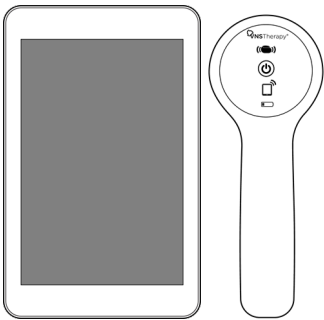


# *PHYSICIAN'S MANUAL*

## VNS Therapy™ Programming System



Model 3100

Model 2000

November 2023

© 1998 – 2023 LivaNova, PLC, London, UK. All rights reserved.

All trademarks and trade names are the property of LivaNova or the property of LivaNova's consolidated subsidiaries and are protected under applicable intellectual property laws. Solely for convenience, LivaNova's trademarks and trade names may appear without the ® or TM symbols, but such references are not intended to indicate in any way that LivaNova will not assert, to the fullest extent under applicable law, LivaNova's rights to these trademarks and trade names. Prior permission from LivaNova is required for the use or reproduction of such intellectual property rights.

# TABLE OF CONTENTS

---

<b>INTRODUCTION</b> .....	<b>6</b>
1.1. Brief Description .....	7
1.2. Compatibility .....	7
1.3. System Communication .....	7
<b>INDICATIONS, WARNINGS, AND PRECAUTIONS</b> .....	<b>8</b>
2.1. Intended Use .....	9
2.2. Warnings .....	9
2.2.1. General .....	9
2.2.2. Security .....	10
2.3. Precautions .....	11
2.3.1. General .....	11
2.3.2. Security .....	11
<b>COMPONENTS</b> .....	<b>12</b>
3.1. Programming System Parts .....	13
3.1.1. Parts Included .....	13
3.1.2. Parts Not Included .....	13
3.2. Programmer Hardware .....	14
3.2.1. Tablet Layout and Functions .....	14
3.2.2. Tablet Battery Status .....	15
3.3. Wand Hardware .....	15
<b>GET STARTED</b> .....	<b>17</b>
4.1. First-Time Programmer Setup .....	18
4.1.1. Unlock the Programmer .....	18
4.1.2. Download and Install the Clinician App .....	19
4.2. The Kiosk .....	20
4.2.1. Clinician App .....	21
4.2.2. Remote Support .....	21
4.2.3. Programmer Settings .....	21
4.3. Programmer Update .....	23
4.4. Connect Wand and Programmer .....	23
4.4.1. Wireless Wand Connection Options .....	24
4.4.1.1. Preferred Wireless Wand .....	24
4.4.1.2. No Preferred Wand .....	24
4.4.2. Wired Wand Connection .....	24
<b>NAVIGATION</b> .....	<b>25</b>
5.1. User Interface Elements for the Clinician App .....	26
5.2. Home & Out-Of-Session Menu .....	28
5.3. Dashboard & In-Session Menu .....	30
5.4. Parameters Screen .....	32
<b>FUNCTION</b> .....	<b>33</b>

---

6.1. Interrogate .....	34
6.1.1. Initial Interrogation .....	34
6.1.2. In-Session Interrogation .....	34
6.2. Parameters .....	34
6.2.1. Stimulation Parameters .....	34
6.2.2. Detection Parameters .....	35
6.2.2.1. Tachycardia Detection and AutoStim .....	35
6.2.2.1.1. Tachycardia Detection Setup .....	35
6.2.2.1.2. Verify Heartbeat Detection .....	35
6.2.2.2. Low Heart Rate Detection .....	36
6.2.2.3. Prone Position Detection .....	36
6.3. Titration Plans .....	37
6.3.1. Guided Titration .....	37
6.3.2. Scheduled Titration .....	37
6.3.3. Titration Plan Rules .....	37
6.4. Day-Night Programming .....	38
6.4.1. Enable or Disable Day-Night .....	39
6.4.2. View or Modify Day-Night Parameters .....	39
6.4.3. Fifteen-Minute Test .....	39
6.5. Events & Trends .....	40
6.5.1. Dashboard .....	40
6.5.2. Events & Trends Screen .....	41
6.5.3. GET MORE DATA .....	43
6.5.4. Events & Trends Data .....	44
6.6. VNS Device Health (System Diagnostics) .....	46
6.6.1. Access VNS Device Health .....	46
6.6.2. System Diagnostics Test Results and Definitions .....	46
6.6.3. Therapy Disabled or Paused .....	47
6.7. Wand Update .....	47
6.8. Wand Settings .....	48
6.9. Backup Data .....	48
6.10. Troubleshooting in the Clinician App .....	48
6.10.1. Out-of-Session VNS Device Reset .....	48
6.10.2. In-Session Troubleshooting .....	48
6.10.2.1. Generator Diagnostics .....	48
6.10.2.2. Magnet Test .....	48
6.10.2.3. AutoStim Test .....	49
<b>GENERAL TROUBLESHOOTING .....</b>	<b>50</b>
7.1. Anomalous Behavior or Non-Responsive System .....	51
7.1.1. Programmer .....	51
7.1.2. Wand .....	51
7.2. Wand Will Not Connect to Programmer .....	51
7.2.1. Possible Causes .....	51
7.2.2. Solution Steps .....	52
7.3. Wand Will Not Communicate with Generator .....	54



---

7.3.1. Possible Causes .....	54
7.3.2. Solution Steps .....	54
<b>MAINTENANCE, HANDLING, AND DISPOSAL .....</b>	<b>55</b>
8.1. System .....	56
8.2. Programmer .....	56
8.3. Wand .....	57
8.4. Disposal .....	57
<b>PROGRAMMING SYSTEM SPECIFICATIONS AND GUIDANCE .....</b>	<b>58</b>
9.1. Wand and Programmer Specifications .....	59
9.2. Wand Electromagnetic Conditions .....	60
9.3. Wireless Security .....	61
<b>CONTACTS AND RESOURCES .....</b>	<b>62</b>
Contacts .....	62
Technical Support .....	62
Regulatory Authority Websites .....	62
Return Product Form .....	62

## LIST OF TABLES

---

Table 1. Compatible Generator Models .....	7
Table 2. Compatible Wand Firmware .....	7
Table 3. Communication Distance .....	7
Table 4. User Interface Elements — Clinician App .....	28
Table 5. Example Adjustments to the Heartbeat Detection Setting .....	36
Table 6. Events & Trends Data .....	45
Table 7. System Diagnostics Test Results and Definitions .....	47
Table 8. Wand and Programmer Specifications .....	59
Table 9. Wand Electromagnetic Emissions .....	60
Table 10. Wand Electromagnetic Immunity .....	60
Table 11. Wand Electromagnetic Immunity to Proximity Fields from RF Wireless Communications Equipment .....	61
Table 12. Programming System Wireless Security Information .....	61

## LIST OF FIGURES

---

Figure 1. Parts Included .....	13
Figure 2. Wand Connected to Programmer .....	23
Figure 3. Events & Trends Card .....	40
Figure 4. Sixty Days of Data Example .....	41
Figure 5. Magnet and AutoStim Event Card Examples .....	41
Figure 6. AutoStim Calendar Events by Day Example .....	42
Figure 7. Updated AutoStim Heatmap Example .....	43
Figure 8. View Timestamps Example .....	44

# Chapter 1

---

## Introduction

Links to the following documents are found at [www.livanova.com](http://www.livanova.com).

- Indication-specific physician's manuals
- VNS Therapy System Glossary
- LivaNova Neuromodulation Symbols and Definitions

Detailed cybersecurity information (e.g., Programmer OS version) is available upon request. For contact information, see "[Technical Support](#)" on page 62.

This topic includes the following concepts:

---

1.1. Brief Description .....	7
1.2. Compatibility .....	7
1.3. System Communication .....	7

## 1.1. Brief Description

The VNS Therapy programming system includes a tablet (Programmer), Model 3100 programming software (Clinician App), and a Model 2000 programming wand (Wand).

The system allows you to perform the following:

- Interrogate compatible VNS Therapy devices
- Adjust VNS Therapy parameters and features
- Assess VNS device health
- Backup Programmer data
- Install Programmer software and Wand firmware updates

## 1.2. Compatibility

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

**Table 1. Compatible Generator Models**

Single Receptacle	Dual-Receptical
Model 1000 SenTiva™	Model 1000-D SenTiva Duo™

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

**Table 2. Compatible Wand Firmware**

Programmer	Wand
Model 3100 v1.1	Model 2000 with firmware version 1.1.2

## 1.3. System Communication

The Wand and the Programmer connect wirelessly or with a USB Type-C cable.

**Table 3. Communication Distance**

System	Communication Distance
<b>Wand and Programmer</b>	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.
<b>Wand and Generator</b>	1 inch or less

# Chapter 2

---

## Indications, Warnings, and Precautions

This topic includes the following concepts:

---

2.1. Intended Use .....	9
2.2. Warnings .....	9
2.3. Precautions .....	11

## 2.1. Intended Use

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

## 2.2. Warnings

Follow these warnings for optimal performance and safety.

### 2.2.1. General

#### 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.

#### Anomalous Behavior

Anomalous behavior may occur (e.g., a nearby Wand erroneously connects to a Programmer). If this happens, see ["General Troubleshooting" on page 50](#).

#### 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. The 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.

## 2.2.2. Security

### Safeguard Against Theft

Safeguard the programming system against theft. Theft could lead to malicious activities against the system.

### Unauthorized Connections

Use the system in a controlled area to prevent unauthorized connections. Do not connect the Programmer to insecure networks (e.g., hotel Wi-Fi, conferences). Monitor the Programmer and the operating environment for signs of cyber attack and take necessary actions. Report incidents to LivaNova. For contact information, see ["Technical Support" on page 62](#).

### Compromised Programmer

Do not use the Clinician App if the operating system or the Programmer is suspected to be compromised.

### Lost or Stolen Programmer

Report lost or stolen Programmer to LivaNova immediately. For contact information, see ["Technical Support" on page 62](#).

### Password Security

Do not provide your password to others. LivaNova Technical Support will never call you to get your tablet password.

### Password Protection

Clean the Programmer screen of smudges after use to stop attackers who try to steal your password pattern or pin. To avoid password theft, guard it as you enter it into the Programmer, even from over-the-shoulder glimpses.

### Unapproved Equipment

Do not connect unapproved equipment (e.g., USB hubs, KVM switches). This can compromise system security, damage the system, and/or cause injury.

## 2.3. Precautions

Follow these precautions for optimal performance and safety.

### 2.3.1. General

#### **Do Not Load Other Software**

Do not load other software onto the Programmer. This may interfere with the efficiency and function of the programming 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. Do not plug the wall charger into an electrical outlet while the Programmer is in use with a patient.

#### **Titration Plans - Epilepsy Only**

Titration plans are only intended for use in epilepsy patients.

### 2.3.2. Security

#### **Non-Clinical Functions**

Do not use the Programmer to perform non-clinical functions (e.g., email, web browsing).

#### **Do Not Circumvent Controls**

Do not circumvent controls on the Programmer (e.g., exit Kiosk Mode) unless directed by LivaNova.

