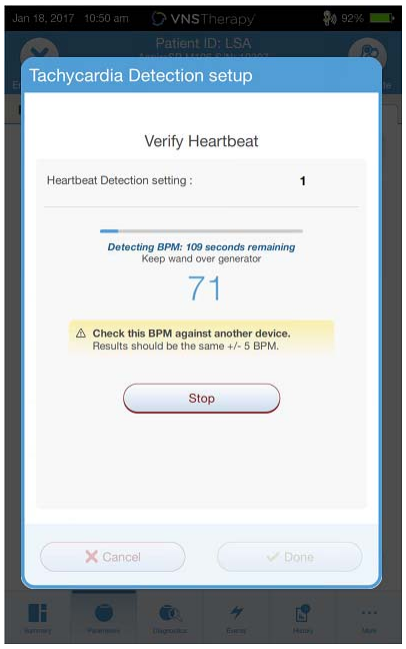
1. Press Verify to advance to the Verify Heartbeat Detection screen (Figure 20). If Detection has been Enabled, the Verify Heartbeat Detection screen will automatically display.

Figure 20. Verify Heartbeat Detection Screen



2. On the Verify Heartbeat Detection screen, tap the Heartbeat Detection setting field to change the value (if desired). Place the wand over the generator and press Start to begin the test.
3. Keep the wand over the generator during the entire Verify Heartbeat Detection process. The generator will transmit a signal and the programmer will display the detected heart rate in beats per minute (BPM) for up to two minutes (Figure 21).

Figure 21. Verify Heartbeat Detection - Test in Progress



4. Wait for the heart rate display to stabilize (at least 10 seconds) and compare the generator-detected heart rate displayed on the programmer with an independent source (such as BPM from another ECG monitor or a manual pulse count). Accurate detection should be within 10% or ±5 bpm, whichever is greater. If the heart rate reported by the programmer is too high, then the Heartbeat Detection setting should be adjusted downward (toward setting 1). If the heart rate reported by the programmer is too low, then the Heartbeat Detection setting should be adjusted upward (toward setting 5). Refer "Troubleshooting" on page 42 for more information.
5. If the heartbeat detection is verified before the end of two minutes, place the wand over the generator and select Stop on the screen.

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

6.3.3.1. Visual Indicators During Verify Heartbeat Detection

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

- ?? indicates lost/no communication, or no heart beats detected by the generator
- <40 BPM will display if the system detects a heart rate below 40 BPM
- >230 BPM will display if the system detects a heart rate above 230 BPM
- Between 40-230, the system-calculated heart rate will display

Caution: For Model 106, if AutoStim or Magnet stimulation is programmed on, the Verify Heartbeat Detection feature may be interrupted if AutoStim or Magnet stimulation is activated during the Verify Heartbeat Detection Process. In this case, ?? will display on the screen. If ?? displays, LivaNova recommends you temporarily disable all output currents for the model 106 (i.e. programmed to 0 mA) and retry the heartbeat verification. After the calibration process is completed, you may reprogram the output currents as appropriate.

6.3.4. Set the AutoStim Threshold

The AutoStim Threshold is a setting on the Detection tab that can be set from 20% to 70% (in 10% increments). This setting allows you to determine minimum heart rate change required for AutoStim,

and should be tailored to the individual patient. For the most sensitive detection and the smallest heart rate change for stimulation, choose 20%. For the least sensitive detection and thus the largest heart rate change for stimulation, choose 70%.

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

6.3.5. Stimulation Settings on the AutoStim Tab

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

6.3.5.1. Detection and Time Restraints

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

Caution: LivaNova recommends you monitor the patient briefly after parameter changes to ensure stimulation is tolerable. LivaNova also recommends the output current for the AutoStim Mode does not exceed the output current for the Normal Mode or the Magnet Mode, especially for patients who experience discomfort.

6.4. Potential Error Conditions Related to Programming

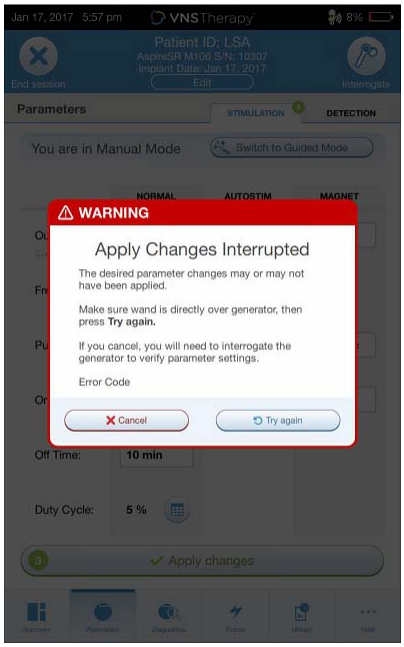
6.4.1. Partial Programming (Model 102R)

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

6.4.2. Partial Programming Interruption (Models 103-106 and 1000)

For models 103-106 and 1000 generators, the device parameters are programmed and verified as a group during a programming event, which is not susceptible to partial programming. If an interruption occurs during programming, the software will display a warning message indicating that the procedure failed and allows the user to retry or cancel the programming operation (Figure 22). If you decide to cancel, interrogate the generator to verify settings before reattempting the programming operation.

Figure 22. Programming Failed Warning Screen



6.4.3. Cross-programming (Model 102 Generators ONLY)

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

7. GUIDED PROGRAMMING

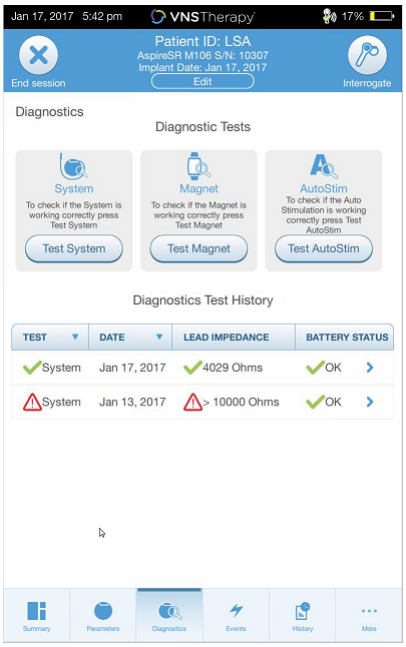
8. SCHEDULED PROGRAMMING

9. Day/Night Programming

10. Device Diagnostics

Several Diagnostics tests are available in the programming software to assess functionality of the implanted system. You may access them after a completed interrogation by selecting **Diagnostics, or Perform Diagnostics on the Summary screen** (see Figure 23).

