



Vivistim[®] Paired VNS[™] System Non-implantable Device Manual for Healthcare Professionals

Wireless Transmitter: Model 2000

Stroke Application and Programming Software (SAPS): Model 4001

NOTE: This page identifies the parts included in this Healthcare Professional's Manual. The information contained herein is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all of the manuals for the Vivistim[®] Paired VNS[™] System and its component parts, nor does this represent full disclosure of all pertinent information concerning use of this product, potential safety complications, or efficacy outcomes. Copies of all Vivistim[®] Paired VNS[™] System manuals are included with the system for full disclosure; copies are also available from MicroTransponder, Inc. This manual contains information that shall not be made available to patients.

Released Version 5

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Vivistim[®] Paired VNS[™] System Quick Start Guide for Therapists

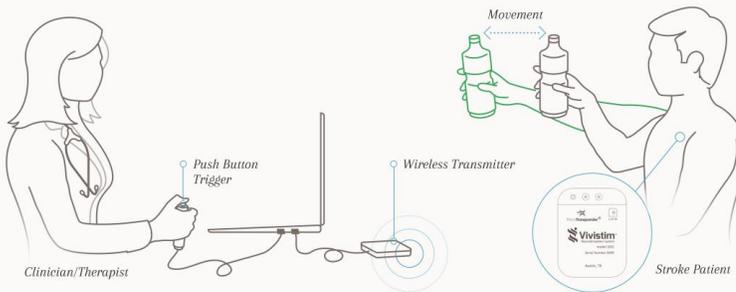
NOTE: Read this manual in its entirety before seeing your first patient.



WARNING: The IPG serial number is the only permanent unique patient identifier detected by the software. Always check the IPG serial number and the patient's physical ID card before saving or over-writing a "Patient ID" in the software to avoid inadvertently misidentifying a patient.

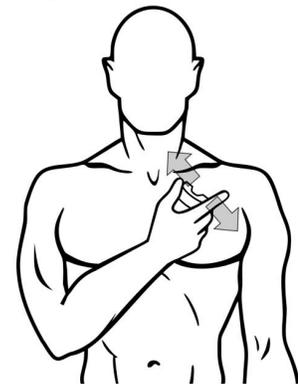
Therapist Trigger Mode

enables the therapist to trigger stimulation using the push button trigger.



Magnet Mode

enables the patient to trigger stimulation using a magnet swipe.



To treat a patient:

1. Connect and Program the IPG. (p. 17)
2. Start and Deliver Treatment. (p. 20)
3. Implement Magnet Mode Before Sending Patient for At-home Therapy. (p. 39)
4. If the patient needs an MRI, read and follow "IPG Settings for MRI Procedures". (p. 51)

Passwords:

Laptop: mti123
SAPS: mti
Reset: reset1

This is the END of the Quick Start Guide.

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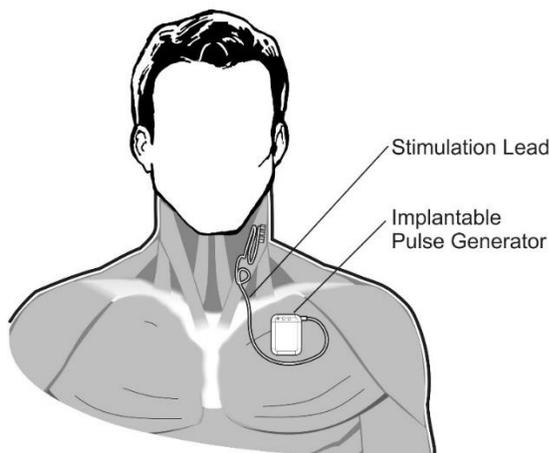
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1 DEVICE DESCRIPTION

The non-implantable components of the MicroTransponder® Vivistim® Paired VNS™ System (Vivistim® System) include the Stroke Application & Programming Software (SAPS) and Wireless Transmitter (WT). The SAPS and the WT enable the clinician to set Paired VNS™ parameters, initiate a therapy session, and test and modify the implanted device and its settings. The complete device system (the Vivistim® System) is shown in Figure 1.1.

A



B

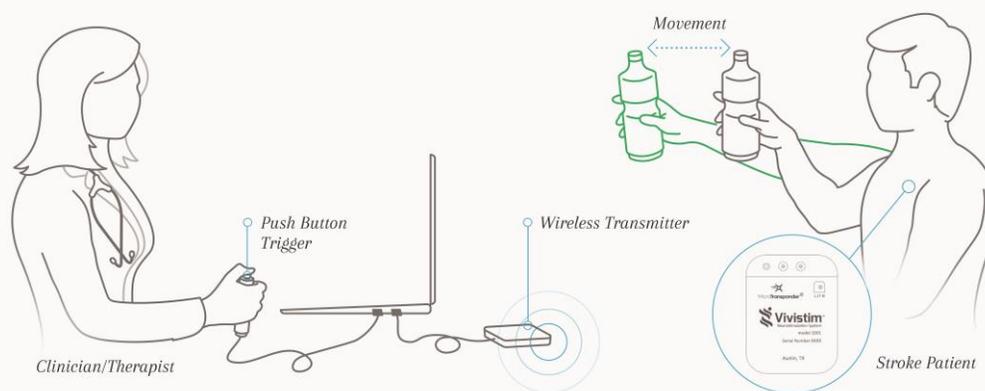


Figure 1.1: (A) Device Placement, (B) In-office Set-up

The Vivistim® System, when used as intended, provides a drug-free way to treat upper extremity motor deficits associated with a stroke by pairing rehabilitation movements with Vagus Nerve Stimulation. The Lead electrodes are attached to the left vagus nerve in the neck. The Lead is tunneled from the neck to the chest, where it is connected to the Implantable Pulse Generator (IPG), and the IPG is placed subcutaneously (or sub-muscularly) in the pectoral region. The SAPS is delivered to the clinician preloaded onto a commercially available laptop. The SAPS, via the WT, allows the clinician to program the output settings of the IPG (e.g., amplitude, frequency, pulse width) and read the status and history of the IPG. The SAPS also stores the number of stimulations, task performed, and IPG status that occur for each rehabilitation activity for future review by the clinician.

The SAPS and WT allow the implanted components (the IPG and Lead) to stimulate the vagus nerve while a rehabilitation movement occurs. The therapist initiates the stimulation using a USB push button or mouse click, so as to synchronize the stimulation with an appropriate timepoint during rehabilitation movements. When directed by a physician and with appropriate programming to the IPG, the patient can initiate at-home use by swiping a magnet over the IPG implant site. Swiping activates the IPG to deliver stimulation for ~ 30 minutes¹ while rehabilitation movements are performed at home. At-home use does not require the use of SAPS or the WT. In addition, the magnet provided to the patient to initiate home therapy also has a safety feature; if the patient desires to stop stimulation, holding the magnet over the device stops stimulation for as long as it is held over the device.

The physician or therapist is responsible for training the patient on use of the magnet and providing the **Microtransponder® Vivistim® Paired VNS™ System Manual for Patients**. The **Microtransponder® Vivistim® Paired VNS™ System Quick Start Guide for Patients** is located in the **Microtransponder® Vivistim® Paired VNS™ System Manual for Patients**, and an additional copy is on the last page of this manual.

Software capabilities include:

- Use of SAPS with the WT by a rehabilitation therapist or neurologist or other physician to interrogate and program an IPG's parameters and assess IPG function
- Use of SAPS with the WT by a rehabilitation therapist or neurologist or other physician to initiate a therapy session during rehabilitation at the clinic
- Use of SAPS without the WT to display the operating histories of all the IPGs interrogated with the laptop
- Use of screen displays that provide prompts and messages to aid in interrogating and programming

Other User Manuals:

- **Microtransponder® Vivistim® Paired VNS™ System Manual for Patients**
- **Microtransponder® Vivistim® Paired VNS™ System Implantable Device Manual for Healthcare Professionals**

1.1 Intended Use / Indication

The MicroTransponder® Vivistim® Paired VNS™ System is intended to be used to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

SAPS is intended for use only with the MicroTransponder Implantable Pulse Generator (IPG) and MicroTransponder Wireless Transmitter.

¹ The clinician is responsible for establishing the duration of stimulation according to clinical best practices.

1.2 SAPS Warnings

NOTE: *The SAPS system, as described herein, should only be used with equipment described in this manual. SAPS should not be used with medical device equipment other than the Vivistim[®] System.*



WARNING: *Do not modify this equipment without authorization of MicroTransponder.*



WARNING: *The use of any software other than that specified herein will violate safety, effectiveness, and design controls of the programmable devices, and such use may result in an increased risk to users and patients.*

1.3 SAPS Package Contents

The SAPS package contains the following:

- Software (installed on commercially available laptop)
- Documentation

1.4 WT Package Contents

The WT package contains the following:

- 1 Wireless Transmitter
- Documentation

2 GETTING STARTED

2.1 Stroke Application & Programming Software (SAPS) Hardware Setup

Figure 2.1: indicates the proper setup:

1. Connect the power cord to the power port on the laptop and connect the other end to the wall outlet.
2. Connect the WT to a USB port on the laptop.
3. (Optional) Connect the push button to a USB port on the laptop.

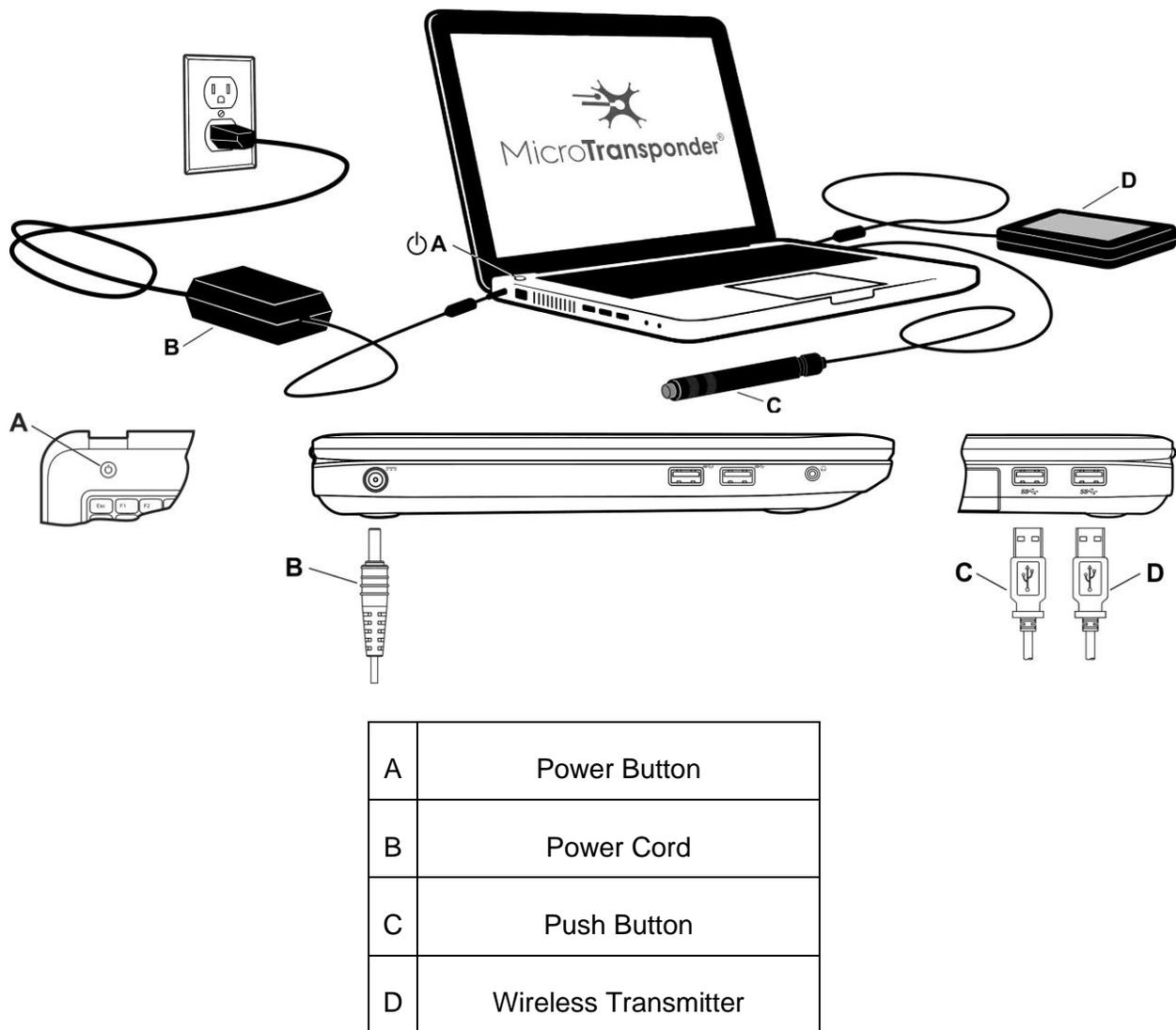


Figure 2.1: SAPS Hardware Set-up Overview

2.2 How to Use the Stroke Application & Programming Software (SAPS)

The SAPS has been pre-installed on the commercially available laptop provided.

1. Position the laptop within 1 m of the IPG implanted in the patient's left chest.
2. Turn the laptop on (Typically the ON button is directly below the laptop screen on the front left, as shown above in Figure 2.1.; although it may also be on the front right or side of the computer; press down).
3. The laptop will power up in the “**microtransponder**” login state. Log into the computer using the password “**mti123**”. This password is case-sensitive.
4. The SAPS loaded onto the laptop will then start. A warning will appear that reminds you to ensure all other applications are closed (see Figure 2.2).



CAUTION: *If the laptop does not automatically launch the SAPS and display the Application Warning Screen (see Figure 2.2), then please reboot your computer and re-launch SAPS (see **Section 13 Troubleshooting**). If this does not correct the issue or you have additional problems, please contact MicroTransponder per **Section 18: Information and Support**.*

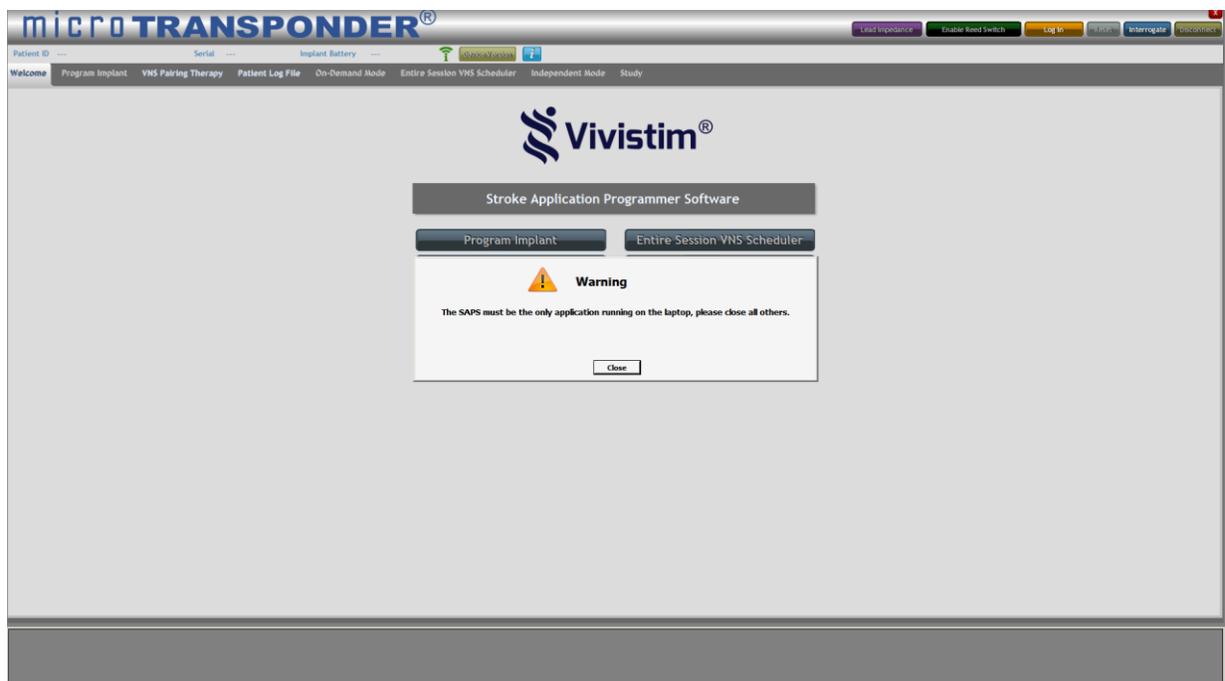


Figure 2.2: Application Warning Screen

5. Select “Close” to dismiss the Application Warning Screen and view the Startup Menu Screen (**Welcome** menu) (see Figure 2.3). Before proceeding to the next section, ensure that you have arrived at this Startup Menu Screen.

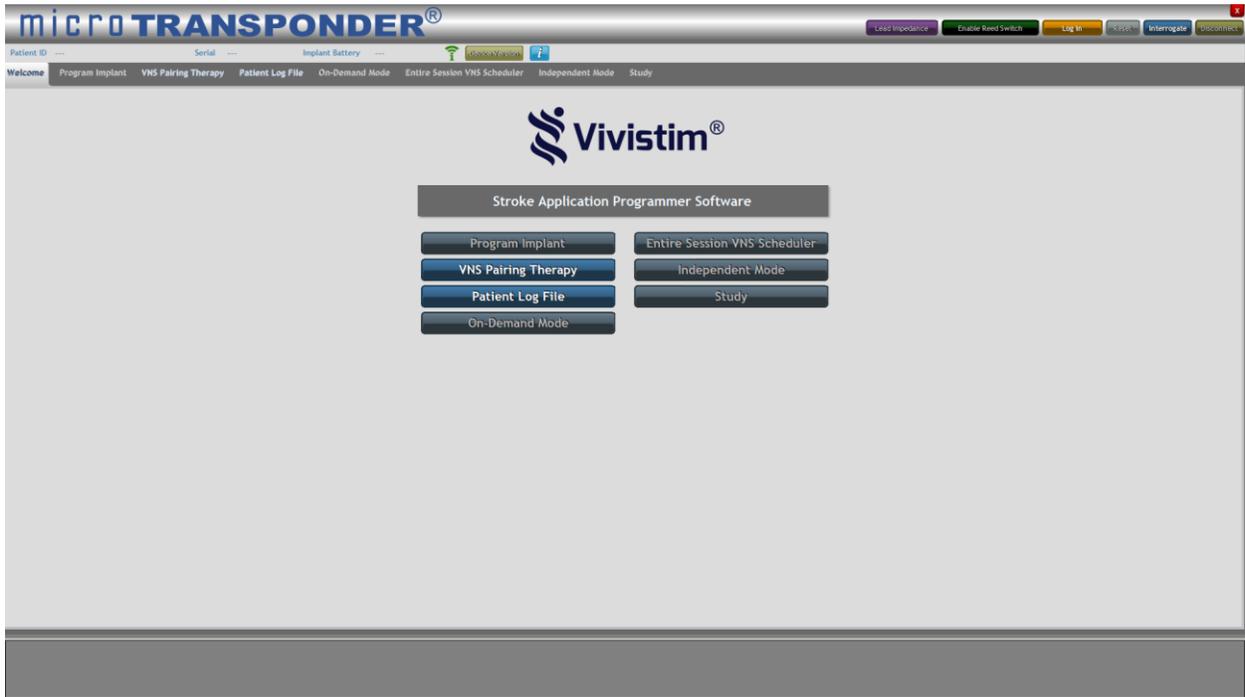


Figure 2.3: Startup Menu Screen—Welcome Menu



CAUTION: If the computer does not display the Startup Menu Screen, see **Section 12: Precautions, Warnings, Contraindications, and Hazards** and **Section 13: Troubleshooting** before proceeding.

For proper operation and communication, the USB plug of the WT must be plugged into a USB port of the laptop. The WT should be positioned within 1 m of the implanted IPG for proper communication. The **Interface** indicator on the SAPS user interface screen will be green in color when the WT is connected properly, red when the WT is disconnected, and alternating white/green when SAPS is communicating (see Figure 2.4).



Figure 2.4: WT Interface “Connected” Indicator

3 USING THE SOFTWARE (SAPS)

Unless a **Log In** has been performed by entering the appropriate password, the only buttons enabled in the **Welcome** menu are the **Patient Log File** and **VNS Pairing Therapy** buttons (see Figure 2.3). These buttons allow the physician or therapist to assign a task and perform a therapy session. To access the rest of the program features, the **Log In** button must be selected (see Figure 3.1).