# Chapter 3

---

## Components

This topic includes the following concepts:

---

3.1. Programming System Parts .....	13
3.2. Programmer Hardware .....	14
3.3. Wand Hardware .....	15



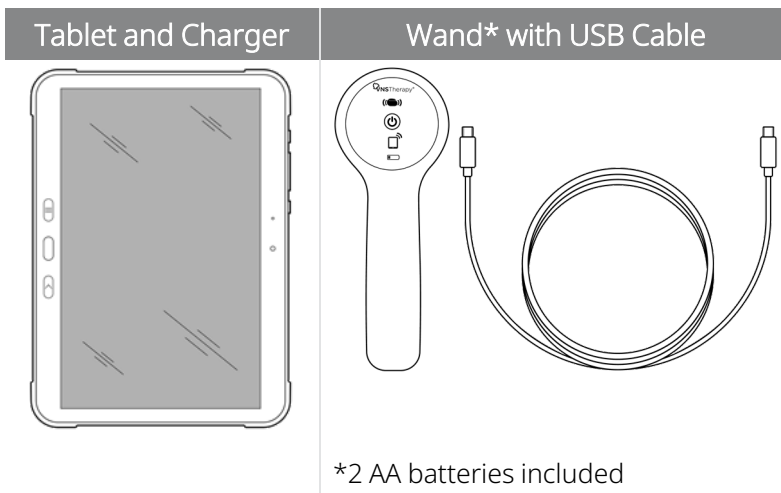
## 3.1. Programming System Parts

The VNS Therapy programming system includes a tablet (Programmer), Model 3100 programming software (Clinician App), and a programming wand (Wand).

**i** NOTE: If parts of the system are missing, contact "[Technical Support](#)" on page 62.

### 3.1.1. Parts Included

Figure 1. Parts Included



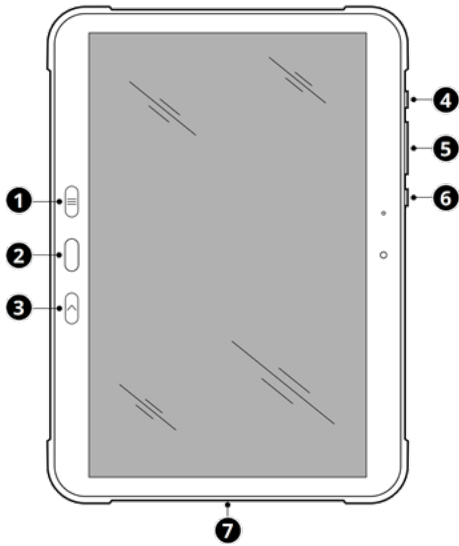
**i** NOTE: The tablet may be bundled with a stylus pen. The use of the stylus pen is not required for Clinician App operation and has not been tested for use with the app. LivaNova does not support, maintain, or replace the stylus pen.


### 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. Programmer Hardware

### 3.2.1. Tablet Layout and Functions



1	<b>Recents key</b>	Opens a list of recent apps.
2	<b>Home key</b>	<p>If the screen is on, press and release to return to the Programmer <b>Home</b> screen.</p> <p>If the screen is locked, press and release to unlock the screen.</p>
3	<b>Back key</b>	Press and release to return to the previous screen.
4	<b>Side key</b>	<p><b>Turn On</b> Press and hold until the Programmer turns on.</p> <p><b>Turn Off or Restart</b> Press and hold until the following choices appear:</p> <ul style="list-style-type: none"> <li>•  Tap to turn the Programmer off.</li> <li>•  Tap to restart the Programmer.</li> </ul> <p><b>Lock or Unlock the Screen when the Programmer is On</b></p> <ul style="list-style-type: none"> <li>• If the screen is off, press and release to unlock the screen.</li> <li>• If the screen is on, press and release to lock it.</li> </ul> <p>The screen locks automatically if the Programmer is not used for a specified period. For instructions on how to change the time, see <a href="#">"Display" on page 22</a>.</p>
5	<b>Volume key</b>	Increase or decrease the volume.
6	<b>Active key</b>	This button is not used with the Clinician App. Nothing will happen when it is pressed.



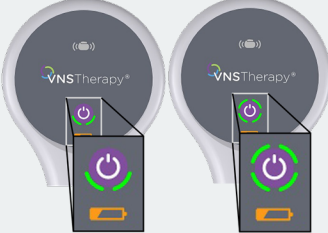
7	<b>USB-C Cable port</b>	<p><b>Charge the battery</b></p> <p>Connect the cable to the wall charger and the tablet. Disconnect the cable and charger from the tablet after it is charged.</p> <p>Do not plug the wall charger into an electrical outlet while the Programmer is in use with a patient.</p> <p>Use only a USB Type-C cable. Use of other cables (e.g., Micro USB) may damage the tablet.</p>
---	-------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

### 3.2.2. Tablet Battery Status


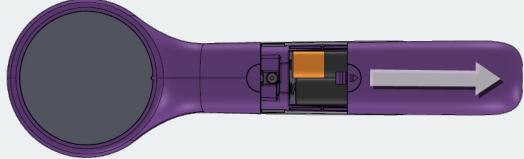
The battery status indicator is in the top right corner of any screen within the Clinician App and on the tablet status bar. Make sure you charge the battery before you start a patient session. If you do not need to use the Programmer for an extended period, unplug it and turn it off to preserve battery life.

**i** NOTE: The maximum charge for the Programmer battery is 85%. The limit is intentional to help preserve battery health.

## 3.3. Wand Hardware

<p><b>Power On Wand</b></p> 	<p>Press and release the power button to turn the Wand on.</p> <p><b>i</b> NOTE: Once powered on, the Wand will automatically power down (standby) after 2 minutes of inactivity to save battery power.</p>
<p><b>OK Battery Indicator</b></p> 	<p>If the battery is OK, green lights illuminate.</p>
<p><b>Low Battery Indicator</b></p> 	<p>If the battery is low, the low battery indicator illuminates.</p>

## Components

<p><b>No Battery Power Indicator – No Communication</b></p>  <p>The image shows a circular VNS Therapy device with a smartphone placed over it. The smartphone screen displays a power button icon and a battery level icon with a low orange bar.</p>	<p>If only the orange battery icon illuminates, communication will not be possible until you replace the batteries.</p>
<p><b>Wand Battery Replacement</b></p>  <p>The image shows a purple Wand device with a battery compartment on the back. A white arrow points to the right, indicating the direction to slide the cover open.</p>	<p>If the battery is low, replace the batteries. Remove the cover located on the back of the Wand.</p>

# Chapter 4

---

## Get Started

This topic includes the following concepts:

---

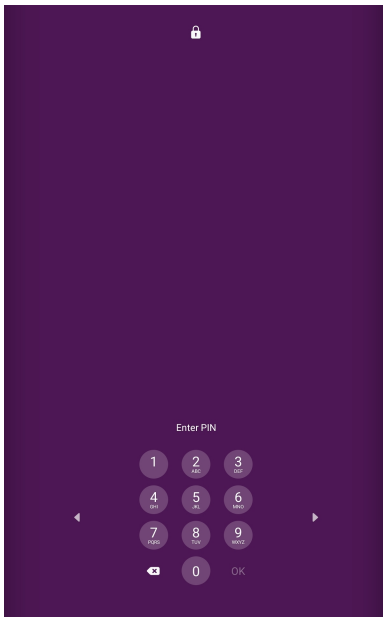
4.1. First-Time Programmer Setup .....	18
4.2. The Kiosk .....	20
4.3. Programmer Update .....	23
4.4. Connect Wand and Programmer .....	23

## 4.1. First-Time Programmer Setup

Internet connectivity is required for first-time Programmer setup. The Programmer is equipped with cellular access and automatically connects to the internet. You can also connect the Programmer through Wi-Fi. A secure Wi-Fi connection is recommended for first-time setup, or in areas of poor cellular coverage.

### 4.1.1. Unlock the Programmer

Use the passcode provided to you by LivaNova to unlock the Programmer. Change the unlock passcode after you access the Programmer for the first time. For details, see ["Screen Lock" on page 23](#).



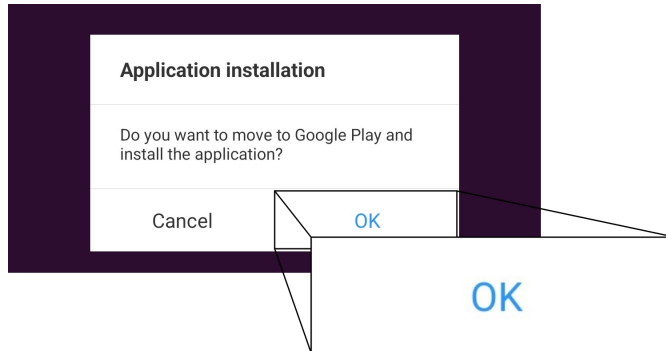
## 4.1.2. Download and Install the Clinician App

When you access the Programmer for the first time, complete the following steps to download and install the Clinician App:

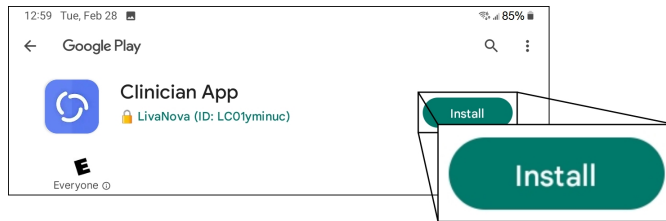
1. Tap the **Clinician App** icon on the Programmer **Home** screen.



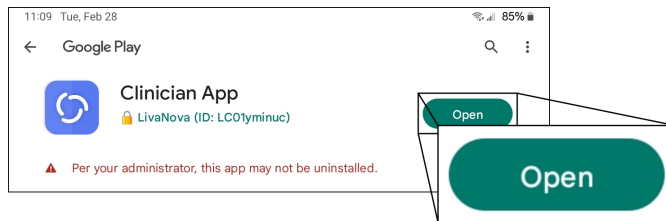
2. Tap **OK** to open to open Google Play.



3. Tap **Install** to download and install the Clinician App.



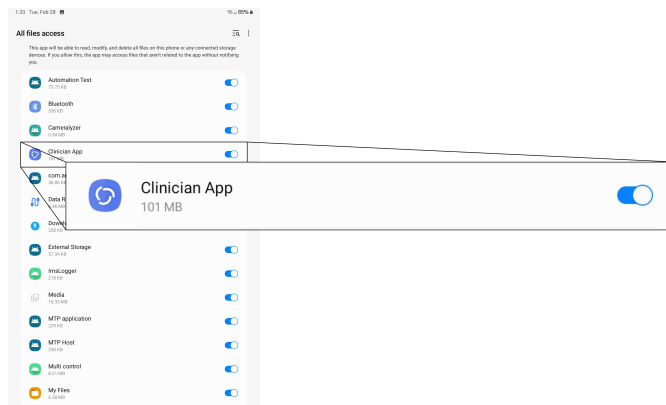
4. Tap **Open**.