Figure 23. Accessing Diagnostics



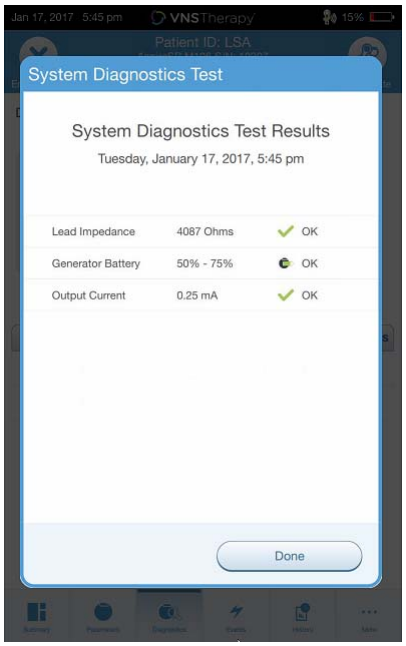
Depending on the model of generator interrogated, you may have access to different types of tests. Typical tests include System Diagnostics, Normal Mode Diagnostics, Magnet Diagnostics, and AutoStim Diagnostics. Make sure to follow all the instructions on the programmer screen, as they vary for each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

It's important to note that the tests described in this section are designed for assessing system functionality using the implanted components. Another test, Generator Diagnostics, is designed specifically for use with a test resistor and should only be accessed for troubleshooting scenarios during implantation surgery. Please see "Troubleshooting" on page 42 for more details on accessing Generator Diagnostics.

10.1. Reading Test Results

Figure 24 shows a typical results screen after completion of a diagnostics test.

Figure 24. Diagnostics Results Example



The various test parameters and their values/meanings across the different diagnostics tests are summarized in the Table 1. Additional details regarding specific diagnostics tests are further detailed in the remaining sections of this physician's manual. For model102 generators, the lead impedance values are estimated based on DC DC code (displayed in previous versions of VNS software) and the conversion between DC DC code and estimated impedance range are listed in Table 2. For abnormal result, refer to the "Troubleshooting" on page 42, for additional instructions.

Table 1. Diagnostic/Parameter Result Summary

Parameter Name(s)	Parameter Description	Parameter Values/ Results	What Does the Value or Result Mean?
Lead Impedance	Indicates measured or estimated impedance when delivering the output current during testing and whether it's within normal range.	M103-106 and 1000: Measured lead impedance value (ohms) and overall status of OK, LOW, or HIGH M102: Estimated lead impedance range (ohms) and overall status of OK, LOW, or LIMIT	**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 Section 14, Troubleshooting for additional instructions. **HIGH or LIMIT**: Impedance is higher than expected and the generator may not be able to deliver the programmed therapy. See Section 14, Troubleshooting for additional instructions.

Parameter Name(s)	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: ■ OK ■ Intensified Follow-up Indicator (IFI) ■ Near End of Service (N EOS) ■ End of Service (EOS)	M103 and subsequent models: OK IFI = Yes N EOS = Yes EOS = Yes M102: OK N EOS = Yes	**OK**: Battery level is within normal operating range and no special attention is required. **IFI = Yes**: The battery has depleted to a level where more frequent clinical monitoring is recommended. **N EOS = Yes**: M103 and subsequent models: The Generator should be replaced as soon as possible. **M102**: A System Diagnostics Test is recommended to verify the Near EOS status. If confirmed, the pulse generator should be replaced as soon as possible. **EOS = Yes**: 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.
Output Current / Current Delivered	Indicates the stimulation output current applied / delivered during the diagnostics test, and overall status of whether the current was delivered	Parameter value	Indicates the stimulation output current applied / delivered during the diagnostic test. **OK**: Current is being delivered at the programmed level. M103-106 and 1000: **LOW**: Programmed current is possibly not being delivered at the specified level. M102: **Limit**: Programmed current is possibly not being delivered at the specified level.

Caution: Battery depletion can occur between visits and may not be detected by the various battery indicators. Therefore, for patients with magnet activation enabled, LivaNova recommends a daily magnet activation by the patient as a means to check stimulation and to consult with the physician to perform diagnostics testing if patient no longer feels stimulation.

Table 2. DC DC Code Conversion and Estimated Impedance Range

DC DC Code	Estimated Impedance Range
0	<1.7 kΩ*
1	1.8-2.8 kΩ*
2	2.9-4.0 kΩ*
3	4.1-5.2 kΩ*
4	5.3-6.5 kΩ*
5	6.6-7.7 kΩ*
6	7.8-8.9 kΩ*
7	>9.0 kΩ*

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

10.2. 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. A successful System Diagnostics during surgery or post-implant shows that both the generator and lead are working properly.

You can perform this test on all generators supported by the VNS Programming Software during implantation and patient follow-up visits. LivaNova recommends you perform this test before other diagnostic tests.

10.3. Normal Mode Diagnostics (Model 102)

The Normal Mode Diagnostics test will let you know if the generator is ready to deliver output current. Perform this test regularly at follow-up visits only if the patient can tolerate at least .75 mA. Any setting less than 0.75 mA with a frequency less than 15 Hz or ON time less than 30 sec will render an unreliable test result. Make sure the patient's settings meets the minimum requirement.

Note: For models 103-106 and 1000 generators, the System Diagnostics test serves the same function as Normal Mode Diagnostics since the test is run at the programmed device settings.

10.4. Magnet Mode Diagnostics

The Magnet Mode Diagnostics test will let you know if the generator is delivering the programmed magnet output current. To do perform this rest, pass the magnet over the generator for at least one second and then place the wand over the generator. This action will enable stimulation at the programmed Magnet Mode output current. If you perform this incorrectly, the test will be invalid and a message will display on the screen indicating the magnet swipe was not detected. Pass the magnet over the generator again to restart the test.

For the model 106 generator, do not leave the magnet over the generator for longer than 3 seconds when performing the Magnet Mode Diagnostics. Otherwise, stimulation will stop and the Magnet Mode Diagnostics results will invalid. In addition, similar to Normal Diagnostics, any setting less than 0.75 mA with a frequency less than 15 Hz or ON time less than 30 sec will result in an unreliable test. Make sure the patient's settings meet the minimum requirement.

10.5. AutoStim Diagnostics (Model 106 and 1000)

The AutoStim Diagnostics test determines whether the device is delivering the programmed AutoStim output current. The desired AutoStim current should be programmed before you perform the AutoStim diagnostic. The result will indicate whether the programmed AutoStim current is being delivered given the lead impedance that is present.

10.6. Generator Diagnostics

The Generator Diagnostics test is designed specifically for use with a test resistor and should only be accessed for troubleshooting scenarios during implantation surgery. Please see "Troubleshooting" on page 42 for more details on using Generator Diagnostics.

10.7. Diagnostic Test Differences Between Models of Generators

Some Diagnostic tests operate differently depending on which model generator is used. These differences are outlined below in Table 3.

Table 3. Diagnostic Test Differences Between Models of Generators

Items of Interest	Model 102(R)	Models 103-106 and 1000
Parameter Settings During System Diagnostics	Stimulates at 1.0mA, 500µs, and 20 Hz **Caution**: Patients with lower parameter settings may feel discomfort during this test.	**Normal Mode Output Current is programmed to 0mA:** Stimulates at 1.0mA, 500µs, and 20Hz. **Normal Mode Output Current is programmed to > 0mA:** Stimulates at the programmed Normal Mode parameters
Parameter Settings During Generator Diagnostics	Stimulates at 1.0mA, 500µs, 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 0mA after the test.	**Normal Mode Output Current is programmed to 0mA:** Stimulates at 0.25mA **Normal Mode Output Current if programmed to > 0mA:** Stimulates at the programmed Normal Mode parameters.
Lead Impedance	Lead impedance is not directly measured. Instead, a DC-DC Converter Code is reported and is indicative of the estimated lead impedance at 1mA and 500µs.	The actual lead impedance measurement is reported.