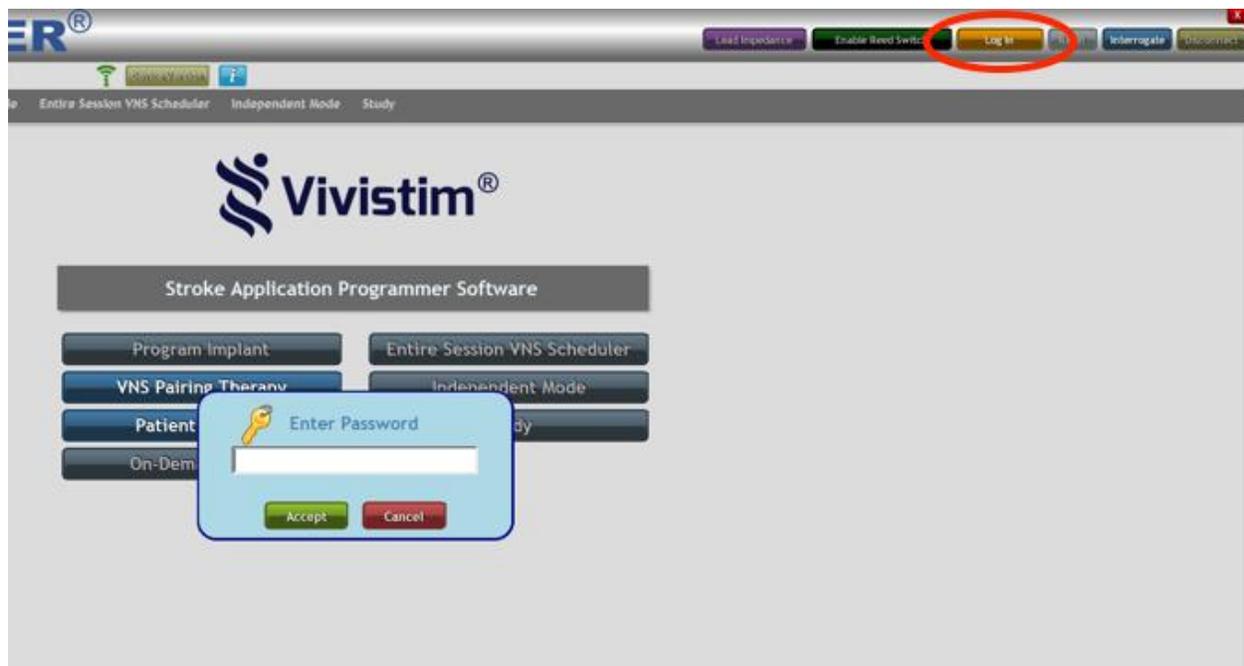


Figure 3.1: Log In

To log in and access all other SAPS screens, select the **Log In** button (upper right menu bar, 4th button from the right) and type the password “**mti**” into the pop-up shown in Figure 3.1.

At this point the program is “unlocked,” and all menus in the program are available (see Figure 3.2).

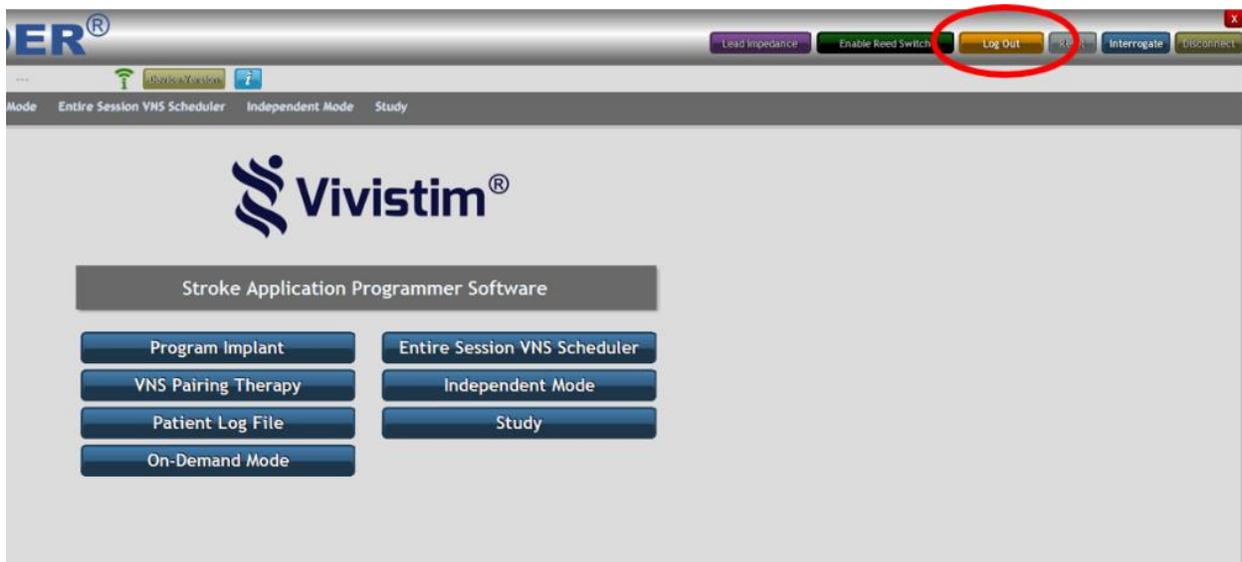


Figure 3.2: Startup Menu Screen—Physician Mode

Notice that the orange **Log In** button has toggled to **Log Out** (circled in Figure 3.2) so that, if desired, the user may select the **Log Out** button and once again remove access to the additional SAPS screens.

After a period of 15 minutes, the **Log In** will time out, and you will need to log back in to continue the session.

3.1 Buttons Versus Tabs

Within the SAPS, there are two types of clickable elements: buttons and tabs (see Figure 3.3).

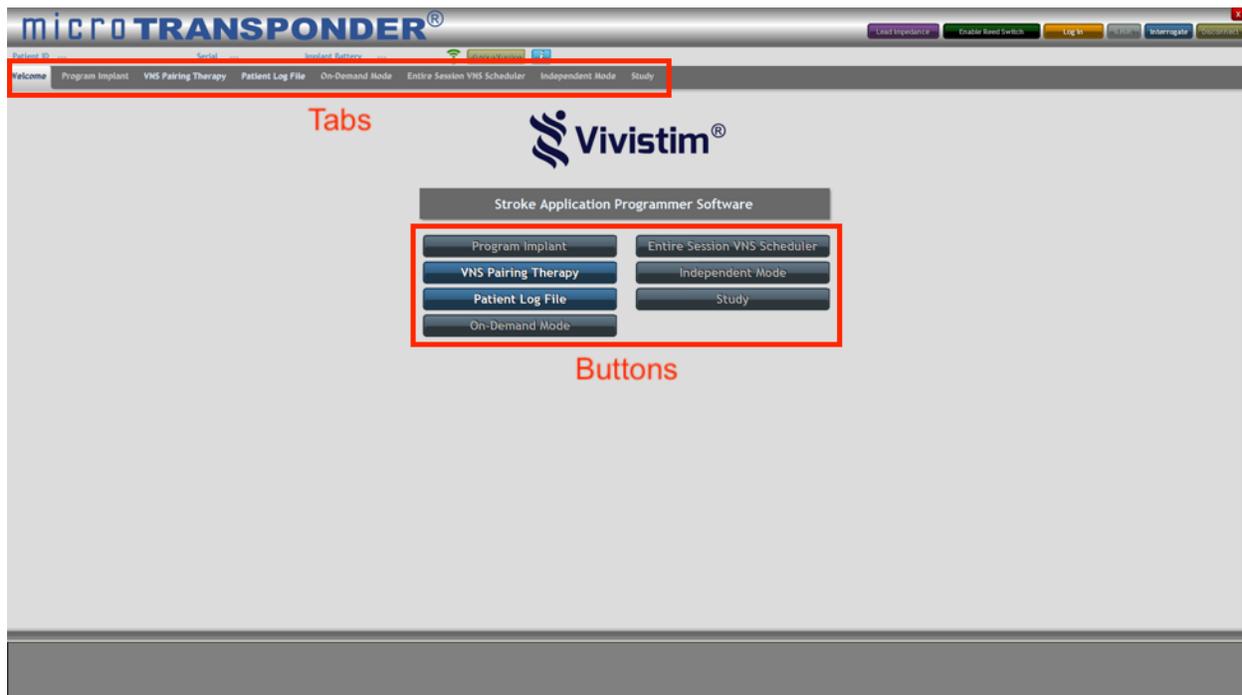


Figure 3.3: Buttons Versus Tabs

The buttons on the **Welcome** screen initiate functions such as programming the implant, initiating **On-Demand Mode**, or accessing the Patient Log File. For example, the **Program Implant** button sends a signal from the WT to the IPG to update the IPG settings with those currently saved in the SAPS.

The tabs at the top of any screen allow the physician to manage the settings of each function. For example, the **Program Implant** tab allows the physician to review and edit the IPG settings.

3.2 Parameter Text Color

When changing parameters for therapy, blue text indicates settings that have not been saved to the IPG (i.e., the **Download to IPG** button has not been pressed), and black text indicates settings that have been saved to the IPG. In Figure 3.4 below, **Frequency, Train Duration, Pulse Width, Train Period, and Magnet Mode** have been saved to the IPG, while **Amplitude** has not.

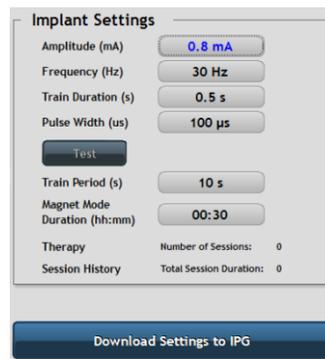


Figure 3.4: Blue Text Indicates Settings Have Not Been Saved

3.3 Overview of SAPS Menus (Tabs) Used for Therapy

Each tab at the top of the SAPS screen corresponds to a particular capability of the system, denoted by the tab's name.

NOTE: See Figure 3.3 for the location of the menus and the corresponding buttons used to access the menus described in this section.



CAUTION: New parameters and therapy modes are not input into the IPG and remain blue in color until the **Test** function or the **Download Settings to IPG** function is used. Always verify that the intended parameters and therapy modes are programmed into the IPG. The suggested method of doing so is by interrogating the IPG and comparing the displayed values to those intended to be programmed. Properly programmed parameters and therapy modes display black in color.

3.3.1 Program Implant Overview

The first tab, **Program Implant**, is used by the physician or therapist to set the patient information, stimulation settings, and therapy mode(s) and allows for impedance checks during implant and follow-up visits. See **Section 4: Programming the Implant** for more detail.

3.3.2 VNS Pairing Therapy Overview

The second tab, **VNS Pairing Therapy**, is used to actually deliver therapy and assign the correlating rehabilitation task. It allows the therapist to either:

- trigger the delivery of stimulation so that stimulation can be synchronized with a specific rehabilitation movement using the **On-Demand Mode** (see **Section 5.1: On-Demand Mode Menu** for more detail), or
- deliver automatic stimulation for a set period of time (stimulate throughout a therapy session using the **Entire Session VNS Scheduler** mode – see **Section 5.2: Entire Session VNS Scheduler** for more detail).

3.3.3 Patient Log File Overview

The third tab, **Patient Log File**, allows the physician or therapist to review on the computer screen or print out specific saved settings that were utilized during the rehabilitation session. For example, the therapist can review each stimulation usage for a given task. See **Section 8 Patient Log File** for more detail.

3.3.4 On-Demand Mode Overview

The fourth tab, **On-Demand Mode**, allows the physician or therapist to set the type of triggering mechanism for on-demand therapy and its settings. See **Section 5.1: On-Demand Mode Menu** for more detail.

3.3.5 Entire Session VNS Scheduler Overview

The **Entire Session VNS Scheduler** menu allows the physician or therapist to program the therapy setting for an entire session without the need for individual triggering. See **Section 5.2: Entire Session VNS Scheduler** for more detail.

3.3.6 Independent Mode

The **Independent Mode** menu allows the physician or therapist to program the stimulation to be delivered independent of user (physician, therapist, or patient) activation. It works similarly to the **Entire Session VNS Scheduler** menu otherwise. Generally, it is not recommended to use this mode. Contact MicroTransponder if you would like to use this mode (**Section 18: Information and Support**).

3.3.7 Study

The **Study** menu is useful if a clinical study is being conducted at the clinic. It allows the physician or therapist to administer therapy based on a subject's treatment group. This menu is password protected. Contact MicroTransponder if you would like to use this mode (**Section 18: Information and Support**).

4 PROGRAMMING THE IMPLANT

The **Program Implant** menu (see Figure 4.1) allows the user to set the patient information, test and set stimulation parameters, set therapy mode(s), and check impedance during implant and follow-up visits.

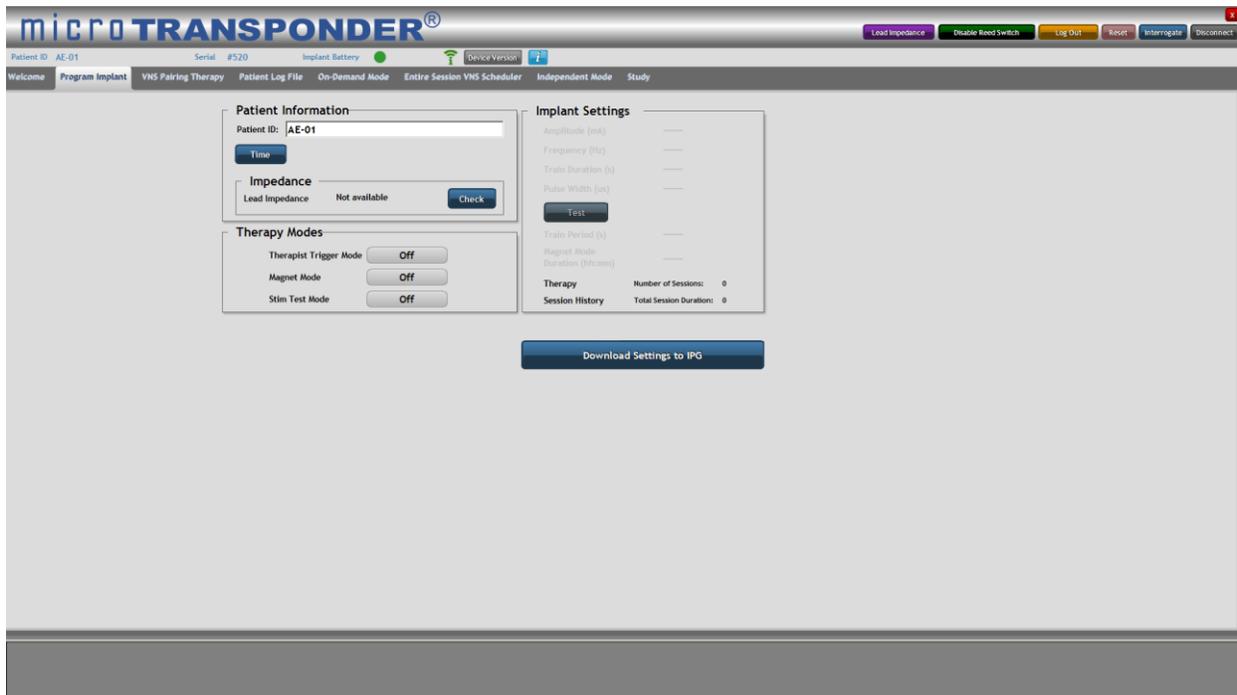


Figure 4.1: Program Implant

4.1 Connecting to a Specific IPG

Perform these six steps before therapy for each patient to connect to their specific IPG.

1. Select the **Disconnect** button to disconnect any IPG that is connected to SAPS that is different from your patient's IPG Serial # (see Figure 4.2). Select "Continue" when prompted to confirm.



Figure 4.2: Disconnect

2. Verify there is no Serial # displayed in SAPS; you will see 3 dashes next to "Serial" if this is the case (see Figure 4.3).



Figure 4.3: Blank Serial #

3. Select **Interrogate** to allow the SAPS to find the patient's IPG (see Figure 4.4 and Figure 4.5).

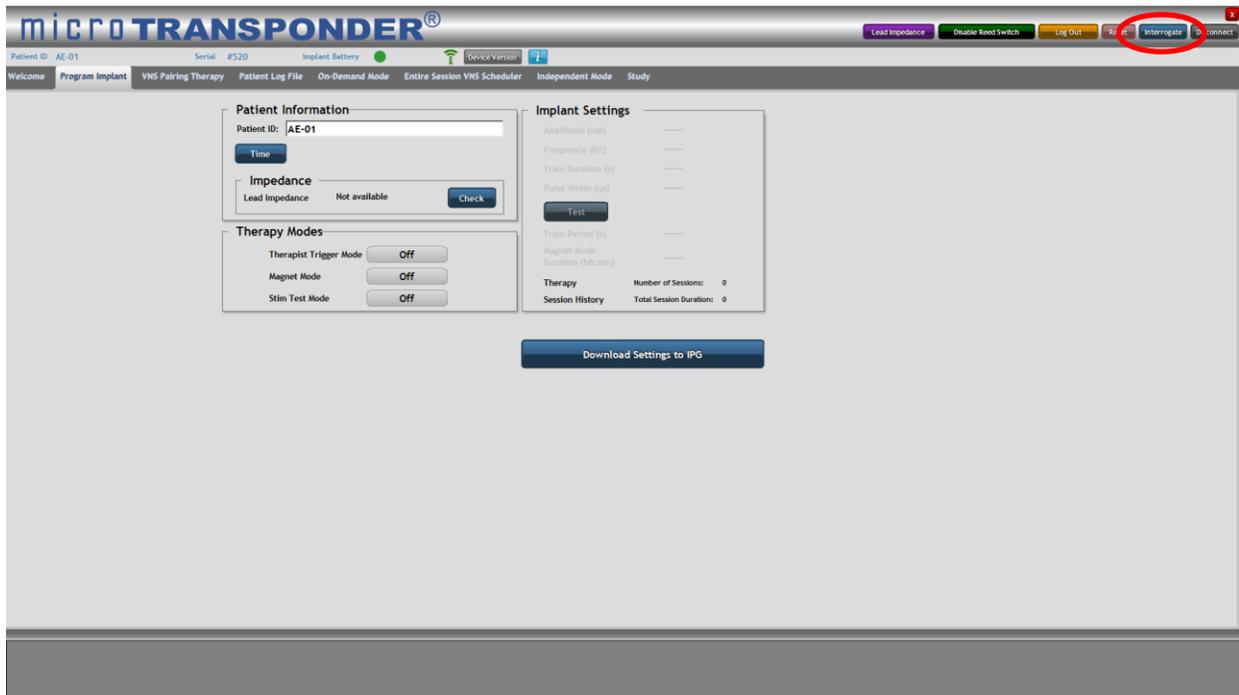


Figure 4.4: Interrogate Button on Screen



Figure 4.5: Interrogate

4. A pop-up menu will appear. Select the IPG whose Serial # matches the one on the patient's Patient Identification Card by clicking on their specific IPG and then pressing the **Select** button (circled in Figure 4.6).

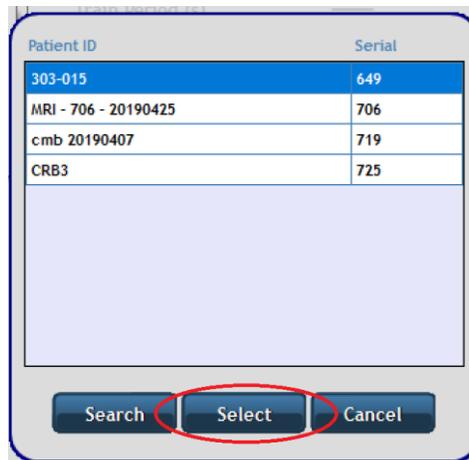


Figure 4.6: Select Button

5. Verify that the selected IPG's Serial # is displayed to the right of "Serial", and check the IPG battery's status, as indicated by the symbol to the right of "Implant Battery" (see Figure 4.7). A green circle indicates an adequately full battery. "ERI" or "EOL" displayed in place of the green circle indicates that the IPG's battery is close to its end of life. You may want to verify the Lead impedance. See **Section 4.5: Impedance**.



Figure 4.7: Serial # and Battery Status

6. You may also want to verify that the IPG date and time are synched with the computer. See the steps below.
 - a. Press the **Time** button (circled in Figure 4.8:).