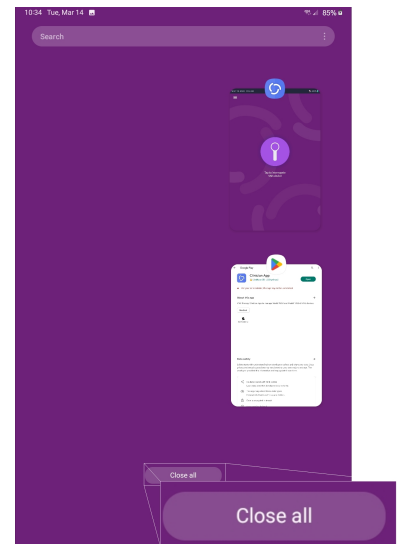
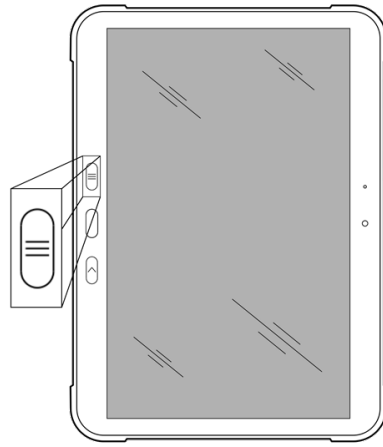
5. Slide the Clinician App toggle to the right to allow the Clinician App to have full access to files and media.



**WARNING:** Do not change any other permissions. This may cause issues with Programmer or Clinician App performance.



6. Press the **Recents** key and tap **Close All**.



7. Tap the **Clinician App** icon on the ProgrammerHome screen to restart the app.



## 4.2. The Kiosk

The kiosk is your home screen to access Programmer settings, Clinician App, and Remote Support.






## 4.2.1. Clinician App



The Clinician App software provides the user interface for you to interact with compatible VNS Therapy devices. Use the Clinician App to interrogate, program and perform device health checks on a supported VNS device. You can also backup Programmer data and access Wand firmware updates through the Clinician App.

## 4.2.2. Remote Support

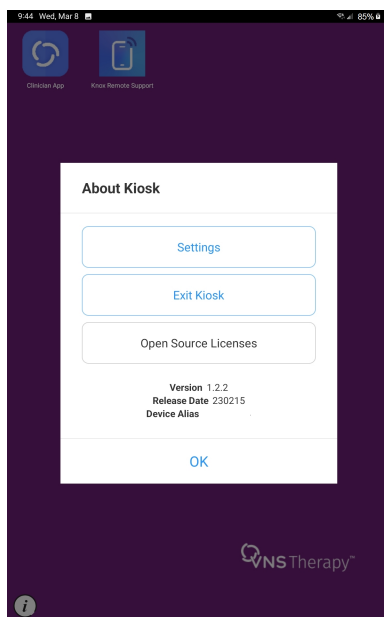


Technical support can connect to the Programmer remotely if it is connected to the internet. If prompted, tap  and enter the access code they provide.

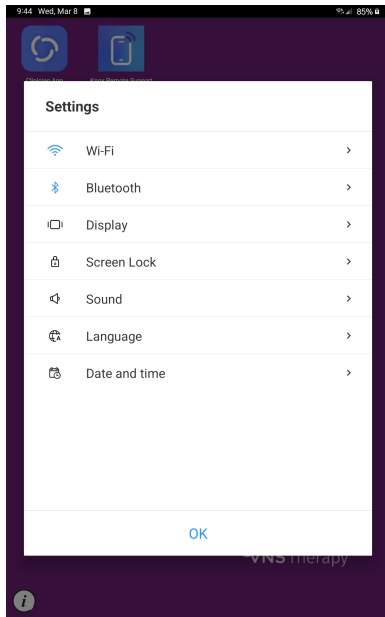
## 4.2.3. Programmer Settings


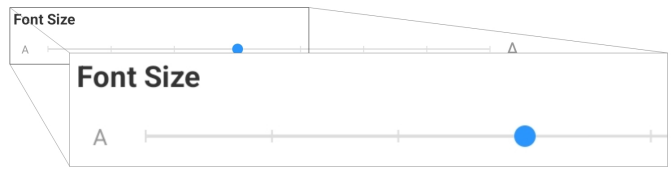
Programmer settings are accessed from the **About Kiosk** screen.

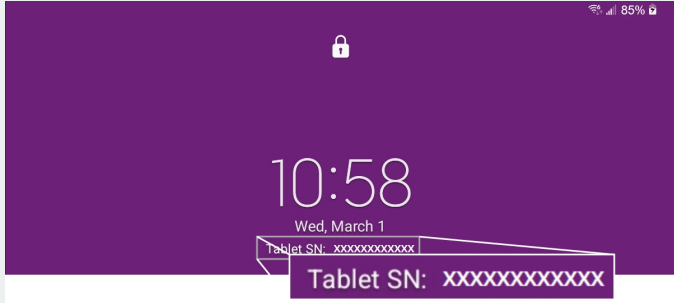
1. Tap the information icon  on the Programmer Home screen.
2. Choose **Settings** from the **About Kiosk** dialog box.



3. Modify settings as described below. Press the **Back** key to return to this menu after you are finished with a setting. Tap **OK** to return to the Programmer **Home** screen.



Wi-Fi	View and connect to available Wi-Fi networks.
Bluetooth®	Bluetooth® is ON by default and must remain ON to use the wireless connection between the Clinician App and the Wand.
Display	<p>Update preferences for screen brightness and screen timeout.</p> <p>Do not change the font size. The default font size selection is pictured below.</p> <p> <b>CAUTION:</b> The Clinician App will not display correctly if you change the font size. If your font size selection is different, change it back to the default selection (4th line from the left).</p> 

<p><b>Screen Lock</b></p>	<p>A screen lock is required for security purposes. The default screen lock type is a personal identification number (PIN), but you can choose to use a swipe pattern or password.</p> <p>Change the Programmer unlock passcode after you access the Programmer for the first time. You must enter your current screen lock credentials to access screen lock options.</p> <p>If you forget your screen lock credentials, contact <a href="#">"Technical Support" on page 62</a>. You will need to provide the tablet serial number, which is displayed on the lock screen.</p> 
<p><b>Language</b></p>	<p>US English is the default system language and the only language that can be displayed in the Clinician App. Any other language changes only apply to the operating system.</p>
<p><b>Date and Time</b></p>	<p>The date and time of the Programmer are automatically set based on location (if connected to the internet). If the Programmer is offline, make manual adjustments, if necessary.</p>

### 4.3. Programmer Update

When the Programmer needs an update, it will be managed by LivaNova.

### 4.4. Connect Wand and Programmer

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

Figure 2. Wand Connected to Programmer



## 4.4.1. Wireless Wand Connection Options

### 4.4.1.1. 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 the preferred Wand.

To setup a preferred Wand, open Wand Settings in the Clinician App when you are out of session.

Alternatively, when you interrogate the VNS device you can select a Wand to become the preferred Wand.

### 4.4.1.2. No Preferred Wand

Choose a Wand as part of VNS device 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.

## 4.4.2. Wired Wand Connection

Included with the system is a USB cable that connects the Wand to the Programmer. Use this as a backup method when a wireless connection is not available or when the Wand firmware must be updated. When you connect to a cabled Wand for the first time, you must accept the permission to allow USB connection.



# Chapter 5

---

## Navigation

This topic includes the following concepts:

---

5.1. User Interface Elements for the Clinician App .....	26
5.2. Home & Out-Of-Session Menu .....	28
5.3. Dashboard & In-Session Menu .....	30
5.4. Parameters Screen .....	32

# 5.1. User Interface Elements for the Clinician App

For information about specific elements within the Clinician App user interface (UI) see the following table.

**Table 4. User Interface Elements — Clinician App**

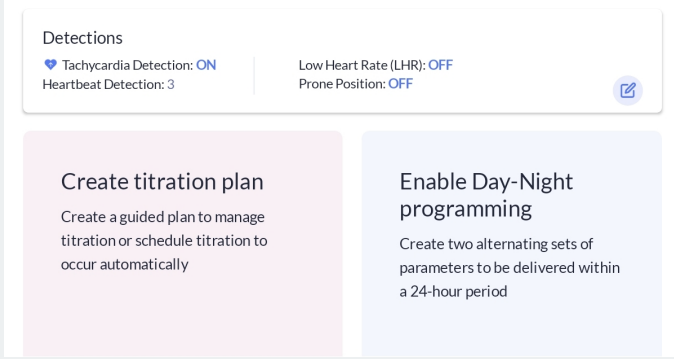
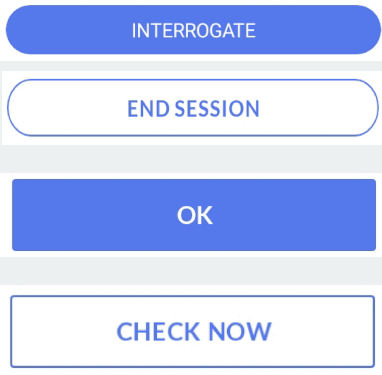


UI	Examples	Description
<p><b>Card</b></p>	 <p>The screenshot shows a card titled 'Detections' with settings for Tachycardia Detection (ON), Heartbeat Detection (3), Low Heart Rate (LHR) (OFF), and Prone Position (OFF). Below this are two action cards: 'Create titration plan' (pink background) and 'Enable Day-Night programming' (blue background).</p>	<p>Cards contain content and actions about a single topic. Tap anywhere on a card for more options.</p>
<p><b>Button</b></p>	 <p>The image shows four buttons: a blue pill-shaped button labeled 'INTERROGATE', a white pill-shaped button with a blue border labeled 'END SESSION', a solid blue rectangular button labeled 'OK', and a white rectangular button with a blue border labeled 'CHECK NOW'.</p>	<p>Buttons trigger an event, action, or command.</p>
<p><b>Navigation Menu</b></p>	 <p>The image shows a standard blue hamburger menu icon with three horizontal lines.</p>	<p>Navigation menus are used globally to allow the user to move from one section of the Clinician App to another. The menu options are specific for in-session or out-of-session functions.</p>
<p><b>Edit Icon</b></p>	 <p>The image shows a blue circular icon with a white pencil and paper symbol inside, representing an edit function.</p>	<p>An edit icon indicates that there are settings available to edit. Tap the card to access editable information.</p>

Table 4. User Interface Elements — Clinician App (continued)