10.8. Potential Error Conditions Observed in Diagnostics

If diagnostics testing is interrupted, follow on-screen instructions to repeat the test and verify the patient's parameters. The model 102 parameters are especially susceptible to be changed to unintended settings during an interrupted diagnostic test due to the break in communication between the programmer and the wand; therefore, it's especially important to re-verify the patient's parameters after a diagnostic test interruption. Always re-interrogate to verify settings after an interrupted diagnostics test.

11. History

12. EVENTS AND TRENDS

13. Managing Programmer Information

14. Programmer Settings

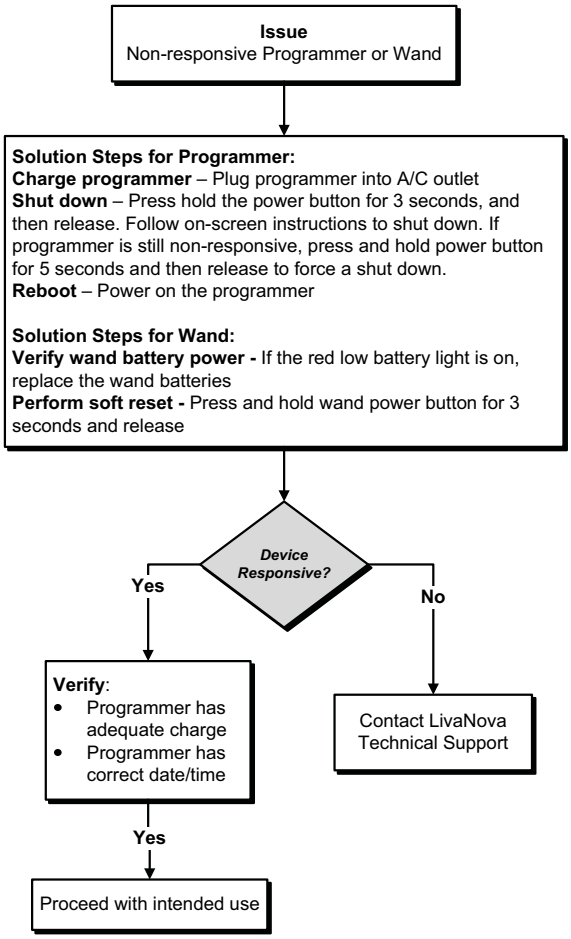
15. TROUBLESHOOTING

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

15.1. Non-responsive Programmer or Wand

If your programmer or wand becomes non-responsive, follow the solution steps in the figure below.

Figure 25. Solution Steps for a Non-responsive Programmer or Wand



15.2. Communication Issues

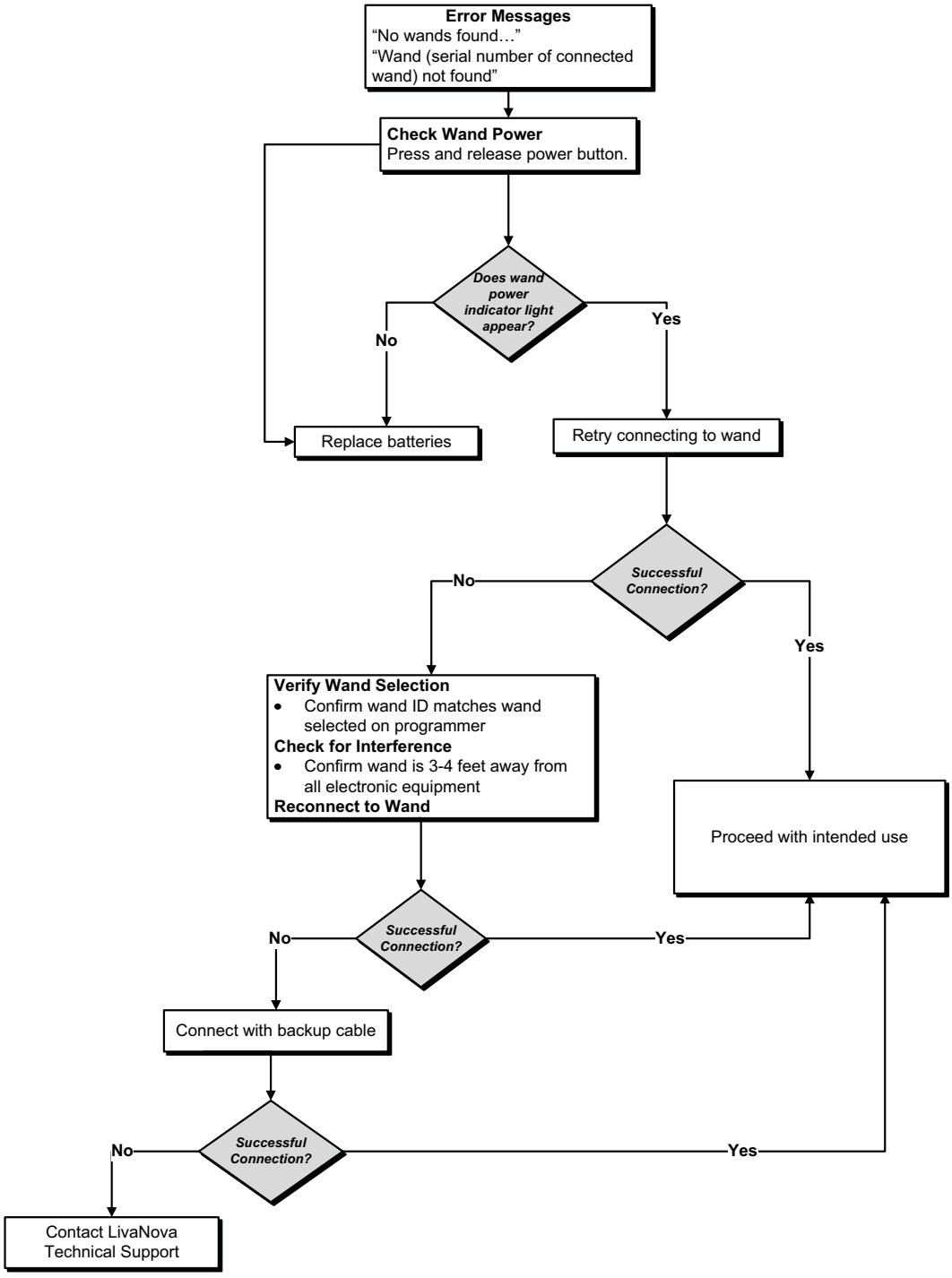
15.2.1. Wand Not Connecting to Programmer (Wireless)

Potential reasons for no wireless connection between the wand and the programmer include the following:

- Wand not powered on
- Depleted wand battery
- Electromagnetic interference (EMI), such as OR lights
- Defective wand or programmer

See Figure 26 for solution steps to resolve problems between the wand and programmer via wireless connection.