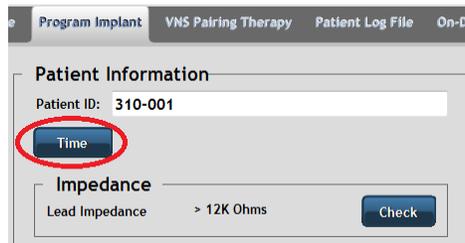


Figure 4.8: Time Button

- b. A window appears showing the Current Device Time and Current PC Time (see Figure 4.9). Generally, the **Set with PC Time** button on the right-hand side is used to synchronize time. Each button can be used as described here:
 - The **Get Time** button to view the current IPG time
 - The **Set Time** button to manually set the IPG time
 - The **Set with PC Time** button to set the IPG time to the current PC time

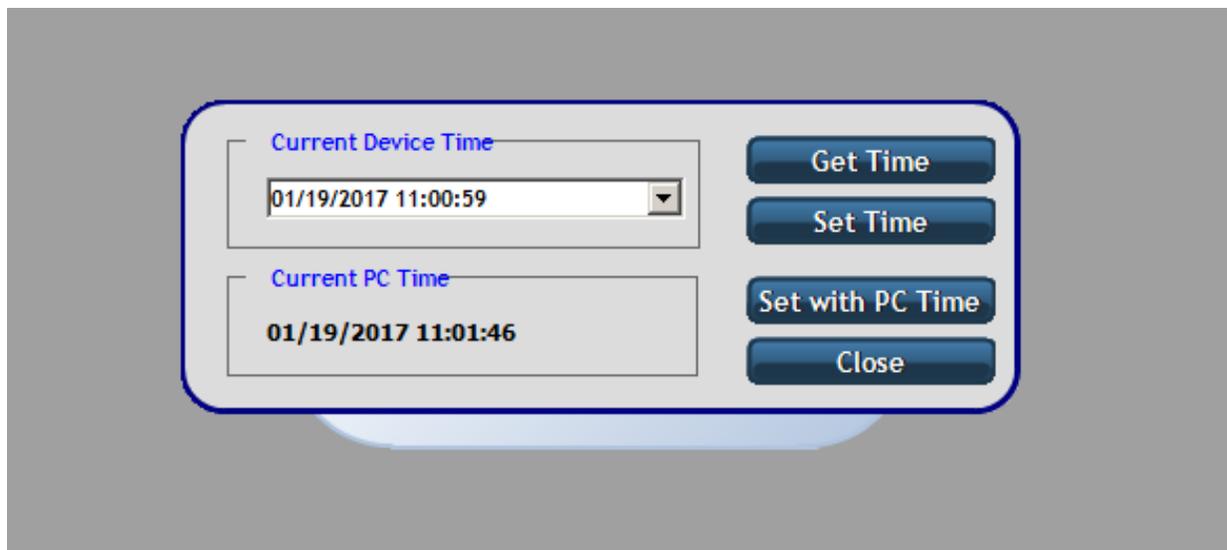


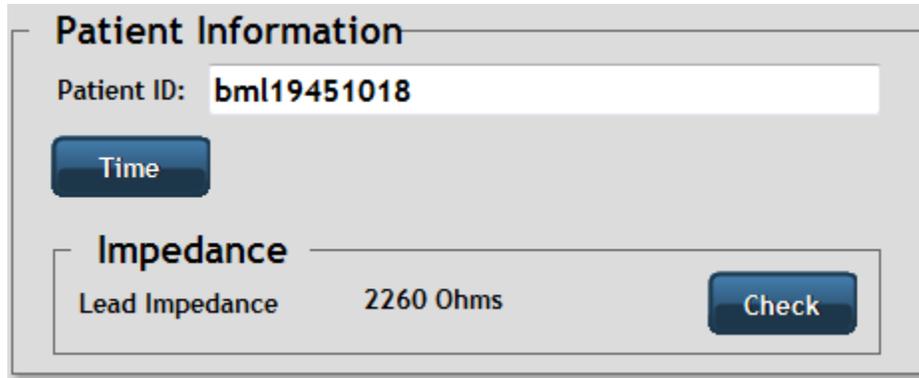
Figure 4.9: Time

4.2 Patient Information (Optional)

The user may enter a patient identification, such as the patient's initials or medical record number, into the SAPS if the user chooses. If the user does not provide a patient identification, the IPG's unique serial number can be used.

1. Enter the patient identification into the **Patient ID** field, as shown in Figure 4.10.
2. Program this Patient ID to the IPG by selecting the **Download Settings to IPG** button, located in the center of the screen (see Figure 4.1).

This is only required to be performed once. SAPS will recognize the programmed Patient ID each time the IPG is interrogated. The IPG retains this information indefinitely.



The screenshot shows a software interface titled "Patient Information". At the top, there is a text input field labeled "Patient ID:" containing the alphanumeric string "bml19451018". Below this field is a blue button labeled "Time". Underneath the "Time" button is a section titled "Impedance". Inside this section, the text "Lead Impedance" is followed by the value "2260 Ohms". To the right of this value is a blue button labeled "Check".

Figure 4.10: Patient ID

4.3 Implant Settings

To enable each of the therapy modes, the button next to the desired **Therapy Mode** is selected and turned on.

1. Turn on your desired **Therapy Mode** to adjust the **Implant Settings**.
2. Each of the implant setting parameters available in the **Implant Settings** menu has a box next to the setting (see Figure 4.11). Select the box to display all available parameters in a drop-down box.
3. Select the appropriate value for each parameter, and program the parameters into the IPG using the **Download Settings to IPG** function. Examples of parameters are shown in Figure 4.12 through Figure 4.15.
4. Once you choose new implant settings, always verify that the implant setting parameters chosen are tolerable for the patient using the **Stim Test Mode** function. See **Section 4.4.1: Stim Test Mode**.

Once the values programmed via the **Test** function or the **Download Settings to IPG** function are input into the IPG, all subsequent therapy sessions will be performed at these parameters. The user can modify the parameters at any time by selecting new parameters and programming them into the IPG.



Figure 4.11: Implant Setting Parameters



CAUTION: Programming the output current to very low levels may result in ineffective therapy.



CAUTION: Programming the output current to excessively high levels may result in patient discomfort. Always verify that settings are tolerable.

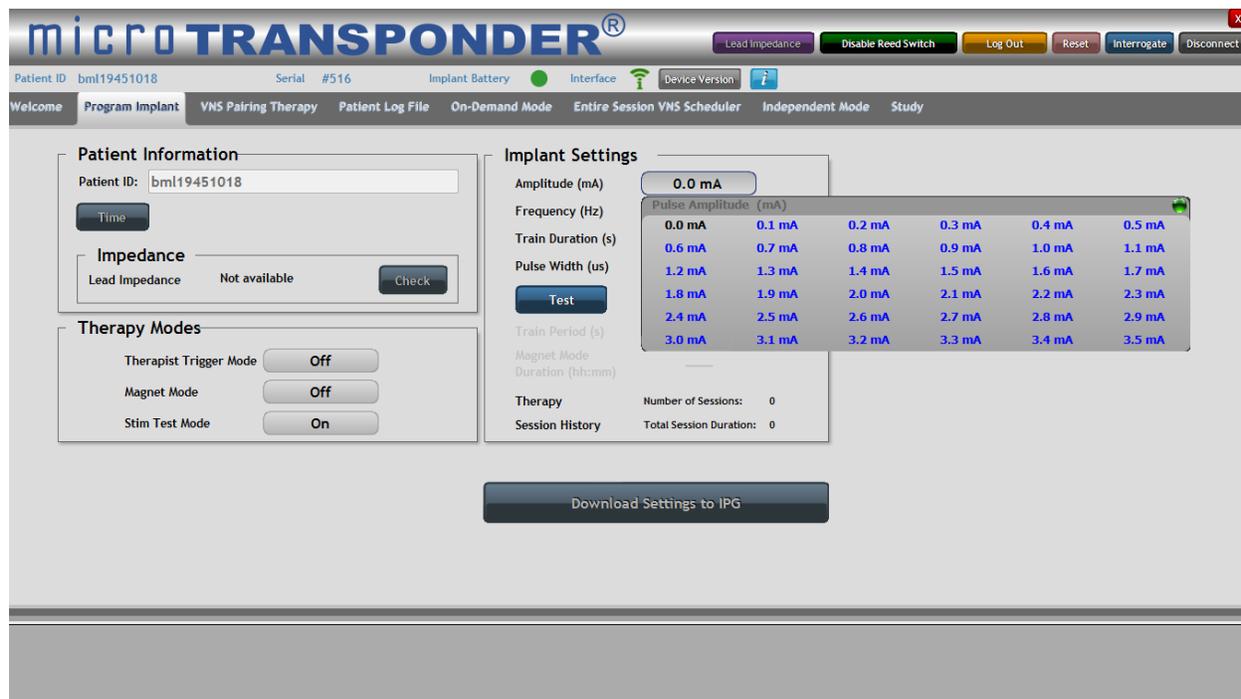


Figure 4.12: Amplitude

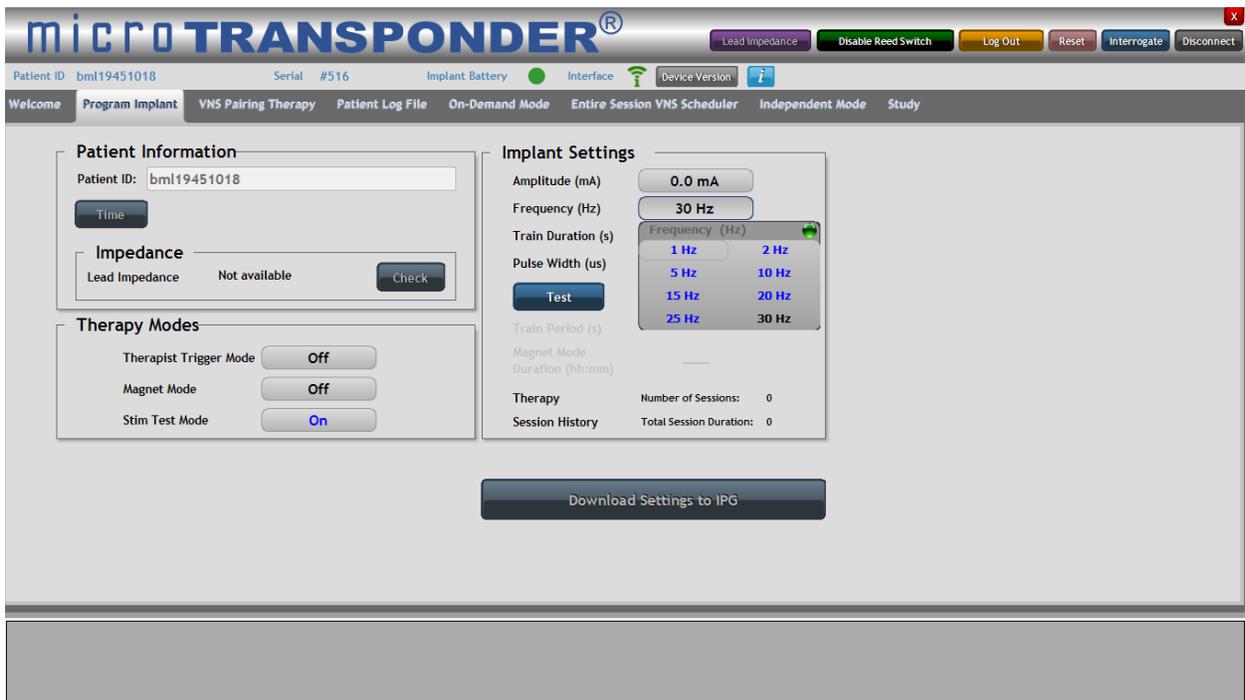


Figure 4.13: Frequency

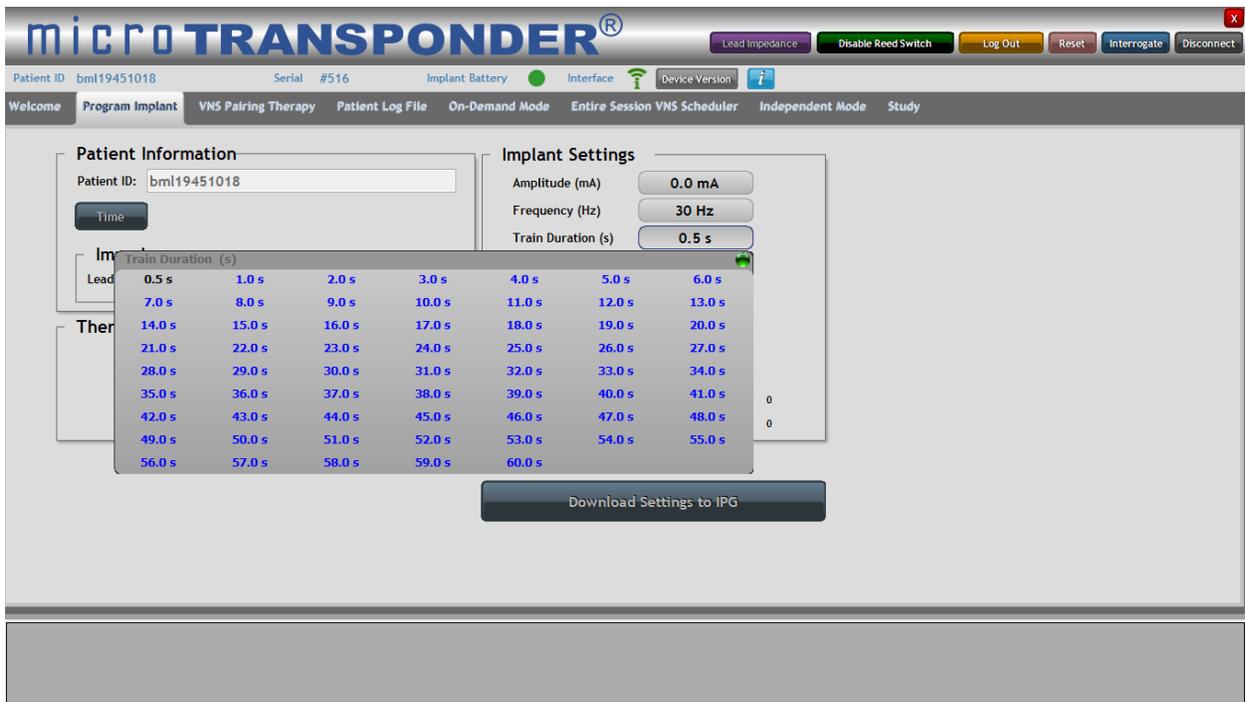


Figure 4.14: Train Duration

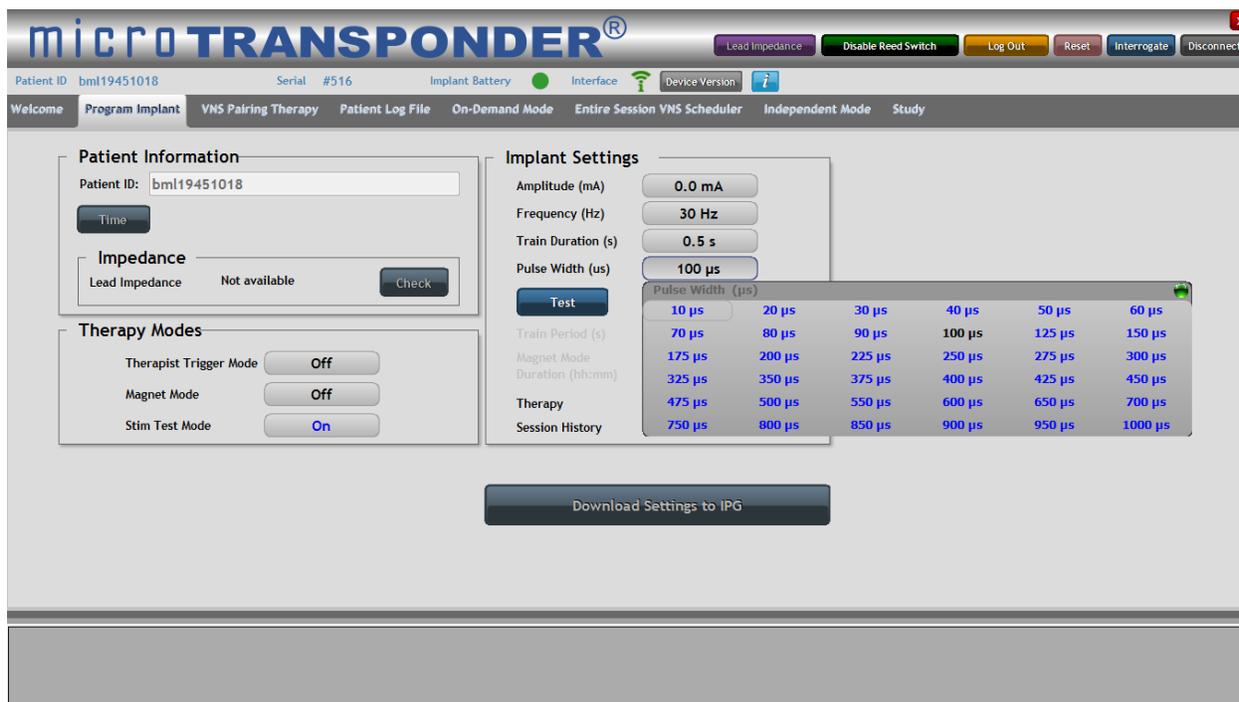


Figure 4.15: Pulse Width

4.4 Therapy Modes

The **Program Implant** menu includes 3 therapy modes: **Stim Test Mode** (see **Section 4.4.1: Stim Test Mode**), **Therapist Trigger Mode** (see **Section 4.4.2: Therapist Trigger Mode**), and **Magnet Mode** (see **Section 7.2: Magnet Mode**).

4.4.1 Stim Test Mode

The **Stim Test Mode** (see Figure 4.16) is used to test the parameters displayed in the **Implant Settings** menu.

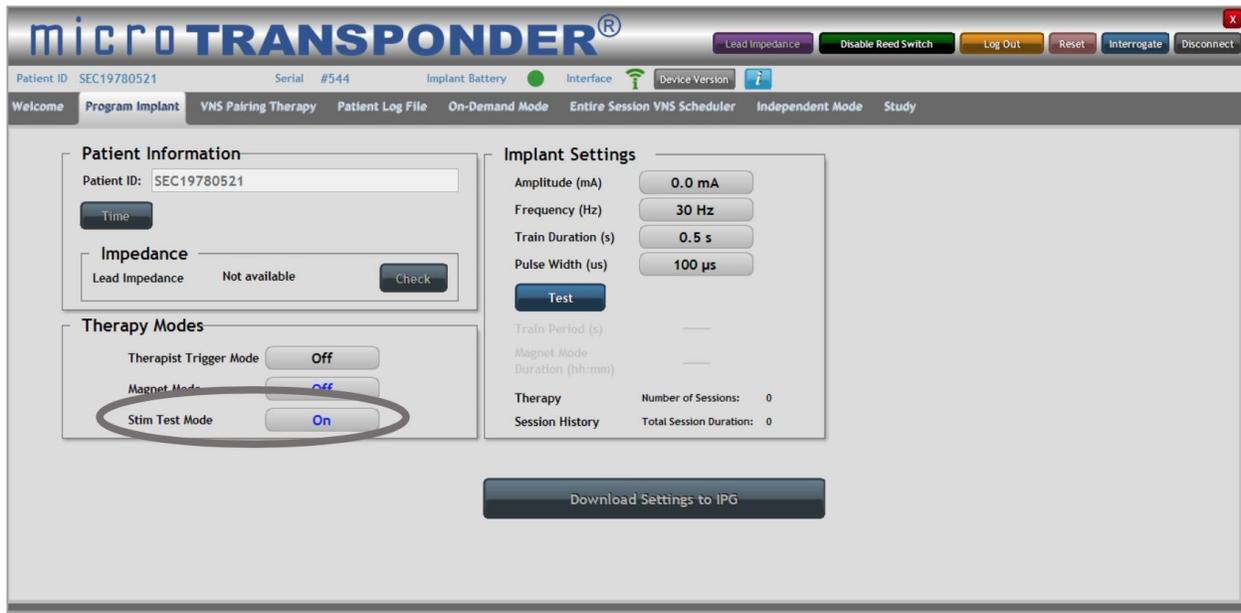


Figure 4.16: Stim Test Mode



Figure 4.17: Implant Settings

1. Select the button next to **Stim Test Mode**. The button will now toggle to **On** (see Figure 4.16).
2. Optionally, you may change the stimulation parameters displayed in the **Implant Settings** menu (see Figure 4.17). For each of the settings (**Amplitude**, **Frequency**, **Train Duration**, **Pulse Width**), click the button next to the setting, and a menu will drop down containing all available parameters for that setting. Then select the appropriate value for each parameter. Example drop-down menus for each parameter are shown above in Figure 4.12 through Figure 4.15.