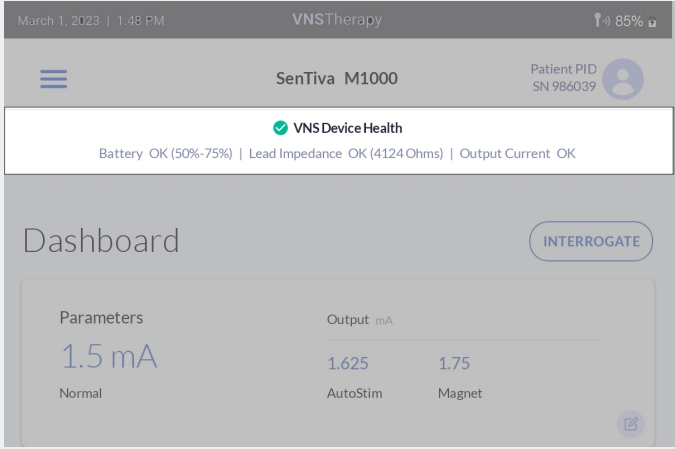
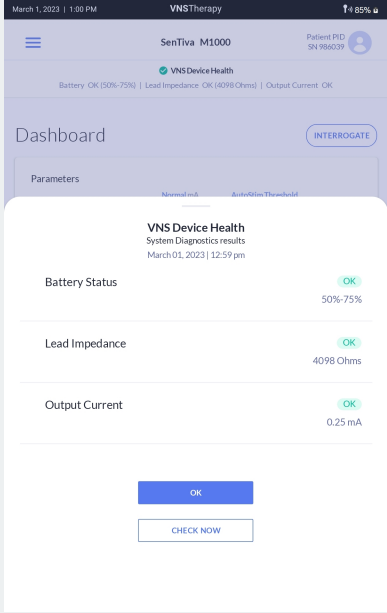
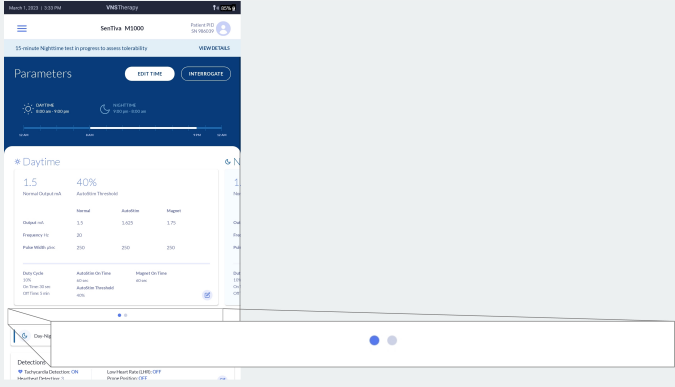
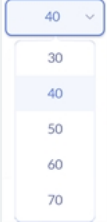
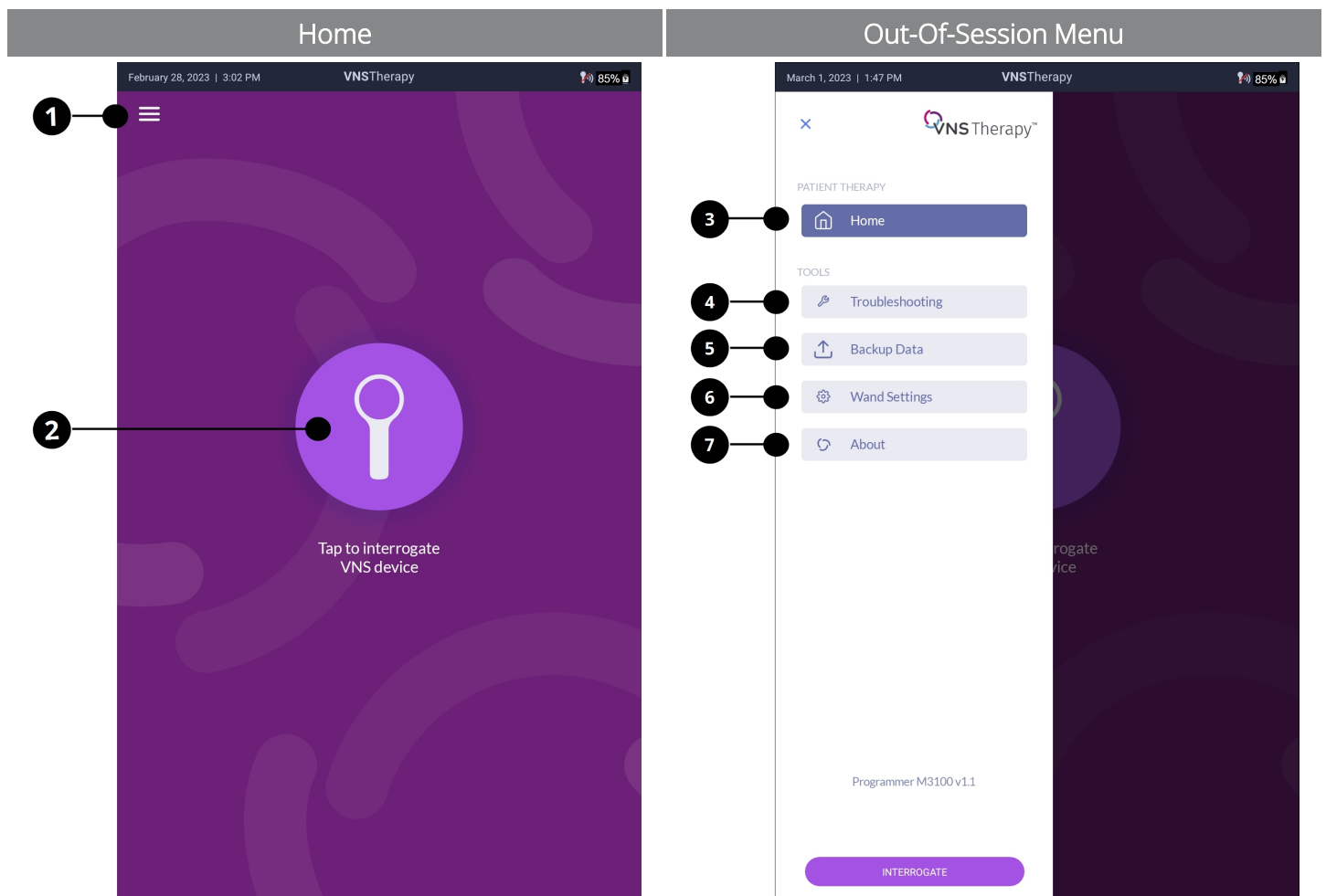
UI	Examples	Description
<p><b>Banner</b></p>	 <p>The screenshot shows the top of the VNS Therapy app interface. At the top, there's a status bar with the date 'March 1, 2023   1:48 PM' and battery level '85%'. Below that, the app title 'VNS Therapy' and patient information 'SenTiva M1000' and 'Patient PID SN 986039' are visible. A prominent banner displays 'VNS Device Health' with a green checkmark and three status items: 'Battery OK (50%-75%)', 'Lead Impedance OK (4124 Ohms)', and 'Output Current OK'. Below the banner is a 'Dashboard' section with a large '1.5 mA' parameter value and an 'INTERROGATE' button.</p>	<p>Banners display prominent messages and related optional actions across the top of the screen. You can tap on a banner to access available options.</p> <p>Status banners are colored based on the severity of the issue:</p> <ul style="list-style-type: none"> <li>• Muted purple – Unknown or neutral information (low priority)</li> <li>• Yellow – Caution (medium priority)</li> <li>• Red – Warning (high priority)</li> </ul>
<p><b>Flyover</b></p>	 <p>The screenshot shows a flyover window overlaid on the dashboard. The flyover is titled 'VNS Device Health System Diagnostics results' and includes the date and time 'March 01, 2023   12:59 pm'. It lists three diagnostic items: 'Battery Status' (OK, 50%-75%), 'Lead Impedance' (OK, 4098 Ohms), and 'Output Current' (OK, 0.25 mA). At the bottom of the flyover, there are two buttons: 'OK' and 'CHECK NOW'.</p>	<p>A flyover appears over another screen and allows you to quickly see summarized information without leaving the main screen. To dismiss the flyover, tap anywhere outside of the flyover or touch and drag the bar on the flyover to the bottom of the screen.</p>
<p><b>Card Carousel</b></p>	 <p>The screenshot shows a card carousel in the 'Parameters' section of the app. The current card is titled 'Daytime' and displays a parameter value of '1.5' with a '40%' indicator. Below the value is a table with columns for 'Normal', 'Daytime', and 'Magnet'. The table contains numerical values for 'Output mA', 'Impedance (ohms)', and 'Max Stimulus (mA)'. At the bottom of the carousel, there are two dots indicating the current position in the sequence.</p>	<p>The card carousel allows you to horizontally scroll between adjacent cards. Cards used in a carousel are strongly related by category, feature, or topic.</p> <p>To view the cards, touch and drag the card right or left.</p>


Table 4. User Interface Elements — Clinician App (continued)

UI	Examples	Description
Drop-downs		Drop-down inputs are compact UI controls that allow you to select an input from a list.

## 5.2. Home & Out-Of-Session Menu







The **Home** screen is the first screen you see after you open the Clinician App. The following information briefly describes the available options.



- 1  Tap the icon to access out-of-session menu options.