Figure 26. Solution Steps For Wand Not Connecting to Programmer (Wireless)



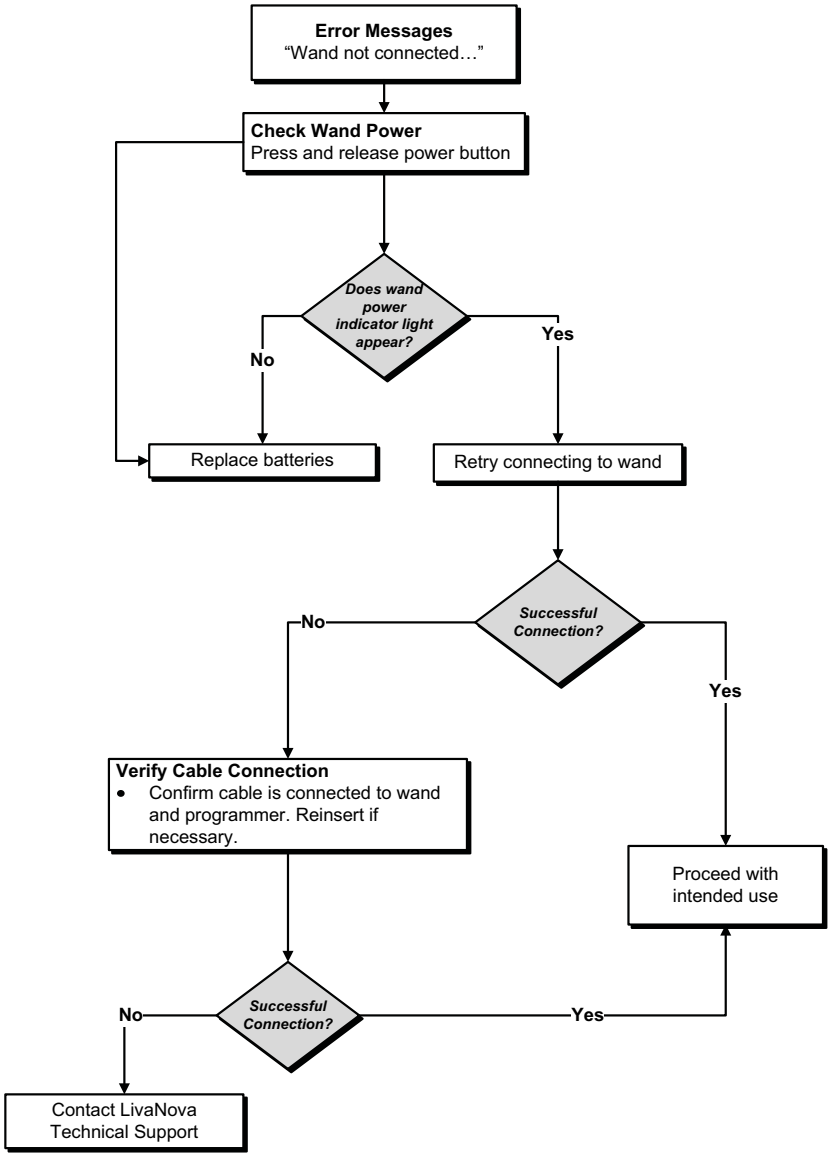
15.2.2. Wand Not Connecting to Programmer (Backup Cable)

Potential reasons for no connection between the wand and the programmer via backup cable include the following:

- Improper cable connection between wand and programmer
- Depleted wand battery
- Improper USB port recognition of the programmer cable
- Defective wand or programmer

See Figure 27 for solution steps to resolve problems between the wand and programmer via backup cable connection.

Figure 27. Solution Steps for Wand Not Connecting to Programmer (Backup Cable)



15.2.3. Wand Not Communicating with Generator

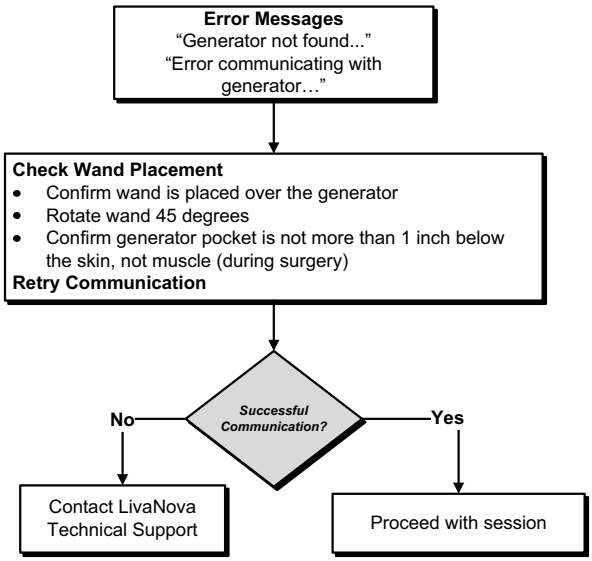
Potential causes for communication issues between the wand and generator include the following:

- Depleted wand batteries
- Moving wand away from generator during communication
- Electromagnetic interference (EMI), such as OR lights
- Generator battery at End of Service (EOS)

- Defective wand, programmer, or generator

See Figure 28 for solution steps to resolve communication problems between the wand and generator.