3. It is recommended to verify that the VNS settings chosen are tolerable for the patient. To verify these settings, select the **Test** button to deliver a single train of stimulation per the parameters displayed in the **Implant Settings** menu. Selecting the **Test** button programs those displayed parameters into the IPG. The **Download Settings to IPG** function does not need to be performed. The user can modify the parameters at any time by selecting new parameters and programming them into the IPG using the **Test** function.

This sequence can be repeated until the patient's IPG is programmed to appropriate parameters.

In the scenario where a **Test** is not performed, the **Download Settings to IPG** button must be selected to program the IPG with the therapy parameters displayed in the **Implant Settings** menu.



CAUTION: If the **Test** function is not performed, new parameters are not input into the IPG until the **Download Settings to IPG** function is used. Verify that the intended parameters are programmed into the IPG. The suggested method of doing so is by interrogating the IPG and comparing the displayed parameters to those intended to be programmed.

4.4.2 Therapist Trigger Mode

The **Therapist Trigger Mode** (see Figure 4.18) is used to enable the physician or therapist to initiate stimulation manually.

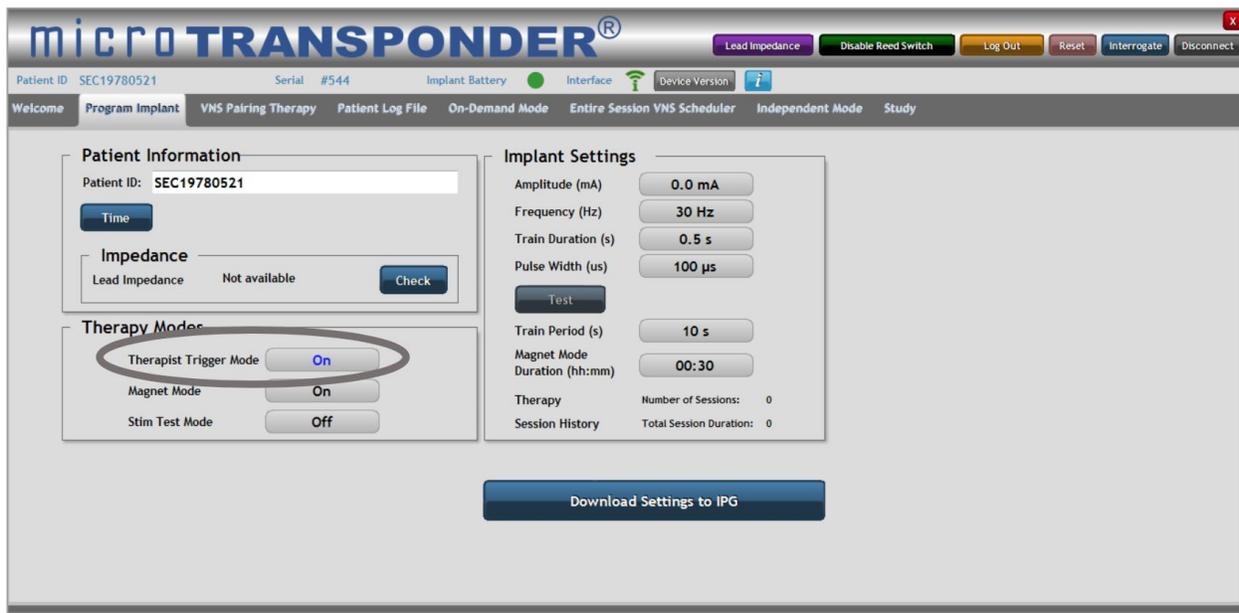


Figure 4.18: Therapist Trigger Mode



Figure 4.19: Implant Settings

1. Select the button adjacent to **Therapist Trigger Mode**. This button will now toggle to **On** (see Figure 4.18).

Therapist Trigger Mode must remain **On** to use **On-Demand Mode** for therapy (see **Section 5.1: On-Demand Mode Menu**) and to initiate a therapy session and trigger stimulation per the **VNS Pairing Therapy** menu (see **Section 5.1.1: On-Demand Mode Therapy via the VNS Pairing Therapy Menu**). The status of the **Therapist Trigger Mode** is reflected in the **On-Demand Mode** menu (see **Section 5.1: On-Demand Mode Menu**) and vice versa.

2. Optionally, you may change the stimulation parameters displayed in the **Implant Settings** menu (see Figure 4.19). See **Section 4.3: Implant Settings**.
3. After all desired parameters have been set, press the **Download Settings to IPG** button to download the chosen parameters to the implant.

Initiation of Paired VNS™ using **Therapist Trigger Mode** is detailed in **Section 5: Delivering Paired VNS™**.

4. It is recommended to verify that the VNS settings chosen are tolerable for the patient. See **Section 4.4.1: Stim Test Mode** for details.

4.5 Impedance

In the **Impedance** portion of the **Patient Information** area of the **Program Implant** menu, the Lead impedance can be checked by selecting the **Check** or **Lead Impedance** buttons (circled in Figure 4.20). Doing so delivers a small current through the Lead to calculate the Lead impedance. This measurement pulse contains minimal charge and is not expected to cause any discomfort, even in the most sensitive patient. The **Lead Impedance** button is available at all times once the user is logged in. See **Section 3: Using the Software (SAPS)**.

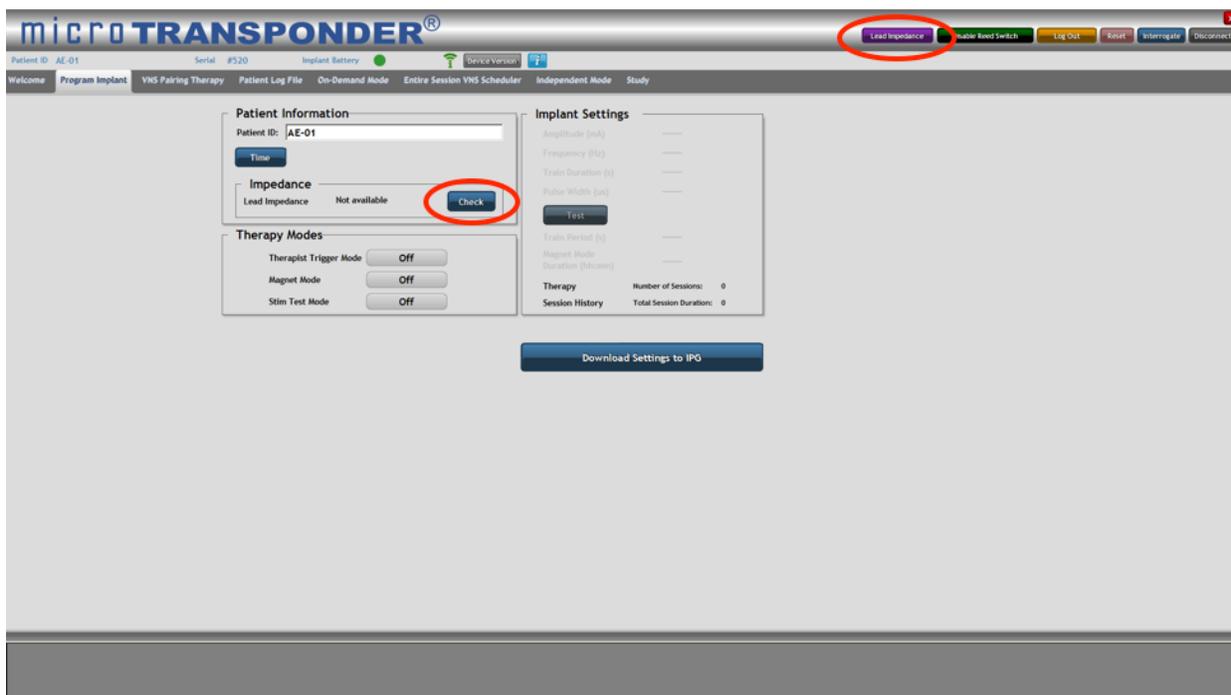


Figure 4.20: Lead Impedance Check

1. Select the **Check** or **Lead Impedance** button (circled in Figure 4.20).

After the **Check** or **Lead Impedance** button is selected, the Lead impedance value is shown (see Figure 4.23). For any value above 10,000 Ω (see Figure 4.21) or less than 250 Ω (see Figure 4.22), the “Warning!” screen informs the patient to contact their physician or therapist to see if any further action needs to be taken.



CAUTION: Changes in Lead impedance are common; therefore, changes of even several thousand ohms occur normally over time. Refer to the **Microtransponder® Vivistim® Paired VNS™ System Implantable Device Manual for Healthcare Professionals** for more information.



Figure 4.21: High Lead Impedance Notification



Figure 4.22: Low Lead Impedance Notification

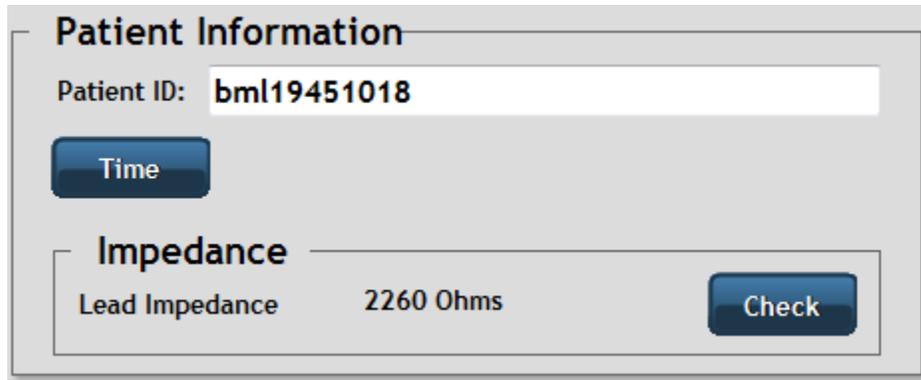


Figure 4.23: Lead Impedance Displayed

5 DELIVERING PAIRED VNS™

After choosing and saving device settings, you can start a stimulation session. The **On-Demand Mode** and **Entire Session VNS Scheduler** menus allow the user to configure the method by which the Vivistim® System delivers stimulation.

- The **On-Demand Mode** menu allows stimulation trains to be individually triggered during a session by the therapist (found in **Section 5.1: On-Demand Mode Menu**).
- The **Entire Session VNS Scheduler** menu allows the stimulation trains for an entire therapy session to be programmed in advance (found in **Section 5.2: Entire Session VNS Scheduler**).

5.1 On-Demand Mode Menu

To begin on-demand stimulation therapy without a magnet:

1. Ensure that the **Therapist Trigger Mode** is **On**, from either the **Program Implant** menu (see **Section 4.4.2: Therapist Trigger Mode**) or from the **On-Demand Mode** menu as shown in Figure 5.1. This must be enabled to utilize the **On-Demand Mode** menu functions. If the button adjacent to **Therapist Trigger Mode** is **Off**, toggle it to **On**.

Enabling **Therapist Trigger Mode** here automatically disables the **Therapy Trigger Mode** in the **Entire Session VNS Scheduler** menu, and vice versa.



CAUTION: Prior to all patient MRI procedures, program the **Therapist Trigger Mode** to **Off**. This also disables **On-Demand Magnet Trigger**.

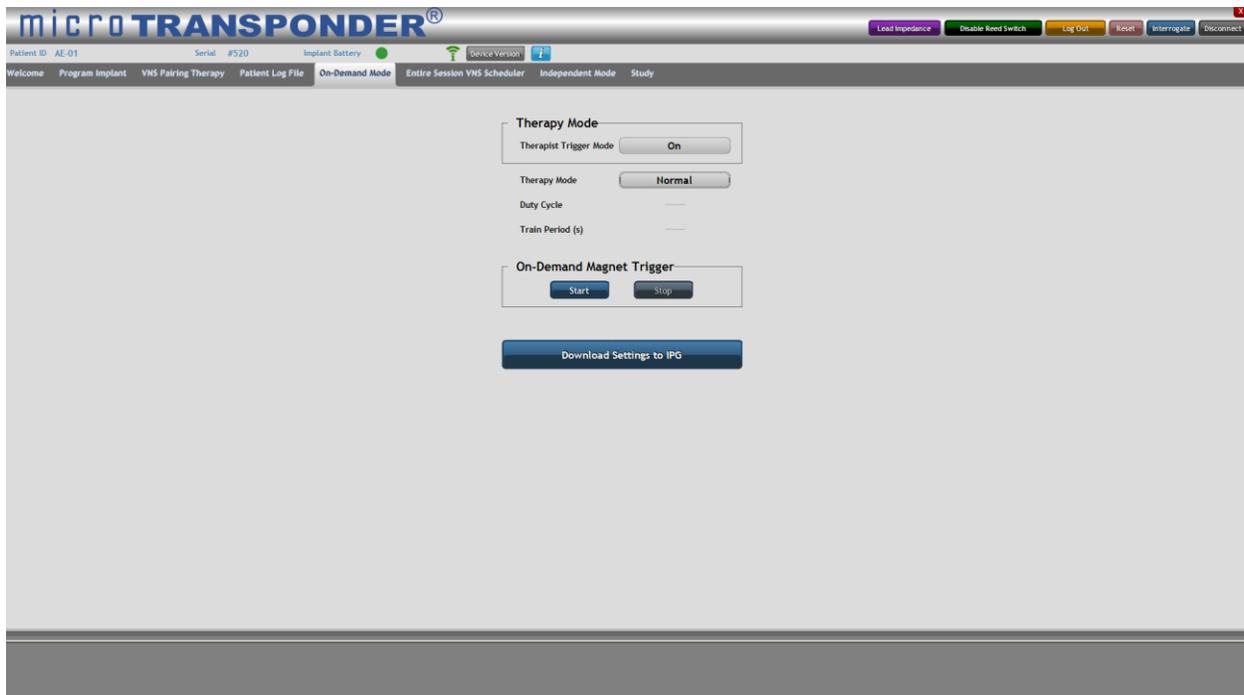


Figure 5.1: On-Demand Mode

2. Program the settings into the IPG by selecting the **Download Settings to IPG** button.
The values of the parameters programmed into the IPG, as displayed in the **Implant Settings** menu, will be delivered to the patient with every triggered therapy.
3. Select desired **Therapy Mode** (Figure 5.1). The **Normal** therapy mode is the default where a single stimulation is delivered when the button is pressed. You can choose to deliver a string of stimulations instead of a single stimulation by selecting the **Continuous** mode and then pressing and holding the push button to start the stimulation and releasing the push button to end the stimulation.
4. In the case where you may prefer to use a magnet to provide the trigger to initiate stimulation, select the **Start** button in the **On-Demand Magnet Trigger** section. This initiates on-demand VNS using a magnet swipe instead of VNS triggered through the **VNS Pairing Therapy** menu. You can choose to deliver a string of stimulations instead of a single stimulation by selecting the **Continuous** mode along with **On-Demand Magnet Trigger** and then using the magnet to start and stop the stimulation.

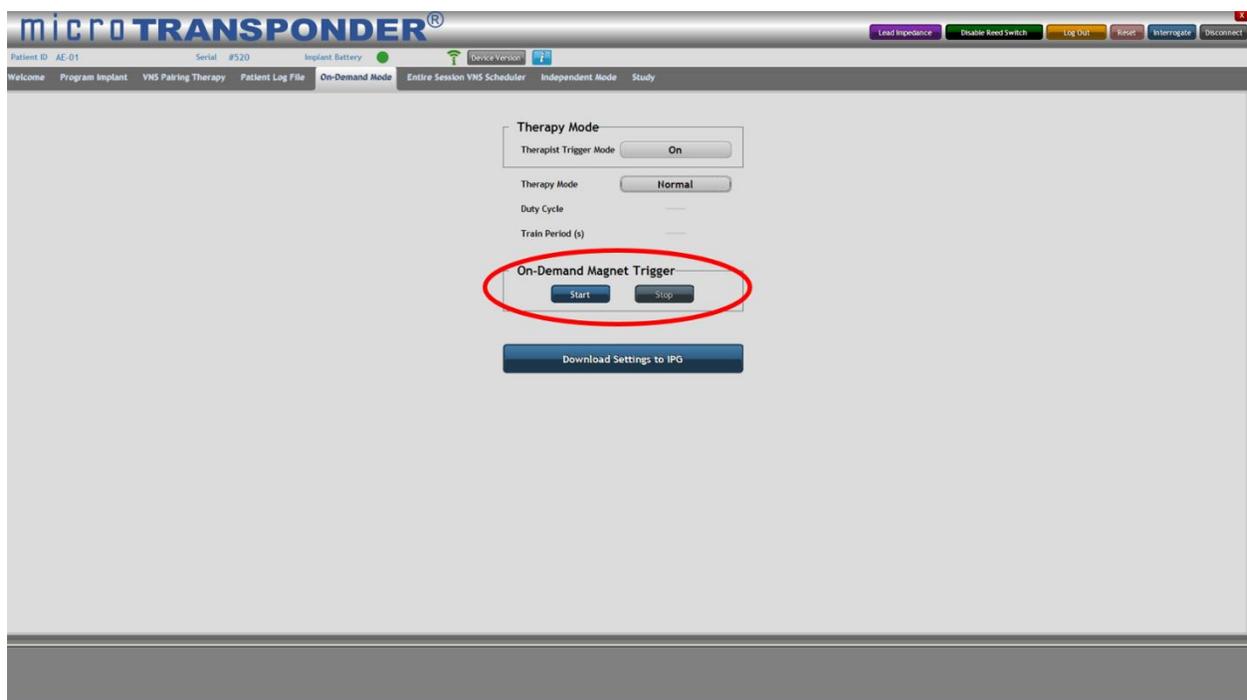


Figure 5.2: Start / Stop On-Demand Magnet Trigger

SAPS prevents the **On-Demand Magnet Trigger** function from operating simultaneously with the **VNS Pairing Therapy** function. Tasks performed during **On-Demand Magnet Trigger** therapy are not captured in the patient log file.

The status of the **Therapist Trigger Mode** is reflected in the **Program Implant** menu (see **Section 4.4.2: Therapist Trigger Mode**) and vice versa.

The on-demand stimulation therapy can now begin via the **VNS Pairing Therapy** menu.

5.1.1 On-Demand Mode Therapy via the VNS Pairing Therapy Menu

The following five steps are an overview of the sequence of events required for delivering this therapy.

1. Select **VNS Pairing Therapy** menu
2. Select task
3. Start Task
4. Deliver Stimulation
5. End Task

5.1.1.1 Select VNS Pairing Therapy Menu

Select the **VNS Pairing Therapy** menu (see Figure 5.3) to initiate a therapy session and trigger stimulation.

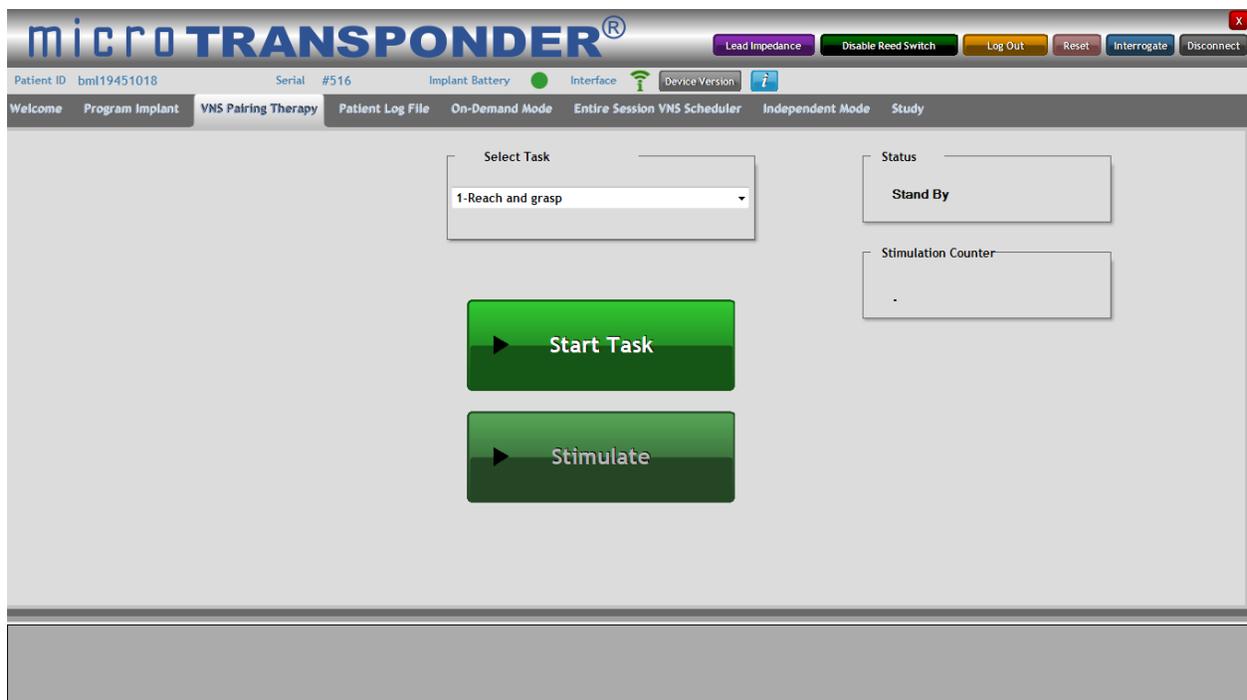


Figure 5.3: On-Demand Mode Therapy via the VNS Pairing Therapy Menu

5.1.1.2 Select Task

Select the specific task (see Figure 5.3) from the drop-down menu by selecting the task drop down menu button and selecting the appropriate task that the patient is going to perform for rehabilitation (see Figure 5.4). The patient log file associates this selected task with the triggered stimulations of the therapy until a different task is chosen. This allows for ease of comparison when the patient log file is reviewed.