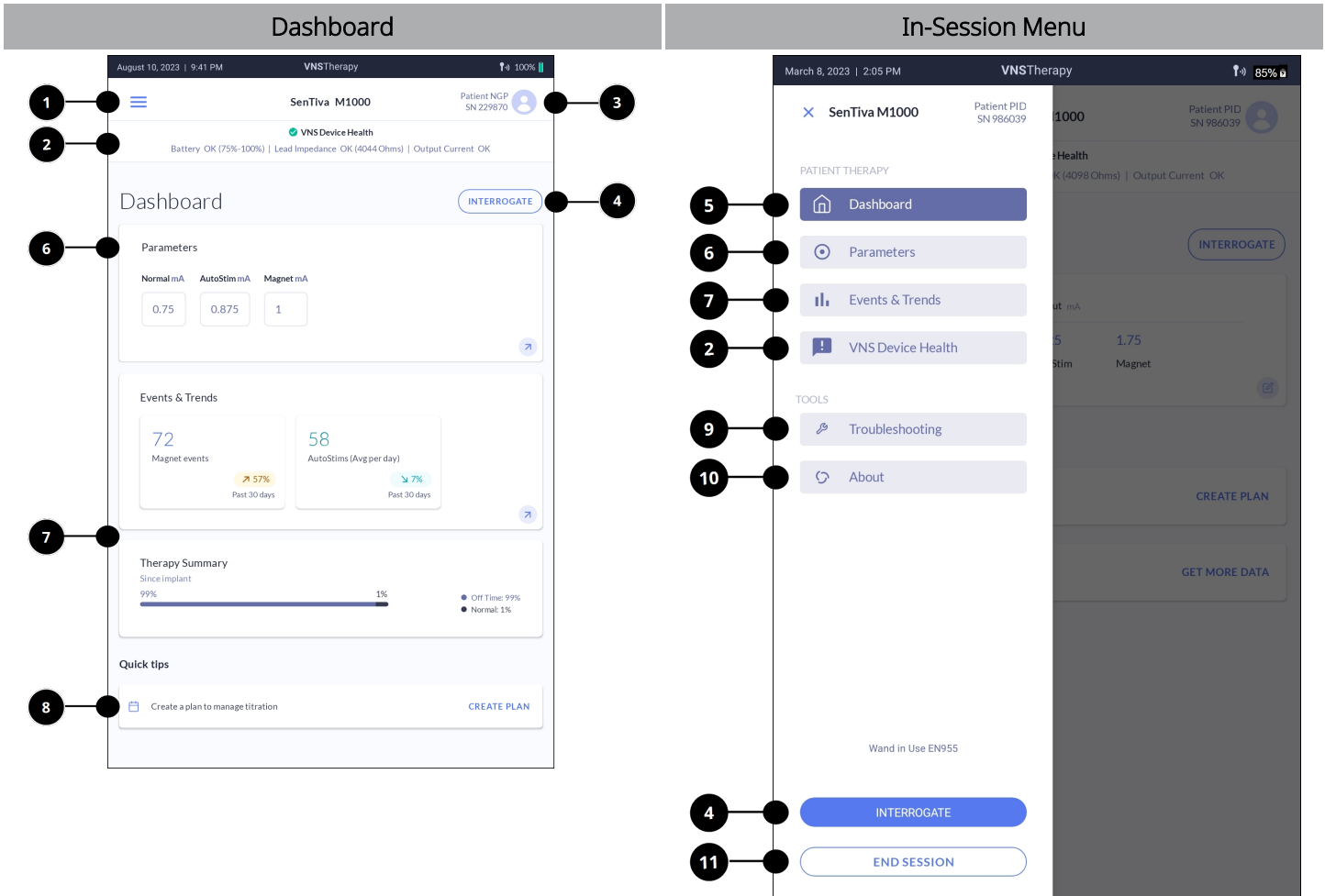





## Navigation

2	 Interrogate	Tap the Wand icon or button to connect to a Wand and communicate with a VNS device to start a patient session. For more information, see <a href="#">"Interrogate" on page 34</a> .
3	 Home	Return to the <b>Home</b> screen from your current location.
4	 Troubleshooting	Access VNS device reset. For more information, see <a href="#">"Troubleshooting in the Clinician App" on page 48</a> .
5	 Backup Data	Backup Programmer data to the LivaNova cloud. For more information, see <a href="#">"Backup Data" on page 48</a> .
6	 Wand Settings	Setup a preferred Wand or check Wand firmware. For more information, see <a href="#">"Wand Settings" on page 48</a> .
7	 About	View Programmer and manufacturer information.






## 5.3. Dashboard & In-Session Menu

The **Dashboard** is the first screen that appears after the interrogation is complete.



1		Access in-session menu options.
2	 VNS Device Health	View the Battery, Lead Impedance, and Normal Output Current delivery status. Tap the banner on the <b>Dashboard</b> to view the VNS Device Health flyover. You can also access the full <b>VNS Device Health</b> screen from the in-session menu, which allows you to run a System Diagnostics test and access history of past tests. For more information, see <a href="#">"VNS Device Health (System Diagnostics)" on page 46</a>
3	 Patient Profile	Access and update patient information (e.g., patient ID, implant date) and view VNS device information (e.g., serial number).

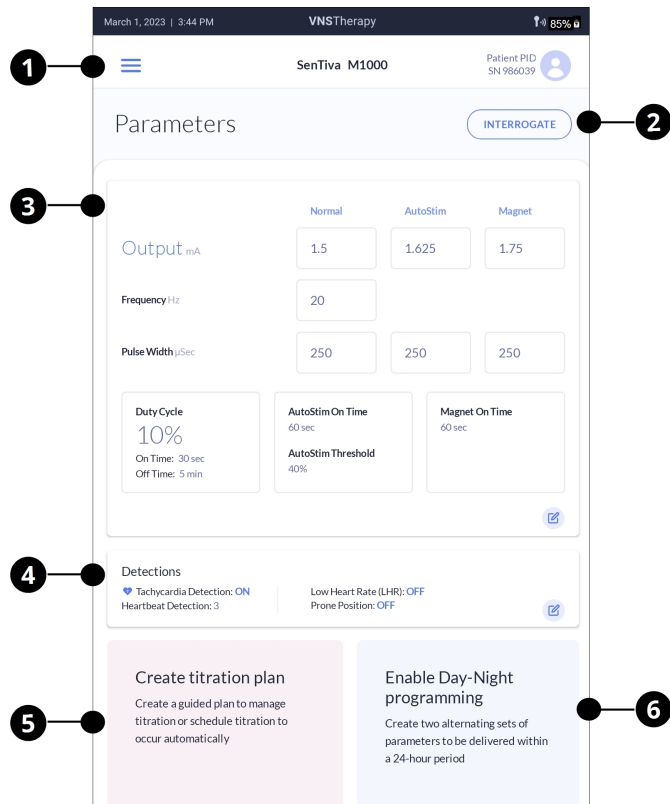
## Navigation

4	INTERROGATE	Retrieves the latest parameter settings from the VNS device. For more information, see <a href="#">"Interrogate" on page 34.</a>
5	 Dashboard	Return to the <b>Dashboard</b> from your current location.
6	 Parameters	View current VNS Therapy parameters. For more information, see <a href="#">"Parameters" on page 34.</a>
7	 Events & Trends	Includes Events & Trends and Therapy Summary cards. For more information, see <a href="#">"Events &amp; Trends" on page 40.</a>
8	Quick Tips	Quick tips inform you about optional features of the Clinician App.
9	 Troubleshooting	Access the Generator Diagnostics, Magnet test, and AutoStim test. For more information, see <a href="#">"Troubleshooting in the Clinician App " on page 48.</a>
10	 About	View Programmer, Wand, and manufacturer information.
11	END SESSION	Ends the patient session and returns to the <b>Home</b> screen.

## 5.4. Parameters Screen

Access parameters from the in-session navigation menu. The **Parameters** screen allows you to view details or access options to edit VNS Therapy parameters.

**i** NOTE: For details on each parameter option, see ["Parameters" on page 34](#).



1		Access in-session menu options.
2	INTERROGATE	Retrieves the latest parameter settings from the VNS device. For more information see <a href="#">"Interrogate" on page 34</a> .
3	Parameters	View current stimulation parameters or tap the card to edit the stimulation parameters for Normal Mode, AutoStim Mode, and Magnet Mode. For more information, see <a href="#">"Parameters" on page 34</a> .
4	Detection	Tap the card to set up Tachycardia Detection, Low Heart Rate Detection, and Prone Position Detection. For more information, see <a href="#">"Detection Parameters" on page 35</a> .
5	Create a titration plan	Tap the card to create a guided or scheduled titration plan. For more information, see <a href="#">"Titration Plans" on page 37</a> .
6	Enable Day-Night programming	Tap the card to enable and set up Day-Night Programming. For more information, see <a href="#">"Day-Night Programming" on page 38</a> .

# Chapter 6

---

## Function

This topic includes the following concepts:

---


6.1. Interrogate .....	34
6.2. Parameters .....	34
6.3. Titration Plans .....	37
6.4. Day-Night Programming .....	38
6.5. Events & Trends .....	40
6.6. VNS Device Health (System Diagnostics) .....	46
6.7. Wand Update .....	47
6.8. Wand Settings .....	48
6.9. Backup Data .....	48
6.10. Troubleshooting in the Clinician App .....	48

## 6.1. Interrogate

### 6.1.1. Initial Interrogation

To view VNS device information on the Programmer, you must connect the Wand and the Programmer, then interrogate the VNS device.



Tap  to get started. If a preferred Wand is set up, it will connect to the Programmer automatically. If there is no preferred Wand, you must choose one to connect with the Programmer every time you interrogate.



NOTE: For information, see ["Connect Wand and Programmer" on page 23](#).

In addition to retrieval of VNS device parameters, a System Diagnostics test is automatically performed as part of the initial interrogation. After the interrogation is complete and a new patient session is established, you can adjust VNS Therapy, view VNS device health, and perform troubleshooting.

### 6.1.2. In-Session Interrogation

When you interrogate in-session, the interrogation retrieves the latest parameters from the VNS device. Unlike the initial interrogation, System Diagnostics is not part of an in-session interrogation.

## 6.2. Parameters

Access stimulation and detection parameters on the **Parameters** screen.

### 6.2.1. Stimulation Parameters


Configure stimulation parameters individually for Normal Mode, AutoStim Mode, and Magnet Mode. The table below details configurable parameters for each mode.

Normal	AutoStim Mode	Magnet Mode
Output Current	Output Current	Output Current
Frequency	Pulse Width	Pulse Width
Pulse Width	ON time	ON time
ON time	AutoStim Threshold	
OFF time		



NOTE: ON time and OFF time are configured through Duty Cycle selection for Normal Mode.

## 6.2.2. Detection Parameters

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

You can configure the VNS device for the following activities:

- Detect heart rate increases and provide AutoStim
- Detect and log low heart rate events
- Detect and log prone position events

The use of these features is optional.

### 6.2.2.1. Tachycardia Detection and AutoStim

To use responsive VNS Therapy, you must configure Tachycardia Detection and AutoStim parameters. Tachycardia Detection monitors the patient's heart rate for increases above a selected threshold during stimulation OFF Time. AutoStim provides stimulation automatically in response to those detected events.

#### 6.2.2.1.1. Tachycardia Detection Setup

When you enable Tachycardia Detection, follow the on-screen prompts to verify heartbeat detection performance and select the AutoStim Threshold setting. The Heartbeat Detection and AutoStim Threshold settings are configurable for individual patient needs.

The Heartbeat Detection setting ranges from 1 to 5. This setting indicates the amount of amplification the VNS device uses to detect heartbeat signals. Setting 1 is the least sensitive setting. It should be used with the largest signals where the need for amplification is low. Setting 5 is the most sensitive setting. It should be used with the smallest signals where the need for amplification is high.

The AutoStim Threshold setting ranges from 20% to 70% in 10% increments. This setting indicates the percentage threshold that the heart rate must increase for AutoStim to initiate. Choose 20% if you want the smallest increase in heart rate before AutoStim starts and 70% if you want the largest increase.

#### 6.2.2.1.2. Verify Heartbeat Detection

When you enable Tachycardia Detection, you must verify the heartbeat detection accuracy of the VNS device. The Verify Heartbeat Detection test is part of the Tachycardia Detection setup. It uses the currently programmed Heartbeat Detection setting to start the test and lasts 2 minutes by default. During this time, compare the heart rate displayed on the screen with the heart rate collected from an independent method (e.g., bpm from another ECG monitor or a manual pulse count). Accurate detection by the VNS device should be within  $\pm 5$  bpm or 10% from the heart rate measured by the independent method. See the table below for examples of how to adjust the Heartbeat Detection setting. It is recommended to change the Heartbeat Detection setting 1 unit at a time.

**Table 5. Example Adjustments to the Heartbeat Detection Setting**

Programmer Heartbeat Detection	Independent Detection Method	Action
90 bpm	60 bpm	Change the setting to a lower less sensitive setting (e.g., 3 to 2)
40 bpm	60 bpm	Change the setting to a higher more sensitive setting (e.g., 3 to 4)
???	60 bpm	The Programmer is unable to detect the heart rate. Hold the Wand directly over the VNS device. If the issue persists, change the setting to a higher, more sensitive one (e.g., 1 to 2).