Figure 28. Solution Steps for Wand Not Communicating with Generator



15.3. High/Low Lead Impedance and Low Output Current Issues

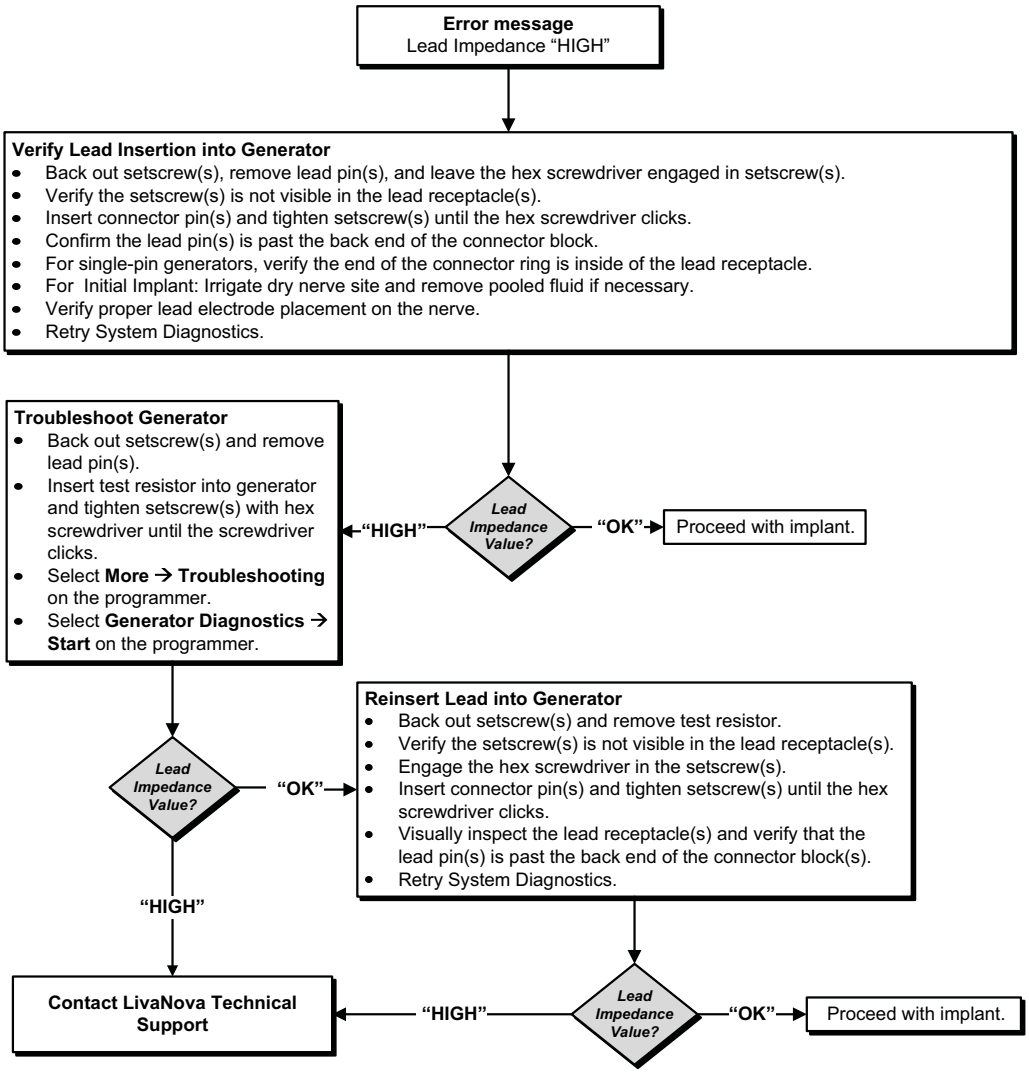
15.3.1. High Lead Impedance in the OR

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

- Improper connection between the lead and the generator
- Incorrect placement of lead on the nerve (initial implant only)
- Allowing nerve to become dry (initial implant only)
- Defective lead or generator

See Figure 29 for solution steps.

Figure 29. Solution Steps for High Lead Impedance in OR



15.3.2. Low Lead Impedance in OR

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

During Initial Implant

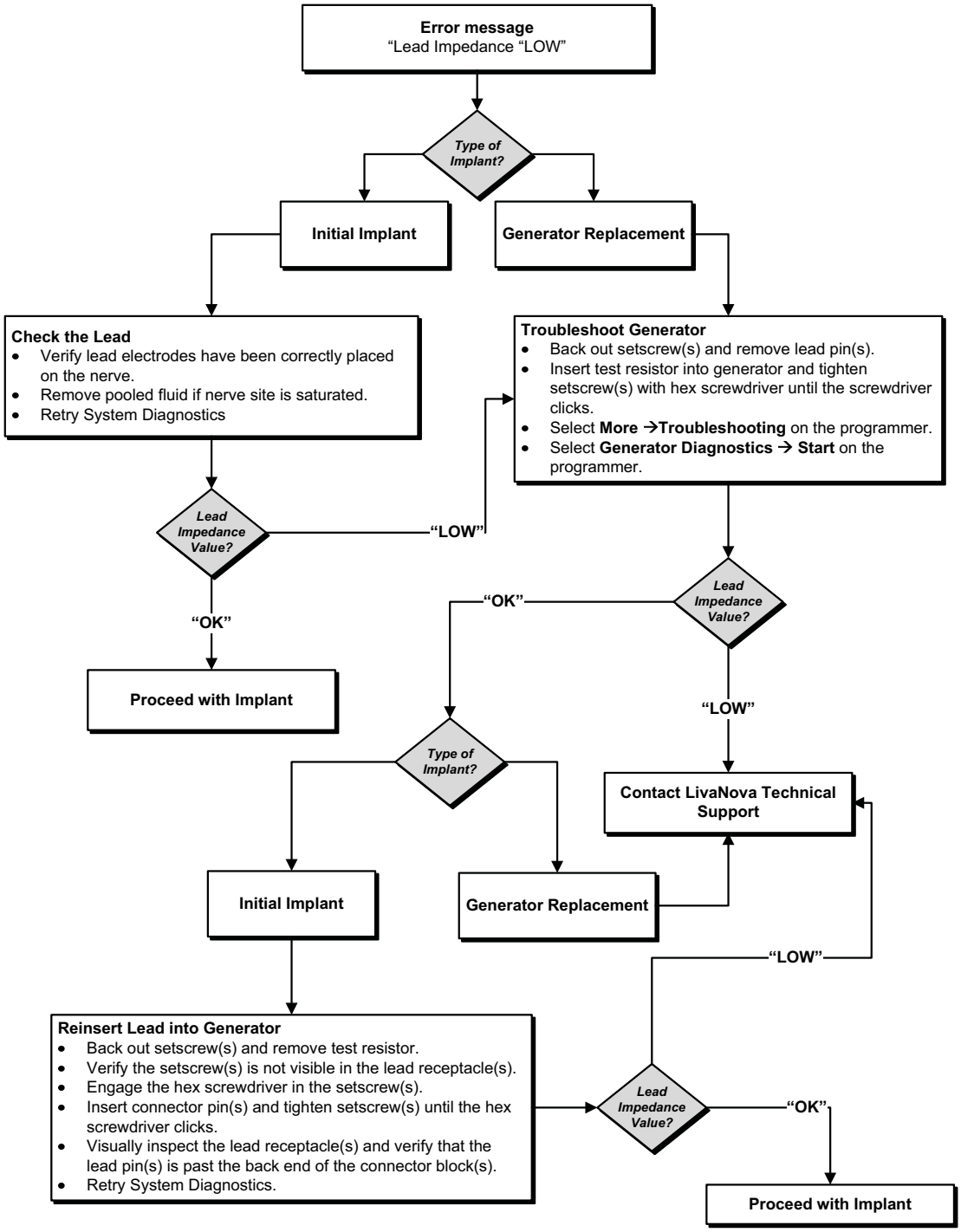
- Incorrect placement of the lead on the nerve
- Excessive irrigation of the nerve
- Defective generator or lead

During Generator Replacement

- Short-circuit condition within the lead
- Defective generator

See Figure 30 for solution steps.