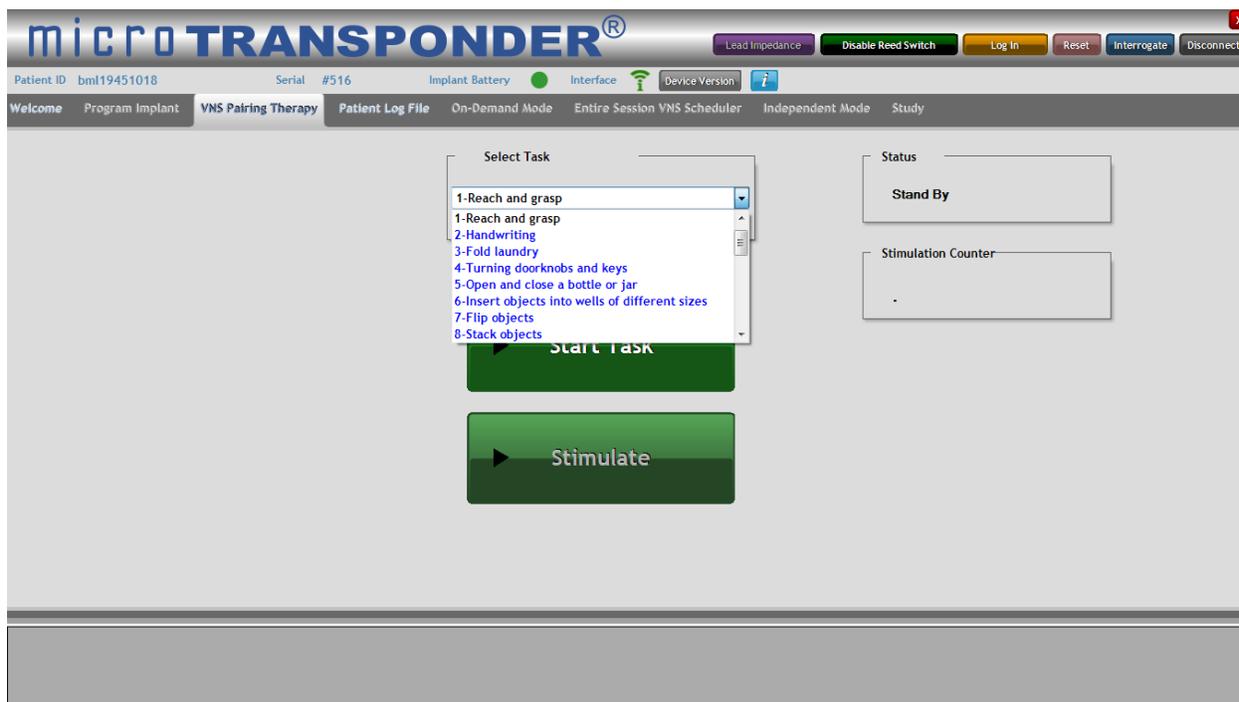


Figure 5.4: Select Task

5.1.1.3 Start Task



CAUTION: Before selecting the **Start Task** button when applying the **Therapist Trigger Mode** for on-demand therapy, verify all laptop connections (see Figure 2.1:), and verify that the WT is an appropriate distance from the patient (see **Section 16.2: Communication Signals**).

Select the **Start Task** button (see Figure 5.5). This enables the system to start a rehabilitation task and allows you to trigger the delivery of stimulation.

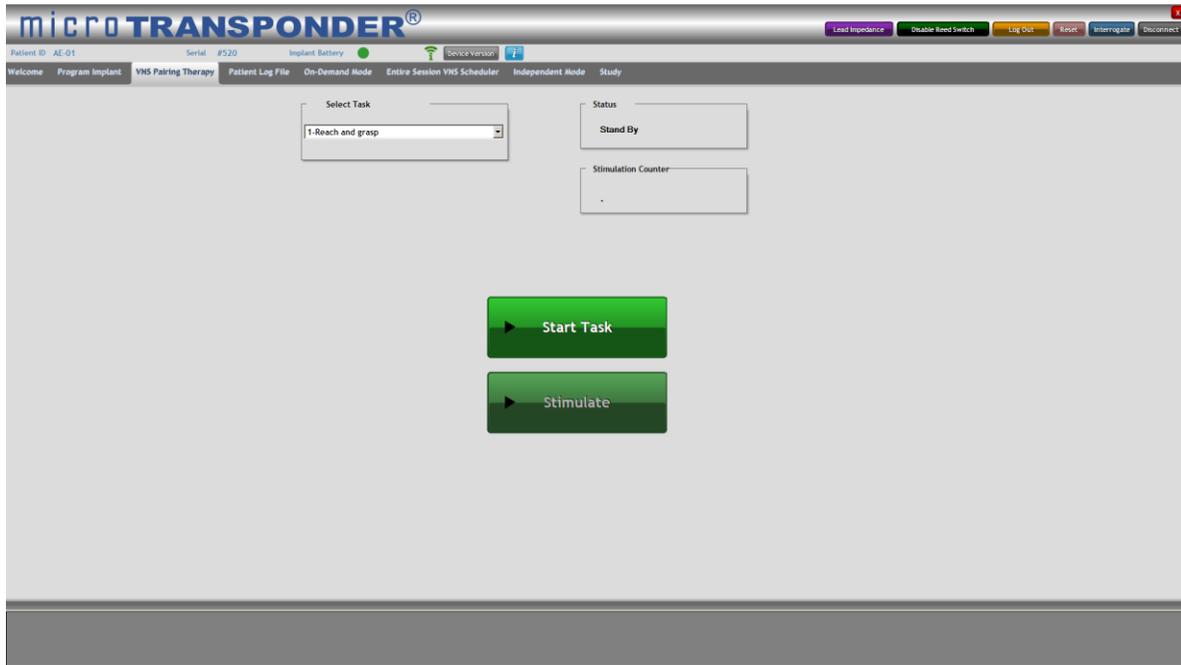


Figure 5.5: Start Task

5.1.1.4 Deliver Stimulation

Once the **Start Task** button is selected, the program establishes a communication session with the device. Notice that both the **Stimulate** and the **End Task** buttons are now available and that the **Status** window is updated to “Ready to Stimulate” (see Figure 5.6).

At any time, you may select the **End Task** button to end the rehabilitation task.

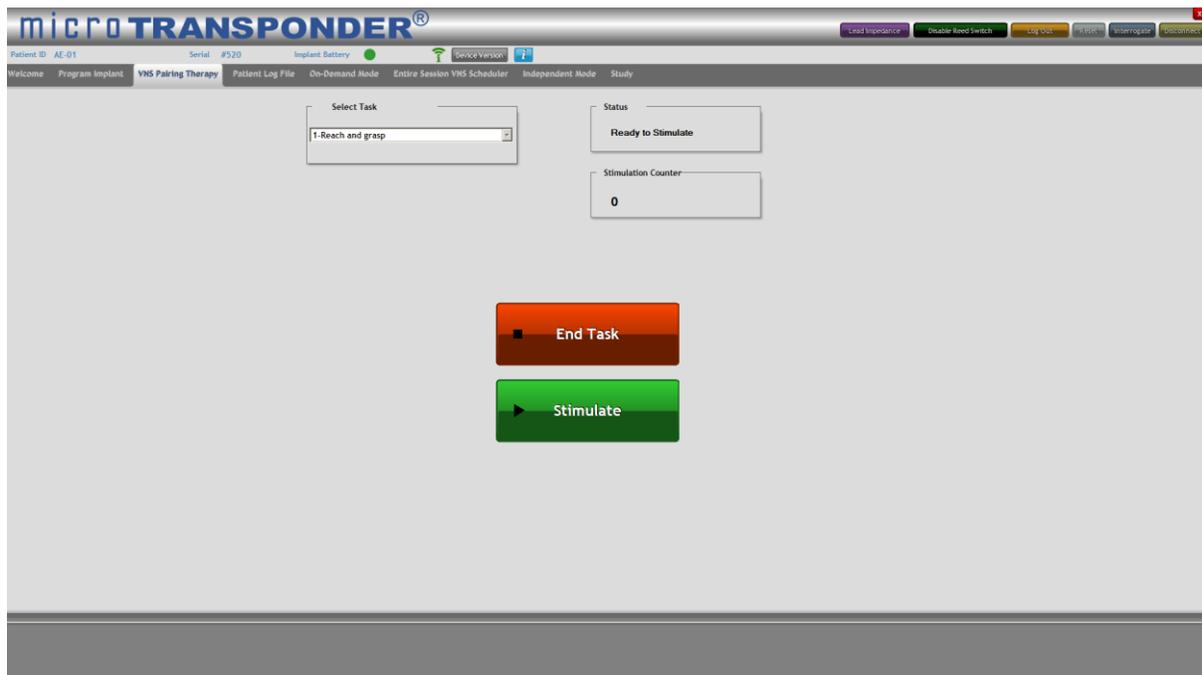


Figure 5.6: Communication Established and Ready to Stimulate

Once a session is initiated, you may trigger stimulation, implementing the programmed IPG therapy parameters. To stimulate, use the mouse and cursor to select the **Stimulate** button or press the push button.

When the stimulation has been triggered, the **Status** window displays “Stimulating” for the length of the stimulation period (see Figure 5.7). Meanwhile, the **Stimulate** button is disabled for double the time of the stimulation train duration (to allow for a 50% duty cycle). Stimulation can occur only as often as twice the stimulation train duration; no duty cycle over 50% is allowed by the software. For example, if a 0.5 second train duration is given, you cannot activate another stimulation for at least 0.5 seconds after the train duration ends.

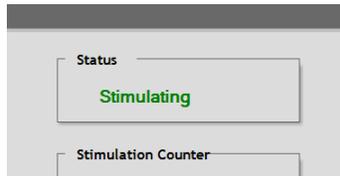


Figure 5.7: Stimulate Selected—Status “Stimulating”

The message “Refractory” appears in the **Status** window for a length of time equal to the programmed stimulation train duration immediately following the “Stimulating” message (see Figure 5.8).

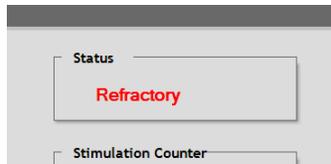


Figure 5.8: Status “Refractory”—No Stimulation Allowed

The value in the **Stimulation Counter** window increases by one for every stimulation delivered. This counter resets to 0 when the current task is ended and a new task started (see Figure 5.9).

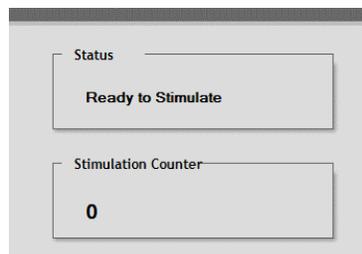


Figure 5.9: Stimulation Counter

Once the stimulation ends and the refractory period has finished, the message in the **Status** window returns to “Ready to Stimulate”, the **Stimulate** button is once again selectable, and a new repetition of the task can be initiated and stimulated (see Figure 5.6).

The user may then continue to deliver stimulation except during the stimulation refractory period.

5.1.1.5 End Task

Upon completing a task, select the **End Task** button (see Figure 5.6) to end the rehabilitation task. Once the **End Task** button has been selected, the **Status** returns to the “Stand by” mode and the system is ready to select a new task and/or begin a new session (see Figure 5.5).

NOTE: The SAPS automatically ends the task if the session is inactive for more than 10 minutes. When the SAPS automatically ends a task, it displays a message that “The IPG is no longer in Therapy Session” (see Figure 5.10). The task can be started where it ended by selecting the **Start Task** button again.

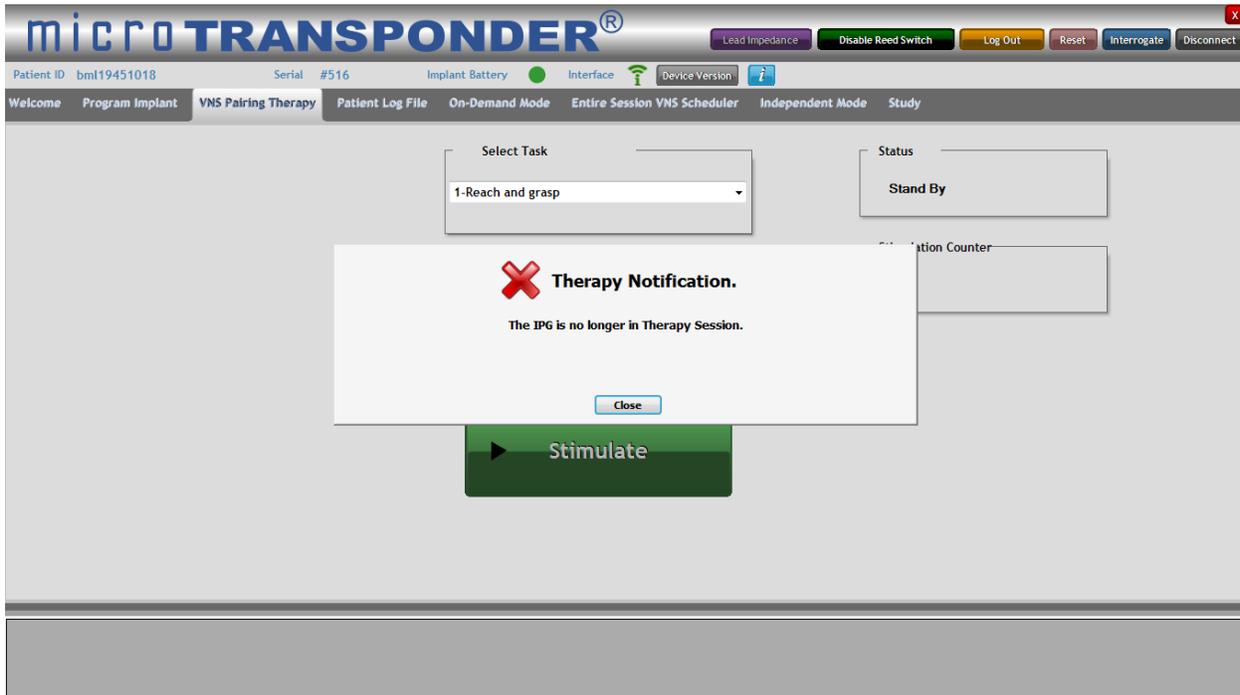


Figure 5.10: Ten Minute Time Out of Task

5.2 Entire Session VNS Scheduler

To begin *Entire Session VNS Scheduler* therapy:

1. Select the *Entire Session VNS Scheduler* tab.

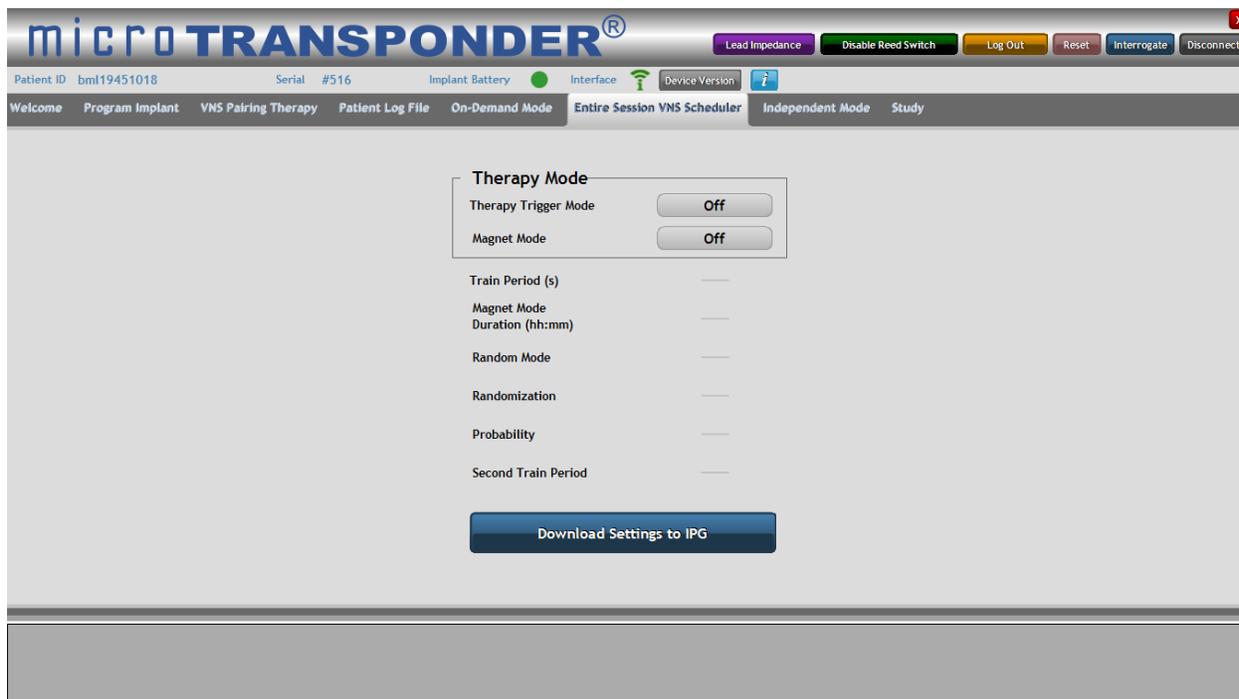


Figure 5.11: Entire Session VNS Scheduler Mode

2. Ensure that either *Therapy Trigger Mode* or *Magnet Mode* is **On** (see Figure 5.12) in the *Entire Session VNS Scheduler* menu or in the *Implant Settings* menu. One of these modes must be enabled to utilize the *Entire Session VNS Scheduler* functions. If the button next to the preferred mode is **Off**, toggle it to **On**.

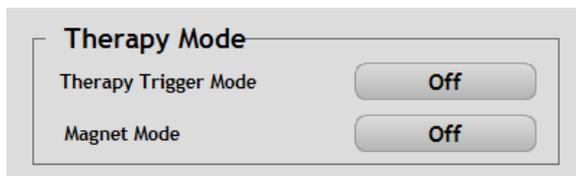


Figure 5.12: Therapy Trigger Mode and Magnet Mode

Enabling *Therapy Trigger Mode* here automatically disables the *Therapist Trigger Mode* in the *On-Demand Mode* menu, and vice versa.

3. Program the settings into the IPG by selecting the *Download Settings to IPG* button.
4. Optionally, you may change the stimulation parameters displayed in the *Implant Settings* menu. See **Section 4.3: Implant Settings**.

NOTE: The values of the parameters programmed into the IPG, as displayed in the *Implant Settings* portion of the *Program Implant* menu, will be delivered to the patient with each triggered therapy session for either the *Therapy Trigger Mode* or *Magnet Mode*.



CAUTION: Once therapy is started, the patient should perform rehabilitation tasks for the duration of the therapy session. If the patient needs to stop stimulation during a session or suspects an issue with the therapy during a session, the patient should contact you for guidance.

Therapy Trigger Mode enables you to initiate a therapy session by triggering the therapy using the mouse and cursor to select the **Start** button on the **VNS Pairing Therapy** menu (see **Section 5.2.1: Therapy Trigger Mode**).