The test automatically stops after 2 minutes, or if you are satisfied with the performance, you can stop it early. Once stopped, you can retest with another Heartbeat Detection setting. If you change the Heartbeat Detection setting, you must retest at the new setting before you can continue with the rest of the Tachycardia Detection setup.

Once Tachycardia Detection is enabled, you can retest periodically to verify heartbeat detection performance. The test automatically starts with the programmed Heartbeat Detection setting. However, if you test with a new setting, the last tested Heartbeat Detection setting remains programmed regardless of its detection accuracy. For example, the Heartbeat Detection setting is 1, but you decide to try the test at setting 2. Even if setting 2 does not accurately detect heartbeats, the VNS device will remain at setting 2 if you exit and do not test another setting. Thus, it is important to ensure accurate heartbeat detection at the last tested setting.

### 6.2.2.2. Low Heart Rate Detection

The Low Heart Rate (LHR) feature detects and logs low heart rate events if the patient's heart rate falls below the selected LHR threshold within 7.5 minutes of an AutoStim or magnet stimulation. The LHR threshold can be set from 30 to 60 bpm in 10 bpm increments. The VNS device stores the timestamps of the most recent 20 LHR events.

The LHR feature is only accessible after Tachycardia Detection is enabled. If Tachycardia Detection is disabled, the LHR feature will also be disabled.

### 6.2.2.3. Prone Position Detection

The Prone Position feature detects and logs prone position events if they occur within 7.5 minutes of an AutoStim or magnet stimulation. The VNS device stores the timestamps of the most recent 20 events.

The Prone Position feature is only accessible after Tachycardia Detection is enabled. If Tachycardia Detection is disabled, the Prone Position feature will also be disabled.

To use the Prone Position feature, calibrate the VNS device with the patient in an upright position and in a supine position. Once the feature is enabled, repeat this calibration if you suspect VNS device migration.



## 6.3. Titration Plans



CAUTION: Titration plans are only intended for use in epilepsy patients.

Titration plans are optional features used in the titration phase of VNS Therapy. In this phase, VNS Therapy parameters are adjusted until the desired target level is achieved. Traditionally, this is programmed through individual parameter updates. In contrast, titration plans allow you to define output current increases in a stepwise protocol. This simplifies the programming process as you can program through protocol steps rather than individual parameters.

There are two different types of titration plans: guided and scheduled. You can enable guided and scheduled titration plans from the **Parameters** screen.

### 6.3.1. Guided Titration

Guided titration allows you to easily apply output current adjustments with a defined protocol during in-person office visits. This feature simplifies programming because you can increase or decrease output currents with a single button.

### 6.3.2. Scheduled Titration

Scheduled titration allows you to apply a pre-defined schedule of output current increases to the VNS device. Once enabled, the VNS device automatically titrates your patient's VNS Therapy per your protocol while the patient is outside the clinical environment. Scheduled titration can decrease the number of required in-person programming visits during the titration phase.

Communicate the dates and times of the titration schedule to your patient and their caregiver so they know when to expect an increase in the VNS Therapy dosage. If the patient cannot tolerate the new dose, instruct the patient to use the magnet to disable stimulation, and follow up with you for an adjustment to their titration plan.



CAUTION: Time-based features do not automatically adjust for daylight saving time or time zone changes. Tell the patient to follow up with their physician for reprogramming if needed.

### 6.3.3. Titration Plan Rules

The following rules apply for titration plans:

#### Titration Plan Parameters

Plan parameters only include output current increases between the steps. The other stimulation parameters (e.g., frequency, duty cycle) are set to the same values for the entire plan.

### Default Plan Values

When you create a new plan, the suggested default plan values are based on the dosing strategy recommended in the *VNS Therapy Generator and Lead Manual for Epilepsy*.

### Configurable Values

For AutoStim Mode and Magnet Mode output current values, only step 1 values are configurable. The plan increment is applied for values after step 1.

### Titration Plan Restrictions and Limitations

- AutoStim Mode and Magnet Mode output currents must be greater than or equal to Normal Mode output current of the same step.
- Edits to a titration plan starts a new plan at the currently programmed Normal Mode output current. Persistent parameters such as frequency and pulse width are retained. AutoStim and Magnet Mode output values are set to manufacturer defaults.
- Plans have a minimum of 2 steps and a maximum of 7 steps.
- After 2 mA, only the 0.25 mA increment is available until the maximum of 3.5 mA is reached.
- Only output current increases are allowed from one step to the next.

### New Titration Plan Step 1 Values

- Guided – Step 1 Normal Mode output current is set to the currently programmed Normal Mode output current plus the selected step increment.
- Scheduled – Step 1 Normal Mode output current is set to the currently programmed Normal Mode output current.

### Scheduled Titration Plan Step Durations

- Minimum step duration – 7 days for increments of 0.125 mA
- Minimum step duration – 14 days for increments of 0.25 mA
- Maximum step duration – 28 days


### Limited Support Titration Plans


Certain titration plans created from predicate programming systems have limited support in the Clinician App. If this is the case, only the supported portions will be displayed in the Clinician App (e.g., Only the scheduled steps will be displayed from a limited support plan that has a mix of scheduled and unscheduled steps). In addition, you will be prompted to start a new plan if you attempt to edit these limited support plans.

## 6.4. Day-Night Programming

Day-Night programming is an optional feature that programs the VNS device to deliver two alternate sets of therapy parameters within 24 hours. This feature allows you to choose unique Daytime and Nighttime settings and define the time each parameter set is active.

After therapy parameters reach a target level, use Day-Night to customize the therapy for the individual patient's needs. Ensure that the patient can tolerate both sets of parameters and communicate to the patient and caregiver when to expect a setting change. As with any therapy setting change, the risks and benefits of altering a patient's known efficacious settings should be considered when adjustments are made.

 CAUTION: Time-based features do not automatically adjust for daylight saving time or time zone changes. Tell the patient to follow up with their physician for reprogramming if needed.

 NOTE: Day-Night programming is not available when the VNS device is in a titration plan.

## 6.4.1. Enable or Disable Day-Night

Enable Day-Night on the **Parameters** screen. The software guides you through the setup of the Day-Night feature. Once enabled, disable the feature through shortcuts on the **Dashboard** or **Parameters** screen.

## 6.4.2. View or Modify Day-Night Parameters

The Day-Night parameters display on separate cards, one for Daytime and the other for Nighttime. The card with the interrogated active parameter set displays first. Swipe left or right on the Daytime or Nighttime card to view details.

Once Day-Night is enabled, modify the stimulation parameters and AutoStim threshold independently for Daytime or Nighttime. You can also change the Day-Night schedule if desired. The minimum duration for Daytime or Nighttime stimulation is 1 hour.

## 6.4.3. Fifteen-Minute Test

When you use Day-Night, you should ensure that the patient tolerates both sets of parameters. To help with this assessment, when you first enable Day-Night or change its parameters, a 15-minute test is automatically applied. During this time, the VNS device uses the parameters from the alternate period to stimulate for 15 minutes. After 15 minutes, the VNS device reverts to the stimulation parameters for the current period. This process allows you to assess patient tolerability for both sets of stimulation.

For example, at a 10 A.M. clinic visit, you enable Day-Night to stimulate at 1.5 mA during the Daytime period of 9 A.M. – 7 P.M. and 1.75 mA during the Nighttime period of 7 P.M. – 9 A.M. When this is programmed, the VNS device stimulates at 1.75 mA for 15 minutes, then reverts to 1.5 mA. The test allows you to assess patient tolerability for the Nighttime setting of 1.75 mA. Otherwise, the 1.75 mA parameter would not be tested for tolerability until 7 P.M.

Additional information about the 15-minute test includes the following:

- The 15-minute test stops if you make parameter changes while the test is in progress.
- Diagnostics tests that run during the test period use the 15-minute test parameters.

- The software displays a status banner when the 15-minute test is in progress. This banner is automatically dismissed after the test is complete or stopped.

## 6.5. Events & Trends

The Events & Trends feature displays magnet stimulation and event detection data from the VNS device and is only available when you are in session.

### 6.5.1. Dashboard

After you interrogate the VNS device, the Dashboard displays the following data:

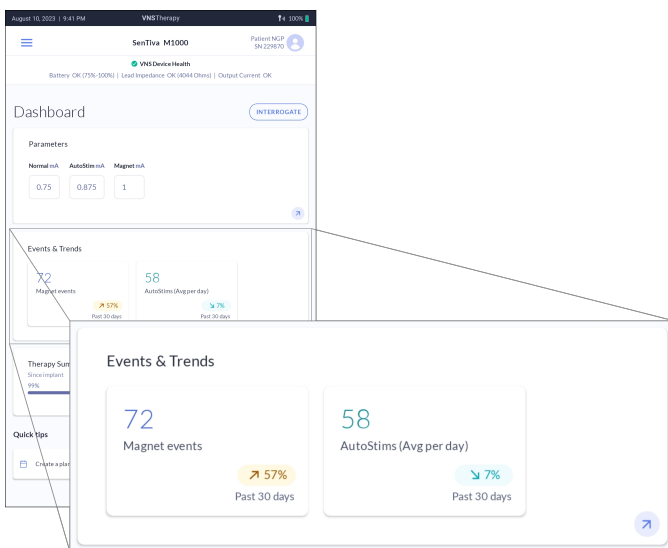
- Total magnet events for the past 30 days and, if available, its trending pattern in comparison to the previous 30-day period
- Average AutoStim events per day for the past 30 days and, if available, its trending pattern in comparison to the previous 30-day period
- A summary of therapy data since the patient's implant



NOTE: The therapy summary is only displayed if the patient ID or implant date is present.

Tap the Events & Trends card to access more Events & Trends screen.