Figure 30. Solution Steps for Low Lead Impedance in OR



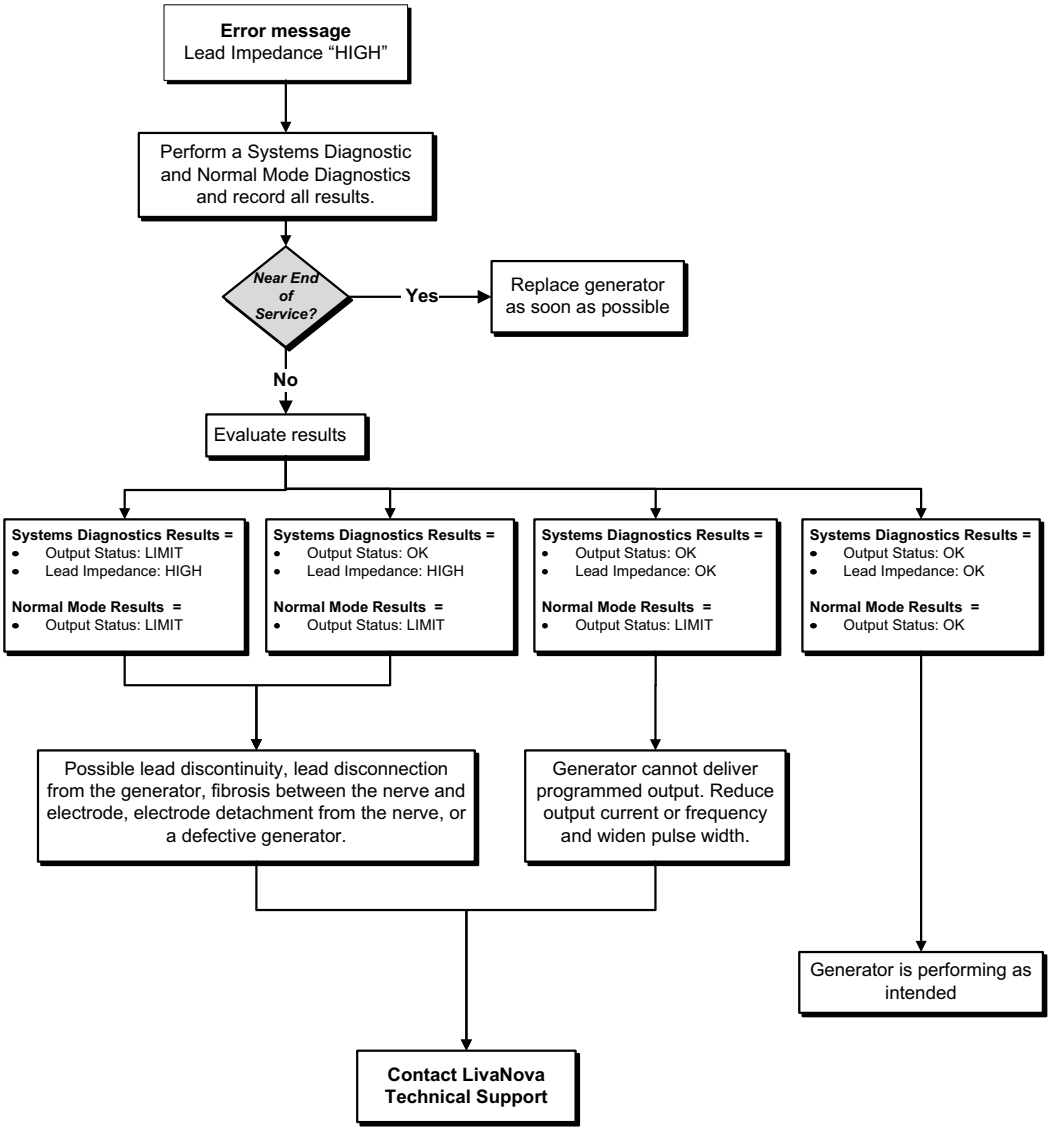
15.3.3. High Lead Impedance at Follow-up Visits (Model 102)

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

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

See Figure 31 for solution steps.

Figure 31. Solution Steps for High Lead Impedance at Follow-up Visits (Model 102)



15.3.4. High/Low Lead Impedance or Low Output Current at Follow-up Visit (Models 103-106 and 1000)

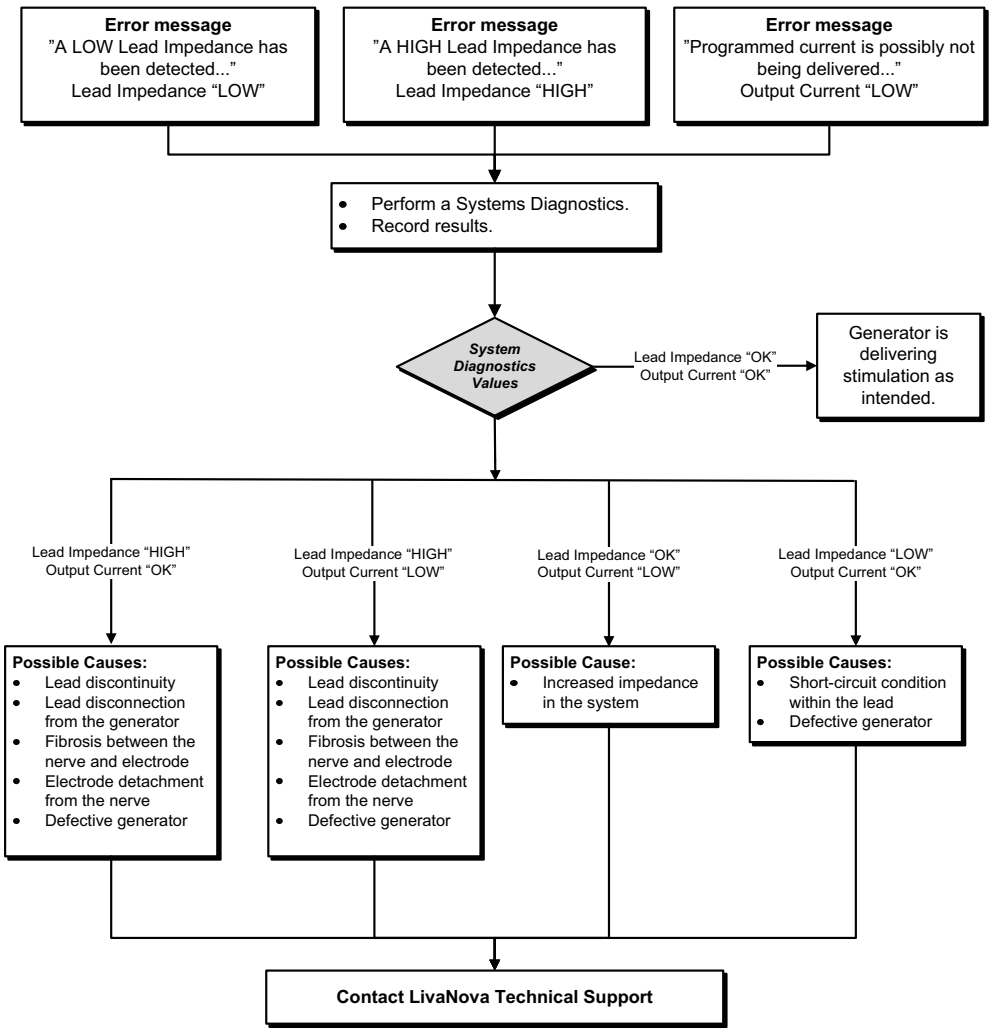
Possible causes for high or low lead impedance or low output current at follow-up visits for models 103-106 and 1000 generators include the following:

- Lead discontinuity

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

See Figure 32 for solution steps.