Magnet Mode enables the user to trigger stimulation using a magnet swipe instead of through the button in the **VNS Pairing Therapy** menu. The status programmed for **Magnet Mode** here is reflected in the **Magnet Mode** setting on the **Program Implant** menu (see **Section 5.2.2: Magnet Mode**) and vice versa.

5.2.1 Therapy Trigger Mode



CAUTION: Before selecting the **Start** button when applying the **Therapy Trigger Mode** for entire session therapy, verify all laptop connections (see **Figure 2.1: SAPS Hardware Set-up Overview**), and verify that the WT is an appropriate distance from the patient (see **Section 16.2: Communication Signals**).

To begin **Therapy Trigger Mode** therapy:

1. In the **Entire Session VNS Scheduler** menu, ensure that the button adjacent to **Therapy Trigger Mode** is toggled to **On** (see **Figure 5.13**) and that steps 1-4 in **Section 5.2: Entire Session VNS Scheduler** have been completed to enable the **Therapy Trigger Mode** therapy.

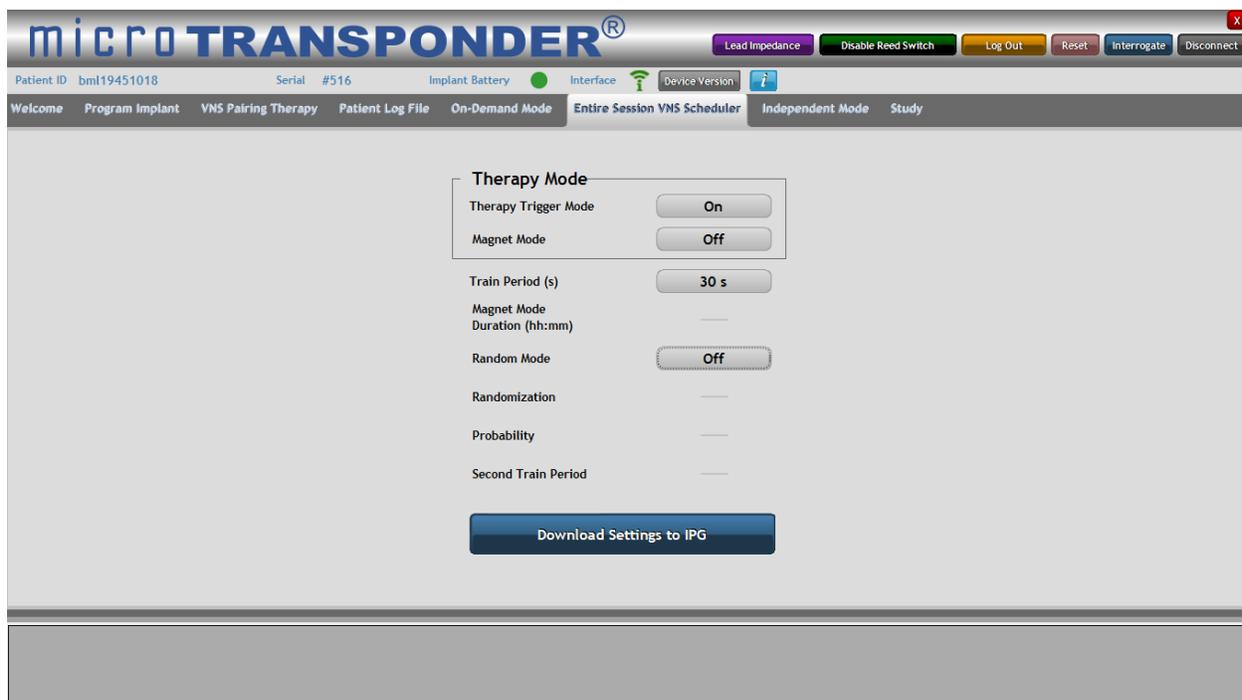


Figure 5.13: Select Therapy Trigger Mode

2. Set the **Therapy Trigger Mode** parameters. Refer to **Section 5.2.3: Setting Parameters** for details on setting all **Therapy Trigger Mode** parameters.
3. Select the **VNS Pairing Therapy** tab.
4. To start stimulation, select the **Start** button (see Figure 5.14).

NOTE: The task list drop-down menu is disabled and not required in this therapy mode.

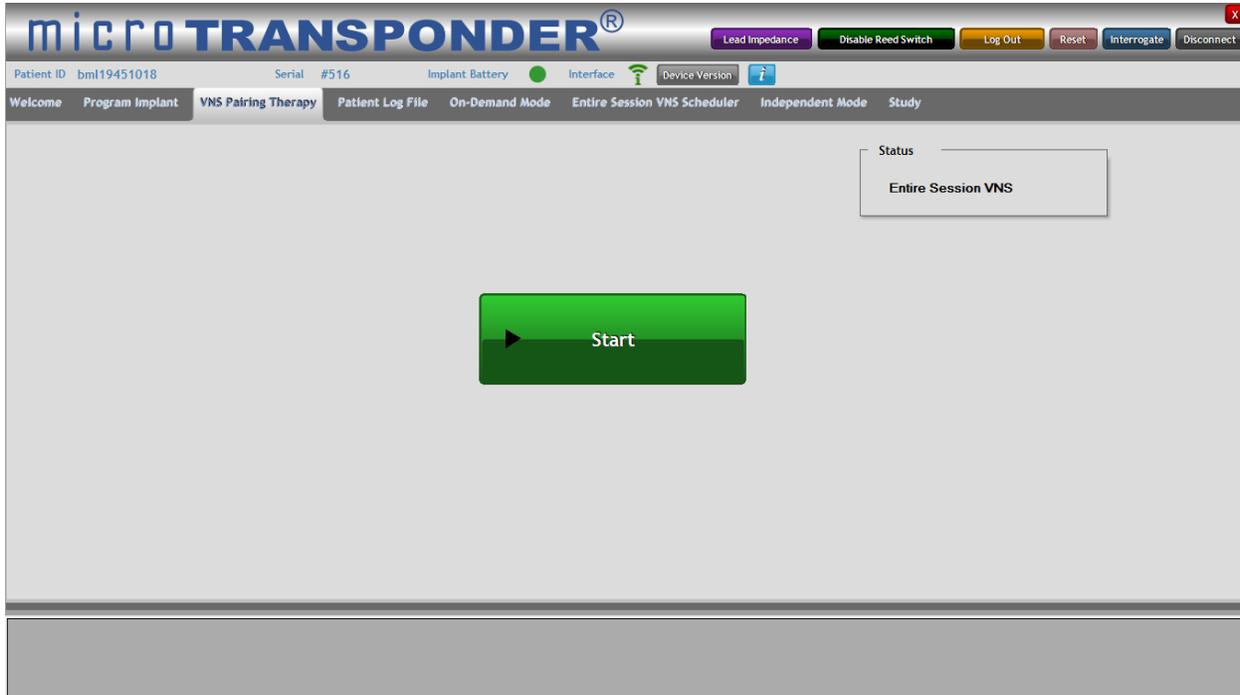


Figure 5.14: Start Therapy Trigger Mode

5. To stop the stimulation upon completion of the therapy session or at any time during the session, select the **Stop** button (see Figure 5.15).

NOTE: The SAPS automatically terminates the session if this session is left inactive for more than 4 hours.

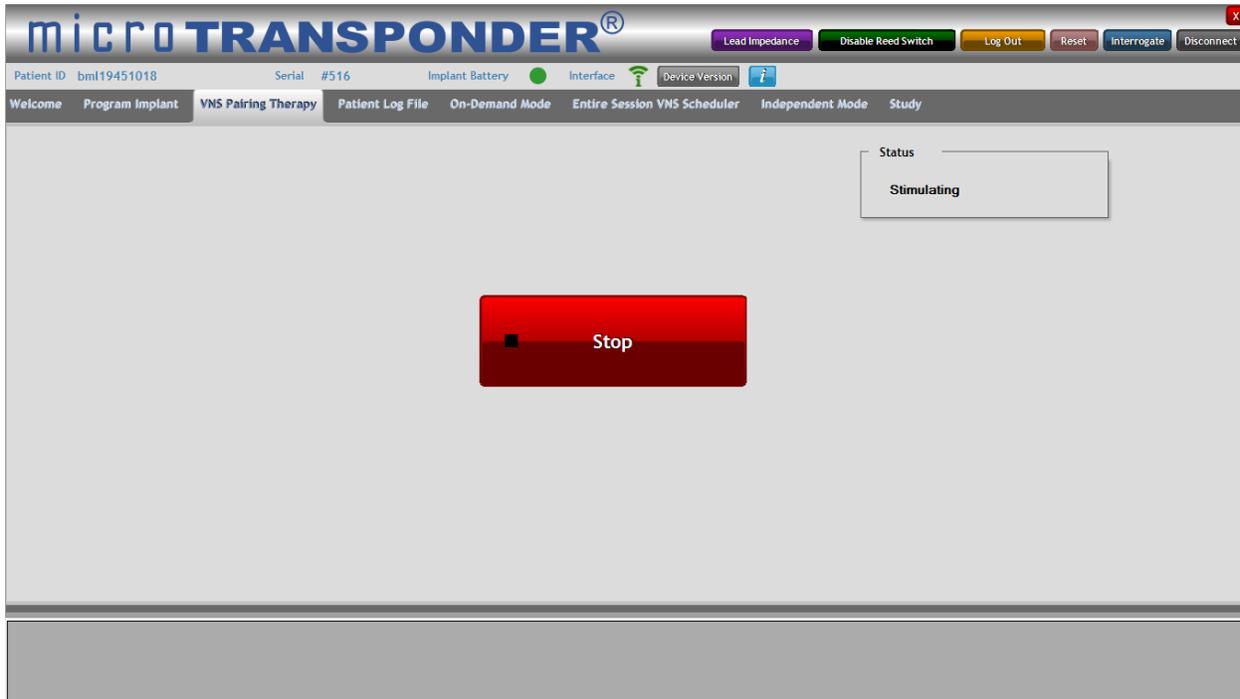


Figure 5.15: Stop Therapy Trigger Mode

5.2.2 Magnet Mode



CAUTION: Prior to all patient MRI procedures, program the **Magnet Mode** to **Off**.

Magnet Mode set to **On** enables you to initiate an **Entire Session VNS Scheduler** therapy session with the use of a magnet. To begin this therapy session:

1. In the **Entire Session VNS Scheduler** menu, ensure that the button adjacent to **Magnet Mode** is **On**.
2. Select the **Magnet Mode Duration**. Refer to **Section 5.2.3: Setting Parameters** for details on setting all **Magnet Mode** parameters.
3. Optionally, you may change the stimulation parameters displayed in the **Implant Settings** menu. See **Section 4.3: Implant Settings**.
4. Program the settings into the IPG by selecting the **Download Settings to IPG** button.

The status of the **Magnet Mode** is reflected in the **Program Implant** menu (see **Section 4: Programming the Implant**) and vice versa.

Once the appropriate device settings for **Magnet Mode** are downloaded to the IPG, stimulation may be triggered using a magnet swipe without further communication from the SAPS.

NOTE: During a patient's first therapy session, give the patient the magnet and review this section and the **Microtransponder® Vivistim® Paired VNS™ System Quick Start Guide for Patients with them**.

5. Remove the magnet cover, if applicable (see Figure 5.16 below).

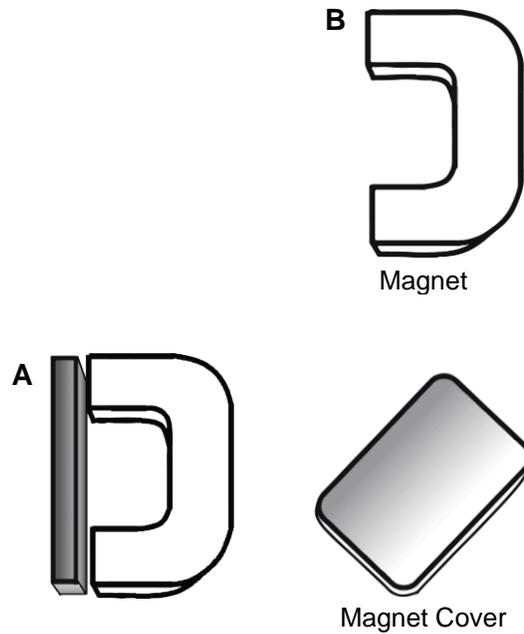


Figure 5.16: Magnet with Cover Attached (A) and Detached (B)

6. To begin stimulation, swipe the magnet across the patient's chest where the IPG is located (see Figure 5.17). This will cause the VNS session to begin for the programmed **Magnet Mode Duration**.

NOTE: The magnet need only be swiped across the patient's chest where the IPG is located to trigger stimulation. Holding the magnet over the IPG for greater than 30 seconds stops the stimulation until the magnet is removed.

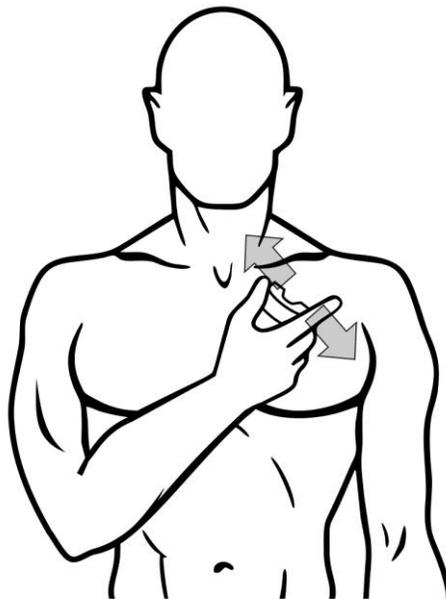


Figure 5.17: Magnet Swipe

5.2.3 Setting Parameters

For each of the settings (***Train Period***, ***Magnet Mode Duration***, ***Randomization***, ***Probability***, and ***Second Train Period***), you must select the button next to the setting to enable all available parameters for that setting, shown in a drop-down box. Not all parameters are available at all the times based on the modes that are chosen. For example, ***Magnet Mode Duration*** is accessible only when ***Magnet Mode*** is enabled. The appropriate value is selected for each parameter. Parameter examples are shown in Figure 4.11 through Figure 4.15. The ***Train Period*** parameter is reflected in the ***Program Implant*** menu (see **Section 7.2: Magnet Mode**) and vice versa.

6 STOPPING STIMULATION

6.1 Magnet Mode

NOTE: Review this section with all patients.

NOTE: A commercial magnet with a pull force rated at 4.5 kg or greater is sufficient to stop stimulation.

In the event that stimulation is too strong or becomes uncomfortable or there is some device malfunction while the patient is at home, you or the patient may stop stimulation.

To stop stimulation, you or the patient must place the magnet over the patient's chest where the IPG is located and hold the magnet in place for at least 30 seconds. Stimulation is stopped for as long as the magnet is placed over the IPG. If at home, the patient should contact their physician (neurologist or physical medicine & rehabilitation [PM&R] doctor) or therapist for an immediate appointment so that the device can be further tested.



CAUTION: In the event that stimulation continues once the magnet has been removed from the patient's chest, the magnet must be placed back over the patient's chest where the IPG is located to stop stimulation. The magnet should be held in place and the patient's physician contacted for further instruction. Stimulation will be stopped as long as the magnet is held in place.

NOTE: During a patient's first therapy session, verify that the patient can terminate stimulation. Also verify that the patient is given an appropriate magnet to take home with them for this use.

6.2 Therapist Trigger Mode

If you are using the **VNS Pairing Therapy** menu of the SAPS, stimulation may also be terminated by selecting **End Task** (see **Section 5.1.1: On-Demand Mode Therapy via the VNS Pairing Therapy Menu** and Figure 5.6).

Selecting **End Task** disables the **Stimulate** button.

6.3 Resetting the IPG / Safe Mode

In the event that the IPG reports a Safe Mode condition, the IPG must be reset to resume programming or therapy. If the IPG reports a Safe Mode condition or needs to be reset for any reason:

1. Contact MicroTransponder per **Section 18: Information and Support**.
2. After contacting MicroTransponder, select the **Reset** button to reset the IPG (see Figure 6.1).



Figure 6.1: Reset Button

3. When prompted (as shown in Figure 6.2), enter the password “reset1”.



Figure 6.2: Password Prompt

4. Select the **Accept** button to complete the reset (see Figure 6.3).



Figure 6.3: Accept Reset

NOTE: A reset of the device will program the device off (output current = 0.0 mA).

NOTE: All settings and device history are preserved. After a successful reset, the IPG stimulation output may be reprogrammed from 0.0 mA as appropriate for the patient to resume operation at their previously programmed settings.

5. The IPG must now be reprogrammed to the appropriate mA setting for the patient.

7 SENDING THE PATIENT HOME



CAUTION: *If the patient will be having an MRI, make sure that all therapy modes are turned to **Off** (see **Section 10: IPG Settings for MRI Procedures**).*

For normal at-home use, make sure that **Magnet Mode** is turned to **On** (see **Section 7.2: Magnet Mode**).

7.1 Things to Review with the Patient

In every patient visit, make sure to review the **Microtransponder® Vivistim® Paired VNS™ System Quick Start Guide for Patients** and discuss the following items with the patient:

- The patient should not pick at their surgical scars, as they may cause infection.
- If the patient experiences any pain or suspects an issue with the device, they should contact you.
- More stimulation is not necessarily better.
- The patient should avoid devices that generate a strong electric or magnetic field.
- The patient should always let you know when they are scheduled to have an MRI.
- The patient should always let you know if they have a lifestyle change. For example, the patient could start playing a sport or start smoking.

In a patient's first visit, make sure to discuss **Section 12: Precautions, Warnings, Contraindications, and Hazards** and **Section 5.2.2: Magnet Mode** in addition to the **Microtransponder® Vivistim® Paired VNS™ System Quick Start Guide for Patients** (see the last page of this manual). Additionally, make sure to address:

- Verify that the patient can terminate stimulation with a magnet.
- Verify that the patient is given a magnet to take home with them for this use.
- Tell the patient how long you have programmed their therapy session to be.
- If the patient has any questions about their magnet, they should contact you.
- If the patient loses their magnet, they can contact you or go to the hardware store and buy a replacement. They must find a magnet of pull force 4.5 kg or greater – a magnet with a pull force lower than 4.5 kg will not activate or deactivate the IPG.

7.2 Magnet Mode



CAUTION: Prior to all patient MRI procedures, program the **Magnet Mode** to **Off**.

The **Magnet Mode** (see Figure 7.1) implements the ability to initiate stimulation with a magnet per the parameters represented in the **Entire Session VNS Scheduler** menu. The button adjacent to **Magnet Mode** must be toggled to **On** and programmed to enable this function. **Off** must be selected and programmed to terminate this capability. The amount of Therapy performed and the Session History are displayed, as shown circled in Figure 7.2.