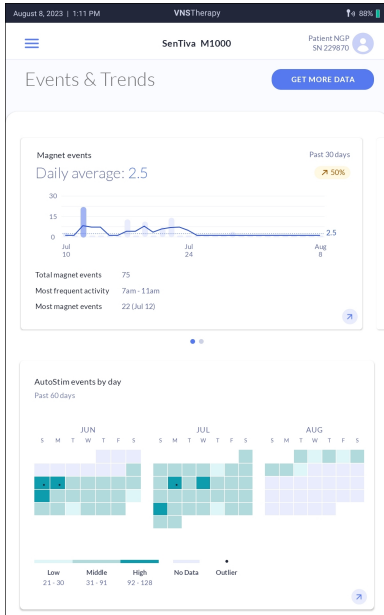
Figure 3. Events & Trends Card



## 6.5.2. Events & Trends Screen

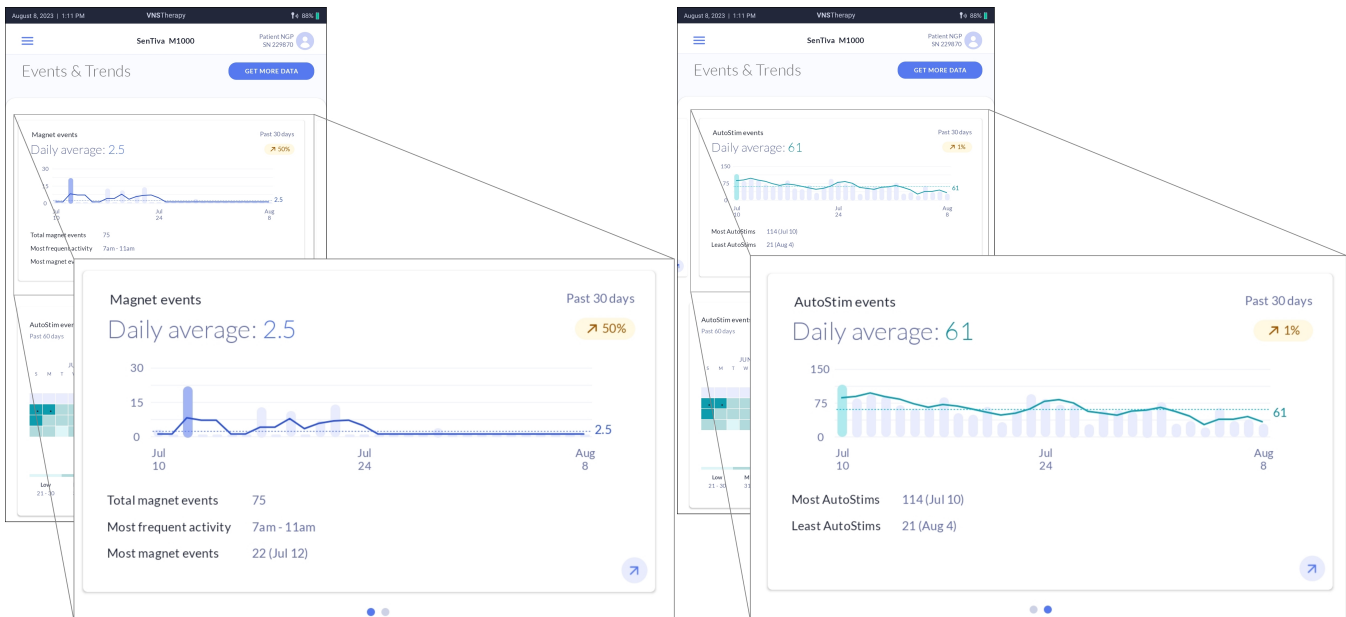
After initial interrogation, you can access VNS device data for the past 60 days.

Figure 4. Sixty Days of Data Example



Swipe on the magnet and AutoStim event cards to view details. Tap on each card to access a full-screen view.

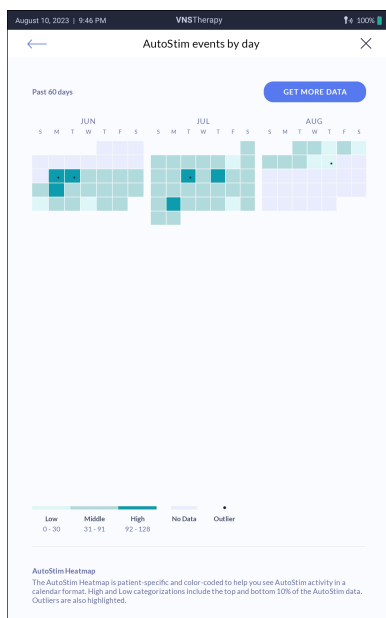
Figure 5. Magnet and AutoStim Event Card Examples



## Function

The AutoStim events calendar (i.e., the AutoStim heatmap) displays 60 days of color-coded AutoStim events. Tap on the card to access a full-screen view. This patient-specific heatmap separates AutoStim activity into high, middle, and low categories. The high and low categorizations include the top and bottom 10% of the AutoStim data. In addition, outliers<sup>1</sup> indicate days when the patient's AutoStim activity is very high or very low compared to their normal activity.

Figure 6. AutoStim Calendar Events by Day Example



<sup>1</sup>Statistically defined as data points greater than or equal to 2.7 standard deviations from the mean.

## 6.5.3. GET MORE DATA

Tap **GET MORE DATA** to download up to 180 days of data from the VNS device. After the data downloads, all events and trends screens are updated with the most recent data. If the Low Heart Rate or Prone Position features are enabled, you can tap **VIEW TIMESTAMPS** on the Events & Trends screen to view the associated timestamps.


 NOTE: For more information, see ["Events & Trends Data" on the next page](#)

Figure 7. Updated AutoStim Heatmap Example

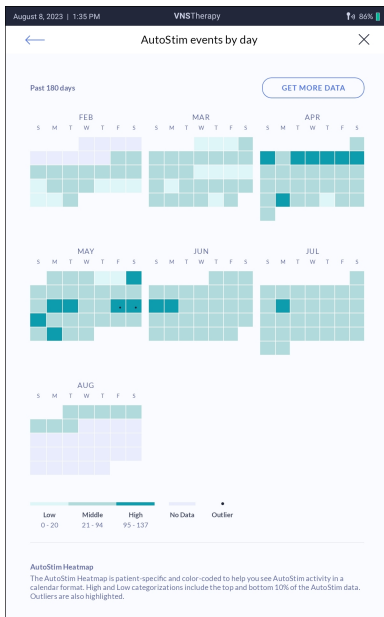
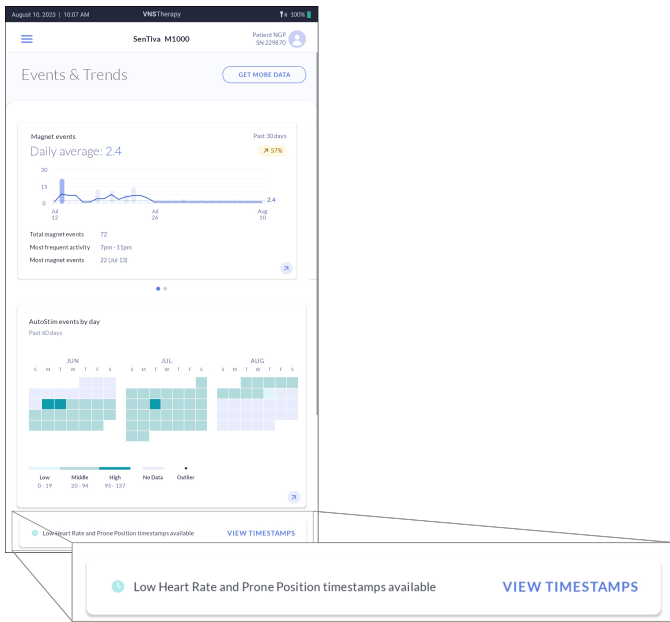


Figure 8. View Timestamps Example



### 6.5.4. Events & Trends Data

The table below shows types of data accessible through Events & Trends for Model 1000 and Model 1000-D VNS devices. You cannot access Events & Trends data if the VNS device is disabled or has out-of-range parameters. In addition, the specific feature must be enabled on the VNS device to see the associated data (e.g., Tachycardia Detection and AutoStim must be enabled to access AutoStim-related data).

Table 6. Events & Trends Data

Screen	Data	Description	Action	Available Data
	Magnet Events	Daily counts of magnet stimulations. Each count is recorded at the <i>start</i> of the stimulation.	After the initial interrogation	Past 60 days
			After you tap GET MORE DATA	Up to 180 days
	Magnet Stimulation Timestamps	Timestamps of magnet stimulations. The recorded time is at the <i>end</i> of the simulation.	After the initial interrogation	Up to 50 most recent timestamps



Table 6. Events & Trends Data (continued)

Screen	Data	Description	Action	Available Data
	AutoStim Events	Daily counts of auto stimulations where the AutoStim output current is > 0 mA. Each count is recorded at the <i>start</i> of the stimulation.	After the initial interrogation	Past 60 days
			After you tap GET MORE DATA	Up to 180 days
	AutoStim Timestamps	Timestamps of auto stimulations where the AutoStim output current is > 0 mA. The recorded time is at the <i>start</i> of the stimulation.	After you tap GET MORE DATA	Up to 350 most recent timestamps
	Low Heart Rate Timestamps	Timestamps of low heart rate events.	After you tap GET MORE DATA	Up to 20 most recent timestamps
	Prone Position Timestamps	Timestamps of Prone position events.	After you tap GET MORE DATA	Up to 20 most recent timestamps

## 6.6. VNS Device Health (System Diagnostics)

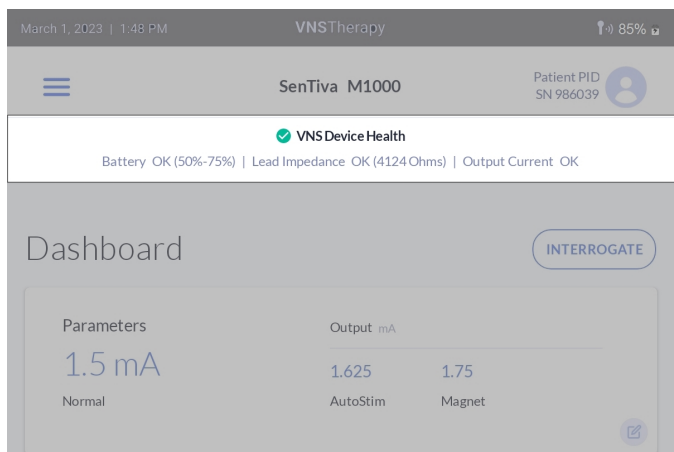
The system diagnostics test collects VNS Device Health information. The information collected includes the following:

- VNS device battery status
- Lead impedance
- Ability to deliver programmed Normal output current

### 6.6.1. Access VNS Device Health

There are two ways to access VNS Device Health (system diagnostics test):

- In-session menu — Select **VNS Device Health**. Perform a system diagnostics test or view a history of past results.
- Dashboard — Select the **VNS Device Health banner**. The information in the banner at the top of the screen updates at the start of the patient session and each time you perform a system diagnostics test during a patient session. Tap on the banner to access additional device health details or to run a new VNS device health check.



### 6.6.2. System Diagnostics Test Results and Definitions

The table below contains possible results and their definitions.

Table 7. System Diagnostics Test Results and Definitions

Battery Status	
OK (15–25%) OK (25%–50%) OK (50%–75%) OK (75%–100%)	The battery is OK.