Figure 32. Solution Steps for High/Low Lead Impedance or Low Output Current at Follow-up Visit (Models 103-106 and 1000)



15.4. Generator Battery Issues

15.4.1. Low Battery/End of Service Indications in OR

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

Prior to Surgery:

- Generator has been recently exposed to low storage temperatures

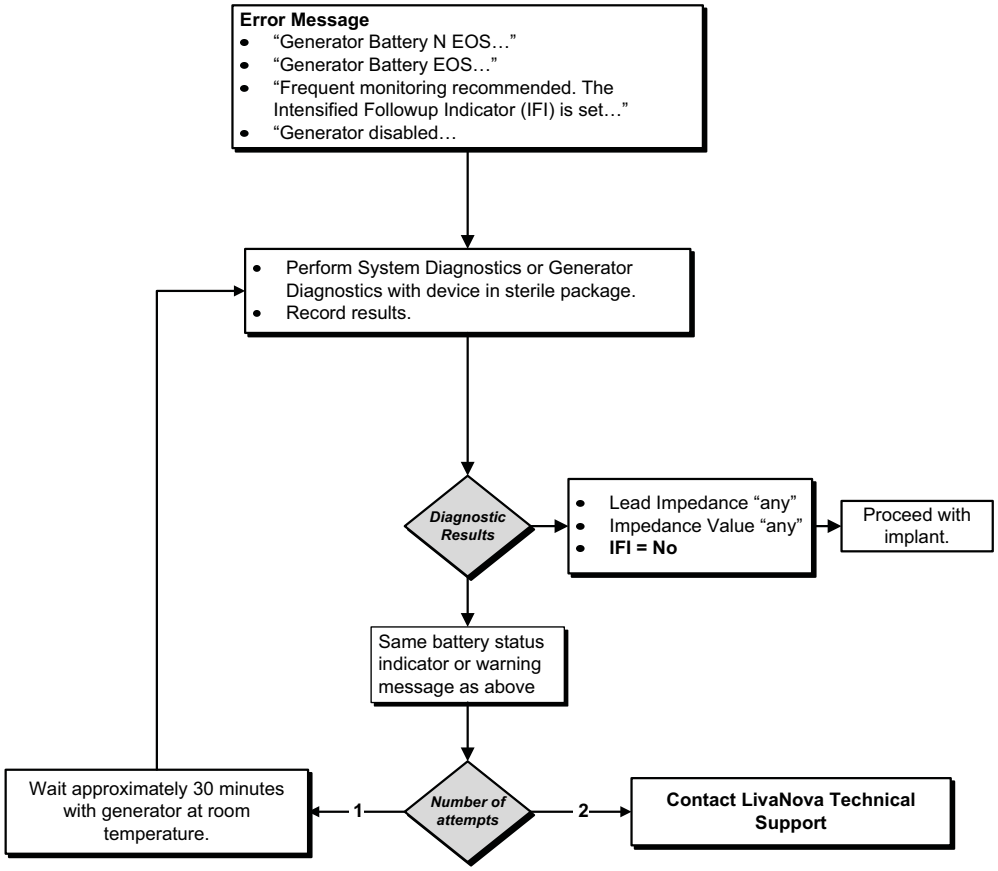
- Defective generator

During Surgery:

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

See Figure 33 for solution steps.

Figure 33. Solution Steps for Low Battery/End of Service Indications in OR



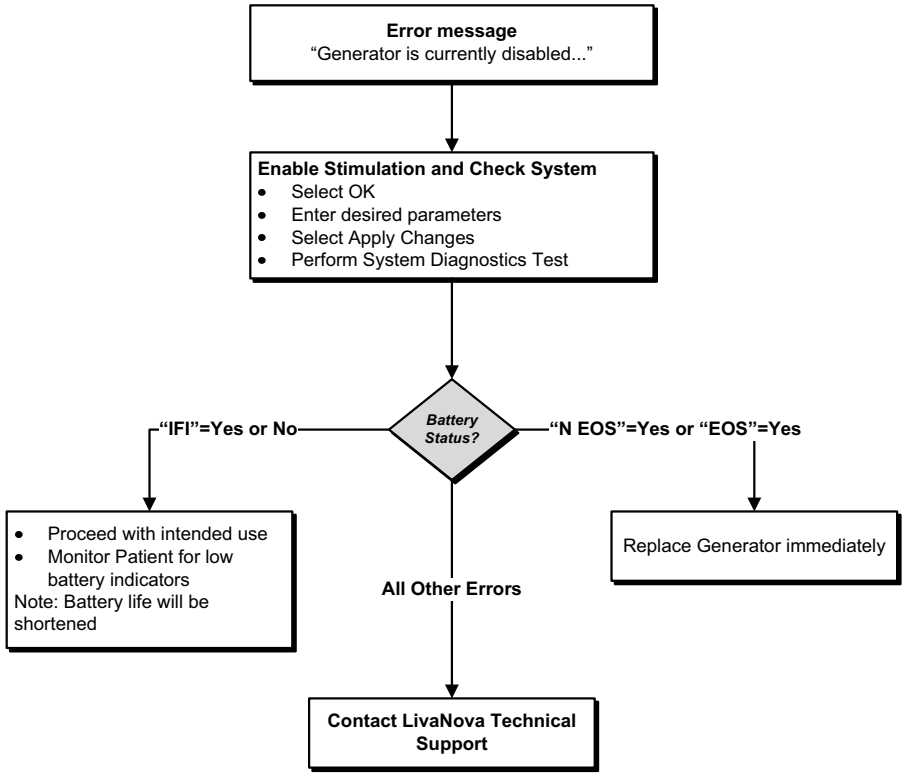
15.4.2. New Generator Disabled Due to EOS at First Interrogation

Generator models 103-106 and 1000 batteries can temporarily drain and become disabled if exposed to certain conditions. These conditions include the following:

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

See Figure 34 for solution steps.

Figure 34. New Generator Disabled Due to EOS at First Interrogation



15.4.3. Sudden Decrease In Remaining Battery Power

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

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

If any device issue is suspected, contact LivaNova Technical Support.