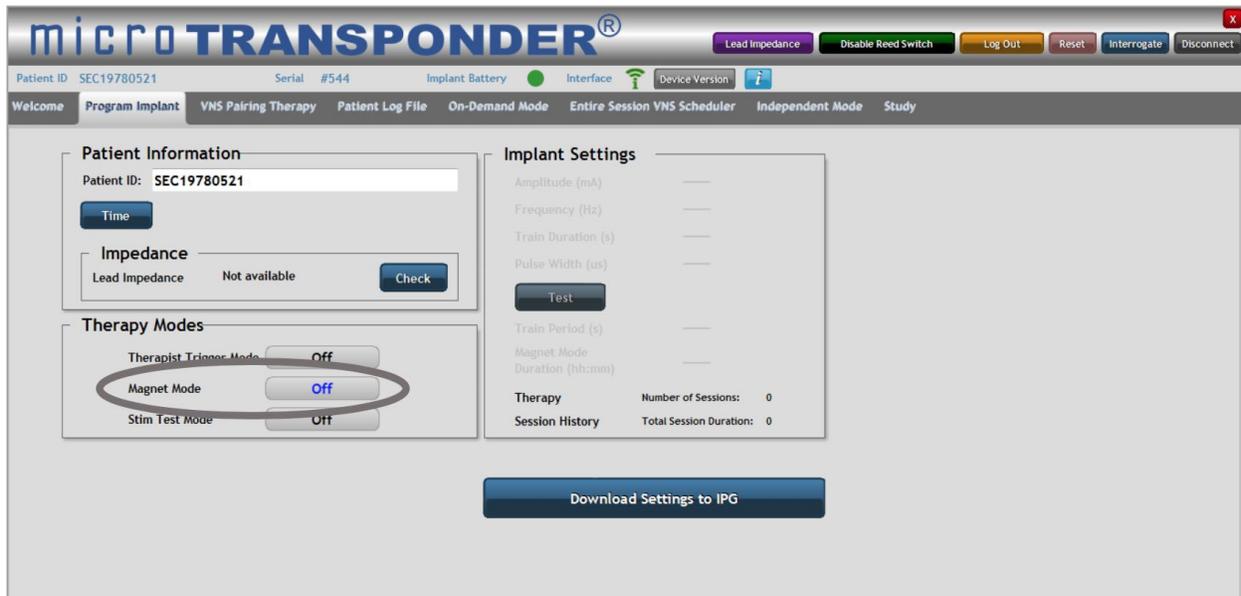


Figure 7.1: Magnet Mode

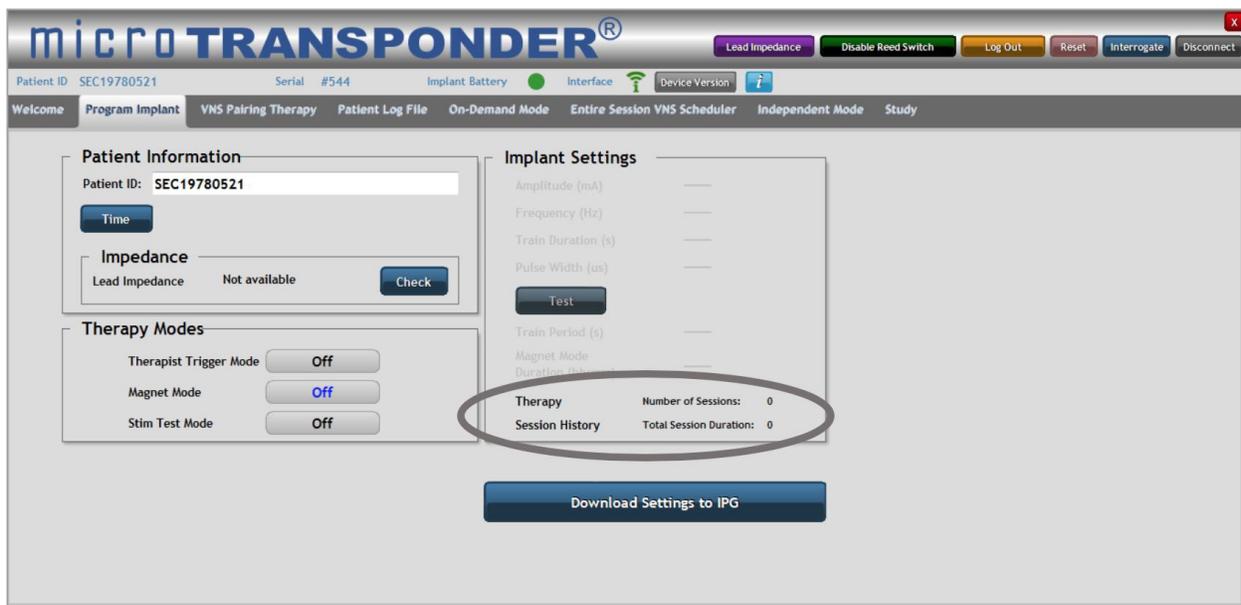


Figure 7.2: Magnet Mode Session History

1. Select the button next to **Magnet Mode**. The button will now toggle to **On** (see Figure 7.1).
2. When this mode is turned on, you are prompted to set the **Magnet Mode Duration** and reminded to save changes, as shown in Figure 7.3. Select “OK”.

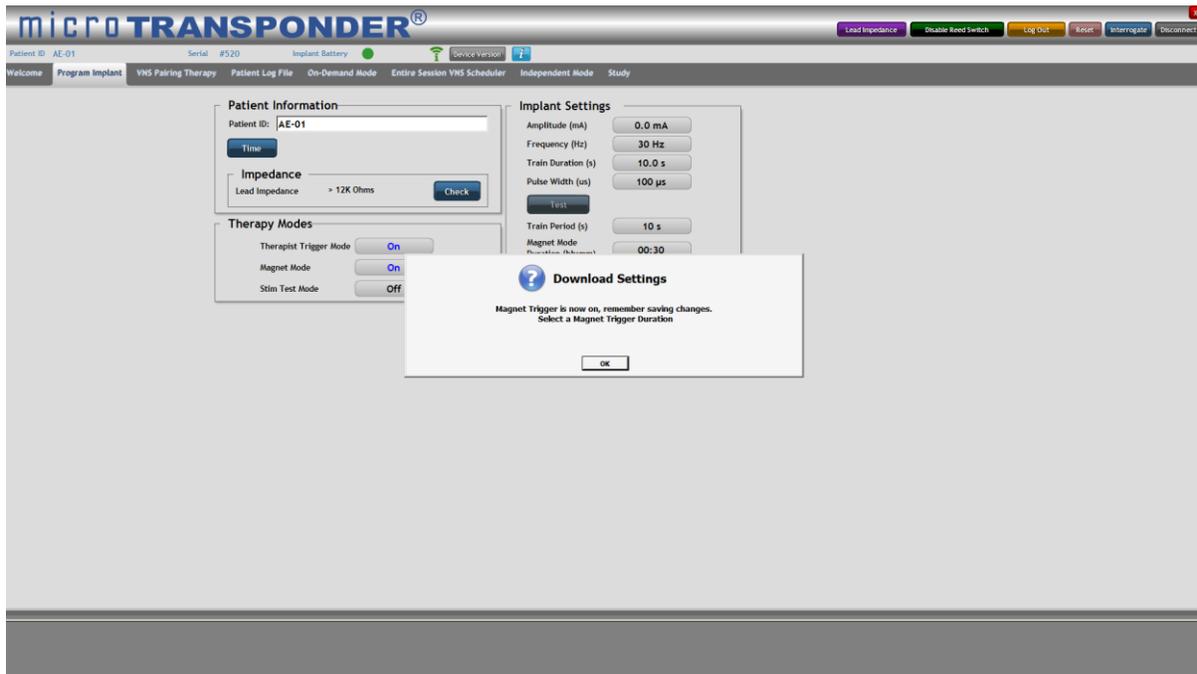


Figure 7.3: Magnet Mode Prompt

3. Optionally, you may change the stimulation parameters displayed in the **Implant Settings** menu. See **Section 4.3: Implant Settings**.
4. After all desired parameters have been set, press the **Download Settings to IPG** button to download the chosen parameters to the implant.

Once the IPG is programmed to respond to the magnet, it is no longer necessary for the patient to be in close proximity to the WT as there is no longer communication required between SAPS and the IPG to trigger stimulation during a task. To trigger stimulation in **Magnet Mode**, the magnet must be swiped across the patient’s chest where the IPG is located.

Parameters programmed for **Magnet Mode** are reflected in the **Entire Session VNS Scheduler** menu (see **Section 5.2: Entire Session VNS Scheduler**) and vice versa.

8 PATIENT LOG FILE

Information on device use is stored in a log file within the device. The **Patient Log File** menu (see Figure 8.1) allows the user to view the information on the computer screen or export the information from the device to a file that can be used later.

- To export the IPG statistics, select the **Read Statistics** button (circled in Figure 8.1). These are saved in .csv format to the hard drive of the laptop.
- To export the SAPS log, select the **Export Log** button. These are saved in .txt format to the hard drive of the laptop. You may choose a particular date range for export or choose to Export All (circled in Figure 8.2).

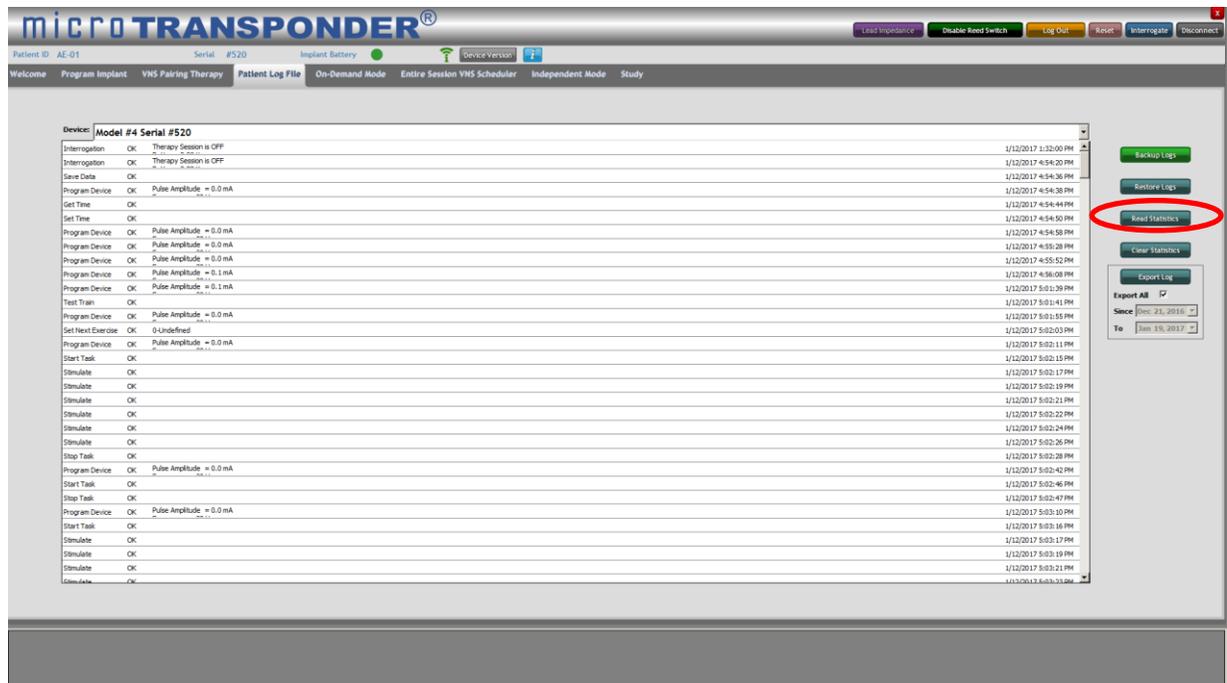


Figure 8.1: Patient Log File—Read Statistics

The screenshot displays the MicroTransponder software interface. At the top, the title bar reads "microTRANSPONDER®" and includes status buttons: "Lead Impedance", "Disable Reed Switch", "Log Out", "Reset", "Interrogate", and "Disconnect". Below the title bar, the patient information is shown: "Patient ID: AE-01", "Serial: #520", "Implant Battery" (with a green indicator), and "Device Version" (with a blue indicator). The main menu includes "Welcome", "Program Implant", "VNS Pairing Therapy", "Patient Log File" (which is the active tab), "On-Demand Mode", "Entire Session VNS Scheduler", "Independent Mode", and "Study".

The "Patient Log File" tab displays a list of events for "Device: Model #4 Serial #520". The log entries include:

- Interrogation OK: Therapy Session is OFF (1/12/2017 1:32:00 PM)
- Interrogation OK: Therapy Session is OFF (1/12/2017 4:54:20 PM)
- Save Data OK (1/12/2017 4:54:36 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 4:54:38 PM)
- Get Time OK (1/12/2017 4:54:44 PM)
- Set Time OK (1/12/2017 4:54:50 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 4:54:58 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 4:55:28 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 4:55:52 PM)
- Program Device OK: Pulse Amplitude = 0.1 mA (1/12/2017 4:56:08 PM)
- Program Device OK: Pulse Amplitude = 0.1 mA (1/12/2017 5:01:39 PM)
- Test Train OK (1/12/2017 5:01:41 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 5:01:55 PM)
- Get Next Exercise OK: 0-Undefined (1/12/2017 5:02:03 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 5:02:11 PM)
- Start Task OK (1/12/2017 5:02:15 PM)
- Stimulate OK (1/12/2017 5:02:17 PM)
- Stimulate OK (1/12/2017 5:02:19 PM)
- Stimulate OK (1/12/2017 5:02:21 PM)
- Stimulate OK (1/12/2017 5:02:22 PM)
- Stimulate OK (1/12/2017 5:02:24 PM)
- Stimulate OK (1/12/2017 5:02:26 PM)
- Stop Task OK (1/12/2017 5:02:28 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 5:02:42 PM)
- Start Task OK (1/12/2017 5:02:46 PM)
- Stop Task OK (1/12/2017 5:02:47 PM)
- Program Device OK: Pulse Amplitude = 0.0 mA (1/12/2017 5:03:10 PM)
- Start Task OK (1/12/2017 5:03:16 PM)
- Stimulate OK (1/12/2017 5:03:17 PM)
- Stimulate OK (1/12/2017 5:03:19 PM)
- Stimulate OK (1/12/2017 5:03:21 PM)
- Stimulate OK (1/12/2017 5:03:33 PM)

On the right side of the interface, there are several buttons: "Backup Log", "Restore Log", "Read Statistics", "Clear Statistics", and "Export Log". The "Export Log" button is circled in blue. Below it, there is an "Export All" checkbox (checked) and a date range selector with "Since" set to "Jan 21, 2016" and "To" set to "Jan 31, 2017".

Figure 8.2: Patient Log File—Export Log

9 INTENTIONALLY BLANK

10 IPG SETTINGS FOR MRI PROCEDURES

Prior to any MRI procedure, all therapy modes must be disabled. These are accessed through the SAPS *Program Implant* menu (see Figure 10.1).

1. Set IPG to 0 mA.
2. Set both **Therapist Trigger Mode** and **Magnet Mode** to **Off**.
3. Select the **Download Settings to IPG** button to save these settings to the IPG.
4. Following the MRI procedure, program the IPG to the appropriate settings to resume stimulation.

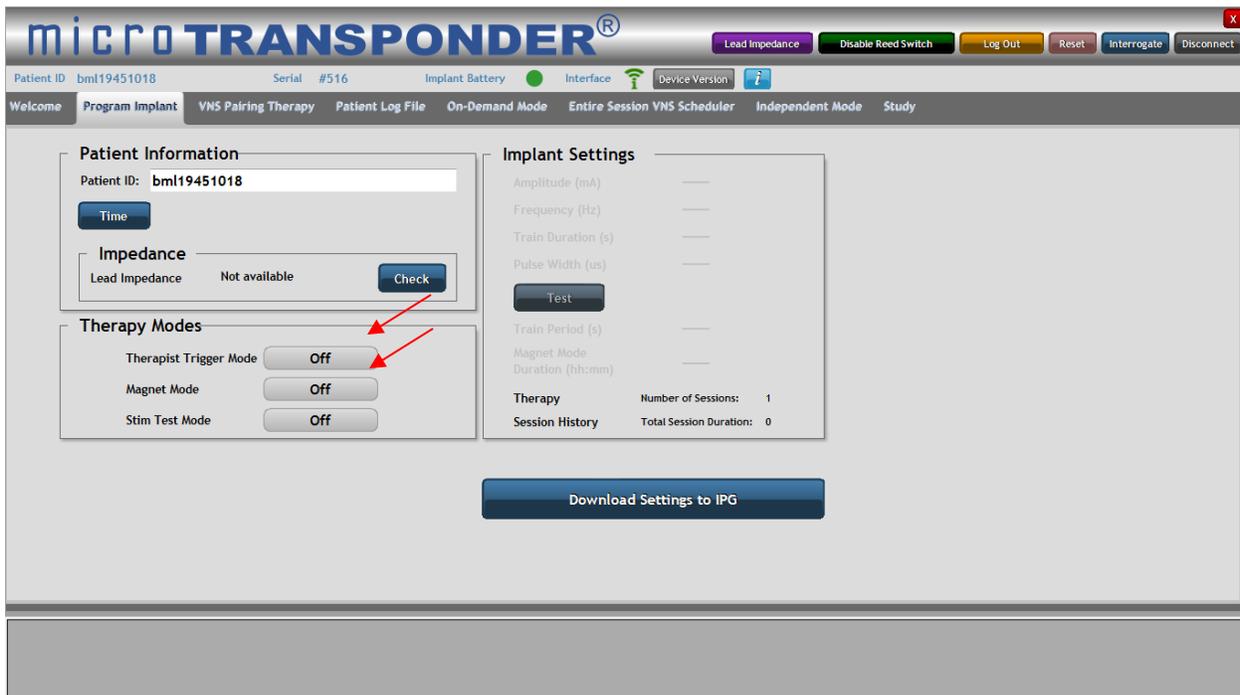


Figure 10.1: IPG Settings for MRI Procedures



CAUTION: All non-implantable components of the Vivistim® System, including the WT, SAPS software, and any off-the-shelf accessories such as the magnet, are considered MR Unsafe and are also to be left outside of the MRI scan room. These could become dangerous flying objects if attracted by the strong magnetic field of the MRI scanner.

11 MAINTENANCE, HANDLING, AND STORAGE

The WT is not permanently affected by exposure to or storage in temperatures in the range of -20°C to 70°C. Humidity up to and including 100% has no effect on the WT. Additionally:

- To clean the WT, wipe it down with a mixture of water, soap, and alcohol.
- The WT is standard lab-type equipment and is reusable.
- Please return the WT to MicroTransponder in the case of malfunction for evaluation and disposal.

12 PRECAUTIONS, WARNINGS, CONTRAINDICATIONS, AND HAZARDS

Refer to the **Microtransponder® Vivistim® Paired VNS™ System Implantable Device Manual for Healthcare Professionals** and the **Microtransponder® Vivistim® Paired VNS™ System Manual for Patients** for additional precautions, warnings, contraindications, and hazards to be avoided relating to the Vivistim® System. Call the physician or contact MicroTransponder if you have any questions (see **Section 18: Information and Support**).

- **Use**—The Vivistim® System should only be prescribed and monitored by physicians who have specific training and expertise in the management of stroke and the use of this device. The IPG, Lead, WT, and SAPS should only be used as part of the Vivistim® System.
-  **WT is MR Unsafe**—The WT must not be exposed to magnetic resonance imaging (MRI).
- **Magnet is MR Unsafe**—The patient must not carry metal (magnets, jewelry, etc.) into the MR scanner room. Metal objects can become dangerous flying objects if attracted by the strong magnetic field of the MRI scanner.
- **Environmental and medical therapy hazards**—Patients should exercise reasonable caution in avoiding devices that generate a strong electric or magnetic field.
- **EMI effects on other devices**—The Vivistim® System should be moved—typically at least 1.8 m (6 ft)—away from equipment with which it may be interfering. Programming or interrogating the IPG may momentarily interfere with other sensitive electronic equipment nearby.
- **Communication**—The IPG “listens” for a communication signal from the WT. Communication usually takes less than 2 seconds but may be prolonged or interrupted in the presence of electromagnetic interference (EMI).



CAUTION: Do not use the Vivistim® System in an environment where explosive or flammable gases are present.



CAUTION: Do not use the Vivistim® System in an environment where the non-implantable components of the system may get wet. These components are not waterproof and should be kept dry, except for normal cleaning with a damp cloth.



CAUTION: Electrostatic discharge (ESD) discharge precautions should be taken before handling the system. A grounded metal object should be touched before touching the laptop, Wireless Transmitter, and push button.



CAUTION: Degradation of the Vivistim® system’s ability to communicate during exposure to frequency ranges associated with television broadcasts (~203 MHz) and frequency ranges associated with satellites (~400 MHz), including global positioning system (GPS) signals found in cellphones and other mobile electronic devices, can occur. Programming and pairing with the system should be performed either outside of these environments or with this equipment turned off.

- **Software restrictions**—No other software shall be loaded onto the SAPS laptop, because it may interfere with proper functioning of the SAPS already installed on the commercially available laptop.
- **Laptop use**—Using the commercial laptop containing SAPS for other purposes (such as internet access) may damage the system or interfere with proper functioning of the SAPS.
- **Use only SAPS software**—The use of any software other than that specified herein will violate safety, effectiveness, and design controls of the programmable devices, and such use may result in an increased risk to users and patients.
- **Interference information**—This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate RF energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.
- **EMI interference**—Programming in the presence of an EMI signal can be difficult or impossible, but problems can usually be resolved by repositioning the patient, the WT, or the EMI source.
- **Avoid large metal structures when programming**—Programming while the IPG and/or patient are on a metal table or near large metal structures can be difficult or impossible, but problems can usually be resolved by placing the WT closer to the IPG or moving to a different location.
- **No internet**—Internet access has been purposely disabled on the laptop. Do not enable the internet on the SAPS laptop.
- **Do not modify equipment**—Do not modify this equipment without the authorization of MicroTransponder. Any modifications to the unit, unless expressly approved by MicroTransponder, could void your authority to operate this equipment.
- **Set laptop time**—It is important that the laptop time be set to the correct local time and periodically verified. This time is used to set the device time and to timestamp the operations in the log file.
- **The magnet effects on other devices**—The magnet provided to the patient to start and stop at-home therapy may damage televisions, computer disks, credit cards, and other items affected by strong magnetic fields. The patient should keep the magnet away from such items.