Table 7. System Diagnostics Test Results and Definitions (continued)

IFI (8%–15%)	The battery has decreased to a level where more frequent clinical monitoring is recommended.
NEOS (0%–8%)	The battery is near end of service. Replace the VNS device as soon as possible.
EOS (0%)	The battery is at end of service and no longer provides stimulation. Replace the VNS device immediately.
Unknown	The battery level is unknown or cannot be assessed. Follow on-screen instructions or retry System Diagnostics.
<b>Lead Impedance (measured value in <math>\Omega</math>)</b>	
OK	The lead impedance is OK.
Low	The lead impedance is lower than expected ( $\leq 600 \Omega$ ). If symptoms such as painful, erratic, or intermittent stimulation are present, this may indicate a short-circuit condition with the lead or a defective VNS device.
High	The lead impedance is higher than expected ( $\geq 5300 \Omega$ ). This could indicate a discontinuity of the lead, fibrosis between the nerve and the lead, poor connection between the generator and lead, or other problems.
Unknown	The lead impedance value is unknown or cannot be assessed. Follow on-screen instructions or retry System Diagnostics.
<b>Output Current</b>	
OK	The programmed Normal output current is delivered.
Low	The programmed Normal output current may not be delivered at the specified level.
Unknown	Programmed output current delivery status is unknown or cannot be assessed. Follow on-screen instructions or retry System Diagnostics.

### 6.6.3. Therapy Disabled or Paused

Therapy is not delivered when the VNS device is disabled or paused (i.e., the magnet is placed over the VNS device). If this occurs, the disabled or paused status displays at the top of the screen. Also, not all diagnostics or tests are available when the VNS device is disabled or paused. Re-enable therapy or move the magnet away from the VNS device before you run diagnostics or tests.

## 6.7. Wand Update

The Clinician App notifies you if a Wand update is available. If the update is optional, you can update the Wand at your convenience. If the update is mandatory, you must update your Wand before you can interact with a VNS device. A USB connection is required for all Wand updates. Follow the on-screen instructions to update your Wand.

## 6.8. Wand Settings

Wand settings are available from the out-of-session menu only. You can set up a preferred Wand, change the preferred Wand or check Wand firmware to identify its version information.

## 6.9. Backup Data

The Backup Data function is available from the Navigation menu when out-of-session only. It allows you to backup Programmer data to the LivaNova cloud.

## 6.10. Troubleshooting in the Clinician App

This section discusses troubleshooting options available in the Clinician App.

### 6.10.1. Out-of-Session VNS Device Reset

Perform a VNS device reset when there is a serious and persistent issue with the VNS device that other troubleshooting techniques have not resolved. This feature should only be used for Model 1000 and Model 1000-D devices. Contact "[Technical Support](#)" on [page 62](#) for assistance.

### 6.10.2. In-Session Troubleshooting


#### 6.10.2.1. Generator Diagnostics

The Generator Diagnostics test verifies that the generator, independent of the lead, functions properly. Perform the test with a test resistor, during troubleshooting scenarios in surgery. For more information, see the indication-specific physician's manual.

 NOTE: The test resistor is in the accessory pack.


The results show battery status, lead impedance value and normal output current delivery status.

#### 6.10.2.2. Magnet Test

 NOTE: This test is only intended for use in epilepsy patients.

Use a patient magnet to check the delivery of programmed magnet parameters. This test is only available when the VNS device is enabled for therapy and the programmed Magnet output current is greater than 0 mA.


### 6.10.2.3. AutoStim Test

 NOTE: This test is only intended for use in epilepsy patients.

Check the delivery of programmed AutoStim parameters. This test is only available when the VNS device is enabled for therapy, Tachycardia Detection is enabled, and the programmed AutoStim output current is greater than 0 mA.

## General Troubleshooting

This section provides solution steps to resolve error conditions with the programming system components. For other programming system issues not included in this section, contact ["Technical Support" on page 62](#).

 NOTE: LivaNova can remotely connect to your programming system for troubleshooting. Discuss the option with Technical Support if this is needed.

This topic includes the following concepts:

---

7.1. Anomalous Behavior or Non-Responsive System .....	51
7.2. Wand Will Not Connect to Programmer .....	51
7.3. Wand Will Not Communicate with Generator .....	54

## 7.1. Anomalous Behavior or Non-Responsive System

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

### 7.1.1. Programmer

1. Ensure that the Programmer is sufficiently charged.
2. Close any open instances of the Clinician App and restart the app.
3. Restart the Programmer.
4. If you experience continued difficulties, contact ["Technical Support" on page 62](#).

### 7.1.2. Wand


1. Ensure sufficient Wand battery level. If the orange low battery indicator is displayed on the Wand, replace the Wand batteries.
2. Perform a soft reset on the Wand. Press and hold the Wand power button for 5 seconds and release. Wait 1 second then press and release the Wand button again. Retry the connection with the Programmer.
3. If Bluetooth® communication is unreliable, use the USB cable to connect the Wand and the Programmer.
4. If you experience continued difficulties, contact ["Technical Support" on page 62](#).

## 7.2. Wand Will Not Connect to Programmer

### 7.2.1. Possible Causes


- Wand not powered on
- Depleted Wand batteries
- *Bluetooth*® not enabled in the Programmer
- Electromagnetic interference (EMI) (e.g., OR lights)
- Improper cable connection between Wand and Programmer
- Improper USB port recognition of the Programmer cable
- Defective Wand
- Defective Programmer

## 7.2.2. Solution Steps

STEP 1	Turn on the Wand.	
STEP 2	Check the Wand power.	
	Does the low battery icon illuminate?	
	IF	THEN
	Yes	Change the batteries and turn the Wand on.
		 NOTE: If you have changed the batteries and there are no green power indicator lights, contact <a href="#">"Technical Support" on page 62.</a>
	No	Are the green power indicator lights on?
	IF	THEN
	Yes	Continue to <b>STEP 3</b>
	No	Contact <a href="#">"Technical Support" on page 62</a>
STEP 3	Check to see if <i>Bluetooth</i> <sup>®</sup> is enabled in the Programmer.	
	IF	THEN
	Yes	Continue to <b>STEP 4</b> .
	No	Enable <i>Bluetooth</i> <sup>®</sup> in the Programmer settings.
STEP 4	Retry the wireless connection to the Wand.	
	Is the connection successful?	
	IF	THEN
	Yes	Proceed with use.
	No	Continue to <b>STEP 5</b> .
STEP 5	Move 3-4 feet away from EMI sources such as other computers or electrical equipment.	
STEP 6	Retry the wireless connection to the Wand.	
	Is the connection successful?	
	IF	THEN
	Yes	Proceed with use.
	No	Continue to <b>STEP 7</b> .



## General Troubleshooting

STEP 7	Perform a soft reset on the Wand. Press and hold the Wand power button for 5 seconds and release. Press the Wand power button again.	
STEP 8	Retry the wireless connection to the Wand.	
	Is the connection successful?	
	IF	THEN
	Yes	Proceed with use.
STEP 9	Connect the Wand with the backup cable.	
	 NOTE: If this is the first time you use a cabled Wand, you must allow permission for the Programmer to connect to the USB.	
	Is the connection successful?	
	IF	THEN
STEP 10	Verify the Wand cable connection. Reinsert if necessary.	
	Is the connection successful?	
	IF	THEN
	Yes	Proceed with use.
STEP 11	Retry the cabled connection to the Wand.	
	Is the connection successful?	
	IF	THEN
	Yes	Proceed with use.
	No	Contact <a href="#">"Technical Support" on page 62.</a>

## 7.3. Wand Will Not Communicate with Generator

### 7.3.1. 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)
- Defective Wand
- Defective Programmer
- Defective generator

### 7.3.2. Solution Steps

1. Confirm that the Wand is placed over the generator.
2. Rotate the Wand 45 degrees.
3. Confirm, during surgery, that the generator pocket is not more than 1 inch below the skin, not the muscle.
4. Retry Communication.
  - If communication was successful, continue with use.
  - If communication is unsuccessful, contact ["Technical Support" on page 62](#).

# Chapter 8

---

## Maintenance, Handling, and Disposal

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

This topic includes the following concepts:

---

8.1. System .....	56
8.2. Programmer .....	56
8.3. Wand .....	57
8.4. Disposal .....	57

# Chapter 8

## 8.1. 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. For instructions, see ["Return Product Form " on page 62.](#)

### Liquids

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

## 8.2. Programmer

### Touchscreen Display

Debris can damage the tablet touchscreen display. Wipe with a soft cloth, using approved cleaners. Be sure to power off the tablet and disconnect the wall / USB charger from the electrical outlet before you clean it.

### Charge and Heating

The tablet and the charger may become hot when plugged into an electrical outlet. If the battery becomes too hot, the charge speed can decrease or not charge at all. If this happens, disconnect the charger from the device and close all open apps, then wait for the tablet to cool before you resume.

### Extended Inactivity

If you do not use your Programmer for an extended period of time, you must allow the Clinician App to have full access permissions again when you relaunch the application.



If a Programmer is unused for 1 year, it locks and requires an unlock code from LivaNova. For contact information, see ["Technical Support" on page 62.](#)

# Chapter 8

---

## 8.3. 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.

## 8.4. 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. For instructions see ["Return Product Form " on page 62.](#)

## Programming System Specifications and Guidance

This topic includes the following concepts:

---

9.1. Wand and Programmer Specifications .....	59
9.2. Wand Electromagnetic Conditions .....	60
9.3. Wireless Security .....	61

## 9.1. Wand and Programmer Specifications

Table 8. Wand and Programmer Specifications

	Wand	Programmer
<b>Storage Conditions</b>		
Temperature	-20 °C to +55 °C	
Relative Humidity	Up to 95%, including condensation	10% to 90%, non-condensing
<b>Operation Conditions</b>		
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 <i>Bluetooth</i> <sup>®</sup> 2.1: 10.4 dBm	N/A
Transmitter Operating Frequency	Inductive: 82 kHz; 89 kHz (102 only) <i>Bluetooth</i> <sup>®</sup> 2.1: 2402 - 2480 MHz	N/A
Receiver Bandwidth	Inductive: 12.5 to 135 kHz <i>Bluetooth</i> <sup>®</sup> 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
<b>Operating System</b>		
Operating System	N/A	Android

## 9.2. Wand Electromagnetic Conditions

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

**Table 9. Wand Electromagnetic Emissions**

EmissionsTest	Compliance Level
RF Emissions CISPR 11	Group 1, Class A
<p><b>i</b> 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.</p>	

**Table 10. 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 11.**

### 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



Table 11. Wand Electromagnetic Immunity to Proximity Fields from RF Wireless Communications Equipment (continued)

Test Frequency	Service	Compliance Level
1720 1845 1970	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	28 V/m
2450	<i>Bluetooth</i> ® 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

## 9.3. Wireless Security

Table 12. 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 <i>Bluetooth</i> ® 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 <i>Bluetooth</i> ® 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:	<a href="http://www.livanova.com">www.livanova.com</a>

## 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	<a href="https://www.fda.gov">https://www.fda.gov</a>
----	-------------------------------------------------------

## Return Product Form

A Returned Product Form is used for the return of any VNS Therapy system component. Call first for a Return Goods Authorization (RGA) number, available from "Technical Support" above. Before device components are returned, disinfect them with Betadine®, Cidex® soak, or other similar disinfectant, and double seal them in a pouch or other container properly labeled with a biohazard warning.

Return Product Forms are posted at [www.livanova.com](http://www.livanova.com).