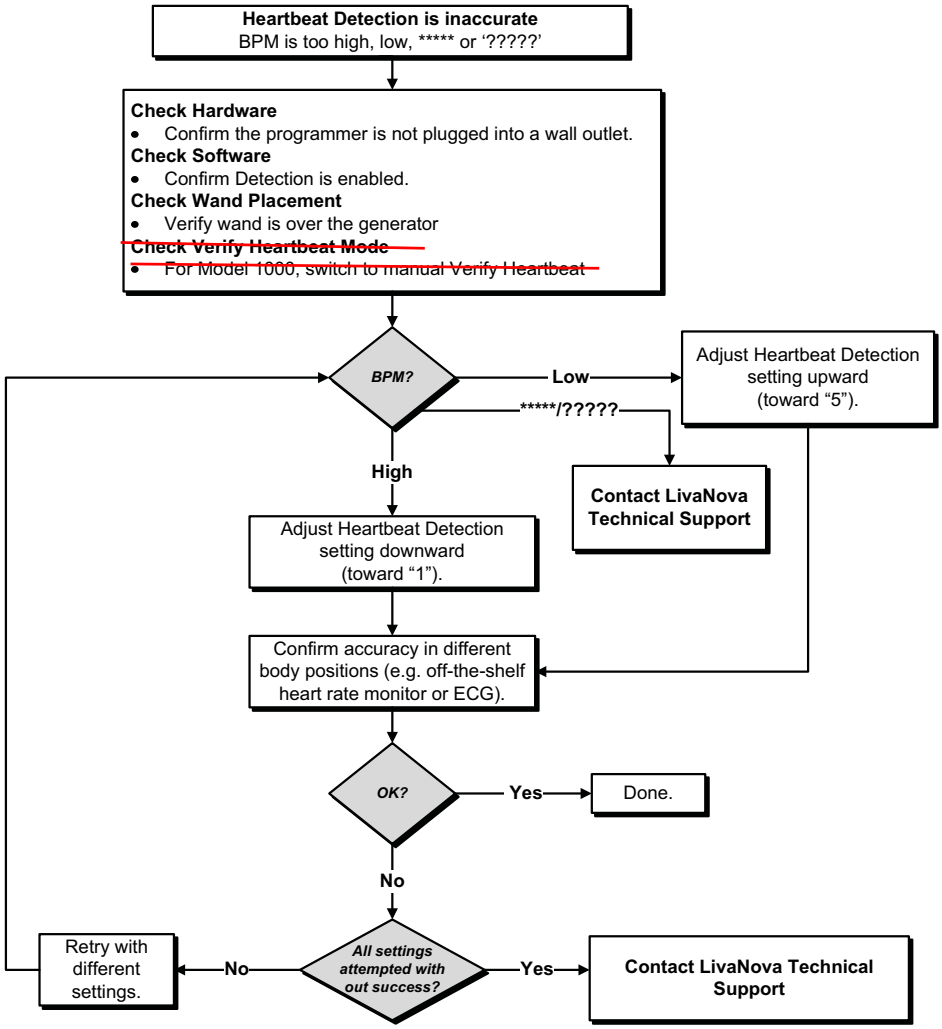
15.5. Heartbeat Detection Issues

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

The heartbeat detection setting may need to be adjusted to correctly detect heartbeats. See Figure 35 for solution steps to correct an over/under detection reading.

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

Figure 35. Solution Steps for Heartbeat Detection Inaccurate in OR or at Follow-up Visit



15.6. Seizure Detection Issues

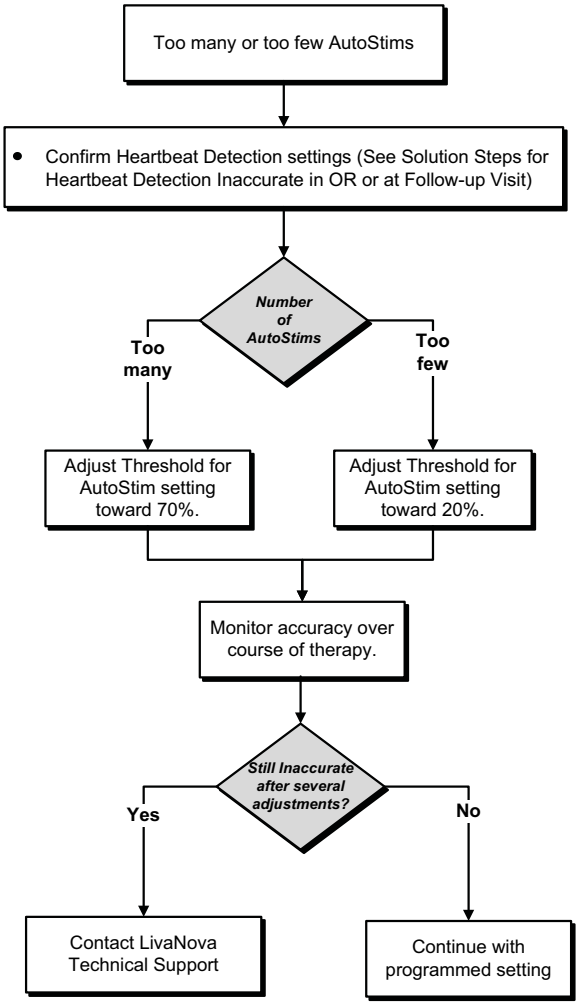
15.6.1. Inaccurate AutoStims at Follow-up Visit for Generator Model 106 and 1000

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

- **Duty cycle** - Because the generator can only detect events during OFF time, the OFF time affects accuracy. Shorter OFF time means less chance for the generator to detect events. Longer OFF time, on the other hand, means more chance for the generator to detect events.
- **Heart rate changes** - Exercise, physical activity, and normal sleep can increase the heart rate and cause the generator to falsely declare an event.

See Figure 36 for solution steps.

Figure 36. Solution Steps for Inaccurate Detection at Follow-up Visit (Model 106)



16. Generator Reset

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

17. MAINTENANCE, HANDLING, AND DISPOSAL

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

- To clean external surfaces of the Programming System components, wipe with pre-moistened or damp cloth using one of the following cleaners: isopropyl alcohol (70-90%), ethanol, or CaviCide®.
- Do not sterilize any parts of the system.
- Regularly inspect the system parts for damage. Return any damaged parts to LivaNova.
- Do not operate the system near water or other fluids. Do not immerse any components in liquids.

17.1. The Programmer

- Debris can damage the programmer touchscreen display. Frequently wipe with a soft cloth, using approved cleaners. Be sure to power off computer and disconnect AC adapter from electrical outlet before cleaning.
- For information on operating and storage conditions, see the programming system specification table on section 17.

17.2. The Wand

- Check the wand battery periodically to verify battery status.

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

- Remove (and install) the battery only when the wand is not in contact with the patient and not connected to the programmer
- Never connect the Programming Wand to external equipment while the battery compartment is open.
- For information on operating and storage conditions, see the programming system specification table in section 17.

17.3. Disposal

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

18. Programming System Specifications and Guidance

18.1. Wand and Programmer Specification

For a complete list of wand and programmer hardware specifications, see the table below.

Table 4. Programming System Specification

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

18.2. Electromagnetic Emissions Guidance for Wand

The wand is intended to be used in the electromagnetic conditions specified in the tables below.

Table 5. Electromagnetic Emissions

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

Table 6. 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

Table 7. Electromagnetic Immunity to Proximity Fields from RF Wireless Communications Equipment

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

19. Contact Information and Support

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

LIVANOVA USA
100 Cyberonics Boulevard
Houston, Texas 77058
Telephone: +1 (281) 228-7200
1 (800) 332-1375 (US and Canada)

LIVANOVA BELGUIM NV
Ikaroslaan 83
1930 Zaventem, Belguim
Telephone: +32.2.720.95.93

For 24-hour Clinical and Technical Support, call:

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

Europe/EMMEA:
Telephone: +32 2 790 27 73

Internet: www.VNSTherapy.com