13 TROUBLESHOOTING

This section provides troubleshooting instructions in 3 parts: **Section 13.1: General Recommendations** and **Section 13.2: Troubleshooting at Patient Follow-up Visits**.

13.1 General Recommendations

13.1.1 Non-responsive Laptop

The SAPS laptop will power up in the **Welcome** menu of the SAPS application. If for any reason this does not occur, power off the laptop and power it back on. If the problem persists, contact MicroTransponder per **Section 18: Information and Support**.

13.1.2 Other Hardware Issues

For all other hardware issues for the laptop, contact MicroTransponder per **Section 18: Information and Support**.

13.2 Troubleshooting at Patient Follow-up Visits

13.2.1 Telemetry Lost in Therapy Visits

An example of an error message following a communication problem is shown in Figure 13.1.

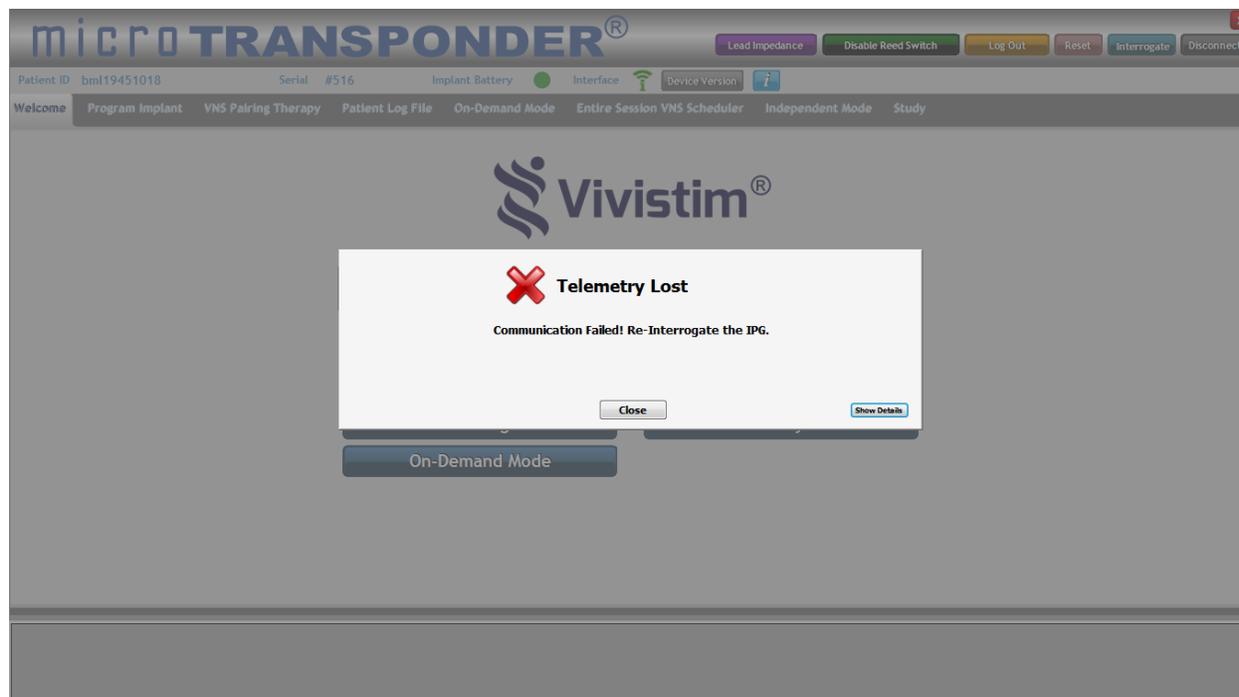


Figure 13.1: Telemetry Lost

A communication problem can cause an error message (such as the “Telemetry Lost” message shown in Figure 13.1) during interrogation, checking impedance, programming stimulation parameters, or while performing any other therapy required communications.

The most common causes of communication problems are connection issues. Performing these steps may restore communication:

1. Verify that the WT is properly connected to the laptop. The USB plug from the WT should be inserted into one of the laptop's USB ports. Figure 2.4 shows the indicator for proper connection.
2. Verify that the patient and IPG are within 1 m of the WT.
3. Verify that the programming problem is not a result of EMI from nearby electrical or magnetic equipment. Examples of possible sources of EMI are laptop displays, portable telephones, fluorescent lighting, OR lights, and magnetic pads for surgical instruments.
4. Verify that the programming problem is not a result of the IPG or WT being placed on a metal table.

Failure of the IPG and WT to clearly communicate with each other at any time can be attributed to several factors, such as:

- WT not properly connected to laptop
- Programming in the presence of an EMI signal (e.g., OR lights, the programming laptop itself, other computers, or other medical devices). This can be difficult or impossible, but problems can usually be resolved by repositioning the patient, the WT, or the EMI source.
- Movement of the patient away from the WT during communication
- Proximity of the IPG or WT to a metal table or large metal object
- Presence of metal barriers between the IPG and WT
- IPG battery at end of life (EOL)
- Software (SAPS) needing to be restarted by restarting computer
- Defective WT
- Defective laptop
- Defective IPG

Communication problems are often intermittent and are rarely related to the IPG. The surrounding environment typically causes these problems.

Restarting the laptop solves most communication and other system issues that are not connection related.

13.2.2 Unable to Initiate Communication

In certain instances, the user may be unable to communicate with the IPG. After trying all other remedies (verifying all connections, restarting the computer, etc.), please contact MicroTransponder for assistance in resetting the IPG. Contact information is provided in **Section 18: Information and Support**.

14 DEVICE LIFETIME

14.1 IPG Lifetime, Removal, and Replacement

All MicroTransponder IPGs eventually require surgical replacement as a result of battery depletion. IPG replacement does not, of itself, require Lead replacement unless a Lead discontinuity (a break) is suspected.

14.1.1 Signs of End of Life for the Vivistim® System

The most common reason for the absence of stimulation is battery depletion, although there may be other reasons. When end of life (EOL) occurs, the IPG will be unable to provide stimulation. If the IPG is not explanted or replaced at EOL, the battery voltage will continue to gradually decrease, and communication with the IPG may not be possible.

14.1.2 Replacement Based on Battery Status Indicators

During patient visits, you will use SAPS to check the status of the patient's IPG (see Figure 4.8:). The SAPS will display warning messages if the battery is nearing its depletion.

15 DEVICE DISPOSAL

Return the SAPS and the WT to MicroTransponder for examination and safe disposal. Please contact MicroTransponder for additional instructions (see **Section 18: Information and Support**).

16 VIVISTIM[®] SYSTEM DEVICES

16.1 Conventions

The SAPS operates in a Windows environment with drop-down menus. Standard mouse and keypad functions are used to navigate through a Windows environment on the laptop.

- The names of selectable buttons (or fields) and drop-down menus appear within the button. Each of these buttons or fields represents an operation, parameter, or parameter value.
- To select a button or field, move the cursor over the button and select the button using the mouse or keypad selector.

A glossary and list of symbols is found in the back of this manual (see **Section 19: Glossary**).

16.2 Communication Signals

The WT communicates wirelessly bidirectionally through the air and tissue with the IPG at a distance up to 1 m from the WT by converting USB communications into radio frequency (RF) communications using a unique, proprietary, and secure protocol that implements the Medical Implantable Band (MICS, ~403 MHz). This ensures that the IPG is not programmable by other MICS programmers and that the WT cannot program other MICS based devices.

The communication portion of the Vivistim[®] System is designed to minimize the possibility of mis-programming or “phantom” programming with the IPG. Phantom programming is the inadvertent programming via environmental sources of electromagnetic interference (EMI). All IPG parameters are programmed and verified during each programming event.

16.3 Wireless Transmitter

The WT (see Figure 16.1) is the bi-directional RF communication link between SAPS and the implanted IPG. The WT uses the FCC-approved MICS band (~403 MHz) to communicate with the IPG at distances of up to 1 m. The WT has a 2 m cable with a USB connector that plugs into the commercially available laptop. The WT is powered via the USB connection on the laptop and does not require any additional power source, such as its own battery or additional power connection.

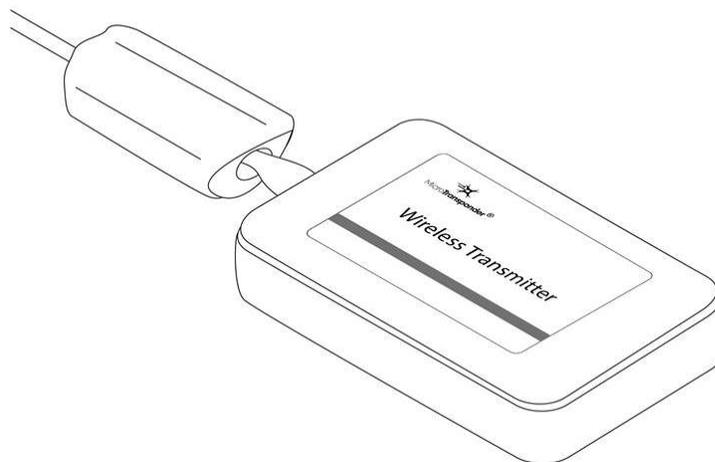


Figure 16.1: Wireless Transmitter

Outer Material	PMMA plastic (plexiglas - black)
Size	~10 cm x 7.5 cm x 2.5 cm; no sharp corners
Cable Length	~2 m
Weight	~131 g
Connector Type	USB
Communication Distance	≤1 m
Communication Band	Medical Implantable Band (MICS, ~403 MHz)

Table 16.1: Characteristics of the Wireless Transmitter

16.4 Stroke Application & Programming Software (SAPS)

The SAPS software was developed by MicroTransponder to manage IPG therapy and therapy information. The SAPS has the following capabilities:

- Allows the physician to set the IPG stimulation parameters
- Allows the physician to check the status of the IPG battery level
- Allows the physician to check the Lead impedance
- Allows the physician to record the rehabilitation task information
- Stores the therapy session history for review at a later time
- Requires the physician to use a SAPS password to access implant programming and therapy functions
- Allows users without the SAPS password (but with the laptop password) to access patient log and therapy information

The software is delivered to the physician pre-installed on a commercially available laptop.

See **Section 3: Using the Software (SAPS)** for more information on use of the SAPS.

16.5 Other Applicable MicroTransponder® Products

- Model 1001 IPG
- Model 3000 Lead

16.6 Applicable Commercial Devices for Use with MicroTransponder IPG

A commercial magnet with a pull force rated at 4.5 kg or greater is sufficient to close the reed switch within the IPG and stop stimulation.

17 GUIDANCE AND MANUFACTURER'S DECLARATION—ELECTROMAGNETIC IMMUNITY

The Wireless Transmitter (Model 2000) is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Transmitter should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Wireless Transmitter must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions	Class B	The Wireless Transmitter is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Not Applicable ¹	
Voltage fluctuation/flicker emissions IEC 61000-3-3	Not Applicable ¹	
¹ The Wireless Transmitter is rated less than 75 W, and the Harmonic current emissions basic standards has no limits for this type of product. The Wireless Transmitter does not have any component that may produce flicker.		

Table 17.1: Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The Wireless Transmitter is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Transmitter should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/-8kV contact +/-2kV, +/-4kV, +/-8kV, +/-15kV air	+/-8kV contact +/-2kV, +/-4kV, +/-8kV, +/-15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/-2 kV for power supply lines	+/-2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	+/- 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	+/-1 kV differential mode	+/-1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	+/-2 kV common mode	+/-2 kV common mode, 1.25/50 μ s	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles < 5% U_T (>95% dip in U_T) For 5 s	<5% U_T (>95% dip in U_T) For 0.5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles < 5% U_T (>95% dip in U_T) For 250 cycles (5 s @50 Hz)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Wireless Transmitter requires continuous operation during power mains interruptions, it is recommended that the Wireless Transmitter be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnet fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Table 17.2: Guidance and Manufacturer's Declaration—ESD and Power Fluctuations

The Wireless Transmitter is intended for use in the radiated electromagnetic fields specified below. The customer or the user of the Wireless Transmitter should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Wireless Transmitter, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$
IEC 61000-4-6	150 kHz to 80 MHz	150 kHz to 80 MHz	
Radiated RF	3 V/m	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
IEC61000-4-3	80 MHz to 2.5 GHz	80 MHz to 2.5 GHz	$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^a Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Wireless Transmitter is used exceeds the applicable RF compliance level above, the Wireless Transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Wireless Transmitter.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.</p>			<p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

Table 17.3: Guidance and Manufacturer’s Declaration—Radiated Electromagnetic Fields

The Wireless Transmitter is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless Transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wireless Transmitter as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter M		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

Table 17.4: Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Wireless Transmitter

Telemetry Description

The Model 1001 IPG and Model 2000 Wireless Transmitter communicate with each other using ultra-low power Medical Implant Communications Service (MICS Band) telemetry in the frequency range 402 – 405 MHz.

18 INFORMATION AND SUPPORT

Prior to contacting MicroTransponder for specific technical help relating to communication, it is recommended that the WT connection be verified and the laptop and SAPS be restarted. Other technical solutions are detailed in **Section 13: Troubleshooting**.

If issues continue, please contact MicroTransponder.



MicroTransponder, Inc.
2802 Flintrock Trace, Suite 226
Austin, TX 78738
www.microtransponder.com
info@microtransponder.com

19 GLOSSARY

19.1 Definitions

Duty Cycle—Percentage of time during which stimulation occurs; stimulation time divided by the sum of signal on and off times.

Electrode—The mechanical and electrical interface of the Vivistim® System to the vagus nerve. The electrode is part of the Lead.

EMI—Electromagnetic interference

EOL (end of life)—The SAPS software displays an EOL indicator when there is less than 5% of the battery remaining. EOL indicates that the IPG will cease to function in the very near future and needs to be replaced for therapy to continue.

ERI (Elective Replacement Indicator)—The SAPS software displays an ERI indicator when there is less than 15% of the battery remaining. This is a warning to the user that the IPG is quickly approaching EOL and may stop functioning in the near future.

High Lead Impedance—For the purposes of the Vivistim® System IFUs, any impedance above 10,000 Ω is considered high. Resistance to the flow of output current produced by the IPG, caused by any of the following: possible fibrosis between the nerve and electrode, dry nerve (during surgery), Lead fracture, Lead disconnection from the IPG, or high battery impedance approaching end of life (EOL).

IPG (Implantable Pulse Generator)—The stimulator portion of the Vivistim® System, typically implanted in the chest below the clavicle. The IPG provides stimulation to the vagus nerve through a connected Lead and Lead electrode.

Lead—An implantable part of the Vivistim® System; delivers electrical impulses from the IPG to the electrodes attached to the vagus nerve; contains flexible conductive wires within a bio-compatible insulating sheath.

Low Lead Impedance—Lower than expected resistance to the flow of output current produced by the IPG potentially caused by a short-circuit condition resulting from a break within the Lead body or connector boot.

MRI—Magnetic resonance imaging

MR Unsafe—An item that poses hazards in all MRI environments.

Output current—Amount of electrical current delivered in a single pulse of a stimulation, measured in mA.

Paired VNS™—VNS delivered by the Vivistim® System.

Patient ID—An identifier assigned by the treating physician; generally programmed at time of implantation.

Pulse width—Duration of a single pulse within a stimulation; measured in μ s.

Signal frequency—Repetition rate of pulses in a stimulation; measured in pulses per second (Hz).

Signal “off” time—Interval between stimulations when there is no stimulation; measured in minutes.

Signal “on” time—Length of time the programmed output current is delivered; measured in seconds.

SAPS (Stroke Application & Programming Software)—Software that allows the physician or therapist to set the VNS parameters and initiate stimulation paired with rehabilitation tasks.

Train—Duration (in seconds) that the signal frequency is output from the IPG.

Vagus nerve—Either of the pair of tenth cranial nerves arising from the medulla and supplying mainly the viscera, especially with autonomic sensory and motor fibers.

Vivistim®—Trade name of MicroTransponder’s Paired VNS™ System for motor deficits associated with stroke.

VNS—Vagus Nerve Stimulation

WT (Wireless Transmitter)—An RF device that connects via a USB plug to the laptop’s USB port and provides communication with the IPG; used in conjunction with SAPS.

19.2 Symbols

This manual and accompanying non-implantable device labeling use these symbols and definitions. Refer to the **Microtransponder® Vivistim® Paired VNS™ System Implantable Device Manual for Healthcare Professionals** for symbols relating to the implantable components of the Vivistim® System.



Caution, pay special attention to the information following the symbol



For USA audiences only

Rx Only

For Prescription use only



For Prescription use only



Communication Distance



Non-ionizing Radiation



Date of Manufacture



Do Not Use if Package is Damaged



Authorized Representative in the European Union



Consult Instructions for Use



Reference Number



Batch Code



Manufacturer



Magnetic Resonance Unsafe



MR Conditional



Serial Number



Temperature Limitation (Storage and Transport)

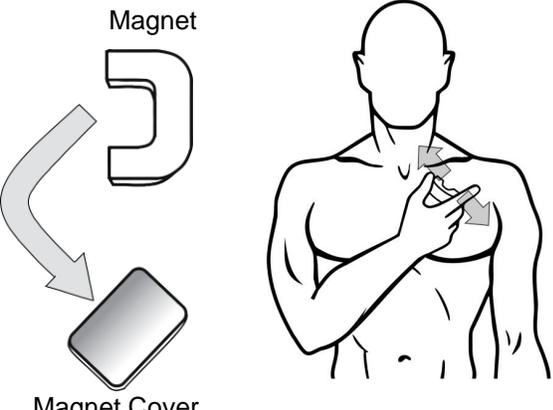
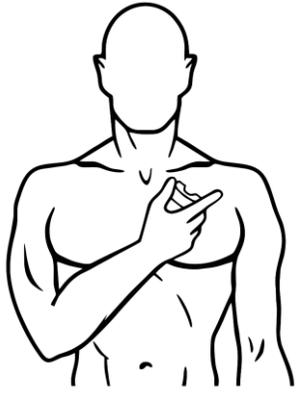
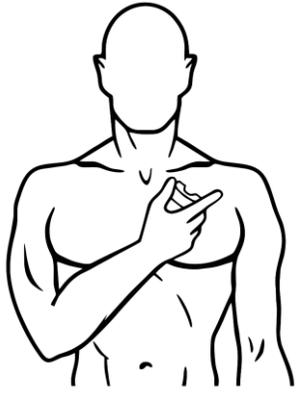


Number of Radio Frequency (RF) Communication Channels



Keep Dry

Vivistim® Paired VNS™ System Quick Start Guide for Patients

<p>1. To turn on your IPG, remove the magnet cover, if applicable, and swipe the magnet once across your chest, above where the IPG is implanted. The IPG will then stimulate your vagus nerve for a therapy session typically lasting 30 minutes.² The device will automatically stop stimulation and shut off at the time programmed by your health care provider. NOTE: You may not feel stimulation.</p>	 <p>Magnet</p> <p>Magnet Cover</p>
<p>2. To stop the stimulation during a session, hold the magnet over the IPG. Continue holding – it will take approximately 30 seconds for the stimulation to stop. When you remove the magnet, stimulation will continue until your therapy session end time.</p>	
<p>3. If you wish to stop the stimulation for the rest of your therapy session, you must hold the magnet over your chest until your therapy session end time.³</p>	
<p>4. If you lose your magnet, you will need to contact your clinician for a new one or replace it with a magnet that is strong enough. A commercial magnet with a pull force rated at 4.5 kg or greater is sufficient.</p>	<p>Magnet Force: 4.5+ kg</p>
<p>5. The magnet provided to you may damage TVs, computer disks, credit cards, and other items affected by strong magnetic fields.</p>	<p>Please keep the magnet away from such items.</p>

Contact your clinician for medical care and medical advice or if you have any questions about your MicroTransponder® Vivistim® Paired VNS™ System.

² Your health care provider may program the session to be shorter or longer than 30 minutes.

³ For example, if your health care provider programmed the session to last 30 minutes and you started your session at 8:00 am, then your session would end at 8:30 am. If you want to completely stop stimulation starting at 8:20 am, then you would need to hold the magnet in place for 10 minutes, which is until the pre-programmed session time would end at 8:30 am.